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

FORM 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2019
- 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)

505 Eagleview Blvd., Suite 212
Exton, Pennsylvania
(Address of principal executive offices)

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

19341
(Zip code)

(484) 348-1600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	IDRA	Nasdaq Capital Market

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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

28,872,026
Outstanding as of October 31, 2019

IDERA PHARMACEUTICALS, INC.
FORM 10-Q

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the safe harbor of the Private Securities Litigation Reform Act of 1995 and the Federal Securities laws. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the Securities and Exchange Commission (the “SEC”) on March 6, 2019 and in our other filings with the SEC. 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 SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

PART I — FINANCIAL INFORMATION**Item 1. Financial Statements.****IDERA PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS**

(In thousands, except per share amounts)	September 30, 2019	December 31, 2018*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,611	\$ 71,431
Short-term investments	8,975	—
Prepaid expenses and other current assets	3,488	1,376
Total current assets	45,074	72,807
Property and equipment, net	123	207
Operating lease right-of-use asset	125	—
Other assets	70	9
Total assets	\$ 45,392	\$ 73,023
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 321	\$ 1,134
Accrued expenses	7,307	7,884
Operating lease liability	138	—
Total current liabilities	7,766	9,018
Other liabilities	—	11
Total liabilities	7,766	9,029
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, \$0.001 par value, Authorized — 70,000 shares; Issued and outstanding — 28,858 and 27,188 shares at September 30, 2019 and December 31, 2018, respectively		
	29	27
Additional paid-in capital	735,254	728,342
Accumulated deficit	(697,658)	(664,375)
Accumulated other comprehensive income	1	—
Total stockholders' equity	37,626	63,994
Total liabilities and stockholders' equity	\$ 45,392	\$ 73,023

* The condensed balance sheet at December 31, 2018 has been derived from the audited financial statements at that date.

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

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Alliance revenue	\$ —	\$ 145	\$ 1,448	\$ 563
Operating expenses:				
Research and development	8,359	8,860	26,485	32,912
General and administrative	3,023	3,984	9,061	11,849
Merger-related costs, net	—	(3,836)	—	1,245
Restructuring costs	5	3,017	181	3,017
Total operating expenses	11,387	12,025	35,727	49,023
Loss from operations	(11,387)	(11,880)	(34,279)	(48,460)
Other income (expense):				
Interest income	249	277	992	759
Interest expense	—	—	—	(11)
Foreign currency exchange gain (loss)	5	(2)	4	(19)
Net loss	\$ (11,133)	\$ (11,605)	\$ (33,283)	\$ (47,731)
Net loss per share applicable to common stockholders - basic and diluted (Note 13)	\$ (0.39)	\$ (0.43)	\$ (1.17)	\$ (1.81)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	28,847	27,175	28,332	26,404
Comprehensive loss:				
Net loss	\$ (11,133)	\$ (11,605)	\$ (33,283)	\$ (47,731)
Other comprehensive income (loss):				
Unrealized (loss) gain on available-for-sale securities	(1)	—	1	—
Total other comprehensive (loss) income	(1)	—	1	—
Comprehensive loss	\$ (11,134)	\$ (11,605)	\$ (33,282)	\$ (47,731)

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

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

(In thousands)	Nine Months Ended September 30,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	\$ (33,283)	\$ (47,731)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,868	4,454
Issuance of common stock for services rendered	92	77
Accretion of discounts on short-term investments	(377)	—
Depreciation and amortization expense	94	395
Loss on disposal of property and equipment	(10)	497
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,298)	1,881
Accounts payable, accrued expenses, and other liabilities	(1,257)	455
Deferred revenue	—	(472)
Net cash used in operating activities	<u>(34,171)</u>	<u>(40,444)</u>
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(44,447)	—
Proceeds from maturity of available-for-sale securities	35,850	—
Proceeds from the sale of property and equipment	11	193
Purchases of property and equipment	(11)	(71)
Net cash (used in) provided by investing activities	<u>(8,597)</u>	<u>122</u>
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	3,857	—
Proceeds from employee stock purchases	97	205
Proceeds from exercise of common stock options and warrants	—	10,166
Payments on note payable	—	(209)
Other	(6)	(7)
Net cash provided by financing activities	<u>3,948</u>	<u>10,155</u>
Net decrease in cash and cash equivalents	<u>(38,820)</u>	<u>(30,167)</u>
Cash, cash equivalents and restricted cash, beginning of period	71,431	112,940
Cash, cash equivalents and restricted cash, end of period	<u>\$ 32,611</u>	<u>\$ 82,773</u>

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

IDERA PHARMACEUTICALS, INC.
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)**

(In thousands, except per share amounts)	For the Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	\$0.001 Par Value				
Balance, December 31, 2018	27,188	\$ 27	\$ 728,342	\$ (664,375)	\$ —	\$ 63,994
Sale of common stock, net of issuance costs	533	1	1,584	—	—	1,585
Issuance of commitment shares	270	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	11	—	26	—	—	26
Issuance of common stock for services rendered	6	—	23	—	—	23
Stock-based compensation	—	—	1,016	—	—	1,016
Unrealized gain on marketable securities	—	—	—	—	2	2
Net loss	—	—	—	(10,974)	—	(10,974)
Balance, March 31, 2019	28,008	\$ 28	\$ 730,991	\$ (675,349)	\$ 2	\$ 55,672
Sale of common stock, net of issuance costs	786	1	2,271	—	—	2,272
Issuance of common stock under employee stock purchase plan	19	—	42	—	—	42
Issuance of common stock for services rendered	14	—	36	—	—	36
Stock-based compensation	—	—	889	—	—	889
Net loss	—	—	—	(11,176)	—	(11,176)
Balance, June 30, 2019	28,827	\$ 29	\$ 734,229	\$ (686,525)	\$ 2	\$ 47,735
Issuance of common stock under employee stock purchase plan	15	—	29	—	—	29
Issuance of common stock upon exercise of warrants	4	—	—	—	—	—
Issuance of common stock for services rendered	12	—	33	—	—	33
Stock-based compensation	—	—	963	—	—	963
Unrealized gain on marketable securities	—	—	—	—	(1)	(1)
Net loss	—	—	—	(11,133)	—	(11,133)
Balance, September 30, 2019	28,858	\$ 29	\$ 735,254	\$ (697,658)	\$ 1	\$ 37,626

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

IDERA PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)
(UNAUDITED)

(In thousands, except per share amounts)	For the Nine Months Ended September 30, 2018					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	\$0.001 Par Value				
Balance, December 31, 2017	24,453	\$ 24	\$ 712,165	\$ (604,494)	\$ —	\$ 107,695
Issuance of common stock under stock purchase plan	7	—	81	—	—	81
Issuance of common stock upon exercise of warrants	2,551	3	9,588	—	—	9,591
Issuance of common stock for services rendered	1	—	23	—	—	23
Stock-based compensation	—	—	1,589	—	—	1,589
Net loss	—	—	—	(20,095)	—	(20,095)
Balance, March 31, 2018	27,012	27	723,446	(624,589)	—	98,884
Issuance of common stock under stock purchase plan	6	—	78	—	—	78
Issuance of common stock upon exercise of options and warrants	151	—	575	—	—	575
Issuance of common stock for services rendered	2	—	22	—	—	22
Stock-based compensation	—	—	1,538	—	—	1,538
Net loss	—	—	—	(16,031)	—	(16,031)
Balance, June 30, 2018	27,171	27	725,659	(640,620)	—	85,066
Issuance of common stock under stock purchase plan	5	—	46	—	—	46
Issuance of common stock for services rendered	3	—	32	—	—	32
Stock-based compensation	—	—	1,327	—	—	1,327
Net loss	—	—	—	(11,605)	—	(11,605)
Balance, September 30, 2018	27,179	\$ 27	\$ 727,064	\$ (652,225)	\$ —	\$ 74,866

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

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2019

(UNAUDITED)

Note 1. Business and Organization

Business Overview

Idera Pharmaceuticals, Inc. (“Idera” or the “Company”), a Delaware corporation, is a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well defined patient populations with serious unmet medical needs. The Company’s current focus is on its Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. The Company believes it can develop and commercialize targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

Liquidity and Financial Condition

As of September 30, 2019, the Company had an accumulated deficit of \$697.7 million and a cash, cash equivalents and short-term investments balance of \$41.6 million. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance tilsotolimod and any future drug candidates through development to commercialization. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company successfully completes development of and obtains marketing approval for tilsotolimod or other future drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years. In order to commercialize tilsotolimod and any future 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.

The Company believes, based on management’s current operating plan, that its balance of cash, cash equivalents and short-term investments on hand as of September 30, 2019 will be sufficient to fund operations into the third quarter of 2020. The Company follows the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company’s ability to continue as a going concern for one year after the date the financial statements are issued. The Company’s balance of cash, cash equivalents and short-term investments on hand as of September 30, 2019 is not sufficient to fund operations past the third quarter of 2020. While there is substantial doubt about the Company’s ability to continue as a going concern through the one-year period from the date these financial statements are issued, management’s plans to mitigate this risk include raising additional capital through the Company’s Common Stock Purchase Agreement (Note 7), “At-The-Market” Equity Program (Note 7), or additional financing or strategic transactions. Management’s plans may also include the possible deferral of certain operating expenses unless additional capital is received.

Reverse Stock Split

On July 27, 2018, the Company effected a 1-for-8 reverse stock split of the Company's outstanding shares of common stock, as authorized at a special meeting of stockholders on June 20, 2018. All share and per share amounts of common stock, options and warrants in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the reverse stock split.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2019 are not necessarily indicative of results that may be expected for the year ending December 31, 2019. 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, 2018 (the “2018 Form 10-K”), which was filed with the SEC on March 6, 2019.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be “cash equivalents.” Cash and cash equivalents at September 30, 2019 and December 31, 2018 consisted of cash, commercial paper and money market funds.

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 3. The Company is required to disclose the estimated fair values of its financial instruments. As of September 30, 2019 and December 31, 2018, the Company’s financial instruments consisted of cash, cash equivalents, investments and receivables and the estimated fair values of such financial instruments approximated their carrying values. As of September 30, 2019, the Company did not have any derivatives, hedging instruments or other similar financial instruments.

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

The Company’s revenues have primarily been generated through collaborative research, development and/or commercialization agreements and other out-licensing arrangements. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance. Each of these types of revenue are recorded as Alliance revenues in the Company’s statement of operations.

See Note 9, “Collaboration and License Agreements” for additional details surrounding the Company’s collaboration arrangements.

Note 2. Summary of Significant Accounting Policies (Continued)

Income Taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either September 30, 2019 or December 31, 2018 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of September 30, 2019 and December 31, 2018, the Company had no uncertain tax positions.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that the Company has or will adopt as of a specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have, a material impact on the Company's present or future financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets, with lease terms of more than 12 months, to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease by a lessee will depend primarily on its classification as a finance or operating lease. However, unlike the previous standard, which required only capital leases to be recognized on the balance sheet, ASU 2016-02 requires both types of leases to be recognized on the balance sheet. This guidance was applicable to the Company's fiscal year beginning January 1, 2019, and the Company adopted ASU 2016-02 in the first quarter of 2019 using the alternative modified retrospective transition method, which allowed the Company to apply the new lease standard to the beginning of the 2019 period and did not require adjusting comparative period financial information. Additionally, the Company elected the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs. As a result of adopting ASU 2016-02, the primary impact on the Company's financial statements was the recognition of a right-of-use asset and corresponding liability of approximately \$0.3 million on its balance sheet as of January 1, 2019 related to its existing Exton, PA facility operating lease.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718)* ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions and was adopted by the Company in the first quarter of 2019. The adoption of this ASU did not have a material impact on the Company's financial statements.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC 820, *Fair Value Measurement*, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured 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. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the nine months ended September 30, 2019.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2019 and December 31, 2018 categorized by the level of inputs used in the valuation of each asset and liability:

(In thousands)	September 30, 2019			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 250	\$ 250	\$ —	\$ —
Money market funds	25,635	25,635	—	—
Other cash equivalents – commercial paper	6,726	—	6,726	—
Short-term investments – commercial paper	4,257	—	4,257	—
Short-term investments – U.S. treasury bills	4,718	4,718	—	—
Total assets	\$ 41,586	\$ 30,603	\$ 10,983	\$ —
Total liabilities	\$ —	\$ —	\$ —	\$ —

(In thousands)	December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 8,446	\$ 8,446	\$ —	\$ —
Money market funds	61,177	61,177	—	—
Other cash equivalents – commercial paper	1,808	—	1,808	—
Total assets	\$ 71,431	\$ 69,623	\$ 1,808	\$ —
Total liabilities	\$ —	\$ —	\$ —	\$ —

The Level 1 assets include money market funds, which are actively traded daily.

Note 4. Investments

The Company's available-for-sale investments at fair value consisted of the following at September 30, 2019:

(In thousands)	September 30, 2019			Estimated Fair Value
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	
Short-term investments – commercial paper	\$ 4,256	\$ —	\$ 1	\$ 4,257
Short-term investments – U.S. treasury bills	4,718	—	—	4,718
Total short-term investments	\$ 8,974	\$ —	\$ 1	\$ 8,975
Total investments	\$ 8,974	\$ —	\$ 1	\$ 8,975

The Company had no realized gains or losses from the sale of investments in available-for-sale securities in each of the nine months ended September 30, 2019 or 2018. There were no losses or other-than-temporary declines in value included in "Interest income" on the Company's condensed statements of operations and comprehensive loss for any securities for the nine months ended September 30, 2019 or 2018.

Note 5. Property and Equipment

At September 30, 2019 and December 31, 2018, property and equipment, net, consisted of the following:

(In thousands)	September 30, 2019	December 31, 2018
Leasehold improvements	\$ 107	\$ 104
Laboratory equipment and other	764	767
Total property and equipment, at cost	871	871
Less: Accumulated depreciation and amortization	748	664
Property and equipment, net	\$ 123	\$ 207

Depreciation and amortization expense on property and equipment was less than \$0.1 million for the three months ended September 30, 2019 and approximately \$0.1 million for the three months ended September 30, 2018. Depreciation and amortization expense was approximately \$0.1 million and \$0.4 million for the nine months ended September 30, 2019 and 2018, respectively. There were no non-cash property additions during the nine months ended September 30, 2019 or 2018.

Note 6. Accrued Expenses

At September 30, 2019 and December 31, 2018, accrued expenses consisted of the following:

(In thousands)	September 30, 2019	December 31, 2018
Payroll and related costs	\$ 1,572	\$ 1,962
Clinical and nonclinical trial expenses	4,968	3,958
Professional and consulting fees	412	605
Restructuring expenses	209	1,147
Other	146	212
Total accrued expenses	\$ 7,307	\$ 7,884

Included in accrued Payroll and related costs as of September 30, 2019 and December 31, 2018 is less than \$0.1 million and \$0.7 million, respectively, of salary continuation severance benefits paid in equal installments through October 31, 2019 to former executives.

Note 7. Stockholders' Equity**Equity Financings***Common Stock Purchase Agreement*

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Lincoln Park has committed to purchase an aggregate of \$35.0 million of shares of Company common stock from time to time at the Company's sole discretion (the "Purchase Agreement"). As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park as a commitment fee (the "Commitment Shares"). The closing price of the Company's common stock on March 4, 2019 was \$2.84 and the Company did not receive any cash proceeds from the issuance of the Commitment Shares. During the nine months ended September 30, 2019, the Company sold 785,848 shares pursuant to the Purchase Agreement, resulting in net proceeds of \$2.3 million.

"At-The-Market" Equity Program

In November 2018, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with JMP Securities LLC ("JMP") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$50.0 million (the "Shares") through JMP as its agent. Subject to the terms and conditions of the Agreement, JMP will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by the Company, by any other method permitted by law, including but not limited to in negotiated transactions. The Company has no obligation to sell any of the Shares, and the Company or JMP may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement. JMP is entitled to a fixed commission of 3.0% of the gross proceeds from Shares sold. During the nine months ended September 30, 2019, the Company sold 532,700 Shares pursuant to the ATM Agreement resulting in net proceeds, after deduction of commissions and other offering expenses, of \$1.6 million.

Common Stock Warrants

In connection with various financing transactions, the Company has issued warrants to purchase shares of the Company's common stock. The Company accounts for common stock warrants as equity instruments, derivative liabilities or liabilities, depending on the specific terms of the warrant agreement. As of September 30, 2019 and December 31, 2018, all of the Company's outstanding common stock warrants were equity-classified. The following table summarizes outstanding warrants to purchase shares of the Company's common stock as of September 30, 2019 and December 31, 2018:

Description	Number of Shares		Weighted-Average Exercise Price	Expiration Date
	September 30, 2019	December 31, 2018		
Issued in May 2013 financing (pre-funded)	1,977,041	1,977,041	\$ 0.08	May 2020
Issued in September 2013 financing (pre-funded)	521,997	521,997	\$ 0.08	Sep 2020
Issued in February 2014 financing (pre-funded)	266,006	269,844	\$ 0.08	Feb 2021
Total	2,765,044	2,768,882		

The table below is a summary of the Company's warrant activity for the nine months ended September 30, 2019:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	2,768,882	\$ 0.08
Issued	—	—
Exercised	(3,838)	0.08
Expired	—	—
Outstanding at September 30, 2019	2,765,044	\$ 0.08

Note 8. Alliance Revenue

Alliance revenue for the three and nine months ended September 30, 2019 and 2018 represents revenue from contracts with customers accounted for in accordance with ASC Topic 606. For the three and nine months ended September 30, 2019 and 2018, Alliance revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

(In thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Out-license arrangement (1)	\$ —	\$ —	\$ 1,447	\$ —
GSK collaboration (2)	—	141	—	424
Vivelix collaboration (3)	—	—	—	56
Other (4)	—	4	1	83
Total Alliance revenue	\$ —	\$ 145	\$ 1,448	\$ 563

- (1) Revenue recognized in connection with the Licensee Agreement, as more fully described in Note 9.
- (2) Revenue recognized in connection with the GSK Agreement, as more fully described in Note 9.
- (3) Revenue recognized in connection with the Vivelix Agreement, as more fully described in Note 9.
- (4) For all periods presented, revenue recognized relates to collaborations which are not material to the Company's current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

Note 9. Collaboration and License Agreements***Option and License Agreement with Licensee***

In April 2019, the Company entered into an amended and restated option and license agreement with a privately-held biopharmaceutical company ("Licensee"), pursuant to which the Company granted Licensee (i) exclusive worldwide rights to develop and market IMO-8400 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-8400 License"), (ii) an exclusive right and license to develop IMO-9200 in accordance with certain IMO-9200 pre-option exercise protocols (the "IMO-9200 Option Period License"), and (iii) an exclusive option, exercisable at Licensee's discretion, to obtain the exclusive worldwide rights to develop and market IMO-9200 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-9200 Option") (collectively, the "Licensee Agreement"). In connection with the Licensee Agreement, the Company transferred certain drug material to Licensee for Licensee's use in development activities. Licensee is solely responsible for the development and commercialization of IMO-8400 and, if Licensee exercises the IMO-9200 Option, Licensee would be solely responsible for the development and commercialization of IMO-9200.

Under the terms of the Licensee Agreement, the Company received upfront, non-refundable fees totaling approximately \$1.4 million and ownership of 10% of Licensee's outstanding common stock, subject to future adjustment, for granting Licensee the IMO-8400 License, the IMO-9200 Option Period License and transfer of related drug materials. In addition, the Company is eligible to receive a \$1 million non-refundable fee upon Licensee exercising the IMO-9200 Option ("Option Fee") and is entitled to certain sub-licensing payments on sublicense revenue received by Licensee, if any. The Company may also be eligible for certain development and sales-based milestone payments and royalties on global net sales for any future products. The Company does not anticipate the receipt of any of the future milestones or royalties in the short term, if ever.

Note 9. Collaboration and License Agreements (Continued)

The Company concluded that the contract counterparty, Licensee, is a customer and accounted for the Licensee Agreement in accordance with ASC 606. As of September 30, 2019, the total transaction price of the contract was \$1.4 million, which excluded the Option Fee and all development and sales milestones as all such payments were fully constrained. Additionally, as of September 30, 2019, there were no remaining performance obligations under the Licensee Agreement. The Company re-evaluates its performance obligations and transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As disclosed above, in connection with the Licensee Agreement, the Company owns 10% of Licensee's outstanding common stock, subject to future adjustment. The Company evaluated the guidance in ASC Topic 321, *Investments-Equity Securities*, and elected to account for the investment using the measurement alternative as the equity securities are without a readily determinable fair value, and the arrangement does not result in Idera having control or significant influence over Licensee. Accordingly, the securities are measured at cost, less any impairment, plus or minus changes resulting from observable price changes and are recorded in Other assets at a value of less than \$0.1 million in the accompanying balance sheets. As of September 30, 2019, the Company considered the cost of the investment to not exceed the fair value of the investment and did not identify any observable price changes.

For the nine months ended September 30, 2019, the Company recognized Alliance revenues of \$1.4 million under the Licensee Agreement, primarily related to the transfer of the IMO-8400 License and IMO-8400 drug product.

Collaboration with Vivelix

In November 2016, the Company entered into an exclusive license and collaboration agreement with Vivelix Pharmaceuticals, Ltd. ("Vivelix") pursuant to which the Company granted Vivelix worldwide rights to develop and market IMO-9200 for non-malignant gastrointestinal disorders, and certain back-up compounds to IMO-9200 (the "Vivelix Agreement"). The Company was previously developing IMO-9200 for potential use in selected autoimmune disease indications. However, the Company determined not to proceed with internal development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of the Company. Under the terms of the Vivelix Agreement, Vivelix was solely responsible for the development and commercialization of IMO-9200 and any designated back-up compounds. In connection with the Vivelix Agreement, Idera also transferred certain drug material to Vivelix for Vivelix's use in its development activities.

Under the terms of the Vivelix Agreement, the Company received an upfront, non-refundable fee of \$15 million and was eligible for future IMO-9200 related development, regulatory and sales milestone payments and sales-based royalties. However, on March 4, 2019, the Company and Vivelix mutually agreed to terminate the Vivelix Agreement. Accordingly, the Company is no longer eligible to receive any future milestone or royalty-based payments and all rights previously granted to Vivelix with respect to IMO-9200 and certain back-up compounds to IMO-9200 reverted back to the Company.

For the nine months ended September 30, 2018, the Company recognized Alliance revenues of less than \$0.1 million related to certain research activities performed by the Company at Vivelix's request, pursuant to the Vivelix Agreement. No such services were performed during the nine months ended September 30, 2019.

Note 9. Collaboration and License Agreements (Continued)

Collaboration with GSK

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

The GSK Agreement also provided GSK with the option to select up to two additional targets at any time during the first two years of the GSK Agreement for further research under mutually agreed upon research plans. Upon selecting additional targets, GSK then had the option to designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. GSK did not select any additional targets for research through expiry of the option period.

Under the terms of the GSK Agreement, the Company received a \$2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. Additionally, the Company is eligible to receive an additional \$18 million in license, research, clinical development and commercialization milestone payments, of which \$1 million would be payable by GSK upon the designation of a development candidate from the initial target and \$17 million would be payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, the Company is eligible to receive royalty payments on sales of licensed products following commercialization at varying rates of up to 5% on annual net sales, as defined in the GSK Agreement.

For the three and nine months ended September 30, 2018, the Company recognized Alliance revenues of \$0.1 million and \$0.4 million, respectively, related to the amortization of the deferred up-front payment received at inception of the GSK Agreement, over the 36-month anticipated performance period, which concluded in the fourth quarter of 2018. Accordingly, no such revenues were recognized during the three and nine months ended September 30, 2019.

Note 10. Restructuring Costs

In July 2018, the Company determined to wind-down its discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close its Cambridge facility. In connection with the reduction-in-workforce, 18 positions were eliminated, primarily in the area of discovery, which represented approximately 40% of the Company’s employees. Of the 18 positions eliminated, 15 were effective July 31, 2018 with the remaining effective during the first half of 2019.

Total restructuring-related charges incurred through September 30, 2019 were \$3.3 million and are comprised of (i) one-time termination costs in connection with the reduction in workforce, including severance, benefits and related costs, of approximately \$2.8 million; (ii) contract termination costs of approximately \$0.2 million in connection with the early lease termination for the Cambridge facility; and (iii) non-cash asset impairments of approximately \$0.7 million, which includes \$0.5 million of fixed asset impairments and \$0.2 million in write-offs of facility-related prepaid expenses; offset by (iv) a non-cash gain of approximately \$0.4 million related to the write-off of the remaining deferred rent liability associated with the Cambridge facility lease.

Note 10. Restructuring Costs (Continued)

The following summarizes restructuring-related activity for the nine months ended September 30, 2019:

(in thousands)	Employee Severance and Benefits	Contract Termination Costs	Asset Impairments	Total
Accrued restructuring balance as of December 31, 2018	\$ 1,147	\$ —	\$ —	\$ 1,147
Charges incurred	181	—	—	181
Cash payments	(1,119)	—	—	(1,119)
Accrued restructuring balance as of September 30, 2019	<u>\$ 209</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 209</u>

As of September 30, 2019, the accrued restructuring balance of \$0.2 million is included in “Accrued expenses” in the accompanying condensed balance sheets. See Note 6.

Note 11. Stock-Based Compensation

As of September 30, 2019, the only equity compensation plans from which the Company may currently issue new awards are the Company’s 2013 Stock Incentive Plan (as amended to date, the “2013 Plan”) and 2017 Employee Stock Purchase Plan (as amended to date, the “2017 ESPP”), each as more fully described below.

Equity Incentive and Employee Stock Purchase Plans***2013 Stock Incentive Plan***

The Company's board of directors adopted the 2013 Plan, which was approved by the Company’s stockholders effective July 26, 2013. Amendments to the 2013 Plan were approved by the Company’s stockholders in June 2014, June 2015, June 2017 and June 2019. The 2013 Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing equity-based incentives. The 2013 Plan allows for the issuance of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards and performance awards. The total number of shares of common stock authorized for issuance under the 2013 Plan is 5,653,057 shares of the Company’s common stock, plus such additional number of shares of common stock (up to 868,372 shares) as is equal to the number of shares of common stock subject to awards granted under the Company’s 2005 Stock Incentive Plan or 2008 Stock Incentive Plan (the “2008 Plan”), to the extent such awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right.

As of September 30, 2019, options to purchase a total of 3,567,161 shares of common stock and 193,625 restricted stock units were outstanding and up to 2,141,103 shares of common stock remained available for grant under the 2013 Plan. The Company has not made any awards pursuant to other equity incentive plans, including the 2008 Plan, since the Company’s stockholders approved the 2013 Plan. As of September 30, 2019, options to purchase a total of 433,470 shares of common stock were outstanding under the 2008 Plan.

In addition, as of September 30, 2019, non-statutory stock options to purchase an aggregate of 393,750 shares of common stock were outstanding. These options were issued outside of the 2013 Plan to certain newly-hired employees in 2017, 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of such new hires’ employment compensation.

Note 11. Stock-Based Compensation (Continued)*2017 Employee Stock Purchase Plan*

The Company's board of directors adopted the 2017 ESPP, which was approved by the Company's stockholders and became effective on June 7, 2017. An amendment to the 2017 ESPP was approved by the Company's stockholders in June 2019. The 2017 ESPP is intended to qualify as an "employee stock purchase plan" as defined in Section 423 of the Internal Revenue Code, and is intended to encourage our employees to become stockholders of ours, to stimulate increased interest in our affairs and success, to afford employees the opportunity to share in our earnings and growth and to promote systematic savings by them. The total number of shares of common stock authorized for issuance under the 2017 ESPP is 412,500 shares of common stock, subject to adjustment as described in the 2017 ESPP. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant. As of September 30, 2019, 337,053 shares remained available for issuance under the 2017 ESPP.

For the nine months ended September 30, 2019 and 2018, the Company issued 45,241 and 18,355 shares of common stock, respectively, under the 2017 ESPP and received proceeds of \$0.1 million and \$0.2 million respectively, as a result of employee stock purchases.

Accounting for Stock-based Compensation

The Company recognizes non-cash compensation expense for stock-based awards under the Company's equity incentive plans over an award's requisite service period, or vesting period, using the straight-line attribution method, based on their grant date fair value determined using the Black-Scholes option-pricing model. The Company also recognizes non-cash compensation for stock purchases made under the 2017 ESPP. The fair value of the discounted purchases made under the Company's 2017 ESPP is calculated using the Black-Scholes option-pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over each plan period.

Total stock-based compensation expense attributable to stock-based payments made to employees and directors and employee stock purchases included in operating expenses in the Company's statements of operations for the three and nine months ended September 30, 2019 and 2018 was as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock-based compensation:				
Research and development				
Employee Stock Purchase Plan	\$ 9	\$ 11	\$ 27	\$ 62
Equity Incentive Plan	328	303	978	1,379
	<u>\$ 337</u>	<u>\$ 314</u>	<u>\$ 1,005</u>	<u>\$ 1,441</u>
General and administrative				
Employee Stock Purchase Plan	\$ 4	\$ 8	\$ 18	\$ 40
Equity Incentive Plan	622	981	1,845	2,949
	<u>\$ 626</u>	<u>\$ 989</u>	<u>\$ 1,863</u>	<u>\$ 2,989</u>
Restructuring costs				
Equity Incentive Plans	\$ —	\$ 24	\$ —	\$ 24
	<u>\$ —</u>	<u>\$ 24</u>	<u>\$ —</u>	<u>\$ 24</u>
Total stock-based compensation expense	<u>\$ 963</u>	<u>\$ 1,327</u>	<u>\$ 2,868</u>	<u>\$ 4,454</u>

During the nine months ended September 30, 2019 and 2018, the weighted average fair market value of stock options granted was \$1.65 and \$7.15, respectively.

Note 11. Stock-Based Compensation (Continued)

The following weighted average assumptions apply to the options to purchase 1,259,016 and 1,091,474 shares of common stock granted to employees and directors during the nine months ended September 30, 2019 and 2018, respectively:

	Nine Months Ended September 30,	
	2019	2018
Average risk-free interest rate	2.1%	2.5%
Expected dividend yield	—	—
Expected lives (years)	3.8	3.8
Expected volatility	83.7%	74.0%
Weighted average exercise price (per share)	\$ 2.76	\$ 12.91

All options granted during the nine months ended September 30, 2019 and 2018 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

Stock Option Activity

The following table summarizes stock option activity for the nine months ended September 30, 2019:

(\$ in thousands, except per share data)	Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,304,531	\$ 18.42	6.6	\$ —
Granted	1,259,016	2.76		
Exercised	—	—		
Forfeited	(60,595)	13.36		
Expired	(108,571)	27.48		
Outstanding at September 30, 2019 (1)	4,394,381	\$ 13.77	7.0	\$ 279
Exercisable at September 30, 2019	2,311,989	\$ 20.34	5.1	\$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The fair value of options that vested during the nine months ended September 30, 2019 was \$3.7 million. As of September 30, 2019, there was \$6.3 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.5 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the nine months ended September 30, 2019:

(\$ in thousands, except per share data)	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2018	—	\$ —
Granted	194,550	3.14
Cancelled	(925)	3.14
Vested	—	—
Nonvested shares at September 30, 2019	193,625	\$ 3.14

As of September 30, 2019, there was \$0.5 million of unrecognized compensation expense related to the restricted stock units, which is expected to be recognized over a weighted-average period of 3.3 years.

Note 12. Related Party Transactions

Overview of Related Parties

Julian C. Baker, a member of the Company's Board until his resignation in September 2018, is a principal of Baker Bros. Advisors, LP. Additionally, Kelvin M. Neu, a member of Company's Board until his resignation in June 2019, is an employee of Baker Bros. Advisors, LP. As of September 30, 2019, Baker Bros. Advisors, LP and certain of its affiliated funds (collectively, "Baker Brothers") held sole voting power with respect to an aggregate of 4,606,786 shares of the Company's common stock, representing approximately 16% of the Company's outstanding common stock.

During the nine months ended September 30, 2019, Baker Brothers made an in-kind pro rata distribution of a total of 60,070 warrants to purchase shares of the Company's common stock to Mr. Baker, Mr. Neu and other investors in Baker Brothers. During the nine months ended September 30, 2018, Baker Brothers exercised warrants to purchase 2,539,541 shares of the Company's common stock at an exercise price of \$3.76 per share for a total exercise price of approximately \$9.5 million.

As of September 30, 2019, Baker Brothers held pre-funded warrants to purchase up to 2,708,812 shares of the Company's common stock at an exercise price of \$0.08 per share.

Board Fees Paid in Stock

Pursuant to the Company's director compensation program, in lieu of director board and committee fees incurred of \$0.1 million during each of the nine months ended September 30, 2019 and 2018, the Company issued 40,158 and 7,067 shares of its common stock, respectively, to certain of its directors. Director board and committee fees are paid in arrears (including fees paid in stock) and the number of shares issued was calculated based on the market closing price of the Company's common stock on the issuance date.

Note 13. Net Loss per Common Share

Basic and diluted net loss per common share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock option awards, common stock warrants and convertible preferred stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the three and nine months ended September 30, 2019 and 2018, diluted net loss per common share applicable to common stockholders was 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 excluded from the calculation of diluted net loss per share were 7,354,976 and 6,093,983 as of September 30, 2019 and 2018, respectively, and consisted of stock options, preferred stock and warrants.

Note 14. 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.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with:

- *our unaudited condensed financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q; and*
- *our audited financial statements and accompanying notes included in our Annual Report on Form 10-K for 2018, or our 2018 Form 10-K, as well as the information contained under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2018 Form 10-K.*

Overview

We are a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is on our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. We believe we can develop and commercialize targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we have entered into and may explore additional collaborative alliances to support development and commercialization.

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

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. We are currently developing tilsotolimod, via intratumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company (“BMS”) in a Phase 3 registration trial. We are also evaluating intratumoral tilsotolimod in combination with nivolumab, an anti-PD1 antibody marketed as Opdivo® by BMS, and ipilimumab for the treatment of multiple solid tumors in a Phase 2 trial.

On November 5, 2019, the U.S. Patent and Trademark Office issued to us U.S. Patent No. 10,463,686 entitled “Immune Modulation With TLR9 Agonists For Cancer Treatment,” which includes tilsotolimod. The patent includes 24 claims directed to methods of treating melanoma with intratumoral administration of tilsotolimod in combination with certain immune checkpoint inhibitor therapies, including inhibitors of the CTLA-4 and PD-1/PD-L1 pathways. The patent is expected to expire in September 2037.

Clinical Development

Tilsotolimod (IMO-2125)

Tilsotolimod (IMO-2125) is a synthetic phosphorothioate oligonucleotide that acts as a direct agonist of TLR9 to stimulate the innate and adaptive immune systems. We are developing tilsotolimod for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) squamous cell carcinoma of the head and neck in combination with nivolumab and ipilimumab, and (iii) microsatellite stable colorectal cancer in combination with nivolumab and ipilimumab. We refer to our tilsotolimod development program as the ILLUMINATE development program.

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the

immune system. Despite these advancements, many patients fail to respond to these therapies. For instance, approximately 50% of patients with melanoma fail to respond to therapy with approved checkpoint inhibitors. Current published data suggests that the lack of response to checkpoint inhibition is related to a non-immunogenic tumor micro-environment. We also believe TLR9 agonists may be useful in other solid tumor types that are refractory to anti-PD1 treatment due, in part, to low mutation load and low dendritic cell infiltration. Because TLR9 agonists, such as tilsotolimod, stimulate the immune system, we believe there is a scientific rationale to evaluate the combination of intratumoral injection of tilsotolimod with checkpoint inhibitors. Specifically, we believe intratumoral injection of tilsotolimod activates a local immune response in the injected tumor, which may complement the effect of the systemically administered checkpoint inhibitors. Currently, there is minimal immunotherapy benefit, post chemotherapy, for patients with squamous cell carcinoma of the head and neck and no approved immunotherapy options for patients with microsatellite stable colorectal cancer.

In studies in preclinical cancer models conducted in our laboratories, intratumoral injection of TLR9 agonists, such as tilsotolimod, has potentiated the anti-tumor activity of multiple checkpoint inhibitors in multiple tumor models. We believe these data support evaluation of combination regimens including the combination of a TLR9 agonist, such as tilsotolimod, with one or more checkpoint inhibitors for the treatment of cancer.

Melanoma

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. Although melanoma is a rare form of skin cancer, it causes the majority of skin cancer deaths. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body, such as the lymphatic system (metastatic disease). Based on internally conducted commercial research, we believe that, by 2025, approximately 26,000 people in the United States will have advanced melanoma appropriate for treatment, of which 8,000 will be refractory to anti-PD1 therapies. Recent advances in therapy, such as immune checkpoint inhibitors, given as single agents or in combination, have improved long-term survival outcomes. However, advanced metastatic melanoma continues to present significant morbidity and mortality as not all patients respond to treatment with checkpoint inhibitors. Some patients who initially respond develop progressive disease requiring further treatment. Consequently, about half of the patients who receive anti-PD1 therapy will require further treatment.

We are currently developing tilsotolimod for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma. Tilsotolimod has received Orphan Drug Designation for the treatment of melanoma Stages IIb to IV and Fast Track designation for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab therapy from the U.S. Food and Drug Administration (“FDA”).



ILLUMINATE-301 - Phase 3 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In the first quarter of 2018, we initiated a Phase 3 trial of the tilsotolimod–ipilimumab combination in patients with anti-PD1 refractory metastatic melanoma, which we refer to as ILLUMINATE-301. This trial will compare the results of the tilsotolimod–ipilimumab combination to those of ipilimumab alone in a 1:1 randomization. This trial originally targeted a sample size of 308 patients and was expected to be conducted at up to 110 sites worldwide. The family of primary endpoints of the trial are overall response rate (“ORR”) by RECIST v1.1 and median overall survival (“OS”). We believe that positive results in either of the primary endpoints could lead to approval in the United States. Key secondary endpoints include ORR by immune-related RECIST, durable response rate, median time to response, median progression free survival (“PFS”) and patient-reported outcomes using a validated scale.

Following feedback from the ILLUMINATE-301 Steering Committee and global melanoma and immunology experts, we elected to make several modifications to the ILLUMINATE-301 trial design which better reflect the current treatment landscape in anti-PD-1 refractory melanoma and increase the probability of success in the trial. We are currently targeting a median OS improvement over ipilimumab alone of greater than or equal to 4.6

months, compared to 6.6 months originally targeted, and an ORR improvement of 10 percentage points over ipilimumab alone, compared to 20 percentage points originally targeted. Accordingly, the target effect size or hazard ratio has been adjusted to 0.71 from 0.63. In order to maintain statistical power, the sample size was increased to 454 from the original target sample size of 308. We have solicited feedback from the FDA and they do not object to these changes. We have also received approval from other global health authorities related to these changes.

As of October 23, 2019, we had 342 patients enrolled, reaching 75% of enrollment. Based on our current enrollment rate, we expect to complete enrollment in the first half of 2020.

As discussed below under the heading “Collaborative Alliances,” in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to supply YERVOY® (ipilimumab), at its cost and for no charge to us, for use in ILLUMINATE-301, including for the increase in sample size.



ILLUMINATE-204 - Phase 1/2 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab or Pembrolizumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of intratumoral tilsotolimod in combination with ipilimumab, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory), which we refer to as ILLUMINATE-204. We subsequently amended the trial protocol to include an additional treatment arm to study the combination of tilsotolimod with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., Inc., in the same patient population. The Phase 2 expansion of our ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at 8 mg tilsotolimod in combination with ipilimumab, 49 of which are evaluable for safety and efficacy. As discussed further below, we reviewed interim data from this trial during the third quarter of 2019. Final data from this trial is anticipated to be submitted for presentation at a major oncology meeting in the first half of 2020.

In this clinical trial, tilsotolimod is administered intratumorally into a selected tumor lesion at weeks 1, 2, 3, 5, 8, 11, 17, 23 and 29 (total of nine doses) together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. For patients who lack superficially accessible disease for injection, tilsotolimod is administered via injection into deep lesions, such as liver metastases, using interventional radiology guidance.

The trial was initiated at The University of Texas, MD Anderson Cancer Center (“MD Anderson”) under the strategic research alliance we entered into with MD Anderson in June 2015, and additional sites have been added through the fourth quarter of 2018. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the anti-tumor activity of tilsotolimod when administered intratumorally in combination with ipilimumab or pembrolizumab. The primary objective of the Phase 2 portion of the trial is to determine the objective response rate to the combinations using immune-related response criteria (“irRC”) and RECIST v1.1 criteria. The secondary objectives of the Phase 2 portion of the trial include the assessment of treatment response utilizing irRC, determination of median PFS and median OS, and to continue to characterize the safety of the combinations. In the Phase 1 portion of the trial, serial biopsies were taken of selected injected and non-injected tumor lesions pre- and post-24 hours of the first dose of tilsotolimod, as well as at 8 and 13 weeks, to assess immune changes and response assessments. In the Phase 2 portion of the trial, biopsies are optional.

Ipilimumab Arm

In the Phase 1 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod, escalating doses of tilsotolimod ranging from 4 mg through 32 mg were evaluated in a total of 18 patients, each of which but one had progressed on nivolumab or pembrolizumab prior to enrollment in the trial. The combination of tilsotolimod and ipilimumab was generally well-tolerated at all dose levels studied. In April 2017, we completed

tilsotolimod dose escalation and, based on the safety and efficacy data and data from translational immune parameters, selected the 8 mg dose level as the recommended dose level for the Phase 2 portion of the ipilimumab arm of the trial.

In April 2017, we initiated enrollment in the Phase 2 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod with the 8 mg dose of intratumoral tilsotolimod. The Phase 2 portion of the trial utilizes a two-stage design to evaluate the objective response rate of tilsotolimod in combination with ipilimumab, compared to historical data for ipilimumab alone in the anti-PD1 refractory metastatic melanoma population. Based on the responses observed, the trial advanced with the expansion of the ipilimumab-tilsotolimod combination arm of ILLUMINATE-204 at the recommended Phase 2 dose of 8 mg tilsotolimod.

The Phase 2 ipilimumab-tilsotolimod combination arm of the ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at the recommended Phase 2 dose. As of August 5, 2019, of the 49 subjects evaluable for efficacy, 13 had a response representing a best overall response rate of 27%. Of the 13 responders, 4 were unconfirmed responses. Additionally, 36 of the 49 patients achieved stable disease or better, representing a disease control rate of 74%. Durable responses (>6 months) were observed in 5 of 9 confirmed responses per RECIST v1.1. Median overall survival (OS) had not yet been reached (min/max: 1.6 months/35 months).

We examined the four unconfirmed responders (of the 13 responders) out of the 49 subjects evaluable for efficacy. As of October 23, 2019, two subjects were confirmed per RECIST v1.1 criteria, one remains unconfirmed, and one experienced disease progression. As for disease control, 35 of the 49 patients achieved stable disease or better (71%). Durable responses (greater than six months) were observed in five of 10 confirmed responses per RECIST v1.1 criteria who were evaluable for durability. The safety profile observed is consistent with previously reported results.

Other key findings from the trial include data demonstrating a systemic antitumor effect on distant uninjected tumors in patients who received tilsotolimod in combination with ipilimumab. Also, data showing clinical responses were observed in patients whose tumors had low HLA-ABC expression before treatment was started. Since HLA-ABC expression is required for ipilimumab anti-tumor activity (Rodig, 2018), evidence of clinical responses in patients with low HLA-ABC expression supports the contribution of tilsotolimod's mechanism of action to overcome resistance to ipilimumab in tumors with this HLA-ABC expression profile. This information has the potential to enhance the overall response rate compared to that expected with ipilimumab alone.

Pembrolizumab Arm

In the Phase 1 portion of the pembrolizumab arm of our Phase 1/2 clinical trial of tilsotolimod, we evaluated escalating doses of tilsotolimod ranging from 8 mg through 32 mg.

We completed enrollment with a total of 9 patients dosed with the combination therapy in the 8 mg, 16 mg and 32 mg dosing cohorts in the Phase 1 dose escalation portion of the pembrolizumab arm of the trial. One patient who was treated at the 16 mg dose has experienced an ongoing complete response by RECIST v1.1 criteria.

Refractory Solid Tumors



ILLUMINATE-101 - Phase 1b Trial of Intra-tumoral Tilsotolimod (IMO-2125) Monotherapy in Patients with Refractory Solid Tumors

In March 2017, we initiated a Phase 1b dose escalation trial of intratumoral tilsotolimod as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, intratumoral tilsotolimod was administered on days 1, 8 and 15 of cycle 1 and on day 1 of each subsequent 21-day cycle, up to 17 cycles (19 total doses). We completed enrollment of a total of 38 patients in four dose-escalation cohorts at doses of 8mg (cohort 1, n=11), 16mg (cohort 2, n=8), 23mg (cohort 3, n=10) and 32mg (cohort 4, n=9). There were no dose-

limiting toxicities observed and tilsotolimod appeared to be generally well-tolerated at each of the dose levels tested. We also completed enrollment of 16 patients in a melanoma expansion cohort, which utilized a Simon's optimal two-stage design, to assess whether tilsotolimod as a single agent (8mg dose) has any statistically relevant clinical activity, as demonstrated for objective response according to RECIST v1.1 criteria, in patients with metastatic melanoma who have progressed on or after treatment with a PD-(L)1 inhibitor.

At the European Society for Medical Oncology Congress in September 2019, we provided an update on ILLUMINATE-101, noting that as of July 1, 2019, a total of 54 patients had been dosed, including 38 patients in the dose-evaluation portion of the trial and 16 patients in the melanoma dose-expansion cohort. Of the 45 evaluable patients, 33% (n=15) had a best response stable disease. Duration of stable disease ranged from 1.5 to 12 months from the start of treatment, with stable disease ongoing for two patients. There were no correlations between dose and efficacy observed.

We completed ILLUMINATE-101 in October 2019. One patient in the melanoma monotherapy cohort achieved an unconfirmed partial response, however, this patient discontinued from the study prior to the confirmation of the response. Additionally, one subject with uterine-leiomyosarcoma had ongoing stable disease for more than one year. This subject is continuing under a treatment IND post-closing of ILLUMINATE-101. Final results from the ILLUMINATE-101 trial are expected to be presented in the first half of 2020.

An additional purpose of this study was to obtain tumor biopsies to assess the effect of tilsotolimod on the tumor microenvironment in multiple types of solid tumors and inform the expansion of the development program beyond melanoma. Translational research in ILLUMINATE-101 demonstrated that tilsotolimod increased dendritic cell activation and upregulated MHC class II and IFN- α signaling which suggests improved antigen presentation, and is similar to that observed and previously reported in the tumor biopsies from the ILLUMINATE-204 melanoma subjects. This observation provided additional rationale to expand the tilsotolimod program to additional solid tumors.

Other Solid Tumors

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, as single agents or in combination, for other solid tumors including, among others, dMMR/MSI-H colorectal cancer ("CRC") and squamous cell carcinoma of the head and neck ("SCCHN").

Nivolumab administered as monotherapy or in combination with ipilimumab has demonstrated benefit and is approved for the treatment of dMMR/MSI-H mCRC. However, in a previously treated microsatellite stable ("MSS") CRC patient population, nivolumab + ipilimumab combination therapy did not produce objective responses. MSS-CRC has been shown to be highly immunosuppressive. Moreover, the tumor microenvironment in MSS-CRC has been shown to keep dendritic cells in an immature state. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to nivolumab and ipilimumab within the immunosuppressive tumor microenvironment ("TME") of MSS-CRC patients.

We believe, based on internally conducted commercial research and information published by the American Cancer Society, that annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and that approximately 50,000 deaths are attributed to CRC. Additionally, we believe that annually in the United States, approximately 64,000 people are diagnosed with SCCHN and there are approximately 14,000 deaths attributed to SCCHN. We also believe that, by 2025, approximately 434,000 people will have tumors (i.e. non-small cell lung cancer, head and neck, colorectal, bladder and gastric) appropriate for treatment, of which 200,000 will be refractory to anti-PD1 therapies.

Squamous cell carcinoma is the most frequent malignant tumor of the head and neck region and develops from the mucosal linings of the upper aerodigestive tract. Although the majority of patients present with loco-regional disease, more than 50% will succumb to recurrent or metastatic disease despite aggressive therapy with surgery, radiation, and/or chemotherapy. Relapsed or metastatic SCCHN ("RM-SCCHN") is currently an incurable disease with a poor prognosis and the mortality rate of patients presenting with advanced disease remains high. Recently, the results from prospectively conducted trials employing the immune-modulating antibodies nivolumab and pembrolizumab following chemotherapy heralded a new era of treatment for RM-SCCHN. Patients responding to these agents have seen durable responses and in controlled studies an overall survival benefit has been demonstrated for the anti PD-1 antibodies versus standard of care chemotherapy. The challenge remains to

increase the percentage of patients responding to these treatments, which currently ranges from 13% to 23% depending on the line of therapy.



ILLUMINATE-206 - Phase 2 Trial of Tilsotolimod (IMO-2125) in Combination with Nivolumab and Ipilimumab for the treatment of Solid Tumors

In December 2018, we submitted an IND application to the FDA to evaluate tilsotolimod administered intratumorally, in combination with nivolumab and ipilimumab in a Phase 2, multi-cohort study that anticipates the study of multiple solid tumors. The basis for this study is supported by data generated from our ILLUMINATE-101 and ILLUMINATE-204 trials, which suggest the mechanism of action for tilsotolimod may be tumor-type agnostic and potentially beneficial in combination with checkpoint modulation in a variety of tumor types. In January 2019, we received notification from the FDA that the study may proceed and initiated the Phase 2, open-label, global, multicohort study for the treatment of specific solid tumors in September 2019. We refer to this study as ILLUMINATE-206.

Each cohort in this study is designed to be conducted in two parts. The purpose of the first part (Part 1) is for signal finding and utilizes a Simon's minimax two-stage design in a single-arm. The primary objective of Part 1 is to evaluate the efficacy (measured by ORR based on RECIST v1.1) of intratumoral tilsotolimod in combination with nivolumab and ipilimumab. Secondary objectives of Part 1 include safety, tolerability, immunogenicity and translational data evaluations. Based on the data from Part 1 of each cohort, expansion of a cohort may be conducted as Part 2. Part 2 objectives will be determined after the decision is made to initiate Part 2 of a given cohort. The start and end of the study will be independent for each cohort.

The ILLUMINATE-206 cohorts are as follows:

- MSS-CRC Cohort: Relapsed/refractory MSS-CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab; and
- RM-SCCHN Cohort: RM-SCCHN in PD-1-refractory patients treated with tilsotolimod in combination with nivolumab and ipilimumab.

We initiated ILLUMINATE-206 beginning with the MSS-CRC Cohort. Within Part 1 of the MSS-CRC Cohort, approximately 65 patients may be enrolled pending data from the signal-finding stage.

As discussed below under the heading "Collaborative Alliances," in March 2019, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab) and OPDIVO® (nivolumab), at its cost and for no charge to us, for use in ILLUMINATE-206.

Collaborative Alliances

In addition to our current alliances, we may explore potential collaborative alliances to support development and commercialization of our TLR agonists and antagonists. Our current alliances include collaborations with AbbVie Inc. (“AbbVie”), and BMS, described below, and GSK and Abbott Molecular, as described in Note 9 of the notes to our condensed financial statements in this Quarterly Report on Form 10-Q and/or in our Annual Report on Form 10-K for the year ended December 31, 2018.

Collaboration with Bristol-Myers Squibb

Effective May 18, 2018, we entered into a clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab), which agreement we refer to as the May 2018 BMS Agreement. Under the May 2018 BMS Agreement, we will sponsor, fund and conduct our ongoing global, open-label, multi-center Phase 3 clinical trial of tilsotolimod in combination with YERVOY® entitled “A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Patients with Anti-PD-1 Refractory Melanoma” in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-301. Under the May 2018 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® in ILLUMINATE-301 and has agreed to manufacture and supply YERVOY®, at its cost and for no charge to us, for use in ILLUMINATE-301.

Effective March 11, 2019, we entered into a second clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab) and OPDIVO® (nivolumab), which agreement we refer to as the March 2019 BMS Agreement. Under the March 2019 BMS Agreement, we will sponsor, fund and conduct a Phase 2, open-label, global, multi-center, multi-cohort study of intratumoral tilsotolimod in combination with YERVOY® and OPDIVO® entitled “Study of Tilsotolimod in Combination with Nivolumab and Ipilimumab For the Treatment of Solid Tumors” in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-206. Under the March 2019 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® and OPDIVO® in ILLUMINATE-206 and has agreed to manufacture and supply YERVOY® and OPDIVO®, at its cost and for no charge to us, for use in ILLUMINATE-206.

Collaboration with AbbVie

Effective August 27, 2019, we entered into a clinical trial collaboration and supply agreement with AbbVie, a global, research-based biopharmaceutical company, to conduct a clinical study to evaluate the efficacy and safety of combinations of an OX40 agonist (ABBV-368), tilsotolimod, nab-paclitaxel and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181), which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will provide a clinical trial supply of tilsotolimod to AbbVie and AbbVie will sponsor, fund and conduct the study entitled “A Phase 1b, Multicenter, Open-Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV-368 plus Tilsotolimod and Other Therapy Combinations in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma”, or the AbbVie Study. Under the AbbVie Agreement, we have agreed to manufacture and supply tilsotolimod at its cost and for no charge to AbbVie for use in the AbbVie Study.

Licensing and Other Arrangements

Option and License Agreement

In April 2019, we entered into an amended and restated option and license agreement with a privately-held biopharmaceutical company, or Licensee, pursuant to which the Company granted Licensee (i) exclusive worldwide rights to develop and market IMO-8400 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans, or the IMO-8400 License, (ii) an exclusive right and license to develop IMO-9200 in accordance with certain IMO-9200 pre-option exercise protocols, or the IMO-9200 Option Period License, and (iii) an exclusive option, exercisable at Licensee's discretion, to obtain the exclusive worldwide rights to develop and market IMO-9200 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans, or the IMO-9200 Option. We refer to this agreement as the Licensee Agreement. In connection with the Licensee Agreement, we transferred certain drug material to Licensee for Licensee's use in development activities. Licensee is solely responsible for the development and commercialization of IMO-8400 and, if Licensee exercises the IMO-9200 Option, Licensee would be solely responsible for the development and commercialization of IMO-9200.

Under the terms of the Licensee Agreement, we received upfront, non-refundable fees totaling approximately \$1.4 million and ownership of 10% of Licensee's outstanding common stock, subject to future adjustment, for granting Licensee the IMO-8400 License, the IMO-9200 Option Period License and transfer of related drug materials. In addition, we are eligible to receive a \$1 million fee upon Licensee exercising the IMO-9200 Option and are entitled to certain sub-licensing payments on sublicense revenue received by Licensee, if any. We may also be eligible for certain development and sales-based milestone payments and royalties on global net sales for any future products. We do not anticipate the receipt of any of the future milestones or royalties in the short term, if ever.

Critical Accounting Policies and Estimates

This management’s discussion and analysis of financial condition and results of operations is based on our condensed 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, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and judgments, which are affected by the application of our accounting policies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be appropriate under the circumstances. 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:

- (i) 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
- (ii) 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 included in our 2018 Form 10-K. However, please refer to Note 2 in the accompanying notes to the condensed financial statements contained in this Quarterly Report on Form 10-Q for updated policies and estimates, if applicable, that could impact our results of operations, financial position, and cash flows. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, stock-based compensation and research and development prepayments, accruals and related expenses, as described under the caption “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” in our 2018 Form 10-K, fit the description of critical accounting estimates and judgments.

New Accounting Pronouncements

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

Financial Condition, Liquidity and Capital Resources

Financial Condition

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009. As of September 30, 2019, we had an accumulated deficit of \$697.7 million. To date, substantially all of our revenues have been from collaboration and license agreements and we have received no revenues from the sale of commercial products. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any commercial products. Our research and development activities, together with our selling, general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. Because of the numerous risks and uncertainties associated with developing drug candidates, and if approved, commercial products, 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.

Liquidity and Capital Resources

Overview

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

- (i) sale of common stock, preferred stock and warrants;
- (ii) exercise of warrants;
- (iii) debt financing, including capital leases;
- (iv) license fees, research funding and milestone payments under collaborative and license agreements; and
- (v) interest income.

We filed a shelf registration statement on Form S-3 on August 10, 2017, which was declared effective on September 8, 2017. Under this registration statement, we may sell, in one or more transactions, up to \$250.0 million of common stock, preferred stock, depository shares and warrants. As of October 31, 2019, we may sell up to an additional \$188.4 million of securities under this registration statement, such amount which includes \$32.7 million of shares which may be issued pursuant to our common stock purchase agreement with Lincoln Park, as described below, and additional shares which may be issued under the ATM Agreement, as more fully described in Note 7 of the notes to our financial statements included in this Quarterly Report on Form 10-Q.

Funding Requirements

We had cash, cash equivalents and short-term investments of approximately \$41.6 million at September 30, 2019. We believe that, based on our current operating plan, our existing cash, cash equivalents and short-term investments will enable us to fund our operations into the third quarter of 2020. Specifically, we believe that our available funds will be sufficient to enable us to:

- (i) continue to execute on:
 - a) the Phase 1 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with pembrolizumab in anti-PD1 refractory melanoma (ILLUMINATE-204);
 - b) the Phase 2 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab in anti-PD1 refractory melanoma (ILLUMINATE-204); and
 - c) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);

- (ii) complete enrollment and continue to execute on our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301);
- (iii) initiate and complete enrollment in the signal-finding stage of Part I of our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC (ILLUMINATE-206);
- (iv) fund certain investigator initiated clinical trials of tilsotolimod; and
- (v) maintain our current level of general and administrative expenses in order to support the business.

We expect that we will need to raise additional funds in order to complete our ongoing clinical trials of tilsotolimod and to continue to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

- (i) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;
- (ii) the cost, timing, and outcome of regulatory reviews;
- (iii) competitive and potentially competitive products and technologies and investors' receptivity to tilsotolimod or any other drug candidates we develop and the technology underlying them in light of competitive products and technologies;
- (iv) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;
- (v) the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into; and
- (vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

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

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 13 of the notes to our financial statements included in our 2018 Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay our clinical trials or relinquish rights to portions of our technology, drug candidates and/or products.

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into the Purchase Agreement with Lincoln Park, pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Lincoln Park has committed to purchase an aggregate of \$35.0 million of shares of Company common stock from time to time at the Company's sole discretion. As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park as a commitment fee, or the Commitment Shares. The Company did not receive any cash proceeds from the issuance of the Commitment Shares. See Item 9B, Other Information, in our 2018 Form 10-K for additional information. As of September 30, 2019, under the Purchase Agreement, the Company has sold 785,848 shares and received proceeds of \$2.3 million, leaving \$32.7 million remaining available to be issued pursuant to this agreement.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the nine months ended September 30, 2019 and 2018:

<i>(in thousands)</i>	Nine months ended September 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	\$ (34,171)	\$ (40,444)
Investing activities	(8,597)	122
Financing activities	3,948	10,155
Decrease in cash and cash equivalents	\$ (38,820)	\$ (30,167)

Operating Activities. Net cash used in operating activities for each of the nine months ended September 30, 2019 and 2018 consists primarily of our net losses adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the nine months ended September 30, 2019, as compared to the 2018 period, was primarily due to decreases in cash outflows related to our prior discovery and other development programs, lower costs resulting from the closure of our Cambridge, Massachusetts office, and no 2019 merger-related costs, partially offset by increased cash outflows related to our current IMO-2125 development program.

Investing Activities. Net cash used by investing activities primarily consisted of the following amounts relating to our investments in available-for-sale securities and purchases and disposals of property and equipment:

- for the nine months ended September 30, 2019, purchases of \$44.4 million in available-for-sale securities, partially offset by \$35.9 million of proceeds from available-for-sale securities; and
- for the nine months ended September 30, 2018, proceeds of \$0.2 million from the sale of property and equipment, partially offset by purchases of less than \$0.1 million of property and equipment.

Financing Activities. Net cash provided by financing activities primarily consisted of the following amounts received in connection with the issuances of common stock:

- for the nine months ended September 30, 2019, \$1.6 million in net proceeds from the issuance of common stock under our "At-the-market" equity program, \$2.3 million in net proceeds from the issuance of common stock under our Purchase Agreement with Lincoln Park, and \$0.1 million in proceeds from employee stock purchases under our 2017 ESPP; and
- for the nine months ended September 30, 2018, \$10.2 million in aggregate proceeds from the exercise of common stock options and warrants, \$0.2 million in proceeds from employee stock purchases under our 2017 ESPP, partially offset by \$0.2 million in payments made on our note prior payable.

Contractual Obligations

During the nine months ended September 30, 2019, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our 2018 Form 10-K.

Off-Balance Sheet Arrangements

As of September 30, 2019, we had no off-balance sheet arrangements.

Results of Operations

Three and Nine Months Ended September 30, 2019 and 2018

Alliance Revenue

Alliance revenues consist of revenue generated through collaborative research, development and/or commercialization agreements and other out-licensing arrangements. The terms of these agreements may include payment to us of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance.

Alliance revenue for the nine months ended September 30, 2019 totaled \$1.4 million primarily related to the out-licensing of certain non-core technology to Licensee during the second quarter of 2019. No such revenues were recognized during the three months ended September 30, 2019. See Notes 8 and 9 to the condensed financial statements in this Quarterly Report on Form 10-Q.

Alliance revenue for the three and nine months ended September 30, 2018 primarily related to the recognition of the \$2.5 million upfront payment received in connection with the execution of the GSK Agreement in November 2015, which has been recognized on a straight-line basis through the fourth quarter of 2018, the end of the anticipated performance period of the agreement. Accordingly, no such revenues were recognized during the three and nine months ended September 30, 2019. See Note 8 and Note 9 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information on our collaboration with GSK. Other amounts recognized during the 2018 period relate to amounts earned in connection with collaborations which are not material to our current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

Research and Development Expenses

For each of our research and development programs, we incur both direct and indirect expenses. We track direct research and development expenses by program, which include third party costs such as contract research, consulting and clinical trial and manufacturing costs. We do not allocate indirect research and development expenses, which may include regulatory, laboratory (equipment and supplies), personnel, facility and other overhead costs (including depreciation and amortization), to specific programs.

In the table below, research and development expenses are set forth in the following categories which are discussed beneath the table:

(\$ in thousands)	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2019	2018		2019	2018	
IMO-2125 external development expense	\$ 6,208	\$ 6,108	2%	\$ 19,308	\$ 16,901	14% (1)
IMO-8400 external development expense	—	—	0%	45	2,607	(98%)(2)
Other drug development expense	2,151	2,056	5%	7,132	8,497	(16%)(3)
Basic discovery expense	—	696	(100%)	—	4,907	(100%)(4)
Total research and development expenses	\$ 8,359	\$ 8,860	(6%)	\$ 26,485	\$ 32,912	(20%)

- (1) *IMO-2125 External Development Expenses.* These expenses include external expenses we have incurred in connection with the development of tilsotolimod as part of our immuno-oncology program. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of tilsotolimod clinical development in immuno-oncology, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of tilsotolimod as part of our immuno-oncology program in July 2015 and from July 2015 through September 30, 2019 we incurred approximately \$59.0 million in tilsotolimod external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of the ongoing Phase 1/2 clinical trial to assess the safety and efficacy of

tilsotolimod in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma (ILLUMINATE-204), the preparation and conduct of our ongoing Phase 1b clinical trial of tilsotolimod monotherapy in patients with refractory solid tumors (ILLUMINATE-101), the preparation for, initiation and conduct of our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab in patients with metastatic melanoma (ILLUMINATE-301), the preparation for our Phase 2 clinical trial of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumor (ILLUMINATE-206), and the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies.

IMO-2125 external development expenses for the three months ended September 30, 2019 were consistent with the corresponding 2018 period. The increase in IMO-2125 expenses during the nine months ended September 30, 2019, as compared to the corresponding 2018 period, was primarily due to increases in costs incurred with contract research organizations to support our ongoing ILLUMINATE-301 trial, which we initiated in the first quarter of 2018, and ILLUMINATE-206, which we initiated in December 2018. The increase was partially offset by decreased expenses related to ILLUMINATE-101 and ILLUMINATE-204.

Going forward, we expect ongoing IMO-2125 external development expenses to be significant as our focus in 2019 continues to be on the clinical development of tilsotolimod (IMO-2125). See additional information under the heading “Financial Condition, Liquidity and Capital Resources” regarding our future funding requirements.

- (2) *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 \$45.4 million in IMO-8400 external development expenses through September 30, 2019, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis, our Phase 1/2 clinical trial in patients with Waldenström’s macroglobulinemia and our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma, or DLBCL, harboring the MYD88 L265P oncogenic mutation, which we discontinued in September 2016; our Phase 2 clinical trial in patients with dermatomyositis, which we determined in July 2018 to discontinue upon completion of final close-out activities; the manufacture of drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with DLBCL harboring the MYD88 L265P oncogenic mutation. In July 2018, we terminated further development of IMO-8400. As a result, we expect IMO-8400 external development expenses to be insignificant in future periods.

The decrease in our IMO-8400 external development expenses during each of the three and nine months ended September 30, 2019, as compared to the 2018 period, was primarily due to our decision to discontinue all development of IMO-8400.

- (3) *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, including IDRA-008. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed. In July 2018, we suspended further preclinical research. As a result, we expect other drug development expenses to be lower in future periods.

Other drug development expenses for the three months ended September 30, 2019 were consistent with the corresponding 2018 period. The decrease in other drug development expenses for the nine months ended September 30, 2019, as compared to the corresponding 2018 period, was primarily due to a decrease in external costs of preclinical programs, including related bulk drug manufacturing.

toxicology studies and awareness and education programs, as we suspended preclinical research activities in July 2018 and focused on the development of our clinical drug candidates.

- (4) *Basic Discovery Expenses.* These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, and our nucleic acid chemistry research programs. These expenses reflect charges for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. In July 2018, we suspended all internal discovery programs. As a result, we expect basic discovery expenses to be insignificant in future periods.

We do not know if we will be successful in developing and commercializing any drug candidate. At this time, and without knowing the results from our ongoing clinical trials of tiltsotolimod, 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. Moreover, the clinical development of tiltsotolimod 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 consist primarily of payroll, stock-based compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

For the three months ended September 30, 2019 and 2018, general and administrative expenses totaled \$3.0 million and \$4.0 million, respectively. For the nine months ended September 30, 2019 and 2018, general and administrative expenses totaled \$9.1 million and \$11.8 million, respectively. The decreases were primarily due to lower employee-related costs and facility-related costs as a result of cost savings realized in connection with our restructuring activities and the closing of our Cambridge, Massachusetts facility post-restructuring in July 2018.

Merger-related Costs, net

Merger-related costs, net consists of charges and, where applicable, credits for transaction and integration-related professional fees, employee retention, and other incremental costs directly related to these activities, which are offset by merger termination fees. See our 2018 Form 10-K for additional information on our previously contemplated merger transaction.

Merger-related costs, net for the three months ended September 30, 2018 amounted to a net credit of \$3.8 million and was comprised of a \$6.0 million fixed expense reimbursement received in connection with the termination of a merger agreement in July 2018, partially offset by \$2.2 million of expenses incurred in connection with transactions contemplated by a merger agreement, including legal and professional fees. Merger-related costs, net for the nine months ended September 30, 2018 amounted to a net charge of \$1.2 million and was comprised of \$7.2 million of expenses incurred in connection with the transactions contemplated by a merger agreement, including legal and professional fees, partially offset by a \$6.0 million fixed expense reimbursement received in connection with the termination of a merger agreement. No such costs were incurred during 2019.

Restructuring Costs

Restructuring costs consist primarily of severance and related benefit costs related to workforce reductions, contract termination and wind-down costs and asset impairments.

Restructuring costs for the three and nine months ended September 30, 2019 totaled less than \$0.1 million and approximately \$0.2 million, respectively. Restructuring costs for both the three and nine months ended September 30, 2018 totaled \$3.0 million. Restructuring costs for all periods were a result of our decision in July 2018 to wind-down our discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close our Cambridge facility.

Interest Income

Interest income for each of the three months ended September 30, 2019 and 2018 totaled approximately \$0.3 million. Interest income for the nine months ended September 30, 2019 and 2018 totaled approximately \$1.0 million and \$0.8 million, respectively. Amounts may fluctuate from period to period due to changes in average investment balances, including money market funds classified as cash equivalents, and composition of investments.

Interest Expense

Interest expense for the nine months ended September 30, 2018 totaled less than \$0.1 million and related to interest incurred on the outstanding principal balance of our note payable, which was paid off in June 2018. Accordingly, no such expense was incurred during the three months ended September 30, 2018 or the three and nine months ended September 30, 2019.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was \$11.1 million and \$11.6 million for the three months ended September 30, 2019 and 2018, respectively, and \$33.3 million and \$47.7 million for the nine months ended September 30, 2019 and 2018, respectively.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There were no material changes in our exposure to market risk from December 31, 2018. Our market risk profile as of December 31, 2018 is disclosed in Item 7A, *Quantitative and Qualitative Disclosures About Market Risk*, of our 2018 Form 10-K.

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 (the “Exchange Act”) as of September 30, 2019. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of September 30, 2019, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors.

Risk factors that may affect our business and financial results are discussed within Item 1A, *Risk Factors*, of our 2018 Form 10-K. There have been no material changes to the disclosures relating to this item from those set forth in our 2018 Form 10-K.

Item 6. Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
*10.1 †	Clinical Trial Collaboration and Supply Agreement, effective August 27, 2019, by and between AbbVie Inc. and Idera Pharmaceuticals, Inc.
*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

* Filed or furnished, as applicable, herewith.

† In accordance with Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted in order for them to remain confidential.

SIGNATURES

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

IDERA PHARMACEUTICALS, INC.

Date: November 6, 2019

/s/ Vincent J. Milano

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

Date: November 6, 2019

/s/ John J. Kirby

John J. Kirby
Chief Financial Officer
(Principal Financial Officer and Principal Accounting
Officer)

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This Clinical Trial Collaboration and Supply Agreement (this “**Agreement**”), made as of August 19, 2019, (the “**Effective Date**”) is by and between AbbVie Inc., a Delaware Corporation, located at 1 N. Waukegan Rd. North Chicago, Illinois 60064 (“**AbbVie**”); and Idera Pharmaceuticals Inc. located at 505 Eagleview Blvd. Suite 212, Exton, PA 19341 (“**Idera**”). AbbVie and Idera are each referred to herein as “**Party**” and are collectively referred to as the “**Parties**.”

RECITALS

WHEREAS, AbbVie and its Affiliates are developing ABBV-368, an intravenously administered, agonistic anti-OX40 monoclonal antibody, and ABBV-181, an intravenously administered anti-PD-1 monoclonal antibody, (also collectively referred to herein as “**AbbVie Compounds**”, and each an “**AbbVie Compound**”) for solid tumor indications, including squamous cell carcinoma of the head and neck; and

WHEREAS, Idera is developing tilsotolimod, an intratumorally administered, synthetic oligonucleotide toll-like receptor 9 agonist (also referred to herein as “**Idera Compound**”) for treatment of certain solid tumor indications, including squamous cell carcinoma of the head and neck; and

WHEREAS, AbbVie desires Idera to supply Idera Compound to AbbVie, and Idera is willing to supply Idera Compound to AbbVie, in accordance with the terms of this Agreement, for use in a clinical study of the AbbVie Compounds in combination with the Idera Compound (Idera Compound and the AbbVie Compounds collectively, the “**Compounds**”, and each, a “**Compound**”) for the treatment of squamous cell carcinoma of the head and neck (the “**Study**”) as set forth in the clinical protocol which is attached hereto as Attachment B (the “**Protocol**”).

NOW, THEREFORE, in consideration of the following mutual promises, covenants and conditions and any sums to be paid, the Parties hereto agree as follows:

1. OVERVIEW

- (a) Subject to the terms and conditions described herein, which shall include the terms and conditions of the attachments hereto, Idera shall supply, on a non-exclusive basis, the Idera Compound to AbbVie free of charge for treatment of subjects participating in the Study in accordance with the Protocol at study centers (“**Study Centers**”) and Attachment A (the “**Supply Addendum**”), as may be amended, and in sufficient quantity and with adequate timeliness for the conduct of the Study.
 - (b) Within [**] days following execution of this Agreement, or as otherwise agreed to the Parties in writing, Idera and AbbVie will also execute a separate (i) safety data exchange agreement (“**SDEA**”), which will set forth the Parties’ respective responsibilities and obligations with respect to the procedures and timeframes for compliance with Applicable Law pertaining to the Study safety reporting for the Compounds; and (ii) quality agreement (“**TQA**”), which will govern the quality of Idera Compound to be supplied hereunder. Upon finalization and execution, the SDEA shall automatically be incorporated herein by reference. In the event of any inconsistency between any of the provisions of the SDEA
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or TQA and this Agreement with respect to safety-related activities or quality-related activities (including compliance with Good Manufacturing Practices and related laws), respectively the provision of the SDEA or TQA, as applicable, shall control. In the event of any other inconsistency between the terms of this Agreement and the TQA or SDEA the terms of this Agreement shall control.

2. STUDY CONDUCT

- (a) General Conduct. Subject to the terms and conditions of this Agreement, AbbVie will sponsor the Study and will have the right and responsibility over the design, conduct and control of the Study (“**Sponsor**”). The Study shall be conducted under AbbVie’s Investigational New Drug application (“**IND**”) in the United States and equivalent clinical trial authorization outside the United States (“**CTA**”), as applicable, for an AbbVie Compound. If a Regulatory Authority requests an additional IND or CTA for the Study, the Parties shall meet and mutually agree on an approach to address such requirement. AbbVie will register the Study on www.clinicaltrials.gov and will comply with all Applicable Law relating to the registration of the Study. “**Applicable Law**,” for purposes of this Agreement, means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity of a Party hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the FDA and any successor agency to the FDA or any corresponding agency or authority performing some or all of the functions of the FDA in any jurisdiction outside the United States (each a “**Regulatory Authority**” and collectively, “**Regulatory Authorities**”) as applicable for where the Study is being conducted, and current International Conference on Harmonization of Good Clinical Practice (“**ICH GCP**”) guidelines.
- (b) Protocol. AbbVie and Idera acknowledge and agree that the Protocol has been finalized by the Parties. Idera consents to AbbVie’s submission of the Protocol to the United States Food and Drug Administration (“**FDA**”) and other applicable foreign Regulatory Authorities for purposes of conducting the Study. Thereafter, any amendments to the Protocol (“**Protocol Amendment**”) will be sent to Idera’s Clinical contact set forth in Attachment C (or as updated) for review and comment. Any comments on a Protocol Amendment by Idera are to be provided to AbbVie within [**] Business Days of Idera receiving the Protocol Amendment, unless the Parties otherwise agree to extend such review period or within the timeframe allotted by a Regulatory Authority, if applicable. AbbVie will make reasonable efforts to incorporate Idera’s comments into the Protocol Amendments (except to the extent material changes relating to the Idera Compound, in which case, such comments shall be incorporated). If no comments are provided by Idera within the given review period, the Protocol Amendment shall be deemed acceptable to Idera. For clarity, material matters relating to the Idera Compound shall include, but are not limited to, the (i) dose and dosing regimen for the Idera Compound, (ii) exclusion criteria and other safety measures applicable to the Idera Compound, and (iii) changes to the Protocol that increase the quantities of the Idera Compound to be supplied hereunder. Notwithstanding the foregoing, AbbVie will not make any changes to the Protocol that would increase the amount of Idera Compound to be supplied to AbbVie for the Study nor shall AbbVie make any changes to the Protocol with regard to the safety information regarding the Idera Compound, without the prior written consent of Idera. AbbVie has the

right to request a teleconference with Idera personnel, as appropriately designated by Idera per such request, to discuss potential changes to the Protocol or Idera's comments to a Protocol Amendment and Idera will use reasonable efforts to accommodate such request.

- (c) Study Centers. AbbVie shall select the clinical investigators ("**Investigators**") and Study Centers. AbbVie will be responsible for contracting with Investigators and Study Centers for the conduct of the Study and will ensure that it has appropriate provisions in its contracts with Study Centers and Investigators to comply with all of the terms and obligations contained in this Agreement, including but not limited to those pertaining to intellectual property and use of Study Data. AbbVie will require that Investigators and Study Centers conduct the Study in accordance with the approved Protocol and Applicable Law and will require that the Study is approved by and subject to continuing oversight by an appropriate Institutional Review Board ("**IRB**") or Ethics Committee ("**EC**").
- (d) Regulatory Actions. AbbVie is solely responsible for, and shall maintain control over, the regulatory files relating to the Study ("**AbbVie Regulatory Files**"), including, but not limited to, any and all safety reporting and regulatory obligations associated with the conduct of the Study, and relating to submitting, obtaining and maintaining an IND and or foreign equivalency file, as applicable, with respect thereto. Upon request, Idera will provide AbbVie with appropriate documentation to support any cross reference to the Idera Compound that AbbVie may need to include in any regulatory filings to conduct the Study. AbbVie has the sole right and responsibility to make submissions in support of AbbVie Regulatory Files and the right to correspond with governmental authorities of any nature in connection with such AbbVie Regulatory Files. AbbVie will ensure that (i) all directions in relation to its obligations as the Study Sponsor from any IRB/EC and/or Regulatory Authority with jurisdiction over the Study are followed and (ii) all Regulatory Approvals from any Regulatory Authority and/or IRB/EC with jurisdiction over the Study are obtained prior to initiating performance of the Study (first subject first dose). Notwithstanding the preceding, nothing in this section shall be construed as prohibiting Idera from replying to direct requests or inquiries from a Regulatory Authority related to use of the Idera Compound in the Study ("**RA-Idera Inquiry**"), or from otherwise making submissions required by Applicable Law or requested by a Regulatory Authority. For each RA-Idera Inquiry, Idera will include AbbVie in its correspondence with the Regulatory Authority, except as subject to Section 2(e) disclosures of CMC Information in which case Idera will notify AbbVie within [**] Business Days of its correspondence with the Regulatory Authority and in doing so provide AbbVie with the details of such correspondence applicable to the Study, subject to redactions of Idera's proprietary and confidential CMC Information. For clarity, as between the Parties, Idera shall remain solely responsible for, and shall maintain control over, all other regulatory files relating to the Idera Compound that do not relate to the Study and are controlled by Idera prior to the Effective Date ("**Idera Regulatory Files**"). Idera has the sole right and responsibility to make submissions in support of Idera Regulatory Files and the right to correspond with governmental authorities of any nature in connection with such Idera Regulatory Files.
- (e) Regulatory Inquiries. If there are any inquiries regarding the technical information that is part of the proprietary and confidential manufacturing, chemistry, controls and testing information associated with Idera Compound ("**CMC Information**"), then any such CMC Information requested would be disclosed directly by Idera to the applicable Regulatory Authority in a timely manner, and in any event within the timeframe required by such

Regulatory Authority. AbbVie shall have no right to directly access the Idera Compound CMC Information. If AbbVie receives any comments or other inquiries from a Regulatory Authority that pertain specifically to the Idera Compound that is not CMC Information, AbbVie will promptly provide such comments to Idera's Alliance Management contact set forth in Attachment C (or as updated) and Idera will provide its response to AbbVie within the timeframe required or requested by the Regulatory Authority ("**Response Period**"), so that AbbVie can forward such response to the Regulatory Authority. In the event that it will take Idera more time to provide a response that encompasses all the information requested by the Regulatory Authority pertaining to the Idera Compound ("**Full Response**"), Idera will notify AbbVie as soon as practicable within the Response Period, and such notice by Idera will provide AbbVie with (i) a partial response with the information available within the Response Period, (ii) the reason a Full Response cannot be provided within the Response Period, and (iii) the timeframe in which Idera will provide the outstanding information necessary for a Full Response. In any event, Idera will use commercially reasonable efforts to promptly provide such responses to AbbVie.

- (f) Compensation for Study Injuries. As between the Parties and subject to Section 13(a) and 13(b), (i) AbbVie shall be fully responsible for reimbursing Study Centers for reasonable medical expenses necessary to treat any Study Injury, and (ii) AbbVie agrees not to approve any written informed consent that states that Idera will provide any such compensation; *provided, however*, that to the extent that any or all of the reasonable medical expenses necessary to treat a Study Injury for which AbbVie provides reimbursement to a Study Center are attributable to the Idera Compound, Idera shall reimburse AbbVie for such expenses.
- (g) Regulatory Submission Reviews. Either Party may request review and comment on a portion of a submission to a Regulatory Authority that relates to the Study ("**Regulatory Submission**") from the other Party ("**Regulatory Submission Request**") by providing the Regulatory Submission Request in writing to the other Party's Alliance Manager and Regulatory contacts set forth in Attachment C (or as updated). The receiving Party shall respond with any comments upon the areas of the Regulatory Submission that relate to the receiving Party's Confidential Information or Compound(s) within [**] days (or as soon as practicable if such request is stated to be required within a shorter timeframe). The requesting Party shall be allowed to redact any of its Confidential Information (defined below) from the Regulatory Submission that is not material to the Regulatory Submission Request.
- (h) Informed Consent. AbbVie will require that Investigators obtain a valid informed consent form ("**ICF**") from each subject participating in the Study in accordance with all Applicable Laws, which will include a valid authorization for the use or disclosure of health information from each Study subject and use of Biological Samples (as defined in Section 7) obtained from such subject, in each case in accordance with the terms of this Agreement. AbbVie will prepare a template patient ICF for the Study to provide to IRBs/ECs and Investigators in order to obtain the aforementioned authorization and pursuant to AbbVie's standard internal processes and procedures, which require inclusion of Compound-specific Standard Safety Risk Language ("**SSRL**") (it being understood that the SSRL portion of the ICF relating to the Idera Compound ("**Idera Compound SSRL**") will be provided by Idera). Idera will provide the Idera Compound SSRL no later than [**] Business Days after execution of the Agreement. Any material changes to the Idera Compound SSRL proposed

by AbbVie or a Third-Party (as defined in Section 7), other than a Regulatory Authority or an IRB/EC, will be subject to Idera's written consent. Idera will provide such consent, or a written explanation for why such consent is being withheld, (i) within [**] Business Days of receiving AbbVie's request if such changes are proposed by AbbVie; and (ii) within [**] Business Days of receiving AbbVie's request if such changes are proposed by a Third-Party. Changes requested by a Regulatory Authority or an IRB/EC that are inconsistent with the Idera Compound SSRL will be incorporated without consent from Idera, *provided that* AbbVie considers in good faith any request by Idera in connection with such requested change.

- (i) Financial Disclosure. AbbVie shall (a) track and collect financial disclosure information from all Investigators involved in the Study and (b) prepare and submit the certification and/or disclosure of the same in accordance with all Applicable Law including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. For purposes of this Section 2(i), the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

"**Business Day**", as used in this Agreement, means any day that banks are open in New York other than a Saturday or Sunday; and "**Study Injury**" means an injury that occurs to a Study subject as a result of (i) the administration of the Compounds or (ii) the performance of Protocol-mandated procedures on Study subjects that such Study subjects would not have received but for their participation in the Study, in each case in accordance with the Protocol.

3. COMMENCEMENT AND TERMINATION

- (a) Expiration. This Agreement shall become effective upon the Effective Date and expire upon the completion or the discontinuation of the Study and completion of all related obligations under this Agreement with respect to the Study (the "**Term**"), unless terminated earlier pursuant to the following provisions. AbbVie shall notify the applicable Regulatory Authorities and IRBs/ECs of the completion, termination or suspension of the Study in accordance with Applicable Law.
- (b) Termination for Breach.
 - i. *Notice and Cure Period*. If Idera or AbbVie is in material breach of this Agreement (the "**Breaching Party**"), the other Party (the "**Non-Breaching Party**") shall give the Breaching Party notice specifying the nature of such material breach. If the breach is capable of cure, the Breaching Party shall have a period of [**] calendar days after receipt of such notice to cure such material breach (the "**Cure Period**") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way any Party's right to notify the other Party of any other breach or to demand the cure of any other breach.
 - ii. *Termination Right*. A Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, provided, however, that if such breach is capable of cure but cannot be cured within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional [**] days

to cure such breach. If the breach is not capable of cure, the Non-Breaching Party shall have the right to terminate this Agreement upon written notice to the Breaching Party.

- (c) Termination for Safety Concern. A Party may terminate this Agreement immediately upon written notice to the other Party if the terminating Party determines in good faith, based on a review of the Study Data or other Study-related know-how or information, that the Study may unreasonably (e.g. seriously and unexpectedly) affect patient safety, or for a similar medical, scientific, or legal concern. If requested by the other Party, the Parties shall discuss such concerns and whether the same can be reasonably addressed without termination.
- (d) Termination by Idera. In the event that (i) Idera reasonably believes that the use of the Idera Compound in accordance with the Protocol is cause for a patient safety concern and changes to the Protocol are not made within a reasonable period of time (not more than [**] Business Days) following a request by Idera to address such safety issue, or (ii) the Idera Compound is not being used as described in the Protocol, and within [**] Business Days following notice to AbbVie, AbbVie does not correct the use of the Idera Compound, then Idera may immediately terminate this Agreement and the supply of the Idera Compound upon written notice to AbbVie.
- (e) Termination for Regulatory Concern. A Party may terminate this Agreement immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound(s) for purposes of the Study. Additionally, either Party will have the right to terminate this Agreement immediately (in whole or in part) upon written notice to the other Party in the event that it determines in its sole discretion to discontinue development of its Compound(s).
- (f) Termination without Cause. AbbVie may terminate this Agreement upon [**] calendar days prior written notice to Idera for any reason.
- (g) No Release. Expiration or termination of this Agreement will not relieve any Party of any liability which accrued hereunder prior to the effective date of such expiration or termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation due prior to such termination.
- (h) Survival. Any terms which by their intent or meaning are intended to survive termination or expiration of this Agreement shall so survive, including without limitation this Section 3(h) and Sections 5, 7 through 20. In addition, in the event of a termination of this Agreement for any reason, the Parties will use reasonable efforts to initiate the cessation of the Study as soon as practicable consistent with subject safety.

4. **FINANCIAL**

- (a) Collaboration Costs and Expenses. Expenses incurred as described in Section 5 (Supply and Use of Compound), Section 6 (Quality) and Section 9 (Intellectual Property) shall be borne or shared by the Parties as provided in such Sections. Expenses incurred as described in Section 2(f) (Compensation for Injuries) shall be borne by AbbVie as provided in such

Section. All other expenses that are directly attributable or reasonably allocable to the conduct of the Study shall be borne by AbbVie.

- (b) Tax. If applicable, AbbVie will pay all taxes, import duties, sales, use or privilege taxes, value-added taxes, excise or similar taxes or duties levied upon a Party or any Affiliate thereof by any jurisdiction, political subdivision or agency for the supply of Idera Compound under this Agreement. If any sum due to be paid to a Party hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and to sign all such documents as will enable the Parties to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall remit such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and provide to payee evidence of the payment of such withholding or similar tax, and otherwise assist payee with respect thereto as payee may request. Any such amounts deducted by the payor in respect of such withholding or similar tax shall be treated as having been paid by the payor and remitted for purposes of this Agreement.
- (c) VAT. Depending on the physical supply of Idera Compound Delivered, value added or similar taxes (“**VAT**”) may be due and charged by Idera or a Third-Party upon importation. AbbVie will pay the amount of VAT properly charged on receipt of a valid tax invoice from Idera or charged on an import customs declaration, issued in accordance with the laws and regulations of the country in which the VAT is due. Each Party agrees that it shall provide to the other Party any information and copies of documents within its control to the extent reasonably requested by the other Party for the purpose of (i) determining the amount of VAT chargeable on any supply made under this Agreement, (ii) establishing the place of supply for VAT purposes, or (iii) complying with its VAT reporting or accounting obligations. The Parties acknowledge and agree that any payment made and any consideration provided under this Agreement are exclusive of VAT.
- (d) Transparency Reporting. Responsibility for reporting payments and other transfers of value under the Physician Payment Sunshine Act, U.S. state transparency and gift laws, the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and other applicable transparency laws, regulations or codes (collectively, the “**Transparency Laws**”) shall lie with the Party making the payment or transfer of value. Interpretation of the Transparency Laws for purposes of reporting any payment or transfer of value shall be in the sole discretion of the Party making the payment or transfer of value. Upon request, each Party agrees to cooperate with the other to provide information necessary to allow the requesting Party to comply with its obligations under the Transparency Laws.

5. SUPPLY AND USE OF COMPOUND.

- (a) Forecast. Following the execution of this Agreement, Idera shall supply, or cause to be supplied, up to the quantities of Idera Compound set forth in the Supply Addendum and on the timelines set forth in the Supply Addendum, in each case, for use in the Study. The amount of Idera Compound specified in the Supply Addendum is the estimated amount of Idera Compound necessary to conduct the Study. AbbVie shall provide Idera with a twelve (12) month rolling forecast for supply of the Idera Compound (“**Supply Forecast**”) each Calendar

Quarter following execution of this Agreement. In the event that AbbVie determines that the quantity of the Idera Compound set forth in the Supply Addendum is not sufficient to complete the Study in accordance with the current version of the Protocol approved by the Parties, AbbVie may request additional Idera Compound, and Idera may supply additional Idera Compound, assuming both Parties agree and the Idera Compound is available. All such additional Idera Compound shall be provided in accordance with requirements set forth in this Agreement, including the Supply Addendum.

- (b) Delivery. Idera will deliver the Idera Compound DDP (Incoterms 2010) to the locations, as relevant, specified in the Supply Addendum (“**Delivery**”). All costs associated with the subsequent transportation, warehousing and distribution of Idera Compound will be borne by AbbVie. AbbVie will: (i) take delivery of the Idera Compound supplied hereunder; (ii) perform the acceptance procedures allocated to it under this Agreement; and (iii) subsequently relabel and pack the Idera Compound as necessary for use in the Study, and (iv) ship such Idera Compound to the applicable Study Centers or local depots in compliance with cGMP, GCP and other Applicable Law and the Supply Addendum. AbbVie and Idera shall provide, from time to time at the reasonable request of the other Party, the following information with respect to the Idera Compound: any applicable chain of custody forms, in-transport qualified shipper(s), records and receipt verification documentation, such other transport or storage documentation as the other Party may reasonably request, and usage and inventory reconciliation documentation related to the Idera Compound. AbbVie shall (i) obtain all required licenses, certificates and permits in connection with the shipment of Idera Compound after Delivery; (ii) to maintain the necessary records to comply with all Regulatory Approvals and Applicable Laws; (ii) ensure proper shipment conditions of Delivered Idera Compound (iii) not re-export Idera Compound except as authorized in writing by Idera and in compliance with Applicable Laws; and (iv) not sell, transfer or dispose of Idera Compound in violation of Applicable Laws.
- (c) Idera Compound ID Testing. For each Delivery of the Idera Compound, AbbVie shall ship an Idera Compound vial sample to Idera’s preferred vendor for ID testing, [**] (“[**]”). Idera will (i) arrange for [**] to conduct this testing, at AbbVie’s expense, and (ii) share the results with AbbVie. Idera shall provide to AbbVie’s GPRD Operations contact, set forth in Attachment C (or as updated), within [**] days after the end of each calendar quarter, a written invoice of the ID Testing costs incurred by Idera during such calendar quarter, if any, and invoice for such costs Idera received from [**]. The Parties shall seek to resolve any questions related to such invoices within [**] days following receipt by AbbVie of Idera’s invoice and supporting documentation; and payment will be made by AbbVie within [**] days after the end of such calendar quarter. All invoiced costs and payments for the ID testing will be in U.S. Dollars.
- (d) Idera Compound Usage. AbbVie will (i) use the Idera Compound solely for purposes of performing the Study; (ii) not use the Idera Compound in any manner inconsistent with this Agreement; (iii) not supply or permit to be supplied, or make available, the Idera Compound to any Third-Party other than as permitted under this Agreement; and (iv) use, store, transport, handle and dispose of the Idera Compound in compliance with Applicable Laws, the Supply Addendum and any additional storage requirements provided in writing (which, for clarity, may be via e-mail) to AbbVie by Idera. AbbVie will not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying structure of the Idera Compound, and in particular will not analyze the Idera Compound by physical,

chemical or biochemical means except as necessary to perform its obligations under this Agreement. Upon the expiration of this Agreement or any termination of this Agreement or the Study, AbbVie shall, at the request of Idera, destroy all remaining supply of the Idera Compound or promptly return at Idera's request; provided, however, that a Study Center or local depot may destroy Idera Compound upon termination or expiration of this Agreement if Applicable Law or such Study Center's policies require that Idera Compound be destroyed.

- (e) Idera Compound Requirements. All Idera Compound supplied by Idera hereunder shall be Manufactured in accordance with current good manufacturing practices (GMPs), Applicable Law, and the requirements set forth in this Agreement. Idera will ensure proper shipment conditions and instruct AbbVie regarding proper storage and shipment conditions for the Idera Compound Delivered. Idera will supply the Idera Compound in accordance with this Agreement, including the provisions of the Supply Addendum, and any mutually agreed logistic arrangements. Idera will provide the following documentation to AbbVie for each batch of Idera Compound provided hereunder, in advance or at time of Delivery:
- i. Certificate of Compliance/Conformance (CoC) where the Certificate of Conformance generated should contain at a minimum the product name, Lot or batch number, expiry date, and date of manufacturing.
 - ii. BSE/TSE Certificate, upon initial Delivery only, unless updates to the BSE/TSE Certificate require Idera to provide to AbbVie.
 - iii. Certificate(s) of Regulatory Compliance for the Idera Compound related to the investigational medicinal product dossier for each country in which the Study is conducted.
 - iv. Certificate of Analysis.
 - v. Lot specific temperature excursion data (maximum allowances and/or remaining allowances as applicable).
 - vi. Tolerance regarding Idera Compound specific storage conditions (e.g. temperature load) originating from Idera.
 - vii. Material Safety Data Sheet (or equivalent) for safe handling of the Idera Compound.
- (f) Shortage; Allocation. In the event of a supply interruption or shortage of Idera Compound, such that Idera reasonably believes that it will not be able to fulfill its supply obligations hereunder with respect to the Idera Compound for the Study, Idera will provide prompt written notice to AbbVie thereof (including the nature of the shortage, quantity of Idera Compound that Idera reasonably estimates it will be able to supply, an adjusted delivery schedule, and a good faith estimate of the date by which the shortage is expected to resolve) and, upon request, AbbVie and Idera will promptly discuss such situation (including how the quantities of Idera Compound that Idera is able to supply hereunder will be allocated within the Study). Idera shall consider in good faith the needs of Study subjects who are actively being treated with the Idera Compound in making its determination.

For purposes of this Agreement, “**Manufacture**”, “**Manufactured**”, or “**Manufacturing**” means all stages of the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable

6. QUALITY

- (a) Quality matters related to the Idera Compound will be governed by the terms of the TQA in addition to the relevant quality terms of this Agreement.
- (b) Non-Conformance.
 - i. In the event that a Party becomes aware that the Idera Compound Delivered hereunder may have a nonfulfillment or unplanned departure of a specified requirement from documented GxP procedures, instructions, requirements, filed specifications, or processes (“**Non-Conformance**”), despite testing and quality assurance activities, then such Party will notify the other Party’s relevant Quality contact set forth in Attachment C (or as updated) within [**] Business Days of becoming aware of the Non-Conformance. Idera and AbbVie will investigate any Non-Conformance as set forth in Section 6(b) (ii) (Investigations) below and any discrepancy between the Parties regarding the determination of Non-Conformance shall be escalated per each of the Party’s respective quality system requirements. AbbVie shall determine whether a shipment of the Idera Compound (or portion thereof) has a Non-Conformance at the time of Delivery within [**] days after the date of Delivery of such Idera Compound (or portion thereof). Any Idera Compound not rejected by written notice to Idera within [**] days of AbbVie’s receipt shall be deemed accepted, except for Idera Compound that is found later to have had latent defect(s) that were not reasonably discoverable within [**] days after receipt of Delivery of such Idera Compound. In the event that any proposed or actual shipment of the Idera Compound (or portion thereof) will be agreed or otherwise determined to have a Non-Conformance at the time of Delivery to AbbVie, then unless otherwise agreed to by the Parties in writing, Idera will use commercially reasonable efforts to replace such Idera Compound as is found to have a Non-Conformance as soon as reasonably practical and at no cost to AbbVie. Any Idera Compound not rejected by written notice to Idera within [**] days of AbbVie’s receipt shall be deemed accepted, except for Idera Compound that is found later to have had latent defect(s) that were not reasonably discoverable within [**] days after receipt of Delivery of such Idera Compound.
 - ii. Investigations. In the event that any Idera Compound proves to be in Non-Conformance, or is suspected of being in Non-Conformance (i.e. a post-release Non-Conformance, potential Non-Conformance or confirmed complaint), AbbVie and Idera quality control/quality assurance staffs shall immediately, or at latest, within one (1) Business Day, advise each other of such defect or suspicion thereof and shall initiate appropriate internal measures to ascertain the validity of such suspicion and/or remedy such defect. Any Non-Conformance related discrepancy between AbbVie and Idera will be resolved in accordance with the provisions set forth in the TQA. Appropriate, commercially reasonable measures shall also be taken to prevent any future occurrence of such defects. The decision to initiate a recall of Idera Compound will be the sole responsibility of Idera. Recalls will proceed in accordance with the Supply Addendum.

- (c) Replacement Compound. In the event Idera Compound is lost or damaged by AbbVie after Delivery, Idera will provide additional Idera Compound (if available for the Study) to AbbVie (“**Replacement Idera Compound**”); provided that AbbVie will reimburse Idera for the Direct Manufacturing Costs and Indirect Manufacturing Costs of such Replacement Idera Compound (without mark-up), unless Idera otherwise agrees in writing to provide such Replacement Idera Compound at no cost to AbbVie. For avoidance of doubt, over-labeling of Idera Compound or removal of Idera Compound labeling shall not constitute damage to Idera Compound provided that, if AbbVie makes any such modifications to the labelling of the Idera Compound, AbbVie shall be solely responsible for ensuring that the revised label complies with all relevant labelling requirements under Applicable Law and such revisions do not amount to potential adulteration or misbranding of the Idera Compound. Except as set forth in the foregoing sentence, Idera will have no obligation to provide Replacement Idera Compound for any Idera Compound supplied hereunder other than such Idera Compound (i) as has been agreed or otherwise determined to have a Non-Conformance at the time of Delivery to AbbVie or (ii) subject to an Idera Recall as described in the Supply Addendum.
- (d) Quality Audits. Each Party will maintain complete and accurate records pertaining to the manufacture, testing, packaging/labeling, storage and delivery/distribution (as applicable) of the Idera Compound hereunder in accordance with the TQA; and, upon request of the other Party, will make such records open to review by the other Party for the purpose of GMP compliance audits/assessments as per the TQA and conducting investigations for the determination of Idera Compound safety and/or efficacy and the other Party’s compliance with this Agreement with respect to the Idera Compound.
- (e) Qualified Person. In the event that Idera Compound is Delivered to AbbVie for use at Study Centers in the European Union (“EU”), Idera will (i) provide a GMP/Inspection Certificate by a Qualified Person and Batch Release signed by a Qualified Person (“QP”) confirming compliance with the Product Specification File for the Idera Compound, including a statement that the manufacturing site(s) for the Bulk Drug Substance and Bulk Drug Product operate equivalent to EU GMP standards and are in compliance with the approved, cross-referenced Idera CTA filing, (ii) upon request, provide AbbVie with the QP Declaration for non-EU manufacturers, and (iii) perform QP confirmation of each batch supplied to AbbVie according to Annex 16 and Annex 13. Idera will maintain complete and accurate supply chain maps in accordance with Annex 16. These supply chain maps shall be considered by Idera during the release of the Idera Compound to AbbVie. Changes to the supply chain impacting the Idera Compound being Delivered to AbbVie shall be communicated to AbbVie prior to the change. AbbVie and Idera QPs shall each maintain their own register (or equivalent document) as a record of batches GMP confirmed or certified by the QP. For purposes of this Agreement, the term “**Bulk Drug Substance**” means any substance that is represented for use in a drug and that, when used in the manufacturing, processing or packaging of a drug becomes an active ingredient or a finished dosage form of the drug; “**Bulk Drug Product**” means the bulk drug material in its final form such that it will not undergo further processing other than packaging to the final deliverable unit; and “**Product Specification File**” means the reference file containing, or referring to files containing, all the information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of an investigational medicinal product.

7. DATA AND RESULTS.

- (a) AbbVie will maintain all Study Data in its database and will provide Idera with quarterly reports on the progress of the Study including enrollment status and interim or final analysis (if applicable). AbbVie shall also provide Idera with the final Clinical Study Report (“CSR”) for the Study promptly following its preparation by AbbVie and in any event at least [**] calendar days prior to submission to any Regulatory Authority. AbbVie will consider in good faith any comments provided by Idera on the CSR within the foregoing described [**]-day period.
- (b) Study Data.
- i. All data, results and reports arising from the Study (collectively, “**Study Data**”) in accordance with this Agreement shall be the property of AbbVie as the Sponsor of the Study and shall be considered Confidential Information of AbbVie.
 - ii. Within [**] days of database lock AbbVie hereby grants Idera and its Affiliates a non-exclusive, worldwide, paid-up, royalty-free license, with the right to grant sublicenses to its subcontractors or collaboration partners (as applicable) (1) who participate in Idera’s research and development programs (2) who are under obligations of confidentiality and restrictions no less stringent than those imposed on Idera under this Agreement and (3) with respect to who Idera has provided advance written notice to AbbVie hereunder, to use Study Data for publication purposes (subject to Sections 10 and 11) and in any research and development program of Idera, except to the extent such use violates any obligation of confidentiality or restrictions imposed on Idera hereunder pursuant to Sections 7 and 8.
- (c) Sample Data.
- i. Samples collected during the Study as set forth in the Protocol (“**Biological Samples**”) may include, without limitation, blood, serum, fluid and tissue biopsy samples collected from subjects enrolled in the Study. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, probes, DNA, RNA, eDNA libraries, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies or other biological substances; and any constituents, progeny, mutants, variants, derivatives, replications, reagents or chemical compounds thereof or derived therefrom.
 - ii. As between AbbVie and Idera, all Biological Samples shall be the property of AbbVie. AbbVie or Idera (or their Third-Party vendor(s)) (1) may receive quantities of Biological Samples for use in research specified in the Protocol, Operations Manual, and/or ICF and (2) shall only use the Biological Samples from Study subjects in accordance with the Protocol, ICF, health information use and disclosure authorization and all Applicable Laws, including but not limited to patient privacy and informed consent laws. AbbVie and/or Idera (or their Third-Party vendor(s)) will analyze and disclose to the other Party the Study results generated directly from the Biological Samples testing.

- iii. AbbVie will have responsibility for all Idera Compound pharmacokinetic testing and anti-drug antibody testing for purposes of the Study (“**Idera Compound PK/ADA Testing**”). Idera will provide letters of authorization that will allow AbbVie to use Idera’s validated methods to analyze Biological Samples from the Study for Idera Compound PK/ADA Testing at Idera’s two bioanalytical vendors. For avoidance of doubt, all bioanalytical results for the AbbVie Compounds and Idera Compound are deemed Study Data.

For purposes of this Agreement, an “**Affiliate**” of an entity shall mean: (1) organizations, which directly or indirectly control such entity; (2) organizations, which are directly or indirectly controlled by such entity; (3) organizations, which are controlled, directly or indirectly, by the ultimate parent of such entity. As used in the immediately preceding sentence, “control” is defined as owning more than fifty percent (50%) of the voting stock of an organization or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization; and “**Third-Party**” means any person or entity other than AbbVie, Idera, or their respective Affiliates.

8. **CONFIDENTIALITY**

- (a) For purposes of this Agreement, “**Confidential Information**” means (i) any proprietary, confidential, non-public information, data, samples, plans, reports, forecasts, technical or commercial information disclosed by or on behalf of a Party (“**Disclosing Party**”) to the other Party or its Affiliates (“**Receiving Party**”); (ii) any information disclosed by or on behalf of a Disclosing Party that (A) is identified as “**Confidential Information**” at the time of disclosure or (B) a reasonable person would understand to be confidential or proprietary due to the context of its disclosure and/or its scope, content, or nature. For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Idera Inventions, Idera Background IP, and Idera Regulatory Submissions shall be Confidential Information of Idera and AbbVie shall be the “Receiving Party”, (ii) all AbbVie Inventions, AbbVie Background IP, Study Data, Study Inventions, and AbbVie Regulatory Submissions shall be Confidential Information of AbbVie and Idera shall be the “Receiving Party”. For clarity, the terms of this Agreement shall constitute Confidential Information.
- (b) Each Receiving Party shall (i) hold in confidence the Disclosing Party’s Confidential Information, and (ii) not use Disclosing Party’s Confidential Information except for purposes of conducting the Study, performing such Party’s obligations under this Agreement, or as otherwise provided herein (including, for the avoidance of doubt, the rights provided for in Section 7(b)(ii) above). The confidentiality, non-use and non-disclosure obligation of this Agreement shall be effective during the Term and for a period of ten (10) years after termination or expiration of the Agreement.
- (c) Disclosures. Except as otherwise provided in this Agreement, the Receiving Party shall not disclose any Disclosing Party Confidential Information without such Disclosing Party’s prior written consent except under the following conditions:
 - (i) Third-Party Disclosures. A Receiving Party may disclose Disclosing Party’s Confidential Information to Third-Parties as necessary to conduct the Study, perform such Party’s obligations under this Agreement, and/or exercise its rights under this

Agreement; provided that such necessary disclosures to a Third-Party will be under a written confidentiality agreement consistent with this Section 8.

- (ii) Affiliate Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to any of its Affiliates, provided that such Affiliates are subject to obligations of confidentiality and non-use substantially equivalent in scope to those set forth in this Section 8. In the event that Confidential Information is so provided by a Receiving Party to its Affiliate, the Receiving Party shall ensure that if, for any reason, such Affiliate no longer qualifies as an Affiliate of the Receiving Party (a "**Change of Control**"), any Confidential Information supplied to such Affiliate shall be either destroyed or returned to the Receiving Party no later than upon such Change of Control, in each case to the extent practicable. Additionally, the Receiving Party shall ensure that its Affiliates establish reasonable safeguards and/or processes to further limit the dissemination of Confidential Information of the Disclosing Party supplied to such Affiliates, such as, without limitation, the establishment of firewalls and limiting access to electronic storage media and/or networks containing Confidential Information so as to be accessible only by those individuals with an actual need to access such Confidential Information.
 - (iii) Internal Disclosures. Except as otherwise expressly set forth herein, each Party shall share the other Party's Confidential Information within its organization to those individuals who need to know such information for purposes of performing its obligations or exercising its rights under this Agreement and who are bound by written obligations of confidentiality and non-use no less restrictive than those contained herein.
 - (iv) Other Permitted Disclosures. Notwithstanding the provisions of this Section 8 and the provisions of Sections 9 - 11, each Party may disclose the terms of this Agreement and Confidential Information of the other Party on a need-to-know basis as provided below to (1) actual or potential lenders or investors of such Party, (2) actual or potential acquirers of such Party, (3) actual or potential strategic partners that are or may be an owner or licensee of intellectual property of the disclosing Party relating to the subject matter of this Agreement, (4) its legal, accounting, tax and other advisors, and (5) clinical trial sites and clinical trial investigators, contract research organizations, laboratories and other subcontractors performing the Study, as well as Regulatory Authorities (in Regulatory Submissions, or otherwise), health authorities, the data safety monitoring and advisory board and IRBs relating to the Study, provided that disclosures to Third-Parties (other than to governmental entities, ECs and IRBs) as permitted by this Section 8(c)(iv) shall be pursuant to written agreements with such Third-Parties with non-disclosure and non-use obligations consistent with this Agreement.
 - (v) Nothing in this Agreement will be construed to restrict a Receiving Party from disclosing Confidential Information as required by Applicable Law or court order or other governmental order or request, provided in each case that Receiving Party shall give Disclosing Party prompt written notice (and in any case at least [**] Business Days' notice) and reasonable assistance in order to allow Disclosing Party to take whatever action it deems necessary to protect its Confidential Information.
- (d) Exceptions. Subject to the foregoing, the obligations of a Receiving Party as set forth in this Section 8 shall not extend to any portion of the Disclosing Party's Confidential Information

which: (1) is disclosed to the Receiving Party by a Third-Party who has no obligation of confidentiality to the Disclosing Party with respect thereto; or (2) is or becomes lawfully part of the public domain by reason of acts not attributable to the Receiving Party; or (3) is developed independently by the Receiving Party without access to or use of the Disclosing Party's Confidential Information as evidenced by the Receiving Party's written records; or (4) is in the Receiving Party's possession prior to disclosure by the Disclosing Party as evidenced by the Receiving Party's written records.

(e) Return of Confidential Information.

(i) Within [**] days following expiration or any termination of this Agreement:

- a. AbbVie shall (1) return Idera Confidential Information to Idera, or (2) destroy such Confidential Information, in each case to the extent practicable; provided, however, AbbVie may retain one (1) copy of such Confidential Information on a confidential basis to ensure compliance with this Agreement and for archival purposes; and
- b. Idera shall (1) return AbbVie's Confidential Information to AbbVie, or (2) destroy such Confidential Information, in each case to the extent practicable; provided, however, Idera may retain one (1) copy of such Confidential Information on a confidential basis to ensure compliance with this Agreement and for archival purposes.

(ii) The foregoing provisions of this Section 8(e) shall not apply to Study Data, which each Party shall have the right to maintain and use in accordance with this Agreement following expiration or termination of this Agreement.

(f) The Parties acknowledge the Mutual Confidential Disclosure Agreement between Idera and AbbVie effective April 13, 2017 and amended effective April 13, 2018 ("**CDA**") and agree that (i) any disclosures of "**Information**" as defined under the CDA shall be treated as Confidential Information under this Agreement, and (ii) from and after the Effective Date this Agreement shall supersede the CDA with respect to the subject matter thereof, provided that the information referenced in clauses (i) of this sentence shall be limited to information related to the subject matter of this Agreement. For all other purposes and information, the CDA shall control.

9. INTELLECTUAL PROPERTY

- (a) Inventorship shall be determined by U.S. patent law. Ownership shall follow inventorship, unless otherwise stated in this Agreement.
- (b) Except as specifically set forth in this Agreement, each Party hereto shall maintain all right, title and interest in any patent, patent application, trade secret, know-how and other intellectual property that (i) was owned by such Party prior to the Effective Date, and/or (ii) was developed outside of the activities under this Agreement and without use of the other Party's Confidential Information, any Study Inventions (as defined below), any Study Data or any Biological Samples ("**Background IP**"), and except as expressly provided herein with

respect to the conduct of the Study, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Background IP of the other Party.

- (c) The Parties agree that all rights to inventions, improvements, know-how, discoveries and creations related solely to the Idera Compound in the absence of any AbbVie Compound or biological markers useful for diagnosis, monitoring or prognosis of response to any treatment with the Idera Compound in the absence of any AbbVie Compound that are conceived or reduced to practice in the course of the Study (“**Idera Inventions**”) will be the exclusive property of Idera; Idera shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for such inventions; and no license is granted to AbbVie with respect thereto. AbbVie hereby assigns (and shall cause its Affiliates and contractors to assign) to Idera all of AbbVie’s rights, title and interest in and to all Idera Inventions and agrees to do all acts and execute all documents as may be reasonably necessary or desirable for Idera to perfect its title in any and all Idera Inventions and otherwise to implement the provisions of this Section 9(c) at no cost to AbbVie, provided that such assignment shall not be construed to abrogate, restrict or encumber any right of AbbVie to exploit any and all Study Data generated, which right AbbVie enjoys by virtue of AbbVie’s ownership of such Study Data as provided at Section 7(b).
- (d) The Parties agree that all rights to inventions, improvements, know-how, discoveries and creations related solely to one or both AbbVie Compounds in the absence of the Idera Compound or biological markers useful for diagnosis, monitoring or prognosis of response to any treatment with one or both AbbVie Compounds in the absence of the Idera Compound that are conceived or reduced to practice in the course of the Study (“**AbbVie Inventions**”) will be the exclusive property of AbbVie; AbbVie shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for such inventions; and no license is granted to Idera with respect thereto. Idera hereby assigns (and shall cause its Affiliates and contractors to assign) to AbbVie all of Idera’s rights, title and interest in and to all AbbVie Inventions and agrees to do all acts and execute all documents as may be reasonably necessary or desirable for AbbVie to perfect its title in any and all AbbVie Inventions and otherwise to implement the provisions of this Section 9(d) at no cost to Idera, provided that (i) with the prior written consent of AbbVie (such consent not to be unreasonably withheld, conditioned or delayed), AbbVie grants to Idera a non-exclusive, royalty-free, fully-paid, irrevocable, perpetual license to use AbbVie Inventions for Idera’s internal research purposes only, and (ii) such assignment shall not be construed to abrogate, restrict or encumber any right of Idera to exploit Study Data in accordance with the license granted to Idera at Section 7(b).
- (e) Subject to Sections 9(c) and 9(d), the Parties agree that all inventions, improvements, know-how, discoveries and creations related to a combination of the Idera Compound with one or both AbbVie Compounds that are conceived or reduced to practice in the course of the Study under this Agreement or as a result of using the Study Data or otherwise in connection with the Study (“**Study Inventions**”), will be the exclusive property of AbbVie. AbbVie shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for such inventions; and no license is granted to Idera with respect thereto. Idera hereby assigns (and shall cause its Affiliates and contractors to assign) to AbbVie all of Idera’s rights, title and interest in and to all Study Inventions and agrees to do all acts and execute all documents as may be reasonably necessary or desirable for AbbVie to perfect its title in any and all Study Inventions and otherwise to implement the provisions of this Section 9(d) at no

cost to Idera, provided that (i) with the prior written consent of AbbVie (such consent not to be unreasonably withheld, conditioned, or delayed), AbbVie grants to Idera a non-exclusive, royalty-free, fully paid, irrevocable (unless this Agreement is terminated for breach as described in Section 3(b)), and sublicensable (with the prior written consent of AbbVie, such consent not to be unreasonably withheld, conditioned or delayed) license to use any Study Inventions, and (ii) such assignment shall not be construed to abrogate, restrict or encumber any right of Idera to exploit Study Data in accordance with the license granted to Idera at Section 7(b).

- (f) Idera acknowledges all rights of issued patents or pending patent applications of AbbVie from previous research and development, and Idera agrees to make no patent application based on AbbVie Confidential Information, and to give no assistance to any Third-Party for such application without AbbVie's written authorization. AbbVie acknowledges all rights of issued patents or pending patent applications of Idera from previous research and development, and AbbVie agrees to make no patent application based on Idera Confidential Information, and to give no assistance to any Third-Party for such application without Idera's written authorization. Subject to Section 9(b), neither Party grants any license or any other rights to the other with respect to issued patents or pending patent applications or other intellectual property from previous research and development.
- (g) Idera shall have the sole right, in its sole discretion, to control the Prosecution and Maintenance and enforcement of any kind with respect to patent rights claiming Idera Inventions, and AbbVie shall reasonably assist and cooperate in filing, Prosecution and/or Maintenance of an Idera Invention. AbbVie shall have the sole right, in its sole discretion, to control the Prosecution and Maintenance and enforcement of any kind with respect to patent rights claiming AbbVie Inventions and/or Study Inventions, and Idera shall reasonably assist and cooperate in filing, Prosecution and/or Maintenance of an AbbVie Invention or Study Invention.

For purposes of this Agreement "**Prosecution**" means defense of invalidity, declaratory judgment, revocation, reexamination, nullity, opposition, or other proceeding in which the validity of a Study patent is challenged in an administrative or legal proceeding, other than such administrative or legal proceeding that is related to an infringement action brought by a Party or a declaratory action defended by a Party.

"**Maintenance**" means the maintenance of such patent rights, as well as re-examinations, reissues, requests for patent term extensions and the like with respect to such patent rights.

10. PUBLICATIONS

- (a) Each Party is committed to fostering the highest standard of conduct related to Study Publications (as defined below) and transparency. Accordingly, the Parties agree that the following shall apply to all Study Publications:
 - (i) Study Publications should be published in a timely manner, in accordance with industry standards, and present scientific information in an accurate and balanced way that does not exclude or inappropriately downplay negative safety or health information; and
 - (ii) AbbVie's and Idera's role in the Study and/or Study Publications shall be disclosed in all Study Publications; and

- (iii) Authorship related to Study Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals”.
- (b) Subject to Section 8 and the Study Publication Review Procedures set forth in Section 10(d), AbbVie, Idera, and/or any Study Center or Investigator (“**Publisher**”) may publish Study Publications in scientific journals or other scholarly media.
- (c) AbbVie will have the first right to publish the final Study results in a Study Publication that is based on Study Data from all Study Centers (the “**Summary Publication**”). Idera agrees not to submit any Study Publication until AbbVie has first published the Summary Publication, provided that Idera may publish in the circumstances where (i) AbbVie declines to publish a Summary Publication within [**] months after database lock of the Study or (ii) after AbbVie’s publication of the Summary Publication.
- (d) Study Publication Review Procedures.
- (i) Idera and AbbVie will, and will ensure any other Publisher will, provide the non-publishing Party a draft of any proposed Study Publication at least [**] Business Days prior to submission of such Study Publication for the non-Publishing Party to ascertain whether any patentable subject matter or Confidential Information are disclosed therein. The non-Publishing Party shall return comments to the Publisher within [**] Business Days after receipt of the draft Study Publication or such shorter time frame as mutually agreed by the Parties (“**Review Period**”), and due consideration shall be given to the non-publishing Party’s comments. Idera and AbbVie agree not to include Confidential Information disclosed by the other Party pursuant to this Agreement (except Study Data) in any Study Publication without the prior consent of the other Party and each Party shall reasonably cooperate to resolve any issues related thereto. Idera and AbbVie will, and will ensure any other Publisher will, delay any proposed Study Publication an additional [**] days in addition to the Review Period in the event the non-publishing Party so requests to enable the non-publishing Party to secure patent or other proprietary protection (“**Delay Period**”).
- (ii) Idera and AbbVie will, and will ensure any other Publisher will (A) keep the proposed Study Publication confidential until expiration of the Review Period and any Delay Period, and (B) delete the other Party’s Confidential Information (other than Study Data), as requested, from any Study Publication.
- (iii) In the event the Parties differ in their conclusions or interpretation of data in the Study Publication, the Parties shall use good faith efforts to attempt to resolve such differences in good faith through appropriate scientific debate, but, subject to the removal of the non-publishing Party’s Confidential Information in accordance with Sections 10(d)(i) and 10(d)(ii), a Publisher shall retain control over the final version of the Study Publication. Notification of Study Publications for review by Idera or AbbVie shall be made to other Party’s Publications and Alliance Management contacts set forth in Attachment C (or as updated).

- (e) Consistent with applicable copyright and other laws, each Party may use, refer to, or disseminate, or have used, referred to or disseminated, reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

For purposes of this Agreement, “**Study Publication**” means any scientific publication or medical communication regarding Study Data in any form that is intended for disclosure to Third-Parties, including, without limitation, manuscripts, abstracts, posters, slides or other materials used for presentations.

11. PUBLICITY; NAME USAGE

- (a) Except as otherwise provided herein, (a) neither Party will have any right, express or implied, to use in any manner the name or other designation of the other Party or its Affiliates or any other trade name, trademark or logo of the other Party or its Affiliates for any purpose in connection with the performance of this Agreement, without prior written consent from the other Party.
- (b) For any press releases related to the Study made by a Party and mutually agreed upon by both Parties, the Party issuing the press release (i) shall use good faith efforts to provide the other Party with a copy of the press release for review and comment at least [**] days before the proposed release, and (ii) may only issue such release with the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed and which may be granted by email). The press release shall not be disseminated until there is mutual agreement of the Parties on the content.

12. WARRANTIES AND CERTAIN COVENANTS

- (a) Each Party warrants and represents to the other Party that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment which would inhibit its ability to perform its obligations hereunder.
- (b) Idera warrants and covenants to AbbVie that it will (i) Manufacture the Idera Compound in accordance with the requirements set forth in this Agreement, Supply Addendum, current GMPs, and all Applicable Laws and regulations, including laws relating to drugs intended for investigational use in humans, (ii) at AbbVie’s request, provide AbbVie with reasonable documentation evidencing the foregoing, as well as all related documentation as needed to support US and international regulatory submissions to any Regulatory Authority and to respond to queries raised during any Regulatory Authority inspections, and (iii) promptly inform AbbVie of any relevant safety information related to the Idera Compound that would impact patient safety or the conduct of the Study.
- (c) AbbVie warrants and covenants to Idera that it will (i) Manufacture the AbbVie Compounds in accordance with the requirements set forth in this Agreement current GMPs, and all Applicable Laws, and regulations, including laws relating to drugs intended for investigational use in humans, and (ii) promptly inform Idera of any relevant safety information related to an AbbVie Compound that would impact patient safety or the conduct of the Study.

- (d) AbbVie warrants and covenants to Idera that it shall store, use, and distribute the Idera Compound in accordance with all Applicable Laws and the requirements set forth in this Agreement and the Supply Addendum.
- (e) EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

13. INSURANCE AND INDEMNIFICATION

- (a) Idera agrees to maintain in force at its sole cost and expense, with reputable insurance companies having an AM Best rating of A-VII or better, commercial general liability insurance in minimum amounts of [**] dollars (\$[**]) per occurrence and [**] dollars (\$[**]) in aggregate and clinical trial insurance in minimum amounts of [**] dollars (\$[**]) per occurrence and [**] dollars (\$[**]) in aggregate. Upon written request, Idera shall provide evidence of such insurance to AbbVie. Idera will provide AbbVie with written notice at least [**] days prior to the cancellation, non-renewal or material change in such insurance; if Idera does not obtain replacement insurance providing comparable coverage within such [**] day period, AbbVie shall have the right to terminate this Agreement immediately. Notwithstanding the foregoing, Idera may upon notice to AbbVie fulfill such requirements by a reasonable self-insurance program.

Except for damages and claims (a) arising out of (i) Idera's breach of Section 8 (Confidentiality) of this Agreement and (ii) Idera's gross negligence or willful misconduct; and (b) that are directly attributable solely to the Idera Compound and not attributable to the AbbVie Compound or the AbbVie Compound in combination with the Idera Compound, in no event shall the total liability of Idera under this Agreement exceed, in aggregate over the Term, [**] dollars (\$[**]).

- (b) AbbVie represents and warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support its obligations and liabilities assumed under this Agreement and the Applicable Laws, in particular towards Study subjects for Study Injury pursuant to Section 2(f). Upon written request, AbbVie shall provide evidence of such insurance to Idera.
- (c) AbbVie agrees to defend, indemnify and hold harmless Idera, its respective Affiliates, and its and their employees, directors, subcontractors and agents (collectively, the "**Idera Indemnitees**") from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding or investigation by a Third-Party including, for the avoidance of doubt, a Study subject (a "**Liability**") to the extent that such Liability (A) was directly caused by (i) negligence, omission, or willful misconduct by any AbbVie Indemnitee (defined below); (ii) a breach by an AbbVie Indemnitee of any of its representations and warranties or any other covenants or obligations of AbbVie under this Agreement; (iii) a violation of any Applicable Law by an

AbbVie Indemnitee with respect to the subject matter of this Agreement; (iv) Study Injuries resulting from administration of one or both AbbVie Compounds in the absence of the Idera Compound or the combination of Idera Compound and one or both AbbVie Compounds; or (B) is determined to be attributable to an AbbVie Compound; except to the extent in each case (A) or (B) that such Liability (1) was directly caused by (X) negligence or willful misconduct on the part of an Idera Indemnitee, (Y) a breach by an Idera Indemnitee of any of its respective representations and warranties or any other covenants or obligations of Idera under this Agreement, or (Z) a violation of Applicable Law by Idera in its performance under this Agreement; or (2) is determined to be attributable to the Idera Compound.

- (d) Idera agrees to defend, indemnify and hold harmless AbbVie, its respective Affiliates, and its and their employees, directors, subcontractors and agents (collectively, the “**AbbVie Indemnitees**”) from and against any Liability to the extent that such Liability (A) was directly caused by (i) negligence, omission, or willful misconduct by an Idera Indemnitee, (ii) a breach by an Idera Indemnitee of any of their respective representations and warranties or any other covenants or obligations of Idera under this Agreement, (iii) a violation of any Applicable Law by an Idera Indemnitee with respect to the subject matter of this Agreement; (iv) Study Injuries resulting solely from administration of the Idera Compound; or (B) is determined to be attributable to the Idera Compound; except to the extent in each case (A) or (B) that such Liability (1) was directly caused by (X) negligence or willful misconduct on the part of an AbbVie Indemnitee; (Y) a breach by an AbbVie Indemnitee of any of its representations and warranties or any other covenants or obligations of AbbVie under this Agreement; or (Z) a violation of Applicable Law by AbbVie in its performance under this Agreement Indemnitee; or (2) is determined to be attributable to an AbbVie Compound.
- (e) Each Party’s indemnification of the other Party is subject to the following conditions:
 - (i) The indemnified Party shall provide notification to the indemnifying Party, within [**] Business Days, of the indemnified Party’s first knowledge of the Third-Party claim giving rise to an indemnity obligation hereunder, provided that any failure to provide notice within such time period shall not relieve the indemnifying Party of its obligations of indemnification, holding harmless and defense with respect to such claim unless the indemnifying Party is materially prejudiced by such delay. Provided that the indemnifying Party is not contesting the indemnity obligation, the indemnified Party shall permit the indemnifying Party to control any litigation relating to such claim and allow the indemnifying Party to assume the defense of any such claim, including, without limitation, the right to select defense counsel and the right to settle any claims or suits at its discretion. The indemnified Party may be represented by independent counsel of its choice and at its cost and expense.
 - (ii) The indemnified Party shall cooperate with the indemnifying Party in the defense of any claim for which indemnification is sought hereunder. If the indemnifying Party fails to defend the claim within a reasonable time, the indemnified Party may assume the defense thereof, and the indemnifying Party will reimburse the indemnified Party for all expenses incurred in connection with such defense (including reasonable attorney’s fees, settlement payments, and payments of judgments) until the indemnifying Party assumes such defense. All rights of the indemnified Party against any Third-Party with respect to which a claim of indemnity was paid hereunder shall be subrogated to the indemnifying Party.

- (f) Nothing in this Section 13 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its servants, agents or employees or to restrict or exclude any other liability of either Party which cannot be so restricted or excluded in law.

14. ASSIGNMENT; SUBCONTRACTING

- (a) Except as otherwise set forth in this Agreement, neither Party may assign or transfer this Agreement or sub-contract any of its obligations without the prior written consent of the other Party; provided however that a Party may assign this Agreement without the prior written consent of the other Party in connection with a merger or a sale of all or substantially all of its assets (or in the case of AbbVie, a sale, contribution, or transfer of all or substantially all of its assets related to one or both AbbVie Compounds). Any assignments or transfers in violation of this Section 14 shall be null and void. Notwithstanding the foregoing, each Party's rights and obligations may be exercised or performed by its Affiliates, provided such Affiliates agree to be bound by this Agreement.
- (b) Notwithstanding the foregoing, each Party will have the right to subcontract or delegate any portion of its obligations hereunder to subcontractors or Affiliates, provided that no such subcontract shall release such Party from any of its obligations under this Agreement. Notwithstanding any delegation of its obligations hereunder, each Party shall (a) remain solely and fully liable for the performance of its Affiliates and subcontractors to which it delegates the performance of its obligations under this Agreement; (b) ensure that each of its Affiliates and subcontractors performs the obligations pursuant to the terms of this Agreement, the SDEA and TQA including the Appendices attached hereto and thereto; and (c) use reasonable efforts to obtain and maintain copies of material documents relating to the obligations performed by such Affiliates and subcontractors that are required to be provided to the other Party under this Agreement.

15. ANTI-BRIBERY AND ANTI-CORRUPTION

Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates, agents and representatives, that in connection with this Agreement and the performance of its obligations hereunder:

- (a) it will comply with its own ethical business practices policy and shall conduct its study-related activities in accordance with Applicable Law including the Anti-Bribery and Anti-Corruption Laws (as defined below);
- (b) it will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to:
- i. any Government Official (as defined below) in order to influence official action;
 - ii. any person (whether or not a Government Official) (A) to influence that person to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (B) to

reward the person for acting improperly, or (C) where that person would be acting improperly by receiving the thing of value; or

iii. any other person while knowing or having reason to know that all or any portion of the money or thing of value will be offered, promised or given to a Government Official in order to influence official action or to any person to influence that person to act improperly.

(c) It will not directly or indirectly solicit, receive or agree to accept any payment or anything else of value in violation of the Anti-Bribery and Anti-Corruption Laws.

For purposes of this Agreement, “**Anti-Bribery and Anti-Corruption Laws**” means the U.S. Foreign Corrupt Practices Act, as amended, the Bribery Act 2010 and any other applicable anti-bribery and anti-corruption laws in any applicable country; and “**Government Official**” means any person employed by or acting on behalf of a government, government-controlled entity or public international organization; any political party, party official or candidate; any person who holds or performs the duties of an appointment, office or position created by custom or convention; and any person who holds him/herself out to be the authorized intermediary of a Government Official.

16. FORCE MAJEURE

If the performance of this Agreement by a Party is prevented, hindered or delayed by reason of any cause beyond such Party’s control (war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent it is necessarily prevented, hindered or delayed; provided if such delay interrupts material performance by [**] days or more, then the other Party will have the right to terminate this Agreement pursuant to Section 3(b).

17. DEBARMENT

Each Party hereby certifies that as of the Effective Date, it has not been, and its principals have not been, debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a(a) and (b), or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. Sec. 1320 a-7b(f)), including, but not limited to the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any Federal agency or program. In the event that during the term of this Agreement, a Party (i) becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible; or (ii) receives notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, sanction, or ineligibility, such Party shall immediately notify the other Party. In the event that a Party or its principals becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible, such Party shall immediately notify the other Party and the other Party shall have the right to terminate this Agreement.

18. GOVERNING LAW

The validity, construction and performance of this Agreement will be governed by and construed for all purposes in accordance with the laws of the State of Delaware.

19. DISPUTE RESOLUTION

If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “**Dispute**”), it shall be resolved pursuant to this Section 19.

- (a) General. Any Dispute shall first be referred to the Senior Leaders of the Parties set forth in Attachment C (or their respective designees), who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Leaders shall be conclusive and binding on the Parties. If the Senior Leaders (or their respective designees, as applicable) are not able to agree on the resolution of any such issue within [**] days (or such other period of time as mutually agreed by the Senior Leaders or their respective designees, as applicable) after such issue was first referred to them, then, except as otherwise set forth in Section 19(b), either Party may, by written notice to the other Party, elect to initiate an alternative dispute resolution (“**ADR**”) proceeding pursuant to the procedures set forth in Section 19(c) for purposes of having the matter settled.
- (b) Intellectual Property Disputes. In the event that a Dispute arises with respect to the validity, scope, enforceability, inventorship or ownership of any intellectual property right, and such Dispute cannot be resolved in accordance with Section 19(a), unless otherwise agreed by the Parties in writing, such Dispute shall not be submitted to an ADR proceeding in accordance with Section 19(c) and instead, either Party may initiate litigation in a court of competent jurisdiction, in any country or other jurisdiction in which such rights apply.
- (c) ADR. Any ADR proceeding under this Agreement shall take place pursuant to the procedures set forth in Attachment D.
- (d) Adverse Ruling. Any determination pursuant to this Section 19 that a Party is in material breach of its material obligations hereunder shall specify a (nonexclusive) set of actions to be taken to cure such material breach, if feasible.
- (e) Interim Relief and Tolling. Notwithstanding anything herein to the contrary, nothing in this Section 19 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute following the ADR procedures set forth in Section 19(c), if necessary to protect the interests of such Party. This Section shall be specifically enforceable.

20. NOTICES

Any notices required or permitted under this Agreement will be in writing, will refer specifically to this Agreement, and will be sent by recognized national or international overnight courier, confirmed facsimile transmission (provided that duplicative copy is provided via confirmed electronic mail, registered mail or certified mail), confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the address as set forth herein. Notices under this Agreement will be deemed to be duly given: (a) when delivered by hand; (b) upon confirmed electronic mail transmission; (c) [**] days after deposit with a recognized national or international courier; or (d) on the delivery date indicated in the return receipt for registered or certified mail. A Party may change its contact information, including but not limited to the Supply Addendum and Attachment C, immediately upon written notice to the other Party in the manner provided in this Section 20. Notwithstanding the foregoing, the Parties acknowledge and agree that specific notices

required to be given under the Attachments hereto shall be made to the contacts, and in accordance with the instructions, provided therein.

If to ABBVIE:

1 N. Waukegan Rd.
North Chicago, Illinois 60064
Attn: Vice President, Associate General Counsel R&D, Alliance Management and Transactions
With a copy to: General Counsel

If to Idera:
505 Eagleview Blvd., Suite 212
Exton, PA 19341
Attn: General Counsel

21. GENERAL PROVISIONS

- (a) Complete Agreement. The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with all attachments hereto, and the TQA and SDEA (once entered into) constitute the entire understanding of the Parties with respect to the subject matter hereof, and, subject to the terms and provisions pertaining to the CDA referenced in Section 8, all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. All attachments referred to in this Agreement are intended to be and are hereby incorporated into and made a part of this Agreement.
- (b) Conflicting Terms. In the event of any inconsistency between any attachments and the terms specified in the body of this Agreement, the terms of the body of this Agreement shall control. In the event of any inconsistency between any of the provisions of the SDEA and this Agreement with respect to safety reporting, the SDEA shall control. In the event of any inconsistency between any of the provisions of the TQA and this Agreement with respect to quality related matters, the TQA shall control. In all other matters, the terms of this Agreement shall control.
- (c) Modification. No changes, amendments or alterations to or of this Agreement shall be effective unless in writing and signed by the Parties hereto.
- (d) Invalid Provisions or Gaps. If single provisions of this Agreement are or become invalid or if there is a gap in the Agreement, the validity of the other provisions shall not be affected. In lieu of the invalid provision or in order to eliminate the gap, the Parties shall negotiate in good faith to agree upon a reasonable provision to carry out as nearly as practicable the original intention of the entire Agreement.
- (e) Affiliate Rights. All rights vested in or created to the benefit of AbbVie under this Agreement shall be deemed to benefit to and to be assignable to any of AbbVie's Affiliates.
- (f) Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver from time to time by a Party of any of its rights or its failure to

exercise any remedy shall not operate or be construed as constituting a waiver of some or any of such Party's rights or remedies under this Agreement.

- (g) Relationship of the Parties. Each Party's relationship to the other Party is that of an independent contractor, and neither Party has authority to bind or act on behalf of the other Party. Nothing in this Agreement is intended or shall be deemed to constitute or create an agency, joint venture, partnership, employer-employee, or fiduciary relationship between the Parties, including for all tax purposes.
- (h) Subsequent Studies. Idera and AbbVie have no obligation to renew this Agreement. Neither Party hereto has any obligation to order, purchase, or recommend the ordering or purchasing of any item or service manufactured or distributed by the other Party. AbbVie is required to procure all quantities of Idera Compound under this Agreement from Idera or its designee. Notwithstanding the foregoing, upon a Party's request to conduct additional clinical study(ies) that include the Compounds, the Parties shall discuss in good faith the possibility of, and the terms and conditions for, conducting such studies, including cost sharing, decision-making and the supply of the Compounds ("**Subsequent Study**"). This Agreement does not create any obligation on the part of Idera to provide the Idera Compound or on the part of AbbVie to provide either AbbVie Compound for any activities other than the Study, nor does it create any obligation or liability if the Parties do not execute an amendment or new agreement for purposes of a Subsequent Study.
- (i) Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile, electronic mail, internet or other suitable electronic means, shall constitute an original signature for purposes of this Agreement.

[The remainder of this page left blank intentionally; signature page follows immediately behind.]

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement.

IDERA PHARMACEUTICALS, INC.

ABBVIE INC.

/s/ VINCENT J. MILANO

/s/ [**]

Signature

Signature

Vincent J. Milano

[**]

Name

President & CEO

Head, Technology Licensing & Collaborations

Title

ATTACHMENT A

SUPPLY ADDENDUM

Idera shall supply Idera Compound, free of charge (including, without limitation, any applicable handling, storage, transportation, warehousing, and distribution costs), at the Delivery locations specified below in sufficient quantity for subjects participating in the Study at Study Centers, based on the estimated quantities and delivery schedule listed below. Any request by AbbVie for Idera Compound in addition to that listed below, will require prior written approval by the Parties, and amendment of the Protocol if appropriate.

1. Supply. Idera will provide the Idera Compound (i) in packaged, inspected and released form with lot number imprinted on the shipping containers, each sealed with a tamper-evident seal, for finishing activities (i.e., labeling, packaging and leafleting) in a similar form that Idera supplies for its own development purposes, (ii) free of charge, and (iii) in sufficient quantity with at least [**] ([**]) months of shelf-life remaining at the time of Delivery to AbbVie. The estimated quantity to be supplied for the Study will be approximately [**] vials, containing 8 mg each of Idera Compound.
2. Shipment. Shipment of the Idera Compound will require a lead time of approximately [**] ([**]) weeks from the time of AbbVie's order, with the exception of the initial Delivery to AbbVie which Idera will use best efforts to Deliver within [**] calendar days.
3. Forecasting. AbbVie will provide Idera with an updated twelve (12) month rolling forecast by product source each calendar quarter.
4. Shipping and Distribution. Idera is responsible for Delivery of Idera Compound to AbbVie at the Delivery locations specified below. AbbVie shall be responsible for shipment of the Idera Compound after Delivery by Idera.
5. Customs. AbbVie shall obtain at its own risk and expense any export license or other official authorization and customs formalities necessary for the export of Idera Compound provided hereunder after Delivery, including but not limited to Study Centers or local depots in the countries to which Idera Compound will be shipped; provided that upon AbbVie's request Idera shall promptly provide customs valuations for the Idera Compound and any other information in its possession or control necessary therefor. Idera shall assist AbbVie with respect to any customs documents to secure a smooth transmission through customs so as to minimize any impact on Idera Compound's shelf-life. AbbVie shall be responsible for all applicable import taxes and duties related to shipment of Idera Compound after Delivery by Idera.
6. Delivery Schedule. Below is the initial estimate of total Idera Compound required from Idera for the Study.

Estimated Study FSFV date: [**]

Estimated Schedule of Deliveries:

<u>Delivery Date</u>	<u>Global Product Quantities</u>
Prior to September 2019	[**] vials
1Q 2020	[**] vials
3Q 2020	[**] vials
TOTAL	[**] vials

7. Delivery Location:

AbbVie Inc.
Dept R43E, Building AP15
1 North Waukegan Road
North Chicago, Illinois 60064
Attn: [**]
E-mail Address: [**]

DRUG RESPONSIBILITY MATRIX

TASK	Responsibility of [**]	Responsibility of [**]
On a quarterly basis, provide Idera with a twelve (12) month rolling forecast of Idera Compound supply needs.	[**]	[**]
Monitor Idera Compound clinical trial supply inventory and submit orders for Idera Compound to Idera [**] ([**]) weeks prior to the date that the Delivery is needed	[**]	[**]
Confirm receipt of order and provide AbbVie with estimated Delivery date.	[**]	[**]
Conduct conference calls to review any significant drug supply issues (if applicable)	[**]	[**]
Provide the following information to AbbVie: <input type="checkbox"/> Material Safety Data Sheet (MSDS) <input type="checkbox"/> Certificate of Compliance/Conformance, where the Certificate of Conformance generated should contain the following at a minimum: <ul style="list-style-type: none">o Product nameo Lot or batch numbero Expiry date	[**]	[**]

<ul style="list-style-type: none"> o Date of manufacturing <input type="checkbox"/> Certificate(s) of Regulatory Compliance for the Idera Compound related to the investigational medicinal product dossier for each country in which the Study is conducted <input type="checkbox"/> Certificate of Analysis <input type="checkbox"/> BSE/TSE Certificate or TSE statement <input type="checkbox"/> Temperature excursion management information <input type="checkbox"/> Customs valuation <input type="checkbox"/> Lot pedigree (upon request) 		
Distribution of clinically packaged Idera Compound to Study Centers	[**]	[**]
Return/destruction of unused Idera Compound at depots/Study Centers (drug accountability/ reconciliation)	[**]	[**]
Maintenance of registrations/licenses/permits (as applicable) that includes authorization to manufacture and distribute the Idera Compound	[**]	[**]
Receipt of Idera Compound and Incoming Inspection when material is received at AbbVie according to AbbVie's SOPs	[**] ¹	[**]
Documentation archiving	[**] ²	[**] ²
Approval of the Idera Compound for use in the Study	[**]	[**]
Retention samples of Idera Compound (re-) packaged by AbbVie	[**]	[**]
Information in case of Idera Compound Complaints, as applicable	[**] ³	[**] ³
Other GMP relevant documents (Idera to provide to AbbVie as required)	[**]	[**]
Return of rejected Idera Compound	[**] ⁴	[**] ⁴
Monitor market with respect to recalls of Idera Compound	[**]	[**]
Inform AbbVie on recalls of Idera Compound concerned lot(s)	[**]	[**] ⁵

- 1 Incoming inspection means: Supply check (e.g. making sure shipping documents match label descriptions and number of items and materials are in good shape, no damage, Tamper Evident Seal (TES) unbroken—if applicable, etc.) and ID Testing as set forth in Section 5(c).
- 2 Idera and AbbVie to archive according to legal requirements and each company’s internal procedures. Also, refer to the TQA for additional requirements for batch and testing and validation/qualification documentation.
- 3 The Party receiving complaints related to Idera Compound supplied to report to the other Party. Refer to the TQA for timing requirements.
- 4 AbbVie reserves the right to return rejected Idera Compound and Idera agrees to accept returned rejected Idera Compound.
- 5 Refer to the TQA for timing requirements.

QUALITY & SUPPLY CONTACTS FOR THE STUDY

IDERA

Function	Name	Contact Information
Product Actions (i.e. recalls, field recoveries, withdrawals)	[**]	[**]
Product Complaint Communications	[**]	[**]
Inspection Management/Agency communications	[**]	[**]
Supply Chain	[**]	[**]
Qualified Person	[**]	[**]

ABBVIE

Function	Name	Contact Information
Quality Assurance Recalls & Recovery	N/A	[**]
Product Complaint Communications	N/A	[**]
Inspection Management/Agency communications	N/A	[**]
Supplier-related Change Notifications	N/A	[**]
Supply Chain	[**]	[**]
Qualified Person	[**]	[**]

ATTACHMENT B

PROTOCOL

*Confidential Materials omitted and filed separately with the Securities and Exchange Commission.
A total of 146 pages were omitted. [**].*

ATTACHMENT C

CONTACTS

Idera Contacts	
<u>Supply/Shipping</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Qualified Person</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Clinical</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Finance</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Study Publications</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Press Releases</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Alliance Management</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Quality</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Pharmacovigilance</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Legal</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Senior Leader</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]

AbbVie Contacts

<u>Clinical</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Study Publications</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>GPRD Operations</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Press Releases</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Collaboration Alliance Manager</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Quality</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Pharmacovigilance</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Legal</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]
<u>Senior Leader</u>	Name: [**] Title: [**] E-mail: [**] Phone: [**]

ATTACHMENT D

ALTERNATIVE DISPUTE RESOLUTION

1. To begin an ADR proceeding, a Party shall provide written notice to the other Party of the Dispute 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 arbitration, add additional issues to be resolved within the same ADR.
2. Within [**] days following the initiation of the ADR proceeding, the Parties shall select a mutually acceptable independent, impartial and conflicts-free neutral to preside in the resolution of all issues in this ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, each Party will select one (1) independent, impartial and conflicts-free neutral and those two (2) neutrals will select a third independent, impartial and conflicts-free neutral within [**] thereafter (such neutral(s), the “**Neutral**”). None of the neutrals selected may be current or former employees, officers or directors of either Party or its Affiliates.
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 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 ruling shall not contain any recitation of the facts or any legal arguments, and the proposed remedy shall not include any punitive damages. The proposed ruling and the proposed remedy collectively shall not exceed one (1) page per issue.
 - (d) a brief in support of such Party’s proposed rulings and remedies; provided, that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
5. Except as expressly set forth in subparagraphs 4(a) - 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.
6. The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:

- (a) Each Party shall be entitled to five (5) hours of hearing time to present its case. The Neutral shall determine whether each Party has had the five (5) 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 therein not only issues it 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) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.
 - (e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the Neutral shall have sole discretion regarding the admissibility of any evidence.
7. 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 ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
8. 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 (1) of the Parties on each disputed issue but may adopt one (1) 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.
9. 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 (1) Party on all disputed issues in the ADR, the losing Party shall pay one hundred percent (100%) of such fees and expenses.
 - (b) If the Neutral rules in favor of one (1) 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.

10. 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.
11. Except as provided in paragraph 9 or as required by law, the existence of the Dispute, any settlement negotiations, the ADR proceeding, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed to be Confidential Information of both Parties. The Neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.
12. All ADR proceedings shall be conducted in the English language.
13. Each Party shall have the right to be represented by counsel in all aspects of any ADR proceeding.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Vincent J. Milano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 6, 2019

/s/ VINCENT J. MILANO

Vincent J. Milano
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, John J. Kirby, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 6, 2019

/s/ JOHN J. KIRBY

John J. Kirby
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 September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vincent J. Milano, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

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

Dated: November 6, 2019

/s/ VINCENT J. MILANO

Vincent J. Milano

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 September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John J. Kirby, Chief Financial Officer, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

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

Dated: November 6, 2019

/s/ JOHN J. KIRBY

John J. Kirby
Chief Financial Officer
