

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

**FORM 10-Q**

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

**04-3072298**

(I.R.S. Employer  
Identification No.)

**505 Eagleview Blvd., Suite 212**  
**Exton, Pennsylvania**

(Address of principal executive offices)

**19341**

(Zip code)

**(484) 348-1600**

(Registrant's telephone number, including area code)

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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

28,843,528  
Outstanding as of July 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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth 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, or the SEC, on March 6, 2019. 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)	June 30, 2019	December 31, 2018*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 39,884	\$ 71,431
Short-term investments	12,489	—
Prepaid expenses and other current assets	1,567	1,376
Total current assets	53,940	72,807
Property and equipment, net	151	207
Operating lease right-of-use asset	171	—
Other assets	70	9
Total assets	<u>\$ 54,332</u>	<u>\$ 73,023</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 457	\$ 1,134
Accrued expenses	5,939	7,884
Operating lease liability	189	—
Total current liabilities	6,585	9,018
Other liabilities	12	11
Total liabilities	6,597	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 — 28,827 and 27,188 shares at June 30, 2019 and December 31, 2018, respectively		
	29	27
Additional paid-in capital	734,229	728,342
Accumulated deficit	(686,525)	(664,375)
Accumulated other comprehensive income	2	—
Total stockholders' equity	47,735	63,994
Total liabilities and stockholders' equity	<u>\$ 54,332</u>	<u>\$ 73,023</u>

\* 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Alliance revenue	\$ 1,448	\$ 163	\$ 1,448	\$ 418
Operating expenses:				
Research and development	10,024	10,880	18,126	24,436
General and administrative	2,895	4,000	6,038	7,481
Merger-related costs, net	—	1,583	—	5,081
Restructuring costs	45	—	176	—
Total operating expenses	12,964	16,463	24,340	36,998
Loss from operations	(11,516)	(16,300)	(22,892)	(36,580)
Other income (expense):				
Interest income	339	271	743	482
Interest expense	—	(4)	—	(11)
Foreign currency exchange loss	1	2	(1)	(17)
Net loss	\$ (11,176)	\$ (16,031)	\$ (22,150)	\$ (36,126)
Net loss per share applicable to common stockholders - basic and diluted (Note 13)	\$ (0.39)	\$ (0.59)	\$ (0.79)	\$ (1.39)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	28,461	27,133	28,070	26,012
Comprehensive loss:				
Net loss	\$ (11,176)	\$ (16,031)	\$ (22,150)	\$ (36,126)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	—	—	2	—
Total other comprehensive income	—	—	2	—
Comprehensive loss	\$ (11,176)	\$ (16,031)	\$ (22,148)	\$ (36,126)

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

## IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

(In thousands)	Six Months Ended June 30,	
	2019	2018
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (22,150)	\$ (36,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,905	3,127
Issuance of common stock for services rendered	59	45
Accretion of discounts on short-term investments	(353)	—
Unrealized gain on available-for-sale securities	2	—
Depreciation and amortization expense	67	321
Gain on disposal of property and equipment	(11)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(423)	69
Accounts payable, accrued expenses, and other liabilities	(2,426)	4,243
Deferred revenue	—	(331)
Net cash used in operating activities	<u>(23,330)</u>	<u>(28,652)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchases of available-for-sale securities	(35,486)	—
Proceeds from maturity of available-for-sale securities	23,350	—
Proceeds from the sale of property and equipment	11	—
Purchases of property and equipment	(11)	(42)
Net cash used in investing activities	<u>(12,136)</u>	<u>(42)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from equity financings, net of issuance costs	3,857	—
Proceeds from employee stock purchases	68	159
Proceeds from exercise of common stock options and warrants	—	10,166
Payments on note payable	—	(209)
Other	(6)	(5)
Net cash provided by financing activities	<u>3,919</u>	<u>10,111</u>
Net decrease in cash and cash equivalents	(31,547)	(18,583)
Cash, cash equivalents and restricted cash, beginning of period	71,431	112,940
Cash, cash equivalents and restricted cash, end of period	<u>\$ 39,884</u>	<u>\$ 94,357</u>

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



**IDERA PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

June 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 June 30, 2019, the Company had an accumulated deficit of \$686.5 million and a cash, cash equivalents and short-term investments balance of \$52.4 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 existing balance of cash, cash equivalents and short-term investments on hand as of June 30, 2019 will be sufficient to fund operations into the second 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 existing balance of cash, cash equivalents and short-term investments on hand as of June 30, 2019 is not sufficient to fund operations past the second quarter of 2020. While there is substantial doubt about the Company’s ability to continue as a going concern through the 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 Securities and Exchange Commission (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 six months ended June 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.

### ***Reclassifications***

The prior year financial statements contain certain reclassifications to the results of operations for the three and six months ended June 30, 2018 to conform to the presentation for the year ended December 31, 2018 included in the 2018 Form 10-K. Merger-related costs of approximately \$1.6 million and \$5.1 million were reclassified from general and administrative expenses to merger-related costs, net for the three and six months ended June 30, 2018, respectively.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be “cash equivalents.” Cash and cash equivalents at June 30, 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 June 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 June 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 six months ended June 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 June 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 June 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 six months ended June 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 June 30, 2019 and December 31, 2018 categorized by the level of inputs used in the valuation of each asset and liability:

(In thousands)	June 30, 2019			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Cash	\$ 250	\$ 250	\$ —	\$ —
Money market funds	36,647	36,647	—	—
Other cash equivalents – commercial paper	2,987	—	2,987	—
Short-term investments – commercial paper	3,496	—	3,496	—
Short-term investments – U.S. treasury bills	8,993	8,993	—	—
<b>Total assets</b>	<b>\$ 52,373</b>	<b>\$ 45,890</b>	<b>\$ 6,483</b>	<b>\$ —</b>
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>

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

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 June 30, 2019:

(In thousands)	June 30, 2019			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
Short-term investments – commercial paper	\$ 3,496	\$ —	\$ —	\$ 3,496
Short-term investments – U.S. treasury bills	8,991	—	2	8,993
Total short-term investments	\$ 12,487	\$ —	\$ 2	\$ 12,489
Total investments	\$ 12,487	\$ —	\$ 2	\$ 12,489

The Company had no realized gains or losses from the sale of investments in available-for-sale securities in each of the six months ended June 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 six months ended June 30, 2019 or 2018.

#### Note 5. Property and Equipment

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

(In thousands)	June 30, 2019	December 31, 2018
Leasehold improvements	\$ 107	\$ 104
Laboratory equipment and other	765	767
Total property and equipment, at cost	872	871
Less: Accumulated depreciation and amortization	721	664
Property and equipment, net	\$ 151	\$ 207

Depreciation and amortization expense on property and equipment was approximately \$0.1 million for each of the three months ended June 30, 2019 and 2018, and approximately \$0.1 million and \$0.3 million for the six months ended June 30, 2019 and 2018, respectively. There were no non-cash property additions during the six months ended June 30, 2019 or 2018.

#### Note 6. Accrued Expenses

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

(In thousands)	June 30, 2019	December 31, 2018
Payroll and related costs	\$ 1,249	\$ 1,962
Clinical and nonclinical trial expenses	3,681	3,958
Professional and consulting fees	446	605
Restructuring expenses	449	1,147
Other	114	212
Total accrued expenses	\$ 5,939	\$ 7,884

Included in accrued Payroll and related costs as of June 30, 2019 and December 31, 2018 is \$0.2 million and \$0.7 million, respectively, of salary continuation severance benefits to be 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 ("Investor"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Investor 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 Investor 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 six months ended June 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 six months ended June 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 June 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 June 30, 2019 and December 31, 2018:

Description	Number of Shares		Weighted-Average Exercise Price	Expiration Date
	June 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)	269,844	269,844	\$ 0.08	Feb 2021
Total	2,768,882	2,768,882		

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

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	2,768,882	\$ 0.08
Issued	—	—
Exercised	—	—
Expired	—	—
Outstanding at June 30, 2019	2,768,882	\$ 0.08

**Note 8. Alliance Revenue**

Alliance revenue for the three and six months ended June 30, 2019 and 2018 represents revenue from contracts with customers accounted for in accordance with ASC Topic 606. For the three and six months ended June 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		Six months ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Out-license arrangement (1)	\$ 1,447	\$ —	\$ 1,447	\$ —
GSK collaboration (2)	—	141	—	283
Vivelix collaboration (3)	—	—	—	56
Other (4)	1	22	1	79
Total Alliance revenue	\$ 1,448	\$ 163	\$ 1,448	\$ 418

- (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 was issued shares representing 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 June 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 June 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 was issued shares representing 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 June 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 three and six months ended June 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 during the three months ended June 30, 2019.

### ***Collaboration with Vivelix***

In November 2016, the Company entered into an exclusive license and collaboration agreement with 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 three and six months ended June 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 three and six months ended June 30, 2019.

### ***Collaboration with GSK***

In November 2015, the Company entered into a collaboration and license agreement with 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.

**Note 9. Collaboration and License Agreements (Continued)**

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 six months ended June 30, 2018, the Company recognized Alliance revenues of \$0.1 million and \$0.3 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 six months ended June 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 supports 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.

Restructuring-related charges incurred, as of June 30, 2019, totaled \$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.

The following summarizes restructuring-related activity for the six months ended June 30, 2019:

<b>(in thousands)</b>	<b>Employee Severance and Benefits</b>	<b>Contract Termination Costs</b>	<b>Asset Impairments</b>	<b>Total</b>
<b>Accrued restructuring balance as of December 31, 2018</b>	\$ 1,147	\$ —	\$ —	\$ 1,147
Charges incurred	173	—	—	173
Cash payments	(859)	—	—	(859)
<b>Accrued restructuring balance as of June 30, 2019</b>	<b>\$ 461</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 461</b>

As of June 30, 2019, the short-term portion of the accrued restructuring balance, or \$0.4 million, is included in "Accrued expenses" in the accompanying condensed balance sheets. See Note 6. The long-term portion of less than \$0.1 million is included within "Other liabilities" in the accompanying condensed balance sheets.



## **Note 11. Stock-Based Compensation**

As of June 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 up to such number of shares of the Company's common stock as equal to (i) 5,653,057 shares of common stock; plus (ii) such additional number of shares of common stock (up to 868,372 shares) as is equal to the sum of the number of shares of common stock subject to awards granted under the Company's 2005 Stock Incentive Plan or the Company's 2008 Stock Incentive Plan (the "2008 Plan") which 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 (subject, however, in the case of incentive stock options to any limitations of the Internal Revenue Code).

As of June 30, 2019, options to purchase a total of 2,992,630 shares of common stock and 193,625 restricted stock units were outstanding and up to 2,703,719 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 June 30, 2019, options to purchase a total of 457,997 shares of common stock were outstanding under the 2008 Plan.

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

#### *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 provides for the issuance of up to 412,500 shares of common stock to participating employees of the Company or its subsidiaries. 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 June 30, 2019, 351,724 shares remained available for issuance under the 2017 ESPP.

For the six months ended June 30, 2019 and 2018, the Company issued 30,570 and 13,112 shares of common stock, respectively, under the 2017 ESPP and received proceeds of less than \$0.1 million during each period 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.

**Note 11. Stock-Based Compensation (Continued)**

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 six months ended June 30, 2019 and 2018 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Stock-based compensation:</b>				
Research and development				
Employee Stock Purchase Plan	\$ 12	\$ 29	\$ 18	\$ 51
Equity Incentive Plan	320	520	650	1,076
	\$ 332	\$ 549	\$ 668	\$ 1,127
General and administrative				
Employee Stock Purchase Plan	\$ 8	\$ 18	\$ 14	\$ 32
Equity Incentive Plan	549	971	1,223	1,968
	\$ 557	\$ 989	\$ 1,237	\$ 2,000
Total stock-based compensation expense	\$ 889	\$ 1,538	\$ 1,905	\$ 3,127

During the six months ended June 30, 2019 and 2018, the weighted average fair market value of stock options granted was \$1.83 and \$9.76, respectively.

The following weighted average assumptions apply to the options to purchase 610,002 and 569,199 shares of common stock granted to employees and directors during the six months ended June 30, 2019 and 2018, respectively:

	Six Months Ended June 30,	
	2019	2018
Average risk-free interest rate	2.3%	2.2%
Expected dividend yield	—	—
Expected lives (years)	4.0	3.9
Expected volatility	82.8%	75.6%
Weighted average exercise price (per share)	\$ 3.02	\$ 17.42

All options granted during the six months ended June 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 six months ended June 30, 2019:

(\$ in thousands, except per share data)	Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
<b>Outstanding at December 31, 2018</b>	3,304,531	\$ 18.42	6.6	\$ —
Granted	610,002	3.02		
Exercised	—	—		
Forfeited	(60,595)	13.36		
Expired	(9,561)	40.42		
<b>Outstanding at June 30, 2019 (1)</b>	3,844,377	\$ 15.99	6.6	\$ 9
<b>Exercisable at June 30, 2019</b>	2,217,289	\$ 21.36	4.9	\$ —

(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.

**Note 11. Stock-Based Compensation (Continued)**

The fair value of options that vested during the six months ended June 30, 2019 was \$2.5 million. As of June 30, 2019, there was \$6.2 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 six months ended June 30, 2019:

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

As of June 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 3.5 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. Baker Bros. Advisors, LP and certain of its affiliated funds (collectively, "Baker Brothers") owned approximately 16% of the Company's common stock as of June 30, 2019. Additionally, Kelvin M. Neu, a member of Company's Board until his resignation in June 2019, is an employee of Baker Bros. Advisors, LP.

During the six months ended June 30, 2019, Baker Brothers made an in-kind pro rata distribution of a total of 60,070 warrants to Mr. Baker, Mr. Neu and other investors in Baker Brothers. During the six months ended June 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 June 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 six months ended June 30, 2019 and 2018, the Company issued 26,331 and 4,727 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 six months ended June 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 6,808,810 and 5,725,883 as of June 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 have 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, or BMS, in a Phase 3 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.

### **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). We believe, based on internally conducted commercial research, that in the United States, by 2025, approximately 25,000 people will have advanced melanoma appropriate for systemic treatment. 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 which means that 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, or 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 irRECIST, 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 have 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 has been increased to approximately 450 from the original target sample size of 308. As of August 7, 2019, we had 294 patients enrolled. Based on our current enrollment rate, we expect to complete enrollment in the first half of 2020.

We have solicited feedback from the U.S. Food and Drug Administration and they do not object to these changes. We also have solicited feedback from other global health authorities related to these changes.

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 manufacture and supply YERVOY® (ipilimumab), at its cost and for no charge to us, for use in ILLUMINATE-301, including for the proposed change 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 tilsotolimod, administered intratumorally, 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 enable an additional 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 9 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, or 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 progression free survival (PFS) and median overall survival (OS), and to continue to characterize the safety of the combinations. In the Phase 1 portion of the trial, serial biopsies are being 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 had been 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 Simon 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 met the pre-specified futility assessment and advanced into the second stage of the Phase 2 portion.

At the 37<sup>th</sup> Annual J.P. Morgan Healthcare Conference in January 2019, we provided an update on our Phase 1/2 trial evaluating tilsotolimod in combination with ipilimumab at the recommended 8 mg dose level, noting that as of our December 2018 data-cut, a total of 37 patients had been dosed at the 8 mg dose level and 34 patients treated at the 8 mg dose level had at least one post-baseline disease assessment. Of these 34 patients, three had a complete response and eight had a partial response, representing an overall response rate of 32.4%. One of the three patients who had a complete response has been continuing off active treatment for more than two years and has remained disease free. Additionally, fifteen other patients who were treated at the 8 mg dose level experienced stable disease. In the aggregate, 26 of the 34 patients achieved stable disease or better, representing a disease control rate of 76.5%. Additionally, as of the response data cutoff date, one patient who was treated at the 4 mg dose had an ongoing partial response and had been off active treatment for more than two years. The combination of tilsotolimod and ipilimumab continues to be well-tolerated.

In addition, other key findings include data demonstrating a clear systemic antitumor effect on distant uninjected tumors from the treatment of tilsotolimod in combination with ipilimumab. Also, data was presented showing that clinical responses were observed in patients whose tumors had low HLA-ABC expression at baseline, before treatment was started. Given that HLA-ABC expression is required for ipilimumab anti-tumor activity (Rodig, 2018), this demonstrates the contribution of tilsotolimod to overcome resistance to ipilimumab in tumors with low HLA-ABC expression, thereby enhancing the overall response rate compared to that expected with ipilimumab alone.

The Phase 2 expansion of our ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at 8mg tilsotolimod in combination with ipilimumab. As of August 5, 2019, of the 49 subjects evaluable for efficacy, 13 had a response representing an overall response rate of 27%, per RECIST 1.1. 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 8 of 13 responders. Median overall survival has not yet been reached (min/max: 1.6 months/35 months). The safety profile observed in this analysis was consistent with previously reported results, with no emergence of new safety signals. We are planning on submitting final results from the ILLUMINATE-204 trial as an abstract for a medical conference in the first half of 2020.

#### *Pembrolizumab Arm*

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

We completed enrollment with a total of 9 patients dosed 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 tilsotolimod administered intratumorally as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, tilsotolimod was administered intratumorally 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 well tolerated at each of the dose levels tested. We also completed enrollment of a total 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 American Association for Cancer Research (AACR) 2019 Annual Meeting in April 2019, we provided an update on ILLUMINATE-101, noting that as of February 28, 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 29 evaluable patients, 13 had a RECIST v1.1 disease assessment of stable disease, with a disease control rate of 45%. Of the 13 patients with stable disease, five had maximum tumor shrinkage greater than 10% below baseline and duration of stable disease ranged from 1.3 to 9.7+ months from start of treatment. There were no correlations between dose and efficacy observed.

To date, there is one unconfirmed RECIST v1.1 partial response reported in the melanoma monotherapy cohort. Additionally, one subject with uterine-leiomyosarcoma has ongoing stable disease for more than one year. This subject is continuing under a treatment IND post-closing of ILLUMINATE-101.

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. Initial translational data confirms robust Type I IFN pathway activation 24 hours following a single intratumoral dose of tilsotolimod, which 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, squamous cell carcinoma of the head and neck (SCCHN) and dMMR/MSI-H colorectal cancer (CRC).

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.

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 TME of MSS CRC patients.

We believe, based on internally conducted research, that annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and there are approximately 50,000 deaths 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.



***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. We received notification from the FDA in January 2019 that the study may proceed and expect to initiate the Phase 2, multicohort study for the treatment of specific solid tumors in the second half of 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. The secondary objectives of Part 1 are to assess tilsotolimod in combination with nivolumab and ipilimumab by evaluating safety, tolerability, plasma concentrations and immunogenicity. 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 initial ILLUMINATE-206 cohorts are as follows:

- Cohort 1: RM SCCHN in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab;
- Cohort 2: RM SCCHN in immunotherapy-refractory patients treated with tilsotolimod in combination with nivolumab and ipilimumab; and
- Cohort 3: Relapsed/refractory MSS CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab.

Within Cohort 1, 41 patients are planned to be enrolled (22 patients in Stage 1 and 19 patients in Stage 2). Within Cohorts 2 and 3, 36 patients each are planned for enrollment (20 patients in Stage 1 and 16 patients in Stage 2). Each cohort is planned to be recruited for the first stage of Part 1.

We expect to initiate ILLUMINATE-206 in the third quarter of 2019, beginning with Cohort 3.

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 BMS, described below, and GlaxoSmithKline Intellectual Property Development Limited, or 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.

## **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 were issued shares representing 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 June 30, 2019, we had an accumulated deficit of \$686.5 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 July 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 our "At-the-market" equity program.

#### *Funding Requirements*

We had cash, cash equivalents and short-term investments of approximately \$52.4 million at June 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 second quarter of 2020. Specifically, we believe that our available funds will be sufficient to enable us to:

- (i) complete enrollment, where applicable, and 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);
  - c) the Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301); and

- d) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);
- (ii) initiate our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of certain solid tumors (ILLUMINATE-206);
- (iii) fund certain investigator initiated clinical trials of tilsotolimod; and
- (iv) 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 a purchase agreement with Lincoln Park Capital Fund, LLC, or 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, which we refer to as 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, 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 July 31, 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 six months ended June 30, 2019 and 2018:

<i>(in thousands)</i>	Six months ended June 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	\$ (23,330)	\$ (28,652)
Investing activities	(12,136)	(42)
Financing activities	3,919	10,111
<b>Decrease in cash and cash equivalents</b>	<b>\$ (31,547)</b>	<b>\$ (18,583)</b>

*Operating Activities.* Net cash used in operating activities for each of the six months ended June 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 six months ended June 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 six months ended June 30, 2019, purchases of \$35.5 million in available-for-sale securities, partially offset by \$23.4 million of proceeds from available-for-sale securities; and
- for the six months ended June 30, 2018, 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 six months ended June 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 employee stock purchases under our 2017 Employee Stock Purchase Plan, or 2017 ESPP; and
- for the six months ended June 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 six months ended June 30, 2019, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

## **Off-Balance Sheet Arrangements**

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



## Results of Operations

### Three and Six Months Ended June 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 three and six months ended June 30, 2019 totaled \$1.4 million primarily related to the out-licensing of certain non-core technology to Licensee. See Note 9 to the condensed financial statements appearing elsewhere in the Quarterly Report on Form 10-Q.

Alliance revenue for the three and six months ended June 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 six months ended June 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 June 30,			Six months ended June 30,		
	2019	2018	% Change	2019	2018	% Change
IMO-2125 external development expense	\$ 7,686	\$ 4,275	80%	\$ 13,100	\$ 10,793	21% (1)
IMO-8400 external development expense	7	1,391	(99%)	45	2,607	(98%)(2)
Other drug development expense	2,331	3,070	(24%)	4,981	6,825	(27%)(3)
Basic discovery expense	—	2,144	(100%)	—	4,211	(100%)(4)
Total research and development expenses	\$ 10,024	\$ 10,880	(8%)	\$ 18,126	\$ 24,436	(26%)

- (1) *IMO-2125 External Development Expenses.* These expenses include external expenses that 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 June 30, 2019 we incurred approximately \$52.8 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.

The increase in our IMO-2125 external development expenses during each of the three and six months ended June 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. 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 June 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 the three and six months ended June 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.

The decrease in other drug development expenses during each of the three and six months ended June 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 tilsetolimod, 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 tilsetolimod 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 June 30, 2019 and 2018, general and administrative expenses totaled \$2.9 million and \$4.0 million, respectively. For the six months ended June 30, 2019 and 2018, general and administrative expenses totaled \$6.0 million and \$7.5 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 and six months ended June 30, 2018 amounted to net charges of \$1.6 million and \$5.1 million, respectively. 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 six months ended June 30, 2019 totaled less than \$0.1 million and approximately \$0.2 million, respectively, and 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. No such costs were incurred during the three and six months ended June 30, 2018.

#### ***Interest Income***

Interest income for each of the three months ended June 30, 2019 and 2018 totaled approximately \$0.3 million. Interest income for the six months ended June 30, 2019 and 2018 totaled approximately \$0.7 million and \$0.5 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 each of the three and six months ended June 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 and six months ended June 30, 2019.

***Net Loss Applicable to Common Stockholders***

As a result of the factors discussed above, our net loss applicable to common stockholders was \$11.2 million and \$16.0 million for the three months ended June 30, 2019 and 2018, respectively, and \$22.2 million and \$36.1 million for the six months ended June 30, 2019 and 2018, respectively.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

As of June 30, 2019, all of our material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. At June 30, 2019, all of our invested funds were invested in money market funds and commercial paper, classified in cash and cash equivalents on the accompanying balance sheet, and commercial paper and U.S. treasury bills classified in investments on the accompanying balance sheet.

Based on a hypothetical 10% adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

### **Item 4. Controls and Procedures.**

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 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 June 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 June 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.**

*Investing in our securities involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the factors discussed in “Part I, Item 1A. Risk Factors” in our most recent Annual Report on Form 10-K for the year ended December 31, 2018, which could be materially and adversely affect our business, financial condition or future results.*

### **Item 5. Other Information.**

(a) As previously disclosed in Part II, Item 9B of the Company’s 2018 Form 10-K filed on March 6, 2019, the Company announced on that date the retirement of Joanna Horobin, M.B. Ch.B, the Company’s former Senior Vice President and Chief Medical Officer, effective July 31, 2019. Dr. Horobin and the Company have subsequently entered into a one-year (subject to renewal) consulting services agreement, effective July 31, 2019, pursuant to which Dr. Horobin has agreed to provide certain consulting services in the area of oncology development. The agreement contemplates hourly compensation for Dr. Horobin’s services with no minimum required service and includes customary terms, including regarding confidentiality and the Company’s ownership of intellectual property rights.

**Item 6. Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
10.1 †	<a href="#">Amendment to the Idera Pharmaceuticals, Inc. 2013 Stock Incentive Plan (Incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 25, 2019)</a>
10.2 †	<a href="#">Amendment to the Idera Pharmaceuticals, Inc. 2017 Employee Stock Purchase Plan (Incorporated herein by reference to Appendix C to the Company's Definitive Proxy Statement on Schedule 14A, filed on April 25, 2019)</a>
*10.3 †	<a href="#">Form of Restricted Stock Agreement under the 2013 Stock Incentive Plan</a>
*10.4 †	<a href="#">Employment Offer Letter, dated June 26, 2019, by and between Idera Pharmaceuticals, Inc. and Elizabeth Tarka</a>
*31.1	<a href="#">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</a>
*31.2	<a href="#">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</a>
*32.1	<a href="#">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</a>
*32.2	<a href="#">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</a>
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

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\* Filed or furnished, as applicable, herewith.

† Indicates a management contract or compensatory plan or arrangement.

**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC.**

Date: August 8, 2019

/s/ Vincent J. Milano

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

Date: August 8, 2019

/s/ John J. Kirby

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



**IDERA PHARMACEUTICALS, INC.**  
**2013 STOCK INCENTIVE PLAN**  
**RESTRICTED STOCK UNIT AGREEMENT**

This RESTRICTED STOCK UNIT AGREEMENT (the "Agreement"), dated as of \_\_\_\_\_ (the "Date of Grant"), is delivered by Idera Pharmaceuticals, Inc. (the "Company") to \_\_\_\_\_ (the "Participant").

RECITALS

The Idera Pharmaceuticals, Inc. 2013 Stock Incentive Plan (the "Plan") provides for the grant of restricted stock units in accordance with the terms and conditions of the Plan. The Board has decided to make this grant of restricted stock units as an inducement for the Participant to promote the best interests of the Company and its stockholders. The Participant hereby acknowledges the receipt of a copy of the official prospectus for the Plan, which is available by accessing the Company's intranet at <https://intranet.iderapharma.com>. Paper copies of the Plan and the official Plan prospectus are available by contacting the General Counsel of the Company. This Agreement is made pursuant to the Plan and is subject in its entirety to all applicable provisions of the Plan. Capitalized terms used herein and not otherwise defined will have the meanings set forth in the Plan.

1. Grant of Stock Units. Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants the Participant \_\_\_\_\_ restricted stock units, subject to the restrictions set forth below and in the Plan (the "Stock Units"). Each Stock Unit represents the right of the Participant to receive a share of common stock of the Company ("Common Stock"), if and when the specified conditions are met in Section 3 below, and on the applicable payment date set forth in Section 5 below.

2. Stock Unit Account. Stock Units represent hypothetical shares of Common Stock, and not actual shares of stock. The Company shall establish and maintain a Stock Unit account, as a bookkeeping account on its records, for the Participant and shall record in such account the number of Stock Units granted to the Participant. No shares of Common Stock shall be issued to the Participant at the time the grant is made, and the Participant shall not be, and shall not have any of the rights or privileges of, a stockholder of the Company with respect to any Stock Units recorded in the Stock Unit account. The Participant shall not have any interest in any fund or specific assets of the Company by reason of this award or the Stock Unit account established for the Participant.

3. Vesting.

(a) Subject to the terms of this Section 3, the Stock Units shall become vested according to the following schedule (each, a "Vesting Date"), provided that the Participant continues to be employed by, or provide service to, the Company and its subsidiaries (the "Employer") from the Date of Grant until the applicable Vesting Date:

Vesting Date	% of Vested Stock Units
[     ] ]	[     ] %
[     ] ]	[     ] %
[     ] ]	[     ] %
[     ] ]	[     ] %
	100%

(b) The vesting of the Stock Units shall be cumulative, but shall not exceed 100% of the Stock Units. If the foregoing schedule would produce fractional Stock Units, the number of Stock Units that vest shall be rounded down to the nearest whole Stock Unit and the fractional Stock Units will be accumulated so that the resulting whole Stock Units will be included in the number of Stock Units that become vested on the last Vesting Date.

(c) Notwithstanding Section 3(a) above, the Stock Units shall vest in full upon the Participant's termination of employment on account of death.

(d) [Notwithstanding Section 3(e) below,] in the event of a Reorganization Event (as such term is defined in the Plan) [other than a Change in Control (as such term is defined below),] before all of the Stock Units vest in accordance with Section 3(a) above, the provisions of the Plan applicable to a Reorganization Event shall apply to the Stock Units, and, in the event of a Reorganization Event, the Board may take such actions with respect to the vesting of the Stock Units as it deems appropriate pursuant to the Plan.

[(e) In the event that there shall occur a Change in Control and if Participant is at such time employed by, or provide service to, the Employer, the Stock Units shall become fully vested upon such Change in Control.

"Change in Control" shall mean the occurrence of any of the following events: (i) a change in the composition of the Board over a period of thirty-six consecutive months or less such that a majority of the members of the Board ceases to be comprised of individuals who are Continuing Members; for such purpose, a "Continuing Member" shall mean an individual who is a member of the Board on the date of this Agreement and any successor of a Continuing Member who is elected to the Board or nominated for election by action of a majority of Continuing Members then serving on the Board; (ii) any merger or consolidation that results in the voting securities of the Company outstanding immediately prior thereto representing (either by remaining outstanding or by being converted into voting securities of the surviving or acquiring entity) less than 60% of the combined voting power of the voting securities of the Company or such surviving or acquiring entity outstanding immediately after such merger or consolidation; (iii) any sale of all or substantially all of the assets of the Company; (iv) the complete liquidation or dissolution of the Company; or (v) the acquisition of "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities (other than through a merger or consolidation or an acquisition of securities directly from the Company) by any "person," as such term is used in Sections 13(d) and 14(d) of the Exchange Act, other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportion as their ownership of stock of the Company; provided however that, where applied to compensation subject to Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"), any acceleration of or change in payment shall only apply (if required by Section 409A) if the Change in Control is also a change in control event described in Treasury Regulation 1.409A-3(i)(5).]

4. Termination of Stock Units. Except as set forth in this Agreement, if the Participant ceases to be employed by, or provide service to, the Employer for any reason before all of the Stock Units vest, any unvested Stock Units shall automatically terminate and shall be forfeited as of the date of the Participant's termination of employment or service. No payment shall be made with respect to any unvested Stock Units that terminate as described in this Section 4.

5. Payment of Stock Units and Tax Withholding.

(a) If and when the Stock Units vest, the Company shall issue to the Participant one share of Common Stock for each vested Stock Unit, subject to applicable tax withholding obligations. Payment shall be made within 30 days after the earlier [earliest] to occur of the following: (i) the applicable Vesting Date, [or] (ii) the Participant's termination of employment on account of death[, or (iii) a Change in Control].

(b) All obligations of the Company under this Agreement shall be subject to the rights of the Employer as set forth in the Plan to withhold amounts required by law to be withheld for any FICA, federal income, state, local and other tax liabilities ("Withholding Taxes"), if applicable. By accepting this Agreement, Participant hereby: (1) elects, effective on the date Participant accepts this Agreement, to sell shares of Common Stock issued in respect of

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the Agreement in an amount having an aggregate Fair Market Value equal to the Withholding Taxes, and to allow UBS Financial Services Inc. (the "Broker") to remit the cash proceeds of such sale to the Company (a "Sell to Cover"); (2) directs the Company to make a cash payment to satisfy the Withholding Taxes from the cash proceeds of such sale directly to the appropriate taxing authorities; and (3) represents and warrants that (i) on the date Participant accepts this Agreement he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Broker from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Common Stock effected by the Broker pursuant to the Agreement, and is entering into the Agreement and this election to Sell to Cover in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Exchange Act, and (iii) it is Participant's intent that this election to Sell to Cover comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act. The Participant further acknowledges that by accepting this Agreement, Participant is adopting a 10b5-1 Plan to permit Participant to conduct a Sell to Cover sufficient to satisfy the Withholding Taxes. To the extent not paid in accordance with the immediately preceding sentence, the Participant shall be required to pay to the Employer, or make other arrangements satisfactory to the Employer to provide for the payment of, any federal, state, local or other taxes that the Employer is required to withhold with respect to the Stock Units.

(c) The obligation of the Company to deliver Common Stock shall also be subject to the condition that if at any time the Board shall determine in its discretion that the listing, registration or qualification of the shares upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issuance of shares, the shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. The issuance of shares, if any, to the Participant pursuant to this Agreement is subject to any applicable taxes and other laws or regulations of the United States or of any state, municipality or other country having jurisdiction thereof.

6. No Stockholder Rights; Dividend Equivalents. Neither the Participant, nor any person entitled to receive payment in the event of the Participant's death, shall have any of the rights and privileges of a stockholder with respect to shares of Common Stock, including voting or dividend rights, until certificates for shares have been issued upon payment of Stock Units. The Participant acknowledges that no election under Section 83(b) of the Code is available with respect to Stock Units. Notwithstanding the foregoing, the Board may grant to the Participant Dividend Equivalents on the shares underlying the Stock Units prior to the Vesting Date, which shall be credited to the Stock Unit account for the Participant and will be paid or distributed in accordance with this Agreement and the Plan.

7. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and payment of the Stock Units are subject to the provisions of the Plan and to interpretations, regulations and determinations concerning the Plan established from time to time by the Board in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (a) rights and obligations with respect to withholding taxes, (b) the registration, qualification or listing of the shares of Common Stock, (c) changes in capitalization of the Company and (d) other requirements of applicable law. The Board shall have the authority to interpret and construe the Stock Units pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

8. No Employment or Other Rights. The grant of the Stock Units shall not confer upon the Participant any right to be retained by or in the employ or service of any Employer and shall not interfere in any way with the right of any Employer to terminate the Participant's employment or service at any time. The right of any Employer to terminate at will the Participant's employment or service at any time for any reason is specifically reserved.

9. Assignment and Transfers. Except as the Board may otherwise permit pursuant to the Plan, the rights and interests of the Participant under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Participant, by will or by the laws of descent and distribution. In the event of

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any attempt by the Participant to alienate, assign, pledge, hypothecate, or otherwise dispose of the Stock Units or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Stock Units by notice to the Participant, and the Stock Units and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Participant's consent.

10. Applicable Law; Jurisdiction. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof. Any action arising out of, or relating to, any of the provisions of this Agreement shall be brought only in the United States District Court for the District of Massachusetts, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in Boston, Massachusetts, and the jurisdiction of such court in any such proceeding shall be exclusive. Notwithstanding the foregoing sentence, on and after the date a Participant receives shares of Common Stock hereunder, the Participant will be subject to the jurisdiction provision set forth in the Company's bylaws.

11. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the General Counsel at the corporate headquarters of the Company, and any notice to the Participant shall be addressed to such Participant at the current address shown on the payroll of the Employer. Any notice shall be delivered by hand, or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service or by the postal authority of the country in which the Participant resides or to an internationally recognized expedited mail courier.

12. Recoupment Policy. The Participant agrees that, subject to the requirements of applicable law, the Stock Units, and the right to receive and retain any Common Stock or cash payments covered by this Agreement, shall be subject to rescission, cancellation or recoupment, in whole or part, if and to the extent so provided under any "clawback" or similar policy of the Company in effect on the Date of Grant or that may be established thereafter.

13. Application of Section 409A of the Code. This Agreement is intended to be exempt from section 409A of the Code under the "short-term deferral" exception and to the extent this Agreement is subject to section 409A of the Code, it will in all respects be administered in accordance with section 409A of the Code. Any provision that would cause this Agreement to fail to satisfy section 409A of the Code shall have no force or effect until amended to comply with section 409A of the Code (which amendment may be retroactive to the extent permitted by section 409A of the Code and may be made by the Company without the consent of the Participant). Any reference in this Agreement to section 409A of the Code will also include any proposed, temporary or final regulations, or any other guidance, promulgated with respect to such Section by the U.S. Department of the Treasury or the Internal Revenue Service. Notwithstanding the foregoing, if the Stock Units constitute "deferred compensation" under section 409A of the Code and the Stock Units become vested and settled upon the Participant's separation from service, payment with respect to the Stock Units shall be delayed for a period of six (6) months after the Participant's separation from service if the Participant is a "specified employee" as defined under section 409A of the Code and if required pursuant to section 409A of the Code. If payment is delayed, the Stock Units shall be settled and paid within thirty (30) days after the date that is six (6) months following the Participant's separation from service. Payments with respect to the Stock Units may only be paid in a manner and upon an event permitted by section 409A of the Code, and each payment shall be treated as a separate payment, and the right to a series of installment payments under the Stock Units shall be treated as a right to a series of separate payments. In no event shall the Participant, directly or indirectly, designate the calendar year of payment.

*[Signature Page Follows]*

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IN WITNESS WHEREOF, the Company has caused its duly authorized officer to execute this Agreement, and the Participant has executed this Agreement, effective as of the Date of Grant.

IDERA PHARMACEUTICALS, INC.

\_\_\_\_\_  
Name:

Title:

I hereby accept the award of Stock Units described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby agree that all decisions and determinations of the Board with respect to the Stock Units shall be final and binding.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant

\_\_\_\_\_



505 Eagleview Boulevard,  
Suite 212, Exton, PA, 19341

June 26, 2019

Elizabeth Tarka  
[Street Address]  
[City, State, Zip Code]

Dear Elizabeth,

On behalf of Idera Pharmaceuticals, Inc., ("Company"), we are pleased to offer you the position of **Chief Medical Officer**, reporting directly to **Vin Milano, President & CEO**. This role will report to our **Exton Pennsylvania** office. Your start date will be determined upon your acceptance of this offer. A summary of the terms of your employment follows.

#### **Exempt Base Salary**

Your base salary will be based on a semi-monthly pay schedule at the rate of **USD \$15,625.00**. This annualizes to a full-time equivalent of **USD \$375,000.00** and will be subject to customary tax withholdings and other payroll deductions. The Company utilizes a semi-monthly pay period, which ends on the 15th and the last day of the month. This position is considered an exempt position for purposes of federal wage-hour law, which means that you will not be eligible for overtime time pay for hours actually worked in excess of 40 in a given work week.

#### **Annual Incentive Plan**

Subject to the terms of the Company's Annual Incentive Plan (AIP) then in effect, you are eligible to earn a target incentive award of **40%** of your annual base salary. Awards are discretionary and the determination of this discretionary award is subject to evaluation of performance at the corporate and individual levels, and other performance criteria as they apply to your position. AIP will be pro-rated in your first year of hire, based on your start date.

#### **Benefits**

You will be eligible to participate in Idera's benefit plans in accordance with the terms and conditions of each plan. Benefits currently include, but are not limited to, medical, dental, vision, life and disability insurance, flexible spending accounts, and a 401(k) savings plan. Full details of these programs, as well as vacation and holidays, will be provided to you under separate cover.

#### **Equity Grant**

Upon joining the Company, you will be granted **130,000** options of Idera Common Stock at an exercise price which is equal to the fair market value on the date of hire. This grant is governed by Idera's Stock Incentive Plan and are granted at the discretion of the Compensation Committee of the Board of Directors.

#### **Waiver and Amendment**

No amendment to this offer shall be valid unless in writing and signed by you and the Head of Human Resources on behalf of the Company.

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**Employment at Will**

While we both fully intend to begin our relationship on a positive note, it is essential to understand our employment arrangement. The Company is an “at will” employer, which means that either of us can terminate our employment arrangement at any time and for any reason or no reason.

For purposes of federal immigration law, you will be required to provide the company with documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to the Company within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

Your employment is fully contingent upon a satisfactory background check and your execution and ongoing compliance with the attached Idera Pharmaceuticals’ Non-Disclosure Agreement, Code of Business Conduct and Ethics Agreement and our Insider Trading and Public Disclosure Policies. If the foregoing is satisfactory, please indicate your agreement by signing and returning to us the enclosed copy of this letter, together with a signed copy of the Non-Disclosure Agreement and a signed Acknowledgement and Understanding form of the Code of Business Conduct and Ethics agreement.

Please carefully review the terms and conditions of this offer as outlined in this letter. Feel free to contact Christina Amendola at 484-348-1665 if there is anything further we can do to assist you.

Please confirm your acceptance of this offer by signing the attached copy of this letter; including specifying your actual start date. If we do not receive these executed documents by the end of the business day on 6/28/2019, the offer set forth in this letter shall terminate.

Congratulations Elizabeth! This position is critical to the continued success and growth of Idera. We are excited to welcome you to Idera and look forward to having you join the team.

Sincerely,

/S/ JILL CONWELL

\_\_\_\_\_  
Jill Conwell  
Head of Human Resources

Agreed and Accepted,

/S/ ELIZABETH TARKA

\_\_\_\_\_  
Elizabeth Tarka

Date: June 26, 2019

\_\_\_\_\_  
Start Date: July 22, 2019

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**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: August 8, 2019

/s/ VINCENT J. MILANO

Vincent J. Milano  
Chief Executive Officer

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**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: August 8, 2019

/s/ JOHN J. KIRBY

John J. Kirby

Chief Financial Officer

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C.  
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 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: August 8, 2019

/s/ VINCENT J. MILANO

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Vincent J. Milano

Chief Executive Officer

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C.  
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 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: August 8, 2019

/s/ JOHN J. KIRBY

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John J. Kirby

Chief Financial Officer

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