

IDERA PHARMACEUTICALS, INC.

Form 10-Q

November 06, 2018

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

FORM 10-Q

---

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

For the quarterly period ended September 30, 2018

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)

---

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
505 Eagleview Blvd., Suite 212 Exton, Pennsylvania	19341
(Address of principal executive offices)	(Zip code)

(484) 348-1600

(Registrant's telephone number, including area code)

---

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

Indicate by check mark whether the registrant has submitted electronically 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	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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	27,181,436
Class	Outstanding as of October 31, 2018



Table of Contents

IDERA PHARMACEUTICALS, INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
<u>PART I — FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Balance Sheets as of September 30, 2018 and December 31, 2017</u>	1
<u>Condensed Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017</u>	2
<u>Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017</u>	3
<u>Condensed Statement of Stockholders' Equity for the Nine Months Ended September 30, 2018</u>	4
<u>Notes to Condensed Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	24
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	39
Item 4. <u>Controls and Procedures</u>	39
<u>PART II — OTHER INFORMATION</u>	
Item 1A. <u>Risk Factors</u>	40
Item 6. <u>Exhibits</u>	41
<u>Signatures</u>	42

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

---

Table of Contents

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,” “prudent,” “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part II, Item 1A “Risk Factors” in this Quarterly Report on Form 10-Q and Quarterly Reports on Form 10-Q filed earlier in 2018, and under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the Securities and Exchange Commission, or the SEC, on March 7, 2018. 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.

Table of Contents

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements.

## IDERA PHARMACEUTICALS, INC.

## CONDENSED BALANCE SHEETS

(In thousands, except per share amounts)	September 30, 2018 (unaudited)	December 31, 2017*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 82,462	\$ 112,629
Prepaid expenses and other current assets	2,518	3,992
Total current assets	84,980	116,621
Property and equipment, net	241	1,472
Other assets	9	324
Total assets	\$ 85,230	\$ 118,417
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,036	\$ 1,334
Accrued expenses	9,171	8,000
Note payable	—	209
Deferred revenue	94	566
Total current liabilities	10,301	10,109
Other liabilities	63	613
Total liabilities	10,364	10,722
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 — 27,179 and 24,453 shares at September 30, 2018 and	27	24

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

December 31, 2017, respectively		
Additional paid-in capital	727,064	712,165
Accumulated deficit	(652,225)	(604,494)
Total stockholders' equity	74,866	107,695
Total liabilities and stockholders' equity	\$ 85,230	\$ 118,417

---

\* The condensed balance sheet at December 31, 2017 has been derived from the audited financial statements at that date.

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

1

---

Table of Contents

## IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Alliance revenue	\$ 145	\$ 164	\$ 563	\$ 729
Operating expenses:				
Research and development	8,860	10,912	32,912	40,288
General and administrative	3,984	3,919	11,849	11,888
Merger-related costs, net	(3,836)	—	1,245	—
Restructuring costs	3,017	—	3,017	—
Total operating expenses	12,025	14,831	49,023	52,176
Loss from operations	(11,880)	(14,667)	(48,460)	(51,447)
Other income (expense):				
Interest income	277	159	759	456
Interest expense	—	(11)	(11)	(40)
Foreign currency exchange loss	(2)	(11)	(19)	(27)
Net loss	\$ (11,605)	\$ (14,530)	\$ (47,731)	\$ (51,058)
Net loss per share applicable to common stockholders - basic and diluted (Note 12)	\$ (0.43)	\$ (0.78)	\$ (1.81)	\$ (2.73)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	27,175	18,704	26,404	18,673
Comprehensive loss:				
Net loss	\$ (11,605)	\$ (14,530)	\$ (47,731)	\$ (51,058)
Other comprehensive income (loss):				
Unrealized (loss) gain on available-for-sale securities	—	(1)	—	17
Total other comprehensive (loss) income	—	(1)	—	17
Comprehensive loss	\$ (11,605)	\$ (14,531)	\$ (47,731)	\$ (51,041)

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



Table of Contents

IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)	Nine Months Ended September 30,	
	2018	2017
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (47,731)	\$ (51,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,454	9,165
Issuance of common stock for services rendered	77	119
Accretion of discounts and premiums on investments	—	94
Depreciation and amortization expense	395	559
Loss on disposal or impairment of property and equipment	497	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,881	(1,639)
Accounts payable, accrued expenses, and other liabilities	455	(393)
Deferred revenue	(472)	(606)
Net cash used in operating activities	(40,444)	(43,759)
<b>Cash Flows from Investing Activities:</b>		
Proceeds from maturity of available-for-sale securities	—	26,870
Proceeds from the sale of property and equipment	193	—
Purchases of property and equipment	(71)	(100)
Net cash provided by investing activities	122	26,770
<b>Cash Flows from Financing Activities:</b>		
Proceeds from employee stock purchases	205	184
Proceeds from exercise of common stock options and warrants	10,166	304
Payments on note payable	(209)	(216)
Payments on capital leases	(7)	(9)
Net cash provided by financing activities	10,155	263
Net decrease in cash, cash equivalents and restricted cash	(30,167)	(16,726)
Cash, cash equivalents and restricted cash, beginning of period	112,940	80,978
Cash, cash equivalents and restricted cash, end of period	\$ 82,773	\$ 64,252

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



Table of Contents

IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except per share amounts)	Common Stock Number of Shares	\$0.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2017	24,453	\$ 24	\$ 712,165	\$ (604,494)	\$ 107,695
Issuance of common stock under employee stock purchase plan	18	—	205	—	205
Issuance of common stock upon exercise of common stock options and warrants	2,702	3	10,163	—	10,166
Issuance of common stock for services rendered	6	—	77	—	77
Stock-based compensation	—	—	4,454	—	4,454
Net loss	—	—	—	(47,731)	(47,731)
Balance, September 30, 2018	27,179	\$ 27	\$ 727,064	\$ (652,225)	\$ 74,866

The accompanying notes are an integral part of these financial statements

Table of Contents

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2018

(UNAUDITED)

Note 1. Business and Organization

Business Overview

Idera Pharmaceuticals, Inc. (“Idera” or the “Company”), a Delaware corporation, is a clinical-stage biopharmaceutical company currently focused on the development, and ultimately the commercialization, of therapeutic drug candidates, including our Toll-like receptor (“TLR”) agonist, tilsotolimod (IMO-2125), for oncology. The Company’s business strategy is 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 believes it can develop and commercialize these targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

Agreement and Plan of Merger

On January 21, 2018, the Company, BioCryst Pharmaceuticals, Inc., a Delaware corporation (“BioCryst”), Nautilus Holdco, Inc., a Delaware corporation and a direct, wholly owned subsidiary of BioCryst (“Holdco”), Island Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, and Boat Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, entered into an Agreement and Plan of Merger (the “Merger Agreement”). The board of directors of each of Idera and BioCryst unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals were received. However, the proposed merger was subject to approval by the stockholders of Idera and BioCryst, and satisfaction of other customary closing conditions, as specified in the Merger Agreement. At a special meeting of BioCryst stockholders held on July 10, 2018, BioCryst’s stockholders voted against the adoption of the Merger Agreement. Following such vote and in accordance with the terms of the Merger Agreement, BioCryst terminated the Merger Agreement. In accordance with the Merger Agreement, BioCryst paid the Company a fixed expense reimbursement amount of \$6 million in July 2018 in connection with the termination of the Merger Agreement. The fixed expense

reimbursement amount is included in “Merger-related costs, net” in the accompanying condensed statements of operations.

### Liquidity and Financial Condition

As of September 30, 2018, the Company had an accumulated deficit of \$652.2 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 its current operating plan, that its existing cash and cash equivalents will enable the Company to fund its operations into the first quarter of 2020. The Company has and plans to continue to evaluate available alternatives to extend its operations beyond the first quarter of 2020.

Table of Contents

Note 1. Business and Organization (Continued)

Reverse Stock Split

As further described in Note 6, 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 condensed 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 nine months ended September 30, 2018 are not necessarily indicative of results that may be expected for the year ending December 31, 2018. 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, 2017 ("2017 Form 10-K"), which was filed with the SEC on March 7, 2018.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be "cash equivalents." Cash and cash equivalents at September 30, 2018 and December 31, 2017 consisted of cash and money market funds.

Restricted Cash

As part of the Company's lease arrangement for its office and laboratory facility in Cambridge, Massachusetts, the Company is required to restrict cash held in a certificate of deposit securing a line of credit for the lessor. As of September 30, 2018 and December 31, 2017, the restricted cash amounted to \$0.3 million and is recorded in "Prepaid expenses and other assets" as of September 30, 2018 and "Other assets" as of December 31, 2017 in the accompanying condensed balance sheets. In July 2018, the Company terminated the lease agreement, effective September 30, 2018, and will no longer be required to restrict cash for this purpose upon payment of the related \$0.2 million lease termination fee which is included in "Restructuring costs" in the accompanying condensed statements of operations. The lease was terminated in connection with restructuring activities which are more fully described in Note 9.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statements of cash flows:

(In thousands)	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 82,462	\$ 112,629
Restricted cash	311	311
Cash, cash equivalents and restricted cash	\$ 82,773	\$ 112,940

Table of Contents

Note 2. Summary of Significant Accounting Policies (Continued)

Financial Instruments

The fair value of the Company's financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 3. The Company is required to disclose the estimated fair values of its financial instruments. As of September 30, 2018, the Company's financial instruments consisted of cash, cash equivalents, and accounts receivable. As of December 31, 2017, the Company's financial instruments consisted of cash, cash equivalents, accounts receivable and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of September 30, 2018 and December 31, 2017. As of September 30, 2018, the Company did not have any derivatives, hedging instruments or other similar financial instruments.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, the Company recognizes the cumulative effect of initially adopting ASC Topic 606, if any, as an adjustment to the opening balance of retained earnings. Additionally, under this method of adoption, the Company applies the guidance to all incomplete contracts in scope as of the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 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. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, it performs the following five steps:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that



is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Table of Contents

Note 2. Summary of Significant Accounting Policies (Continued)

Alliance Revenues

The Company's revenues have primarily been generated through collaborative research, development and/or commercialization agreements. 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 statements of operations.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps:

- (i) identification of the promised goods or services in the contract;
- (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- (iii) measurement of the transaction price, including the constraint on variable consideration;
- (iv) allocation of the transaction price to the performance obligations; and
- (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

See Note 8, "Collaboration and License Agreements" for additional details regarding the Company's collaboration arrangements.

As part of the accounting for these arrangements, the Company allocates the transaction price to each performance obligation on a relative stand-alone selling price basis. The stand-alone selling price may be, but is not presumed to be, the contract price. In determining the allocation, the Company maximizes the use of observable inputs. When the stand-alone selling price of a good or service is not directly observable, the Company estimates the stand-alone selling price for each performance obligation using assumptions that require judgment. Acceptable estimation methods include, but are not limited to: (i) the adjusted market assessment approach, (ii) the expected cost plus margin approach, and (iii) the residual approach (when the stand-alone selling price is not directly observable and is either highly variable or uncertain). In order for the residual approach to be used, the Company must demonstrate that (a) there are observable stand-alone selling prices for one or more of the performance obligations and (b) one of the two criteria in ASC 606-10-32-34(c)(1) and (2) is met. The residual approach cannot be used if it would result in a stand-alone selling price of zero for a performance obligation as a performance obligation, by definition, has value on a stand-alone basis.

An option in a contract to acquire additional goods or services gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that the Company considers in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, the Company recognizes revenue when those future goods or services are transferred or when the options expire.

Table of Contents

Note 2. Summary of Significant Accounting Policies (Continued)

The Company's revenue arrangements may include the following:

**Up-front License Fees:** If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

**Milestone Payments:** At the inception of an agreement that includes research and development milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect Alliance revenues and earnings in the period of adjustment.

**Research and Development Activities:** If the Company is entitled to reimbursement from its collaborators for specified research and development activities or the reimbursement of costs associated with patent maintenance, the Company determines whether such funding would result in Alliance revenues or an offset to research and development expenses. Reimbursement of patent maintenance costs are recognized during the period in which the related expenses are incurred as Alliance revenues in the Company's statements of operations.

**Royalties:** If the Company is entitled to receive sales-based royalties from its collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its collaboration and license arrangements.

Manufacturing Supply and Research Services: Arrangements that include a promise for future supply of drug substance, drug product or research services at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in Alliance revenues when the licensee obtains control of the goods, which is upon delivery, or as the services are performed.

The Company receives payments from its licensees based on schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Table of Contents

Note 2. Summary of Significant Accounting Policies (Continued)

Merger-related Costs, net

Merger-related costs, net includes amounts related to the transactions contemplated under the Merger Agreement, which was terminated in July 2018, as more fully described in Note 1. The line item includes charges incurred for transaction and integration-related professional fees, employee retention costs, and other incremental costs directly related to the potential merger. These costs were offset by the \$6 million termination fee, which was received by the Company in July of 2018.

Restructuring Costs

Restructuring charges are primarily comprised of severance costs related to workforce reductions, contract termination and wind-down costs and asset impairments. In accordance with ASC 420, Exit or Disposal Cost Obligations, the Company recognizes restructuring charges when the liability has been incurred, except for one-time employee termination benefits that are incurred over time. Generally, one-time employee termination benefits (i.e. severance costs) are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments. Other costs will be recorded as incurred. Asset impairment charges have been, and will be, recognized when management has concluded that the assets have been impaired in accordance with ASC 360-10-35, Impairment or Disposal of Long-Lived Assets, or other applicable authoritative guidance. See Note 9 for additional details.

Income Taxes

In accordance with ASC 270, Interim Reporting, and ASC 740, Income Taxes, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2018 and 2017, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either September 30, 2018 or December 31, 2017 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of September 30, 2018 and December 31, 2017, the Company had no uncertain tax positions.

In December 2017, the Tax Cuts and Jobs Act (“TCJA”) was signed into law. Among other things, the TCJA permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective

for tax years including or commencing January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, GAAP requires companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. This revaluation resulted in a provision of \$27.6 million to income tax expense and a corresponding reduction in the valuation allowance in the fourth quarter of 2017. As a result, there was no impact to the Company's statement of operations and comprehensive loss as a result of reduction in tax rates. The Company's preliminary estimate of the TCJA and the remeasurement of its deferred tax assets and liabilities is subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the TCJA, changes to certain estimates and the filing of the Company's tax returns. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the TCJA may require further adjustments and changes in the Company's estimates. The final determination of the TCJA and the remeasurement of the Company's deferred assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the TCJA.

Table of Contents

Note 2. Summary of Significant Accounting Policies (Continued)

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was subsequently amended by several other ASU’s related to Topic 606 to, among other things, defer the effective date and clarify various aspects of the new revenue guidance including principal versus agent considerations, identifying performance obligations, and licensing, and include other improvements and practical expedients (as amended, “ASU 2014-09”). The Company adopted ASU 2014-09 in the first quarter of 2018 using the modified retrospective transition method. See “Revenue Recognition” above. To date, the Company has derived substantially all of its revenues from a limited number of license and collaboration agreements. The consideration the Company is eligible to receive under these agreements includes upfront payments, research and development funding, contingent revenues in the form of commercial and development milestones and option payments and royalties. Each of the Company’s license and collaboration agreements has unique terms and was evaluated separately under Topic 606. With respect to its license and collaboration agreements with Vivelix Pharmaceuticals, Ltd. (“Vivelix”) and GlaxoSmithKline Intellectual Property Development Limited (“GSK”), there was no material impact to Alliance revenues for any of the years presented upon adoption of Topic 606. Additionally, there were no revisions to any balance sheet components of Alliance revenues such as accounts receivable and deferred revenues or beginning retained earnings as a result of the adoption of the modified retrospective method. The primary impact on the Company’s financial statements was that revised or additional disclosures were made with respect to revenues and cash flows arising from contracts with customers, which are included in Notes 7 and 8.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities (“ASU 2016-01”). The amendments in ASU 2016-01 address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The Company adopted ASU 2016-01 in the first quarter of 2018. The adoption of this new standard did not have a material impact on the Company’s financial position or results of operations.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230) — Restricted Cash (“ASU 2016-18”). The amendments in ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash and restricted cash equivalents. Accordingly, amounts generally described as restricted cash or restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 in the first quarter of 2018, and the guidance has been retrospectively applied to all periods presented. The total of the Company’s cash, cash equivalents and restricted cash is described earlier in this Note 2.



Recently Issued (Not Yet 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 primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, ASU 2016-02 will require both types of leases to be recognized on the balance sheet. This guidance is applicable to the Company's fiscal year beginning on January 1, 2019. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements and related disclosures. The Company expects that the majority of its operating lease commitments will be subject to this guidance and anticipates the recognition of additional assets and corresponding liabilities related to the adoption of the standard.

Table of Contents

## Note 3. Fair Value Measurements

## Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC 820, Fair Value Measurement, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

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

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

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the nine months ended September 30, 2018.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2018 and December 31, 2017 categorized by the level of inputs used in the valuation of each asset and liability:

(In thousands)	September 30, 2018			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	\$ 17,746	\$ 17,746	\$ —	\$ —
Total assets	\$ 17,746	\$ 17,746	\$ —	\$ —
Total liabilities	\$ —	\$ —	\$ —	\$ —

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

December 31, 2017

(In thousands)	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	\$ 66,183	\$ 66,183	\$ —	\$ —
Total assets	\$ 66,183	\$ 66,183	\$ —	\$ —
Total liabilities	\$ —	\$ —	\$ —	\$ —

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

Table of Contents

## Note 4. Property and Equipment

At September 30, 2018 and December 31, 2017, property and equipment, net, consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Leasehold improvements	\$ 104	\$ 671
Laboratory equipment and other	764	5,261
Total property and equipment, at cost	868	5,932
Less: Accumulated depreciation and amortization	627	4,460
Property and equipment, net	\$ 241	\$ 1,472

Depreciation and amortization expense on property and equipment was approximately \$0.1 million and \$0.2 million for the three months ended September 30, 2018 and 2017, respectively, and approximately \$0.4 million and \$0.6 million for the nine months ended September 30, 2018 and 2017, respectively. There was less than \$0.1 million in non-cash property additions during each of the nine months ended September 30, 2018 and 2017.

During the three months ended September 30, 2018, the Company recorded asset impairments related to its property equipment in the amount of \$0.5 million in connection with restructuring activities more fully described in Note 9.

## Note 5. Accrued Expenses

At September 30, 2018 and December 31, 2017, accrued expenses consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Payroll and related costs	\$ 1,705	\$ 3,108
Clinical and nonclinical trial expenses	4,859	3,495
Professional and consulting fees	497	1,317
Restructuring expenses	1,905	—
Other	205	80
Total accrued expenses	\$ 9,171	\$ 8,000

Note 6. Stockholders' Equity

On June 20, 2018, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation, as amended, to effect a reverse stock split of the Company's outstanding shares of common stock at a ratio within a range from 1-for-4 to 1-for-8 and set the number of authorized shares of the Company's common stock at a number determined by calculating the product of 280,000,000 multiplied by two times (2x) the reverse stock split ratio. On July 27, 2018, the Company implemented a 1-for-8 reverse split of its issued and outstanding shares of common stock (the "Reverse Split"), and set the number of its authorized shares of common stock to 70,000,000. The Reverse Split became effective on July 27, 2018 at 5:00 p.m., Eastern Time, and the Company's common stock began trading on the Nasdaq Capital Market on a Reverse Split-adjusted basis at the opening of trading on July 30, 2018. As of a result of the Reverse Split, every eight shares of the Company's issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Split resulted in any of the Company's stockholders owning a fractional share, which was settled in cash. In connection with the Reverse Split, there was no change in the nominal par value per share of \$0.001. The Reverse Split did not change the number of authorized shares or par value of the Company's preferred stock.

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 warrants as equity instruments, derivative liabilities, or liabilities, depending on the specific terms of the warrant. As of September 30, 2018 and December 31, 2017, all of the Company's outstanding warrants were equity-classified.

Table of Contents

## Note 6. Stockholders' Equity (Continued)

The following table summarizes outstanding warrants to purchase shares of the Company's common stock as of September 30, 2018 and December 31, 2017:

Description	Number of Shares		Weighted-Average Exercise Price	Expiration Date
	September 30, 2018	December 31, 2017		
Issued in May 2013 financing	—	2,700,791	\$ 3.76	May 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	5,469,673		

The table below is a summary of the Company's warrant activity for the nine months ended September 30, 2018:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2017	5,469,673	\$ 1.90
Issued	—	—
Exercised (1)	(2,700,791)	3.76
Expired	—	—
Outstanding at September 30, 2018	2,768,882	\$ 0.08

(1) During the nine months ended September 30, 2018, a related party exercised certain of these warrants as more fully described in Note 11.

## Note 7. Alliance Revenue

Alliance revenue for the nine months ended September 30, 2018 and 2017 represents revenue from contracts with customers accounted for in accordance with ASC Topic 606, which the Company adopted in the first quarter of 2018, as more fully described in Note 2. There was no impact to Alliance revenue previously recognized by the Company as a result of the adoption of ASC Topic 606.

For the three and nine months ended September 30, 2018 and 2017, Alliance revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
GSK collaboration (1)	\$ 141	\$ 141	\$ 424	\$ 698
Vivelix collaboration (2)	—	14	56	14
Other (3)	4	9	83	17
Total Alliance revenue	\$ 145	\$ 164	\$ 563	\$ 729

(1) For all periods presented, revenue recognized primarily relates to the amortization of the deferred up-front payment received at inception of the Company's collaboration and license agreement with GSK Agreement, as more fully described in Note 8. Revenue recognized for the nine months ended September 30, 2017 also includes an additional \$0.1 million related to additional research services provided in connection with the collaboration and license agreement with GSK.

(2) For the nine months ended September 30, 2018, revenue recognized relates to services provided under the research program provided for under the Company's exclusive license and collaboration agreement with Vivelix, as more fully described in Note 8.

Table of Contents

## Note 7. Alliance Revenue (Continued)

- (3) 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.

The following table presents changes in the Company's contract assets and liabilities during the nine months ended September 30, 2018 and 2017:

(In thousands)	Nine months ended September 30, 2018			
	Beginning	Additions	Deductions	Ending
Contract assets	\$ —	\$ —	\$ —	\$ —
Contract liabilities:				
Deferred revenue	\$ 566	\$ —	\$ (472)	\$ 94

(In thousands)	Nine months ended September 30, 2017			
	Beginning	Additions	Deductions	Ending
Contract assets	\$ —	\$ —	\$ —	\$ —
Contract liabilities:				
Deferred revenue	\$ 1,263	\$ —	\$ (606)	\$ 657

During the nine months ended September 30, 2018 and 2017, the Company recognized Alliance revenues of \$0.5 million and \$0.6 million, respectively, as a result of changes in the contract liability balances associated with its contracts with customers. Revenue recognized during each of the nine months ended September 30, 2018 and 2017 were included in the contract liability at the beginning of each respective period. As of September 30, 2018, contract liabilities consisted of deferred revenue related entirely to the Company's collaboration and license agreement with GSK and were included in Deferred revenue in the accompanying condensed balance sheet.

See Note 8 for additional details regarding the Company's collaboration arrangements.

## Note 8. Collaboration and License Agreements

## 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, an antagonist of TLR7, TLR8, and TLR9, for non-malignant gastrointestinal disorders (the “GI Field” or “Field” as defined in the Vivelix Agreement), 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 is 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.

Pursuant to the Vivelix Agreement, Vivelix could request that the Company create, characterize and perform research on back-up compounds (the “Research Program”). Such activity was to be mutually agreed upon and moderated by the Joint Research Committee (“JRC”) established under the Vivelix Agreement. The research period commenced with the execution of the agreement and may last for up to three years. As a result of the Company’s decision to wind-down its discovery operations as described in Note 9, in July 2018, the Company informed Vivelix that no additional research projects will be undertaken by the Company.

Table of Contents

Note 8. Collaboration and License Agreements (Continued)

Vivelix has certain rights under the agreement whereby it may exercise (i) the right of first refusal to develop and commercialize products in any available field (“Right of First Refusal”), (ii) the right of first negotiation to obtain an exclusive license for any compound controlled by Idera that has activity in the field of inflammatory bowel disease (“Right of First Negotiation”) and (iii) the right to request an expanded Field beyond the GI Field (“Expanded Field Option”).

Under the terms of the Vivelix Agreement, the Company received an upfront, non-refundable fee of \$15 million. In addition, the Company will be eligible for future IMO-9200 related development, regulatory and sales milestone payments totaling up to \$140 million, including development and regulatory milestones totaling up to \$65 million and sales milestones totaling up to \$75 million, and escalating royalties ranging from the mid single-digits to low double-digits of global net sales, which percentages are subject to reduction under agreed upon circumstances. As it relates to back-up compounds, including certain compounds controlled by the Company as of the effective date of the Vivelix Agreement and/or those created at Vivelix’s request under the Research Program, the Company will be eligible for related designation payments and development, regulatory and sales milestone payments totaling up to \$52.5 million, including development and regulatory milestones totaling up to \$35 million and sales milestones totaling up to \$17.5 million and escalating royalties ranging from the mid single-digits to low double-digits of global net sales, which percentages are subject to reduction under agreed upon circumstances. Under the terms of the agreement, the Company has performed research services, as requested by Vivelix and at Vivelix’s expense. To date, Vivelix has not designated any back-up compounds subject to the Research Program, such right which expires on the third anniversary of the end of the Research Period.

At the effective date of the Vivelix Agreement, Baker Bros. Advisors LP and certain of its affiliated funds (collectively, “Baker Brothers”) beneficially owned approximately 7.0% of the Company’s outstanding common stock and affiliates of Baker Brothers constituted two of the seven directors on the board of directors of the Company. Baker Brothers also owned a controlling financial interest of Vivelix at the effective date of the Vivelix Agreement and as of December 31, 2017, and affiliates of Baker Brothers constituted two of the four directors on the board of directors of Vivelix. However, the boards of the Company and Vivelix share no common board members. See Note 11 for information on related parties of the Company as of September 30, 2018.

Pursuant to the Vivelix Agreement, Vivelix conducted two clinical studies on IMO-9200 in the field of inflammatory bowel diseases. While there were no apparent safety signals identified in either study, there was no apparent benefit associated with IMO-9200 at the doses studied compared with placebo. As a result, Vivelix has decided to terminate ongoing development activities related to IMO-9200. However, a final decision by Vivelix on whether to continue working on IMO-9200 or terminate the Vivelix Agreement has not been made as of November 4, 2018.

Accounting Analysis under ASC 606

In evaluating the Vivelix Agreement in accordance with ASC Topic 606, the Company concluded that the contract counterparty, Vivelix, is a customer. The Company identified the following performance obligations as of the inception of agreement: (i) a research and commercialization license for IMO-9200 and back-up compounds to IMO-9200 (the “IMO-9200 License”) and (ii) drug materials transferred, which were both deemed to be distinct. The Company determined that participation in the JRC was immaterial in the context of the contract. Consistent with the guidance under ASC 606-10-25-16A, the Company disregarded immaterial promised goods and services when determining performance obligations.

The Company concluded that the IMO-9200 License was distinct within the context of the contract (i.e. separately identifiable) because it has stand-alone value from other promised goods and services as Vivelix could benefit from the IMO-9200 License on a stand-alone basis and sell the compound in the market without any additional involvement or participation from Idera. Additionally, Idera has no further obligations related to the IMO-9200 License. In the event that Vivelix does not make a designated compound payment, the license to back-up compounds reverts back to Idera at the end of the research term at no cost or payment by either party. The services provided under the Research Program relate to the back-up compounds and Vivelix would be able to conduct research and development activities with external third parties, as IMO-9200 is at an advanced enough stage where Idera’s expertise would not be required. Accordingly, the IMO-9200 License is a separate performance obligation.

Table of Contents

Note 8. Collaboration and License Agreements (Continued)

The Company concluded that the drug materials transferred identified at the inception are also distinct within the context of the contract (i.e. separately identifiable) because they have standalone value from other promised goods and services based on their nature. Accordingly, the drug materials transferred are a separate performance obligation.

Allocable arrangement consideration at inception of the Vivelix Agreement was comprised of the up-front payment of \$15 million. The \$15 million was allocated based on the relative stand-alone selling prices of each performance obligation. Allocated revenue associated with the IMO-9200 License was recognized at the inception of the Vivelix Agreement in the fourth quarter of 2016 as Vivelix was granted an exclusive, perpetual license to develop and commercialize IMO-9200 and certain back-up compounds to IMO-9200, subject to certain designation milestone and royalty payments, and the performance obligations of Idera under the agreement were extinguished at that point. Allocable revenue associated with drug materials transferred shortly after the inception of the agreement was recognized upon delivery, also in the fourth quarter of 2016.

At inception of the contract, the transaction price included only the \$15.0 million up-front consideration received. None of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Similarly, other variable consideration related to services that may be provided under the Research Program and back-up compound designation payments were fully constrained. Any consideration related to sales-based royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Vivelix and therefore have also been excluded from the transaction price. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Revenue associated with goods and services provided to Vivelix under the Research Program have been immaterial to date and such revenue is recognized as the related performance obligations under each research project are satisfied. See Note 7 for details on revenue recognized in connection with the Company's collaboration with Vivelix for the three and nine months ended September 30, 2018 and 2017.

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"). The initial collaboration term is currently

anticipated to last between two and four years. In connection with the GSK Agreement, GSK identified an initial target for the Company to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan, which is estimated to take 36 months to complete. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. If GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

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

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

Table of Contents

Note 8. Collaboration and License Agreements (Continued)

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 was eligible to receive a total of up to approximately \$100 million in license, research, clinical development and commercialization milestone payments, of which \$9 million of these milestone payments would have been payable by GSK upon the identification of the additional targets, the completion of current and future research plans and the designation of development candidates and \$89 million would have been payable by GSK upon the achievement of clinical milestones and commercial milestones. As a result of GSK not selecting additional targets during the two-year option period, the Company is now only eligible to receive a total of up to approximately \$20 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 upon commercialization at varying rates of up to 5% on annual net sales, as defined in the GSK Agreement.

Accounting Analysis under ASC 606

In evaluating the GSK Agreement in accordance with ASC Topic 606, the Company concluded that the contract counterparty, GSK, is a customer. The Company identified the following performance obligations as of the inception of the agreement: (i) research services, combined with the license for Idera's proprietary technology related to the initial target (collectively, the "Collaboration License and Research Services") and (ii) daily options to extend the Collaboration License and Research Services. The Company determined that participation in the JSC and materials transferred were deemed immaterial in the context of the contract. Consistent with the guidance under ASC 606-10-25-16A, the Company disregarded immaterial promised goods and services when determining performance obligations.

The Company concluded that the research services related to the initial target and collaboration license to the Company's proprietary technology related to the initial target were not capable of being distinct as the collaboration license related to the initial target is highly interdependent upon the research services to be provided related to the initial target. As it relates to the assessment of standalone value, the Company determined that GSK cannot fully exploit the value of the collaboration license without receipt of the research services from the Company. The research services involve unique skills and specialized expertise, particularly as it relates to the Company's proprietary technology, which is not available in the marketplace. Accordingly, GSK must obtain the research services from the Company which significantly limits the ability for GSK to utilize the collaboration license for its intended purpose on a standalone basis. Similarly, the Company concluded that the daily option to extend the collaboration license and the daily option to extend the research services were also highly interdependent as the license has no value to GSK without the accompanying research services using the Company's proprietary technology. Accordingly, the Collaboration License and Research Services were determined to represent a single performance obligation and the daily options to extend the Collaboration License and Research Services were determined to represent a single performance obligation. Factors considered in this determination included, among other things, the capabilities of the

collaborator, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement.

Allocable arrangement consideration at inception of the GSK Agreement consisted of the up-front payment of \$2.5 million. The \$2.5 million was allocated based on the relative stand-alone selling prices of each performance obligation, calculated based on the expected period of time over which the initial license term will be in place, as well as the expected period of time over which the optional renewals occur. The Company will recognize the consideration allocated to the Collaboration License and Research Services over time as GSK is receiving the benefit of the Company's expertise and know-how on an on-going basis as the research progresses towards the goal of the development candidate designation for the initial target. The exercise of the daily options to extend the Collaboration License and Research Services are treated as a continuation of the contract and allocated consideration is recognized point-in-time upon commencement of each daily exercise.

Table of Contents

## Note 8. Collaboration and License Agreements (Continued)

At inception of the contract, the transaction price included only the \$2.5 million up-front consideration received. None of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The up-front payment of \$2.5 million was recorded as deferred revenue in the Company's balance sheet upon receipt and is currently being recognized as revenue on a straight-line basis over the estimated 36-month research plan period, which approximates the timing in which performance obligations are satisfied. See Note 7 for details on revenue recognized in connection with the Company's collaboration with GSK for each of the three and nine months ended September 30, 2018 and 2017.

## Note 9. 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 are being eliminated, primarily in the area of discovery, representing approximately 40% of the Company's employees. Of the 18 positions being eliminated, 15 were effective July 31, 2018 with the remaining expected to be eliminated by December 31, 2018.

Restructuring-related charges for both the three and nine months ended September 30, 2018 totaled \$3.0 million and were comprised of (i) one-time termination costs in connection with the reduction in workforce, including severance, benefits and related costs, of approximately \$2.4 million; (ii) contract termination costs of approximately \$0.2 million in connection with the early lease termination for the Cambridge facility, as further discussed below; (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.

(\$ in thousands)

Employee Severance	Contract Termination	Asset Impairments	Total
-----------------------	-------------------------	----------------------	-------



	and Benefits	Costs		
Accrued restructuring balance as of December 31, 2017	\$ —	\$ —	\$ —	\$ —
Charges incurred (1)	2,436	225	694	3,355
Cash payments	(625)	(61)	—	(686)
Non-cash settlements	(24)	—	(694)	(718)
Accrued restructuring balance as of September 30, 2018	\$ 1,787	\$ 164	\$ —	\$ 1,951

(1) Excludes \$0.4 million gain due to the write-off of the remaining deferred rent liability associated with the termination of the Cambridge, Massachusetts facility lease.

As of September 30, 2018, the short-term portion of the accrued restructuring balance, or \$1.9 million, is included in “Accrued expenses” in the accompanying condensed balance sheets. See Note 9. The long-term portion of less than \$0.1 million is included within “Other liabilities” in the accompanying condensed balance sheets.

Table of Contents

Note 9. Restructuring Costs (Continued)

In connection with the closing of its Cambridge facility, on July 27, 2018, the Company entered into a termination agreement with the landlord terminating the lease agreement, dated October 31, 2006, as amended, between the Company and the landlord effective September 30, 2018. The Company leased its facility at 167 Sidney Street in Cambridge under the lease agreement. Under the terms of the termination agreement, the Company has agreed to pay an early termination fee of \$0.2 million. The Company recorded a charge for the \$0.2 million early termination fee and a non-cash gain of \$0.4 million due to the write-off of the remaining deferred rent liability associated with the lease in the third quarter of 2018. The Company completed the consolidation of its operations to its Exton, Pennsylvania location in the third quarter of 2018.

Note 10. Stock-Based Compensation

Equity Compensation Plans

2013 Stock Incentive Plan

The Company's board of directors adopted the 2013 Stock Incentive Plan (as amended to date, the "2013 Plan"), which was approved by the Company's stockholders effective July 26, 2013. 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) 3,153,057 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 (the "2005 Plan") or the Company's 2008 Stock Incentive Plan (the "2008 Plan" and, together with the 2005 Plan, the "Existing Plans") 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 September 30, 2018, options to purchase a total of 2,418,332 shares of common stock were outstanding and up to 941,192 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 Existing Plans, since the Company's stockholders approved the 2013 Plan. As of September 30, 2018, options to purchase a total of 511,093 shares of common stock were outstanding under these earlier plans.

In addition, as of September 30, 2018, 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 Employee Stock Purchase Plan (the "2017 ESPP") which was approved by the Company's stockholders and became effective on June 7, 2017. The 2017 ESPP provides for the issuance of up to 62,500 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 September 30, 2018, 38,763 shares remained available for issuance under the 2017 ESPP.

Table of Contents

## Note 10. Stock-Based Compensation (Continued)

For the nine months ended September 30, 2018 and 2017, the Company issued 18,355 and 16,490 shares of common stock, respectively, under the 2017 ESPP and the Company's 1995 Employee Stock Purchase Plan and received proceeds of approximately \$0.2 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.

Total stock-based compensation expense attributable to stock-based payments made to employees and directors and employee stock purchases included in operating expenses in the Company's statements of operations for the three and nine months ended September 30, 2018 and 2017 was as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock-based compensation:				
Research and development				
Employee Stock Purchase Plans	\$ 11	\$ 26	\$ 62	\$ 68
Equity Incentive Plans	303	563	1,379	5,904
	\$ 314	\$ 589	\$ 1,441	\$ 5,972
General and administrative				
Employee Stock Purchase Plans	\$ 8	\$ 18	\$ 40	\$ 48
Equity Incentive Plans	981	1,016	2,949	3,145
	\$ 989	\$ 1,034	\$ 2,989	\$ 3,193
Restructuring costs				
Employee Stock Purchase Plans	\$ 24	\$ —	\$ 24	\$ —
	\$ 24	\$ —	\$ 24	\$ —
Total stock-based compensation expense	\$ 1,327	\$ 1,623	\$ 4,454	\$ 9,165

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

During the nine months ended September 30, 2018 and 2017, the weighted average fair market value of stock options granted was \$7.15 and \$8.08, respectively. The following weighted average assumptions apply to the options to purchase 1,091,474 and 520,812 shares of common stock granted to employees and directors during the nine months ended September 30, 2018 and 2017, respectively:

	Nine Months Ended September 30,	
	2018	2017
Average risk-free interest rate	2.5%	1.7%
Expected dividend yield	—	—
Expected lives (years)	3.8	4.0
Expected volatility	74.0%	86.5%
Weighted average exercise price (per share)	\$ 12.91	\$ 12.88

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

Table of Contents

## Note 10. Stock-Based Compensation (Continued)

## Stock Option Activity

The following table summarizes stock option activity for the nine months ended September 30, 2018:

(\$ in thousands, except per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	2,675,184	\$ 23.52	6.5	\$ 5,805
Granted	1,091,474	12.91		
Exercised	(858)	12.77		
Forfeited	(279,444)	18.16		
Expired	(163,181)	47.56		
Outstanding at September 30, 2018 (1)	3,323,175	\$ 19.31	6.7	\$ 1,249
Exercisable at September 30, 2018	1,958,773	\$ 22.96	5.0	\$ 714

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

The fair value of options that vested during the nine months ended September 30, 2018 was \$5.1 million. As of September 30, 2018, there was \$9.1 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.7 years.

## Note 11. Related Party Transactions

## Overview of Related Parties

Youssef El Zein, a member of the Company's Board until his resignation in October 2017, is a director and controlling stockholder of Pillar Invest Corporation ("Pillar Invest"), which is the general partner of Pillar Pharmaceuticals I, L.P. ("Pillar I"), Pillar Pharmaceuticals II, L.P. ("Pillar II"), Pillar Pharmaceuticals III, L.P. ("Pillar III"), Pillar Pharmaceuticals IV, L.P. ("Pillar IV") and Pillar Pharmaceuticals V, L.P. ("Pillar V") and a limited partner of Pillar I, Pillar II, Pillar III, Pillar IV and Pillar V. Entities affiliated with Pillar Invest and Participations Besancon ("Besancon"), an investment fund advised by Pillar Invest having no affiliation with Mr. El Zein, Pillar I, Pillar II, Pillar III, Pillar IV, Pillar V or Pillar Invest (collectively, the "Pillar Investment Entities"), owned approximately 9% of the Company's common stock

as of September 30, 2018.

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 18% of the Company's common stock as of September 30, 2018. Additionally, one of the Company's directors, Kelvin M. Neu, was an employee of Baker Bros. Advisors, LP as of September 30, 2018.

#### Pillar Investment Entities

During the nine months ended September 30, 2018, Besancon exercised warrants to purchase 150,000 shares of the Company's common stock at an exercise price of \$3.76 per share for a total exercise price of approximately \$0.6 million.

#### Baker Brothers

During the nine months ended September 30, 2018, Baker Brothers exercised warrants to purchase 2,539,541 shares of the Company's common stock at an exercise price of \$3.76 per share for a total exercise price of approximately \$9.5 million.

As of September 30, 2018, Baker Brothers held pre-funded warrants to purchase up to 2,768,882 shares of the Company's common stock at an exercise price of \$0.08 per share.

Table of Contents

Note 11. Related Party Transactions (Continued)

Board Fees Paid in Stock

Pursuant to the Company's director compensation program, in lieu of director board and committee fees incurred of \$0.1 million during each of the nine months ended September 30, 2018 and 2017, the Company issued 7,067 and 6,538 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 12. Net Loss per Common Share

Basic and diluted net loss per common share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock option awards, common stock warrants and convertible preferred stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the three and nine months ended September 30, 2018 and 2017, 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 that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect, were 6,093,983 and 9,124,279 as of September 30, 2018 and 2017, respectively, and consisted of stock options, preferred stock and warrants.

Note 13. 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.





## Table of Contents

### 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 2017, or our 2017 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 2017 Form 10-K.

#### Overview

We are a clinical-stage biopharmaceutical company currently focused on the development, and ultimately the commercialization, of therapeutic drug candidates, including our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. Our business strategy is 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. We believe we can develop and commercialize these targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we 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 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. We are also investigating the combination of intratumoral tilsotolimod in combination with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., Inc. for the treatment of anti-PD1 refractory metastatic melanoma and tilsotolimod for the treatment of various solid tumors.

#### Termination of Merger Agreement

On January 21, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with BioCryst Pharmaceuticals, Inc., or BioCryst, Nautilus Holdco, Inc., a direct, wholly owned subsidiary of BioCryst, or Holdco, Island Merger Sub, Inc., a direct, wholly owned subsidiary of Holdco, and Boat Merger Sub, Inc., a direct, wholly owned subsidiary of Holdco. The board of directors of each of Idera and BioCryst unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals were received. However, the proposed merger was subject to approval by the stockholders of Idera and BioCryst, and satisfaction of other customary closing conditions, as specified in the Merger Agreement.

At a special meeting of BioCryst stockholders held on July 10, 2018, BioCryst's stockholders voted against the adoption of the Merger Agreement. Following such vote and in accordance with the terms of the Merger Agreement, BioCryst terminated the Merger Agreement on July 10, 2018.

In accordance with the Merger Agreement, BioCryst paid us a fixed expense reimbursement amount of \$6 million in connection with the termination of the Merger Agreement.

Table of Contents

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, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab. We are also investigating the combination of intratumoral tilsotolimod and pembrolizumab for the treatment of anti-PD1 refractory metastatic melanoma and intratumoral tilsotolimod in various solid tumors. 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. 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.

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. These data have been presented at several scientific and medical conferences from 2014 through the second quarter of 2018. 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 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 large 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). Additionally, despite recent advances in therapy, such as immune checkpoint inhibitors, advanced metastatic melanoma continues to present significant morbidity and mortality.

We are currently developing tilsotolimod for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma. We believe, based on internally conducted commercial research, that in the United States, by 2025, approximately 20,000 people will have metastatic melanoma and over 50% will not have responded to first-line anti-PD1 therapy. 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.

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.

## Table of Contents

### 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 in the same patient population. 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 third quarter of 2018. We anticipate that more sites will be added, to bring the total number of participating sites for the trial to up to twelve. 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. We anticipate that the Phase 2 portion of the trial will include a total of up to 60 patients dosed at the 8 mg dose, including some patients from the Phase 1 dose escalation portion who meet the efficacy criteria for the Phase 2 population, and expect that enrollment in the Phase 2 portion will be completed by the end of 2018.

At the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018, 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 May 9, 2018, the data cut-off date for the presentation, a total of 26 patients had been dosed at the 8 mg dose level and 21 patients treated at the 8 mg dose level had at least one post-baseline disease assessment. Of these 21 patients, two had a complete response and six had a partial response under RECIST v.1.1 criteria, representing an overall response rate of 38%. One of the two patients who had a complete response has been continuing off active treatment for more than two years and has remained disease free. Additionally, seven other patients that were treated at the 8 mg dose level experienced stable disease, including two patients who had stable disease for at least 24 weeks, which is considered to represent meaningful clinical benefit. In the aggregate,

## Table of Contents

15 of the 21 patients achieved stable disease or better, representing a disease control rate of 71%. 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.

At the European Society for Medical Oncology Congress in October 2018, we presented further data from the data set presented at ASCO, with key findings demonstrating a clear systemic antitumor effect on distant uninjected tumors from the treatment of tilsotolimod in combination with ipilimumab as well as data demonstrating the contribution of tilsotolimod to overcome resistance to ipilimumab in patients with low HLA-ABC expression.

### 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 have completed enrollment of a total of six patients in the 8 mg and 16 mg dosing cohorts in the Phase 1 dose escalation portion of the pembrolizumab arm of the trial and are continuing to enroll patients in the 32 mg dosing cohort. One patient who was treated at the 16 mg dose has experienced an ongoing complete response by RECIST v1.1 criteria.

### 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, will have a sample size of approximately 300 patients and will be conducted at up to 110 sites worldwide. The primary endpoints of the trial are overall response rate by RECIST v1.1 and median overall survival (OS). Key secondary endpoints include overall response rate (ORR) by irRECIST, durable response rate, median time to response, median progression free survival (PFS) and patient reported outcomes using a validated scale.



We have held discussions with and plan to continue to engage with regulatory authorities regarding the paths to registration for tilsotolimod in combination with ipilimumab in anti-PD1 refractory metastatic melanoma patients, including potentially through an accelerated approval process based on an interim analysis of the Phase 3 trial with the final analysis providing the confirmatory data for full approval.

As discussed below under the heading “Collaborative Alliances,” in May 2018, we entered into a clinical trial collaboration and supply agreement with Bristol-Myers Squibb Company, or 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.

#### Phase 1b Trial of Intratumoral 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 monotherapy in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, tilsotolimod is 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 have completed enrollment in four dose-escalation cohorts of approximately eight patients per cohort at doses of 8mg (cohort 1), 16mg (cohort 2), 23mg (cohort 3) and 32mg (cohort 4). Based on

## Table of Contents

data from the first four dose-escalation cohorts, we may enroll a fifth cohort based on the recommended Phase 2 dose.

We are also currently enrolling a melanoma expansion cohort to assess the clinical activity of tilsotolimod monotherapy (8mg dose) in patients with metastatic melanoma who have progressed on or after treatment with a PD-(L)1 inhibitor. We anticipate that this cohort will enroll up to 22 subjects. The melanoma expansion cohort will use a Simon's optimal two-stage design to test for clinically and statistically relevant clinical activity. The melanoma expansion cohort will stop if an interim futility analysis shows there is insufficient evidence of a clinically relevant response rate after eight patients (Stage 1).

## Clinical Research Support Agreement

In April 2018, we entered into a clinical development support agreement with Pillar Partners Foundation, or Pillar Partners. Under the terms of the agreement, Pillar Partners agreed to provide direct funding to support three investigator initiated clinical trials to further strategically expand the clinical research of tilsotolimod into broader melanoma populations and other solid tumors, and we agreed to provide tilsotolimod for these trials. During the third quarter of 2018, Pillar Partners sought additional consideration in order to provide their funding. As a result, in October 2018, we terminated the agreement with Pillar Partners; however, we expect to move forward with certain of the investigator initiated clinical trials of tilsotolimod originally contemplated under such agreement. We believe these trials will allow us to expand our knowledge and understanding of the various cancer types and combinations in which tilsotolimod could play a significant role in improving outcomes of patients.

## 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, as described below, and Vivelix, GSK, and Abbott Molecular as described in Note 8 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, 2017.

## 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 our TLR-9 agonist tilsotolimod (IMO-2125) with BMS's therapy YERVOY® (ipilimumab), which agreement we refer to as the BMS Collaboration and Supply Agreement.

Under the BMS Collaboration and Supply 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 BMS Collaboration and Supply 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.

## Table of Contents

### Other Programs

In July 2018, following an analysis of our gene-silencing technology platform and our research portfolio, we decided to suspend our rare disease and discovery programs as part of our overall strategy to more narrowly focus our capital resources on the development and commercialization of tilsotolimod.

#### IMO-8400 for Rare Diseases

We have been developing IMO-8400, an antagonist of TLR7, TLR8 and TLR9, for the treatment of rare diseases, and had selected dermatomyositis as our lead clinical target. In December 2015, we initiated a Phase 2, randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability and treatment effect of IMO-8400 in adult patients with dermatomyositis. In June 2018, we reported that the trial did not meet its primary endpoint of statistically significant change from baseline in the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) activity score versus placebo. As a result, in July 2018, we made a decision to discontinue this clinical program upon completion of final close-out activities.

#### IMO-9200 for Autoimmune Disease

We have developed a second novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. In 2015, we completed a Phase 1 clinical trial of IMO-9200 in healthy subjects as well as additional preclinical studies of IMO-9200 for autoimmune diseases. In 2015, we determined not to proceed with the development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of our company. In November 2016, we entered into an exclusive license and collaboration agreement with Vivelix Pharmaceuticals, Ltd., or Vivelix, granting Vivelix worldwide rights to develop and market IMO-9200 for non-malignant gastrointestinal disorders, which agreement we refer to as the Vivelix Agreement. On November 4, 2018, Vivelix notified us that they decided to terminate ongoing development activities related to IMO-9200. However, a final decision as to whether Vivelix will continue working on IMO-9200 or terminate the Vivelix Agreement has not been made as of November 4, 2018. See Note 8 of the notes to our condensed financial statements in this Quarterly Report on Form 10-Q for additional information.

#### IDRA-008 Development

In January 2017, we announced that we had selected IDRA-008 as our first nucleic acid chemistry research program candidate that we plan to enter into clinical development and that we were planning to develop IDRA-008 for a

well-established liver target. In January 2018, we announced that IDRA-008 was targeted at Apolipoprotein C-III (APOC-III) and was being developed for the treatment of Familial Chylomicronemia Syndrome (FCS) and Familial Partial Lipodystrophy (FPL) which had available pre-clinical animal models and well-known clinical endpoints. During the first quarter of 2018, we completed our pre-clinical analysis for IDRA-008 and based upon the outcome of pre-clinical pharmacology studies, including a comparative pharmacology study with the competitive development asset Volanesorsen, and IND-enabling safety evaluation, we made a data-driven decision to not advance IDRA-008 into clinical development.

#### Nucleic Acid Chemistry Compound—Undisclosed Renal Target

In November 2015, we entered into a collaboration and license agreement with GlaxoSmithKline Intellectual Property Development Limited, or GSK, to license, research, develop and commercialize pharmaceutical compounds from our nucleic acid chemistry technology for the treatment of selected targets in renal disease, which agreement we refer to as the GSK Agreement. Under this collaboration, we have created multiple development candidates to address the target designated by GSK in connection with entering into the GSK Agreement. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. If GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

Table of Contents

Corporate Consolidation and Wind-down of Discovery Operations

In July 2018, following an analysis of our gene-silencing technology platform and our research portfolio, we decided to suspend our rare disease and discovery programs, including our nucleic acid chemistry research program, as part of our overall strategy to more narrowly focus on the development and commercialization of tilsotolimod. In connection with this focused strategy, we closed our operating facility in Cambridge, Massachusetts and consolidated our operations to our Exton, Pennsylvania location.

In connection with these actions, we are eliminating a total of 18 positions, primarily in the area of discovery, representing approximately 40% of our employee base. Of the 18 positions being eliminated, 15 were effective July 31, 2018 with the remaining three expected to be eliminated by December 31, 2018. We have incurred one-time termination costs in connection with the reduction in workforce, which includes severance, benefits and related costs, of approximately \$2.4 million for the quarter ended September 30, 2018 and expect to incur an additional \$0.2 million for the quarter ended December 31, 2018. We have incurred approximately \$0.5 million and \$0.2 million, respectively, for non-cash impairment charges against the carrying values of equipment previously used in our Cambridge facility and prepaid expenses for facility-related contracts for the quarter ended September 30, 2018. Additionally, we entered into a lease termination agreement on July 27, 2018 with ARE-MA-Region No. 23 LLC which terminated our lease agreement for our Cambridge facility, effective September 30, 2018. We incurred a \$0.2 million early termination fee, although the lease termination is expected to result in annual cash savings of approximately \$2.0 million.

Table of Contents

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 2017 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 2017 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.

## Table of Contents

### Financial Condition, Liquidity and Capital Resources

#### Financial Condition

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009. As of September 30, 2018, we had an accumulated deficit of \$652.2 million. To date, substantially all of our revenues have been from collaboration and license agreements and we have received no revenues from the sale of commercial products. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any commercial products. Our research and development activities, together with our selling, general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. Because of the numerous risks and uncertainties associated with developing drug candidates, and if approved, commercial products, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available or when we will become profitable, if at all.

#### Liquidity and Capital Resources

##### Overview

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

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

We filed a shelf registration statement on Form S-3 on August 10, 2017, which was declared effective on September 8, 2017. Under this registration statement, we may sell, in one or more transactions, up to \$250.0 million of common stock, preferred stock, depository shares and warrants. As of October 31, 2018, we may sell up to an additional \$192.5 million of securities under this registration statement.

#### Funding Requirements



We had cash and cash equivalents of approximately \$82.5 million at September 30, 2018. We believe that, based on our current operating plan, our existing cash and cash equivalents will enable us to fund our operations into the first quarter of 2020. Specifically, we believe that our available funds will be sufficient to enable us to:

- (i) complete enrollment 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;
  - b) the Phase 2 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab in anti-PD1 refractory melanoma;
  - c) the Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma; and
  - d) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types; and
- (ii) fund certain investigator initiated clinical trials of tilsotolimod.

## Table of Contents

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

- (i) the results of our clinical development activities in our tilsotolimod program and our ability to advance tilsotolimod 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 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 such as ours specifically; and
- (v) 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 12 of the notes to our financial statements included in our 2017 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.

## Cash Flows

The following table presents a summary of the primary sources and uses of cash for the nine months ended September 30, 2018 and 2017:

(in thousands)	Nine months ended September 30,	
	2018	2017
Net cash provided by (used in):		
Operating activities	\$ (40,444)	\$ (43,759)
Investing activities	122	26,770
Financing activities	10,155	263
Decrease in cash, cash equivalents and restricted cash	\$ (30,167)	\$ (16,726)

Operating Activities. Net cash used in operating activities for each of the nine months ended September 30, 2018 and 2017 consists primarily of our net losses adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the nine months ended September 30, 2018,

## Table of Contents

as compared to the 2017 period, was primarily due to decreases in cash outflows related to our discovery and development programs, including payments to contract research organizations, partially offset by merger-related costs.

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

- for the nine months ended September 30, 2018, proceeds of \$0.2 million from the sale of property and equipment, partially offset by purchases of less than \$0.1 million of property and equipment; and
- for the nine months ended September 30, 2017, proceeds from the maturity of \$26.9 million of available-for-sale securities, partially offset by the purchase of \$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 and payments on our note under our loan and security agreement with Oxford Finance LLC, or our note payable:

- for the nine months ended September 30, 2018, \$10.2 million in aggregate proceeds from the exercise of common stock options and warrants, \$0.2 million in proceeds from employee stock purchases under our 2017 Employee Stock Purchase Plan, partially offset by \$0.2 million in payments made on our note payable; and
- for the nine months ended September 30, 2017, proceeds of \$0.3 million from the exercise of common stock options and warrants and proceeds of \$0.2 million from employee stock purchases under our 1995 Employee Stock Purchase Plan, partially offset by approximately \$0.2 million of payments made on our note payable.

## Contractual Obligations

During the nine months ended September 30, 2018, 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, 2017, except as follows:

- On July 27, 2018, we entered into a termination agreement with ARE-MA-Region No. 23 LLC (the “Landlord”) terminating, effective September 30, 2018, the lease agreement, dated October 31, 2006, as amended, between us and the Landlord, for our facility at 167 Sidney Street in Cambridge, Massachusetts. As a result of the lease termination, our contractual commitments related to our operating leases, as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, would be revised as follows, as of September 30, 2018:

As of September 30, 2018

(in thousands)	Total	2018	2019	2020	2021 and thereafter
Operating leases (1)	\$ 504	\$ 206	\$ 209	\$ 89	\$ —
Total	\$ 504	\$ 206	\$ 209	\$ 89	\$ —

(1) Included in the contractual commitment amount for the 2018 period is the lease termination fee of approximately \$0.2 million which was paid to the Landlord of our Cambridge facility in October 2018. Subsequent to October 2018, our material operating lease commitments relate solely to the lease for our Exton, Pennsylvania facility, which expires on May 31, 2020, subject to a three-year renewal option exercisable by us.

#### Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements.

Table of Contents

## Results of Operations

## Three and Nine Months Ended September 30, 2018 and 2017

## Alliance Revenue

Alliance revenue for the three and nine months ended September 30, 2018 and 2017 was comprised of the following:

(\$ in thousands)	Three months ended			Nine months ended		
	September 30, 2018	September 30, 2017	% Change	September 30, 2018	September 30, 2017	% Change
GSK collaboration	\$ 141	\$ 141	0%	\$ 424	\$ 698	(39%) (1)
Vivelix collaboration	—	14	-100%	56	14	300% (2)
Other	4	9	(56%)	83	17	388% (3)
Total Alliance revenue	\$ 145	\$ 164	(12%)	\$ 563	\$ 729	(23%)

(1) GSK collaboration revenues for the three and nine months ended September 30, 2018 and 2017 primarily relate to the recognition of a \$2.5 million upfront payment received in connection with the execution of the GSK Agreement in November 2015, which was initially recorded as deferred revenue. We are recognizing this deferred revenue as revenue on a straight-line basis over the anticipated performance period under the GSK Agreement. The decrease in GSK collaboration revenues during the nine months ended September 30, 2018 as compared to the corresponding 2017 period is due primarily to a change that we made during the second quarter of 2017 with respect to our anticipated performance period under our collaboration with GSK from the original estimate of 27 months to an updated estimate of 36 months, which we accounted for on a prospective basis. Additionally, the nine months ended September 30, 2017 period includes \$0.1 million recognized for additional services provided for under the GSK Agreement. See Note 8 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information on our collaboration with GSK and the related accounting treatment.

(2) Vivelix collaboration revenues for each of the nine months ended September 30, 2018 and 2017 relate to research services provided for under the Vivelix Agreement. See Note 8 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information on our collaboration with Vivelix and the related accounting treatment.

(3)

Other revenues are comprised of 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.

Table of Contents

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			Nine months ended		
	September 30, 2018	2017	% Change	September 30, 2018	2017	% Change
IMO-2125 external development expense	\$ 6,108	\$ 1,788	242%	\$ 16,901	\$ 7,620	122% (1)
IMO-8400 external development expense	—	1,824	(100%)	2,607	7,505	(65%) (2)
Other drug development expense	2,056	5,093	(60%)	8,497	12,939	(34%) (3)
Basic discovery expense	696	2,207	(68%)	4,907	6,647	(26%) (4)
Severance and option modification expense	—	—	0%	—	5,577	(100%) (5)
Total research and development expenses	\$ 8,860	\$ 10,912	(19%)	\$ 32,912	\$ 40,288	(18%)

(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 September 30, 2018 we incurred approximately \$33.2 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), 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 nine months ended September 30, 2018, as compared to the corresponding 2017 period, was primarily due to increases in costs incurred with contract research organizations to support (i) our ongoing ILLUMINATE-204 trial, which we initiated in December 2015, (ii) our ongoing ILLUMINATE-101 trial, which we initiated in March 2017, and (iii) our ongoing ILLUMINATE-301, which we initiated in the first quarter of 2018.

(2) IMO-8400 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities



conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately \$45.4 million in IMO-8400 external development expenses through September 30, 2018, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis, our Phase 1/2 clinical trial in patients with Waldenström's macroglobulinemia and our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma, or DLBCL, harboring the MYD88 L265P oncogenic mutation, which we discontinued in September 2016; our Phase 2 clinical trial in patients with dermatomyositis, which we determined in July 2018 to discontinue upon completion of final close-out activities; the manufacture of drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with DLBCL harboring the MYD88 L265P oncogenic mutation. In July 2018, we terminated further development of IMO-8400. As a result, we expect IMO-8400 external development expenses to be insignificant in future periods.

The decrease in our IMO-8400 external development expenses during each of the three and nine months ended September 30, 2018, as compared to the corresponding 2017 period, was primarily due to costs incurred during the 2017 period on clinical development of IMO-8400 for B-cell lymphomas, including our trials in Waldenström's macroglobulinemia and DLBCL harboring the MYD88 L265P oncogenic mutation, which we did not incur in 2018 as a result of our decision in September 2016 to

Table of Contents

discontinue development of IMO-8400 for treatment of B-cell lymphomas and focus on the development of IMO-8400 for the treatment of dermatomyositis. Additionally, the decrease during the three months ended September 30, 2018, as compared to the corresponding 2017 period, was also attributed to us terminating further development of IMO-8400 in July 2018, which resulted in adjustments to certain accruals that offset costs incurred during the period.

(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 nine months ended September 30, 2018, as compared to the corresponding 2017 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 lower in future periods.

The decrease in basic discovery expenses during each of the three and nine months ended September 30, 2018, as compared to the corresponding 2017 period, was primarily due to decreases in payroll, lab supplies and facility overhead expenses as a result of our restructuring initiatives, including the suspension of all internal discovery programs and closing of our Cambridge, Massachusetts facility.

(5) Severance and Options Modification Expense. These expenses include charges for severance benefits provided pursuant to a separation agreement entered into in April 2017 in connection with the resignation of our former President of Research, effective May 31, 2017. Of the \$5.6 million incurred, \$1.3 million relates to severance pay in the form of salary continuation payments which is being paid over a two-year period through May 31, 2019 and a pro-rated 2017 bonus payment, and \$4.3 million relates to non-cash stock-based compensation expense resulting from modifications to previously issued stock option awards.

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 trial of tilsotolimod, 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 tilsotolimod 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.

## Table of Contents

### General and Administrative Expenses

General and administrative expenses consist primarily of payroll, stock-based compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

For the three months ended September 30, 2018 and 2017, general and administrative expenses totaled \$4.0 million and \$3.9 million, respectively. For the nine months ended September 30, 2018 and 2017, general and administrative expenses totaled \$11.8 million and \$11.9 million, respectively.

### 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.

Merger-related costs, net for the three months ended September 30, 2018 amounted to a net credit of \$3.8 million and was comprised of a \$6.0 million fixed expense reimbursement received in connection with the termination of the Merger Agreement in July 2018, partially offset by \$2.2 million of expenses incurred in connection with the transactions contemplated by the Merger Agreement, including legal and professional fees. Merger-related costs, net for the nine months ended September 30, 2018 amounted to a net charge of \$1.2 million and was comprised of \$7.2 million of expenses incurred in connection with the transactions contemplated by the Merger Agreement, including legal and professional fees, partially offset by a \$6.0 million fixed expense reimbursement received in connection with the termination of the Merger Agreement. No such costs were incurred during 2017.

### Restructuring Costs

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

Restructuring costs for the three and nine months ended September 30, 2018 totaled \$3.0 million and are 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 2017.

### Interest Income

Interest income for the three months ended September 30, 2018 and 2017 totaled approximately \$0.3 million and \$0.2 million, respectively. Interest income for the nine months ended September 30, 2018 and 2017 totaled approximately \$0.8 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 nine months ended September 30, 2018 and 2017 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.

### Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was \$11.6 million and \$14.5 million for the three months ended September 30, 2018 and 2017, respectively, and \$47.7 million and \$51.1 million for the nine months ended September 30, 2018 and 2017, respectively.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As of September 30, 2018, 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 September 30, 2018, all of our invested funds were invested in a money market fund, classified in cash and cash equivalents on the accompanying balance sheet, and a certificate of deposit, classified in restricted cash and other assets 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 September 30, 2018. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of September 30, 2018, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Changes in Internal Controls. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

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, 2017 and “Part II, Item 1A. Risk Factors” in our subsequent Quarterly Reports on Form 10-Q, which could be materially and adversely affect our business, financial condition or future results.



Table of Contents

Item 6.Exhibits.

Exhibit No.	Description
10.1	<u>Employment Offer Letter, dated August 20, 2018, by and between Idera Pharmaceuticals, Inc. and Bryant D. Lim</u>
31.1	<u>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</u>
31.2	<u>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</u>
32.1	<u>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</u>
32.2	<u>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</u>
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

Table of Contents

SIGNATURES

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

IDERA PHARMACEUTICALS, INC.

Date: November 6, 2018 /s/ Vincent J. Milano  
Vincent J. Milano  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 6, 2018 /s/ John J. Kirby  
John J. Kirby  
Vice President of Finance  
(Principal Financial Officer and Principal Accounting Officer)