IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 06, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017

or

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

For transition period from to .

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	04-3072298 (I.R.S. Employer Identification No.)
167 Sidney Street	
Cambridge, Massachusetts	02139
(Address of principal executive offices)	(Zip code)

(617) 679-5500

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. (Check one):

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	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	194,870,303
Class	Outstanding as of November 1, 2017

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “pr “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the Securities and Exchange Commission, or the SEC, on March 15, 2017. 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.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except per share amounts)	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,941	$ 80,667
Short-term investments	1,400	28,347
Prepaid expenses and other current assets	3,669	2,030
Total current assets	69,010	111,044
Property and equipment, net	1,412	1,853
Restricted cash and other assets	327	334
Total assets	$ 70,749	$ 113,231
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 849	$ 556
Accrued expenses	6,119	7,394
Current portion of note payable	285	292
Current portion of deferred revenue	563	1,111
Total current liabilities	7,816	9,353
Deferred revenue, net of current portion	94	152
Note payable, net of current portion	—	209
Other liabilities	759	168
Total liabilities	8,669	9,882
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, $0.001 par value, Authorized — 280,000 shares; Issued and outstanding — 149,680 and 149,065 shares at September 30, 2017 and	150	149

December 31, 2016, respectively		
Additional paid-in capital	651,498	641,687
Accumulated deficit	(589,568)	(538,470)
Accumulated other comprehensive loss	—	(17)
Total stockholders' equity	62,080	103,349
Total liabilities and stockholders' equity	$ 70,749	$ 113,231

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

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	2017	2016	2017	2016
Alliance revenue	$ 164	$ 323	$ 729	$ 918
Operating expenses:				
Research and development	10,912	9,393	40,288	28,817
General and administrative	3,919	3,907	11,888	11,601
Total operating expenses	14,831	13,300	52,176	40,418
Loss from operations	(14,667)	(12,977)	(51,447)	(39,500)
Other income (expense):				
Interest income	159	90	456	320
Interest expense	(11)	(19)	(40)	(63)
Foreign currency exchange (loss) gain	(11)	3	(27)	32
Net loss	$ (14,530)	$ (12,903)	$ (51,058)	$ (39,211)
Basic and diluted net loss per common share (Note 14)	$ (0.10)	$ (0.10)	$ (0.34)	$ (0.32)
Shares used in computing basic and diluted net loss per common share	149,638	121,389	149,385	121,332
Net loss	$ (14,530)	$ (12,903)	$ (51,058)	$ (39,211)
Other comprehensive gain (loss):				
Unrealized (loss) gain on available-for-sale securities	(1)	13	17	133
Comprehensive loss	$ (14,531)	$ (12,890)	$ (51,041)	$ (39,078)

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

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended September 30,	
(In thousands)	2017	2016
Cash Flows from Operating Activities:		
Net loss	$ (51,058)	$ (39,211)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,165	5,127
Issuance of common stock for services rendered	119	129
Accretion of discounts and premiums on investments	94	466
Depreciation and amortization expense	559	484
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,639)	(48)
Accounts payable, accrued expenses, and other liabilities	(393)	937
Deferred revenue	(606)	(833)
Net cash used in operating activities	(43,759)	(32,949)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	—	(2,946)
Proceeds from maturity of available-for-sale securities	26,870	29,946
Proceeds from sale of available-for-sale securities	—	1,974
Purchases of property and equipment	(100)	(369)
Net cash provided by investing activities	26,770	28,605
Cash Flows from Financing Activities:		
Proceeds from exercise of common stock warrants and options and employee stock purchases	488	111
Payments on note payable	(216)	(193)
Payments on capital lease	(9)	(6)
Net cash provided by (used in) financing activities	263	(88)
Net decrease in cash and cash equivalents	(16,726)	(4,432)
Cash and cash equivalents, beginning of period	80,667	26,586
Cash and cash equivalents, end of period	$ 63,941	$ 22,154

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

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IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2017

(UNAUDITED)

(1) Organization

Business Overview

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

Idera is focused on the clinical development of drug candidates for oncology and rare diseases characterized by small, well-defined patient populations with serious unmet medical needs. The Company believes it can develop and commercialize these targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

The Company’s pipeline of drug candidates includes IMO-2125, IMO-8400 and IDRA-008.

Toll-Like Receptors

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

The Company's TLR agonist lead drug candidate IMO-2125 is an agonist of TLR9. The Company is developing IMO-2125 for the treatment by intra-tumoral injection of multiple oncology indications both in combination with checkpoint inhibitors and as monotherapy. The Company is currently developing IMO-2125 for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma and for administration as a single agent intra-tumorally in multiple tumor types.

The Company's TLR antagonist lead drug candidate is IMO-8400, which is an antagonist of TLR7, TLR8 and TLR9. The Company is developing IMO-8400 for the treatment of rare diseases and has selected dermatomyositis as its lead clinical target. The Company selected this indication for development based on the reported increase in TLR expression in this disease state, expression of cytokines indicative of key TLR-mediated pathways and the presence of auto-antibodies that can induce TLR-mediated immune responses.

Third-Generation Antisense

The Company is developing its 3GA technology to "turn off" the mRNA associated with disease causing genes. The Company has designed 3GA oligonucleotides to specifically address challenges associated with earlier generation antisense and RNAi technologies.

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The Company has selected IDRA-008 as its first 3GA candidate to enter clinical development. The Company is planning to develop IDRA-008 for a well-established liver target with available pre-clinical animal models and well-known clinical endpoints.

Liquidity and Financial Condition

At September 30, 2017, the Company had an accumulated deficit of $589.6 million. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company or its collaborators successfully complete development and obtain marketing approval for the Company's drug candidates, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

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

The Company believes, based on its current operating plan, that its existing cash, cash equivalents and investments, together with the net proceeds from its common stock offering and the exercise of common stock warrants in October 2017 as more fully described in Note 18, will enable the Company to fund its operations into the second quarter of 2019. The Company has and will continue to evaluate available alternatives to extend its operations beyond the second quarter of 2019.

(2) New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation (Topic 718), which is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years. As of January 1, 2017, the Company adopted this standard, which had the following impacts on its financial statements. (1) ASU 2016-09 requires organizations to recognize all income tax effects of awards in the statement of operations when the awards vest or are settled. The Company's net operating loss deferred tax assets increased by $1.4 million and were offset by a corresponding increase in the valuation allowance given the Company’s continued loss position. Accordingly, the adoption of this portion of ASU 2016-09 had no impact on the Company’s Accumulated deficit. (2) ASU 2016-09 allows organizations to repurchase more shares from employees than they could previously purchase for tax withholding purposes without triggering liability accounting. The adoption of this portion of ASU 2016-09 had no impact on the Company’s financial statements. (3) ASU 2016-09 allows companies to make a policy election to account for forfeitures as they occur. The Company has made the policy election to account for forfeitures as they occur and has used the modified retrospective transition method, resulting in less than a $0.1 million reduction in Additional paid-in capital and an increase in Accumulated deficit as of January 1, 2017, to reflect the cumulative effect of previously estimated forfeitures.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was amended by ASU No. 2015-14 (as amended, “ASU 2014-09”). ASU No. 2014-09 requires an entity to recognize revenue from the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In particular, this ASU addresses contracts with more than one performance obligation, as well as the accounting for some costs to obtain or fulfill a contract with a customer, and provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers. This ASU is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within that fiscal year. Early adoption of this ASU is permitted only for fiscal years beginning after December 15, 2016, including interim periods within that fiscal year. This guidance is applicable to the Company's fiscal year beginning January 1, 2018 and the Company expects to adopt ASU 2014-09 in the first quarter of 2018 using the modified retrospective transition method. To date, the Company has derived its revenues from a limited number of license and collaboration agreements. The consideration the Company is eligible to receive under these

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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 that need to be evaluated separately under the new standard. The Company is substantially complete with its initial assessment of its two active license and collaboration agreements, and currently does not expect the adoption of the ASU to have a material impact on its financial statements but is expected to result in expanded footnote disclosures. The Company will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusion.

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 current U.S. Generally Accepted Accounting Principles (“U.S. GAAP”), the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current U.S. GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. This guidance is applicable to the Company's fiscal year beginning January 1, 2019. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. GAAP for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2017 are not necessarily indicative of results that may be expected for the year ending December 31, 2017. 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, 2016, which was filed with the SEC on March 15, 2017.

(4) Financial Instruments

The fair value of the Company’s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 6, “Fair Value of Assets and Liabilities.” The Company is required to disclose the estimated fair values of its financial instruments. The Company’s financial instruments consist of cash, cash equivalents, available-for-sale investments and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of September 30, 2017 and December 31, 2016. As of September 30, 2017 and December 31, 2016, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the note issued under the Company’s loan and security agreement, which is discussed in Note

5(a) to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, including put and call features which the Company determined are clearly and closely associated with the debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial.

(5) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2017 and December 31, 2016 consisted of cash and money market funds.

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(6) Fair Value of Assets and Liabilities

The Company applies the guidance in FASB Accounting Standards Codification (ASC) Topic 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 using assumptions that market participants would use in pricing the asset or liability (the “inputs”) into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company’s estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management’s interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2017 and December 31, 2016 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2017				
Assets				
Money market funds	$ 49,637	$ 49,637	$ —	$ —
Short-term investments – municipal bonds	1,400	—	1,400	—
Total Assets	$ 51,037	$ 49,637	$ 1,400	$ —
Total Liabilities	$ —	$ —	$ —	$ —
December 31, 2016				
Assets				
Money market funds	$ 67,580	$ 67,580	$ —	$ —
Short-term investments – corporate bonds	19,729	—	19,729	—
Short-term investments – municipal bonds	8,618	—	8,618	—
Total Assets	$ 95,927	$ 67,580	$ 28,347	$ —
Total Liabilities	$ —	$ —	$ —	$ —

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond and municipal bond investments, the fair value of which may not represent actual transactions of identical securities. The fair value of corporate and municipal bonds is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders' equity on the Company's balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value at September 30, 2017 or December 31, 2016.

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(7) Investments

The Company’s available-for-sale investments at fair value consisted of the following at September 30, 2017 and December 31, 2016:

	September 30, 2017			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Short-term investments – municipal bonds	$ 1,400	$ —	$ —	$ 1,400
Total short-term investments	1,400	—	—	1,400
Total investments	$ 1,400	$ —	$ —	$ 1,400

	December 31, 2016			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Short-term investments – corporate bonds	$ 19,740	$ (11)	$ —	$ 19,729
Short-term investments – municipal bonds	8,624	(6)	—	8,618
Total short-term investments	28,364	(17)	—	28,347
Total investments	$ 28,364	$ (17)	$ —	$ 28,347

The Company had no realized gains or losses from the sale of available-for-sale securities during the nine months ended September 30, 2017 and 2016. Additionally, there were no losses or other-than-temporary declines in value included in the Company’s statements of operations and comprehensive loss for any securities for both the nine months ended September 30, 2017 and 2016. See Note 4, “Financial Instruments,” and Note 6, “Fair Value of Assets and Liabilities” for additional information related to the Company’s investments.

(8) Property and Equipment

At September 30, 2017 and December 31, 2016, net property and equipment at cost consisted of the following:

(In thousands)	September 30, 2017	December 31, 2016
Leasehold improvements	$ 671	$ 671
Laboratory equipment and other	5,158	5,127
Total property and equipment, at cost	5,829	5,798
Less: Accumulated depreciation and amortization	4,417	3,945
Property and equipment, net	$ 1,412	$ 1,853

Depreciation and amortization expense on property and equipment was $0.2 million for both the three months ended September 30, 2017 and 2016, and $0.6 million and $0.5 million for the nine months ended September 30, 2017 and 2016, respectively. There were less than $0.1 million in non-cash property additions during both the three months and nine months ended September 30, 2017 and 2016.

(9) Restricted Cash

As part of the Company’s lease arrangement for its office and laboratory facility in Cambridge, Massachusetts, the Company is required to restrict cash held in a certificate of deposit securing a line of credit for the lessor. As of September 30, 2017 and December 31, 2016, the restricted cash amounted to $0.3 million held in certificates of deposit securing a line of credit for the lessor. The lease expires August 2022.

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(10) Accrued Expenses

At September 30, 2017 and December 31, 2016, accrued expenses consisted of the following:

(In thousands)	September 30, 2017	December 31, 2016
Payroll and related costs	$ 2,704	$ 2,498
Clinical and nonclinical trial expenses	2,838	3,577
Professional and consulting fees	476	840
Equipment purchase	—	368
Other	101	111
	$ 6,119	$ 7,394

Included in accrued payroll and related costs as of September 30, 2017 is the current portion, or $0.6 million, of the remaining $1.0 million of salary continuation severance benefits to be paid in equal installments through May 31, 2019 to a former executive. The long-term portion of $0.4 million is included within Other liabilities in the Company's balance sheet as of September 30, 2017.

(11) Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss for the nine months ended September 30, 2017 and 2016 is comprised of reported net loss and any change in net unrealized gains and losses on investments during each period, which is included in accumulated other comprehensive income (loss) on the accompanying balance sheets.

The following table includes the changes in the accumulated balance of the component of other comprehensive income (loss) for the nine months ended September 30, 2017 and 2016:

(In thousands)	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016

Accumulated unrealized loss on available-for-sale securities at beginning of period	$	(17)	$	(134)
Change during the period		17		133
Accumulated unrealized loss on available-for-sale securities at end of period	$	—	$	(1)

(12) Collaboration with GlaxoSmithKline Intellectual Property Development Limited

Collaboration Overview

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

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At any time during the first two years of the GSK Agreement, GSK has the option to select up to two additional targets, for further research under mutually agreed upon research plans. GSK may then designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. To date, GSK has not selected any additional targets for research.

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

Under the terms of the GSK Agreement, the Company received a $2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. The Company is eligible to receive up to approximately $100 million in license, research, clinical development and commercialization milestone payments. Approximately $9 million of these milestone payments are payable by GSK upon the identification of the additional targets, the completion of current and future research plans and the designation of development candidates. Approximately $89 million is payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, the Company is eligible to receive royalty payments on sales upon commercialization at varying rates of up to five percent on annual net sales, as defined in the GSK Agreement.

Accounting Analysis

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

The Company has determined that GSK's options to choose up to two additional targets and to purchase additional collaboration licenses for the Company's proprietary technology related to each additional target are substantive options. GSK is not contractually obligated to exercise the options. Moreover, as a result of the uncertain outcome of the research activities, there is significant uncertainty as to whether GSK will decide to exercise its options for any additional targets. Consequently, the Company is at risk with regard to whether GSK will exercise the options. To date, no such options have been exercised. The Company has determined that GSK's options to choose up to two additional targets and to purchase additional collaboration licenses for the Company's proprietary technology related to each additional target are not priced at a significant and incremental discount.

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

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

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Allocable arrangement consideration at inception of the GSK Agreement is comprised of the up-front payment of $2.5 million, which was allocated to the R&D Services Unit of Accounting. No amount was allocated to the JSC Deliverable because the related best estimate of selling price was determined to be de minimis. The $2.5 million was recorded as deferred revenue in the Company's balance sheet and is being recognized as revenue on a straight-line basis over the Company's estimate of the period over which the Research Services are delivered. In the second quarter of 2017, the Company revised its estimate of the research period from 27 months to 36 months, which is being accounted for on a prospective basis.

Payments to be received in connection with GSK's identification of additional targets and designation of development candidates are considered substantive options as a result of the uncertainties related to the research, development and commercialization activities, and the uncertainty as to whether GSK will exercise the options. The substantive options are not priced at a significant incremental discount. Accordingly, the substantive options are not considered deliverables at the inception of the arrangement and the associated option exercise payments are not accounted for at inception of the agreement. To date, no such options have been exercised.

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

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

The Company recognized as revenue $0.1 million and $0.3 million of deferred revenue related to the GSK Agreement during the three months ended September 30, 2017 and 2016, respectively, and $0.6 million and $0.8 million of deferred revenue for the nine months ended September 30, 2017 and 2016, respectively. This revenue is classified as alliance revenue in the accompanying statements of operations and comprehensive loss.

There was $0.7 million of deferred revenue related to the GSK Agreement at September 30, 2017, of which $0.6 million is reflected in current portion of deferred revenue and $0.1 million is reflected as long-term deferred revenue in the accompanying balance sheet.

(13) Stock-Based Compensation

The Company recognizes all stock-based payments to employees and directors as expense in the statements of operations and comprehensive loss based on their fair values. The Company records compensation expense over an award's requisite service period, or vesting period, based on the award's fair value at the date of grant. The Company's policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors. The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

Total stock-based compensation expense recognized using the straight-line attribution method and included in operating expenses in the Company's statements of operations and comprehensive loss was $1.6 million for both the three months ended September 30, 2017 and 2016, and $9.2 million and $5.1 million for the nine months ended September 30, 2017 and 2016, respectively. Included in the $9.2 million recognized during the nine months ended September 30, 2017 is $4.3 million of stock-based compensation resulting from modifications to previously issued stock option awards in connection with the resignation of an executive in the second quarter of 2017, which is recorded in Research and development expense. Additionally, as of September 30, 2017, there was approximately $10.9 million of unrecognized compensation expense related to non-vested stock options which is expected to be recognized over a weighted-average period of 2.2 years.

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The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The following weighted average assumptions apply to the options to purchase 4,166,500 and 3,281,000 shares of common stock granted to employees and directors during the nine months ended September 30, 2017 and 2016, respectively:

	Nine Months Ended September 30,	
	2017	2016
Average risk free interest rate	1.7%	1.4%
Expected dividend yield	—	—
Expected lives (years)	4.0	4.2
Expected volatility	86.5%	92.8%
Weighted average grant date fair value (per share)	$ 1.01	$ 1.77
Weighted average exercise price (per share)	$ 1.61	$ 2.65

The expected lives and the expected volatility of the options granted during the nine months ended September 30, 2017 and 2016 are based on historical experience. All options granted during the nine months ended September 30, 2017 and 2016 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

(14) Net Loss per Common Share

For the three and nine months ended September 30, 2017 and 2016, basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share as the effects of the Company’s potential common stock equivalents are antidilutive. Total antidilutive securities were 72,981,524 and 73,115,102 for the nine months ended September 30, 2017 and 2016, respectively, and consist of stock options, convertible preferred stock and warrants.

(15) Stockholders’ Equity

Common Stock Warrant Exercises, Stock Option Exercises and Employee Stock Purchases

The Company issued common stock as a result of warrant exercises, stock option exercises and employee stock purchases as follows during the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
(In thousands)	Shares	Proceeds	Shares	Proceeds
Warrant exercises	409	$ 287	—	$ —
Stock option exercises	7	17	—	—
Employee stock purchases	132	184	79	111
Total	548	$ 488	79	$ 111

Subsequent to September 30, 2017, entities affiliated with a related party exercised common stock warrants as more fully described in Note 18.

Common Stock – 2017 Follow-on Public Offering

Subsequent to September 30, 2017, the Company sold 38,333,334 shares of its common stock, par value $0.001 per share, in an underwritten public offering, including shares sold in the overallotment, at a price per share of $1.50 as more fully described in Note 18.

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(16) Related Party Transactions

The Company issued 66,954 and 66,915 shares of common stock during the nine months ended September 30, 2017 and 2016, respectively, in lieu of director board and committee fees of $0.1 million for each nine-month period, pursuant to the Company's director compensation program. The number of shares issued was calculated based on the market closing price of the Company's common stock on the issuance date.

Subsequent to September 30, 2017, entities affiliated with a related party exercised common stock warrants as more fully described in Note 18. Additionally, subsequent to September 30, 2017, entities affiliated with a related party participated in an underwritten public offering of shares of the Company's common stock as more fully described in Note 18. See Notes 9(d), 14 and 15 to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 for further discussion of related parties.

(17) Deferred Tax Assets

The Company's deferred tax assets are determined based on temporary differences between the financial reporting and tax bases of assets and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized. For the nine months ended September 30, 2017 and 2016, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the future realization of the deferred tax assets, the Company has recorded full valuation allowances against its otherwise recognizable deferred tax assets at September 30, 2017 and December 31, 2016.

(18) 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.

2017 Follow-on Public Offering

On October 30, 2017, the Company completed a follow-on underwritten public offering, in which it sold 33,333,334 shares of common stock at a price to the public of $1.50 per share for aggregate gross proceeds of $50.0 million ("2017 Offering"). On November 1, 2017, the Company sold an additional 5,000,000 shares of common stock pursuant to the exercise in full of the underwriters' 30-day option to purchase additional shares of the Company's common stock at the public offering price less underwriting discount. The estimated net proceeds to the Company from the 2017 Offering, including the exercise by the underwriters of their option to purchase additional shares and after deducting underwriters' discounts and commissions and other offering costs and expenses, were approximately $53.8 million.

Baker Bros. Advisors LP, and certain of its affiliated funds (collectively, "Baker Brothers"), entities affiliated with two of the Company's directors, participated in the 2017 Offering and purchased 8,000,000 shares of the Company's common stock at the price offered to the public. As of October 30, 2017 Baker Brothers held 18,306,757 shares of the Company's common stock, warrants to purchase up to 20,316,327 shares of the Company's common stock at an exercise price of $0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of the Company's common stock at an exercise price of $0.01 per share.

Common Stock Warrants

In October 2017, entities affiliated with Pillar Invest Corporation, a related party, exercised warrants to purchase 6,842,844 shares of common stock at a total exercise price of $4.8 million.

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Proposed Reverse Stock Split Common Stock Offering

In October 2017, the Company's board of directors (the "Board") adopted, subject to stockholder approval, an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of our common stock by a whole number ratio of not less than 1-for-4 and not more than 1-for-8, and in connection therewith to set the authorized number of shares of common stock at the number determined by calculating the product of 280,000,000 and two times the actual reverse stock split ratio. Also in October 2017, the Board submitted a proposal to its stockholders to approve the amendment to the Company's Certificate of Incorporation at a special meeting of stockholders expected to be held in January 2018. If approved, the Board would have the authority to set the ratio and timing of the reverse stock split and implement the reverse stock split.

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

Overview

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

Our business strategy is focused on the clinical development of drug candidates for oncology and rare diseases characterized by small, well-defined patient populations with serious unmet medical needs. 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.

TLR Modulation Technology Platform

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

Our TLR agonist lead drug candidate IMO-2125 is an agonist of TLR9. Our TLR antagonist lead drug candidate is IMO-8400, which is an antagonist of TLR7, TLR8 and TLR9.

We are developing IMO-2125 for the treatment by intra-tumoral injection of multiple oncology indications both in combination with checkpoint inhibitors and as monotherapy. We are developing IMO-8400 for the treatment of rare diseases and have selected dermatomyositis as our lead clinical target.

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

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 stimulate the immune system, we believe there is a scientific rationale to evaluate the combination of intra-tumoral injection of our TLR9 agonists with checkpoint inhibitors. Specifically, we believe intra-tumoral injection of our TLR9 agonists 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, intra-tumoral injection of TLR9 agonists has potentiated the anti-tumor activity of multiple checkpoint inhibitors in multiple tumor models. These data have been presented at several scientific and medical conferences from 2014 through 2017. We believe these data support evaluation of combination regimens including the combination of a TLR9 agonist and a checkpoint inhibitor for the treatment of cancer.

We are currently developing IMO-2125 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 have failed first-line anti-PD1 therapy. We also believe TLR9 agonists may be useful in other solid tumor types that

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are refractory to anti-PD1 treatment due in part to low mutation load and low dendritic cell infiltration.   We believe, based on internally conducted commercial research, that in the United States, by 2025, approximately 160,000 people will have tumor types that are addressable with current immunotherapy and approximately 70,000 of those people will have tumor types that are anti-PD1 refractory.

In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of IMO-2125, administered intra-tumorally, in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory). We subsequently amended the trial protocol to enable an additional arm to study the combination of IMO-2125 with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., in the same patient population. In this clinical trial, IMO-2125 is administered intra-tumorally into a selected tumor lesion at weeks 1, 2, 3, 5, 8 and 11, together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. IMO-2125 is being administered via deep injection (using interventional radiology guidance) in patients lacking superficially accessible disease for injection.

In the Phase 1 portion of the ipilimumab arm of this clinical trial, escalating doses of IMO-2125 ranging from 4 mg through 32 mg in the ipilimumab arm were evaluated. In the Phase 1 portion of the pembrolizumab arm of this clinical trial, escalating doses of IMO-2125 ranging from 8 mg through 32 mg in the pembrolizumab arm are being evaluated. 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 during 2017. We anticipate that more sites will be added, to bring the total number of participating sites for the trial to ten. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the anti-tumor activity of IMO-2125 when administered intra-tumorally in combination with ipilimumab or pembrolizumab. The primary objectives of the Phase 2 portion of the trial are to characterize the safety of the combinations and determine the activity of the combinations utilizing immune-related response criteria. Additionally, a secondary objective of the Phase 2 portion of the trial is to assess treatment response using RECIST v1.1 criteria. 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 IMO-2125, as w