

IDERA PHARMACEUTICALS, INC.

Form 10-Q

May 09, 2018

[Table of Contents](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended March 31, 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

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IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(617) 679-5500

(Registrant's telephone number, including area code)

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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.

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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 | 217,310,991                      |
| Class                                    | Outstanding as of April 30, 2018 |

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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 March 31, 2018 and December 31, 2017</u>  | 1    |
| <u>Condensed Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2018 and 2017</u> | 2    |
| <u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2018 and 2017</u>                        | 3    |
| <u>Condensed Statement of Stockholders' Equity for the Three Months Ended March 31, 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>                | 23   |
| Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>   | 38   |
| Item 4. <u>Controls and Procedures</u>  | 38   |
| <u>PART II — OTHER INFORMATION</u>  |      |
| Item 1. <u>Legal Proceedings</u>  | 39   |
| Item 1A. <u>Risk Factors</u>  | 39   |
| Item 5. <u>Other Information</u>  | 39   |
| Item 6. <u>Exhibits</u>   | 40   |
| <u>Signatures</u>   | 41   |

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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 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.

This Quarterly Report on Form 10-Q also contains statements about our proposed strategic combination with BioCryst Pharmaceuticals, Inc. Many risks and uncertainties could cause actual results to differ materially from these forward-looking statements with respect to the pending transaction. These risks, as well as other risks associated with the pending transaction, are more fully disclosed under “Risk Factors” in the joint proxy statement/prospectus that is included in the registration statement on Form S-4 (File No. 333-223255) that was filed by Nautilus Holdco, Inc. with the SEC, on March 29, 2018 in connection with the pending merger.

In addition, any forward-looking statements, including any statements about the proposed transaction, 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)  | March 31,<br>2018<br>(unaudited) | December 31,<br>2017* |
|---|----------------------------------|-----------------------|
| <b>ASSETS</b>   |                                  |                       |
| Current assets:   |                                  |                       |
| Cash and cash equivalents   | \$ 107,459                       | \$ 112,629            |
| Prepaid expenses and other current assets   | 2,651                            | 3,992                 |
| Total current assets  | 110,110                          | 116,621               |
| Property and equipment, net   | 1,320                            | 1,472                 |
| Restricted cash and other assets  | 321                              | 324                   |
| Total assets  | \$ 111,751                       | \$ 118,417            |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                  |                       |
| Current liabilities:  |                                  |                       |
| Accounts payable  | \$ 1,668                         | \$ 1,334              |
| Accrued expenses  | 10,224                           | 8,000                 |
| Current portion of note payable   | 131                              | 209                   |
| Current portion of deferred revenue   | 376                              | 566                   |
| Total current liabilities   | 12,399                           | 10,109                |
| Other liabilities   | 468                              | 613                   |
| Total liabilities   | 12,867                           | 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 — 280,000 shares; Issued and outstanding — 216,095 and 195,625 shares at March 31, 2018 and | 216                              | 196                   |

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|  |            |            |
|--|------------|------------|
| December 31, 2017, respectively            |            |            |
| Additional paid-in capital                 | 723,257    | 711,993    |
| Accumulated deficit                        | (624,589)  | (604,494)  |
| Total stockholders' equity                 | 98,884     | 107,695    |
| Total liabilities and stockholders' equity | \$ 111,751 | \$ 118,417 |

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\* The condensed consolidated 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

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Table of Contents

IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

| (In thousands, except per share amounts)  | Three Months Ended<br>March 31, |             |
|---|---------------------------------|-------------|
|   | 2018                            | 2017        |
| Alliance revenue  | \$ 255                          | \$ 378      |
| Operating expenses:   |                                 |             |
| Research and development  | 13,556                          | 11,485      |
| General and administrative  | 6,979                           | 4,081       |
| Total operating expenses  | 20,535                          | 15,566      |
| Loss from operations  | (20,280)                        | (15,188)    |
| Other income (expense):   |                                 |             |
| Interest income   | 211                             | 153         |
| Interest expense  | (7)                             | (16)        |
| Foreign currency exchange loss  | (19)                            | (6)         |
| Net loss  | \$ (20,095)                     | \$ (15,057) |
| Net loss per share applicable to common stockholders - basic and diluted (Note 12)  | \$ (0.10)                       | \$ (0.10)   |
| Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted | 199,037                         | 149,100     |
| Comprehensive loss:   |                                 |             |
| Net loss  | \$ (20,095)                     | \$ (15,057) |
| Other comprehensive income (loss):  |                                 |             |
| Unrealized gain on available-for-sale securities  | —                               | 16          |
| Total other comprehensive income  | —                               | 16          |
| Comprehensive loss  | \$ (20,095)                     | \$ (15,041) |

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)  | Three Months Ended<br>March 31, |             |
|---|---------------------------------|-------------|
|   | 2018                            | 2017        |
| <b>Cash Flows from Operating Activities:</b>                                |                                 |             |
| Net loss  | \$ (20,095)                     | \$ (15,057) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |             |
| Stock-based compensation  | 1,589                           | 1,784       |
| Issuance of common stock for services rendered                              | 23                              | 43          |
| Accretion of discounts and premiums on investments                          | —                               | 74          |
| Depreciation and amortization expense                                       | 169                             | 176         |
| Changes in operating assets and liabilities:                                |                                 |             |
| Prepaid expenses and other current assets                                   | 1,341                           | (2,205)     |
| Accounts payable, accrued expenses, and other liabilities                   | 2,416                           | (2,183)     |
| Deferred revenue  | (190)                           | (278)       |
| Net cash used in operating activities                                       | (14,747)                        | (17,646)    |
| <b>Cash Flows from Investing Activities:</b>                                |                                 |             |
| Proceeds from maturity of available-for-sale securities                     | —                               | 16,720      |
| Purchases of property and equipment   | (14)                            | (30)        |
| Net cash (used in) provided by investing activities                         | (14)                            | 16,690      |
| <b>Cash Flows from Financing Activities:</b>                                |                                 |             |
| Proceeds from employee stock purchases                                      | 81                              | 57          |
| Proceeds from exercise of common stock warrants                             | 9,591                           | —           |
| Payments on note payable  | (78)                            | (70)        |
| Payments on capital lease   | (3)                             | (4)         |
| Net cash provided by (used in) financing activities                         | 9,591                           | (17)        |
| Net decrease in cash, cash equivalents and restricted cash                  | (5,170)                         | (973)       |
| Cash, cash equivalents and restricted cash, beginning of period             | 112,940                         | 80,978      |
| Cash, cash equivalents and restricted cash, end of period                   | \$ 107,770                      | \$ 80,005   |

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<br>Number of<br>Shares | \$0.001 Par<br>Value | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|--|-------------------------------------|----------------------|----------------------------------|------------------------|----------------------------------|
| Balance, December 31, 2017   | 195,625                             | \$ 196               | \$ 711,993                       | \$ (604,494)           | \$ 107,695                       |
| Issuance of common stock under stock<br>purchase plan              | 53                                  | —                    | 81                               | —                      | 81                               |
| Issuance of common stock upon exercise of<br>common stock warrants | 20,406                              | 20                   | 9,571                            | —                      | 9,591                            |
| Issuance of common stock for services rendered                     | 11                                  | —                    | 23                               | —                      | 23                               |
| Stock-based compensation   | —                                   | —                    | 1,589                            | —                      | 1,589                            |
| Net loss   | —                                   | —                    | —                                | (20,095)               | (20,095)                         |
| Balance, March 31, 2018  | 216,095                             | \$ 216               | \$ 723,257                       | \$ (624,589)           | \$ 98,884                        |

The accompanying notes are an integral part of these financial statements

Table of Contents

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 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 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 nucleic acid chemistry 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 nucleic acid chemistry technology, the Company is developing drug candidates to turn off the messenger RNA (“mRNA”) associated with disease causing genes.

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.

Agreement and Plan of Merger

As further described in Note 2, in January 2018, the Company entered into an Agreement and Plan of Merger with BioCryst Pharmaceuticals, Inc. and affiliated entities. However, as the merger has not yet been completed, the Company has prepared these financial statements as if the Company will remain an independent reporting company,

and accordingly, these financial statements do not include any of the potential accounting impacts that may result from the Agreement and Plan of Merger.

#### Liquidity and Financial Condition

As of March 31, 2018, the Company had an accumulated deficit of \$624.6 million. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance its 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 and obtains marketing approval for the Company's drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

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 third quarter of 2019. The Company has and plans to continue to evaluate available alternatives to extend its operations beyond the third quarter of 2019.

Table of Contents

Note 2. 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 (“Merger Sub A”), and Boat Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco (“Merger Sub B”), entered into an Agreement and Plan of Merger (the “Merger Agreement”). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, (a) Merger Sub A will be merged with and into Idera (the “Idera Merger”), with Idera surviving as a wholly owned subsidiary of Holdco, and (b) Merger Sub B will be merged with and into BioCryst (the “BioCryst Merger”, and, together with the Idera Merger, the “Mergers”), with BioCryst surviving as a wholly owned subsidiary of Holdco. Upon completion of the Mergers, Holdco will operate as a combined company under the name Valenscion Incorporated.

Under the terms of the Merger Agreement, each share of BioCryst common stock will be exchanged for 0.50 shares of Holdco stock and each share of Idera common stock will be exchanged for 0.20 shares of Holdco stock. The exchange ratio reflects an “at market” combination based upon the approximate 30-day average volume weighted trading prices for each company. On a proforma, fully diluted basis, giving effect to all dilutive stock options, units and warrants, BioCryst stockholders will own 51.6 percent of the stock of the combined company and Idera stockholders will own 48.4 percent.

The board of directors of each of Idera and BioCryst has unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals have been received. However, the Mergers are subject to approval by the stockholders of both companies and satisfaction of other customary closing conditions, as specified in the Merger Agreement. A special meeting of Idera stockholders and a special meeting of BioCryst stockholders to vote on the proposal to adopt the Merger Agreement and the transactions contemplated thereby, including the Mergers, are expected to occur on July 10, 2018. Simultaneously with the execution of the Merger Agreement, Baker Brothers, a significant stockholder of each company, entered into a voting and support agreement and agreed to vote in favor of the transactions contemplated by the Merger Agreement. Baker Brothers owns approximately 18% of the issued and outstanding Idera common stock and approximately 14% of the issued and outstanding BioCryst common stock.

The foregoing description of the Merger Agreement is not a complete description of all the parties’ rights and obligations under the Merger Agreement and is qualified in its entirety by reference to the Merger Agreement, which was filed as Exhibit 2.1 to the Company’s Current Report on Form 8-K filed with the SEC on January 22, 2018.

Note 3. 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 months ended March 31, 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.

Table of Contents

## Note 3. Summary of Significant Accounting Policies (Continued)

## 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 March 31, 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 March 31, 2018 and December 31, 2017, the restricted cash amounted to \$0.3 million and is recorded in “Restricted cash and other assets” in the accompanying balance sheets. The lease expires in August 2022.

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:

|  | March 31,<br>2018 | December<br>31,<br>2017 |
|--|-------------------|-------------------------|
| (In thousands)                             |                   |                         |
| Cash and cash equivalents                  | \$ 107,459        | \$ 112,629              |
| Restricted cash                            | 311               | 311                     |
| Cash, cash equivalents and restricted cash | \$ 107,770        | \$ 112,940              |

## 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 4. The Company is required to disclose the estimated fair values of its financial instruments. The Company’s financial instruments consist of cash, cash equivalents, receivables and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of March 31, 2018 and December 31, 2017. As of March 31, 2018 and December 31, 2017, 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 7 to the financial statements included in the 2017 Form 10-K. The note includes 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.

## 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.

Table of Contents

Note 3. Summary of Significant Accounting Policies (Continued)

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.

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

Table of Contents

Note 3. Summary of Significant Accounting Policies (Continued)

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.

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 statement of operations.

Table of Contents

Note 3. Summary of Significant Accounting Policies (Continued)

**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.

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 months ended March 31, 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 March 31, 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 March 31, 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 in 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 3. 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 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 revised or additional disclosures were made with respect to revenues and cash flows arising from contracts with customers, which are included in Notes 8 and 9.

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 cash, cash equivalents and restricted cash is described earlier in this Note 3.



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 January 1, 2019. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

Table of Contents

## Note 4. 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 three months ended March 31, 2018.

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

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

| (In thousands)     | March 31, 2018 |           |         |         |
|--------------------|----------------|-----------|---------|---------|
|                    | Total          | Level 1   | Level 2 | Level 3 |
| Assets             |                |           |         |         |
| Money market funds | \$ 66,372      | \$ 66,372 | \$ —    | \$ —    |
| Total Assets       | \$ 66,372      | \$ 66,372 | \$ —    | \$ —    |

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Total Liabilities \$ — \$ — \$ — \$ —

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 5. Property and Equipment

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

| (In thousands)                                  | March 31,<br>2018 | December 31,<br>2017 |
|---|-------------------|----------------------|
| Leasehold improvements                          | \$ 671            | \$ 671               |
| Laboratory equipment and other                  | 5,265             | 5,261                |
| Total property and equipment, at cost           | 5,936             | 5,932                |
| Less: Accumulated depreciation and amortization | 4,616             | 4,460                |
| Property and equipment, net                     | \$ 1,320          | \$ 1,472             |

Depreciation and amortization expense on property and equipment was approximately \$0.2 million in each of the three months ended March 31, 2018 and 2017. There were no non-cash property additions during the three months ended March 31, 2018 and less than \$0.1 million in non-cash property additions during the three months ended March 31, 2017.

## Note 6. Accrued Expenses

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

| (In thousands)                          | March 31,<br>2018 | December 31,<br>2017 |
|---|-------------------|----------------------|
| Payroll and related costs               | \$ 1,569          | \$ 3,108             |
| Clinical and nonclinical trial expenses | 5,177             | 3,495                |
| Professional and consulting fees        | 3,328             | 1,317                |
| Other                                   | 150               | 80                   |
| Total Accrued expenses                  | \$ 10,224         | \$ 8,000             |

## Note 7. Stockholders' Equity

## 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 March 31, 2018 and December 31, 2017, all of the Company's outstanding warrants were equity-classified.

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

| Description                               | Number of Shares  |                      | Weighted-Average<br>Exercise Price | Expiration Date |
|---|-------------------|----------------------|------------------------------------|-----------------|
|   | March 31,<br>2018 | December 31,<br>2017 |                                    |                 |
| Issued in May 2013 financing (1)          | 1,200,000         | 21,606,327           | 0.47                               | May 2018        |
| Issued in May 2013 financing (pre-funded) | 15,816,327        | 15,816,327           | 0.01                               | May 2020        |
| Issued in September 2013 financing        | 4,175,975         | 4,175,975            | 0.01                               | Sep 2020        |
| Issued in February 2014 financing         | 2,158,750         | 2,158,750            | 0.01                               | Feb 2021        |
| Total                                     | 23,351,052        | 43,757,379           |                                    |                 |

(1) Subsequent to March 31, 2018, the holder of the remaining May 2013 financing warrants, a related party, exercised these warrants as more fully described in Note 13.

Table of Contents

## Note 7. Stockholders' Equity (Continued)

The table below is a summary of the Company's warrant activity for the three months ended March 31, 2018:

|                                  | Number of<br>Warrants | Weighted-Average<br>Exercise Price |
|----------------------------------|-----------------------|------------------------------------|
| Outstanding at December 31, 2017 | 43,757,379            | \$ 0.24                            |
| Issued                           | —                     | —                                  |
| Exercised (1)                    | (20,406,327)          | 0.47                               |
| Expired                          | —                     | —                                  |
| Outstanding at March 31, 2018    | 23,351,052            | \$ 0.03                            |

- (1) During the three months ended March 31, 2018, a related party exercised certain of these warrants as more fully described in Note 11.

## Note 8. Alliance Revenue

Alliance revenue for the three months ended March 31, 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 3. 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 months ended March 31, 2018 and 2017, Alliance revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

| (In thousands)            | Three months<br>ended<br>March 31, |        |
|---------------------------|------------------------------------|--------|
|                           | 2018                               | 2017   |
| GSK collaboration (1)     | \$ 142                             | \$ 371 |
| Vivelix collaboration (2) | 56                                 | —      |
| Other (3)                 | 57                                 | 7      |
| Total Alliance revenue    | \$ 255                             | \$ 378 |

- (1) For the three months ended March 31, 2018, revenue recognized primarily relates to the amortization of the deferred up-front payment received at inception of the GSK Agreement, as more fully described in Note 9. For the three months ended March 31, 2017, revenue recognized includes \$0.3 million related to the amortization of the deferred up-front payment and \$0.1 million related to additional research services provided in connection with the arrangement.
- (2) For the three months ended March 31, 2018, revenue recognized relates to services provided under the research program provided for under the Vivelix Agreement, as more fully described in Note 9.
- (3) For each of the three months ended March 31, 2018 and 2017, revenue recognized relates to 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.