IDERA PHARMACEUTICALS, INC.
Form 10-K
March 07, 2018
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the Fiscal Year Ended December 31, 2017

OR

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

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	04-3072298
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

167 Sidney Street	02139
Cambridge, Massachusetts	(Zip Code)
(Address of principal executive offices)	

(617) 679-5500

(Registrant's telephone number, including area code)

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

Title of Class:	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Act. Yes No

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 the 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer	Accelerated filer	Non-accelerated filer (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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $203,037,675 based on the last sale price of the registrant’s common stock as reported on the Nasdaq Capital Market on June 30, 2017 (the last business day of the registrant’s most recently completed second fiscal quarter).

As of February 15, 2018, the registrant had 195,635,196 shares of common stock outstanding.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Form 10-K) and the documents we incorporate by reference contain 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, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” “would” and simi are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part I, Item 1A “Risk Factors.” These factors and the other cautionary statements made in this Annual Report on Form 10-K and the documents we incorporate by reference should be read as being applicable to all related forward-looking statements whenever they appear in this Annual Report on Form 10-K and the documents we incorporate by reference.

This Annual Report on Form 10-K 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, and these risks, as well as other risks associated with the pending transaction, are more fully disclosed 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 U.S. Securities and Exchange Commission 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 Annual Report on Form 10-K is filed with the Securities and Exchange Commission 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.

Item 1.Business.

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 nucleic acid chemistry technology (formerly referred to as 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 nucleic acid chemistry technology, we are developing drug candidates to turn off the messenger RNA, or mRNA, associated with disease causing genes. We believe our nucleic acid chemistry 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, via intra-tumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company. We are also investigating the combination of intra-tumoral IMO-2125 in combination with pembrolizumab for the treatment of anti-PD1 refractory metastatic melanoma and intratumoral IMO-2125 in various solid tumors as monotherapy. We are developing IMO-8400 for the treatment of dermatomyositis.

Nucleic Acid Chemistry Technology Platform

We are developing our nucleic acid chemistry technology to “turn off” the mRNA associated with disease causing genes. We have designed gene silencing oligonucleotides to specifically address challenges associated with earlier generation antisense and RNAi technologies.

We have selected IDRA-008 as our first nucleic acid chemistry research program candidate that we plan to enter into clinical development. IDRA-008 targets the Apolipoprotein C-III (APOC-III) gene and is being developed for the treatment of Familial Chylomicronemia Syndrome (FCS) and Familial Partial Lipodystrophy (FPL) which have available pre-clinical animal models and well-known clinical endpoints. We expect our development decision to be made based on the totality of IND-enabling studies and our comparator pharmacology study with the competitive development asset Volanesorsen.

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Agreement and Plan of Merger

As further described in Note 17 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, on January 21, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with BioCryst Pharmaceuticals, Inc., a Delaware corporation, or BioCryst, Nautilus Holdco, Inc., a Delaware corporation and a direct, wholly owned subsidiary of BioCryst, or Holdco, Island Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, or Merger Sub A, and Boat Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, or Merger Sub B. 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 us, or the Idera Merger, with us surviving as a wholly owned subsidiary of Holdco, and (b) Merger Sub B will be merged with and into BioCryst, or the BioCryst Merger, which we refer to together with the Idera Merger as the Mergers, with BioCryst surviving as a wholly owned subsidiary of Holdco. Holdco will be renamed prior to the closing of the Mergers.

At the effective time of the Mergers, which we refer to as the Effective Time, (i) each share of common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time (other than the shares that are owned by us, BioCryst, Holdco, Merger Sub A or Merger Sub B or any wholly owned subsidiary of ours, BioCryst, Holdco, Merger Sub A or Merger Sub B) will be converted into the right to receive 0.20 of a newly issued share of common stock, par value $0.01 per share, of Holdco and (ii) each share of preferred stock, par value $0.01 per share, issued and outstanding immediately prior to the Effective Time (other than the shares that are owned by us, BioCryst, Holdco, Merger Sub A or Merger Sub B or any wholly owned subsidiary of ours, BioCryst, Holdco, Merger Sub A or Merger Sub B) will be converted into the right to receive an amount of Holdco common stock based on their liquidation preference.

We expect to consummate the Mergers in the second quarter of 2018. However, we have prepared this Annual Report on Form 10-K and the forward-looking statements contained in this Annual Report on Form 10-K as if we were going to remain an independent company.

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Research and Development Programs

The following table summarizes certain information regarding our drug candidates and development programs.

Drug Candidate(s)	Indication / Application	Development Status
Clinical Programs for the Modulation of Specific Toll-like Receptors		