

BIOCRYST PHARMACEUTICALS INC

Form 425

March 07, 2018

Filed by Idera Pharmaceuticals, Inc. pursuant to Rule 425

Under the Securities Act of 1933

and Deemed Filed Pursuant Rule 14a-12

Under the Securities Exchange Act of 1934

Subject Company: BioCryst Pharmaceuticals,

Commission File No. of Subject Company: 000-23186

**Idera Pharmaceuticals Reports Fourth Quarter and Year End 2017 Financial Results and Provides Corporate Update**

**EXTON, PA and CAMBRIDGE, MA March 7, 2018** Idera Pharmaceuticals, Inc. ( Idera ) (NASDAQ: IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel nucleic acid-based therapeutics for oncology and rare diseases, today reported its financial and operational results for the fourth quarter and year ended December 31, 2017.

Our company made tremendous progress throughout 2017 advancing our development programs and we expect the first half of 2018 to be marked by a number of key inflection points for each of these programs, stated Vincent Milano, Idera's chief executive officer. In 2018, we are continuing to enroll patients in the ILLUMINATE 204 Phase 2 trial of IMO-2125, with the next planned data update at ASCO and completion of enrollment expected by year end. We also recently initiated the Phase 3 ILLUMINATE 301 trial. For IMO-8400, we plan to report top-line data from our Phase 2 trial in dermatomyositis by the end of the 2nd quarter. We also intend to finalize our development plans for our lead nucleic acid chemistry research candidate, IDRA-008 shortly, continued Milano.

In January, we announced our proposed merger with BioCryst Pharmaceuticals, Inc. that we believe will build greater and more sustainable value for the benefit of stockholders as well as patients with rare diseases beyond what we could achieve alone. The Idera Board determined this combination was compelling from both a strategic and financial perspective following a careful evaluation of a range of strategies to enhance long-term stockholder value. The transaction will create a leading rare disease company with a robust pipeline including two promising Phase 3 rare disease programs and combines synergistic discovery engines that will not only expand the number of rare diseases we can target but create meaningful opportunities for differentiation in the market through joint small molecule and

oligo treatments. Importantly, joining with BioCryst will also enable us to achieve cost synergies and increase our financial strength and flexibility, Milano expressed.

**Clinical Development Program Updates:**

**ILLUMINATE (IMO-2125) Clinical Development**

**ILLUMINATE 204** Phase 1/2 trial of IMO-2125 in combination with ipilimumab or pembrolizumab in patients with PD-1 refractory metastatic melanoma:

- As of March 7, 2018, enrolled 26 patients at 8 mg (RP2D) dose with ipilimumab, enrollment completion expected by year end 2018;
  - 5 of the first 10 evaluable patients at the 8 mg dose of IMO-2125 were responders (50% Overall Response Rate [ORR]);
-

- 7 trial sites currently enrolling patients with goal of expansion to 10 sites during first half of 2018;
- In pembrolizumab combination arm of the trial, phase 1 dose escalation continues into the last dosing cohort (32 mg); and
- Next clinical data update expected at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018.

**ILLUMINATE 101** Phase 1b trial of intratumoral IMO-2125 monotherapy in patients with refractory solid tumors:

- Completed enrollment in first two cohorts (11 patients treated with 8 mg dose of IMO-2125, 8 patients treated with 16 mg dose of IMO-2125);
- Two subjects in cohort 1 (8 mg) continue IMO-2125 monotherapy on the 101 study as of March 7, 2018; and
- Enrollment of third cohort has commenced (8 patients to be treated with 23 mg dose of IMO-2125).

**ILLUMINATE 301** Randomized phase 3 trial of IMO-2125 in combination with ipilimumab versus ipilimumab alone in patients with PD-1 refractory metastatic melanoma:

- Trial initiated in Q1 2018;
- Approximately 80 sites planned for trial participation across 12 countries;
- Planned enrollment of approximately 300 patients with Overall Response Rate (ORR) and Overall Survival (OS) as primary endpoints; and

- U.S. Food and Drug Administration granted Fast Track Designation for IMO-2125 in combination with ipilimumab for treatment of PD-1 refractory metastatic melanoma in fourth quarter of 2017.

**Pioneer (IMO-8400) Development Activities**

**PIONEER** Phase 2 trial of IMO-8400 in adult patients with dermatomyositis:

- Enrollment concluded during Q3 2017 (30 patients); and
- Topline phase 2 trial data expected in Q2 2018.

**Nucleic Acid Chemistry Research Group**

**IDRA-008 Development Activities:**

- Selected apolipoprotein C-III (APOC-III) as first gene target for development for treatment of familial chylomicronemia syndrome (FCS) and familial partial lipodystrophy (FPL);
  - Completion of pre-clinical toxicology and IND-enabling studies in Q1 2018;
  - Pre-clinical pharmacology study in cyno-model comparing IDRA-008 to competitive clinical development asset, volanesorsen expected to readout towards the latter part of Q1 2018;
  - Development decision for IDRA-008 expected during Q2 2018; and
-

- The Company is continuing to evaluate rare-disease opportunities for application of its core nucleic acid chemistry research capability and expertise to yield innovative oligonucleotide therapeutic concepts that address significant unmet medical needs.

## Financial Results

### Fourth Quarter Results

Net loss applicable to common stockholders for the three months ended December 31, 2017 was \$14.9 million, or \$0.09 per basic and diluted share, compared to net income applicable to common stockholders of \$0.8 million, or \$0.01 per basic and diluted share, for the same period in 2016. Revenue in the fourth quarter of 2017 was nominal and primarily related to our collaboration with GSK. Revenue in the fourth quarter of 2016 was \$15.3 million, primarily related to the agreement we entered into with Vivelix in November 2016 in which we received an upfront, non-refundable fee of \$15 million. Research and development expenses for the three months ended December 31, 2017 totaled \$10.4 million compared to \$11.0 million for the same period in 2016. General and administrative expense for the three months ended December 31, 2017 totaled \$4.8 million compared to \$3.5 million for the same period in 2016.

### Full Year Results

Net loss applicable to common stockholders for the year ended December 31, 2017 was \$66.0 million or \$0.42 per basic and diluted share, compared to net loss applicable to common stockholders of \$38.4 million, or \$0.30 per basic and diluted share, for the same period in 2016. Revenue for the year ended December 31, 2017 was \$0.9 million compared to revenue of \$16.2 million for the same period in 2016. Revenue in the 2017 period primarily related to our collaboration with GSK. Revenue in the 2016 period primarily related to collaborations with both GSK and Vivelix, including an upfront, non-refundable fee of \$15 million received in connection with the Vivelix Agreement. Research and development expenses for the year ended December 31, 2017 totaled \$50.7 million compared to \$39.8 million for the same period in 2016. General and administrative expenses for the year ended December 31, 2017 totaled \$16.7 million compared to \$15.1 million for the same period in 2016.

As of December 31, 2017, our cash, cash equivalents and investments totaled \$112.6 million compared to \$109.0 million as of December 31, 2016. We currently anticipate that, based on our current operating plan and without taking into account the transaction with BioCryst, our existing cash, cash equivalents and investments will fund our operations into the second quarter of 2019.

### Corporate Updates:

On January 22, 2018, BioCryst Pharmaceuticals, Inc. (BioCryst) and Idera jointly announced the signing of a definitive merger agreement to create a company focused on the development and commercialization of medicines to serve patients suffering from rare diseases. The combined company will be renamed upon closing, and will be led by Vincent Milano, the current chief executive officer of Idera. Jon Stonehouse, the current chief executive officer of BioCryst, will serve as a member of the Board of Directors. The transaction is subject to approval by the stockholders of both companies, as well as the satisfaction of customary closing conditions. The transaction is expected to be completed by the

end of the second quarter of 2018.

---

## About Idera

Harnessing the approach of the earliest researchers in immunotherapy and the Company's vast experience in developing proprietary immunology platforms, Idera's lead development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera continues to invest in research and development, and is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from rare, life-threatening diseases. To learn more about Idera, visit [www.iderapharma.com](http://www.iderapharma.com).

## Additional Information and Where to Find It

In connection with the proposed mergers, Nautilus Holdco, Inc. (Holdco) has filed with the U.S. Securities and Exchange Commission (the SEC) a Registration Statement on Form S-4 (as may be amended from time to time, the Registration Statement) that includes the preliminary joint proxy statement/prospectus of BioCryst and Idera and that also will constitute a prospectus of Holdco. These materials are not yet final and will be amended. Once the Registration Statement is declared effective by the SEC, each of BioCryst and Idera will mail the definitive joint proxy statement/prospectus included therein to their respective stockholders. BioCryst, Idera and Holdco will also file other documents with the SEC regarding the proposed transaction. These documents are not substitutes for the definitive joint proxy/prospectus that will be filed by each of BioCryst and Idera with the SEC and mailed to stockholders. **BEFORE MAKING ANY VOTING DECISION, IDERA'S AND BIOCRYST'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF IDERA AND BIOCRYST WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGERS OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION.** Investors and stockholders may obtain free copies of these materials and other documents filed with the SEC (when available) by BioCryst, Idera and Holdco through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Idera and BioCryst make available free of charge at [www.iderapharma.com](http://www.iderapharma.com) and [www.biocryst.com](http://www.biocryst.com), respectively (in the Investors section), copies of materials they file with, or furnish to, the SEC.

## Participants in the Solicitation

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Idera, BioCryst and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Idera and BioCryst in connection with the proposed mergers. Security holders may obtain information regarding the names, affiliations and interests of Idera's directors and officers in Idera'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 and its definitive proxy statement for the 2017 annual meeting of stockholders, which was filed with the SEC on April 28, 2017. Security holders may obtain information regarding the names, affiliations and interests of BioCryst's directors and officers in BioCryst's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on February 27, 2017 and its definitive proxy statement for the 2017 annual meeting of stockholders, which was filed with the SEC on April 12, 2017. Additional

---

information about the interests of BioCryst's directors and officers and Idera's directors and officers in the proposed mergers can be found in the above-referenced Registration Statement. These documents may be obtained free of charge from the SEC's website at [www.sec.gov](http://www.sec.gov), Idera's website at [www.iderapharma.com](http://www.iderapharma.com) and BioCryst's website at [www.biocryst.com](http://www.biocryst.com).

### **Forward-Looking Statements**

This press release 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. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's merger with BioCryst and the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans, and objectives of management, are forward-looking statements. The words believes, anticipates, estimates, plans, expects, intends, could, should, potential, likely, projects, continue, will, and would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether the Company consummates its merger with BioCryst; whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary results reported in this release, will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results described in this release will be indicative of the results that will be generated in future clinical trials, including in clinical trials in different disease indications; whether products based on Idera's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and such other important factors as are set forth under the caption "Risk factors" in the Registration Statement and the Company's Annual Report on Form 10-K filed on March 15, 2017. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

---



**Idera Pharmaceuticals, Inc.****Condensed Statements of Operations****(In thousands, except per share data)**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Alliance revenue	\$ 173	\$ 15,281	\$ 902	\$ 16,199
Operating expenses:				
Research and development	10,365	11,007	50,653	39,824
General and administrative	4,828	3,531	16,716	15,132
Total operating expenses	15,193	14,538	67,369	54,956
(Loss) income from operations	(15,020)	743	(66,467)	(38,757)
Other income (expense), net	94	79	483	368
Net (loss) income	\$ (14,926)	\$ 822	\$ (65,984)	\$ (38,389)
Net (loss) income per common share applicable to common stockholders				
Basic	\$ (0.09)	\$ 0.01	\$ (0.42)	\$ (0.30)
Diluted	\$ (0.09)	\$ 0.01	\$ (0.42)	\$ (0.30)
Weighted-average number of common shares used in computing net (loss) income per share applicable to common stockholders				
Basic	157,398	146,255	157,398	127,597
Diluted	157,398	151,930	157,398	127,597

**Idera Pharmaceuticals, Inc.****Condensed Balance Sheet Data****(In thousands)**

	December 31,	
	2017	2016
Cash, cash equivalents and investments	\$ 112,629	\$ 109,014
Other assets	5,788	4,217
Total assets	\$ 118,417	\$ 113,231
Total liabilities	\$ 10,722	\$ 9,882
Total stockholders' equity	107,695	103,349
Total liabilities and stockholders' equity	\$ 118,417	\$ 113,231

Source: Idera Pharmaceuticals, Inc.

---

IDERA PHARMACEUTICALS Contact:

Robert A. Doody, Jr.

VP, Investor Relations & Communications

Phone (617) 679-5515

RDOODY@IDERAPHARMA.COM

---