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BIOCRYST PHARMACEUTICALS INC

Form 425

April 02, 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, Inc.

Commission File No. of Subject Company: 000-23186

The following includes a transcript of a presentation made by Jon Stonehouse, Chief Executive Officer of BioCryst Pharmaceuticals, Inc. ( BioCryst ), and Vin Milano, Chief Executive Officer of Idera Pharmaceuticals, Inc. ( Idera ), at the 17th Annual Needham Healthcare Conference on March 27, 2018.

<<Analyst, Needham & Company, LLC>>

Alright, thanks for coming. Welcome to the 17th Annual Needham Healthcare Conference. I would like to introduce Jon Stonehouse, CEO of BioCryst.

<<Jon Stonehouse, President, Chief Executive Officer>>

Thank you Steve. And thanks to Needham for inviting us to present at this year's Needham Healthcare Conference. I'll be focusing this presentation on our proposed merger with Idera. And I have the good fortune of having Vin Milano the CEO of Idera to join me in this presentation.

So both companies Idera and BioCryst have a long history and both companies have explored different therapeutic areas over that long history. But the recent focus, probably the last five years for BioCryst and maybe the last couple for Idera has been to build a rare disease company. And the combination of our two companies, will build a powerhouse company that can provide more patients with rare disease unique and important therapies.

To learn more about our proposed merger, you can look at additional information, and where to find it on Slide 2. I would strongly encourage you to read the S4 that we recently updated because it has a lot of information on the rationale, the background, and valuation of the deal.

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Of course, I'll be making some forward-looking statements. Those statements have risks and the risk factors can be found in our most recent filings on our website and the SEC website.

So, what is this, why does this merger in combination create sustainable value. The first point is it gives us the scale and the competitive strength to build a very unique rare disease company. And that's important because the rare disease therapeutic area is getting more crowded and being competitive and having scale matters to be successful.

We have the opportunity to have more assets in the portfolio in the combined company and that allows us to have more opportunities to bring innovative medicines to the market which creates value and it also spreads the risk. So, another important reason for the combination.

Both companies have spent decades refining their craft in respective discovery engines, the oligonucleotide platform at Idera and the structure based drug design at BioCryst and

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together we can do more. And together we may be able to go to unique targets that alone we otherwise couldn't.

We're bringing together two really experienced teams both on the commercial side and the clinical side. And lastly the combination of these two companies gives the new company much greater financial, flexibility and financial strength. And I'll go into more detail about that in a bit.

So on Slide 5, are some highlights of the combination. It's a stock for stock transaction, it's basically a merger of equals. Based on the fully diluted share count as of the announcement on January 22, BioCryst shareholders get slightly more of the new company than Idera. The company as I said before will have a good amount of cash on the balance sheet but the opportunity to bring in additional and I'll talk about that in a minute.

A very experienced board, Vin will be the new CEO of a company that will be named Valenscion and I'll let him later describe the meaning behind that name. It will be headquartered in Exton, Pennsylvania and the research center will be in Birmingham Alabama. Obviously the closing of the deal is subject to shareholder votes at both Idera and BioCryst. We have an important voting support agreement from our largest shareholder of both companies. And lastly we expect the deal to close in the second quarter.

It's a really balanced combination of companies. Both companies bring a lot to the table. If you look at BioCryst, we've got this desire to bring oral drugs for rare diseases forward and Idera has been a pioneer in the area of oligonucleotides and again these two discovery engines bring unique approaches to go after different targets but combined may add even more.

It's a pipeline that you'll see in a couple of slides that's very full, two Phase 3 programs in the combined company and other programs behind it. And both companies have Phase 3 ready assets that we think are the diamonds of each company that will add the near term value to the combined company.

The building blocks for building this patient centric rare disease company are the robust pipeline that we have with this combination, the synergy of the two discovery engines, the financial strength and the compliment of leadership between the two companies. I'll go into each of these in a bit more detail.

So, let me spend a little bit of time talking about the two lead programs. There's differences around these programs, there's similarities and then there's a fit. Let me start with the similarities. Both programs are entering Phase 3, we made announcements in the first quarter. Vin and I made a commitment that we would keep the trains running on time and that we would do no harm to the lead programs and we're off to a good start in the new year by getting our Phase 3 studies up and running.

Both programs bring meaningful value to both companies. It's slightly different with IMO-2125 in that it could be applied to many, many different tumor types, which creates much greater value in terms of dollar and patient potential to treat. But it also goes beyond the financial capabilities of even the combined company to be able to exploit that. And, so I'll talk a bit more about the plans for that in a minute.

On the BioCryst side, we've got a market that we can manage. A rare disease market a prophylaxis for HAE potentially even acute treatment of HAE and with the team from Idera, the former viral pharma team that actually was the pioneer in building the prophylaxis market. We think even in a competitive space that we can be very competitive with this profile.

Both programs have what I would say are really strong datasets, they are different but they're both very supportive that these drugs work as advertised. On the BioCryst side there's a randomized controlled clinical trial, we've referred to as APeX-1. On the Idera side there's a number of different datasets that lead to convincing response rates and also supporting translational data that leads us to conclude that 2125 will not only work in metastatic melanoma, refractory melanoma but also in another tumor types by turning cold tumors hot.

And then lastly, as I said before the opportunity and the potential for creating real value with the numbers of patients, melanoma alone in the refractory setting could be around 8,000 patients. With HAE it is around 6,000 to 7,000 patients. But you go beyond melanoma with 2125 and you're getting up to 15,000, 18,000 patients in head and neck and bladder and there's a real broad opportunity to go after many more patients that are suffering from these cancers.

As, I said before and this is one of the things that was really exciting for us when we started talking to Idera. Is they recognized that to fully exploit this compound and to get it to as many patients suffering from as many cancers as possible that it's got to be put in the hands of somebody that has the capital and the experience and the resources to fully develop it and fully commercialize it and compete. And so the plan is to take that generate data that's compelling and then ultimately do a pretty standard licensing deal with upfront payment, clinical milestones, and royalties that will bring in cash into the combined company.

There may be a situation where the new company retains metastatic melanoma because that's about the size of a rare disease commercial effort but that'll be a matter of economics at the end of the day in terms of what the deal looks like in out licensing to a potential partner. And so, the fit that I think is most exciting about this combination the synergy, if I can use that word is that we'll be able to use the capital that comes from what I would call not only upfront payments but steady cash flow from milestones and eventually royalties to fund not only the launch of 7353 but to continue to fund the rest of the pipeline for the new company Valenscion.

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There's also what I would refer to as things, that make the whole greater than the sum of the parts in this key combination or merger amplifier's as we refer to. So, if you look at Slide 9, I've already talked about the fact that we've got a great profile with our one pill once a day, prophylactic therapy with 7353. But let's not fool ourselves, it's a competitive marketplace. Shire is playing in this space, CSL is playing in this space and having the expertise of Vin, Dan Solen and the team that created the HAE prophylactic market will be very useful in combination with Lynne Powell and her team's experience in other rare diseases including HAE.

Having the ability as I said before to take capital through other non-dilutive licensing opportunities whether it's the deal I talked about with 2125 or our plan is to out license Japanese rights for 7353, that capital to be able to either invest in the pipeline or invest in the launch of our compound is extremely important in a merger amplifier as well. I have talked about the ability to spread risk over more assets in the portfolio. And I've also talked about the complement of the discovery engines but let me go into that in a bit more detail.

So, as I said before both companies have spent decades refining their skills on the Idera side on oligonucleotide on the BioCryst side structure based drug design. At BioCryst we knew that at some point we would hit a limit to the number of rare diseases we could go after with a small molecule on an enzyme target by blocking that target, there's only so many rare diseases that you can go after and at some point we would hit a wall.

With the oligonucleotide platform from Idera that allows the new company to go to a number of different places that BioCryst alone could not have gone to. But what's really interesting is when you combine the two together and this is more in the hypothesis stage but it's certainly worth testing which is can we take an oligonucleotide that primarily goes to the liver or the kidney somewhere else by linking it to a small molecule that has a receptor to some other part of the body that could be a unique approach that others might not be able to do.

Can we use an oligo in a small molecule on different targets in the same disease to be able to treat disease more effectively, the example that I've used in the past is FOP, we know that the bad actor in that disease is ALK2, we have an ALK2 in early preclinical development but if you can adjust the ALK2 dosage by hitting the disease with an anti-inflammatory like 8400 from Idera that might be a really nice combination for tackling FOP. So we see a lot of real synergy in the combined discovery efforts.

As I mentioned before in a picture paints a thousand words if you look on Slide 7, clearly it's a much bigger pipeline of both rare disease compounds, as well as supportive assets for bringing in additional capital into the company and so not only opportunity to have more drugs to get to market but to spread risk.

And then beyond the two lead programs 7353 for prophylaxis and 2125 in various tumor types, there's more compounds granted on a higher risk basis in terms of their earlier stage of development. But very interesting from our perspective and if they hit could

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create real upside for the new company in that 7353 with our liquid oral formulation for acute attacks where we're currently running a study called ZENITH. And then IMO-8400 for a really nasty disease dermatomyositis where read out will come towards the end of the second quarter.

I mentioned before the track record and the complement of skills, as I said Vin and Dan building the prophylaxis market. Lynne with experience at CSL on a number of different compounds including HAE compounds as she's worked on in the past, the clinical group of Bill and Joanna and then Business Development with Clayton Fletcher really build out a very nice and experienced leadership team.

And then in terms of catalysts and what you can expect from the new company, there's just more with the combined company. We had said when we announced this merger that we keep the trains running on time. And as I said before, we both recently announced the start of in the case of Idera, the start of the Phase 3 trial for 2125 and in the case of 7353 in BioCryst the start of APeX-2, it will be a readout as I said before of 8400 in its Phase 2 study the end of second quarter. There will be read out of an ongoing Phase 2 trial around the time of ASCO an abstract has been submitted, if it's accepted it will be at that time, if not it will be around that time at ASCO. And then in the second half of this year, we'll be reading out the 750 milligram of the high dose cohort for ZENITH and those results and then ongoing results on 2125 and any progress on strategic partnerships. So a number of different near-term value building events.

I mentioned before that the combined company as a pro forma cash balance of 243 million at the end of last year but there's opportunities to bring in additional capital, that capital gets us into the third quarter of 2019, the combined company. We've already seen some additional capital being brought into Idera with the exercise of some options that brought in what was \$9.5 million. There's an opportunity to refinance the mid-cap debt that BioCryst has which is another \$23 million. This plan the runway that I described assume that we'd have to pay that off but it's highly likely that we'll be able to refinance that in the new company.

There's an opportunity to bring additional capital through the replenishment of the 2009 U.S. government stockpile of, wrap of that and we expect that we'll know a lot more about the procurement of that this year and some other opportunities that in total could range anywhere from 50 to 60 maybe even north of \$60 million in additional capital that gives us extended runway and gives us more time to do the next piece, which I think is even bigger chunk of capital that could be brought into the company and that is get some partnerships done to bring real capital into the company.

I talked about 2125 and I also mentioned that we're going to be looking for a partner for 7353 in Japan. You have more leverage when you have more data and you create more competition having that additional capital in a longer runway allows the new company to have that leverage. So stay tuned on that front.

We got really good reviews when we came out of the gate from our analysts, in particular at BioCryst covering us and understood the value of the combination. And the value of all the things that I've just shared with you, Vin and I and Bill Sheridan and then Bob Doody and others have been spending a lot of time on the road. And I think we're becoming increasingly confident that there's a lot of support by investors for this deal.

And the last I think important point is could we have considered doing something else and both companies did, both companies have had a similar philosophy that combining two companies could make a stronger, better, higher value, sustainable value company. And so if you read the S-4 in the background section, you'll get a sense of the path that both companies and their boards took and how we landed on combining these two companies together as the best option.

And so as I said at the beginning really what is driving creating sustainable value with this combination is this scale and competitive position to make us a unique rare disease player, having more assets in a broader portfolio to diversify the pipeline and spread risk and have the opportunity to bring more things to the market. The synergy with the discovery engines, the compliment of the skill set of the leadership. And lastly the strength and flexibility financially that the combined company has.

So we're really excited about combining these two companies from an integration planning standpoint, we're making great progress and it's full speed ahead to the closing of this deal. So Vin, I don't know if you want to add any other comments.

<<Vincent Milano, Chief Executive Officer>>

Thanks Jon. I would just echo a couple of things that Jon said is first of all, I'm very excited to be part of what we're creating here with Valenscion. But I take back to my days with ViroPharma, lives a long journey there 18 years, watched the company go up, go down, go up, go down. And what are the some of the things I learned, I learned that you need to have a strong balance sheet to survive.

Valenscion is going to have a strong balance sheet, you need to have options in your portfolio, Valenscion is going to have lots of options. But probably the most important ingredient is people and shared purpose ingredients. And what unique about what Jon and I are trying to put together here with the rest of our teams is that we have a shared purpose around patients with an appreciation for what I call compassionate capitalism, the more patients that we treat, the more money we can make and the better our shareholders will do.

So it's really a great combination here and having the ability to reflect and look in the mirror, we are both small companies and Valenscion, we are going to still be a small company but twice the size of either of our companies alone. The ability for us to focus and deliver to the marketplace products that matter to patients is actually what drives ultimately what we're trying to do here. And I think if we—as we look at both 7353 for hereditary angioedema, which I have a history with and a depreciation for and 2125 in

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PD-1 refractory melanoma. These are two very, very attractive products for the patient and docs who treat these patients.

So we're off to a great start, it's hard to actually believe that you can create a startup company with all the ingredients that we're going to be able to create Valenscion with. So we are extremely excited about it, we've been on the road together quite a bit in the last eight weeks. But it's been a great, great process so far we look forward to getting it done and getting to work. So I appreciate you give me the chance to be here with you guys today, I look forward to giving you the first Valenscion update after we close the deal. Thanks Jon.

<<Jon Stonehouse, President, Chief Executive Officer>>

Sure. So we've got a few minutes left, I don't know if there are any questions. Yes?

Q&A

<Q>: The history on the name?

<A Jon Stonehouse>: Yeah, yeah, the history on the name.

<A Vincent Milano>: So the name Valenscion is a combination of two words, the first part of the word is Valens, Latin for strong, powerful, healthy and effective. And the second part of the name Cion is descendant of a notable family and we feel like we're two descendants creating this notable family and created the word Valenscion.

<<Analyst, Needham & Company, LLC>>

Great, there are no more questions. Thanks for your interest.

<<Vincent Milano, Chief Executive Officer>>

Thank you very much.



<<Jon Stonehouse, President, Chief Executive Officer>>

Have a good day.

**About BioCryst Pharmaceuticals**

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule medicines that address both common and rare conditions. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, galidesivir, a potential treatment for filoviruses, and a preclinical program to develop oral Alk-2 inhibitors for the treatment of fibrodysplasia ossificans progressive (FOP). RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of

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influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Japan, Taiwan and Korea. Post-marketing commitments for RAPIVAB are ongoing, as well as activities to support regulatory approvals in other territories. For more information, please visit the Company's website at [www.BioCryst.com](http://www.BioCryst.com).

### **About Idera Pharmaceuticals**

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 ), and the SEC has declared effective on March 29, 2018, a Registration Statement on Form S-4 (as may be amended from time to time, the Registration Statement ) that includes the joint proxy statement of BioCryst and Idera and that also constitutes a prospectus of Holdco. BioCryst, Idera and Holdco may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the definitive joint proxy statement/prospectus or Registration Statement or any other document that may be filed by each of BioCryst and Idera with the SEC. BEFORE MAKING ANY VOTING DECISION, IDERA'S AND BIOCRYST'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE 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 TRANSACTION OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY 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

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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, 2017, which was filed with the SEC on March 7, 2018 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, 2017, and any amendments thereto, which was filed with the SEC on March 12, 2018 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 the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties, and important factors that could cause actual events or results to differ materially from Idera's or BioCryst's plans, estimates or expectations. Given these uncertainties, you should not place undue reliance on these forward-looking statements. With respect to the transactions contemplated by the merger agreement between Idera and BioCryst, these factors could include, but are not limited to: (i) Idera or BioCryst may be unable to obtain stockholder approval as required for the mergers; (ii) conditions to the closing of the mergers may not be satisfied; (iii) the mergers may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement of the mergers on the ability of Idera or BioCryst to retain and hire key personnel and maintain relationships with patients, doctors and others with whom Idera or BioCryst does business, or on Idera's or BioCryst's operating results and business generally; (v) Idera's or BioCryst's respective businesses may suffer as a result of uncertainty surrounding the mergers and disruption of management's attention due to the mergers; (vi) the outcome of any legal proceedings related to the mergers; (vii) Idera or BioCryst may be adversely affected by other economic, business, and/or competitive factors; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; (ix) risks that the mergers disrupt current plans and operations and the potential difficulties in employee retention as a result of the mergers; (x) the risk that Idera or BioCryst may be unable to obtain governmental and regulatory approvals required for the transactions, or that required governmental and

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regulatory approvals may delay the transactions or result in the imposition of conditions that could reduce the anticipated benefits from the transactions contemplated by the merger agreement or cause the parties to abandon the transactions contemplated by the merger agreement; (xi) risks that the anticipated benefits of the mergers or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (xii) the impact of legislative, regulatory, competitive and technological changes; (xiii) risks relating to the value of the new holding company shares to be issued in the mergers; (xiv) expectations for future clinical trials, the timing and potential outcomes of clinical studies and interactions with regulatory authorities; (xv) the risk that the credit ratings of the combined company or its subsidiaries may be different from what the companies expect; (xvi) economic and foreign exchange rate volatility; (xvii) the continued strength of the medical and pharmaceutical markets; (xviii) the timing, success and market reception for Idera's and BioCryst's products; (xix) the possibility of new technologies outdating Idera's or BioCryst's products; (xx) continued support of Idera's or BioCryst's products by influential medical professionals; (xxi) reliance on and integration of information technology systems; (xxii) the risks associated with assumptions the parties make in connection with the parties' critical accounting estimates and legal proceedings; (xxiii) the potential of international unrest, economic downturn or effects of currencies, tax assessments, tax adjustments, anticipated tax rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs; and (xxiv) other risks to the consummation of the mergers, including the risk that the mergers will not be consummated within the expected time period or at all. These risks, as well as other risks associated with the proposed mergers, are more fully discussed in the joint proxy statement/prospectus included in the Registration Statement filed with the SEC in connection with the proposed mergers. While the list of factors presented here is, and the list of factors presented in the Registration Statement are, considered representative, no such list should be considered a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward looking statements. Consequences of material differences in results as compared with those anticipated in the forward-looking statements could include, among other things, business disruption, operational problems, financial loss, legal liability to third parties and similar risks, any of which could have a material adverse effect on BioCryst's or Idera's consolidated financial condition, results of operations, credit rating or liquidity. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that Idera and BioCryst file from time to time with the SEC. The forward-looking statements in this document speak only as of the date of this document. Except as required by law, Idera and BioCryst assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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