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BIOCRYST PHARMACEUTICALS INC

Form 425

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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 Jefferies 2018 Global Healthcare Conference on June 7, 2018.

<<Brian Tanquilut, Analyst, Jefferies Group LLC>>

Hi, good morning and welcome to the Jefferies Global 2018 Healthcare Conference. My name is Brian. I'm part of the investment banking group here.

It's my great pleasure to introduce you today Jon Stonehouse, CEO of BioCryst Pharmaceuticals.

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

Thanks Brian. Good morning. Thank you to Jefferies for inviting us to this year's Healthcare Conference.

The focus of our presentation today is going to be on our proposed merger with Idera. And I'm fortunate to have with me the CEO of Idera, Vin Milano who will be sharing some of the recent data that was presented at ASCO this week. In addition, on his team Bob Doody, Head of IR and Joanna Horobin, the Chief Medical Officer. And then from BioCryst we have Bill Sheridan our Chief Medical Officer and Tom Staab our Chief Financial Officer.

So that the combination of these two companies, we believe builds a real player in the rare disease space. With the scale and the resources and the assets to compete in bringing forward marketed products with a full pipeline and a discovery engine to backfill that pipeline to patients who are suffering from debilitating rare diseases and are in desperate need for what we have.

And we believe, I believe even stronger, having been to ASCO this week that the assets from the combined company make a much more valuable company. So Slide 2, just gives you the additional information that you need about the merger and where you can find it.

Highly likely that Vin and I will be making some forward-looking statements, those statements have risk factors and the risk factors can be found on the website listed on Slide 3.

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So, as I said at the beginning, we believe that the combination of these two companies can create substantial value for shareholders. First, it's about scale, the two companies combined have the resources, the pipeline, the people, the ability to go after more targets than either of us could do alone.

Quite frankly and Vin and I, have said this multiple times being a small cap public company, going after rare diseases is a tough job right now. And, so having that scale just gives us the opportunity to accelerate creating value and have a higher probability of creating bigger value. You'll see that the combined company has a very full pipeline of both late stage and mid-stage compounds.

There is synergy in the two discovery engines. We can go after more targets because these are two distinctly different approaches to discovering new therapies but in combination, we believe that there's some synergy that can provide unique therapies that perhaps others can't.

The skill set of the team compliments each other and allows us to be competitive in the marketplace, and while we believe we have an asset with 7353 that will be very competitive as an oral agent, where all others are injectable. We're competing with the likes of Takeda and CSL. And that's no small task and so having people that have done this before makes a huge difference.

And then, lastly the access to capital non dilutive capital, the balance sheet that we have are all important things that give us more flexibility as a combined company than either of us alone.

Slide 5, is the combination highlights. I won't go through this in any great detail other than pointing out to you that the cash position has been updated to the March 31 numbers, which is approximately \$204 million in net cash.

So, as I said at the beginning, we want to be a leader in the rare disease space. With this combined company and I think it's pretty obvious at BioCryst that with our HAE program and the desire to leverage our structure based drug design capability to bring oral drugs for rare diseases that we have a novel spot in the rare disease world. I think Idera sometimes gets pigeonholed as an immuno-oncology company. When in fact, the segment of melanoma that they're going after is in fact a very rare disease.

And the desire is to leverage their capability, their discovery capability to build a rare disease company going after therapies for patients with rare disease. So, we're combining the discovery engines, we're combining the pipelines, and we're combining the late stage programs to build something that we think will put us in a very competitive position.

When you look at the pipeline slide on Slide 7, it's obvious, that there's more shots on goal. And anybody who's been in this business long enough knows that you need multiple shots on goal because there's attrition in our business. Some things, don't make it. And so having two Phase 3 compounds, two Phase 2 compounds and some early stage programs

and the ability to put more in the clinic with our two discovery engines is really important in balancing risk for shareholders.

So, if you look at the pipeline in a bit more detail, you see as I said before two Phase 3 compounds and two Phase 2 compounds, which makes it in and of itself more attractive than the two individual companies on their own. I think what's also important is the compounds that we're working on in these late stage clinical programs, are uniquely different, they're in areas of high unmet medical needs.

And where patients are just desperate to get these compounds, when you're in that situation if you're successful in bringing those to market, the likelihood that you're going to create real value is very high, when you have things that patients really want. And we have that with 7353, 2125, the acute treatment for 7353 and 8400 for dermatomyositis.

And Vin will go through in a bit more detail of 2125 in the recent data from ASCO. So with that I will turn it over to Vin.

<<Vin Milano, Chief Executive Officer>>

Thank you Jon. Good morning everyone. How is everyone doing today? I'd like to also extend my thank you to Jefferies for allowing Jon and I to share the stage here this morning to share the story of what we'll call Valenscion should we consummate this merger on July 10.

As Jon mentioned 2125 or it's now known as tilsotolimod is the centerpiece of the Idera part of the contribution here to this merger. And as Jon also shared, we had a very exciting ASCO weekend into the early part of this week, where we provided an update on the data coming out of our Phase 2 part of the study, the program of the ILLUMINATE program for clinical development here.

What's the primary objective here, you may know in PD-1 refractory melanoma there are no drugs approved to treat this condition. These patients are left to clinical trials and physicians judgmental on what alternatives might work. So, we are trying to provide that alternative and the benchmark that we've established for success is 35% objective response rate.

Why did we choose 35% in our Phase 2 study component because of the drug that is used the most in this setting is ipilimumab and the ipilimumab response rate is only 13%. So our belief is that if we can demonstrate at least a 35% response rate in this Phase two open label study, that we can definitively claim that the difference between those two response rates is attributed to tilsotolimod. And, of course one of the challenges in the use of ipilimumab in the real world is its toxicity profile. And so, a secondary objective is to see what the toxicity and tolerability profile of the combination looks like.

So, on this swim lane plot I'm going to show you two charts, you may have seen them if you followed us at ASCO. I am going to show you the swim lane plot and then the



waterfall plot. On this one the headline here is that our objective response rate after the first 21 patients is 38.1%. So north of the 35% target that we've established and importantly again in the real world, is that we have a 71.4% disease control rate, which is the combination of our two complete responders, our six partial responders and then a number of patients who have improved to stable disease.

And what's very important on this slide is if you look at the top patients, that's one of our complete responders, who's now out over two years with his response. Patient was referred to Hospice. His wife begged him to go into one more study, he chose to go into ours and two years later he remains a complete responder. So a highly powerful story for the people of Idera and soon to be Valencion but a very important message here that we see durability of response in the patients that we're treating to-date.

As we move to the second slide here the waterfall plot, I want to highlight the depth of the responses you can see. On the right hand side, we're continuing to see evolving responses and they're getting deeper and deeper. In our pembro combination arm we have one responder out of the first six patients. And that patient transferred from partial response or proven partial response to a complete response.

So, the data is emerging very favorably. For comparison purposes, we are using RECIST 1.1 responses. So this is the regulatory standard by which we will be measured and again we're incredibly encouraged by the data that we have to-date and again this is all very fresh it was presented at ASCO on Monday.

So I'll move here, this is in some regard, this is redundant to what I was just sharing with you on the data slide. But the one other point I would add to you is the toxicity profile of the compound. Again you can go back and look at our specific data that we presented at ASCO and you'll see that when it comes to immune related adverse events, we had about a 24% of our patients had an immune related adverse event. I think that's an important number when you compare it to ipilimumab alone is I think reported about 60%.

So we're seeing essentially a tripling of the response rate in a meaningful reduction in these IR related adverse events so far in our study. This is a winning combination in the context of providing a real alternative to these patients.

In addition to the ILLUMINATE-204 study, we have initiated a Phase 3 study ILLUMINATE-301, we have this initiating our targeting 80 sites across the globe over 300 patients and we're going to compare 2125 with tilsotolimod and ipi to ipi alone. And we have a two-pronged regulatory approach which will continue to discuss and work through with the FDA the both approaches seek to pursue an expedited approval.

The first and maybe the base case would be that in the Phase 3 study, we have both objective response rate and overall survival as essentially co-primary endpoints, we would look to pursue an expedited approval on the ORR and then confirm with OS. But because of the quality of the data and the depth the responses that we've seen to-date in

the ILLUMINATE-204 study, we do want to discuss with the agency whether 204 could be in and of itself an expedited approval pathway.

And as you probably know, it's very important in the context of any expedited approval that you have a confirmatory study to get to the final endpoint underway. So this strategy allows us to pursue either of course, the FDA will weigh in heavily on which choice we get to pursue.

And this is the design of the study, it's again ipi standalone versus ipi and tilosolimod combined, this will be the head-to-head randomized study of about 300 patients. With regards to the timing of both of these studies, we do expect to complete the enrollment of the targeted 60 patients and ILLUMINATE-204 by the end of this year with the full dataset on those 60 patients by the middle of next.

We haven't yet committed to the timeframe on the completion of enrollment and data in the 301 study, as we've just gotten underway with site initiation visits and want to have some experience with enrollment before we make some bold predictions.

So with that, I think I'll turn it back over to Jon. And again I'll say thank you for taking the time to listen to us today and we look forward to continuing the dialogue.

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

So I hadn't been to ASCO in over a decade, back in my days at Merck KGaA when we had Erbitux and I have to say it is still the crazy zoo it's always been. But enthusiasm at the poster, I mean they were mobbed at the poster and it was great to see the amount of interest at the poster, the attendance at the poster discussion session and the attendance at the investor dinner, a number of conversations I had with individual investors and investigators was that this data is extremely interesting and compelling.

And I'm convinced that this is the TLR9 that some big player in this space is going to want to put in their toolbox and that's going to create real value for the combined company. So this isn't just about putting two companies together and it's the same as having two of these or the stocks of these two companies in your portfolio. There is an amplification that comes value that comes from the combination of these two companies.

And I'll give you some examples, so the first one is having the team that had created the prophylactic market to help in the launch of 7353 is very, very valuable. And as I said before, this is going to be competitive space. The competitors are going to have a head start, yes, we have a better profile drug but having an experienced team to be able to compete is critically important to creating value.

I talked about the interests or potential interests by big players in 2125. Our ability to get a deal done and the cash flow that comes to that can then be used for other parts of the company, whether it's investing in clinical development, whether it's investing in the

launch of 7353. This gives us flexibility to be able to go ahead on our own without being solely dependent on the capital markets for capital.

I've talked before about shots on goal and diffusing risk. And then lastly I've talked about the ability to put the two discovery engines together and how that may differentiate and let me explain that a bit further.

So oligonucleotides primarily go to the liver and the kidney in terms of their delivery. And so that limits you in the number of diseases that you can treat with oligonucleotides, which is the base of the discovery engine of Idera. One of the things that we're exploring in the combination is to use a small molecule like a warhead to carry an oligonucleotide to some other part of the body that allows it to deliver it to another part of the body other than the liver and the kidney. This could be highly differentiating in terms of what diseases we're able to go after. And again is another amplification of value for the combined company.

I've talked about the skill set of the combined team not only is it on the commercial front but on the clinical side as well, very experienced teams led by Joanna and Bill that have tons of experience, not only in developing drugs that get approved but also involved in many launches as well.

The new company Valenscion will be in a very solid capital position, I said that we've got approximately \$204 million of cash on the balance sheet as of the end of the first quarter. There are a number of ways to bring in additional non-dilutive capital, some smaller, some bigger like a partnership with 2125. And then there are synergies that come from combining the two companies \$20 million of cash synergies in year two and \$30 million in year three. So that gives us again the flexibility, the financial flexibility to do things on our own that the two individual companies would not be able to do.

And both boards of each of the companies considered other options before deciding that this was the best combination. At BioCryst, probably since I started almost 11 years ago, we've been having conversations with companies over the years. I've always believed that two smaller companies if you could find the right fit would make a stronger, better, bigger, longer sustainable value company than trying to struggle through that on their own. And so the idea that neither company went through a process of really evaluating what their options were, as well as going alone is nonsense. And this was by far the most interesting option and one that we feel can really create better value for shareholders.

And I think another important piece was the balance of risk and the balance of value across both companies. We've been incredibly transparent in what led us to through the diligence and ultimately to assessing the value of individual compounds in different indications and assessing the probabilities of success.

And you can see on Slide 20, the valuations are the peak sales projections and the probabilities of success for each of the compounds. None of these compounds have 100% chance of success in making it to the market that would just be irresponsible to think



about a slam dunk on any one of these molecules. And so it's important again to have multiple shots on goal so that we recognized that there may be some attrition in this combined pipeline but there's still a very good chance at creating real value. And ultimately what this led to is a very similar value, similar risk and ultimately similar value across both companies that lead us to the exchange ratio that we believe is fair.

So let me end where I began which is we believe that this combination of these two companies creates a real player in the rare disease space. I'd love to be able to stand up here and say that as individual company BioCryst or Idera that we've got a great chance of getting there on our own. We've been trying but we believe that this is way, way better because of the scale. The two companies combined if you look at the valuations today, the two companies combined could be \$1 billion Company, with a reverse back it could be a double-digit dollar stock.

And that's a better launching pad for the success that we believe will come with the advancement of our other programs, the full pipeline, the synergy with the discovery engines, the skill set of the combined teams and the financial flexibility are all things that make this a compelling argument for combining these two companies. So as Vince said, we postponed the vote until July 10 to give people the time to see the additional data. We've doubled the number of patients now treated with 2125 and the result as Vince said is still very compelling, clinically meaningful and I think highly attractive to players in the space of I-O.

So we ask that, you give us your yes vote for this merger. And we're happy to take any questions that you may have in the breakout session. Thank you.

#### **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 influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. 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 May 23, 2018, a Post-Effective Amendment to the 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 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 2018 annual meeting of stockholders, which was filed with the SEC on May 22, 2018. 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 2018 annual meeting of stockholders, which was filed with the SEC on May 10, 2018. 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

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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 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

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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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