CONCERT PHARMACEUTICALS, INC.
Form DEFA14A
March 07, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934

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o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
o Definitive Proxy Statement
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CONCERT PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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Additional Information about the Transaction and Where to Find It This communication is being made in respect of the proposed asset sale with Vertex. The proposed asset sale and the asset purchase agreement will be submitted to the shareholders of the Company for their consideration and approval. In connection with the proposed asset sale, the Company will file a proxy statement with the SEC. This communication does not constitute a solicitation of any vote or proxy from any shareholder of the Company. Investors are urged to read the proxy statement carefully and in its entirety when it becomes available and any other relevant documents or materials filed or to be filed with the SEC or incorporated by reference in the proxy statement, because they will contain important information about the proposed asset sale. The definitive proxy statement will be mailed to the Company's shareholders. In addition, the proxy statement and other documents will be available free of charge at the SEC's internet website, www.sec.gov. When available, the proxy statement and other pertinent documents may also be obtained free of charge at the Investors section the Company's website, www.concertpharma.com, or by directing a written request to Concert Pharmaceuticals, Inc., Attn: Corporate Communications and Investor Relations, in writing, at 99 Hayden Ave, #500, Lexington, MA 02421. The Company and its directors, executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies in connection with the proposed asset sale. Information about the Company's directors and executive officers is included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 6, 2017. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the proposed asset sale when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

Company Name: Concert Pharmaceuticals, Inc. (CNCE) Event: Cowen and Company 37th Annual Health Care Conference Date: March 6, 2017

<<Marc Frahm, Analyst, Cowen and Company>> I am Marc Frahm from the Biotech team here at Cowen. Welcome back to the Health Care Conference, today we are really happy to have Concert here and their CEO, Roger Tung to tell us more about their Company. And working on deuterated versions mostly of approved drugs. Especially with today's news with your deal with Vertex and hear more about the whole pipeline.

<<Roger Tung, Co-Founder, President and Chief Executive Officer>> Thank you very much Marc and thanks to all of you for being here. It's very much a pleasure to be here presenting on behalf of Concert and sharing our enthusiasm for maturing pipeline including CTP-656, the subject of our recently announced agreement with Vertex which I'll be speaking more about during the presentation.

During the presentation I will be making forward-looking statements and for more information on the use and meaning of those forward-looking statements I'll refer you to our annual 10-K filed with the SEC. I also will be making commentary about the pending transaction with Vertex and for information on that also, feel free to contact investor relations at Concert Pharmaceuticals and we will be filing information with the SEC regarding it.

So, the recent news that we had to announce today was an Asset Purchase Agreement for CTP-656 with Vertex Pharmaceuticals, which we believe will be a very important and very positive event for patients because this allows the drug to be combined with the widest pipeline of correctors that exists in the industry. And potentially to be used broadly for the homozygous delta F508 population, which is the largest patient population and is not addressed adequately by ivacaftor or CTP-656 alone.

We also think, that it is great deal for shareholders of the Company, in that it provides a very substantial financing for a pipeline allowing us to see some important events moving forward without having to do a diluted equity raise for the Company.

During 2017, we have a number of events going on that will be important. One of them is the development of CTP-543 or proprietary JAK1/2 inhibitor that we are taking forward from moderate to severe alopecia areata. We expect that to be moving forward, in the coming weeks. CTP-656 in the U.S., which we are continuing to work on and I will say a little bit about – more about that in the coming slide. And we also have, through our partners work at Avanir Pharmaceuticals, the ongoing Phase 3 studies for AVP-786 for the treatment of Alzheimer's agitation.

So I'd like to just note that there are two different ways in, which we use deuterium technology, conceptually. One of them, which includes our compound such as CTP-656 is to use deuterium modification of an existing drug to enhance the properties of that compound and use it in the clinical indication for which the pre-existing compound is been approved. The other way, in which we use the technology is to leverage existing pharmacology of the drugs such as ruxolitinib in the case of CTP-543 or dextromethorphan in the case of AVP-786 and used to deuterium to enable leveraging that pharmacology to go into a new indication. And I'll take you through, some of that during the course of the slides. So we created CTP-656 as a compound that we hoped would address some of the shortcomings of existing drugs in particular to simplify and enable better adherence to CF medications. And the results of that, was a specific version of ivacaftor that contains non- deuterium items that we've been developing as CTP-656. The potency of this compound is comparable to that's seen for ivacaftor, but it has a significantly longer half-life, and a much improved pharmacokinetic profile and we believe that it's suited for once daily dosing, which would also enable potentially combination therapies with other agents such as VX-661 and potentially other compounds to be dosed as once daily combinations, which is something that we would not have access to given our lack of correctors or other modulators in our pipeline. We entered into an asset purchase agreement, which I'll talk a little bit more on the subsequent slide. And the basis for this is, we will transfer all rights to CTP-656 and of other pre-clinical CF assets in our pipeline to Vertex and in exchange will receive upfront of a $160 million payment and have the potential to receive an additional $90 million in milestones. Those milestones comprise a $50 million, milestone based on approval in the U.S. of a combination therapy containing or including CTP-656 and in Europe for gaining pricing and reimbursement of a combination therapy and that would enable another $40 million milestone payment to us. Importantly we believe that Vertex has got a rich pipeline of compounds, with which to combine CTP-656, we believe they have the intent and the means and the knowledge of how to do so and in this sense we believe that they're a prime partner for the assets. Now I should mention that closing of the transaction, will be subject to shareholder votes and also other customary events including HSR clearance. So this is something that we'll take a little bit time to have the proxy filed shareholder vote conducted in HSR clearance reached. We feel that there is – that this is something which is very beneficial to the development of the product into patients and look forward to that series of events. On closing, we project that the cash that will be available to us on a pro forma basis will be sufficient to take Concert into 2021 to potentially start realizing royalties on the AVP-

786 products should that be successful and be approved and also see some important clinical events with CTP-543 including initiation of pivotal studies with that PEG compounds. So we think that is a very favorable deal for shareholders. We are continuing to conduct the U.S. Phase 2 study with CTP-656. As a reminder, this was initiated December of last year and is being conducted in – are projected 30 to 40 patients with a four week duration of treatment primary endpoint. And this will be a sweat chloride, which is powered for with that number of patients, we will also be looking for FEV1 as an important aspect of the study design. This will be conducted with three active doses of CTP-656, 21, 100 and 150 milligrams versus placebo and there will be an open-label arm of – there is an open-label arm of Kalydeco. We continue to project that the study could readout before the end of the year. Although given our pending transaction with Vertex this is of course subject to transfer the asset to them. With that, I'd like to move to CTP-543, which becomes really the focus of our attention going forward for our pipeline. We believe that there is a very significant unmet need, there are no approved treatments for alopecia areata, and there is a significant patient population as I'll note in the next slide. Our target is the oral treatment of alopecia areata in patients with moderate-to-severe disease, which we are describing or we are defining as individuals who have lost 50% or more of their scalp hair in the more severe forms of disease as you can see in the lower picture of patients can lose the entirety of their scalp and body hair and this is a difficult situation for those patients. CTP-543 is as I noted an example where we're taking a known mechanism of action in this case the inhibition of Janus 1 and Janus 2 kinases or JAK1/2 and we are now putting it towards a different use. In this case, we think that it's clinically significantly de-risked as I show elsewhere but the base compound, the non-deuterated ruxolitinib is approved for a different purpose for the treatment of certain blood disorders including myelofibrosis and polycythemia vera. And we do not believe it will be developed as oral medication for the treatment of alopecia areata. And we are in the process of doing so and believe that we're at or close to the forefront of development of a new medication for this indication. We expect our Phase 2a study to initiate in the coming few weeks before the end of this month. Now for those of you who may not be very familiar with alopecia areata. It is a fairly common autoimmune disorder that is observed we believe at any given time in somewhere between upwards of half a million up to maybe 650,000 patients in the U.S. Many of the individuals with less severe disease will have remissions of the disease but in the more severe cases such as the ones that we're targeting remission is uncommon. It also is an indication which can be life long in which we anticipate will require chronic therapy through this mechanism. In affected individuals particularly those with the more severe forms of the disease, it can really be a devastating indication often core morbid with psychiatric sequelae such as anxiety and depression it's also observed to co-exist with other disease states including other autoimmune diseases, thyroid diseases and a variety of other indications. There are

currently no FDA approved treatments for this disease and a great pent up demand for treatment. We are particularly encouraged that FDA is aware of this indication and appears focused on trying to find a way forward for new treatments of it. They have selected it as one of the relatively few areas that they will be conducting a patient-focused drug development initiative meeting during the course of this coming year. As I indicated, we believe that there's been significant de-risking of the JAK1/2 mechanism and by extension CTP-543 in the alopecia areata indication. And this work was conducted by investigators at Columbia University led by Julian Mackay-Wiggan who conducted an open-label study of 12 patients with moderate-to-severe alopecia areata which they defined is 30% or greater loss of scalp hair. And they treated those individuals with 20 milligrams twice daily of ruxolitinib or JAK 5. And the before and after pictures that's emerged from this are quite stark. So out of the 12 patients that they treated in the study nine were considered to be responders which mention in their case U0% or greater remission of hair loss and the nine individuals are shown in before and after pictures in each of these sets of photos here. And as you can see, there was a quite remarkable regrowth of hair in many of the individuals with an average regrowth of over 90% across that patient cohort. And this is at the approved dose of the drug of 20 milligrams twice daily, which is used in the mild fibrosis indication, halfly the drug was generally quite well tolerated, there were no dropouts due to adverse effects of the drug, no serious adverse events that were noted in the trial. And so we are encouraged in the potential to find a safe and effective dose of CTP-543 which operates by this mechanism for the treatment of alopecia areata.

We recently completed the Phase 1 single and multiple ascending dose studies and reported out data in the recent American Dermatology Association meeting this week, in fact. And we saw a very well behaved profile for the compound is shown here, in essence nothing that we saw was unexpected or alarming. And this provided us with the information that we needed to choose the doses to take into our Phase 2a study which again we project start this month. The drug was well tolerated with no serious adverse events. We saw pharmacodynamic indications of potential advocacy with the compound including in particular interferon- gamma-mediated STAT1 phosphorylation being inhibited by the drug, Xyrem. So for CTP-543 we intend to initially carry out approximately 100 patient Phase 2a study with four different active doses of drug versus placebo, those being 4, 8, 12 and 16 milligrams twice daily versus placebo. The endpoint will be responder endpoint of those individuals who have had at least 50% regrowth of hair is measured by the Severity of Alopecia Tool or SALT score. We expect a rapid enrollment in this trial given the pent-up demand for it and we hope to have top line data read out this calendar year.

And like then to turn my attention briefly to AVP-786. As I indicated, this is another situation were deuterium modification of a known drug; in this case, dextromethorphan which is widely used as an antidepressant agent is being leveraged to enable the use of that drug for a different indication. In this case, for the treatment of agitation and aggression symptoms in patients with dementia are secondary to Alzheimer's disease. This is another – in this case, extremely large indication we believe, there are no approved medicines for Alzheimer's agitation. We estimate that approximately 50% of Alzheimer's patients have aggression and agitation symptoms. So this has the potential to be a very substantial indication for which our partners, Avanir and Otsuka, have the possibility of being first to market. They are conducting currently two primary efficacy Phase 3 studies, which are scheduled to be completed in Q3 of 2018. And based on successful completion of those studies and commercialization of the drug, we tend to receive both milestones and royalties are the latter being in the mid single- to low double-digit, percentages of sales are cheered on a country-by-country basis, and this could be – we think quite meaningful to us as a company. So the financial results were reported earlier this morning. I will highlight that in the event of successful close of the Vertex deal that on a pro forma basis we will have over $250 million in cash and cash equivalents, which we think will be sufficient to fund us into 2021 based on our current operating plan. So we are focused on continuing to execute plan, all eyes in the company will be to get to the closing of the Vertex deal. And we will continue to oversee and conduct the Phase 2 study in the U.S. for CTP-656, and again, project that course is on track again pending the potential transfer to Vertex. CTP-543, we have checked off a couple of boxes there with the Phase 1 data that we have conducted and completed. Initiation of Phase 2a, again, which will happen – we project shortly and hoped for top line results this calendar year. So we will have a breakout session, and I will be happy to take any questions that you may have at that time.