CONCERT PHARMACEUTICALS, INC.
Form DEFA14A
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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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(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.

Concert Pharmaceuticals Fourth Quarter 2016 Financial Results March 6, 2017 C: Justine Koenigsberg; Concert Pharmaceuticals; VP of IR C: Roger Tung; Concert Pharmaceuticals; President, Co-Founder, CEO C: Jim Cassella; Concert Pharmaceuticals; Chief Development Officer C: Ryan Daws; Concert Pharmaceuticals; CFO P: Adam Walsh; Stifel; Analyst P: Mike King; JMP Securities; Analyst P: Jeff Hung; UBS; Analyst P: Difei Yang; Aegis; Analyst P: Bert Hazlett; BTIG; Analyst +++ presentation Operator^ Good day, ladies and gentlemen. Welcome to the year-end investor update conference call. (Operator Instructions) As a reminder, this conference is being recorded. I would now like to turn the conference over to Justine Koenigsberg, Vice President, Investor Relations. You may begin. Justine Koenigsberg^ Thank you. Good morning, and welcome to Concert Pharmaceuticals' fourth quarter 2016 investor update. Our press release announcing our CTP-656 transaction and our financial results were issued earlier this morning, and electronic copies of our press releases are also available on our website at concertpharma.com. Joining me this morning with prepared remarks are Roger Tung, our President and CEO; Jim Cassella, our Chief Development Officer; and Ryan Daws, our CFO. We will also be joined by Nancy Stuart, our Chief Operating Officer, for the Q&A portion of the call. Our remarks today will focus on the CTP-656 agreement and the CTP-543, as well as our financial results. As a remainder, today's discussion will include forward-looking statements about our future expectations, plans and prospects. These statements are subject to risks and uncertainties that may cause actual results to differ materially from those projected. A description of these risks can be found in our most recent 10-K filed with the SEC. Any forward-looking statements speak only as of today's date and we assume no obligation to update any forward-looking statements made on today's call.

With that, I would now like to turn the call over to Roger. Roger Tung^ Thank you, Justine. Good morning. As we announced earlier today, we have entered into an asset purchase agreement with Vertex Pharmaceuticals for CTP-656 or once daily potentiator for cystic fibrosis. Under the agreement, Vertex will pay us up to $250 million including $160 million at closing. We believe this is an important deal, which will provide the best path to advance CTP-656 as a treatment for cystic fibrosis patients. We believe that Vertex is best suited to bring 656 forward, given their arsenal of pipeline products, clinical expertise in cystic fibrosis and commercialization capabilities. In addition to benefiting CF patients, this transaction will be transformative for Concert. Without requiring a dilutive equity raise, we expect that the upfront cash provided will fund the Company into 2021, while our pipeline products advance to several key milestones. In particular, we project that we will be able to progress CTP-543 into pivotal evaluation, broaden our proprietary development pipeline and potentially begin to realize royalties for AVP-786 under our license agreement with Avanir. The transaction is subject to shareholder approval and other customary closing conditions including HSR clearance. Upon closing, we will receive a $160 million payment. We will also have the potential to receive two future milestone payments totaling $90 million, a $50 million payment is due on U.S. approval and $40 million is due on reaching agreement on reimbursement in the first of the United Kingdom, Germany or France. Within our cash guidance timeframe, we expect significant advancement of CTP-543 and AVP-786. We are on track to advance CTP-543 into a Phase 2a clinical trial in patients with moderate to severe alopecia areata this month. It is our intent to complete the six- month primary efficacy analysis by the end of 2017. We are keenly focused on implementing this clinical trial expeditiously, and we believe this study will provide important information on the safety and efficacy profile of 543 in patients with alopecia areata over a broad dose range. We are finding a larger Phase 2b trial to be initiated in R018 before advancing the program into Phase 3. In addition, Avanir is currently evaluating AVP-786 in the two Phase 3 primary efficacy clinical trials for the treatment of agitation due to Alzheimer’s dementia. These trials which are fully funded by Avanir are expected to be completed in July 2018. Under our development and license agreement, we are eligible to burn additional milestone payments upon regulatory approvals of AVP-786. We are also eligible to receive tiered royalties ranging from the mid single to low double-digit percentages on net sales of AVP-786 on a country-by-country basis, as well as commercial milestones. In the event of successful trial results and approval of AVP-786, we believe we will begin to realize the Avanir royalties within our cash guidance. We are continuing the U.S. Phase 2 trial for CTP-656, as planned. We initiated a randomized placebo controlled,

multicenter dose ranging Phase 2 trial in late December last year. More than a dozen study sites will participate and patients are being actively recruited. Our enthusiasm for V56 remains high, and we look forward to closing this transaction. Vertex is going to pioneer in advancing treatments for cystic fibrosis, and we believe they have the capabilities to rapidly advance CTP-656 for future combination therapy. Before I turn the call over to Jim, I'd like to thank Bob Silverman, our General Counsel for his service and dedication to Concert. After 10 years, Bob has decided to begin transitioning from the Company. As a result, Lynette Herscha, who's been serving as Associate General Counsel at Concert, will become our new General Counsel, effective June 1st. We are pleased that Bob will continue his employment with the Company in a legal advisory role. Lynette has amply demonstrated her capabilities at Concert and is well-positioned to step into the General Counsel role and what we expect to be a seamless transition. I would like to pause here and ask Jim to discuss the CTP-543 program, and then Ryan will review our 2016 financial results before we open the call to questions. Jim Cassella^ Thanks, Roger. We are very excited by the opportunity that CTP-543 represents as a potential new treatment for alopecia areata; a challenging autoimmune disorder in which the immune system attacks hair follicles, resulting in patchy or complete hair loss. As a reminder, CTP-543 is a deuterium-modified analog or ruxolitinib, Janus kinases inhibitor or JAK inhibitor that's commercially available for certain blood disorders. We recently completed the Phase 1 program for CTP-543, which included an open-label crossover study designed to evaluate the metabolic profile of a single dose of CTP-543 compared to ruxolitinib in 12 healthy volunteers. Consistent with our experience with deuterium programs, no new metabolites were observed with 543. We also recently completed analysis of the pharmacodynamic data we collected from the 543 multiple ascending dose trial. We assessed several measures including inhibition of IL-6 stimulated STAT3 phosphorylation and inhibition of interferon-gamma-stimulated STAT1 phosphorylation. As expected, we observed a dose-related reduction in IL-6 stimulated phosphorylated STAT3. Importantly, we also found that interferon-gamma-mediated STAT1signalling was significantly inhibited. Interferon-gamma is believed to be important in the pathology of alopecia areata. We presented full PK results in a poster at the American Academy of Dermatology's Annual Meeting this past weekend. We were pleased to have the opportunity to present these data and to share our excitement with researchers and clinicians over the potential of 543 as a new treatment option from moderate to severe alopecia areata. The Phase 1 program supports our roadmap ahead for further CTP-543 clinical development. The Phase 1 studies were designed to determine the safety, tolerability,

metabolite and pharmacokinetic profile of 543 as well as determine doses for the planned Phase 2a clinical trial. Given the overall exposure and safety parameters observed in Phase 1, we selected 4, 8, 12 and 16 milligrams BID of CTP-543 as the doses we will evaluate in our Phase 2a trial. The Phase 2a trial in patients with moderate to severe alopecia areata is expected to begin this month. It is our intent to complete the six-month primary efficacy analysis by the end of 2017. We believe this study will provide important information on the safety and efficacy profile of CTP-543. Our goal, as always, is to develop innovative treatments to offer important and meaningful benefits to patients. We look forward to advancing our pipeline in 2017. Now let me turn the call over to Ryan to review our 2016 financial results. Ryan Daws^ Thank you, Jim. As I walk through our fiscal 2016 financial results, please reference the financial tables found in today's press release. Looking first at revenue. Revenue was a $174,000 for 2016 compared to $66.7 million for 2015. The 2016 revenue is primarily non-cash deferred revenue recognized under our Celgene and Jazz collaboration. As a reminder, in 2015, we recognized $50.2 million under our agreement with Auspex as well as $10 million in development milestones under our collaborations with Celgene and Avanir. On the expense side, research and development expenses were $37 million for 2016 compared to $28.9 million in 2015, an increase of $8.1 million. Increase in research and development expenses was due to increased expenses associated with the development of CTP-656 and CTP-543. General and Administrative expenses were $14.4 million for R016 compared to $13.1 million in 2015; increase of $1.3 million in G&A expenses was primarily related to non-cash stock-based compensation. Our 2016 net loss was $50.7 million or $2.28 per share. For 2015, our net income was $24.2 million or $1.14 per share. As a result of the onetime offset, change in control payment, we were profitable for fiscal year 2015. We ended the year with $96.2 million in cash, cash equivalents and investments. Upon closing of the CTP-656 agreement with Vertex, we expect our cash will be sufficient to fund the Company into 2021 under our current operating plan. Any tax implication from this transaction is likely to be modest, given our significant NOL balance. This concludes our prepared remarks. We would be happy to address any questions. +++ q-and-a Operator^ (Operator Instructions) Adam Walsh from Stifel. Adam Walsh^ I have a few questions. The first question is regarding the structure of the deal. I noticed that there was no royalty stream attached to any potential -- anything

beyond approval for CTP-656 and any combination regimen that Vertex may market. Can you comment on your thought around the deal structure? That's question number one. Ryan Daws^ We prioritized receiving a larger upfront that allows us to fund our business through 2021. In addition to the upfront, we have the opportunity to receive two significant pre-commercial milestone payments. Adam Walsh^ And then, given the fact that Vertex has Kalydeco currently, would you expect any anti-trust issues kind of merge as you try to close this transaction, can you speak to that? Roger Tung^ We believe this is the best way for a combination therapy to move forward. And we really don't expect that will be an issue. Adam Walsh^ And then my final question -- sorry for hogging them out here. But on AVP-786, I noticed in Otsuka's recent slide deck, they show that there may be some data coming out, some Phase 2 data in October of this year on residual schizophrenia. But, you did not mention that in your remarks. Can you comment on your expectations for data flow for 786 this year? Roger Tung^ Well, we are focused on the Phase 3 study with Alzheimer's agitation, the Phase 2 programs are not something that we have as a major focus program. Clearly, we'll keep track of the results from that, but those are not the greatest value drivers in our view. Operator^ Mike King from JMP Securities. Mike King^ Is the $160 million upfront payment non-contingent? In another words, if there is some, whatever, force majeure you have some unforeseen toxicity or whatever in the Phase 3 trial, is the agreement still valid? Ryan Daws^ Yes, there are few instances where they could recover the $160 million but it's not related to clinical trial results; it's more nuance legal issues, for example fraud. So, it's common to an agreement like this, but no, there would not be following deal closing an ability to come back to the 160. There is an escrow of 16 million that would cover any indemnities that we may have over the next 18 months. Mike King^ And then, since I've got Ryan, are you going to book this as a onetime revenue amount or will that be amortized or how is that going to be handled for accounting purposes, and does it book in a position where you might have to pay tax on the upfront? Ryan Daws^ Yes. So, we're still assessing the accounting implication of this. I think it's most likely to be received this year, but we still have a number of conversations to have with our accountants. We do believe that the potential tax implications will be modest.

We have a significant NOL balance. And so, we don't expect that it would be a significant payment. Mike King^ Okay, great. And then just quickly on 543, if we can suggest a half life that's roughly the equivalent of ruxolitinib. I am just wondering from that standpoint, is there really any major differentiation between 543 and ruxolitinib, based on the duration. Jim Cassella^ So, yes, we did see a modest increase in the overall exposure with the deuterated 543. However, you're correct; we did not see any meaningful or significant increase in the half life in relationship to ruxolitinib. Mike King^ Right. But, what did that mean from a standpoint of differentiation? Roger Tung^ Mike, we saw in terms of the human exposure, increase in the exposure of the compound which is comparable to what we observed preclinically and what we expected to see. We are really relying on the facts that the underlying mechanism of action of the compound, JAK 1, 2 inhibition appears to be quite effective in the treatment of alopecia areata. So, our intent is to take the compound forward in an indication in which ruxolitinib is not approved and one where we believe there is an opportunity to have a significant effect on disease. Operator^ Jeff Hung from UBS. Jeff Hung^ Can you provide more color on the development of 656? It sounds like you will continue to run the Phase 2 trial. So, how will the two companies make clinical development decisions going forward and would you transition development responsibilities to Vertex after the current Phase 2 study? Roger Tung^ Hi, Jeff. Thanks very much for the question. So, we are running the Phase R trial and we will continue to run the Phase 2 trial until closure of the deal. And at that point, we will work with Vertex to transition this over to their control. Jeff Hung^ Okay. In the meantime, I guess, can you stay if you've had any additional interactions with the FDA on 656 or set a date for formal meeting to discuss the thoughts on washout period? Roger Tung^ We have not had any further updates from FDA. Jeff Hung^ And then, I guess given this asset purchase, how should we be thinking about the impact on your spend going forward? Ryan Daws^ I think it's a little early to assess the impact on this year's burn, for example; I think that's going to be dependent upon when the deal closes. Obviously, there will be fewer expenses associated with 656 in the future. And so, there should be some offset. But 543, as we mentioned, will be going into a Phase 2b and then ultimately pivotals in this projected cash guidance period. So, I think over time, expenses will

probably move up in the near to medium term probably flat to down. Jeff Hung^ And then the last question is that I guess now that Vertex is acquiring 656, how is your thinking about the backfilling of the pipeline change? Are there certain areas that you would focus more attention on going forward? And would you be able to bring another pipeline candidate to the clinic, this year for instance? Thanks. Roger Tung^ Yes. Well, one of the things that this does, which is great for us frankly, is it allows us strategically to focus our intention fully on the advancement of 543 towards our registration and ultimately approval on sales. And that's for small companies always a challenge balancing too many things. So, that's a great hope for us. We do intend to work towards broadening our pipeline. We don't have any specific timeframe guidance in which we will be bringing new programs into the pipeline, but it is our intent to do so. And it certainly gives us the ability, the financial heft to be able to continue moving our pipeline along to some very important inflections without having to do any further dilutive equity raises. Operator^ Difei Yang from Aegis. Difei Yang^ Just a quick follow-up on the deal. What is the rough timeframe you're expecting on the closing to take place; is it fairly near-term or is it towards the yearend as when on the Phase 2 will probably be completed? Ryan Daws^ So, we expect that it will close no later than October 31st of this year. I think to the extent we can secure governmental approvals and shareholder approval sooner, then it would present an opportunity to close the deal sooner. Difei Yang^ So, just turning to CTP-543, and would you talk to us about why you think Incyte or the drug Jakafi, they're not going to pursue alopecia areata? Roger Tung^ So, we think that there is really two things that would make that reasonably unlikely to happen. The first of them is that Jakafi is indicated and is sold in a fairly rare condition that myelofibrosis being the main indication and polycythemia vera also being labeled for the drug. The drug is priced according to the rare disease indications with average wholesale prices of well over $100,000 per year, which is not in the range which would be really generally acceptable for a dermatologic agent. The other is that our belief is that the relationship that Incyte has with its partners, in particular Lilly propensity development of ruxolitinib in most inflammatory and autoimmune indications. Operator^ Bert Hazlett from BTIG. Bert Hazlett^ Just one, not to find a point on it but just to understand the deal structure. Once the deal closes, all expenses associated with 656 development shift to Vertex or is there any residual expense for the Phase 2?

Ryan Daws^ No, it does shift. They take on all responsibility for our CF business including the 656 trial for example. Bert Hazlett^ And with regard to the overall thought behind the deal, just why now in terms of the licensing of 656? Roger Tung^ Well, I think that this is a time in which Vertex is moving forward a number of its combinations, as you are aware, and this could be an opportune time for them to include 656 in potential combination therapies. I think from our perspective, this provides us with a really nice opportunity, as I indicated earlier, to strategically focus on our 543 work. It prevents us from having to do a dilutive equity raise, which we were not eager to do, if we didn't have to. And it comes at a time where it allows us to bridge two and through the readout of the AVP-786 Phase 3 studies. Bert Hazlett^ I know you talked a little bit about the acceleration of the pipeline, Roger as well, that this might enable. Should we expect more specifically more compounds moving into the clinic in the next, let's say 18 to 24 months; is that the overarching goal here? Roger Tung^ It certainly is our intent to continue broadening out the pipeline. That's probably not an unreasonable timeframe but we really aren't providing specific guidance at this time. Operator^ Mike King from JMP Securities. Mike King^ It's sort of a logical analog at Bert's question. Roger, can you comment at this point about whether you feel like the additional capital allows you to either accelerate the timelines for 543 and/or perhaps expand the other indications for use? Roger Tung^ We certainly will be exploring the possibility of looking at other indications, Mike. And, I don't think it would accelerate it but I think the timeframe for the clinical studies is really set by what we have to do to get it to a registration. And so, we're really not going to be able to move faster than we have been. But, this will allow us, we believe to get into the registration studies which we think will be a value-creating event for the Company. Operator^ (Operator Instructions) I am showing no further questions. I would now like to turn the call back to Justine Koenigsberg for any further remarks. Justine Koenigsberg^ Great. Thank you. Thank you, everyone, for joining us today. We look forward to keeping you updated on our progress. We will be participating at the Cowen conference this afternoon, and the Roth and Barclays conferences next week. And we hope to see many of you there. This concludes our call. Thank you. Operator^ Ladies and gentlemen, thank you for participating in today's conference. This concludes today's program, you may all disconnect.