

KERYX BIOPHARMACEUTICALS INC

Form 425

June 28, 2018

Filed by Akebia Therapeutics, Inc.

Pursuant to Rule 425 under the Securities Act of 1933

Commission File No.: 001-36352

Subject Company: Keryx Biopharmaceuticals, Inc.

Commission File No.: 000-30929

Date: June 28, 2018

**Akebia Therapeutics**

**and Keryx**

**Biopharmaceuticals**

**Joint Corporate**

**Conference Call**

**Thursday, June 28<sup>th</sup> 2018**

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**Operator:** Good day ladies and gentlemen, and welcome to the Akebia Therapeutics and Keryx Biopharmaceuticals Joint Corporate Conference Call. At this time all participants are in a listen-only mode. Later, we will conduct a question and answer session, and instructions will be given at that time. If anyone should require operator assistance please press \* then 0 on your touchtone telephone. As a reminder, this conference call may be recorded.

I would now like to turn the conference over to Amy Sullivan, Senior Vice President, Corporate Affairs. You may begin.

### **Introduction**

Amy Sullivan

*SVP Corporate Affairs, Keryx Biopharmaceuticals, Inc.*

Thank you Nicole. Good morning, this is Amy Sullivan. Thank you for joining us today to discuss the merger of Akebia Therapeutics and Keryx Biopharmaceuticals. Today's call will be archived, and a replay will be available after this call on Akebia's corporate website, [www.akebia.com](http://www.akebia.com), and Keryx's corporate website, [www.keryx.com](http://www.keryx.com).

I would like to remind everyone that all statements made during the call that relate to future results and events, including the proposed merger are forward-looking statements that are based on current expectations. Actual results and events could differ materially from those discussed here. Please refer to the information on the forward-looking statements slide in the presentation as well as the additional information contained in the regulatory filings for both companies. The forward-looking statements in this call speak only as of the original date of this call and we undertake no obligation to update or revise any of these statements.

Presenters on today's call are John Butler, President and Chief Executive Officer of Akebia Therapeutics, and Jodie Morrison, Interim Chief Executive Officer of Keryx Biopharmaceuticals. Also with us on today's call are Jason Amello, Akebia's Senior Vice President and Chief Financial Officer and Scott Holmes, Keryx's Senior Vice President and Chief Financial Officer.

I'd now like to turn the call over to John Butler, Akebia's President and Chief Executive Officer. John?

### **Merger**

John Butler

*President and Chief Executive Officer, Akebia Therapeutics, Inc.*

Thanks Amy, and good morning everyone. This is an exciting day for Akebia and Keryx and I'm happy to be here with Jodie to introduce the merger of our two companies. Together our companies are combining to create a fully-integrated biopharmaceutical company focused on developing and delivering innovative products for patients with kidney disease. We believe this combination will create significant value and growth opportunities for all of our stakeholders.



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I'm going to start today's presentation by giving a brief overview of the transaction highlights and the terms. Then turn it over to Jodie to discuss Keryx and its FDA-approved marketed product Auryxia. After that I'll go into some detail around Akebia's innovative Phase III product candidate vadadustat. Akebia's CFO Jason Amello and Keryx's CFO Scott Holmes will be joining us for Q&A.

So turning to slide four, as you can see highlighted here, the strategic and financial drivers of the merger are compelling. The transaction establishes us as a leading renal company with an enhanced market position with a large and growing market opportunity, beyond what either company could be independently. The company will be fully integrated and include highly complementary renal assets. We'll talk about those assets, Keryx's approved product Auryxia and Akebia's Phase III product candidate vadadustat in much more detail in a few minutes.

But at a high level what we want you to take away is that the combined company creates potential for accelerated growth and organizational synergies. Together we'll have the opportunity to provide the nephrology community, subject to vadadustat's FDA approval, a portfolio of renal products that can address the needs of non-dialysis dependent and dialysis dependent chronic kidney disease patients in the US. We will also have an established renal development, manufacturing and commercial organization that, together with Keryx's existing presence and our collective leadership expertise in the commercial renal market, provides the combined company with the infrastructure to maximize sales of Auryxia while driving launch momentum for vadadustat in the United States, subject to FDA approval.

The leadership of the new company will reflect the strengths and capabilities of both Akebia and Keryx. I'll be the Chief Executive Officer of the combined organization, and will be supported by a group of leaders who have a long track record of success developing, launching and commercializing products for patients with kidney disease. Finally, the combined company will be in a strong financial position with flexibility to support Auryxia, the launch of vadadustat, if approved by the FDA, and to develop new products.

The combined company expects cost synergies of greater than \$250 million realized within five years following closing versus each company as a standalone, driven by efficiency across all areas of the business but particularly by the leverage of having a single commercial organization promoting multiple products. All of these attributes make clear the opportunity for value creation and will support the combined company in being a partner of choice in renal.

Now turning to slide five, the terms of the transaction are straightforward. Under the agreement which boards of both companies unanimously approved the transaction will be consummated through an all stock merger. Keryx shareholders will receive 0.37433 common shares of Akebia for each share of Keryx they own. The exchange results in an implied equity ownership in the combined company of approximately 49.4% for Akebia shareholders and approximately 50.6% for Keryx shareholders on a fully diluted basis.

The new company's board of directors will consist of nine directors, four of whom are Akebia directors and four of whom are Keryx directors. Keryx will appoint the Chairperson of the board of the combined company. We expect the transaction to be completed by the end of

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2018 subject to customary closing conditions including the approval of shareholders of both companies.

The Baupost Group, which owns approximately 21.4% of the outstanding Keryx common stock, has agreed to convert its outstanding convertible notes of Keryx into shares of Keryx common stock prior to closing and it's entered into a voting agreement in support of the transaction. We consider this a strong endorsement from a sophisticated investor. Muneer Satter, Chairperson of the board of Akebia and a shareholder who owns approximately 5.3% of outstanding Akebia common stock, has also agreed to support the transaction by entering into a voting agreement.

Looking now at slide six, you get a deeper sense of the strategic opportunity inherent in this transaction. The assets being brought together under the combined company are highly complementary. Patients with CKD who are anemic are often iron deficient and Auryxia is the only oral iron tablet approved in the United States to treat dialysis-dependent CKD patients for hyperphosphatemia and non-dialysis dependent CKD patients for iron deficiency anemia.

As kidney disease progresses patients have a reduced ability to make erythropoietin or EPO, the protein that's necessary to produce red blood cells. Vadadustat's mechanism of action is designed to mimic the physiologic production of EPO and enhance the mobilization of iron, which of course is necessary for effective red cell production. With both products, if vadadustat is approved, our combined company will have a portfolio with the potential to manage anemia across the spectrum of patients with CKD.

We believe this represents a game-changing opportunity that will create value, not just for our shareholders, but for the patient community as well. We will leverage Akebia's strong research and development capabilities as well as our global commercial collaboration and Keryx's manufacturing, sales, marketing and medical affairs capabilities, including their longstanding commercial relationships with the nephrology community.

I truly believe in Auryxia and its significant potential in both IDA and hyperphosphatemia. Early in my career I spent many years as a sales rep and I know from personal experience the sales professional's always looking for what's the next product in your bag. This is an important motivator that helps drive current performance. With Auryxia and potentially vadadustat we'll be recognized as not only a leader in renal but as the leader in the management of anemia for patients with chronic kidney disease. We believe that this will be extremely motivating for all of our employees, but particularly for our salesforce and will help maximize the growth of Auryxia. We are creating a company with a substantial pipeline and an appetite to grow the portfolio beyond what's available today.

Keryx's US sales and marketing organization and its medical affairs teams have been working for the past three years to establish relationships and build strong awareness within the nephrology community to address the needs of patients with CKD. This represents a huge opportunity to advance and accelerate the curve for vadadustat subject to its FDA approval, which has always been the foundation of Akebia's vision.

Importantly, while there's incredible power in bringing these therapeutic assets under one roof there's also incredible power in the combination of the teams. We will have a combined team with the potential to make a dramatic difference in this market. We've talked about Keryx's commercial team, which includes an experienced marketing team and field team of

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approximately 130 professionals, including an experienced salesforce and a strong market access capability. Keryx also brings about 15 field-based medical affairs professionals who have longstanding relationships with key opinion leaders in nephrology.

In addition, Akebia brings a dedicated and talented research and development organization that's driving a 7,000-patient clinical program with physicians treating CKD patients at more than 600 unique investigational sites across 30 countries. Who would be a better partner for the clinical development of a novel renal product candidate?

This creates a partner of choice in the renal community, attractive to other companies in the space developing products and seeking a partner. This is a key component of this transaction. We've truly have a platform with which to grow and become one of the leading renal companies in the world.

Slide seven gives you a quick snapshot of the companies participating in today's renal market and how we think this transaction allows us to break out of the pack. Combined we'll have a market capitalization of approximately \$1.3 billion, assuming full conversion of Keryx's outstanding convertible notes and a fully integrated organization. This significant financial and organizational strength and flexibility, coupled with our highly complementary nephrology portfolio will be a key differentiator in the market. I'd also point out that Akebia already has important existing collaborations with large companies in the upper-right section of this slide with respect to vadadustat, which only strengthens its commercial potential.

I'd now like to turn it over to Jodie who'll provide more of an overview on Auryxia.

### **Auryxia**

Jodie Morrison

*Interim Chief Executive Officer, Keryx Biopharmaceuticals, Inc.*

Thanks John. First, I want to echo John's enthusiasm for this merger. The combination of Akebia and Keryx will create a fully-integrated company focused on the development and commercialization of medicines for patients with kidney disease. Starting on slide eight, Auryxia was first approved as a treatment for hyperphosphatemia in CKD patients in dialysis. As John mentioned, our commercial and medical affairs teams have been in the field for three years now establishing relationships and building awareness of Auryxia in the nephrology community. Keryx has become known as an organization that cares for patients with a robust patient service program and as a team that can be relied upon as a resource for the nephrology community. We are leveraging this position as we continue to launch in our second indications.

The approval of Auryxia for iron deficiency anemia in non-dialysis CKD patients was an important milestone for Keryx and for the nephrology community at large, as it represents the first new medicine to be approved for this indication in nearly a decade. We are working to change the nephrology community's view on treating anemia with Auryxia, the only oral iron table FDA approved to treat this historically difficult to treat patient population.

Before Auryxia physicians had two choices to treat IDA and in the non-dialysis CKD patients: traditional oral iron and IV iron. And neither was optimal as the desired clinical result is



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rarely obtained with traditional oral iron and physicians were hesitant to use IV iron because of the inconvenience and potential safety risks to their patients. We are changing that paradigm and gaining physician acceptance and changing behavior as it relates to oral treatment options. And we believe this will help launch momentum for vadadustat subject to FDA approval.

We have an advantage in our second indication in that physicians have awareness and clinical familiarity with Auryxia related to its first indication for the treatment of hyperphosphatemia in dialysis-dependent CKD patients. An additional advantage is that in this promotionally sensitive market our share of voice is high as very few companies promote a medicine for the treatment of anemia to the nephrology community.

Since approval late last year our field force have invested significant time and effort in the IDA launch. We believe we are beginning to see that investment pay off in the prescription advantage trajectory for the product. Auryxia's optimizing the treatment paradigm for patients with CKD. By combining with Akebia Keryx shareholders gain access to a renal development company with a Phase III product candidate that has a large market opportunity, which will position our combined companies to direct the [inaudible] patients with kidney disease including non-dialysis dependent and dialysis-dependent patients.

Now turning to slide nine, we discussed on our earnings call last month that we're making good commercial progress. That pace continues, and we expect [inaudible] to grow more than 100% through the first-half of this year, supported by high awareness of the IDA indication and continued breadth and depth of prescribing. Growing demand for prescriptions across both indications continues to drive revenue growth. During the first quarter we reported nearly 35,000 prescriptions, translating into \$20.6m in Auryxia sales. It's important to note that all of the medications in the hyperphosphatemia market declined in absolute prescription count in the first quarter while Auryxia continued to grow. We anticipate strong continued growth through 2018 and beyond.

Our sales representatives have been doing a great job ensuring that they're in dialogue with target physicians on a regular basis. They're communicating with them about Auryxia's ability to potentially help even more of their patients, even those with IDA and those with elevated serum phosphorus levels. Based on physicians' experience with Auryxia and our broad formulary status, we expect that we'll be able to continue to accelerate the movement of physicians along the adoption curve with IDA for non-dialysis patients.

Before I turn the call back over to John I'd like to thank the Keryx employees for their hard work over the years and into the future. Your dedication, vision for the company we are today and your unwavering commitment to our patients has built a remarkable company. We have a great medicine in Auryxia and I believe we can help build on the current momentum to accelerate growth across the two indications, helping even more patients with CKD. I feel lucky to have gotten to be part of such an incredible group of employees and I'm excited to see what the future brings for us. This transaction does what we set out to do two years ago. To build a leading renal company with multiple indications for Auryxia and a renal pipeline. I believe that our ability to grow will be significantly enhanced as a result of this transaction.

And with that, I'll turn the call back over to John.



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## **Vadadustat**

John Butler

*President and Chief Executive Officer, Akebia Therapeutics, Inc.*

Thanks Jodie. Moving on to slide ten and before I discuss vadadustat in greater detail I want to take a step back and look at the overall opportunity for vadadustat against the backdrop of the current injectable ESA market. The fact is patients with anemia due to CKD, a serious and debilitating disease, are long overdue for innovation. The last time these patients saw meaningful innovation was almost 20 years ago when the first long-acting injectable ESAs went on the market. As is well-known, injectable ESAs carry box warnings pertaining to serious potential side effects. Dialysis-dependent patients rely on these treatments and a portion of non-dialysis patients go under-treated because physicians are hesitant to prescribe the injectables. HIF-PHIs and vadadustat is one, represent an opportunity for a new class of treatment and they hold the potential to be an oral alternative to injectable ESAs.

Moving along to slide 11, we believe that vadadustat has the potential to set a new standard of care in renal anemia. Vadadustat is a small molecule inhibitor of hypoxia inducible factor prolyl hydroxylase, or HIF-PHI, which we're developing as an oral once daily and three times weekly treatment for anemia associated with chronic kidney disease or CKD. The novel HIF mechanism offers the potential for a more coordinated physiologic response to increase EPO and mobilize iron, compared to the supra-physiologic levels of EPO achieved with current ESA therapy.

Why is this important? There've been multiple landmark studies showing the relationship between treatment with ESAs, hemoglobin levels and elevated cardiovascular risk. In analysis of one of these studies it was shown that it was the EPO level that drove the increased cardiovascular risk. If you look at the graph on the left this is vadadustat delivered orally once a day to healthy volunteers in a PK study. The drug has a short half-life, gets into the cell, stabilizes HIF, resulting in a temporary increase in EPO levels which then return to baseline.

If you look at the graph on the right this is the starting dose of darbepoetin or [inaudible] which is the comparator in our Phase III program. Even at that lower starting dose you see a very substantial rise in EPO levels. The chart on the left shows that vadadustat avoided a supra-physiologic EPO level. This feature of vadadustat has the potential to translate into a differentiated safety profile. The ESA market is a large market of over \$7 billion globally across all indications including oncology use, \$5 billion of which is in renal anemia. But this remember was more than \$12 billion in 2006 before the safety concerns with ESAs were identified.

Let me talk a bit more about vadadustat's Phase III development outlined in slide 12. Akebia's continuing to make good progress. The Phase III vadadustat program includes approximately 7,000 patients across 100s of sites around the globe. This program consists of the PROTECT program in non-dialysis CKD patients and the INNOVATE program in dialysis-dependent CKD patients. These trials are open label, active control, non-inferiority cardiovascular outcomes trials. The active control in all four studies is an ESA, darbepoetin alfa. For PROTECT and INNOVATE the primary efficacy endpoint is an assessment of the

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change in hemoglobin from baseline to the primary efficacy period and the primary safety endpoint is an assessment of major adverse cardiovascular outcomes.

We just completed a successful type C meeting with the FDA where we aligned on our statistical analysis plan in advance of our NDA filing. And we're making operational progress as well. Our largest trial INNOVATE CONVERSION has completed enrolment in the US, and we expect to complete enrolment globally in both INNOVATE studies this year. The MACE[?] rate continues to track within our range of expected rates and we believe we'll have topline readout in the fourth quarter of 2019 or the first quarter of 2020 subject to MACE approval.

The MACE rate for the PROTECT program continues to track in the expected range as well. We expect enrolment for both PROTECT studies to continue in 2019 as we continue to [inaudible] the required MACE events. We now expect topline data by mid-2020 subject to MACE approval.

Moving to slide 13, this slide describes the magnitude of this opportunity and how Auryxia's commercial opportunity is highly complementary to vadadustat in terms of the types of patients to treat. The combined company will compete in an approximately \$4 billion market of more than 2.2 million patients with CKD under a nephrologist's care in the U.S.

The key to focus on is the amount of growth potential that exists across the non-dialysis market, as only 16% of non-dialysis patients are treated with ESAs and less than 20% of these patients have an optimal response to OTC iron. This supports a 2-3-times revenue growth potential in non-dialysis-dependent patients.

On slide 14 you can see that clearly the strategy and financial drivers of the merger are compelling. The combined company will have an expanded and highly-complementary nephrology portfolio with approved and target indications in iron deficiency anemia, hyperphosphatemia, and anemia associated with CKD, subject to FDA approval.

Ensuring the successful integration of the two companies will be a top priority. Fortunately, that integration will benefit from the shared roots of many of our employees and from the close geographic location; we are separated by a short drive. There are so many patients living with kidney-related illnesses that need better treatment options. Illnesses like FSGS, Alport's, polycystic kidney disease, hyperoxaluria, hyponatremia just to name a few. The combined company will have a clear mission to continue to explore a new therapeutic option to help address the needs of patients with kidney disease.

Jodie?

### **Closing Remarks**

Jodie Morrison

*Interim Chief Executive Officer, Keryx Biopharmaceuticals, Inc.*

Thanks John. As summarized on slide 15, we believe this is an exciting step forward for Akebia and Keryx, as well as for our shareholders, patients and employees. The combined company will have an established renal development, manufacturing and commercial organization that, together with Keryx's existing commercial presence and the two companies' leadership expertise in the commercial renal market, provide the combined company with the



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infrastructure to maximize sales of Auryxia and drive launch momentum for vadadustat, pending approval in the US.

As we bring the companies together, our mission will be clear: to maximize the potential of both Auryxia and vadadustat and to continue to identify, develop and commercialize new therapeutic options for the needs of patients with kidney disease.

We believe that delivering on this mission ultimately will create significant shareholder value. The transaction is a highly synergistic model at merger with that is expected to unlock the value and strength in our financial profile. In addition to top-line synergies, we highlight the total cost synergies we expect to achieve from this transaction in the first five years, post-close, which will come from efficiencies across all areas of the organization but in particular from the leverage created by having one commercial organization in the combined company.

The combined company expects cost synergies of greater than \$250 million, realized within five years following closing. The transaction further strengthens our company and will be a significant catalyst for achieving the next stage in our company's growth, resulting in many exciting new opportunities as we continue to execute on our combined strategy. We are confident in our ability to successfully integrate our two companies and I look forward to working with John and the combined world-class management team to capture and expand potential that we will have together.

Both John and I, our respective boards and Keryx's largest shareholder share our confidence in the path ahead. Thank you again for joining us today and I'll now turn it back over to the operator for questions.

### Q&A

**Operator:** Thank you. Ladies and gentlemen, if you have a question at this time please press \*, then 1, on your touchtone telephone. If your question has been answered, or you wish to remove yourself from the queue, please press the # key. In order to allow time for others, we ask that you please limit yourself to one question and one follow-up. You may rejoin the queue for additional. Again, please press 1\*.

Our first question comes from the line of Ben Liu[?] of Raymond James. Your line is now open.

**Jodie Morrison:** Hey Ben. Good morning, Ben. Right, operator, looks like Ben might not be there, so maybe let's go onto the next question, please.

**Operator:** Our next question comes from the line of Kennen Mackay of RBC Capital Markets. Your line is now open.

**Lennox[?] (RBC Capital Markets):** Hi, this is Lennox on for Kennen. Congrats on the transaction and thanks for taking the question. I just wanted to touch briefly upon kind of the potential contracting, or potential future contracting agreements you might have in place and sort of what the synergies are there and how that might broaden the already-existing footprint. I just wondered if you could provide any color on that, especially as it relates to Akebia's Vifor agreement and how that translates into all of this. Thank you.

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**John Butler:** Sure, thanks for the question. So, of course, the agreement we have with Vifor, which allows us access to the Fresenius network for vadadustat, where vadadustat will be the only HIF product that Vifor can sell into their relationship with Fresenius is really unchanged by this transaction. You know, the real heart of this transaction is the opportunity to build a company, to have the leverage of the products and certainly that product leverage will be reflected in all of the ways we think about the market going forward.

We mentioned the market access team that we have here at Keryx, who's done an outstanding job with Auryxia. We expect that having that team in place will certainly allow us a head start as we move towards launch of vadadustat.

**Lennox:** Great, thanks John and if I could have one more follow-up

**John Butler:** Yeah.

**Lennox:** It's relating to the Phase III for vadadustat. I was just wondering what are kind of the pulls in terms of the top-line results now being expected kind of in the back half of 2019, or early 2020 and also if you're still aiming to do the [inaudible] I just wanted to get a sense of from why the of the shift in timelines and whether that remains the goal.

**John Butler:** Yes. So, you know, we constantly are looking at the underlying MACE rate in the program and the enrolment rate as well and you know, look to regularly update that. And as I mentioned, you know, the MACE rate is within the range that we expected, both in INNOVATE and in PROTECT. But you know, kind of looking at the pace of that rate and kind of assessing as we get further and further into the trial, we're able to narrow the range down of when we expect to see data and this it really feels like, you know, quite an accurate range for us to be expecting data.

So, again, INNOVATE, as we expected, the dialysis program has enrolled very quickly; you know, dialysis patients are much more captive and the PROTECT program has taken a bit longer to enroll, again as we expected. But now, you know, kind of given that pace, the number of patients we have as I said, the largest trial, the INNOVATE conversion trial, is fully enrolled in the US, so we've done quite well there and expect to have that fully enrolled globally by the end of the year.

So, you know, we feel really confident now in our expectations around these timelines.

**Lennox:** Okay, fabulous. Thanks for the color and congrats again.

**John Butler:** Thanks.

**Operator:** Thank you. Our next question comes from the line of Reni Benjamin of Raymond James. Your line is now open.

**Ben Liu (Raymond James):** Good morning guys, this is Ben for Reni Benjamin, can you hear me okay?

**Jodie Morrison:** Yeah, we can hear you now, Ben.

**Ben Liu:** Yeah, sorry. Sorry for probably some technical issue here. So apologies if my questions have already been answered; I have a couple for both Jodie and John. So the first one is, with the combined entity, will there be any changes in terms of the marketing strategies for Auryxia?



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**Jodie Morrison:** I think at this time there is no intended changes to the strategy for Auryxia, although I will point that, certainly, having access to the leadership the combined leadership will contribute to sort of driving growth over time. Heavy confidence on our end of John Butler and we're excited to have him be the incoming CEO at the closure of this transaction. His obvious experience in this area is of great interest and excitement on our end.

**John Butler:** Yeah, so as Jodie pointed out and I do have a pretty good awareness of the hyperphosphatemia market, having, you know, worked on Renagel and Renvela at Genzyme for you know, since the launch actually. We grew that to an over-\$1 billion product while I was running that company. So but I think what's most exciting for me is, you know and this kind of speaks to the strength of the merger you look at the Vice President of Marketing here at Keryx worked with me at Genzyme, we were a great team there and you know, I see us working together to find ways to maximize the value of the product here. You know, I'm excited to work on a product that has the kind of potential that Auryxia has.

**Ben Liu:** Got it, that's helpful. Let me then can you comment on do you see any competition between Auryxia and the HIF agent in the pre-dialysis setting, given that both are positioned to treat anemia and that the use of the HIF agent may actually reduce, or eliminate, the use of EFAs?

**John Butler:** Yeah, you know, let me take that because obviously this is the question that I got well before the merger and there really is no competition between these products. If you think about anemia in the non-dialysis population, you know, the first thing that physicians always look at is if a patient has iron deficiency anemia. You know, that's generally where they present first, and they'll treat them with iron. When they're as their kidneys continue to fail and the GFR continues to decline, they have the inability to make EPO and that's the point where you today need to use injectable EFAs.

Now, with the HIF product, as you rightly pointed out, we're increasing EPO levels and we're mobilizing iron more effectively. But mobilizing iron isn't replacing iron, right? So you still need to replace iron. Now, you may be able to reduce or eliminate the IV iron that you need, we'll see, you know, what comes from our Phase III study. But we believe that you still will need oral iron and when you think about a product with Auryxia's profile, it really does seem like a great combination to have the two products in one company.

**Ben Liu:** Got it, that's very helpful. If I may, just one last question for you, John. I think you mentioned that some studies showed that high levels of EPO might be the reason for the cardiovascular events. So I was wondering, given the MOA of the HIF agents, is this fair to assume that maybe if you get the hemoglobin level over 13 over 13, you may actually there may not be any problems in terms of safety issues there?

**John Butler:** Well it's a that's a very interesting question and one unfortunately we won't get from our an answer we won't get from our Phase III program because, you know, in the Phase III program we are working towards hemoglobin levels that are consistent with global guidelines today, which is 10-11 in the US and 10-12 outside the US. So, you know, the first step is that we have to show that we can increase hemoglobin levels into that target range and you know, basically the bar for regulatory approval is that we go to it less safely than

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ESAs. But of course it's that differentiation on safety and that difference in how we impact EPO levels that we really feel is the opportunity to show a safety difference.

You know, once we get to that first step, we can think about showing that you can treat patients to normal hemoglobin levels. That's certainly something you know, as certainly as a patient-focused company, as we both are, is something that's in the front of our minds as we think about the continued development of vadadustat.

**Ben Liu:** Got it, that's very helpful. Thank you both. Good luck going forward.

**John Butler:** Thank you.

**Jodie Morrison:** Thank you.

**Operator:** Thank you and ladies and gentlemen, as a quick reminder, we ask that you please limit yourself to one question. Our next question comes from the line of Bert Hazlett of BTIG. Your line is now open.

**Robert Hazlett (BTIG):** Yes, thank you. Congratulations on the deal and I guess my question is with regard to the sales force. Is I think you mentioned 130 professionals. Is the sales force right-sized in your view and does this portend any particular movement one way or another, either an enlargement of the sales force as you have success for the existing product maybe earlier than you thought you might, as you look at the vadadustat progression through the clinic? Thanks.

**Jodie Morrison:** Yeah, absolutely. So, starting with the Auryxia and the sales force that currently is in existence for Auryxia, we believe that it is right-sized for the current market and we believe that we're seeing that translate in the projections and the numbers we're seeing come out into the first quarter and into the second quarter now. As we move forward, I think there's an opportunity to really evaluate that as we move, in March, towards vadadustat regulatory approval and launch. And so I'll let John speak to that kind of as a long-term consideration.

**John Butler:** Yeah, so Bert, when you think about the kind of the commercial organizations in this space, you know, when we launched at Genzyme we had like 38 reps. We ultimately grew that grew that to about 170 over time but that was with, again, multiple products in the bag and a very large revenue base to support it.

But if you look at you know, Keryx was at about 90, Relypsa's sales force was at about 100-110 I think it was so, you know, you're very much in the right range to capture I think there's 7,000 nephrologists and you know, you're seeing, I think, about 5,000 prescribe about 80%. So when you do the math, this is the right-sized sales force. Again, I think that in the combination there are opportunities to invest on the sales and marketing side, maybe not in a larger sales organization but with the marketing programs, etc., that can enhance and that's something, you know, I look forward to sinking my teeth into as we combine the companies.

**Robert Hazlett:** Okay, thank you for the color.

**Operator:** Thank you. Our next question comes from the line of Yigal Nochomovitz of Citigroup. Your line is now open.

**Yigal Nochomovitz (Citigroup):** Hi, thanks for taking the question. Could you give us a little bit more background on some of the points of differentiation for your HIF drug, relative





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to the FibroGen one, as well as, I believe, GSK also has a drug earlier in development? Thank you.

**John Butler:** Yeah, Yigal, so those are the three products that are in Phase III development in the US and Europe. FibroGen's product, roxadustat is about a year, I think, ahead of us, based on the timelines they've given. GSK's product is a bit behind. And you know, again, all our you know, some of the differentiation is really in the development program. If you look at roxadustat's program, they have some differences in the way they design their non-dialysis program, particularly where they're doing a placebo control. You know, they are also have shown that they have some drug-drug interactions with statins that we haven't seen with vadadustat. And you know, at the end of the day, though, I think the way to think about this market is that this is a \$7 billion global market and multiple players will have the opportunity to be successful. So, you know, we think there are some areas to differentiate us from both roxadustat and daprodustat. Let's see the Phase III data play out and you know, at the end of the day, there's a lot of room in the market today and a lot of room as I mentioned, this was a \$12 billion market a lot of room to grow the market in the future.

**Yigal Nochomovitz:** Okay, thank you. And then just one question on the financial metrics for the merger. Can you discuss just how this \$250 million in savings is going to be distributed across the five years; something on the pacing of that?

**Jason Amello:** Yes, so the \$250 million is going to be coming over the five years. Obviously, there'll be some savings coming in on the onset of the merger but they'll be playing out primarily over the commercial organization, where we don't have to have dual organization, too, for the combined products. So that's a significant saving that will be realized as the product grows over that time period, plus normal administrative synergies that will take place as we integrate the companies.

**John Butler:** So really as we thought about it, you know, we would start to build a commercial organization about 2020, so you know, the bulk of the savings would come from 2020 onwards.

**Operator:** Thank you. Our next question comes from the line of Difei Yang of Mizuho Securities. Your line is now open.

**Alex[?] (Mizuho Securities):** Hey, good morning guys, this is Alex, actually, on for Difei. Congrats on the merger and thanks for taking the question. I was wondering if you could maybe give us a little bit of detail on sort of how this transaction how this merger came about? Thank you.

**John Butler:** Sure, well, you know, I think this is one of those situations where the companies obviously knew each other well. As you might recall, I was Chairman of Board at Keryx until last September but, you know, again being in this space and you know, as you kind of hear from the conversation, both being in Boston and you know, both being in renal, have kind of overlapping people who were at Genzyme or other companies together we just knew each other very well. And you know, both had expressed a desire to build renal you know, world-class renal companies and you know, as we thought about it and we thought about the product synergies, you know, we decided that this is something we should talk about. And you know, it was really last December that Greg Madison and I first had a conversation about taking a look. And you know, we did work from that time on and it just you know, the

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value-creation opportunity here just made so much sense for both sides and you know, the strategic fit was just, you know, so ideal that, you know, we the boards agreed, Baupost agreed, who we know is a very savvy investor and you know, was willing to convert their note to see this happen and allow the company to start from the position of real financial strength. It just it really came together.

**Jodie Morrison:** Yeah, I echo that sentiment and I think, you know, deals happen when the parts come together and in this case it was a great synergy and complementary deal to put together.

**Operator:** Thank you. Our next question comes from the line of Jason Kolbert of HC Wainwright. Your line is now open.

**Jason Kolbert (HC Wainwright):** Great. Thank you so much. Congratulations. Can you just talk a little bit about the Baupost decision and a little bit about I know that there was some additional monies that could have been taken down, and what is the financial resources of NewCo look like today? Thank you.

**Scott Holmes:** Sure. This is Scott Holmes. I'll take the Baupost component of that and I'll hand it to Jason for the combined resources.

So, you know, the Baupost, as people are well aware, during the first quarter we restructured the Baupost or early part of second quarter I should say, we restructured the Baupost agreement and took in an additional \$10 million in capital as part of Keryx and reset that convert. So, there's no additional capital beyond that that 10 million, and that's already come into Keryx. So, you know, Baupost agreed to convert their note in conjunction with this transaction and they'll do so just prior to closing. But other than that, there's no additional capital from Baupost.

With regards to the assets of the combined company, I'll pass it to Jason.

**Jason Amello:** Yeah. So, you know, when you look at the combined cash position of the company pro forma as of the end of March would be about \$453 million. When you combine that with the \$250 million of synergies that we talked about over a five-year period, that positions the company nicely to to capitalize on the benefits of a combined company.

Also, you know, as we had previously guided, also the cash that Akebia had was to fund the operations into Q1 of 2020. There's no change to that and, obviously, now with the combined companies and maximizing their sales of Auryxia, we feel that we're at a very good position going forward.

**Scott Holmes:** And looking at, you know, a company with a strong balance sheet and cash in the bank, a growing revenue stream and also, Akebia folks know prepaid quarterly how R&D payments from our partner Otsuka is really and the conversion of the Baupost note, really leaves us in a very strong financial position for the combined company.

**Jason Amello:** Yeah. Jason, just one more point on that reflecting on your original question that the additional capital you may be referring to is our ability to borrow under an asset-based revolver with our lender to determine. I'll leave it at that. We expect to enter that soon and that will give us the ability to borrow up to \$40 million of additional capital based on our receivables and inventory balances. So, that, that capital certainly solidifies things for Keryx as well as we move forward.



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**Operator:** Thank you. Again, ladies and gentlemen, if you have a question at this time please press \*1. Our next question comes from the line of Ed Arce of HC Wainwright. Your line is now open.

**Ed Arce (HC Wainwright):** Hi, guys. Thanks for taking my questions and congrats as well from me on, you know, putting together this deal.

My my question is just and I apologize if this had already been asked, but I I had some issues with the phone. But wanted to ask about the process of your integration as you look forward over the next few months. What are some of the key activities involved with that? Could you see some changes as a result of that in particular with the commercial force? And, and I m thinking, you know, could there be in particular any meaningful increase upon the approval of vadadustat, especially as you look to the potential opportunity of comarketing with Otsuka? Thanks.

**John Butler:** Yeah. So, you know, the great thing about about this merger is, you know, this is truly a merger where you have, you know the two priorities from this point forward are continue to drive Auryxia sales and continue to drive the Phase III program for vadadustat. And, you know, very fortunately from a distraction standpoint, if you will, and in integration, there s not a lot of overlap between those. So, you know, the two organizations, you know, will continue to drive those pieces separately. Of course, you know, the companies kind of the VG&A function, etc., you know, all will, will continue to work towards merging and, as I said, kind of geographically we re we re kind of across the river from each other so it s, you know, there s no need to rush into anything there. So, you know, integration is always a lot of work. There s no question about that. But, you know, in this case, there s so much familiarity between the employee bases and so much distinction in what each is doing and bringing that, you know, we feel that the integration process will be, you know, will be pretty straight forward.

Now, thinking about launching vadadustat I think, as Jodi mentioned, you know, we think that the commercial organization, you know, from your modeling perspective, you know, this is a commercial organization that hits the, the nephrology community well. As you recall in our Otsuka agreement, we re sharing responsibility 50/50 for commercialization. And, you know, in that case, we ll be sitting down with Otsuka and looking at which company will will contribute which pieces of commercialization. So, you know, much of this is to be discussed. Obviously, Otsuka knew about that we were talking about this transaction and was very supportive of it, but it clearly will be a conversation we need to have about the best way to deploy resources. As you recall, they re just launching their new product for polycystic kidney disease, Jynarque, and putting dedicated renal sales force in place as well. So, you know, thinking about when we launch vadadustat we ll have tremendous commercial presence between the two companies and that will only strengthen the launch. But, you know, without a need to significantly step up, you know, our spending.

**Jodie Morrison:** Yeah. I ll add to that too just from inventive to employee s perspective, I think that the complimentary nature of, of these two companies can t be underscored enough. I think it really creates a remarkable company that had consistent missions between the two companies. I think, from a cultural perspective, that s going to be critically important, and I think we ll be able to draw on the experience from both that group as well as the larger talent

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pool as we grow and move forward. So, I think it's a unique situation in that case as we think about that sort of lack of overlap and that complimentary nature of this deal.

**John Butler:** Very unique.

**Operator:** Thank you. And our next question comes from the line of Matt Kaplan of Ladenburg Thalmann. Your line is now open.

**Matt Kaplan (Ladenburg Thalmann):** Hi, good morning. Can you hear me?

**John Butler:** Yes.

**Matt Kaplan:** Great. Well, congrats on, on the transaction. It looks very interesting. I wanted to dig into some of the cost savings assumptions that you, you put forward in terms of 250 million over the next five years. You detailed kind of some assumptions especially with commercial organization, but what about on the D side and other costs associated with, with the two companies combined? Can we expect some synergy there as well?

**Jason Amello:** Yeah. So, when you look at the synergies on the commercial side, Keryx has about 150-person sales force both covering commercial and med affairs. So, when you look at the size of that relative to commercializing two products, significant savings there in terms of not needing to build out that, that additional sales force when you're looking at average cost of each rep. It gets very easy to get to that \$250 million on the commercial side alone.

On the development side, of course, that's primarily a big focus on the, on the Akebia side of the house. Obviously, we will continue to invest in that program to ensure that we have a Phase III program that enables us for registration. So, we are always looking at making the most efficient use of capital in that area. Obviously, it's a bit of a large trial, so, you know, efficiencies there are -- are -- will happen over time. But other than that, I think most of those synergies come from the commercial, med affairs and then obviously that the administrative functions of combining both companies.

**Scott Holmes:** If -- if you do think about the R&D organization, for instance, you know, we are continuing to build the organization at Akebia in preparation for, for the filing approval. So, you know, what are the areas that we're hiring? Regulatory affairs, quality, safety, et cetera. And, you know, it will be a great opportunity to look at the, at the Keryx organization and understand where we can find synergies. And synergies doesn't mean we're letting go of people here. We're combining the two organizations and not having to hire people that are in our plan now and deploying people at Keryx more efficiently on vadadustat.

So, and then, as you look at the programs at each company, I think they'll -- we will sit down and, you know, what are the ways that we can drive R&D to maximize the value of both of these products? You know, whereas before we were each thinking about the product individually and I think that creates opportunities for, for synergies and leverage as well as driving synergies, on the revenue side, increased growth on the -- you know, on the revenue side. So, you know, that's work that's in progress obviously, but, you know, something we've been thinking about as we've gone through this process but now we can really kind of get down to the starting to think about it and then drive it once the, the merger closes.

**Operator:** Thank you. And our next question comes from the line of Yigal Nochomovitz of Citigroup. Your line is now open.



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**Yigal Nochomovitz:** Thanks. I just had one quick follow-up. Regarding the choice of of naming the combined entity Akebia versus Keryx. I'm assuming, John, that's because you're you're the CEO of Akebia, and so it's simpler that way? Or or the reason I ask because it's 49.4% of the Akebia shareholders versus 50.6% for Keryx, so it wasn't necessarily obvious that it should be Akebia. But, anyway, curious what you thought.

**Jodie Morrison:** That's a fair question.

**John Butler:** It's a fair question. But it's you know, the thing is both companies have brands that are recognized in the community and strong in the community. And so, you know, the idea of kind of finding another brand didn't really make sense, you know, you'd be giving up that brand equity. And so, you know, a choice had to be made and and so, you know, both boards and and management agreed that Akebia made sense.

**Operator:** Thank you. And I'm showing no further questions at this time. I'd like to hand the call back over to John Butler for any closing remarks.

**John Butler:** Thanks very much, operator. And thanks to everyone for coming on the call today. We really look forward to continuing to update you about this exciting merger between Akebia and Keryx. Thanks very much for your participation today. We'll talk soon.

**Operator:** Ladies and gentlemen, thank you for participating in today's conference. That does conclude today's program. You may now disconnect. Everyone have a great day.

[END OF TRANSCRIPT]