

KERYX BIOPHARMACEUTICALS INC

Form 425

August 09, 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

Akebia Therapeutics, Inc.

Commission File No.: 001-36352

Date: August 9, 2018

Corporate Conference Call

Wednesday, 8th August 2018

Corporate Conference Call

Wednesday, 8th August 2018

Opening Remarks

John Garabo

Director of Communications, Akebia

Preamble

Good afternoon, everyone, and thanks for joining us for Akebia's Second-Quarter 2018 Financial Results and Media Update Call. Today's call will be archived, and a replay will be available on our corporate website, www.akebia.com. Before we begin, I would like to remind everyone that this conference call includes forward-looking statements. Each forward-looking statement contained in this call is subject to risks and uncertainties that could cause actual results to differ materially from those described in this statements.

Additional information regarding these factors appears under the heading Risk Factors in our quarterly report on form 10Q from the quarterly period ended 30th June 2018, and in our press release issued earlier today, both of which are available on our corporate website. Please refer to this press release for additional information regarding Akebia's proposed merger with Keryx Biopharmaceuticals. 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. I would now like to turn the call over to John Butler, Akebia's President and Chief Executive Officer. John?

Major Accomplishments

John Butler

President, CEO, Akebia

Highlights and Key Figures

Thanks John. Good afternoon, everyone, and thanks for joining us. On today's call, I will be highlighting our major accomplishments over the past few months. Jason Amello, our Chief Financial Officer will review our financial results for the quarter and I will close with our outlook for the remainder of 2018 before opening the call to questions. Dr. Rita Jain, our Chief Medical Officer and Nikki Hadas, our General Counsel will join us for Q&A.

Keryx Merger

Keryx Biopharmaceuticals

At the end of June, Akebia and Keryx Biopharmaceuticals shared the exciting news that we are combining to create a fully integrated biopharmaceutical company focused on developing and delivering innovative products to patients with kidney disease. We believe this combination has the potential to create significant value and growth opportunities for all of our stakeholders, including shareholders. This transaction is expected to close by the end of 2018. There is a strong strategic rationale for this combination. At a high level, it creates the potential for accelerated growth and for

organizational and product synergies, by bringing the best of Keryx and Akebia together.

Corporate Conference Call

Wednesday, 8th August 2018

Keryx, of course, brings Auryxia, an FDA-approved drug with two renal indications and a strong growth trajectory, as well as experienced commercial and medical affairs teams, who have been in the field for the last three years building relationships within the nephrology community. Akebia brings a talented R&D organization driving an approximately 7,000-patient global Phase III program for our product candidate vadadustat, which has the potential to change the standard-of-care for patients with anemia due to chronic kidney disease, a multi-billion-dollar market.

Leadership

Akebia and Keryx

Akebia also brings established collaborations with multiple companies to deliver vadadustat to patients and markets around the world, subject to the drug's regulatory approval in these markets. The combined R&D, medical, manufacturing and commercial functions along with Keryx's existing presence in the medical community and our collective expertise in the commercial renal market will provide 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. Upon this approval, the combined company will offer nephrologists a portfolio of renal products to address the needs of non-dialysis dependent and dialysis dependent chronic disease patients in the United States.

The current executive leadership team at Akebia will serve as the executive leadership team at the combined company with the addition of a Chief Commercial Officer. I feel confident that this team can build on the momentum that Keryx has already driven and identify and leverage new growth opportunities to ultimately build a premier company. We expect the combined company to have a unique footprint in the biopharma space, as a fully integrated renal company with an anticipated pro forma market cap of over a billion dollars. As a result, we will have the potential to be a partner of choice, increasing our engagement with the renal community and pursuing strategic business transactions that will further grow our business and realize value for shareholders and for patients.

Vadadustat Development

Clinical trials

Turning to the Vadadustat Clinical Development Program, we have continued to make important progress. This past quarter, we completed US enrollment of our Phase III INNO2VATE Conversion Trial, and we are targeting full enrollment for the INNO2VATE program by the end of 2018. We expect topline results in the fourth quarter of 2019 or the first quarter of 2020, subject to the accrual of MACE. In addition, our Phase III PRO2TECT Program continues to enroll in 27 countries.

We are pleased with the pace of the current enrollment and by simply maintaining this pace, we expect topline results for the program to come in mid-2020, subject to the accrual of MACE. We also initiated our Phase II FO2RWARD Study in dialysis dependent patients with topline results expected in the first half of 2019. This study is designed to provide us with additional data to differentiate and characterize vadadustat in the marketplace, subject to vadadustat's regulatory approval.

This past quarter, we also completed a type-c meeting with the FDA, in which we aligned with the agency on our statistical analysis plans, ahead of our planned NDA filing for vadadustat.

Corporate Conference Call

Wednesday, 8th August 2018

Finally, our collaboration partner Mitsubishi Tanabe continues its Phase III studies of vadadustat in non-dialysis dependent and dialysis dependent CKD subjects in Japan, with data readout expected in 2019. Now, as a reminder, these studies for Japan are not MACE dependent.

Now, I will turn the call over to Jason for a review of our financials.

Financials

Jason Amello

Chief Financial Officer, Akebia

Second Quarter

Thank you, John, and good afternoon, everyone. The second quarter of 2018 was an important quarter for Akebia from a financial perspective. In addition to the Q2 announcement of the merger with Keryx which is subject to satisfaction of the closing conditions, it would provide near-term commercial revenue and cash flow. Akebia financial results for the second quarter of 2018 demonstrate the company's continued advancement of its Vadadustat Development Program and the significant financial leverage obtained from its collaboration partners.

Net loss comparison

Akebia reported a net loss for the second quarter of 2018 of \$34.1 million or \$0.60 cents per diluted share, as compared to a net loss for the second quarter of 2017 of \$21.5 million or \$0.53 cents per share. Looking at the net loss on six-month year-to-date basis, it is important to note that the net loss of 2018, actually decreased by 13% as compared to the same period of 2017 despite increases in our development expenses.

Specifically, net loss for the six months ended June 2018 was \$57.5 million or \$1.09 per share as compared to a net loss of \$66.1 million or \$1.66 per share for the same period of 2017. This reduction in net loss is primarily due to the consummation of the Otsuka International Collaboration in late April 2017, which demonstrates the beneficial impact of our partnerships on our financial performance, and as this collaboration was operational for the entire six months versus the comparable six months of 2017.

P&L

Otsuka agreements

Looking at the components of the P&L for the quarter, on the revenue side, we are recognizing revenues under three collaboration arrangements: our Otsuka US agreement, our Otsuka International agreement and our MTPC agreement. It is important to point out that these collaborations are considered multiple-element arrangements under the Revenue Recognition Guidance, namely ASD-606. This generally means that noncontingent payments will be recognized over the life of the arrangement based on how activities under the arrangement are performed or delivered by Akebia versus when payments are actually received.

Corporate Conference Call

Wednesday, 8th August 2018*Collaboration*

Revenue is therefore recognized on a proportional performance basis as the underlying services are performed and costs are incurred. Collaboration revenue, the majority of which relates to the Otsuka agreements, was \$48.8 million for the second quarter of 2018 compared \$28.5 million for the second quarter of 2017. The increase in collaboration revenue relates to our continued advancement of Vadadustat Development Program and the associated accumulative costs incurred to date for the program on a proportionate performance basis. Collaboration revenue recognized for the second quarter of 2017 relates to revenue recognized from the Otsuka US agreement and beginning in late April 2017 from the Otsuka International agreement. Revenue recognized from MTPC during the second quarter of 2018 was not significant, since MTPC is conducting and funding the vadadustat Phase III program in Japan and as we have substantially completed our responsibilities to provide clinical supply to MTPC.

R&D Expenses

Moving to our research and development expenses, R&D expenses were \$71.9 million for the second quarter of 2018 compared to \$43.8 million for the second quarter of 2017. The increase is primarily attributable to an increase in external costs related to the continued advancement of the PRO2TECT and INNO2VATE Phase III Program, including ongoing enrollment, the manufacture of drug substance and drug product, and regulatory activities, as well as other clinical and preclinical activities. R&D expenses were further increased by headcount, consulting and facility-related costs required to support our growing R&D programs.

We do expect R&D expenses to increase significantly for 2018 as we target to fully enroll our INNO2VATE Phase III program by the end of 2018, and as we continue to advance our Phase III program in the FO2RWARD Study, prepare to initiate the Trilogy 2 Study, as well as develop our other product candidates. Despite this expected increase in R&D, it is important to keep in mind that a significant portion of the costs are reimbursed by our collaboration partner, namely Otsuka, which gets recorded as collaboration revenue, as I previously mentioned.

Admin Expenses

General administrative expenses were \$12.5 million for the second quarter of 2018 compared to \$6.9 million for the second quarter of 2017. The increase of \$5.6 million was primarily due to an increase in legal and other professional fees, related to the proposed merger with Keryx and an increase in cost to support the research and development programs, including headcount and compensation. We expect our GA expenses to increase in future periods to support our continued research and development and as we prepare for commercialization of vadadustat.

Capital Position

Turning to our capital position, we ended the second quarter of 2018 with cash, cash equivalents and available-for-sale securities of approximately \$402 million compared to \$393 million at the end of the first quarter of 2018. This higher cash balance in the second quarter is due to the timing of receipt of cost share prepayments from Otsuka versus the timing of our actual payments for certain expenses, which can vary from quarter to quarter.

Corporate Conference Call

Wednesday, 8th August 2018

We expect our existing cash resources, including the quarterly committed cost share funding from Otsuka, to fund our current operating plan into the first quarter of 2020.

We ended the second quarter of 2018 with approximately 56.9 million shares outstanding or 62.4 million shares on a diluted basis, inclusive of outstanding options and RSUs. Lastly, looking forward to the merger, the combined company will have an unaudited pro forma cash balance as of 30th June 2018 of approximately \$452 million, which along with the expected cost synergies of greater than \$250 million to be realized, five years following the closing and the potential for increasing Auryxia revenues are expected to provide the combined company with significant financial strength and flexibility to enable to continued growth.

With that, I will turn it back to John.

Vision for Future

John Butler

President, CEO, Akebia

Innovation

Thanks, Jason. Our vision is and has always been to building a leading innovation-driven, fully integrated renal company. Our planned merger with Keryx means that subject to the satisfaction of the closing conditions for the merger, we are just months away from realizing this vision. It is a big accomplishment and an incredibly exciting time for us. In the months ahead, we will continue to drive the vadadustat program forward as we plan for a successful integration with Keryx. I would like to take this time to say how much I appreciate all of the hard work and dedication of the employees of both companies and how proud I am for the opportunity to lead this talented team into the future. Now we will open the line for questions.

Q&A

Bert Hazlett (BTIG): Congrats on the progress. Just, John, you mentioned briefly in the opening remarks and in the press release about the type-c meeting with FDA. Could you describe a little bit more about what needed to be aligned and the results of that meeting? Then I have a question on financials.

John Butler: Sure. I think, Bert, I will have Rita Jain, our Chief Medical Officer who ran the meeting, answer the question on the FDA.

Rita Jain: Certainly, we did have a very productive meeting with the FDA and as is not unusual, we wanted to discuss details of our statistical analysis plans for the global Phase III programs prior to completion of the studies and submission of our registration package. Without getting into too much detail, we did align on some aspects of analysis for key endpoints in the trials and overall the interaction was quite productive and included our partner, Otsuka.

John Butler: I think given the length of the trial, just the opportunity to interact with the FDA again is always a positive thing to keep in touch with them.

Bert, you said you had a question on financials?

Corporate Conference Call

Wednesday, 8th August 2018

Bert Hazlett: I did, and I guess just a quick one on the MACE rate. Maybe you referred to it, but has the MACE rate been greater or less than what you have expected in the study to this point? Can you comment?

John Butler: Yes. I think the way we have talked about it in the past is still the case, it is within the range of what we expected. I think saying high or low, it is just too early to make that determination. However, it is within the range. Rita, you would agree with that?

Rita Jain: Yes, thanks.

Bert Hazlett: Okay, terrific. Our operating expenses, our estimates were a bit low relative to this quarter, relative to what they came in. Could you just talk to maybe some of the pacing of the operational expenses throughout 2018?

Jason Amello: Sure. We look to R&D. The R&D program just in general is expanding as we continue to enroll the patients and as we are targeting to fully enroll INNO2VATE by the end of this year. That pace continues. We are continuing to invest in the program to optimize that and as we are starting startup activities as well for the other trials. That ramp will continue. We generally have been increasing year over year as this trial gets closer and closer to being enrolled. That is primarily the driver on the R&D expense.

On the G&A side, the big driver there was really the costs pertaining to the planning for the merger. Most of our G&A is commensurate with a normal increase from the R&D spend support that. As you know, it is a very large trial. We obviously need a certain amount of G&A to support that activity with the CROs and so forth. I think you should expect both of these line items to increase commensurately with each other, borrowing the one-off transaction cost from the merger.

Allison Bratzel (Piper Jaffray): Just one quick one from me. I did not see anything in the release on timing for TRILOGY. Could you just confirm timing of trial initiation for that? Is that not until next year now? Remind us what you are hoping to see from that trial. Thanks.

Rita Jain: We are targeting the end of '18 or early '19 to initiate the TRILOGY trial, as we have previously discussed. The TRILOGY trial is planned as a Phase III study that will evaluate dosing of Vadadustat as compared to Epogen. We will look at switching from a variety of ESA products onto Vadadustat. We are evaluating the potential for QD and TIW therapy. Although, we have not fully finalized the protocols yet. That will still be additional detail that we will provide at a later point.

Allison Bratzel: Got it. Thank you.

Ed Arce (H.C. Wainwright): Just wondering in general how the merger integration is progressing.

John Butler: As we said on the call, I had an expectation that given some of the similarities of the companies and the shared experiences, that there would be a similar culture across the two companies. I am happy to say that that really is what we are seeing. A lot of these mergers really do hang on having similar cultures that can be easily integrated. While we are very different companies and that has been helpful also, frankly, that you have a commercial company and a development company so there is not a lot of people worrying about

Corporate Conference Call

Wednesday, 8th August 2018

synergies translated as jobs. We are just fundamentally very similar in our approach and our philosophy around putting patients first, etc., and a real commitment to the space. Of course, the geographic proximity makes it a lot easier for people to communicate face to face on an ongoing basis. I would say that I am very pleased with the progress we are making from an integration standpoint. I have a lot of confidence in the strength the company will have when this merger closes.

Ed Arce: Great. Thanks a lot.

Difei Yang (Mizuho): Hi, good afternoon and thanks for taking my question. John, post-integration, post-closing of the deal, where do you see the immediate growth area with Keryx's product portfolio?

John Butler: Yes. I do not think we have to wait for post-closing. You look at the momentum that Keryx has on the product. They reported their Q2 earnings this morning and almost \$26 million in revenue, which is very consistent with very strong growth and consistent with our expectations. When you think about the two indications, we see very, very robust growth opportunities in both indications. Hyperphosphatemia is a much more mature market, of course, and a much more competitive market. However, when you look at the growth that they have seen there, still growing share significantly, but share is still in the single digits, there is lots of opportunity. The KDIGO guidelines are changing to encourage people away from calcium as a second-line agent. That creates an opportunity.

There are multiple opportunities to grow on the hyperphosphatemia side. It is very important. I know that having communicated with the sales team multiple times since we announced the merger, that they are very focused on this. It is critical to maintain that focus on hyperphosphatemia. It is great to sell the new indication, IDA. However, hyperphosphatemia is a very important growth area. However, IDA is where there is significant momentum, as well. It is a very clear field. It is the only prescription iron product available in iron deficiency anemia. All of the outside market research we see suggests physicians increasing their adoption of the product, their trial of the product and that their experience is very positive.

Continuing to build on the momentum in IDA I think will be critical. Looking for other opportunities to enhance the growth in hyperphosphatemia will be there as well. However, as I said, the current commercial team there is going a great job of building momentum. Much stronger momentum than they have had at any time in the past. We obviously think there are other areas that we can add to that. However, it is always easier to drive further momentum when the line is moving in the right direction.

Difei Yang: Okay. Thank you for the additional color.

John Butler: Thanks, Difei.

Kennen MacKay (RBC Capital Markets): Maybe just to follow up with Rita on that FDA Type C meeting here on this data analysis. Really wondering if you can perhaps get a little bit more granular in terms of what changes were made to the statistical analysis plan versus those that were set about in your prior end of Phase II or pre-Phase III Type B meetings with the FDA.

Corporate Conference Call

Wednesday, 8th August 2018

Rita Jain: First of all, at the end of Phase II meetings, while there was some high-level discussion of the endpoints and comments around analysis, actually at that time, the formal statistical analysis plans that we used to analyze the studies were not fully prepared and were not reviewed with FDA. At this meeting, we had provided them with the full statistical analysis plans for all four studies. This was quite a significant conversation. I think for a number of reasons, we are not going to go into more detail. However, as I said, we were very pleased with the alignment that we reached with FDA. We have good clarity on the key points of our efficacy and safety endpoints, which allows us to fully move forward and be ready to analyze the data at the point of study completion. As you recall, we will be looking at those efficacy and safety and MACE data when we complete our study.

John Butler: Kennen, that is the normal process. You do not finalize statistical analysis plan when you are having your end of Phase II meeting. This is the way it is normally done. However, obviously, I think as Rita pointed out, in a study as complex as these, the SAP is an important box to check to get alignment with the agency.

Kennen MacKay: No, that is incredibly helpful color. I appreciate the added granularity there and it sounds like much more of a potentially even more comprehensive meeting than what we think about it during a Type C meeting. Beyond that, just wondering if I could get your perspectives on the competitive dynamic in HIF-prolyl-hydroxylase inhibitors space. One of your competitors just announced completion of enrollment in their US Phase III programs and had mentioned expecting topline data in Q4 and a potential NDA in first half '19. I was wondering if you could run us back through any timing or trial differences that are behind your expectations for INNO2VATE data in Q4. Based on the enrollment rating into PRO2TECT, wondering maybe when we could hope to see full enrollment there or a ballpark or what supports your expectations for data from PRO2TECT in mid-2020. Thank you very much.

John Butler: I think looking at the competitive dynamics that you mentioned, that really is not a change from I believe what had been disclosed previously. This timing of filing by mid-'19 for the first HIF-PH in the US I think is very consistent with what we have been expecting. All of our plans are unchanged from that perspective.

Maybe, Rita, do you want to comment on PRO2TECT enrollment and any of the trials dynamics?

Rita Jain: Yes. I think I might start by saying that we believe both INNO2VATE and PRO2TECT are progressing well. As you know, with MACE outcomes trials, as the programs get further along, in terms of both enrollment and accrual of MACE events, we are better able to estimate the timeline to study completion. John mentioned earlier that for the INNO2VATE program, we have finished enrollment for the larger of the two studies, the conversion study in the US, and we are targeting completion of enrollment at the end of '18 for INNO2VATE. For PRO2TECT, what we have seen is a very steady rate of enrollment over the first half of this year. Now, we continue to push on enrollment. However, what we have decided to do is take an approach of estimating that the enrollment rate will not change until the completion of the trial.

Now, obviously, the other piece that we are looking at is the accrual of the MACE events. Obviously, that progresses also. What we are seeing for both INNO2VATE and PRO2TECT is that the MACE rates are running in the range that we expect it. That gives us confidence in

Corporate Conference Call

Wednesday, 8th August 2018

the timeline that we are providing for study completion. We did not specify when PRO2TECT will complete enrollment because there are a number of factors that might come into our decision when to stop enrollment. However, within that range of factors, it really still does provide for topline data at the timeline that we indicated.

John Butler: Rita, correct me if I am wrong. The further you get in, given MACE's time to first event, the impact of what the underlying MACE rate is, is far greater than the impact of enrollment at this point than when you ultimately see.

Rita Jain: Yes. That is why, as I noted, there could be a range of timing for finishing enrollment or some decisions we make there. However, in large part, we do not expect it to impact when we will get topline data. Certainly, if our MACE rate were to change, that would be a factor, but it is tracking to what we expect.

John Butler: Even within the range, high or low, makes a difference. That is why you might want to continue enrolling or not. It is an insurance policy in a way too.

Rita Jain: Exactly.

John Butler: Does that help, Kennen?

Kennen MacKay: That does. Thank you.

John Butler: Thanks very much, and thanks everyone for joining us today. Have a great evening.

[END OF TRANSCRIPT]

Forward-Looking Statements

Statements in this communication regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding the expected benefits of the pending merger with Keryx, including but not limited to expected synergies, value creation, growth potential, and the combined company's portfolio; the closing of the pending merger with Keryx, including the timing thereof; the competitive position of the combined company following completion of the merger with Keryx, including but not limited to being a partner of choice for the renal community and for companies developing renal products; plans and goals for the combined company following completion of the merger with Keryx; the potential for vadadustat to provide a new oral standard of care to patients with anemia due to CKD; the rate and timing of enrollment of our clinical trials; the anticipated timing of the availability and presentation of clinical trial data and results; the benefits, including the potential effect on commercial position, of the designs of our studies; the potential characterization and differentiation information we believe will result from the designs of our studies; potential and anticipated payments from our collaborators, including the timing thereof; expectations regarding financial position, including the period of time our cash resources and committed funding from our collaborators will fund our current operating plan. The terms anticipate, expect, goal, may, opportunity, plan, potential, target, will and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including that Akebia or Keryx may be unable to obtain stockholder approval as required for the pending merger; conditions to the closing of the pending merger may not be satisfied; the pending merger may involve unexpected costs, liabilities or delays; the effect of the announcement of the pending merger on the ability of Akebia or Keryx to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom Akebia or Keryx does business, or on Akebia's or Keryx's operating results and business generally; Akebia's or Keryx's respective businesses may suffer as a result of uncertainty surrounding the pending merger and disruption of management's attention due to the pending merger; the outcome of any legal proceedings related to the pending merger; Akebia or Keryx may be adversely affected by other economic, business, and/or competitive factors; the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; risks that the pending merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the pending merger; the risk that Akebia or Keryx may be unable to obtain governmental and regulatory approvals required for the transaction, or that required governmental and regulatory approvals may delay the transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; risks that the anticipated benefits of the pending merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; other risks to the consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all; rate of enrollment in clinical studies of vadadustat; the rate of major adverse cardiovascular events in PRO2TECT and INNO2VATE; the risk that clinical trials may not be successful; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; the actual funding required to develop and commercialize Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the clinical studies of vadadustat

and the availability of financing to cover such costs; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete preclinical and clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the scope, timing, and outcome of any ongoing legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, and other filings that Akebia may make with the U.S. Securities and Exchange Commission (the "SEC") in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this communication, and Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this communication.

Additional Information and Where to Find It

In connection with the proposed merger, Akebia and Keryx plan to file with the SEC and mail or otherwise provide to their respective stockholders a joint proxy statement/prospectus regarding the proposed transaction. BEFORE MAKING ANY VOTING DECISION, AKEBIA S AND KERYX S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF AKEBIA AND KERYX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders will be able to obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Akebia and Keryx, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Akebia and Keryx make available free of charge at www.akebia.com and www.keryx.com, respectively (in the Investors section), copies of materials they file with, or furnish to, the SEC.

Participants in the Merger Solicitation

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. Security holders may obtain information regarding the names, affiliations and interests of Akebia s directors and officers in Akebia s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018. Security holders may obtain information regarding the names, affiliations and interests of Keryx s directors and officers in Keryx s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia securities by Akebia s directors and executive officers or the holdings of Keryx securities by Keryx s directors and executive officers have changed since the amounts set forth in Akebia s or Keryx s respective proxy statement for its 2018 annual meeting of stockholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger will be included in the joint proxy statement/prospectus relating to the proposed merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC s website at www.sec.gov, Akebia s website at www.akebia.com and Keryx s website at www.keryx.com.