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VKTX - Q3 2019 Viking Therapeutics Inc Earnings Call

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PRESENTATION

Operator

Welcome to the Viking Therapeutics 2019 Third Quarter Financial Results Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded today, November 5, 2019. I would now like to turn the conference over to Viking's Manager of Investor Relations, Stephanie Diaz. Please go ahead, Stephanie.

Stephanie Diaz - *Vida Strategic Partners Inc. - President & CEO*

Hello, and thank you all for participating in today's call. Joining me today is Brian Lian, Viking's President and CEO; and Michael Morneau, Vice President of Finance and Administration. Before we begin, I'd like to caution that comments made during this conference call today, November 5, 2019, will contain forward-looking statements within the meaning of the Securities Act of 1933 concerning the current beliefs of the company, which involves a number of assumptions, risks and uncertainties. Actual results could differ from these statements, and the company undertakes no obligation to revise or update any statement made today. I encourage you to review all of the company's filings with the Securities and Exchange Commission concerning these and other matters. I'll now turn the call over to Brian Lian for his initial comments. Brian?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Thanks, Stephanie, and thanks to everyone listening on the webcast or by phone. Today, we'll provide an overview of our third quarter financial results as well as an update on recent progress and developments related to our pipeline programs and operations. During the third quarter, Viking laid the groundwork for key milestones that we believe will be important value drivers for the company in 2020 and beyond. With respect to VK2809, our novel thyroid receptor beta agonist, this included completing the chronic toxicity studies required for long-term dosing in humans and preparing for the initiation of our planned Phase IIb trial in patients with biopsy-confirmed NASH.

With respect to VK0214, our second thyroid receptor beta agonist, during the quarter, we continued the work required to initiate a Phase I proof-of-concept study in X-linked adrenoleukodystrophy or X-ALD, which we expect to commence in the first half of 2020. I will provide additional detail on our development activities in a few minutes. But first, we'd like to review our third quarter financial results.

I'll now turn the call over to Mike Morneau, Viking's Vice President of Finance and Administration, to discuss our financial results. Mike?

Michael Morneau - *Viking Therapeutics, Inc. - VP of Finance & Administration*

Thanks, Brian. In conjunction with my comments, I'd like to recommend that participants refer to Viking's 10-Q filing with the Securities and Exchange Commission, which we expect to file later today for additional details. I'll now go over the financial results for the third quarter and 9 months ended September 30, 2019.

Our research and development expenses for the 3 months ended September 30, 2019, were $5.3 million compared to $5.7 million for the same period in 2018. The decrease in expenses were primarily due to decreases in stock-based compensation, manufacturing for our drug candidates and clinical and preclinical studies partially offset by an increase in expenses related to services provided by third-party consultants. Our general and administrative expenses for the 3 months ended September 30, 2019, were $2.2 million compared to $1.7 million for the same period in 2018. The increase in expenses was primarily due to increased stock-based compensation, services provided by third-party consultants and professional fees partially offset by a decrease in expenses related to salaries and benefits.

For the 3 months ended September 30, 2019, Viking reported a net loss of $5.7 million or $0.08 per share compared to a net loss of $6.6 million or $0.11 per share in the corresponding period in 2018. The decrease in net loss and net loss per share for the 3 months ended September 30, 2019, was primarily due to an increase in interest income recorded in the third quarter of 2019 versus that recorded in the same period of 2018. Our research and development expenses for the 9 months ended September 30, 2019, were $17.1 million compared to $14 million for the same period in 2018. The increase in expenses was primarily due to increased manufacturing for our drug candidates, preclinical studies, salaries and benefits, and services provided by third-party consultants partially offset by a decrease in expenses related to clinical studies.

Our general and administrative expenses for the 9 months ended September 30, 2019, were $6.7 million compared to $5.2 million for the same period in 2018. The increase in expenses was primarily due to increased stock-based compensation, services provided by third-party consultants and professional fees. For the 9 months ended September 30, 2019, Viking reported a net loss of $18.3 million or $0.25 per share compared to a net loss of $16.8 million or $0.32 per share in the corresponding period in 2018. The increase in net loss for the 9 months ended September 30, 2019, was primarily due to an increase in research and development and general and administrative expenses noted previously partially offset by an increase in interest income as well as the elimination of the expenses related to the change in fair value of the debt conversion feature liability due to the repayment of the Ligand Note in May 2018.

The decrease in net loss per share for the 9 months ended September 30, 2019, was primarily driven by the additional weighted average shares outstanding at September 30, 2019, versus those weighted average shares outstanding at September 30, 2018, given the public equity financings that occurred in 2018.

Turning to the balance sheet. At September 30, 2019, we had cash, cash and equivalents and investments totaling $288.1 million. And as of October 31, 2019, Viking had [72,263,516] shares of common stock outstanding. This concludes my financial review, and I'll now turn the call back over to Brian.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Thanks, Mike. As I stated at the beginning of the call, during the third quarter, we were focused on completing the important work that we believe will facilitate achievement of key corporate milestones. I'll first discuss the progress made in preparing for our planned Phase IIb study of VK2809 in patients with biopsy-confirmed nonalcoholic steatohepatitis or NASH.

As a reminder, VK2809 is an orally available small molecule agonist of the thyroid hormone receptor that possesses selectivity for liver tissue as well as the beta receptor subtype, suggesting promising therapeutic potential in a range of lipid disorders, including NASH. In September of 2018, we announced positive results from a Phase II trial of VK2809 in patients with hypercholesterolemia and nonalcoholic fatty liver disease. Participants in this study were randomized to receive VK2809 doses of 5 milligrams daily, 10 milligrams daily, 10 milligrams every other day or placebo for 12 weeks. We were pleased to report that the trial achieved both its primary and secondary endpoints, demonstrating potent reductions in liver fat content as well as improvements in plasma lipid measures.

As we reported at AASLD last year and at EASL this year, with respect to the trial's primary endpoint, VK2809-treated patients demonstrated statistically significant reductions in LDL cholesterol compared with placebo-treated patients. In addition, VK2809-treated patients experienced statistically significant improvements in other lipids, including triglycerides and the atherogenic proteins, apolipoprotein B and lipoprotein(a). With respect to the key secondary endpoint, VK2809-treated patients experienced significant reductions in liver fat as assessed by MRI-PDFF. Specifically, patients receiving VK2809 dosed at 5 milligrams daily for 12 weeks experienced a median relative reduction in liver fat content of approximately 54% from baseline. Patients receiving VK2809 doses of 10 milligrams every other day experienced a median relative liver fat reduction of approximately 57% from baseline, and patients receiving VK2809 doses of 10 milligrams daily experienced a median relative liver fat reduction of approximately 60% from baseline.

Across all VK2809 cohorts, the median relative reduction in liver fat was approximately 57%. By comparison, patients receiving placebo experienced a median relative reduction in liver fat of approximately 9%. The trial also included a responder analysis, which was intended to identify patients who experienced a 30% or greater relative reduction in liver fat content. This is an important threshold as multiple studies have demonstrated that a liver fat reduction of 30% or more correlates with an increased probability of improved overall histology. The results of this analysis were positive. All patients treated with VK2809 dosed at 5 milligrams daily experienced at least a 30% reduction in liver fat content. Approximately, 77% of patients receiving VK2809 dosed at 10 milligrams every other day demonstrated at least a 30% reduction in liver fat. And for patients treated with VK2809 doses of 10 milligrams per day, approximately 91% experienced at least a 30% reduction in liver fat.

The responder rate across all VK2809 cohorts in this study was approximately 88%. By comparison, approximately 17% of patients receiving placebo demonstrated a response. In considering the multiple drug candidates currently in development to treat NASH and the many data readouts announced in the last year, we believe the observed response rate to VK2809 is unmatched by any other oral compound currently in development. In addition to the robust efficacy observed, VK2809 has also demonstrated an encouraging safety and tolerability profile. In the Phase II study, no serious adverse events were reported among patients receiving VK2809 or placebo, and the overall numbers of adverse events were relatively evenly distributed across treatment arms.

We believe VK2809's unique potential to improve liver health, while also providing global cardiovascular benefits through reductions of systemic lipids, is a key differentiating factor when compared to many other agents currently in development. For these reasons, we believe VK2809 is the most promising candidate for the treatment of NASH in development today, and we are excited to be advancing it through the clinic.

To this end, we continue to aggressively move forward with our development plans for VK2809, and we are pleased to report that we recently filed an IND application with the FDA's Division of Gastroenterology and Inborn Errors Products. We are currently focused on the important ramp-up activities required for conducting our planned Phase IIb study in patients with biopsy-confirmed NASH. Today, we are fully engaged in training, preparing and supplying our clinical sites in order to facilitate a smooth and efficient study initiation. We currently plan to initiate the study this quarter. As we have previously described, we expect the trial to evaluate more than one dose of VK2809 for up to 12 months and plan to enroll patients with F2 and F3 fibrosis as well as a limited number with F1 fibrosis. We will provide more detail on study design when the trial is initiated.

I'll now provide an update on our VK0214 program. VK0214 is being evaluated as a potential treatment for X-linked adrenoleukodystrophy or X-ALD, a devastating disease for which there is no approved therapeutic treatment. X-ALD is caused by a defect in a peroxisomal transporter called ABCD1. This defect can result in an accumulation of very long-chain fatty acids in plasma and tissue, and it is these elevated very long-chain fatty acid levels that are believed to contribute to the severe cerebral and motor neuron toxicities that are characteristic of the disease.

The thyroid beta receptor is an important potential target for therapeutic intervention in X-ALD because it is a known regulator of very long-chain fatty acid metabolism. Like VK2809, VK0214 is an orally available small molecule thyroid receptor agonist that possesses selectivity for the beta

receptor subtype. To date, results from in vitro and in vivo studies have demonstrated that administration of VK0214 results in a significant reduction of very long-chain fatty acids in both plasma and tissue, potentially leading to a therapeutic benefit.

These promising results for VK0214 were achieved through our ongoing collaboration with the Kennedy Krieger Institute, one of the world's leading X-ALD research centers. Both the Kennedy Krieger Institute and Viking teams are excited by our findings to date and eager to advance this program into the clinic. We are currently conducting IND-enabling work for VK0214 and plan to initiate a proof-of-concept study in humans in the first half of 2020.

Turning to corporate matters. It is important to note that as we advance both VK2809 and VK0214 simultaneously through the clinic, we continue to carefully manage our financial resources. As a result, we completed the third quarter with approximately $290 million in cash and equivalents. We remain confident that these funds are sufficient to allow completion of multiple clinical inflection points including studies of VK2809 in NASH as well as proof of concept studies with VK0214 in X-ALD. In conclusion, the considerable work conducted during the third quarter has readied us for the critical milestones that lie ahead. With respect to VK2809, we recently completed chronic toxicity studies to support long-term dosing in humans. The results of these studies, along with additional clinical and nonclinical data, form the basis of an IND application that was recently filed with the FDA. We remain on track to initiate our planned Phase IIb clinical trial in biopsy-confirmed NASH by year-end.

With respect to VK0214, we continue to conduct the IND-enabling work that will allow us to initiate a Phase I proof-of-concept study in X-ALD and we remain on track to begin this trial in the first half of next year.

Finally, to support the advancement of these as well as our earlier-stage programs, we continue to carefully manage spending and have maintained a strong balance sheet that we believe will see the company through key milestones, including our planned clinical studies. We look forward to providing updates on our pipeline programs and other corporate developments as they are available.

This concludes our prepared comments for today. Thanks again for joining us, and I'd now like to open the call for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Steve Seedhouse with Raymond James.

Timur Ivannikov - *Raymond James & Associates, Inc., Research Division - Senior Research Associate*

This is Timur Ivannikov on for Steve Seedhouse. Congratulations on your IND filing. So we had a question about your Phase IIb study design. Could you talk about the most important considerations that you're waiting for, for the FDA to confirm? For example, I think you need permission to run for 12 months versus only 3 months prior so it would be good to have no severe restrictions? And also, you would like to test a wide dose range. I guess, what type of design confirmation from the FDA, would you consider a win for Viking?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Thanks, Timur. So what we said in the past, and what I'll say again here is that, we'll be disclosing the details of the trial design at the time of initiation. We would certainly plan for a longer-term study than 3 months, and we would hope to be able to enroll patients with Type 2 diabetes and those sorts of features. So we'll have more to say when we're able to, but we're not going to make a lot of details -- we're not going to give a lot of details on that trial design on this call.

Timur Ivannikov - *Raymond James & Associates, Inc., Research Division - Senior Research Associate*

Okay. And then, I guess, in terms of your preparation activities for Phase IIb study, could you talk a little bit more about the kind of dialogue you've had with clinical study centers and potential investigators? And could you talk about your -- the readiness of your contractor manufacturer to supply VK2809 for Phase IIb? Not sure if they've had to manufacture this amount before.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, thanks. It's a good question. So we -- like any company embarking on a larger study, we have been planning for quite some time to initiate the study. And I think all of those processes are moving forward, as would be expected. And we expect when the trial is initiated that multiple sites will be open for enrollment. There's no real update on manufacturing. We're fully prepared to supply the study, that's not an issue. And so right now, we're looking forward to getting started.

Operator

Our next question comes from Joon Lee with SunTrust.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Submission of the IND. So I noticed your cash is basically untouched from the prior quarter. What's your year-end cash guidance? And when do you expect a ramp in cash spend as you open clinical trial sites?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

So, cash did tick down a little bit in the quarter, but it has remained I think pretty robust. It will tick up in the fourth quarter and in 2020. We haven't given any guidance but it will be I would say materially higher than it was in the first 3 quarters of this year.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

And regarding the IND and the trial design, are you able to say or provide any color to the extent that you're able to on how it compares to other Phase IIb NASH studies. Is it fair to assume that it's very similar or should we actually wait until the first patient is enrolled to get insight into the design of the trial?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

No, that's a good question Joon. So we've used as a template the other Phase IIb studies that I think are relevant for us looking at MRI, maybe a little bit earlier and histology a little bit later. And so we'll have all the parameters on the end points and so forth when we're able to start. But that would be the template, you've seen it in a couple of our competitors, a longer-term study with an MRI interim and then histology later.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

And not to belabor this point, but is it fair to assume that the enrollment criteria are also similar or are there differences that we should wait for?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. This is a key question, I think, for everybody, and we'll have the inclusion/exclusion criteria. Once we initiate the study, we'll discuss that a little bit more. But yes, we would intend for it to enroll similar populations to other Phase IIb NASH studies.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Excellent. And then lastly, will you PR a press release when you start the study and the first patient is enrolled.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

We'll have a press release when we start the study, yes.

Operator

Our next question comes from Derek Archila with Stifel.

Unidentified Analyst

This is [Avan] on for Derek. Just wondering if the Phase IIb is going to be U.S., ex U.S. or both?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, thanks. So right now, it's primarily U.S. We will be preparing to move into other countries, but the initial study will be primarily U.S.

Operator

Our next question comes from Jay Olson with Oppenheimer.

Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

Congrats on all the progress this quarter. Can you please explain the key differences between the IND you just filed with the Gastro division compared to the previous IND you filed with the metabolic division? And then I had one follow-up question.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. So the prior IND -- this is a great question. The prior IND in the metabolic division was really -- it utilized a protocol that the prior owner of the study of the compound had cleared with the FDA for a 12-week study in hypercholesterolemia. And so we took that study and added certain endpoints that were relevant to NASH, like the measures of liver fat content as well as adjusting the enrollment criteria. The current IND is quite a bit different. It's targeting patients with biopsy-confirmed NASH, the endpoints are primarily related to liver, although we will be looking at plasma lipids. And importantly, a lot more data went into this IND. So the prior IND was a 13 -- had a 13-week tox. We have substantially more tox data here as well as, obviously, the Phase II data that -- from the completed study. So a lot more data in this IND in a completely different protocol.

Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

Great. That's very helpful. And then as a follow-up question, can you just talk about the key differences between the profiles of your 2 thyroid beta agonists and how those profiles line up with the 2 different indications you plan to study them in?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. So they're different chemical structures, and a key difference is that the 2809 molecule has a prodrug moiety that's cleaved in liver by CYP3A4. The 0214 molecule is a little bit more diffused, it's not a liver-directed prodrug. And we thought that, that might be more relevant to X-ALD. Truth be told, we think both compounds are probably pretty suitable for NASH. But in the animal studies, 0214 looked really, really promising for X-ALD. It's got a little bit better selectivity for the beta receptor over the alpha receptor. It's still single-digit nanomolar on the KI. And the PD profile is just a little bit different. It's slightly different biological characteristics. The solubility characteristics are slightly different. So that's just a different molecule, so it's got a slightly different profile on those metrics.

Operator

Our next question comes from David Bautz with Zacks Small-Cap Research.

David Bautz - *Zacks Small-Cap Research - Senior Biotechnology Analyst*

I'm curious if you could quantify how recently you were able to get the IND filed. And with as large as that filing presumably is, is there any chance that the FDA could take more than 30 days to get back to you on it?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, it's a key question. We're not going to give any details around timing. You raised a really interesting point that the size of this IND is, I'd say, quite a bit larger than your typical IND, whether that impacts the review time, we don't know, but it's a good point.

David Bautz - *Zacks Small-Cap Research - Senior Biotechnology Analyst*

Okay. And as far as potentially partnering 2809, do you think it will be necessary to have biopsy-confirmed data before a partner is ready to come in?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

So a better question for potential partners, but my feeling is, no. I think that we've seen activity in the past that was made on earlier-stage data. But some of the comments we hear are along those lines. We'd like to see histology data, but others seem to be maybe holding that as less of a hurdle. So it all depends on the partner. But I don't think it's a gating -- I don't think it's a black and white gating factor.

David Bautz - *Zacks Small-Cap Research - Senior Biotechnology Analyst*

Okay. And do you think partners are more interested maybe in 2809 as a monotherapy or do you hear more interest about using it as part of a combination therapy?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. Again, that's -- it depends on the other party. I think the -- it feels like there is a shift a little bit more to combination therapies. I know everybody's been talking about this for quite some time what mechanisms might play well together. And it does feel like the partnering interest may be is drifting in that direction a little more heavily than it was, say, a year ago. But it's not for everybody. I mean, some, I think, are certainly satisfied with single agents.

Operator

Our next question comes from Andy Hsieh with William Blair.

Tsan-Yu Hsieh - *William Blair & Company L.L.C., Research Division - Senior Research Analyst*

Congratulations on the progress. I have one that is related to disease progression. So for patients who experience greater than 30% or even 50% reduction in liver fat but did not subsequently benefit histologically, do you have a view about what's going on in these patients?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, this is a great question. I don't know. It seems like when you look at these published analyses and presentations at conferences. The probability is higher that you'll see a histologic benefit, but it's not 100%. It just seems that you see better histologic responses and a larger histologic response in patients who have that 30% or greater liver fat reduction. But it doesn't hold true for everybody. And maybe that is related to some underlying genetic predisposition, I don't know.

Tsan-Yu Hsieh - *William Blair & Company L.L.C., Research Division - Senior Research Analyst*

Okay. And a strategic question, I guess, I was very surprised by the Alzheimer's drug approval in China earlier this week. And so I'm curious about your thoughts regarding the China market for Viking. Given the reform efforts there, it seems like drugs could potentially get conditional approval. And then if you need a larger patient safety database or efficacy, it seems like they rely on real-world data, so it really provides you with a rapid to-market strategy. Just wondering about your thoughts there.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, this is an interesting question, Andy. Thanks. So we do -- I'm sure everybody does, so we do regularly field inbound interest from parties in China. And your point is well taken that maybe the philosophy is a little bit different there, maybe more constructive that allows you to move forward more easily. I'd say that's offset by the differences in features of the disease, the Asian population tends to get a little bit more of a skinny NASH so the NASH is a little different, I think, in that population, and that would likely require you to step back and run a proof-of-concept study in that population prior to getting into registration. It's not a huge difference but it does offset the potentially more conciliatory regulatory path. But I -- we're always open to talking to those partners, and we do have some conversations ongoing. And if we decide to do anything, we'll certainly let you know.

Operator

Our next question comes from Yale Jen with Laidlaw & Company.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

Just 2 quick ones. First one is for the Phase IIb study. I know you're not going to talk much about the details but would you also include patients have -- obese patients as one of the possibility or how you think about that particular issue?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. I think the only restriction on obesity is the ability to fit into the MRI machine. So we would expect to enroll obese patients unless there's some unexpected limitation there.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

Okay. That's good to know. And maybe just the last question, a little bit of housekeeping, which is that you mentioned that the fourth quarter, your expense will increase more substantially. Would that be basically, I assume, in the R&D side or would any other, sort of, aspect will be changed as well?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, it would be almost exclusively on the R&D side.

Operator

Our next question comes from Pasha Sarraf with SVB Leerink.

Michael Holden Kratky - *SVB Leerink LLC, Research Division - Associate*

Brian, this is Mike on for Pasha. I know you've touched on this earlier, but I just wanted to confirm if you would note that will you have a press release for the FDA acceptance of that IND? Or is it really just going to be the start of that Phase IIb study?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

So I think that the difference there will be relatively minor, so we will have it on the initiation, which we would hope to be very nearly concurrent with the clearance.

Michael Holden Kratky - *SVB Leerink LLC, Research Division - Associate*

Got it. That makes sense. And then second question, just in terms of how you're thinking about dosing for the Phase IIb study. I know you'll talk more about the study design once you get the confirmation, but just curious what doses you're confident that you'd be pursuing in a Phase IIb study versus any additional ones that you'd like to pursue based on what the FDA says.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. So we've always said that there will be some overlap from the Phase IIa study. And then we would also like to explore lower doses as well because it looked like in that study, all 3 cohorts were sort of similar in efficacy. They were just, sort of, clustered on the far end of the dose-response curve. So we think we can come down and still realize, I think, pretty attractive efficacy, but we do want to have some overlap with that study for comparative purposes.

Operator

And our next question comes from Mayank Mamtani with B. Riley FBR.

Unidentified Analyst

Brian, this is [Wayne] on for Mayank. So the first question I have is seeing your dialogue with Phase IIb design, what are your learnings on the FDA stance on the acceptable NASH resolution definition? Because it seems like we may have another way to define any upcoming liver meetings, so which definition do you intend to advance with in determining the efficacy for the VK2809?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes. I think we'll -- as I said to -- in response to another question, the design and endpoints will be pretty similar to other Phase IIb's that have been reported. And I think most of these studies include all of the registration -- both of the registration endpoints as well as different subsets of those registration endpoints. So we'd be no different there. We'd certainly want to understand which of the 2 registration endpoints are more promising for the compound.

Unidentified Analyst

Okay. And the other one is, how do you think the FDA perceives the wider therapeutic window that you had observed in the Phase II and AASLD study as well as what you may have observed in your preclinical chronic toxicity study? Are there any perspective on how this inform the dose level you'd like to take forward?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Well, we selected the planned doses based on what we saw in the Phase II. We didn't see any reason to dose higher. But we did think that we could probably realize efficacy at lower exposures. I think we have adequate coverage on the toxicity side, the animal tox side, to allow all of the planned doses to move forward but maybe that was our thinking.

Unidentified Analyst

Congrats on the progress.

Operator

Our next question comes from Joe Pantginis with H.C. Wainwright.

Joseph Pantginis - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Brian, I'll preface this question by saying, we obviously don't get these kinds of details from companies in general, but I did want to focus on the tox for a second. Obviously, one could assume that you're encouraged by what you see for the longer-term tox. I was just curious, is there anything that you can point to? Was it pretty vanilla with longer-term tox? You're pleased with the details? Anything that stuck out? So anything that you could provide would be helpful.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Joe, I know it's obviously a really key question. We're not going to give a lot of detail and that's pretty consistent with industry standards and with our prior comments as well. I think, though, that we're comfortable with what we have observed in the longer-term studies. We do not have the final analyses completed. But so far, I think we're okay with what we see. But just not going to be able to give a lot more detail there, but I appreciate the interest and the question.

Operator

(Operator Instructions) Our next question comes from Scott Henry with Roth Capital.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Just a couple very quick questions. With 2809, are there any expectations for interim data? And I'm just trying to get a sense of when we may get our first look at the data in any form.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, Scott. It's an important point. So we do -- if you look at some of the prior Phase IIb studies that look at MRI early, that MRI data set is made available prior to the histology data, and we hope to follow that playbook as well.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. And do you have any, kind of, sense of when we may see that, assuming the trial starts enrolling and it enrolls on track?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, it's hard to predict right now. I think we'd want to get a little ways into the study and see what enrollment looks like versus our projections before making a prediction.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. Fair enough. Second question, just with regards to 214 for X-ALD. I guess, first, do you expect to file the IND in Q4 or will it be an early 2020 event? And I don't know if you can give any color on how that -- what we should expect in that first, kind of, proof-of-concept trial.

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, it's going to be in 2020 when we file the IND. And that study, what we've indicated in the past is, it will likely be, kind of, a seamless adaptive design where you initiate with the single-ascending dose in healthy volunteers and then roll into a multiple-ascending dose in healthy volunteers and then roll into a short-term proof-of-concept study in patients. And so we would hope to be in a position to have some preliminary results toward the end of next year if all goes well.

Operator

Our next question comes from Jason McCarthy with Maximum Group (sic) [Maxim Group].

Jason Wesly McCarthy - *Maxim Group LLC, Research Division - Senior MD*

I was just going to keep on the 0214. As the company looks to really diversify its clinical portfolio, can you talk a little bit about the activity around the adrenoleukodystrophy space? Because it's been very difficult from a drug development perspective, historically, but there's been a lot of activity on the gene therapy side targeting ABCD1 but 0214 is clearly different. It's involved with ABCD2. And maybe you could discuss that and how these 2 approaches could be unique and/or even complementary to each other?

Brian Lian - *Viking Therapeutics, Inc. - President, CEO & Director*

Yes, Jason. So we would likely target with 0214 the, initially anyway, the adult population and that's the adrenomyeloneuropathy population. The gene therapies have typically targeted the childhood cerebral form of the disease, which is the rapidly progressive, often fatal, form of the disease. We think that 0214 could complement gene therapies particularly during the engraftment period while the gene therapy is, sort of, taking hold, so to speak because it will, we expect, ameliorate the elevations in very long-chain fatty acids. And then when you get the natural ABCD1 expression, that should take over. But in the adult population, the gene therapies aren't being as actively pursued, and we think that 0214 is particularly promising there. So that would be our initial focus.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Stephanie Diaz for any closing remarks.

Stephanie Diaz - *Vida Strategic Partners Inc. - President & CEO*

Thank you again for your participation and continued support of Viking Therapeutics. We look forward to updating you again in the coming months. Have a good day.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.