Arcutis

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Chris Shibutani: Good afternoon, everybody, and thank you for joining us at the Goldman Sachs Healthcare Conference. My name is Chris Shibutani. And along with my colleagues, we are thrilled to welcome you to the presentation, and we're especially excited to have Arcutis once again. And here on stage with me, Frank Watanabe, President and CEO. And in the audience, we also have David Topper, who is the Chief Financial Officer, and other members of the team here. Frank, thank you for joining us once again.

Frank Watanabe: Thanks for having us. Good to see you, as always.

Chris Shibutani: Sadly, we're not as much in your neighborhood, and thank you for trekking all the way across the country.

Frank Watanabe: The weather...

Chris Shibutani: I know. It's getting a little bit dicey, but your making yourself here physically present, very valuable and much appreciated.

So, let's catch up a little bit on Arcutis. It's been a story that's been going through a lot of the evolution. You're always trying to do important, but sometimes difficult, things, including looking at markets that maybe don't get as well appreciated by the traditional Big Pharma companies, making sure that you're interrogating and approaching things in tactics that are slightly differentiated. Not everything has necessarily worked, but we're coming through a more challenging period here. So, tell us a little bit about Arcutis and how you're feeling about where we're at with the company and the objectives mid-24.

Frank Watanabe: You encapsulated sort of our approach well. I think we're a little bit of orthogonal thinkers. We were created as a company to address what we saw as a gap in dermatology. People weren't really innovating in some of these larger markets where biologics maybe aren't appropriate, and we saw an opportunity to really come up with innovative new therapies that address unmet needs.

And I think it's always challenging launching drugs, but I think things continue to evolve and improve. We launched our first product, the cream for plaque psoriasis. It's coming up on two years ago. It was approved in July of '22. I think that product continues to gain momentum, and the clinician feedback has been very good.

Then we had the approval of our foam in seborrheic dermatitis in December, which I think is one of these neglected diseases that you mentioned. And that launch has, I think, gone phenomenally well. And I think that's partially a reflection of prior experience with ZORYVE cream. The doctors knew the drug already, and they felt confident with it. But also, it was a reflection of the lack of innovation and the high unmet need in seborrheic dermatitis. And so, we've seen a really nice uptake in the foam as well.

And then we're waiting eagerly for final word from the FDA on the approval of our third product, which is another version of our cream for atopic dermatitis. That PDUFA is July 7. And so, we'll be launching in atopic dermatitis sometimes later the summer.

And then we have communicated that we plan on filing for our fourth approval in scalp psoriasis sometime during the third quarter of this year.

So, lots of exciting things happening. Product continues to perform clinically very well.

And I think one of the other areas that we've tried to innovate is around access and reimbursement. That also continues to go very well for us, and we've had good success with the cream and commercial coverage. We are now starting to pick up Medicare and Medicaid coverage. Had a Florida win actually earlier this year. So, we're on formulary for Florida Medicaid and expect to see more progress on that front as the year progresses. And the foam has done very well on coverage, and that's allowed us also to then really get our gross-to-nets down rapidly to what we think is close to being steady state pretty quickly on both products.

Chris Shibutani: I think it's interesting, you're a veteran in the industry. You come from a heritage where there's a lot of understanding of scientific clinical development, yourself personally. The company is based in Westlake Village, which obviously is the home to one of the large-cap biotech and biopharma brethren. And so, there's a lot of insight and capabilities and know-how within that ecosystem within that community.

I was always struck by the fact that there's this identification of opportunities for which there's typically initial skepticism in terms of, like, the usual playbook of just where you go. And I think, particularly, for dermatology, you always see moderate to severely, actively, sort of progressive disease. And the real landscape of patients out there and the magnitude of clinical unmet need probably is a bunch of kind of silent people, except for the sound of a lot of scratching that's probably happening, who have more the mild and moderately active disease. And they're like, "Hey, what about us? What are we able to do to address our symptoms? We're not hospitalized, but we have significant needs."

And boy, there is amongst clinicians and patients kind of almost a psychological gulf between going from, "Here's a band-aid. It's called topical steroids. It'll help you for a bit. Can't take it for long. And then, by the way, there's a pretty big gulf before we get to some wonderful, very sophisticated treatments, but involve typical injections and quite expensive." And so, that unmet need, which is, just said commonly, because there's a lot that's perhaps overused, is something that you have very specifically targeted strategically.

And you're doing it with topical treatments that make me think metaphorically of things that are, like, it's not quite a drug device, but there's a drug presentation and formulation component to it. And I think that always actually translates, to a certain extent, to some element of competitive barrier to entry, as well as durability.

And the irony is I think that, separate from the molecule, your carrier is actually, in some respects, some of the special sauce that has made it possible.

Frank Watanabe: Absolutely. No question about it.

Chris Shibutani: So, maybe let's just talk a little bit about the product. Because it's one thing to track script trends and stuff like that. And maybe it's been a little while, and especially since the stock has reawokened, talk to us about the product, the presentations – because we have the cream, we have the foam – and the importance and the relevance of that when you're selling stuff to people who have a problem.

Frank Watanabe: Sure. And so, I think it really goes back to the foundation of Arcutis. I was one of three guys at the beginning. I think you know the other two. So, David Osborne was our Chief Technical Officer. He's retired now. But David is probably the best topical formulator in the whole industry. Thirty-six FDA-approved drugs that he's invented And then, Howard Welgus was our first Chief Medical Officer, who's a dermatologist, 40 years in dermatology. And that gives us that deep understanding of what are the problems that derms and their patients are dealing with. And I'm very proud to say that we have eight dermatology clinicians at the company - eight – which is what gives us that understanding.

But the formulation is absolutely critical. A drug doesn't work if a patient doesn't take it. And if it causes irritation at the site of application or if it's greasy or it stains their clothes, those are all going to affect their compliance to the drug. And so, we intentionally designed formulations that were cosmetically elegant, pleasing to the patient, but also were effective in delivering the drug.

In addition to that, some of the diseases we're treating, the formulations of many drugs can actually work against the efficacy of the drug. So, every single topical anti-inflammatory drug, except for ZORYVE, has what's called penetration enhancers in them. It helps to deliver the drug. And these literally punch holes in the skin so that the drug can get in.

We knew that was a bad thing to do, particularly in a disease like atopic dermatitis. And so, we don't use any penetration enhancers. We formulated our drug so that it's matching the pH of the skin. So, you're not changing the pH of the skin, which can also change the microbiome, which can affect the disease.

We use a – when you mix oil and water, like when you're making salad dressing, you need what's called an emulsifier to get them to mix together. Most emulsifiers will strip oil, moisturization out of the skin. We chose a surfactant that doesn't strip moisture from the skin.

So, it's been very intentional about how we think about designing our formulation so that the formulation is working with the drug, and not against it. And that was important in psoriasis. It's more important in seborrheic dermatitis. It will be very important in atopic dermatitis. And it aids both in the efficacy, we think, as well as in compliance to the medication.

Chris Shibutani: Right. The carrier itself, like a little bit of a secret sauce, but almost too good. I remember going to the American Academy of Dermatology meeting when it was in Boston, put the back of your hand out there, and it was amazing. You held an analyst meeting, and from that standpoint, recognizing the patient experience was very much about the immediacy

of temporal relief. You said, "Other drugs may cause irritation." I think you were kind. I think there's plenty of anecdotes about it causing outright painful circumstances and sending you to a different clinician to distract you from your original itch problem because you had something more acute going on.

So, a product that really addresses a lot of unmet need here.

Let's talk about the commercialization strategy here, perhaps in terms of the journey. There's been a couple of opportunities to reset. But it started with a tactic that engaged sort of the complexities and the imperfections of the pricing environment. It's been able to work at a certain level, perhaps not. And therefore, like any approach, you've had to tweak it.

So, maybe talk about your comfort with where you are with your pricing strategy now and what you've learned since the launch and, in particular, how that's fitting in with any adaptations.

Frank Watanabe: So, I would actually maintain that our pricing strategy has been right from the outset and it continues to be right. And I think the fact that we just won coverage for Florida Medicaid is a good example of that. And I can actually disclose here, I guess, because it's a public forum, we will get Texas Medicaid here very shortly as well.

Chris Shibutani: You heard it here first, folks.

Frank Watanabe: And that's important. About half of the atopic dermatitis market and half of the seborrheic dermatitis market are Medicare and Medicaid patients. We didn't want to just ignore those patients like, unfortunately, many companies do. And so, we priced our drug in such a way that we could get good Medicare and Medicaid coverage. We're starting to pick up Medicaid. We bid on Medicare business. We expect to start getting Medicare coverage later this year as well.

And you think about the size of the opportunity. Half of all patients being government-pay patients, not commercial patients, that's a big opportunity. And because of the way we've priced it, our government book of business will be about as profitable as our commercial business as well. So, we're not giving up a lot of margin and we have a big market expansion.

So, we think it's the right strategy. It means that we're able to serve more patients, help more people with their disease, and create more shareholder value because it's going to drive growth in the sales volume.

Chris Shibutani: The gross-to-net has been a notorious debate with new product launches. It's been a bit notorious, in part, because people are less familiar with some of the dynamics when you think about this category of drug. We're more familiar with stuff that, like, starts at $15,000 to $20,000 per year, and you have all these patient assistant programs here. So, you're kind of navigating probably a zone that certainly investors are less familiar with. And you have a couple of competitors who publicly talked about ambitions about what kind of gross-to-nets they could achieve, found that that is a not easily attained objective here.

Where we're at now, approaching the two-year anniversary, how should we be thinking about what gross-to-nets are currently across your business and where we could be,

maybe some reasonable objective – let's pander a bit to our investor clients – say by the end of this year, entering into '25?

Frank Watanabe: So, maybe I'll start with the end in mind. The unfortunate reality of drug pricing in America today is, for a retail product, you have to pay a rebate to the PBM or to the government. You have to pay the distributor. You have to pay the pharmacy. And the insurance companies continue to shift costs onto the patient. And you want the patient to have a reasonable co-pay so that they fill their prescription. So, you have to pay patient co-pay assistance as well.

You add up those things, and for a retail product that's going to probably eat up 50% of your list price. Sometimes more. If you're paying very large rebates, your gross-to-net is going to be really, really bad.

But 50-ish percent is sort of best in class. We have continued to state that we thought we would get into the 50s with our gross-to-net. And I'm really pleased to say at the end of the first quarter, we were already in the low 60s. And that's with a new product launch in the quarter. So, we're getting very close to what we expect to be steady state, which is in the 50s.

One of our competitors has also done that. They've shown that it can be done with the right programs in place. And I feel confident we'll be able to get there.

I think we'll probably get to steady state by the end of this year on ZORYVE cream and psoriasis. ZORYVE foam in seb derm is rapidly catching up, and it will not be that far behind. And then, the atopic dermatitis launch, as we pick up coverage, we'll rapidly get to that point as well.

But I think we feel very confident. And I would say investors should look at our track record. We've been able to deliver every quarter, bringing that gross-to-net down. And low-60s already, I think is a good performance. But we think we can improve on it.

Chris Shibutani: Seb derm. It's almost been a broken record with you talking. "You guys don't appreciate the market opportunity in seb derm." And myself and a couple of other analysts who you've known well for many years are like, "Yes, Frank. Okay. We don't appreciate it." Sure enough, it's been quite an opportunity. Talk about the indication and maybe share with us some of the aspects of the interface here. Because it's something we clearly didn't quite get, and you've been able to execute.

Frank Watanabe: I think it's understandable. No one has worked in this space in years. So, it's not like anyone has looked at seb derm very recently. But it's a big market. They're about 10 million Americans with seborrheic dermatitis; about four million of them are on drug treatment today. And the challenge is that the existing therapies weren't very good. They didn't work very well, and they didn't fit with patients' lifestyles. A shampoo, for example, that you're supposed to use once a day and leave in your hair for 10 minutes. Well, a lot of women don't wash their hair every day. So, that's not going to work for them. Or greasy steroids you're having to apply to your face. None of them worked very well, and patients weren't very compliant to them. And frankly, doctors were often reluctant to treat it because it was such a hassle and they knew it wasn't going to work.

We designed our foam – and I actually have the foam in my pocket if you'd like to try it.

Chris Shibutani: I live for show-and-tell.

Frank Watanabe: So, I'll just give you a little squirt.

Chris Shibutani: That's actually a big squirt.

Frank Watanabe: But you just take this very nice foam, you part your hair, you rub it on, and that's it. It doesn't mess up your hair. It doesn't change your hair color. And then if you have any left over or you have it on your skin, you just rub it in and it's gone.

Chris Shibutani: Wow. The blood-brain barrier thing is remarkable. I'm having complex thoughts now all of a sudden. We're solving the world's problems. Very cool product.

Frank Watanabe: Great formulation. Fantastic efficacy. Eighty percent of patients had IGA success at only Week Eight. One in two patients were completely clear at Week Eight. This is amazing efficacy, far better, I think, than the other therapies.

And we saw – seb derm is hallmarked by itch. That's probably the thing that bothers patients the most. We saw itch response in 48 hours with seb derm. So, what we're hearing from clinicians – I've been talking to a lot of clinicians lately – it performs so well in their clinic that they're actually starting to look for new patients to treat for seb derm.

So, we're really excited. I think it's a major step forward in the standard of care. It's helping patients. It's making doctors' lives easier. And frankly, it makes our doctors look good, because all of a sudden the patient's seb derm is gone, they're not itching anymore, they're happy.

Chris Shibutani: Help us a little bit with the modeling here and the forecasting, because the revenue trajectory has been strong from the get-go and some of the commentary that you've had have meant – let people think about parts of that equation. There was seemingly some element of pent-up demand...

Frank Watanabe: No question.

Chris Shibutani: ...that you were able to capture early on. So, where are we in this? Because investors are often trying to, like, understand. It was almost like inventory stocking.

Frank Watanabe: No, that wasn't inventory stocking. (inaudible)

Chris Shibutani: (inaudible). We see the net revenue print and then we're trying to figure out where do I project from here. So, help us out.

Frank Watanabe: Q1, the uptake in Q1 was – it shocked even us. It was so rapid. And I think that was a reflection of the fact that the unmet need was so high that a lot of dermatologists had pre-specified lists of patients they were going to start on ZORYVE. I even had doctors tell me that they'd already started writing prescriptions before the approval and just told the patient, "Hey, call me and I'll tell you when you can fill it."

So, we had this big bolis of patients that hit us in Q1. And I would have loved if that trend had continued, but we knew it wasn't going to last. So, we've seen moderating in the growth trend, which we told folks that would happen.

But there are a lot of these patients out there. Four million patients-plus being drug treated. We're running at a really nice clip of NRXs every week. The drug is performing. Doctors are able to get it. So, I think we'll be able to sustain this growth trend that we're seeing right now since, say, the end of the quarter. We think that's very sustainable, if not we could see even some acceleration as time goes on.

Chris Shibutani: Your products translate very well in terms of communicating directly to the consumer, the end market, and their patients. How do you think about C (ph)? How should David be thinking about allocating budget towards marketing spend; in particular, the direct-to-consumer angle?

Frank Watanabe: So, we have a direct-to-consumer effort ongoing. We had since early on in the psoriasis launch, and seb derm has a DTC component, and AD will as well. Linear TV is really challenging – normal broadcast TV. Very expensive. You're competing against Tesla and Starbucks and everyone else for that ad space.

Chris Shibutani: Pfizer.

Frank Watanabe: Pfizer.

Chris Shibutani: Super Bowl ads.

Frank Watanabe: Yes. When you have a $75,000-a-year drug, you can buy TV ads, right? It's hard to do with a drug that might be $2,000 a year. So, I don't see us doing linear TV.

But certainly, direct-to-consumer is part of our marketing mix, and it's something that, as I said, we've been doing for quite a while.

Chris Shibutani: Returning to the foam aspect of the coverage, how do you see that mix? And what do you need to do in order to improve coverage there? Is the price point that much different so that we're going to go live through? Because it is still ZORYVE, the brand. There's cream and there's foam presentations. So, what is the fine print in terms of, do you have to restart all over? Is this a new product? I think you actually have some advantages of already at least a foot in the door, if not the name brand at the top of the (inaudible).

Frank Watanabe: We actually have more than that. So, the PBMs – the three big PBMs – viewed ZORYVE foam as a line extension to ZORYVE cream. And so, we got coverage from the three PBMs at approval, effectively. And that's one of the reasons why our gross-to-nets have improved so much, is that we're not going back to reset again.

We still have to negotiate with the downstream plans to get coverage, and we're in the process of doing that now, but even that has been substantially accelerated because we got the PBMs so quickly.

We expect something similar to happen with atopic dermatitis as well. We expect that to be considered a line extension. So, you're not going back to square one on coverage.

We reported at the end of Q1 – we were, what, nine weeks into the launch at the end of the quarter – that one in two foam scripts already were being reimbursed. That's unheard of in this day and age to have half of your scripts covered at nine weeks. And that's continued to improve, and we'll provide an update at the end of Q2 as well on where we stand.

On the cream, we're sitting at about three in four scripts being covered by insurance.

And that gets back to the whole conversation on gross-to-net. We don't make any money for shareholders if it's a non-covered script. We actually – we're losing money until we change the way that we handle non-covered scripts. What investors should care about is how many of our prescriptions are we getting paid for, and then how much are you getting paid, which is the gross-to-net story.

And I think on both those fronts – coverage rates and our gross-to-nets – we've performed very well, which I think comes back again to our pricing and access strategy.

Chris Shibutani: And strategically, it's always felt as if it's a category where when we talk to sort of the community dermatologists, they're always hungry for freebies and samples and stuff, and using that as a strategy. Do you feel that that's going to be necessary as you continue to launch, and particularly into AD? It's never really been the front foot of what you've approached the market with.

Frank Watanabe: So, sampling is certainly an important part of topical drug administration, although we don't sample the foam just because of the complexity of making really small cans of the foam. The can is quite big, a 60-gram can. So, we're not sampling the foam.

The cream, we continue to sample. I think that's an expectation in dermatology. We don't give away free drug. I think it's a little bit like crack. You get people addicted to it and then you want to take it away, it doesn't go well. So, we've never engaged in free drug. We didn't have a coupon program. We don't have a cash offer because the risk of abuse of cash offers is so high. And I think that's one of the things that has hamstrung a number of the topical drugs in the past, is that they got people addicted to all this free drug and then when they asked them to start paying for it, they're like, "What?" So, if you never start, you don't have to stop. And because we were, frankly, quite quick in getting insurance coverage, it was never really an issue for us.

Chris Shibutani: Right. I know for sure there's something very deep and philosophical in there as well, but it certainly also translates well to a business strategy for you guys.

Data on atopic dermatitis, remind us about the profile. Here, the numbers are vast. The patients are not a monolith. You have all sorts of age groups. Talk about what the strategy is for positioning ZORYVE in AD.

Frank Watanabe: In fact, you may have seen we released some new data on Monday from our long-term extension at the Revolutionizing atopic dermatitis meeting in Chicago.

I think the product profile looks great. We're seeing itch improvement in 24 hours, instead of 48 hours, in atopic dermatitis. At Week Four, around 40% of patients have an EASI-75. And what was interesting and what we released on Monday is that the longer patients are on the drug, the better they get. So, by the end of 56 weeks of treatment, which was the end of this long-term study, two in three patients had an EASI-75 response. It's a very nice response.

And very interestingly, one of the other things that we released on Monday was once patients got to clear, you could switch them to a twice-a-week maintenance dose. And we were able to maintain most people at clear, almost clear, on twice weekly dosing instead of daily dosing. And that's the first time that someone's done that in a pivotal study, showed that you could use maintenance dose to prevent the next flare, instead of using

drugs to chase that next flare, waiting until the patient is flaring and then trying to treat it. We're actually preventing those flares.

So, we think that profile looks really compelling. Safety and tolerability is excellent, as it's been in every other indication. And I think we have a profile that allows us to compete in first line against topical steroids and topical TCIs, which is where most patients are. Dupixent is a great drug, but we can't afford to have 90% of patients on Dupixent. Some patients will progress to Dupixent. Not a problem. Great drug. But for the majority of patients who are on steroids or TCIs, we think ZORYVE is a better option for the patient.

Chris Shibutani: I mean, it's interesting, because when you look at the actual data on Dupixent, less than 10% – I think it's 8% or 9% across several different studies – of patients who theoretically would be eligible are taking the medicine. And very often there's all sorts of reasons, including cost and sort of, like, concerns about taking an injectable therapeutic, but it is a very materially undermet need across the patient spectrum there.

Talk about expanding the presence. There's elements of what you have said historically acknowledging that some of these derm markets are very much within the domain of primary care, and a smaller company would be able to benefit by somehow being positioned either through a partnership with a sort of more deliberately expansive commercial organization. Where are you in the thinking of that process? And maybe even just taunt us a little bit with some timelines, because this is always a work in progress, but we're actually crescendoing with seb derm and some of the data points here.

Frank Watanabe: So, about half of seb derm patients are treated outside of dermatology, and about half of atopic dermatitis patients are treated outside of dermatology. The majority of those patients are in primary care or pediatrics. And so, I think we've been saying for quite some time that it was our objective to have a partner in primary care. We don't want to do it ourselves because that's a good way to waste a lot of shareholder money, building our own primary care sales force. But we've been saying for a while that that was a goal of ours.

We are actively in discussions with potential partners. I've said previously and continue to believe that it's very likely that we'll have an agreement by the end of the year for a partnership in primary care. And that's about the right timing for us with the atopic dermatitis approval coming up. We didn't need it right at launch because we've got to win with the dermatologists first. But there is obviously an immense opportunity to serve patients and to create shareholder value through a primary care partnership, and I feel very confident about our ability to pull that off.

Chris Shibutani: What's that species? Is it someone who's a little bit more in sort of the consumer orientation? Is it one of the typical immunology big players that we think of?

Frank Watanabe: Well, I mean, the ideal profile is a company that has a pretty good sized existing primary care sales force and it has the capacity to promote our product in their sales force. What you don't want to do is partner with a company that has a GLP-1, because that's going to be their priority all day long. You want someone who's going to really focus on your product and drive the success of your product. And there are a number of companies that fit that profile.

Chris Shibutani: I can think of several. We can talk about it later. We can sort of blink one, blink twice, et cetera. But I think that there's certainly some sales bags out there that this can be very logical for.

Help educate me on something. I know that we have an sNDA for scalp and body psoriasis. How does that differ? Sometimes you have label indications that it's like, "Well, this was approved. I'm already using it this way." There's always the practice of medicine. What's the impact that we should think about?

Frank Watanabe: So, big picture, about 40% of psoriasis patients have psoriasis on their scalp. Many of those patients have it also elsewhere on their body. Our cream is really designed for use on the body. It's not the ideal formulation for putting in your hair. So, we formulated the foam originally, actually, for scalp psoriasis, and then we sort of stumbled into seb derm based on talking with dermatologists. But it was originally designed for scalp psoriasis.

And it works very well in scalp psoriasis. We've already done the Phase III study. We also – in the Phase III, we looked at efficacy in the scalp and, separately, efficacy on the body. And what we saw was that the foam performs identical to the cream on the body in treating psoriasis, and it actually outperforms on the scalp. So, we had a 70% IGA success rate on the scalp in our Phase III trial.

So, a really nice formulation. If a patient has scalp psoriasis, they just use the one foam everywhere. They don't need two prescriptions, which is a big change. If they don't have scalp psoriasis, they'll probably get the cream. I think some patients may prefer the foam and may use the foam even if they don't have scalp psoriasis. We're pretty agnostic to which one the patients use. We just want to treat patients and create shareholder value.

But we'll file that in third quarter. Expect approval probably middle of next year, something like that. And then we'll be going in with the tailwinds of the psoriasis launch and the seb derm launch and the AD launch as we launch in scalp.

Chris Shibutani: Is seb derm a seasonal phenomenon by any chance?

Frank Watanabe: All of these diseases are. Seb derm and atopic dermatitis both have skin barrier defects. And so, dry and cold air tend to exacerbate it, and warm and wet air tend to mitigate it. Psoriasis responds to sunlight, and that's why people use UV to treat it.

So, there is seasonality to all of these diseases. You see a lot of seasonality with biologics. I used to work on Enbrel, and we could see it all the time. You don't see a lot of seasonality, in general, in topical prescriptions because the patients are only filling their prescriptions a couple of times a year. But where you do see seasonality is in patients coming into the office. As we go into spring and summer, there are less people flaring, they're not going to their doctor. As fall and winter come along, they're flaring, and they're going to their doctor. And so, I think that may impact more on the NRX trend than the TRX trend, but there clearly is a seasonal component to all these diseases.

Chris Shibutani: Outside the U.S., any updated thoughts?

Frank Watanabe: So, we've out-licensed in China and Greater Asia. We did the deal last year in China and Greater Asia. We did a deal with Japan earlier this year. I think Europe, the challenge really is reimbursement. And it's an evolving landscape for topical reimbursement in Europe. So, we're monitoring that situation, and I think we'll make a decision as that becomes clearer. I wouldn't say it's our top priority right now.

And then we are on the market in Canada with the cream for psoriasis – we have our own operation in Canada – and we're awaiting approval for the foam hopefully later this year in Canada as well.

Chris Shibutani: Let's turn a little bit briefly to what else is next, the pipeline. You have two assets here: ARQ-255, a JAK1 inhibitor, topical suspension. Talk about where you're aiming that for and where we're at.

Frank Watanabe: So, 255, yes, is our topical JAK inhibitor, formulated in what we call deep dermal drug delivery, or 4D technology. This is a formulation that Osborne invented that actually allows us to deliver drug down the hair follicle to the base of the hair follicle, which is where the inflammation in the AA is occurring.

Chris Shibutani: Alopecia areata.

Frank Watanabe: Yes. Traditionally, topical JAKs have not worked in alopecia areata because they're not penetrating enough, and that was why we developed 255, was to get down to the inflammation.

We're in a Phase I trial right now, mostly focused on safety and efficacy, but that will unlock our ability to go into Phase II and really look at the efficacy of the drug. Clearly, JAKs work in AA. We've already got one approved – two approved. And so, we just need to get the drug where it needs to be, and it should work.

So, we're excited about that program. And we'll have hopefully data before too long, although, again, mostly around safety and tolerability.

And then our other pipeline program is ARQ-234. That's a fusion protein against an immune checkpoint target called CD200R. Very excited about that program as well. CD200R is one of these targets, like OX40, that you seem to be able to reset the immune system if you agonize these targets. And there is early evidence that, like OX40, if you hit this target, you can get patients clear, but then you have this long period of efficacy off of drug. And so, we think that this is probably the next frontier in the treatment of severe atopic dermatitis.

Chris Shibutani: Great. We will make sure to touch base upon some of the financial dimensions. Talk about how comfortable you are about prospects of ultimately becoming profitable, as well as what the cash is right now.

Frank Watanabe: So, we're a biotech company. So, I don't know that profitability is my top priority, but certainly self-sustaining is an important component. We did a raise earlier this year, in February. We feel like we're very well capitalized. And our new CFO I think has taken to saying, on current plans, we may not need to do any more equity raises. Our burn is relatively stable right now and we have – sorry, our OpEx spend is relatively stable, and our revenues are increasing. And so, our cash burn is obviously going down.

We ended last quarter with a little over than $400 million on the balance sheet. So, we feel good about where we are from a financial position.

Chris Shibutani: It certainly seems to be a stable position. And those investors are quite happy, from what I understand.

Frank Watanabe: I would hope so, but we've got to keep keeping them happy.

Chris Shibutani: Excellent. Frank, thank you for taking the time. We appreciate getting this update.

Frank Watanabe: Great. Appreciate it. Thank you.

Chris Shibutani: Thank you so much.