

Company Name: Arcutis Biotherapeutics, Inc. (ARQT)
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<<Tyler Van Buren, Analyst, TD Cowen>>

Okay, great. Good morning, everyone, and welcome to TD Cowen's I&I Summit and it's a privilege to be hosting a fireside chat with management team from Arcutis. My name is Tyler Van Buren, Senior Biotech Analyst. And from Arcutis, we have Frank Watanabe, the CEO; Latha Vairavan, the Chief Financial Officer; and Patrick Burnett, the Chief Medical Officer. So thanks again for joining me here at the tail end of earnings for discussion. It's a pleasure to have you all.

And for those of you in the audience, if you have questions, you can submit them via the portal and I should see them on the tab that I have here and I'll do my best to get them asked, but maybe we'll go ahead and get straight into it given that we've got a quick 20 minutes. I want to spend most of our time talking about LCM or life cycle management as well as the pipeline, given that that's more of an emerging topic. And we've already discussed the quarter, but want to just touch on that real quick. You guys had another very strong quarterly performance, posted an Investor Day even for the first time announced guidance.

So maybe you could start just by talking about that performance. What led to the impressive growth in both the cream and the foam and what gives you confidence in the 2026 guidance that you all set?

<<Frank Watanabe, President and Chief Executive Officer>>

Yeah, sure. So I think that, that, that there are a number of factors working in our favor, right? First and foremost, the product performs, right? The feedback we get from clinicians is really outstanding both in terms of the efficacy as well as the safety and tolerability of ZORYVE. It's really changing the way that they manage a lot of these inflammatory skin conditions. And doctors are finding also that it's relatively easy to access ZORYVE, which is a key consideration as they adopt the product more. So I think all of those factors are working to our favor.

And then the other I think very helpful tailwind is that there is an accelerating trend in dermatology away from topical steroids, right? We're seeing more and more discussions in the specialty about the need to appropriately manage the use of topical steroids and think about advanced topical therapies like ZORYVE as a foundational therapy for the long-term management.

So all of those things combined I think was what led to very strong growth in volume in Q3. And we've seen a nice steady growth trend in Q4 as well. We had the benefit of some, I think maybe slightly unexpected improvement in price as well, which contributed to a portion of that overperformance in Q3. We were not expecting huge improvements in Q4 in price, but we're at a

very, very good place price wise already. So I don't know that we have a whole lot more room to improve.

And then Tyler, second half of your question there. Sorry...

<<Tyler Van Buren, Analyst, TD Cowen>>

Just on 2026 guidance, why you guys decided to give it, what makes you confidence in your ability to achieve that guidance and maybe briefly state that for the audience.

<<Frank Watanabe, President and Chief Executive Officer>>

Sure. So I think that the exact timing really was tied to the fact that we were doing an Investor Day, which was really tied to the greater clarity around our corporate strategy and also the fact that we had a number of things that were hitting the Street like the Phase 2 studies and the imminent Phase 1 in with ARQ-234. We really felt like it was time to explain to you all what we were doing around life cycle management and the pipeline. And so the R&D Day made sense or the Investor Day made sense.

And then issuing guidance in the context of the Investor Day also probably made sense versus waiting another quarter. If you think about it, we did almost \$100 million in Q3, so it's a \$400 million on an annualized basis. So to say, we can grow to \$455 million to \$470 million I think feels very reasonable to us. We feel good about the number we put out. I think it's a little higher than what consensus was. But I think it's a number that we feel like we can deliver.

<<Tyler Van Buren, Analyst, TD Cowen>>

Okay, great. And your regulatory group has been very productive, very efficient, nearly all shots on goal have been successful with the approvals and you are continuing to expand into pediatric indications. But you also mentioned ongoing efforts to generate these targeted incremental data sets in indications, in existing indications, but focusing on like palmoplantar and nail psoriasis, scarring alopecias and seb derm patients. So can you just talk about your efforts there and how that might continue to expand growth?

<<Frank Watanabe, President and Chief Executive Officer>>

Sure, yeah. Patrick, you want to take that one?

<<Patrick Burnett, Chief Medical Officer>>

Yeah. I mean I think there's really kind of two components to it. One is sometimes highlighting where it is that, that we may be able to perform in one of these diseases where steroids, to do something steroids are not able to do. And I think a great example of that is actually palmoplantar psoriasis and particularly nail psoriasis. We know that if you inject the proximal nail fold with steroids or put a super potent topical steroid, you sometimes can get a little bit of benefit. But they're really well published papers documenting actually bone loss because the nail

is adherent to the bone. So that's actually been an area where if you had nail psoriasis, you pretty much had to push patients into a systemic treatment. And now what we're talking about being able to do is actually to apply the drug directly to that proximal nail fold. There were some published cases that showed really interesting results.

And the concept here is that, this would kind of push ZORYVE to the front of the line as the preferred patient choice now, already for with the foam for scalp and body psoriasis, now if you have nail involvement, right, really kind of trying to like, highlight how it is that this drug is able to do things that, that healthcare providers weren't able to do with topicals previously. I think our unique kind of response in palmoplantar psoriasis is another example of that.

That's always been kind of a bit of an arms race when trying to manage those patients with topical steroids, because you had to go right to the absolute most potent topical steroid that you had, because it just didn't seem to penetrate particularly well. And we've seen some really remarkable cases that have been shown with ZORYVE in those difficult to treat patient populations. And then just touching on the last one, the seb derm and scarring alopecia, that's really – that's one of the beautiful things about this role. Is it – when you put a drug like ZORYVE out there, you just learn a ton. And I know Frank is in exactly the same situation. When we're at these meetings, like, we hear the most amazing stories coming back from healthcare providers and we learned from the hair community about this overlap between seborrheic dermatitis and some scarring alopecias, especially one called CCCA, which is really overrepresented in African-American patients who have tightly coiled hair.

And what they've seen is that patients who have CCCA tend to have, about half of them have seborrheic dermatitis and the belief is that by treating the seborrheic dermatitis that you may be able to actually decrease the driving force for this scarring process, which is irreversible. And when we heard that, we thought, well, this is definitely a place where – if we can show some data, demonstrating that this is a safe and effective treatment in those patients that that would be beneficial to the community. And again, highlight an aspect of ZORYVE foam that you can't really do with steroids or other products.

<<Tyler Van Buren, Analyst, TD Cowen>>

Wonderful, thanks for that. Very interesting. Before we get to the formal lifecycle management programs, have a question in the portal here already. Someone just asked for you to elaborate on the IP position of the ZORYVE franchise, maybe just current status of where the litigation is and ultimately your confidence in the IP and where the IP goes out to.

<<Frank Watanabe, President and Chief Executive Officer>>

Yeah. So we have 20 – 23 patents covering various reformulations issued in the United States. 22 of those apply to both the foam and the cream, combination of formulation patents, pharmacokinetic patents and method of use patents. And we feel very good about the strength of those patents. There's a 23rd patent that applies to the foam only and extends its coverage to 2041, excuse me. I think that the case with Padagis, the whole situation with Padagis, who is the anti-filer is a good example of why we feel very good about our IP. They would have had to

work around our patents, which is very difficult to do. And then you have to have a working drug right on the other end. I don't know exactly what happened with the FDA, but something really bad happened with the FDA with that product and it was never approved or conditionally approved. And that was why they asked us to stay the litigation.

That hasn't changed. I don't know that we're ever going to start the litigation again. I'm not sure, if they'll ever going to solve the problem they ran into. They have also now burned the first to file opportunity, the six-month exclusive into our Hatch-Waxman since they were first to file, even though they didn't get approved. So we feel good about our IP situation. I think if Padagis were to try again or someone else were to come along, we will assert our patents. And I feel very confident in our ability to prevail and enforce. I only have to win on one claim, on one patent to block in the anti-filer, right? And I've got a whole lot, I don't know the exact number of claims, but hundreds of claims that we can enforce. And it's just – it's not going to be easy for someone to genericize this drug without violating your IP.

<<Tyler Van Buren, Analyst, TD Cowen>>

Yeah. And just to follow-up on that with one question, formulation of topicals was a lot more top of mind. I feel like a decade ago or more when a lot more topicals were being developed and that formulation IP was pretty strong indefensible, right? And maybe you could just talk a little bit about the formulation, why it's special, what the hurdle was that you had overcome and the people involved with the formulation and why not anyone is able to do this.

<<Frank Watanabe, President and Chief Executive Officer>>

Yeah, there are very few people in the industry who can formulate topically, right. And for many years everyone relied on a company in California called Dow Pharmaceutical Sciences. The lead scientist at Dow Pharmaceutical Sciences was a guy by the name of David Osborne. Valeant bought DPS, I don't know, 15 years ago and David retired. David is the founder of Arcutis and has formulated all of our topical products. He's taught everyone else in the industry how to formulate topical, right, sort of the godfather of topical formulation.

Specifically with regard to roflumilast and ZORYVE, roflumilast is a really difficult molecule to work with. It's very, very hydrophobic. And water based creams are predominantly water. ZORYVE is 50% to 60% water depending on the formulation. So roflumilast doesn't like it, right? So it was very difficult for us to dissolve roflumilast in an aqueous formulation. We finally found a chemical that would do it and we have patents on that. And then we found that once you got it dissolved, it wanted to crystallize back out again, which makes it inert. So we had to find another chemical that prevented the crystallization. We have patents on that.

And then when you make a water based cream, you need an emulsifier to get the water and the oil to mix. And we developed – sorry, with a very novel emulsifier that had never been used in pharmaceuticals before, which provides some of the aesthetic and also therapeutic properties of the formulation. It doesn't dry the skin, it's non-irritating and we have patents around the use of that emulsifier. So we have three critical ingredients in addition to roflumilast. We have patents on each one of them.

And then to make it even harder, when we got in the clinic, we found that topical roflumilast has this very unusual pharmacokinetic profile, different than topicals normally and different than oral roflumilast. And we were able to obtain a number of patents that relate to the pharmacokinetic profile of topical roflumilast as well. So, if you have the same PK, you violate my IP, if you have different PK, you're not a generic. Right. So it makes a very, very difficult challenge for a generic filer to navigate.

<<Tyler Van Buren, Analyst, TD Cowen>>

Yep. Certainly a few barriers there that you highlighted. Thanks so much for that color. So let's get into lifecycle management. So you've highlighted the potential across 40 plus future indications for ZORYVE. Could you maybe walk through how you prioritized HS and vitiligo, among other indications? Are there any other indications beyond HS and vitiligo that you're also interested in out of those 40 plus?

<<Frank Watanabe, President and Chief Executive Officer>>

Yeah. Patrick, you want to take that one?

<<Patrick Burnett, Chief Medical Officer>>

Yeah. I think vitiligo and HS are two indications that kind of right off the bat checked two of the different aspects that we wanted to make sure if we advance something into a full development program, that it had what looked to be a compelling clinical profile and was definitely providing satisfaction of an unmet need for that patient population. Then the other aspect was that, we wanted them to be a commercially reasonable product that would be meaningful for our commercial business as we would get it approved. And so those two kind of clearly stood out.

Based on, for the clinical profile what we're really going off of to-date, and this is why we wanted to run these Smaller Phase 2 proof-of-concept studies. What we've been going off of to-date are case reports from healthcare providers that had a difficult to treat patient and they treated them with ZORYVE off-label for one of these indications. And part of what we do on the medical side is really monitor this so that we can understand the kind of safety and efficacy as it's evolving in the real world. That's one of our obligations. But then also to kind of make a decision as to whether or not some of them would be reasonable to carry forward into a full development program.

And so vitiligo, what we saw is that particularly in pediatric patients, which can be very difficult to treat, a relatively quick turnaround in the amount of affected skin that patients were – that patients were getting. And then with hidradenitis suppurativa, where topical treatment really hasn't been meaningful, and there hasn't really been a role for topical steroids or other topical inflammatory treatments, even though that we know that this is an inflammatory disease. Some of the case reports that we were seeing showed clinical benefit in a couple of weeks, where we're thinking about 16-week endpoints for a lot of the biologics. So it could be that a topical approach

there, getting local high drug concentrations early could put you on a completely different trajectory than what we think about responses for this disease.

And we both know that the commercial opportunity there is meaningful if you can deliver a profile that is competitive. And so that's the role of the Phase 2 studies that we're running is then we really understand what is that denominator for those responses? How common are they? And what is the kind of kinetics of the clinical response and the symptomatology response that we're seeing. And that'll help us to put together, what that true profile would look like and then decide on conducting a full development program.

<<Tyler Van Buren, Analyst, TD Cowen>>

Great. And as we think about the potential across these inflammatory dermatoses and the efficacy or mechanism, NHS or vitiligo, you guys have talked about this pleiotropic PDE4 inhibition mechanism of action. So maybe you could just elaborate on that a bit and what gives you confidence that it really could work well beyond the existing approved indications?

<<Patrick Burnett, Chief Medical Officer>>

Yeah, and I think the best examples there for this pleiotropic mechanism. We understand that this is a drug that's working against inflammation, but I think what differentiates it and that mechanism for PDE4 inhibitors is really well understood and was kind of the driving force for the original development of them as a treatment. What has been learned over the last five to 10 years is that actually changing cyclic AMP signaling, which is what PDE4 does topically in the skin, can impact even the signal transduction of itch within neurons. And so then we saw evidence of that and the importance of that in our current approved indications.

And then we went back and started to hear about vitiligo patients with these rapid responses. And when we had our seborrheic dermatitis data and saw particularly in African American patients with darkly pigmented skin, where you get a lot of hypopigmentation with seborrheic dermatitis, that even in the eight-week clinical trial we were seeing repigmentation and restoration of that patient's normal pigmentation in a timeline that didn't really make sense for what we expected based on what just topical anti-inflammatories like steroids had done in the past, we went and looked deeper in to that mechanism. Of course, cyclic AMP is an important role in pigment and melanocyte biology. And so, it allows us to potentially have two different mechanisms to bring to bear for a disease like vitiligo where we're reducing the inflammation, the autoimmune component of it, but then also protecting those melanocytes and restoring their function based on the same cyclic AMP modulation.

<<Tyler Van Buren, Analyst, TD Cowen>>

Okay. That's great. And a couple – maybe a couple follow-ups on HS and vitiligo. First on HS, obviously, you're running these smaller Phase 2 studies, you haven't quite guided to yet when we will get data, but hopefully you guys are able to enroll quickly and maybe we could see data next year. That's my speculation. But as we think about that readout, I imagine you're going to be looking at traditional high score endpoints that we see with other trials. Maybe you could

confirm that. And then also, if you look at a lot of these systemic therapies and HS trials and datasets, there's a fair amount of variability that we've seen. It's a tougher population, certainly more difficult than psoriasis. When you look from like Phase 2 to Phase 3, do you think there's a potential for a topical where you're treating kind of right at the site of disease to maybe get in there penetrate and have a response maybe a little bit better or more precisely than a systemic agent in HS specifically?

<<Patrick Burnett, Chief Medical Officer>>

Yeah. I think as we think about what the treatment for HS looks like topically, we would definitely focus on the more kind of like mild to moderate patients. I think as a patient develops into kind of like draining fistulas and tunnels, then at that point they definitely will be needing a systemic treatment. But what we've seen as we look at the responses to even some of the best systemic treatments that are out there is that patients are left with a substantial amount of disease in the end. And so adjunctive therapy between a topical and a systemic, even for those patients in the severe realm will be probably become standard of care. And we think that this could fit really well into that. And then what you're talking about is essentially the entire spectrum of the disease, from patients at their various earliest stages to then treating patients with a very severe disease who have been moderately improved but still have substantial residual disease on a systemic.

<<Tyler Van Buren, Analyst, TD Cowen>>

Okay. And then just to follow up on vitiligo, talking about this rapid effect potentially even compared to Opzelura, I guess again, so obviously the anti-inflammatory component is similar, but you're saying that there's a cyclic AMP mechanism where you're protecting melanocytes, where you believe that you may – that may lead to the more rapid effects. Can you just elaborate on that a bit?

<<Patrick Burnett, Chief Medical Officer>>

Yeah. So that's the hypothesis is that the speed of onset for the mechanism itself, from an inflammatory standpoint, that is something that we anticipate will be similar to other anti-inflammatories. We have always had a very rapid response, so we think we're going to be right up there with the best of those. But then I think the second component, working on the melanocyte is something that we believe could lead to a more rapid onset and potentially even a more comprehensive restoration of the patient's pigmentation. Because that's also something that I think is really important. Sometimes you get a partial restoration of pigment, which may be resulting from controlling the inflammation, but not actually kind of like helping to protect the melanocytes and drive them all the way through to kind of restore their normal function.

<<Tyler Van Buren, Analyst, TD Cowen>>

Okay, great. I know we're up on time, but have to ask about two, three, four. So maybe just one question on that program since it's approaching the clinic. Maybe you could talk briefly about

the CD200R agonist mechanism of action, how it's differentiated versus others, like Lilly's program, and specifically why you're excited about it in the AD treatment landscape?

<<Frank Watanabe, President and Chief Executive Officer>>

Patrick, I think that one's for you too.

<<Patrick Burnett, Chief Medical Officer>>

Yeah, great. Yeah. No, we – this is a really interesting molecule. So this is a fusion protein that has an extended half-life built into it, engineered into the FC portion, but then it has two of the native ligands, and those native ligands have also been modified with mutations to increase their binding affinity to the ligand. So there – yeah, so now you have two ligands being presented to the CD200 receptor, and that differentiates from the Lilly program because that was a monoclonal antibody that bound outside of that ligand binding site and then would agonize the receptor. So really a very different mechanistic approach to CD200.

And the reason we think the CD200 pathway is really interesting is there's some really good GWAS data that associates that with atopic dermatitis. Lilly provided validation of the treatment in atopic dermatitis with their early phase study. But then, I think that the concept of being able to down regulate inflammation rather than suppressing, rather than providing immune suppression, but kind of restoring immune balance is one that is really important in atopic diseases because we know that that's a disease of hypersensitivity to the immune system. And so I think it's a really good fit based on those components. So we're really excited about bringing that into the clinic in the first quarter of next year.

<<Tyler Van Buren, Analyst, TD Cowen>>

Perfect. With that, we're well over time, so we'll go ahead and wrap it up. But Frank, Latha, Patrick, thank you very much...

<<Frank Watanabe, President and Chief Executive Officer>>

Always, it's a pleasure my friend.

<<Tyler Van Buren, Analyst, TD Cowen>>

...and the opportunity to discuss the pipeline. And thanks to everyone for joining. And I believe we've got at 9:30 is the next session with Dianthus. So thanks again to everyone for logging in.

<<Frank Watanabe, President and Chief Executive Officer>>

[Indiscernible] (0:24:03) hard time for me.

<<Tyler Van Buren, Analyst, TD Cowen>>

Thank you.

<<Latha Vairavan, Chief Financial Officer>>

Thanks, Tyler. Bye.

<<Frank Watanabe, President and Chief Executive Officer>>

Take care, Tyler. Good to see you. Bye-bye.

<<Tyler Van Buren, Analyst, TD Cowen>>

Have a good day. Bye.