

Company Name: Arcutis Biotherapeutics, Inc. (ARQT)
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<<Analyst, Guggenheim Securities>>

All right. Well, good afternoon, everybody, and welcome again to Guggenheim's SMID Cap Biotech Conference. We host this every February and we're really thrilled to once again have Arcutis Biotherapeutics here with us today.

To my immediate right is Todd Edwards, the Chief Commercial Officer and to his right is David Topper, Chief Financial Officer. So Arcutis has been a company that we followed since IPO, and it's obviously been an exciting story. A lot of progress over the last 12 months in particular but as we just sort of look at the setup for 2025, maybe David, you can kind of kick us off with the sort of the financial not outlook, because I know you haven't offered that yet, but how you're thinking about 2025 and then Todd, the setup for the commercial access opportunity and the acceleration or the continued strong growth of scripts?

<<David Topper, Chief Financial Officer>>

Yeah, as you said, we haven't come out with earnings yet, so I'll be a little careful. But several weeks ago we did pre-announce revenue. We said, quote, approximately 63, which was ahead of you – ahead of I think all the consensus out there and we feel great about that momentum. I think we feel that going into 2025 we have a lot of momentum. That momentum comes from multiple sources, which I think makes it even more certain.

Things like CoA, a couple of new products that will get approved in 2025, Medicare, Medicaid, lots of things I think working in our favor that sort of convince us that we can continue to show the kind of growth we've been showing. That doesn't mean you don't have some ups and downs and one quarter is better than another. But for the full year 2025, we feel great.

<<Analyst, Guggenheim Securities>>

Great. Todd?

<<Todd Edwards, Chief Commercial Officer>>

So first and foremost we're very pleased with the performance as or even 2024. So we're set up nicely for 2025. And what I mean by that is in as you're aware in 2024 we launched ZORYVE foam for seborrheic dermatitis earlier in the year. We've had significant adoption of that product and acceleration. Furthermore, in August of last year, we launched ZORYVE for atopic dermatitis, thus far a very successful launch of that product.

Not only that, we've had growth with our ZORYVE 0.3%. Its rises so good robust growth across all three products in 2024 with some significant acceleration in Q4 of all three products. And

what I would attribute that to is in July 1st of last year, we meaningfully expanded the sales force. So a higher share of voice, that's helping acceleration in 2024. Not only that, but we see what I will frame as a portfolio effect. So the portfolio was very synergistic, meaning that now that we have three products on market, it's more of an opportunity for dermatologists to get experienced with ZORYVE, when they get that experience, they get positive feedback from the patient. It tends to accelerate the portfolio as a whole, which we saw in Q4 is good growth.

Not only that, we took strides to really make some meaningful improvements in our gross-to-net and we're able to do that to drive our gross-to-net down into the 50s. So as we launch into 2025, I think 2024 is a great springboard to set us up in a very strong position to continue this momentum. What I'm looking forward to in 2025 is we have a PDUFA action date on May 22. That's for ZORYVE foam in psoriasis body and scalp. In addition to that, in the fourth quarter this year, a likely approval in atopic dermatitis for ages 2 to 5. We're now proved down to age 6. So some more additives to the portfolio which will continue to help us continue our growth in 2025.

<<Analyst, Guggenheim Securities>>

Great. And on the access side, maybe you can help us understand the opportunity in Medicare. A lot of early decisions around price, there was some challenges associated with that initially. But as you said, one of the things that we've always loved about this story and the opportunity for ZORYVE is two products, two formulations, four indications. It just that portfolio effect seems obvious but tie in the pricing decision and why it actually matters.

<<Todd Edwards, Chief Commercial Officer>>

Yeah, when we price the ZORYVE, we strategically price the product. And what I mean by that is we made sure that we priced it below the CMS specialty threshold to enhance our ability as far as the negotiations of discounts and rebates with the Medicare Part D payers and PBMs. Not only that, it helps us relative to co-pay offsets for the patient within Part D. And by doing this, it minimizes the rebates and discounts we have to offer. It keeps those similar to that of the commercial business, which keeps us to maintain a positive gross to net as we pick up the Part D access.

<<Analyst, Guggenheim Securities>>

Great. And in terms of opportunities, where you see a real sort of patient expansion opportunity, maybe just – maybe David, if you can contextualize a little bit of the sort of size of the market, what do you – what is Arcutis going after in terms of this, the market opportunity from your perspective?

<<David Topper, Chief Financial Officer>>

Yeah, we look at the total addressable market as being somewhere in the sort of 15 million, 16 million sort of people. And we get there. One of the biggest slices of that obviously are the people that are currently using steroids, right. I mean, that's the real opportunity here and there's been progress made, but there's a long way to go. So even with the sort of robust sales

performance that we had in the fourth quarter and in 2024, we think we've sort of barely scratched that surface. We sort of estimate that roughly that we're at about a 2% market share and I mean, that's the leading branded product, but it's still only 2%. Right. So you don't have to get a very big increase in that share to be a giant product.

<<Analyst, Guggenheim Securities>>

Yeah. Can we talk a little bit about the individual indications then? Maybe we can kind of break down the sort of competitive landscape and how ZORYVE is positioned in psoriasis at this point, just as sort of your initial core indication. How's that trending? What's the – and do you have enough information on relative market share or any information that you can share with us along those lines?

<<David Topper, Chief Financial Officer>>

Yeah, relative to the competitive landscape, there's primarily one. I won't frame them as a competitor, but option within the market that's the now Organon's VTAMA. As indicated for psoriasis, it was first to launch into the market and shortly thereafter ZORYVE did.

ZORYVE has now, when you look at the TRx performance has outperformed that product as a unique product, but also as a portfolio and whole. And I think what's driving that uptake is relative to, once again, the dermatology experience. ZORYVE is a product that has exceptional tolerability, meaning the dermatologist isn't going to get callbacks.

It also has no limitations of use, meaning it can be used anywhere on the body for any duration of time. So this creates simplicity in prescribing for that dermatologist and it's highly effective relative to the patient benefit. So we've seen continued growth for ZORYVE within psoriasis and continue to expect that as we go forward.

<<Analyst, Guggenheim Securities>>

Great. And the types of patients that are actually getting this for psoriasis, is it all mild patients? Is it – are you getting, are you capturing add on or sorry, mild to moderate Are you capturing add on to more serious patients?

<<Todd Edwards, Chief Commercial Officer>>

Yeah, we're seeing – it's a good question. We're seeing mild-to-moderate and the opportunity for us. And why I didn't frame that our products a competitor because our opportunity, as David mentioned, is steroids. If you look within dermatology last year, across the three inflammatory diseases where we offer a product, as Dave mentioned, there are 16 million topical steroids written.

So patients are converting from steroids to ZORYVE and they are a cross section of mild-to-moderate patients that are making that conversion. So significant market opportunity and we continue to see increases in adoption of the product from steroids.

<<Analyst, Guggenheim Securities>>

Great. And vertical growth almost early last year of the seborrheic dermatitis indication. You guys did a phenomenal job executing into that launch and now through the full year. What's the opportunity this year in seb derm from your perspective just 2025 and then going forward?

<<Todd Edwards, Chief Commercial Officer>>

Yeah. I think there's significant opportunity for ZORYVE foam within seb derm. And what I mean by that is that there's 10 million patients that are diagnosed with seborrheic dermatitis. You think about the treatment options. Until ZORYVE foam was approved, there was no innovation in this space for two decades. What was available to patients was like ketoconazole shampoos, steroids which are not friendly to a patient regimen, they're very cumbersome for the patient to treat their seborrheic dermatitis.

You think about using a ketoconazole shampoo, you got to use it every day. A lot of people don't wash their hair every day. You got to stand in the shower for 30 minutes. So these were cumbersome non-effective treatments. Now with ZORYVE foam being a once a day treatment and the foam that's we've got tremendous variability relative to that vehicle. I continue to see the opportunity to be robust uptake of this product.

<<Analyst, Guggenheim Securities>>

Great. As we then move into atopic dermatitis, there's kind of two opportunities that I have segmented from my own like historical experience in consulting and watching Elidel launch and the kinds of patients that we're actually getting Elidel and protopic. And it seems to be almost heavily biased to a pediatric population when we sort of evaluated it at the time. What's most interesting about the opportunity for ZORYVE and AD, and you also chose to partner and collaborate with Kowa, so maybe how's that collaboration evolving?

<<Todd Edwards, Chief Commercial Officer>>

You talk about Kowa?

<<David Topper, Chief Financial Officer>>

I'll take Kowa first. So the Kowa operation really began towards the end of September. So it's still very new. We knew going in that it's a much longer sort of sales cycle, right, selling to primary care physicians. And so we didn't expect much if anything in 2024 and it was a non-zero number but it was not a hugely meaningful one. We – I think we do expect to have meaningful contribution in 2025.

<<Analyst, Guggenheim Securities>>

Okay.

<<David Topper, Chief Financial Officer>>

And I think in terms of market and information, we – once it becomes meaningful, we will give out some data, so people understand what the size is and what the economics are for us.

<<Analyst, Guggenheim Securities>>

Great. Okay. That's super helpful. And then just the AD opportunity as you see it, how does that sort of evolve and scale?

<<Todd Edwards, Chief Commercial Officer>>

Yeah. We see very similar to psoriasis, seb derm, what I mean by that is, it's the steroid conversion, significant amount of patients that continue to this day to cycle on steroids due to the habit of dermatologists prescribing steroids. You mentioned Peds. There's a significant opportunity there because of early onset of the disease. And when you think about ZORYVE, it's a very patient friendly product, great safety profile, high level tolerability. So this product serves well not only to adults but to the Ped population.

In addition to that, we receive a lot of positive feedback relative to the vehicle itself, how moisturizing it is to the skin. And as we know, atopic dermatitis is a skin barrier defect. So I think these kind of attributes that differentiate the product is what's helping us have this very successful launch in atopic dermatitis.

<<Analyst, Guggenheim Securities>>

Great. And as we sort of continue to move through the year, how much of a contributor should we anticipate Medicare could be this year versus when you feel like Medicare Part D could be a meaningful contributor to the franchise? Are we talking about sort of slower access and launch this year into Medicare Part D? But then – and when do you feel like you'll kind of be hitting your stride?

<<Todd Edwards, Chief Commercial Officer>>

Yeah. The Medicare Part D access is a longer cycle, a longer process due to the CMS guidelines and how they can contract and add products to the formulary. So it is a longer process. We see it how this will be additive. It's similar to the commercial business. What I mean by that is, it doesn't all come on at one time. It's going to be segmented by as we get access with one of the Part D PBMs.

So it's going to be phased overtime. So I see this starting to have the effect in mid-2025 of this year and then moving forward through the rest of the year into 2026. So it will be a slower formulary approval process. But I think we can see something meaningful first – mid this year.

<<Analyst, Guggenheim Securities>>

Great. And as we look at the sort of progress of sales through the balance of this year, David, maybe you can help us. At our last conference in November, I think we started counting the number of times that you were talking about not needing to raise equity. So I assume that that will to be the mantra here as well. But equally important, people are really starting to ask us a lot of questions about timeline to profitability. So maybe you could help us, yeah.

<<David Topper, Chief Financial Officer>>

Well, I mean, it's true that your bankers are very disappointed that, saying, we're not going to come back to the market. So they won't earn fees that way. And we're still saying that in a steady state scenario in any event. And I am – I have continued to say that we will be at that cash flow breakeven point in 2026.

<<Analyst, Guggenheim Securities>>

Yeah.

<<David Topper, Chief Financial Officer>>

We – I don't know if you noticed, but when we pre-announced revenue a few weeks ago, we also let it be known that we had burned about \$2 million of cash in the quarter.

<<Analyst, Guggenheim Securities>>

Yeah.

<<David Topper, Chief Financial Officer>>

So that's a pretty low burn, obviously, now some of that is related to certain working capital items and things that kind of come back in the next quarter. But it's still a pretty efficient operation.

<<Analyst, Guggenheim Securities>>

Yeah, sounds good. And in terms of your needs, Todd, when you look at the need for adding reps or scaling up, are those – are there really any needs along those lines to sort of grow the sales and marketing effort?

<<Todd Edwards, Chief Commercial Officer>>

I think in the sales effort, we expanded the field of sales organization as I mentioned July of last year and that was a meaningful expansion. So I very much think that we are right size for the dermatology markets. I don't think there's going to be a need for an expansion in the near-term. Relative to marketing – marketing has continued to create brand awareness, but also patient awareness as an example if you heard or not, but relative to seborrheic dermatitis, we just

announced a partnership with Odell Beckham Jr. as you're probably aware, an iconic NFL football player. He is a seb derm patient and a current user of ZORYVE foam.

So we look forward to working with him to create that a patient awareness. And so if we're doing that seborrheic dermatitis and then how do we scale this across psoriasis and atopic dermatitis, so that we're making certain that we're creating that awareness with patients to have them take action to see their dermatologist and then continuing to create brand awareness across the dermatology community.

<<Analyst, Guggenheim Securities>>

And is there a point where rather than sort of the targeted advertising that we've seen with ZORYVE that's been ongoing, is there a point where DTC actually becomes meaningfully value added? Have you initiated a DTC campaign or plan to?

<<Todd Edwards, Chief Commercial Officer>>

Yeah, we are. I'll frame it. As far as DTC, we will not move forward with what I'll call Linear TV, it's just – it's not...

<<Analyst, Guggenheim Securities>>

Yeah. So you're not going for the Super Bowl.

<<Todd Edwards, Chief Commercial Officer>>

Not going for the Super Bowl. It's just not – we would look at it, it's just not a good return on our investment. But relative to direct to consumer, we're using Connected TV like Hulu and such, or social media and other media outlets to make certain that we're meeting the patients where they're getting their information.

<<Analyst, Guggenheim Securities>>

Yeah.

<<Todd Edwards, Chief Commercial Officer>>

So we can really have a positive impact relative to the investments we're making in DTC.

<<Analyst, Guggenheim Securities>>

Got it. Great. As we sort of advance forward, there's a lot of questions around when do you feel it's necessary to augment the portfolio, to expand the portfolio, potentially add additional pipeline assets and the assets that are already being worked on? Maybe you can talk a little bit about that, David?

<<David Topper, Chief Financial Officer>>

Well, we do have two earlier stage assets, ARQ-234 and ARQ-255. ARQ-255 is in the clinic of the Phase 1b trial, which is going to sort of give us mostly safety data sometime in the first half of this year. ARQ-234 is not yet in the clinic. We're taking steps to make that decision. So we think both of them are promising. But obviously, it's too early for me to tell you much there, I think. In terms of outside BDI, I actually, oops, manage that process. And we are – on the one hand, very, very, very active at looking at candidates out there. Some are shown to us, some we find ourselves. And there's a lot of things to look at. We have set the bar very, very high. Okay. If we find something that kind of meets that high bar and meets our criteria, we won't be afraid to do it. We don't feel like we have to. We think we have a great commercial product and some good early stage products, but we are on the prowl at all times.

<<Analyst, Guggenheim Securities>>

Great. As we sort of think about the individuals is sort of the characteristics of the day-to-day modeling as we think about that. Fourth quarter, extremely strong. I'm sure you guys have a good sense of refill rates in that, and I know that that can be a concentrated period. What did that look like in the fourth quarter and how should we be thinking about the first quarter specifically?

<<Todd Edwards, Chief Commercial Officer>>

Yeah. We see refill rates when you look at ZORYVE 0.3 for psoriasis, around 40% of the total volume. For ZORYVE foam, it's around 35%. And with atopic dermatitis, we're still very recent within that launch. That's refill rates across those two products that we expect at this point in time in the life cycle of the product. I think for psoriasis, it's pretty much steady state, around that 40%. I think once ZORYVE foam reaches that, that's where the refill rate will be at a lower volume. I think for first quarter, though, we did have – as we typically see in the first quarter, some of the refills from January pulled into December where patients wanted to get their refills before their deductibles and co-pays increased.

So there will be, what I'll call some mild volatility within the first quarter. As we see – we have to offset those higher co-pays, higher deductibles. We saw some of those refills pulled into December. And not only that, patients at times are switching their insurer in the month of January. So when they do, they have to get recertified for ZORYVE. So we will see a little bit of disruption that we are expecting, but nonetheless, we look at the early trends as far as the TRxs, we're very encouraged.

<<Analyst, Guggenheim Securities>>

Great. And David, there's always that question of, okay, follow the scripts, how laser focused. But we always get the question on gross to net and how to think about it. So as we just sort of work our way through the individual line items, how would you kind of encourage us to think about the first quarter, because it seems like Arcutis stock tends to trade very much so on how – what's behavior around the quarter for the short-term at least?

<<David Topper, Chief Financial Officer>>

Yeah. I think what we've been trying to get people to understand is the team's done a great job, but I think we're now at the sort of steady state level when it comes to gross to net. Okay. And in this country, it's hard to do better than the 50s, which is where we are. It can vary a little bit within the 50s, depending on what quarter you're talking about, but we think that's where it is and that's where it's going to stay. And so the growth, which again we're very optimistic about, I think is volume related, not gross to net related.

<<Analyst, Guggenheim Securities>>

Okay, so we'll focus on – we just focus on the scripts. And that's sort of the dynamic going forward. Great.

<<Todd Edwards, Chief Commercial Officer>>

We will see a little bit volatility in that gross to net in the first quarter for the reasons I mentioned.

<<Analyst, Guggenheim Securities>>

Yeah. So kind of a low 50s rate that can go a little bit to the mid and then...

<<Todd Edwards, Chief Commercial Officer>>

Yeah, it's going to go higher in Q1 and then it will start to come back down as we – as those co-pays and such deductibles start to lower as we go through the year.

<<Analyst, Guggenheim Securities>>

Great. Okay. And in terms of just sort of the – sort of longer term opportunity, you kind of characterized it in scripts. We can – or at least the large opportunity. But for ZORYVE itself, how are you guys thinking about the revenue opportunity for ZORYVE itself? Not just the opportunity within. If you took over the entire steroid market, boy, would it be a big product. But just maybe kind of lay out what you think are kind of realistic expectations long-term for ZORYVE.

<<David Topper, Chief Financial Officer>>

Well, it used to be certainly – before I got to the company, I think what the team was saying to the market was that each one of those indications could be somewhere between \$750 million and \$1.2 billion. We probably should think about and update that number. But if you go back to what I said before about our rough market share calculations at 2% at our current run rate, right. I mean, if you took the entire steroid market, you'd be 50 times that. So I'm not counting on that. But what I do know what makes me very comfortable is that even at only 10% to 15% market share, right, you're 5 to 8 times the size, which is a big number.

<<Analyst, Guggenheim Securities>>

And I guess, Todd, I'm sure you look back at the launches of the calcineurin inhibitors before they got slapped with the black box. What was the trajectory of growth there? And is that something you think is achievable? And admittedly, that was with one indication.

<<Todd Edwards, Chief Commercial Officer>>

Yeah, it was one indication. As you know, it was robust growth when it launched. And I think there's very much that type of launch trajectory and uptake and adoption of the ZORYVE products and portfolio, because as you mentioned, this is a portfolio of assets, not one product. So across the portfolio, each individual unique product, I think we'll continue to see robust adoption through 2025 and beyond.

<<Analyst, Guggenheim Securities>>

Great. And David, obviously, just as we do get this question, occasionally, but how do you think about the sort of strategic opportunities for the company, outside interest, if it were to emerge, there's a lot of questions around topicals have been for years, but you guys are changing the dialogue.

<<David Topper, Chief Financial Officer>>

Yeah, I think the old wives tale, if you will, about topicals was that they were \$200 million to \$300 million kind of products. We've clearly proved that's wrong already, right. We're at \$250 million run rate for the fourth quarter. So it's clearly going higher than that. I think – so I think skepticism around size potential is abating a lot, right. And I think, I would think, I'm not trying to predict a buyer, but I would think that that broadens the interest level in a company like ours. We're not planning on it. We're perfectly happy to run this business. We think it's going to be very successful. But I think the skepticism out there is going away.

<<Analyst, Guggenheim Securities>>

Yeah. You're breaking investor rules to some degree, which is really good thing.

<<David Topper, Chief Financial Officer>>

Yes. Yes.

<<Analyst, Guggenheim Securities>>

All right, well, that's great. Thank you so much for joining us. Great to have Arcutis at our February conference again and look forward to seeing you guys well throughout the balance of the year, but also at our conference in November as well.

<<David Topper, Chief Financial Officer>>

Great. Thanks so much.

<<Todd Edwards, Chief Commercial Officer>>

Thank you.