Arcutis Biotherapeutics, Inc. (Q1 2025 Results)
May 6, 2025

Corporate Speakers

- Amanda Sheldon; Arcutis Biotherapeutic, Inc.; Healthcare Communications Leader
- Frank Watanabe; Arcutis Biotherapeutic, Inc.; President and Chief Executive Officer
- Todd Edwards; Arcutis Biotherapeutic, Inc.; Chief Commercial Officer
- Patrick Burnett; Arcutis Biotherapeutic, Inc.; Chief Medical Officer
- Latha Vairavan; Arcutis Biotherapeutic, Inc.; Chief Financial Officer

Participants

- Vikram Purohit; Morgan Stanley; Executive Director, Equity Analyst
- Seamus Fernandez; Guggenheim Securities; Senior Managing Director
- Uy Ear; Mizuho; Analyst
- Tyler Van Buren; TD Cowen; Managing Director, Senior Biotech Equity Research Analyst
- Kambiz Yazdi; Jefferies; Analyst
- Serge Belanger; Needham & Company; Analyst
- Douglas Tsao; HC Wainwright; Senior Analyst

PRESENTATION

Operator^ Good day. Welcome to Arcutis Biotherapeutic 2025 First Quarter Financial Results Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. I would now like to hand the call over to Amanda Sheldon. Please go ahead.

Amanda Sheldon^ Thank you, Heidi. Good afternoon, everyone. Thank you for joining us today to review our first quarter 2025 financial results and business update. Slides for today's call are available on the Investors section of the Arcutis website.

On the call today are Frank Watanabe, President and CEO; Patrick Burnett, Chief Medical Officer; Todd Edwards, Chief Commercial Officer; and Latha Vairavan, Chief Financial Officer.

I would like to remind everyone that we will be making forward-looking statements during this call. These statements are subject to certain risks and uncertainties, and our actual results may differ.

We encourage you to review all of the company's filings with the Securities and Exchange Commission including descriptions of our business and risk factors. With that, let me hand the call over to Frank.

Frank Watanabe^ Thank you, Amanda. Thank you, to everyone for joining us today. Before I delve into the quarterly details, I want to take a moment to thank David Topper, who will retire in

a couple of weeks, for his many important contributions to Arcutis, both in his time as our CFO and during his many years as a consultant to our company. We wish him all the best in this next stage of life.

I am very pleased to welcome Latha Vairavan to our first earnings call as our CFO, a role she officially assumed this morning. Latha has been an integral part of our team for many years, and she is fully prepared to step up to this new role. I could not be more excited about her joining our senior leadership team. Turning to our results. If you take nothing else away from our call today I want to highlight four key points.

First, our team continues to execute exceptionally well most notably our commercial and R&D teams, as evidenced by yet another strong quarter performance across our portfolio and our continued progress in advancing our pipeline.

Second, with multiple upcoming catalysts and expanding markets, we are confident in our ability to sustain our growth throughout 2025 and beyond.

Third, the most important of these market expansion opportunities is the conversion from the very large top of the steroid market, and we are seeing tangible signs of growing momentum in that shift. And fourth, we are very pleased with our progress in Q1 in protecting our intellectual property.

I am grateful to work with such a dedicated and stellar team who are building the leading topical franchise, one that is outperforming historical precedents in dermatology. ZORYVE is endowed with a unique combination of attributes including efficacy and safety, rapid onset, reliability and the ease of use for both clinicians and patients that has allowed us to build a segment-leading franchise. Let's turn now to Slide five of the deck.

We had a robust start to 2025, and our first quarter performance was very much in line with our expectations. As our results indicate, commercial execution continues to be a key strength of our business, and we expect sustained growth of the ZORYVE portfolio this year and beyond.

In the first quarter, we reported revenues of $63.8 million, representing nearly a doubling of revenues year-over-year, excluding the non-recurring reduction in reserves for product returns of $4.1 million, as reported in Q4 of 2024. As is typical for any retail pharmaceutical product, revenues were down compared to the fourth quarter due to the typical first quarter deductible resets and insurance changes.

It's really quite remarkable that despite those typical headwinds, our sales were nearly flat, with only a 2% decline versus the prior quarter, which is very unusual compared to other branded topicals, or frankly, nearly every other product on the market where substantial drops Q4 and Q1 are typical.

Impressively, we delivered prescription demand growth of 10% compared to Q4, despite the typical pull forward of demand into Q4 as patients filled prescriptions early in anticipation of their copay resets. Blended gross to nets have remained relatively steady as expected with some minor anticipated quarterly fluctuations related to the reset of patient deductibles and plan changes. And as Q1 progressed, we saw our GTNs quickly trend back down towards steady state.

The vast majority of patients with psoriasis, AD and seb derm are currently treated with topical steroids, so there is an immense opportunity for future growth of ZORYVE across our indications. And as Patrick and Todd will discuss more in just a few minutes, during Q1, we saw clear and growing momentum in that shift.

We expect to further expand ZORYVE's approved indications in 2025, beginning with the anticipated May 22nd approval of ZORYVE foam for scalp and body psoriasis. We are also eagerly anticipating another approval for ZORYVE cream, this time a 0.05% concentration for atopic dermatitis in children ages two to 5, with an expected approval in October.

Finally, we announced in April that at the request of Padagis, we had agreed to a joint stipulation to stay the ongoing patent litigation with them over their topical roflumilast ANDA. We agreed to this because it extends the 30-month stay we are entitled to under Hatch-Waxman for as long as the Padagis requested stay in the case remains in place, and it also allows us to delay or even avoid the cost of litigation and the distraction of litigation. Let me be clear, we are not and have not previously been in any settlement discussions with Padagis.

We have not wavered in our confidence in the strength and breadth of our patent portfolio that reflects the innovations we have generated since our company's inception. We are confident in our legal position against Padagis. If and when the stay is lifted, we will continue to fight against Padagis' attempts to circumvent our legally issued patents on our psoriasis cream.

Now turning to Slide 6, touching again on the immensity of our target market of 17 million patients. The size of this opportunity, coupled with ZORYVE's unique and compelling value proposition, provides us with strong conviction in our ability to continue to grow our product portfolio beyond what has historically been typical with other topical brands.

Patrick, Todd and I were out visiting clinicians all last week, and the feedback we heard from them on ZORYVE's performance is outstanding, only adding to our confidence in ZORYVE's future potential.

As we've shared in the past, half of the treated patients in our targeted indications are treated in the derm setting and the other half are being treated outside of the dermatology office, primarily by primary care physicians and pediatricians.

Our launches thus far, along with our upcoming launches if approved, continuously expanding coverage and the Kowa commercial partnership enable us to access the entire 17 million patient opportunity, another unique feature in the branded topical space.

But as shown on the chart on the right, 94% of topical prescriptions written for our target patients are still for topical steroids, topical calcineurin inhibitors, antifungals and vitamin D analogs. Our long-term growth relies on shifting this use to ZORYVE as the go-to topical treatment.

Encouragingly, we are seeing growing evidence that dermatology clinicians are starting to shift away from these products, and as the leading branded non-steroidal, ZORYVE is positioned to be the primary beneficiary of that shift. Todd and Patrick will delve deeper into the evidence we are seeing of this growing shift, and Todd will go into further detail on how we view revenue and script growth trends evolving throughout 2025. Arcutis as a company has had the good fortune to be presented with a rare opportunity, combining an immense market with a strong and well-recognized brand, which can create significant value for all of our stakeholders.

Our team recognizes the uniqueness of our compelling position and remains highly focused on growing ZORYVE to its peak sales potential. With that, let me turn it over to Todd to provide some more color on where we are in our launch and how we will continue to execute on our vision.

Todd Edwards^ Thank you, Frank. In Q1, once again we delivered strong sales results, leveraging the strength of our product portfolio, and are pleased by the continued positive response to ZORYVE from HCPs and patients, and excited by the growth opportunities ahead of us. On Slide 8, this quarter, we achieved $68.3 million in net product revenue for ZORYVE, reflecting a 196% growth year-over-year.

Importantly, we saw strong sequential volume growth, and our blended gross to net remained in the 50% range, even with the typical temporary reversion and gross to net compared to Q4 2024. All commercial stage companies face challenges in the first quarter due to deductible resets, changes in patient insurance plans and prescription refills pulled forward into December.

ZORYVE is not exempt from these challenges, and we did see some impact on Q1 revenue, but we are delighted that these had minimal impact on our Q1 performance with only a slight decline in net sales compared to Q4.

We are particularly pleased that despite these customary headwinds, ZORYVE unit demand grew 10% quarter-over-quarter. Encouragingly, prescription trends in Q2 point to sustained growth continuing from Q1 and foretell solid performance for the remainder of the year with expected volume and revenue growth throughout 2025.

On Slide 9, you can see that ZORYVE prescription volume has reached another record high at 17,000 weekly scripts on a rolling 4-week average basis. In 2024, growth inflections were driven by the launches of ZORYVE foam for seborrheic dermatitis and ZORYVE cream 0.15% for atopic dermatitis.

Looking towards 2025, later this month, we anticipate the addition of a psoriasis body and scalp indication for the foam formulation, pending approval. We expect this additional indication will reinforce our strong growth trend, although we would not anticipate the same magnitude of growth acceleration as with the seb derm launch. Furthermore, we anticipate another label expansion in October, adding atopic dermatitis in ages two to 5, which should be an additional catalyst for growth.

As expected, prescription volume declined from December to January due to the expected pull-forward of refills into December. However ZORYVE quickly rebounded within weeks, recovering from the early dip and delivering growth across the entire portfolio. We expect this positive trend to continue as we gain share in the large topical steroid market. On Slide 10, we highlighted our strong and robust insurance coverage.

On the left, you'll see that we've achieved a remarkable position in terms of insurance reimbursement with approximately 80% of total ZORYVE prescriptions being reimbursed, a steady state and optimal level across the portfolio.

Since our last update, we've further broadened payer access for atopic dermatitis, which is now largely in line with psoriasis and seb derm coverage, and we expect to see further improvement in gross to net for this indication. In addition, we have secured expanded Medicaid coverage and established a strong presence.

ZORYVE is now covered with a single step through a steroid or better for 53% of state Medicaid lives, and we've seen strong quarter-over-quarter unit growth in this channel. The other point I want to highlight on this slide is that the profitability of our ZORYVE franchise continues to improve, driven by the high rate of reimbursed prescriptions across the portfolio. This positions us well for the future as we continue to grow prescription volume in 2025 and beyond, and we expect revenue to scale proportionately with that growth.

Our commercial partner, Kowa, continues to make steady progress within the targeted primary care and pediatric segments. As expected, the primary care selling cycle requires more frequent engagements to build familiarity, given that many providers have limited exposure to topical non-steroidal treatments and historically default the steroid use.

Physician feedback has been encouraging as education efforts increase, highlighting ZORYVE's unique profile as a safe, effective non-steroidal option that they can be used anywhere on the body for any duration with exceptional tolerability.

Importantly, with recent changes to the prescription process, the ease and reliability of prescription fulfillment will be a key differentiator with both physicians and staff. We remain confident in Kowa's ability to expand adoption in primary care.

We're already seeing positive indicators from early prescriber uptake, an encouraging signal for growth in this large and relatively untapped segment.

On Slide 12, I'd like to draw your attention to the left side of the slide. We are on a mission to convert steroid prescriptions to ZORYVE and to expand the overall branded topical market.

As you can see, the immense topical steroid market has declined by 200 basis points over the past year, with that share being captured by branded topicals led by ZORYVE. This is an early but meaningful sign of our success, and Patrick will delve into the drivers behind this in a moment. Keep in mind, branded topicals still represent only a small portion of the overall market, which highlights the immense opportunity ahead for ZORYVE as clinicians continue to transition from steroids to non-steroid treatments, a trend we expect to accelerate.

I'm excited to share tangible evidence of our momentum. ZORYVE has continued to expand its leadership as the number1 branded non-steroidal topical. In the most recent week, ZORYVE captured a 41% share of that segment. On the right side of the slide, you'll see how ZORYVE is consistently gaining share, further validating our growth trajectory.

On Slide 13, as we've emphasized over the past several quarters, ZORYVE is uniquely positioned in the topical arena with multiple formulations to treat three major inflammatory skin conditions, and a fourth indication for foam scalp and body psoriasis is pending with the PDUFA date set for May 22. ZORYVE stands out for its rapid, reliable relief, its ability to be applied anywhere on the body, used for any duration and its exceptional tolerability.

It offers a simple once-daily regimen with predictable patient access through consistent reimbursement and copay support. This growing portfolio effect allows dermatologists to take a personalized, multifaceted approach to managing complex skin conditions, making ZORYVE their go-to treatment solution across indications.

On Slide 14, I'd like to delve into a recent analysis we conducted on prescribing behavior among clinicians. Unsurprisingly, we found that clinicians who prescribe ZORYVE across multiple indications write significantly more prescriptions overall.

But what is remarkable is the evidence of the portfolio effect that I mentioned previously. As these healthcare providers recognize the value ZORYVE brings to patients, they're able to expand its use across a broader portion of their practice.

For example, clinicians treating only one indication averaged three prescriptions per prescriber, while those prescribing for all three indications averaged 31 prescriptions per prescriber, a 10-fold increase.

We expect this amplification to increase further with the potential approval of our foam formulation for body and scalp psoriasis. With that, I'll now turn it over to Patrick for an R&D update.

Patrick Burnett^ Thank you, Todd. I'm on Slide 16. We're now approaching several key milestones in 2025. And first, we have the FDA PDUFA target action date for ZORYVE foam for plaque psoriasis of the scalp and body down to the age of 12 on May 22, 2025, and we're highly optimistic about an on-time approval there.

Second, we have an anticipated approval in October for ZORYVE cream 0.05%, a dose specifically developed for the treatment of mild to moderate AD in two- to five-year olds. We also continue to generate the necessary additional data that should ultimately support expanding the psoriasis indication down to the age of two as well.

In our early stage pipeline, we look forward to the Phase Ib readout for ARQ-255, our topical JAK in alopecia areata, around the middle of 2025. We expect to file the IND for ARQ-234, our biologic CD200 receptor agonist for atopic dermatitis, in the second half of 2025.

Now moving on to Slide 17. We've been talking to you for several quarters about the growing momentum among clinicians for a shift away from steroids toward non-steroidal topical agents that are safer for long-term use for these chronic conditions, and in Q1, there were a number of notable events that really prove out and highlight that trend.

For example, in January, a panel of some of the leading dermatology experts in the U.S. published consensus guidelines on the use of topical steroids as well as recommendations for the incorporation of advanced targeted topicals into the treatment regimen. I would call your attention to that group's conclusions shown on the lower left of the slide.

Similarly during Q1, a journal targeted to dermatology NPs and PAs published an extensive review on steroid safety concerns. And again I would point you to the conclusions of that paper shown on the lower right. These are powerful calls to action from dermatology clinicians directed toward their dermatology colleagues.

These are only two of several recent research reports and publications highlighting the risk and cumulative effect of steroids. Last month, new Canadian consensus guidelines for the topical treatment of atopic dermatitis were published, recommending that steroids be reserved for short-term use due to greater risk of adverse events including skin atrophy, hypopigmentation and other systemic effects.

In March, the NIH published research that identified for the first time the pathophysiology of topical steroid withdrawal, also called TSW. This is a condition caused by long-term steroid use that leads to redness, itching and scaling, which can be difficult to distinguish from the underlying skin disease that was originally being treated by the steroid.

As more evidence emerges for how the cessation of long-term topical steroid use can result in TSW, as well as criteria to help distinguish this condition from eczema, we expect more opportunities for the treatment of this condition will emerge as well.

Now on Slide 18, turning to our expected upcoming indication for scalp and body psoriasis. I wanted to share with you some impactful images of the benefits of our investigational ZORYVE foam in treating psoriasis of the scalp and body from our ARRECTOR clinical trial.

In the top row, you can see a female patient with significant scalp and neck plaques that were initially rated a score of three, or moderate, on the Investigator Global Assessment, or IGA scale. These lesions were then significantly improved after only two weeks of treatment, and the patient was subsequently rated as an IGA score of 0 or clear by eight weeks.

Similar efficacy can be seen in the bottom images of another patient with extensive body psoriasis with thick, brightly erythematous lesions on the back who was likewise treated with ZORYVE foam and dramatically improved from a baseline of moderate psoriasis to also be clear, an IGA of 0, by eight weeks.

Now this degree of improvement is quite remarkable and it highlights the strength of ZORYVE foam on both the scalp and the body. When combined with its ease of use and broad patient access, makes ZORYVE highly compelling to healthcare providers. These results are highly representative of our Phase III trial results in which about two in three individuals achieved scalp IGA success and nearly half achieved body IGA success. With that, I'll pass it over to Latha.

Latha Vairavan^ Thank you, Patrick. Before I begin, I want to thank David Topper for his guidance and mentorship over the past year and especially during this transition. I am honored to step into the CFO seat during a very exciting period of Arcutis' commercial growth.

I'm on Slide 20, showing financial results both year-over-year and quarter-over-quarter for the first quarter of 2025. We generated net product revenues in the quarter of approximately $63.8 million, which is up 196% from Q1 of 2024.

Recall that Q4 2024 number included a non-recurring $4.1 million adjustment for reduction in reserves for product returns. Last quarter, we noted that this number should be excluded from forward-looking calculations. Without this non-recurring revenue, net product revenues only declined by 2% quarter-over-quarter, reflecting the healthy state of our launches.

I will remind you that in Q1 2024, we executed an out-license deal in Japan with Sato, which brought in $25 million of non-dilutive capital, and we also received $3 million milestone payment from our Chinese partner, Huadong. This quarter, we received another milestone payment from Huadong of $2 million.

Cost of sales in the first quarter were $8.8 million compared to $3.3 million in 2024, primarily due to catch-up amortization of the $10 million owed to AstraZeneca for reaching a sales milestone of $250 million of cumulative net sales.

For the first quarter of 2025, our R&D expenses were $17.5 million, which is down 24% from $23.1 million in the first quarter of 2024 due to decreases in the development cost of topical roflumilast programs and approximately 21% compared to the fourth quarter of 2024. Recall that

Q4 2024 benefited from a onetime $3 million credit we received related to a closeout of our roflumilast study.

SG&A expenses were $64 million for the first quarter of 2025 versus $54.8 million in the same period last year, up 17% as we invested in our commercial organization and our current and future launches.

SG&A expenses were also up approximately 11% as compared to the fourth quarter of 2024, primarily due to higher promotional spend for our current and upcoming ZORYVE launches. Our SG&A spend in Q2 will be higher than Q1 associated with the scalp and body psoriasis launch and then normalize in the second half of the year.

We expect this stable level to carry into 2026. This expense stabilization, combined with the tremendous growth potential of our ZORYVE portfolio, gives us continued confidence that we can reach cash breakeven in 2026.

I want to take a moment to comment on the impact of tariffs on our business. We are a global operation with sales in the United States and Canada. All of our intellectual property for ZORYVE is domiciled in the United States.

We currently manufacture the majority of our product in the U.S., and our API is sourced from Spain. We have also started manufacturing at a facility in Canada to mitigate any supply chain risks.

As we have previously mentioned, our cost of sales is pharma-like. If a tariff were applied to our entire unit cost, it would be immaterial, estimated to be less than a percentage point impact on our cost of sales. The impact of tariffs on Arcutis will likely be no greater than on any other pharma company and substantially less than many.

So we do not anticipate there will be a significant issue for Arcutis, particularly compared to our peers with extensive non-U.S. manufacturing networks and/or a significant portion of their intellectual property held overseas.

I am now on Slide 21. You can see we had cash and marketable securities of $198.7 million on our balance sheet as of March 31, 2025, which translates to a cash burn from operations in the quarter of approximately $30 million.

Q4 2024 had several onetime anomalies that benefited our cash burn for the quarter, for we are back to a more typical use of cash. Q1 burn was still lower than that of Q3 2024, and we expect our quarterly cash burn to continue trending downward as our revenues grow and we approach cash flow breakeven sometime in 2026.

We have total debt of $107.6 million and have the option to withdraw $100 million, in whole or in part, at our discretion through the middle of 2026, providing us with significantly enhanced

flexibility. The success of our ZORYVE portfolio and the economies of scale we are generating will permit us to invest in the business for continued growth and long-term durability. With that, I will hand it back to Frank for some closing comments.

Frank Watanabe^ Thanks, Latha. I will finish up where I began. Arcutis continues to execute exceptionally well driving growth of ZORYVE and advancing our pipeline. We are confident in our ability to sustain our growth throughout 2025 and beyond, considering all of the opportunities ahead of us.

We are seeing tangible evidence of an accelerating shift from topical steroids to newer non-steroidals, and we are delighted with our progress in protecting our intellectual property. Our growing revenues, coupled with the strength of our balance sheet, puts us in a strong position to continue investing for the future, and we remain optimistic about achieving cash breakeven in 2026. With that, we'll open up the call for Q&A.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) The first question comes from the line of Vikram Purohit from Morgan Stanley.

Vikram Purohit^ We have two. So first, thinking about the cadence of ZORYVE performance throughout the rest of the year. Is there anything you'd point out on seasonality, cyclicality that we should keep in mind that could impact kind of quarter-over-quarter trends?

Then secondly, for the alopecia areata readout expected in the middle of this year, what would you set in terms of expectations for what we can learn and what you hope to see for the product profile?

Frank Watanabe^ Vikram, good to hear from you. Yes, Todd, can you maybe address the cadence quarter-over-quarter, and then, Patrick, if you could address the 255 readout?

Todd Edwards^ Yes. As we experienced last year over the summer months, we do expect a modest seasonal impact to our performance. However I think what's very important to point out here is that, as mentioned, we'll be launching foam for scalp and body psoriasis.

Not only that, we continue to see a positive impact about this portfolio effect that I mentioned earlier, which continues to provide us an opportunity to convert, say in the steroid market, which is a significant opportunity for us, which will continue to drive revenue growth in 2025. So yes, we will see some seasonality, but we continue to be very positive relative to these other value drivers that we're providing in the market.

Patrick Burnett^ Okay. So picking up on the question, Vikram, for ARQ-255. So this is a Phase Ib trial that we conducted, and it's primarily focused on evaluating safety, tolerability and then

pharmacodynamics. We also looked at the PK and had some biomarker work in addition to some kind of early responses that we were looking for for clinical response for hair growth.

So this is a three-month trial. The primary endpoint for most pivotal trials is six months. So what we're really focused on is just getting an early read on what might be able to be achieved with ARQ-255. So we're really looking forward to reading out the data from this in the middle of 2025.

Operator^ Your next question comes from the line of Seamus Fernandez from Guggenheim Securities.

Seamus Fernandez^ So Todd, just wanted to get a sense for how the additional scalp psoriasis and body psoriasis opportunity can accelerate and expand the use of ZORYVE foam. Obviously that's kind of a standout product within the portfolio at this point and continues to be so. Just trying to get a better understanding of how that can potentially expand utilization of the foam more broadly.

Is it your view that it will cannibalize cream or expand the market and the overall penetration? Then the second question is actually just help us understand where we are in the lifecycle of ZORYVE as it relates to potential impacts of seasonality, whether or not we would see anything like that, given the mild to moderate treatment opportunity that you have in atopic dermatitis where sometimes in the summer months, we could see some seasonality. But it seems pretty early in the lifecycle of ZORYVE to see an impact there, but just wanted to get your thoughts.

Todd Edwards^ Yes. Thank you for the question. So we don't anticipate any meaningful cannibalization of ZORYVE cream 0.3%. And let me be a little bit more specific about that is that we expect a broader and increased utilization of ZORYVE for the psoriasis patient. Specifically what I mean is that ZORYVE offers something that no other competitor can offer relative to the differentiation that I think that both patients and providers will value.

And that is that we're going to offer optionality and choice, meaning that once a psoriasis patient is seen by the dermatologists, based upon where that psoriasis is located, as an example, if it's in a hair-bearing area, that that clinician will probably prefer to use the foam given the unique formulation for hair-bearing areas, whether it be the scalp or for -- such as genital psoriasis.

If it's on the body, they may select to use the 0.3% cream psoriasis. But nonetheless, we expect broader, more significant utilization of ZORYVE across the two products given that unique value proposition that we will offer.

I will point out though with psoriasis patients, the data suggests that 80% of those patients do have scalp involvement. So we do anticipate increased utilization of the foam for those patients with either scalp or hair involvement.

Moving to your second question relative to seasonality in atopic dermatitis. As mentioned earlier, we will expect some seasonality impact to the product. But nonetheless, we continue to see strong growth of ZORYVE demand across atopic dermatitis and other aspects of the portfolio.

But I think what's important to mention that I mentioned on my opening comments is this portfolio effect. We continue to see as more prescribers prescribe across the portfolio, they prescribe more of ZORYVE.

And what's important about that is the provider has more experience as they write this product, which creates more efficiencies in their writing, more predictability, not only for the provider but also for the staff, where they can become more efficient and effective in processing those prescriptions. I believe this portfolio effect that will be compounded by the ZORYVE foam launch for psoriasis will continue to drive strong demand growth over 2025.

Frank Watanabe^ Let me just maybe expound just a little bit more on the first point because we get this question a lot. I think it's very unlikely that patients will get switched from the cream to the foam once the foam is approved. So that's cannibalization.

I think going forward, what we probably will see is an increased use of the foam in new starts for psoriasis patients, keeping in mind that, as Todd mentioned, about half the patients with psoriasis have scalp involvement. But I think what's really more important is that none of the other non-steroidal options have a formulation that's suitable for treatment of the scalp.

And it's quite challenging to treat scalp psoriasis even with steroids, A, because of safety concerns around proximity to the face and especially the eyes, and B, because there aren't a lot of good steroid formulations that are suitable for the scalp either.

So if you're a clinician who's treating a large number of patients who have scalp involvement, ZORYVE foam now being approved, or soon to be approved for scalp psoriasis, gives you a great new option and a great new reason to choose ZORYVE over the other non-steroidals and over the topical steroids that you've historically been using. So we really believe that this is going to be an important element of our continued ability to grow the franchise.

Operator^ Your next question comes from the line of Uy Ear from Mizuho.

Uy Ear^ Congrats on the solid quarter. So maybe first question. Just help us understand the cadence of the gross to net as we go through the year. Understandably that the first half of the year, I think on the fourth quarter, you're expecting sort of maybe on the higher end of the 50s.

Should we expect that to decline towards the middle and then towards the low end as we approach the end of the year? So that's the first question.

The second question is, on one of your slides, I think it's Slide 12 where you showed a 4% growth in the topical branded product in first quarter of 2024 and then 6% in this quarter. Given that like

VTAMA and ZORYVE cream 0.3% and other products, Opzelura and stuff like that have been in the market at least for the last four years, what is it that drove this significant market share?

Frank Watanabe^ Todd, do you want to talk about the gross to net trend?

Todd Edwards^ Yes. I'll talk about the gross to net trend. As mentioned in the opening comments, we did see some impact on gross to net early in the first quarter due to the deductible resets. But since that time have seen improvements and are in the steady state of the 50%.

We anticipate to remain within the 50% gross to net, although we will see improvement through the year as those deductible resets continue to decrease as we roll through the second, third and fourth quarter of the year and are confident that we'll remain in the 50% range for gross to net.

Frank Watanabe^ Then with regard to your question about the trend in conversion, I think first of all, it's important to remember that Opzelura has been out for about four years. ZORYVE for psoriasis has only been out for three, and VTAMA's been out for about three. ZORYVE for seb derm has only been out a year, and AD has only been out for about six months.

So we're still in very early stages of the process. I think also if you go back to 2021 when Opzelura was approved, the branded non-steroidal market, as I recall was around 1%. So you've seen a really dramatic growth in that market over the last four years with the addition of new products and as doctors adopt these products more.

I think a 50% increase in a 12-month period is really pretty remarkable and I think speaks to the acceleration of the trend that Patrick and Todd talked about. Clearly, we are working against a fairly ingrained habit, which is the use of topical steroids.

But as Patrick mentioned, what we are increasingly hearing is clinicians telling each other that they really need to rethink their use of topical steroids and adopt these newer agents. So we think that that trend will only continue as they have better options and new options like ZORYVE foam for plaque psoriasis and the expansion of our AD label down to the age of two.

Uy Ear^ Is it just the new -- the addition of the new product that's accelerating this trend, or is it also something else? I guess I just wanted to get a better sense of why all of a sudden, I guess we see this significant acceleration when other non-topical's been on the market for quite a while as well.

Frank Watanabe^ Yes. Well I think you have to look at the clinical profile of those non-steroidals. Remember back when the TCIs launched in 2020 -- sorry, in 2000, excuse me. Those two products rapidly ramped up to $600 million in annual sales in their fourth year on the market, and then they got the boxed warning, which has been and continues to be a major impediment to the use of TCIs, especially in children with atopic dermatitis. Those drugs also do have some local tolerability issues, and they're twice a day.

Then you had Eucrisa come out in 2017, as I recall. Clearly, not an optimal non-steroidal that has never been very successful, particularly because of the local tolerability but also fairly limited efficacy and an ointment that's twice a day. So that wasn't a great option either.

So it really wasn't until the emergence of Opzelura and then ZORYVE and tapinarof that doctors had really reasonable non-steroidal options that could compete with topical steroids. I think that's why you've seen this growth from, as I said, about 1% prior to the emergence of the newer advanced topical therapies to 7% in about four years.

So really, I think it's all being driven by the clinical profile. And prior to the emergence of these new advanced topical therapies, the only option that doctors really had that were good drugs were topical steroids. It was only thing that's really worked.

Operator^ We will take our next question, and the question comes from the line of Tyler Van Buren from TD Cowen.

Tyler Van Buren^ Can you guys please elaborate on the current split of patients, ZORYVE patients being treated in the derm office versus primary care? And I know you mentioned the 50/50 of the addressable patient population, but is that ultimately where you expect the split of patients to end up?

And the second question is, as we think about the Kowa efforts, just maybe you could elaborate on some of the barriers to PCPs prescribing that are different from derms and what tactics Kowa is employing to knock them down in order to contribute to revenues meaningfully this year.

Frank Watanabe^ Yes. Thanks, Tyler. Good to hear from you, too. So in terms of the split, the patients split about 50/50 across derm and non-derm settings. The non-derm settings are primarily primary care and pediatrics.

Today our business is overwhelmingly dermatology. Remember, our primary care and pediatric efforts are fairly nascent, and it's going to take a little time. Todd will mention -- go into more detail about that in just a minute.

I think it's hard to say where we ultimately land. I do think that primary care and pediatrics will over time become major contributors to growth for the franchise. But I don't know that we'll get to a 50/50 split because there are any number of other dynamics like payer mix that also could factor into it. But I do think it will be an important contributor to growth over the long term. Todd, do you want to talk a little bit about Kowa?

Todd Edwards^ Yes, absolutely. Relative to Kowa, Kowa does continue to make steady progress to what I'll call the dynamics of the PCP selling cycle. We do expect them to have a positive impact to our revenue in 2025.

But like all new sales forces or new product launches, especially within primary care, it takes a high level of engagement and frequency with that primary care physician to initiate a trial of the product. So we're confident that Kowa will continue to progress and have that type of impact.

But you think about within the primary care or ped market, there's been no promotion of non-steroidals. Kowa is the first to do it within these two market segments. So it does take a little bit of extra time in that selling cycle to be able to educate not only the provider, but also to educate the staff relative to the process of fulfilling that prescription. But Kowa continues to engage there, create interest, and we are seeing positive signals as we move forward.

Operator^ Your next question comes from the line of Kambiz Yazdi from Jefferies.

Kambiz Yazdi^ A few on my end. What are the next steps after litigation stay? Or you do a joint status update at some point? Then separately, maybe on ARQ-255, what are the key learnings from ARQ-252 and oral baricitinib? Then as a third and last question, kind of what's the white space in alopecia areata for a new topical treatment?

Frank Watanabe^ Sure. Let me address the IP question, and then Patrick, maybe you can talk about 255 in alopecia areata. So with regard to the patent litigation, the stay is an indefinite stay. The reason that Padagis requested the stay is not something I could discuss. That's something that you would need to discuss with them.

But I think that it is not unreasonable for one to conclude that they must have had some problem with their development or with the FDA. They filed in February of 2024 with the FDA, their ANDA. Under the GDUFA guidelines, which are the same as PDUFA, they should have received a conditional approval in November of 2024. To the best of our knowledge, they did not receive that. So I can't -- I don't know what the issue is, but clearly they've had some issue.

The quarterly updates that we are to provide jointly to the court really are just to update the court on the status of the dispute, let's say between the two companies. They are also required to share with us their FDA correspondence so that we can see if that program is moving forward and when. And at such a time as we feel that it's necessary to move forward with litigation again we have that option.

We also will benefit from the remainder of our 30-month Hatch-Waxman stay should the litigation restart. But honestly, I don't know whether the litigation will ever progress, whether their program will ever progress. You really have to talk about that with Padagis. Then Patrick, do you want to address the questions around 255 in alopecia areata?

Patrick Burnett^ Yes, absolutely. So I think most importantly, it's important to note that ARQ-255 is a completely unrelated formulation to ARQ-252. So we had the challenge of being able to get sufficient drug with 252 into the skin. With 255, this is not a solution. The drug's not dissolved. It's actually a suspension of the JAK inhibitor.

It's designed to be able to deliver the drug down the hair follicle and to overcome, I would say what has been the biggest challenge for any topical approach for alopecia areata, which is just the depth of the hair follicle, which is where the relevant inflammation is which is where the target is for this treatment.

So we took a unique approach with that. Now with regard to the oral, we know that the oral actually works in alopecia areata. It's a very potent JAK inhibitor. So that's important. The key issue is just to overcome getting the drug to where it needs to go.

With regard to the second part of your question and the white space in alopecia areata, we know that the oral systemic administration of JAK inhibitors for patients with extensive alopecia areata can be a treatment option, and many patients have benefited from that.

I think the white space is really in several different places for that patient journey. One of them would be patients leading up to where they get to their 50% scalp involvement that would make them a candidate for systemic treatment.

And many patients, even when they get there, aren't very keen on being long term on the JAK inhibitor and being -- because many of these patients are younger and may not be wanting to go on to a systemic immune suppressant for a long period of time. Then the other one is once a patient may have had a good benefit from being on a JAK inhibitor, what's the long-term potential for managing that patient?

You would at some point want to think about withdrawing that immune suppression and seeing if the disease is resolved kind of while the patient was on treatment. That would be another opportunity for being able to have a topical option. So I think there are many different places where a topical would be appropriate for use even in an environment where we have systemic JAK inhibitors that work.

Operator^ Your next question comes from the line of Serge Belanger from Needham.

Serge Belanger^ A couple for Frank and Todd. Going back to the 1Q performance, it looks like you were able to avoid the usual seasonality or not see the typical seasonality. Just curious if that was a function of strong growth that allowed you to avoid it, or there was something more specific in terms of a better reauthorization process that minimized the seasonality.

Then secondly, I think on Slide 10, you highlighted that 80% of ZORYVE franchise prescriptions are currently covered by insurance. Curious if we should expect some additional improvements on that number over time.

Frank Watanabe^ Yes. Todd, do you want to take this?

Todd Edwards^ Yes. Relative to Q1, let me just take a step back, specifically. First, let me address the revenue, as mentioned in the opening comments. We did see some impact on our gross to net early in the quarter. Of course that was due to the patients change in insurance as well as the deductible resets that typically occur during that time.

But nonetheless, we were able to swiftly improve on our gross to net in Q1 to where we made sure that we stayed within the steady state of the 50%, which is very encouraging and will -- could be a positive signal as we roll forward into the year. Relative to demand, as mentioned earlier, we had 10% quarter-over-quarter growth, Q1 versus Q4.

I think there's a direct correlation relative to the momentum that we have built with this franchise. When you think about ZORYVE's differentiation relative to other options within the market, being able to offer three unique ZORYVE products for three unique skin inflammatory diseases really makes ZORYVE a one-stop solution for both the provider and the patient, and I think that portfolio effect continues to resonate with both providers and patients.

We expect that only to be amplified once we get the foam scalp and body launch, and we'll continue that momentum as we roll through 2025.

Frank Watanabe^ You want to address the coverage?

Todd Edwards^ Yes. Relative to the coverage rate, we mentioned that we're kind of in an optimal steady state relative to 80% covered or reimbursed prescriptions. We anticipate that we will stay -- relative to the improvement, we'll stay within that 80% range.

We have very good coverage of ZORYVE across all three products now which is leading to those reimbursed rates that we see, which I think was a contributor relative to maintaining a positive gross to net during Q1. So we expect minimal change, and we'll stay within that steady state of 80% covered reimbursed prescriptions.

Frank Watanabe^ And let me just touch a little bit on the demand point, too. Again I think some investors maybe aren't used to this dynamic. But Q4 is typically very strong as patients pull forward demand before the deductible resets.

We certainly saw that if you look at Slide nine in our deck, there is a very clear demand spike in Q4. And many brands experience actually a decline in demand then in Q1 because the patients aren't filling scripts in January that they filled in December. So the fact that we were able to grow quarter-over-quarter in spite of that demand pull forward, I think it's really pretty notable.

If you look at many of the other branded topicals, they have been largely flat in the quarter compared to Q4, whereas we've been able to deliver yet another strong quarter of demand growth in Q1. I think that bodes well for us going forward as well.

Todd Edwards^ And if I could mention one other dynamic. If you think about what Frank mentioned relative to the pull forward of the refills into December, when you look at that demand increase that we had in Q1, those are NBRxs. That means they're new-to-brand Rxs.

So we're driving new growth of new prescriptions in January, which is going to lead to incremental refills, say in Q2, Q3 and Q4 this year. So once again a very positive signal relative to the health of the business.

Operator^ We will take our final question. Your final question comes from the line of Douglas Tsao from HC Wainwright.

Douglas Tsao^ I'm just curious, as we look ahead to the approval for the foam into scalp and body psoriasis, I'm just curious because when we first saw the foam get approved to the market, we saw a very rapid adoption.

We've obviously seen as you've added additional indications some incremental growth, but perhaps less dramatically. What is your expectation? And how should we think about the trajectory from the addition of that indication fairly soon?

Frank Watanabe^ Yes. So Douglas, that's really an important question. The launch of the foam in seborrheic dermatitis was a very, very unique unicorn kind of situation, one that I have never experienced in three decades in the business, and I don't think Todd has either. That was a disease that where there had been no innovation in over two decades. A very large population, very high level of dissatisfaction with existing therapies.

And I can tell you from -- I know for a fact that I spoke with a number of clinicians early last year who had literally hundreds of patients lined up waiting to go on the foam. So the minute we got approved, there was a vertiginous uptake of the foam, the likes of which I have never seen before. And certainly, we actually honestly hadn't expected when we launched it, not that pace.

I don't think that scalp is of that same degree of unmet need. There are options. You can use biologics, which some of them are very, very good. The scalp is one area that maybe doesn't respond as well but it does respond. There are steroid options for use on the hair.

So you don't have this complete absence of good options, I think in scalp, although ZORYVE is a very, very competitive option. So I wouldn't expect to see that sort of almost vertical trajectory in scalp psoriasis.

I think that there probably are some doctors who are using the foam already, although I don't think that's probably widespread because they need to code it as seb derm to get it reimbursed. So I think what we're likely to see is the scalp indication allowing us to continue our growth trajectory.

If you go again back to Slide 9, how do we continue to grow that franchise at a fairly continuous rate? I think foam is going to be an important contributor to that as will be AD in two to fives. But I wouldn't expect to see a sudden spike in our demand after the approval.

Douglas Tsao^ And if I can with just a follow-up. How much education and how much promotional sensitivity do you expect to see with the scalp and body indication with the foam?

Frank Watanabe^ Well I mean all of these diseases are highly promotionally sensitive. I think that the scalp data, as Patrick showed you in the photographs and also the IGA success data, that the data is very, very compelling.

So it will be important for our reps to get out and educate clinicians on the effectiveness of ZORYVE and the safety and tolerability of ZORYVE in scalp psoriasis, which there has not been any promotional educational efforts to date.

So I think that there will be some -- there will be incremental upside from the scalp indication as we get out and start promoting this data and also because it will help streamline the reimbursement process for using the foam in scalp psoriasis as well. Todd, I don't know if you have any other additional thoughts you want to add?

Todd Edwards^ No. you covered it very well.

Operator^ This concludes today's question and answer session. I'll now hand back for closing remarks.

Frank Watanabe^ Well I'll just once again thank everyone for calling in. I know this is a very, very busy time of the year with quarterly earnings, so we appreciate you guys making the time and appreciate all the great questions, and we look forward to talking to you all next quarter. Thanks.

Operator^ This concludes today's conference call. Thank you for participating. You may now disconnect.