

Arcutis Biotherapeutics, Inc. (Q4/FY 2024 Earnings)
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Corporate Speakers

- Latha Vairavan; Arcutis Biotherapeutics, Inc.; Vice President of Finance and Corporate Controller
- Todd Watanabe; Arcutis Biotherapeutics, Inc.; President and Chief Executive Officer
- L. Edwards; Arcutis Biotherapeutics, Inc.; Chief Commercial Officer
- Patrick Burnett; Arcutis Biotherapeutics, Inc.; Chief Medical Officer
- David Topper; Arcutis Biotherapeutics, Inc.; Chief Financial Officer

Participants

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

PRESENTATION

Operator^ Good day. And welcome to Arcutis Biotherapeutics 2024 Fourth Quarter and Full Year Financial Results Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. I will now hand the call over to Latha Vairavan, Vice President of Finance and Corporate Controller. Please go ahead.

Latha Vairavan^ Thank you. Good afternoon, everyone. And thank you for joining us today to review our fourth quarter and full year 2024 financial results and business updates. Slides for today's call are available on the Investor 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 David Topper, 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.

Todd Watanabe^ Thank you, Latha. And thank you to everyone for joining us today. Before we get started, I want to highlight three key themes that we're going to focus on throughout the call today. First of all, we had very strong execution throughout 2024.

Second, we believe we are nicely set up to continue growing ZORYVE in 2025 and beyond. And third, the key to our success going forward is going to be driving the shift away from topical steroids.

So with that, let me turn to Slide 5 of the deck. Closing out a very strong fourth quarter and full year for 2024, we are optimistic about the strong foundation we have established for the entire ZORYVE portfolio and for continued growth of our franchise this coming year and beyond. I want to take this moment to thank the entire Arcutis team for their hard work and exceptional execution in 2024.

We are building a leading topical brand, one that we believe will outperform historical predicates based on its remarkable efficacy and safety, rapid onset, unique formulation, and the ease of use for both clinicians and patients. This past year, we launched ZORYVE foam for seborrheic dermatitis and ZORYVE foam 0.15% cream for atopic dermatitis and also broadened patient access across indications.

In 2025, we'll further expand ZORYVE's approved indications, continue to expand our prescriber base beyond dermatology, further penetrate the government payer segment, and focus on taking market share from topical steroids.

We're especially excited about our May 22, PDUFA date, for an expected indication in scalp and body psoriasis, which will provide another opportunity for doctors to prescribe ZORYVE foam to meet a substantial unmet medical need. We continued our strong sequential revenue growth.

For the quarter, we had revenues of \$71 million, with \$69 million of that coming from the ZORYVE franchise. This includes a nonrecurring adjustment of \$4 million that David will address in detail later.

On an annual basis, we had total revenues of \$197 million, with ZORYVE product sales of \$167 million, 471% growth year-over-year, and we are just scratching the surface of this very large and attractive market.

We expect substantial continued momentum in 2025, and Todd will provide further detail on how we view revenue and script growth trends evolving throughout 2025. Blended gross-to-nets have reached steady state in the 50s, although we expect to see some quarterly fluctuations related to patient deductibles, particularly in the first quarter, as is typical for nearly every product. Regardless, we expect gross-to-nets to remain in the 50s, and Todd will provide some additional color on what we expect for gross-to-nets as the brand matures.

Looking towards 2025, we believe we are well positioned to achieve further strong revenue growth. Our psoriasis and seb derm indications continue to grow. We are still very much in new launch mode for atopic dermatitis, and we expect to add further indications and label expansions in the coming year, providing us with significant growth opportunities ahead. Turning to Slide 6.

I want to emphasize the sizable growth opportunity we have in our target markets.

We've shared this slide with you before, but we've now updated this slide to include the opportunity in AD patients ages two to five, based on our supplemental NDA with an anticipated PDUFA sometime in Q4 of 2025.

Dermatologists treat well over 8 million patients across our approved indications, and we've already secured broad access to the roughly 4.5 million commercially insured patients treated by derms.

We're now making great progress in gaining Medicare and Medicaid coverage, which is expanding ZORYVE usage into the almost 4 million dermatologists treated patients with government insurance. Furthermore, our Kowa commercial partnership permits us to simultaneously pursue the more than 8.5 million patients being treated outside of the dermatology office for these indications. This includes primary care physicians and pediatricians for whom ZORYVE represents an ideal, easy-to-use topical anti-inflammatory agent.

Within each of these large segments outlined on the slide, the vast majority of patients are currently treated with topical steroids, but clinicians are starting to shift away from these products, although we're only in the very early stages of this transition in medical practice.

And Patrick's going to talk more about the shift away from steroids in just a few minutes. Moving to Slide 7. We are confident in our ability to sustain our growth because of four significant tailwinds that are going to propel ZORYVE forward in the years to come. Let's dig into those tailwinds a little bit further. First, we continue to educate physicians on our three approved indications while continuing to expand the ZORYVE product label.

As mentioned, we have an expected approval in scalp and body psoriasis in May, as well as anticipated expanded indications for pediatric patients in both atopic dermatitis and eventually psoriasis. These expanded pediatric indications are especially important for our commercial partner, Kowa, and reinforce ZORYVE as a first line topical agent to a broad prescriber base that now encompasses primary care physicians and pediatricians.

Second, with our commercial coverage established, we are now engaging with government payers across both Medicare and Medicaid, which encompass approximately 3.7 million incremental patients in dermatology offices and many more in primary care and pediatrics.

We have been rapidly gaining wins in Medicaid, with ZORYVE already available for one in two Medicaid patients, and Todd will provide some more color on that front. Third, our partners at Kowa are now promoting ZORYVE to high potential primary care doctors and pediatricians, and we expect them to gain growing traction as 2025 progresses.

We look forward to meaningful contribution from this co-promote beginning this year and growing from there. And finally, with our broad product offerings, comprehensive patient access, and differentiated product profile for both doctors and patients, Arcutis is now well positioned to

take meaningful market share from the 16 million topical steroid prescriptions written by dermatologists for our approved indication each year.

There has been growing momentum in that direction, and Todd and Patrick will delve into this further. Taken together, this immense market size, coupled with the excellent efficacy and safety of ZORYVE and its ease of use and access, make us highly optimistic regarding our future prospects and committed to grow ZORYVE to its peak sales potential. With that, let me turn it over to Todd to provide some further commentary around our launch progress, reimbursement, and the outlook for 2025.

L. Edwards^ Thank you, Frank. We're extremely enthusiastic about the growth and the expansion of our product portfolio, the strong response from HCPs and patients, and the immense opportunities that lie ahead. This quarter, we achieved \$69.4 million, \$65.4 million before the nonrecurring adjustment in net product revenue for ZORYVE, reflecting 46% growth over the third quarter.

Without our nonrecurring adjustment for product return reserves and \$166.5 million in net product revenue for the full year, a growth of 471% over last year. This strong performance continued the robust quarter-over-quarter growth trend that we have seen throughout the year.

This robust revenue growth was driven primarily by prescription growth across the portfolio of ZORYVE products, along with a slight gross-to-net percentage improvement, with the blended gross-to-net remaining in the low 50s for Q4.

Looking forward to 2025, in the first quarter, we expect the typical gross-to-net impact driven by deductible resets and insurance plan changes for the new year.

As we know well this phenomenon negatively impacts sales of many products across the pharmaceutical space, but as is typical, we expect gross-to-net to quickly trim back to steady state in subsequent quarters. Turning to volume. We anticipate sustained growth and are encouraged by the trends so far this year.

It is common to see a decline in prescription volume growth for products in January following the end of year demand pull forward, and we are seeing such a decline for many of the other branded topical nonsteroidals.

While the typical Q1 gross-to-net fluctuation will affect total net product revenue, we are encouraged we've been able to sustain and even expand the number of scripts written to date in 2025 compared to Q4 '24.

Speaking of Q4 prescription volume, on Slide 10, you can see that ZORYVE prescription volume has reached another record high at 16,000 weekly scripts. Quarter-over-quarter prescription growth was 44% over Q3, and prescriptions grew 334% on a year-over-year basis. You can clearly see the inflections and growth during 2024 due to the launches of ZORYVE foam and seb derm and 0.15% cream for atopic dermatitis.

However, in Q4, I want to emphasize that we delivered growth across our entire product portfolio. Every indication has grown, and we expect this key trend to persist as we continue to take share from the enormous topical steroid market. I will delve into the drivers of this phenomenal growth next.

On Slide 11, I want to discuss the factors that led to the exceptional growth we achieved in Q4, and that we expect to drive continued growth and success in 2025. The first of these is our atopic dermatitis launch, which is still generating an inflection in prescriptions, as you saw on the prior slide.

Quite simply, physicians are recognizing that our once daily nonsteroidal anti-inflammatory can be used safely and effectively anywhere on the body affected by atopic dermatitis, for any duration, and are appreciating the ease of reimbursement and prescription fulfillment established by our team. The second growth factor is our sales force expansion that occurred in late June, which has significantly enhanced our share of voice across derm clinicians.

With the multiple indications and formulations, we have created a unique portfolio versatility effect, which allows dermatologists multiple approaches to treating complex skin conditions using one or more ZORYVE products. This is the third growth driver and creates an amplification effect upon each of the individual strengths of the cream, as well as the foam formulation.

By this, I mean that doctors now have a spectrum of options with respect to which ZORYVE strength and formulation is tailored to each specific indication. This optionality and flexibility drive an overall increase in the use of the entire ZORYVE portfolio, which is rapidly becoming the go-to solution for dermatologists.

We expect this to be a sustainable advantage into 2025 and beyond, and should be further amplified by the addition of a new foam indication for body and scalp psoriasis in the second half of 2025, and a subsequent pediatric label expansion. Lastly, I want to highlight the strong execution of our entire commercial organization, which has been steadily picking up commercial and government coverage, delivering effective and targeted messages, and beginning our drive to convert over a meaningful percentage of the topical steroid market.

Slide 12 is an important slide where I want to make two key points. One is that our commercial coverage is quite good, and overall portfolio gross-to-net, as we said last quarter, has reached steady state. We expect the portfolio gross-to-net to be in the 50s throughout 2025.

First, to the left, you can see we have a strong position with prescriptions covered by insurance. We are at a steady state and an optimal point for psoriasis and seb derm at 80%, and we are continuing to improve cover prescriptions for atopic dermatitis currently at 65%. I'm delighted to report that since our last update, we have secured Medicaid coverage in two additional states, Ohio and Illinois.

We have now secured Medicaid coverage in states that represent approximately one in two Medicaid beneficiaries, and we expect to add further states through 2025. Importantly, the quality of Medicaid coverage is very strong. We are also making progress in our negotiations with Medicare Part D programs.

Now moving to gross-to-net. In the chart on the right, we highlight the progressive improvements in our blended gross-to-net over time. Our blended gross-to-net across all three indications in Q4 was similar to Q3 in the low 50s. Our gross-to-net has reached a steady state and will be in the 50s throughout 2025.

As Frank stated earlier, we do expect some variability in the first quarter due to a reset of patient deductibles and changes of insurance plans, which both occur early during each year across all covered drugs.

As we have reiterated, we expect that Q1 gross-to-net will be at the higher end of the 50s range, but will quickly return to steady state and remain in the 50s throughout the year. I am extremely excited to share some market research data with you on Slide 13. We recently conducted research to assess unaided awareness of ZORYVE, as well as the most affected ZORYVE messages that doctors are hearing and remembering.

We were extremely pleased both with the overall brand awareness of ZORYVE, as well as with the magnitude of improvement we have achieved over time. In psoriasis, unaided awareness grew from 55% in the second quarter to 63% in the fourth quarter.

Our foam formulation used in the seb derm is even more widely recognized, and unaided awareness grew from 75% in Q2 to 88% in Q4. This means that just about every dermatologist is aware of ZORYVE foam and can rapidly recall it when prescribing to an appropriate patient. For the atopic dermatitis 0.15% ZORYVE cream formulation, which launched in mid-2024, unaided awareness grew from 2% in Q2 to 44% in Q4.

This is an impressive gain since we are still early in the launch. Tolerability and ease of use are really the standout messages for ZORYVE. Doctors remember that we are the only topical nonsteroidal agent approved across three inflammatory skin indications.

Additionally, the most motivating message for dermatologists focuses on ZORYVE's ease of use, which we view as a clear differentiator for our product. Earlier this month, we were delighted to announce a partnership with Odell Beckham Jr., or OBJ, an iconic professional football player who was affected by seborrheic dermatitis, and who is a current ZORYVE foam user.

In the past 20 years, patients with seb derm had no innovation available to them. As a result, many retreated from care, resigning themselves to their condition. They were frustrated that nothing was available to help them. They lived with the embarrassing, itchy, flaky redness on their scalp, face, and body, and had to endure repeated shampoos and steroids, causing more frustration.

We believe that increasing patient awareness of seb derm and destigmatizing the disease will prompt a return to treatment for many of these patients. This important next step in the ZORYVE foam promotion strategy aligns well with the high level of unaided awareness for ZORYVE and positive clinical experience for the dermatologist, as well as the strong coverage position.

OBJ will be key in the coming year to executing our ZORYVE foam patient awareness initiatives. OBJ's personal story of struggling with seb derm, his symptoms, and all the treatments he tried will resonate with these patients, and as a ZORYVE foam patient himself, he will share the meaningful difference using ZORYVE foam has made on his life.

We are ecstatic at the early reception from this new partnership. Not only does OBJ have a massive social media following of more than 17 million followers, but in the first week alone, interviews with him in mass media outlets like People, Prevention, Cosmopolitan, and Forbes have generated well over 1.5 billion media impressions.

I would be remiss if I didn't also point out that at this time we do not anticipate launching broadcast TV DTC advertisements as part of the OBJ partnership. Rather, we will rely on his celebrity reach, social media presence, digital advertising, and publicity to generate public awareness.

Thus, while there is some incremental SG&A spending associated with this partnership, we are talking low double-digit millions, not tens or hundreds of millions in incremental span. On Slide 15, I want to reiterate the majority of prescriptions across all three ZORYVE indications are for topical steroids.

Of the 24 million topical prescriptions written by dermatology clinicians in our three current indications during 2024, roughly 16 million were for topical steroids, when in contrast, 1.4 million prescriptions were for branded topical nonsteroidals, and around a 0.5 million were for ZORYVE, highlighting the immense growth opportunity as clinicians transition away from steroids to newer topical agents, which we will expect them to do, as Patrick will discuss shortly.

Our greatest opportunity is steroid conversions to ZORYVE, growing the entire branded topical marketplace. As we are already the leading branded topical in NRxs, we believe that by focusing our energy on steroid conversion, we can impact more patients and continue to grow ZORYVE.

Slide 16 highlights the strength of the ZORYVE differentiated offering, which encompasses three formulations of ZORYVE, and the expected fourth indication of scalp and body psoriasis with the PDUFA upcoming in May 2025. ZORYVE's differentiation is rapid relief on any part of the body, for any duration, high tolerability, and quick onset of itch relief.

Additionally, it is a simple-to-use, once-daily treatment, and is easily accessible to patients with the same predictable reimbursement process and co-pay card across our entire portfolio. With that, I would now like to turn it over to Patrick to provide a brief R&D update. Patrick?

Patrick Burnett^ After a strong series of accomplishments in 2024. First, we have an upcoming FDA PDUFA action date for ZORYVE foam in scalp and body psoriasis down to the age of 12 on May 22, 2025, and all aspects of the submission remain on track.

Second, we have an anticipated approval in Q4 2025 for ZORYVE cream 0.05%. It's a dose specifically developed for the treatment of mild to moderate AD in two to five-year-olds. We expect to initiate an additional trial of ZORYVE cream at the 0.05% dose in mild to moderate AD patients ages three to 24 months during 2025.

Moreover, we continue to generate the necessary additional data that should ultimately support expanding the psoriasis indication down to the age of two. In our early-stage pipeline, we look forward to the Phase Ib readout for ARQ-255, our topical JAK in alopecia areata, in the first half of 2025.

We expect to file the IND for ARQ-234, our biologic CD200 Receptor agonist for atopic dermatitis later in 2025. However we do acknowledge that Lilly has deprioritized their CD200R program and we'll continue to evaluate our own asset as we progress this program.

Now on Slide 19, we can see that the dermatology community is coalescing around increased awareness of the challenges of managing patients with chronic inflammatory skin diseases, like psoriasis, AD, and seborrheic dermatitis with topical steroids.

These include local tolerability issues, safety concerns and limitations on duration of dosing for more potent steroids. This view is being expressed more and more frequently, both in published literature and at important medical conferences attended by dermatologists, as evidence against steroid overutilization amounts.

For example, the Journal of Clinical Anesthetic Dermatology, NPPA Journal, recently ran a lengthy article reviewing the concerns of managing inflammatory skin diseases with topical steroids and recommending clinicians move toward greater use of nonsteroidal agents like ZORYVE. We're also now in the busiest season for derm meetings, with several major meetings just wrapping up and the AAD a week away. So I want to share some of what we're hearing.

Indicative of this evolution in the thinking are statements such as those two that we've included at the bottom of Slide 19, reflecting the stance from the podium at Maui Derm about topical steroids, going away as a mainstay of AD, as well as the response from a derm provider after a recent presentation on steroid overuse and its impact on her practice and her communication with patients.

I've been in dermatology for over 20 years, and this is not a conversation that I've heard before. It is roflumilast of what took place when biologics came onto the scene and old school immunosuppressants were set aside in the long-term management of psoriasis and AD. Now importantly, the profile of ZORYVE is perfectly positioned to step into this space this opening.

In our clinical trials, we studied patients who previously used topical steroids and were able to demonstrate that ZORYVE is well positioned both as first line treatment as well as for those patients who've already tried and failed topical steroids.

And we did this across all of our development programs. Taking AD as an example and looking at the right side of Slide 19, in our integument studies, we showed that ZORYVE cream 0.15% has excellent clinical improvement for atopic dermatitis patients, even in those who have previously failed topical steroids.

We believe that data like this, combined with the changing consensus on steroid use, should drive a prolonged shift away from steroids that will benefit patients and our brand. With that, I'll pass it over to David.

David Topper^ Thanks, Patrick. I'm on slide 21, showing financial results both year-over-year and quarter-over-quarter for the fourth quarter. We generated net product revenues in the quarter of approximately \$69.4 million, which is up 413% from Q4 of 2023 and 55% from Q3 of this year.

For all the reasons outlined by Frank and Todd, we believe we are still very much in the early stages of our growth with significant upside remaining. In January, ahead of the JPM conference, we preannounced unaudited product sales of approximately \$63 million.

While we outpaced that estimate a bit in terms of actual sales in Q4, the amount by which we beat it was principally due to a reduction in reserves we were holding for product returns of \$4.1 million. Excluding this nonrecurring adjustment, we had net product revenues of \$65.3 million for the fourth quarter. That nonrecurring amount should be excluded for forward-looking calculations.

For the fourth quarter, our R&D expenses were \$14.5 million, which is down 39% from \$23.8 million in the fourth quarter of 2023 due to decreases in the development cost of topical roflumilast programs and down approximately 26% compared to the third quarter of 2024 this year. The reduction in R&D expenses was also due in part to a one-time Q4 credit of \$3 million we received related to a closeout of our roflumilast studies.

SG&A expenses were \$57.6 million for the fourth quarter of 2024 versus \$48.7 million in the same period last year, up 18% as we invested in our commercial organization and our current and future launches. SG&A expenses were essentially flat as compared to last quarter.

Our continued strong revenue growth supports our belief that we are investing appropriately in the tremendous growth potential of our ZORYVE portfolio, and we continue to believe that we will reach cash break-even in 2026.

On slide 22, for the full year '24, we generated net product revenues of \$166.5 million, which is up 471% year-over-year. Total revenues in 2024 were \$196.5 million, up 230% year-over-year.

Based on the ZORYVE revenue run rate we saw in Q4, we ended the year at an annual run rate of approximately \$250 million in product sales. Frank and Todd have highlighted the tailwinds for the full year 2025 and beyond that should allow us to build on this impressive growth including new indications, expansion into government payers, broadening of our prescriber base, and our efforts to take meaningful share from topical steroids.

For the full year 2024, our R&D expenses were \$76.4 million, down 31% from 2023 due to decreases in development costs of topical roflumilast programs. Recall that a large portion of the expenses included in the R&D line item are comprised of medical affairs activities, supporting ZORYVE commercialization, which will not decline over time.

In 2025, we expect a similar level in R&D as in 2024, a year in which we will advance ARQ-234 and ARQ-255 with minimal spend for our topical roflumilast program and continued investment in our medical affairs activities. SG&A expenses were \$229.4 million for the full year 2024, versus \$185.1 million in the same period last year, up 24% to support a significantly higher level of revenue growth.

In 2025, we do expect an increase in SG&A expenses, considering our launch in scalp and body psoriasis, the annualized cost of the increased sales force, and sustained marketing efforts supporting all ZORYVE indications.

On slide 23, you can see we had cash and marketable securities of \$228.6 million on our balance sheet as of December 31, 2024, which translates to a cash burn from operations in the quarter of less than \$1 million.

We had great revenue growth in Q4 and lower expenses due to the R&D credit I noted earlier, and some of expenses rolling over into 2025. This along with a few working capital items led to our low cash burn.

Q4 was a bit of an anomaly but moving forward we expect higher SG&A and modestly higher cash burn in the first quarter and as Frank indicated previously we expect our quarterly cash burn to continue trending down in the long run as our revenues grow and we reach cash flow break-even sometime in 2026.

In October we repaid a \$100 million of our debt facility which will significantly lower our interest expense in 2025. We have the option to redraw that \$100 million in whole or in part at our discretion in the middle of 2026 providing us with significantly enhanced flexibility.

We believe our current capital together with the available \$100 million in debt, our growing ZORYVE revenue stream and improving economies of scale will allow the company to reach cash flow break-even in 2026 even as we continue to invest in the business for continued growth and long-term durability. To reiterate what we have said previously we do not expect to return to the equity market to support our existing business. With that I'll hand it back to Frank for some closing comments.

Todd Watanabe^ Thanks, David. So in closing, let me reiterate our three key messages. Our business is strong as we wrap up a stellar 2024. We look forward to continued growth of the ZORYVE portfolio in 2025 and beyond.

And the key to that continued growth is the growing shift from topical steroids to nonsteroidals in our large target market of 17 million patients. After our significant efforts last year, ZORYVE is now the #1 branded topical product, but as you saw, this is just a drop in the bucket of the enormous topical steroid market.

We're excited about the opportunity ahead of us. And in 2025, we will continue to tackle it comprehensively using multiple levers, like our new indications and label expansions, our primary care partner, our consumer outreach with OBJ, and our continuously improving reimbursement coverage. Lastly, as David said, we have line of sight to break-even in 2026,

which will further improve the overall characteristics of our business and create optionality for even more growth. And with that, we'll conclude and open the call up to Q&A.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question coming from the line of Vikram Purohit with Morgan Stanley.

Vikram Purohit^ So we had two, just one on the quarterly release. So you clarified a big chunk of the delta between the preannouncement and the actual 4Q results of roughly \$69 million, but for the residual roughly \$2 million, was that related to inventory or another factor? If you could clarify that, that would be helpful. And then secondly, had a question for you on IP.

There's been some investor interest and questions in the upcoming claim construction hearing in your ongoing IP lawsuits. So just wanted to ask if you could speak to your kind of confidence in protecting the IP for the ZORYVE franchise going forward and how you feel about that process?

Todd Watanabe^ Okay. Sure, Vikram. Thanks for your question. So David, maybe can you go in a little more detail around the delta between what we had preannounced for Q4 and this final Q4 print and what was driving that?

David Topper^ Sure. Couple of things I'd say. First of all, as mentioned, we did make an adjustment for the reserves we had accumulated for product returns. That total adjustment was essentially a bit over \$5 million, but a \$1 million and change of that was due to the fourth quarter of 2024 itself.

So we can't refer to that as an adjustment. So that's a part of it. The other part I would chalk up to us being conservative when we preannounce revenue, simple as that.

Todd Watanabe^ And then Vikram, with regard to your second question, I think it's a completely understandable question, it's one we get a lot.

What I can say at this point is you made reference to the upcoming Markman hearing, that's scheduled to occur in April 2025. You can review what's publicly available on the court docket, but we can't comment beyond that specifically vis-a-vis the Markman hearing.

What I will say is, is that, as we have said before, we are very confident in the strength of our IP portfolio and our ability to maintain exclusivity of ZORYVE, and we intend to vigorously defend our intellectual property rights as appropriate.

Operator^ Our next question coming from the line of Tyler Van Buren with TD Cowen.

Tyler Van Buren^ And congratulations on the exceptional execution on commercial front heading into year end. So I think many people were surprised by the growth in weekly prescriptions that we saw with ZORYVE cream heading into year end and quarter-over-quarter in Q4 relative to what we saw in Q3 versus Q2.

So can you elaborate on the impact? I mean you talked about multiple drivers, but can you elaborate on the impact that the sales force expansion had? How much it was expanded by? And whether you'll continue to expand it as sales increase moving forward?

Todd Watanabe^ Yes. So Tyler, just to clarify, are you asking specifically about the growth of the cream or the 0.3% cream or you're just asking generally about the growth that we're seeing across the board in prescriptions?

Tyler Van Buren^ Generally about the growth, I'd be curious to hear about the cream and psoriasis, if you have any additional color there since there was really significant quarter-over-quarter growth for Q4 versus Q3 as opposed to Q3 versus Q2.

Todd Watanabe^ Sure, sure. Yes, Todd, can you maybe go in a little more detail about our view specifically with regard to Q4 and the growth at both the portfolio level and then maybe if you have any color around each of the individual SKUs?

L. Edwards^ Portfolio growth. As mentioned, portfolio growth is primarily driven by volume growth, the slight -- on net revenue, a slight increase with gross-to-net.

But nonetheless, as mentioned, we did see growth across the entire product portfolio, which we're very encouraged by. More specific to ZORYVE cream for psoriasis, we think about the, what I'll call the versatility effect that I mentioned earlier within my script, providers are now being able to get clinical experience with ZORYVE across three different products: across one for seb derm; one for atopic dermatitis; and now psoriasis, and that's amplifying the increased utilization of these products across the portfolio to include increased utilization of ZORYVE cream for psoriasis, so we're very encouraged by that.

In reference to the sales force expansion that we had on June 1, increasing the share of voice, that was definitely a driver of the increased prescription growth that we saw in Q4. And we believe that we are currently right sized for the dermatology market with the portfolio that we're managing today.

Operator^ And our next question coming from the line of Seamus Fernandez with Guggenheim.

Seamus Fernandez^ So just wanted to circle up on the momentum in the business.

Can you just give us a little bit of color on fourth quarter, how the refills were sort of coming in? Was there clear proof from your perspective that there was an increase in the resell rate? And just wondering how the, sort of, the estimate of the tubes per year is actually coming in relative to your expectations on a go forward basis as we think about the growth in the overall market? And then the second question is just, very quickly.

Consensus is kind of between \$280 million, \$285 million this year. Just wondering how you guys are thinking about the opportunity for sustained growth and the opportunities to see the scripts perhaps maintain this very strong linear trajectory that we saw through the balance of 2024?

Todd Watanabe^ Sure. Okay. If the -- Arcutis team, if you guys could pause just a second before you start answering your question, I think that the very front end of your question answers are getting clipped off.

So Todd, if you could, comment maybe on the momentum in Q4 and particularly around what we're seeing with refills, the indicators of the pull forward that we believe happened. And then also maybe comment on, our current thinking around, tube per year consumption.

And then also, if you could maybe touch on the opportunity for sustained growth again. And then David, I think it would be helpful if you can give maybe some color around our current thinking around consensus for 2025.

L. Edwards^ Yes, Frank, I'll start. Relative to the twos per year, as we've communicated before, we expect ZORYVE cream 0.3% for psoriasis on the average tubes per patient per year, to be around two tubes per year, and for ZORYVE foam, for seb derm, likely around two to three cans per year.

For atopic dermatitis, it's still early within the launch, but we expect on average 2 tubes per year for an atopic dermatitis patient. And then in reference to Q4 and refills, we're very encouraged by the refill rates with ZORYVE cream for psoriasis, which was around 40% of the total volume as refills. And then for ZORYVE foam, for Seb Derm, it was around 38% of refills, and atopic dermatitis, still early in the launch for the refills, but nonetheless, once we mature that product, it'll likely be similar to ZORYVE cream and psoriasis, around 40% within the refills.

As Frank mentioned, we did see some pull forward in December from Q1 due to patients wanting to get their prescriptions refilled prior to their deductibles being reset, so we did see some pull forward into December. But nonetheless, we're very encouraged with the prescription trends and growth here in Q1, albeit that we -- still that we had that pull forward from January into December.

We continue to see robust prescription growth despite some of the typical disruption that we see in the first quarter with patients switching insurances have to be recertified for product like ZORYVE, and we fully expect to continue this momentum throughout 2025.

David Topper^ Hope I'm not being cut off. As for the estimates that are out there, we are very comfortable with the consensus out there for the full year of 2025, definitely comfortable.

I think it's important to think a lot about how those revenues will be distributed across quarters for the year. You've heard Todd say a couple of times now that first quarter for the product like many, many other products can be affected by a slight change in gross-to-net as deductibles get reset and so forth.

So while obviously prescription growth is extremely robust, there can be an impact on revenue. I'm just thinking about how to distribute that \$280 million to \$285 million across the four quarters.

Operator^ And our next question coming from the line of Serge Belanger with Needham.

Serge Belanger^ Couple of questions. The first one, I guess, a follow-up to the guidance or the consensus number and how we should model 2025.

On Slide 6, you highlighted about 4 million patients are covered by Medicare and Medicaid. Just curious how many of them had coverage at the start of the year and when do you expect they will have coverage throughout the year? And then, second question, more of a broader strategy question.

David highlighted how well the company has capitalized and the near-term break-even point is on the horizon in 2026. So just curious, how much of a priority in the near to medium-term is profitability for the company given that you do have a pipeline and you've discussed BD in the past?

Todd Watanabe^ Sure. So Todd, if you could maybe address the -- and Serge, you're asking about, the amount of Medicare and Medicaid patients had coverage at the beginning of 2025 or the beginning of 2024?

Serge Belanger^ '25.

Todd Watanabe^ Okay. Yes. So Todd, if you could maybe, talk a little bit more about where we stand with regard to Medicare and Medicaid as of the beginning of this year, and how that will translate into patient opportunity for 2025. And then, when you're done talking about that, I'll come back to the question around profitability and the pipeline.

L. Edwards^ Yes. Thank you, Frank, for the question. Specifically to Medicaid, we're very pleased with the Medicaid coverage that we've been able to secure up to the start of 2025, and that would be that one in two Medicaid beneficiaries now have access to ZORYVE, and one of the things very important to highlight is not only the improved access we've had relative to Medicaid, but the quality of that access.

And what I mean by that, as an example, if you look at the state of California with Medi-Cal, there is no step edit for ZORYVE, so it's a first line therapy within the state of California. If we look at the state of Florida, you have to step through ZORYVE to be able to access Vtama within psoriasis. So high quality Medicaid coverage, and one in two Medicaid beneficiaries have access to ZORYVE.

Specifically, to Medicare, to Medicare Part B, we can continue to have our discussions and negotiations with the Medicare Part B PBMs as they navigate the implementation of the IRA, the Inflation Reduction Act.

Implementation of the IRA has operationally slowed those discussions down in that process with the PBM, but nonetheless, we're very optimistic that we'll be able to accelerate these discussions and continue to improve on our Part D access as we navigate through 2025.

Todd Watanabe^ And then, Serge, with regard to your question around profitability, this is obviously something that the leadership team thinks a lot about at Arcutis.

I think getting the cash break-even is very important because it gives us a degree of operational flexibility as we think about running the business for the future. The first priority has to continue to be investing in the growth of ZORYVE. And as I think, Todd mentioned during the call we feel like we have the right level of investment.

It's something that we constantly evaluate, whether there are incremental opportunities or whether there are opportunities to save money in terms of ZORYVE investment. But we feel we're at the right point right now in terms of investing in ZORYVE growth.

We do have a number of pipeline programs as Patrick outlined. And those will hopefully progress, but they're fairly early stage. So we don't expect really significant burn on those programs in the near-term. But they eventually will impact our spend.

And then with regard to business development, I would say that we remain very opportunistic. We're always looking at interesting opportunities and opportunities where we feel like we can grow shareholder value.

But we don't believe that that business development is something that we have to do, right? It's not an imperative given the strength of our existing franchise and our internal pipeline. So it's sort of an odd question as a biotech company to think about profitability.

We're really focused on driving revenue growth and driving shareholder value first. And I think, us paying dividends is probably not the right way to do that, at least not for the foreseeable future. So we'll continue to be very judicious in our investments, whether that's vis-a-vis ZORYVE or the pipeline or business development. But if we do see opportunities to use the capital that we have to grow shareholder value, then we'll certainly take advantage of those opportunities.

Operator^ And our next question coming from the line of Ey Ear with Mizuho Group.

Uy Ear^ So I have two questions. The first one is, with the upcoming approval of the foam in psoriasis, just wondering what is the indication that you're expecting? Is it psoriasis in general? Or is it like psoriasis with scalp involvement? And how do you think that this -- what's the strategy for this indication or for this foam product?

Do you think that they'll probably cannibalize more of the cream or do you expect more patients to convert to the foam? Just wondering what your thoughts are there. And secondly, what do you expect from the Phase Ib data for ARQ-255?

Todd Watanabe^ Sure. So Patrick, maybe if you could start out by addressing the 255 question and what we expect from our Phase I study. And then if you could also maybe comment on what we filed for and what we expect in terms of the indication for -- the expanded indication for ZORYVE foam. And then, Todd, if you could go into, the strategy for the foam launch in scalp and how we see that playing with the 0.3% cream.

Patrick Burnett^ Absolutely. Thanks, Frank. Yes. So starting with 255, this is a Phase Ib study. We have -- we had 12 healthy volunteers, then we had 30 plus alopecia areata patients that were

treated for three months. Our goal with this is really to understand the kind of PK exposure safety and tolerability first in this early-stage trial.

And then also with the inclusion of alopecia areata patients, to get an understanding from both a biomarker and an early clinical response whether or not there's some indication that we were getting an engagement of the target, which has been a challenge for topical treatment of alopecia areata.

And so, we're really going to be focusing on those safety and tolerability data primarily. And keep in mind, this is a three-month treatment, and the pivotal timeline for an alopecia areata trial is typically six months of therapy. So we would really just be seeing the first evidence of efficacy in that readout. Now moving on to the scalp and body indication for psoriasis with the foam.

In our pivotal trial, we had coprimary endpoints of body IgA as well as scalp IgA. And so we anticipate the indication to be inclusive of all psoriasis, but then also specifically calling out scalp in a similar way roflumilast of what we saw with the cream indication where we had a broad indication for the treatment of psoriasis, but then it specifically called out inclusive of those patients with intertriginous disease. So we would anticipate that kind of broad indication for the foam as well.

L. Edwards^ Yes, and then I'll respond relative to the strategy for the ZORYVE foam for scalp and body psoriasis. We're incredibly excited about this upcoming approval.

We want to be able to differentiate our offering to both dermatologists and patients, and what I mean by that is we want to be able to create and present optionality and choice, meaning that we're going to provide a ZORYVE foam formulation for psoriasis and a ZORYVE cream to where the provider and the patient have the choice with what is best suited for that patient to be determined by their dermatologist.

And you have to remember relative to psoriasis, and this pertains to the ZORYVE foam, is that for psoriasis patients, approximately 50% of them have some type of scalp involvement. So we believe by offering that type of choice and optionality, we can drive significant conversions from the steroid market over to ZORYVE foam or to ZORYVE cream.

And this will accelerate the entire market as far as the uptake of these products and the conversion from steroids over to the two differentiated offerings that we'll have for providers and patients in psoriasis.

Todd Watanabe^ If I could maybe just add just a little bit more color because we continue to get this question. I think that it is wrong to think about the foam cannibalizing the cream. What I think might happen is is that there will be a shift in the growth pattern in psoriasis from cream to foam.

But I think it's very unlikely that the patient that's on the cream is actually going to switch then to the foam. So cannibalization is probably not the right way to think about this.

And ultimately, what matters to us and what matters to shareholders is the growth of total ZORYVE 0.3% in the psoriasis market. And we're quite confident that the addition of the foam and the addition of the scalp and body indication is going to accelerate the growth of ZORYVE 0.3% cream and foam in psoriasis and put us in a very, very strong position.

Operator^ Our next question coming from the line of Kambiz Yazdi with Jefferies.

Kambiz Yazdi^ Just a couple for me. What proportion of 4Q sales are attributable to the Kowa PCP partnership? And the second question I have is, do you expect 1Q OpEx to remain roughly in line with 4Q excluding commissions to Kowa? Will commissions to Kowa be included in the SG&A line of 1Q OpEx?

Todd Watanabe^ Sure. I think probably David, you can address both of those. If you could address what from Kowa was in Q4, and then also our thoughts around Q1 OpEx with and without the Kowa commission.

David Topper^ Sure. As we've been saying for several months now the Kowa sales force and their efforts really got started in September. And so at no time did we really expect a meaningful contribution from them in 2024. And in fact, while it was not certainly a non-zero number, it was not a significant amount.

We do expect a meaningful contribution in 2025. The commission that we pay Kowa is will be in the SG&A line. So you will see an increase there. And what we've committed to is that when that contribution becomes meaningful, that we will give information -- as we report quarterly results, we will give information on volumes and commissions and so forth so that people understand the magnitude of that contribution.

Operator^ And our next question coming from the line of Douglas Tsao with HC Wainwright.

Douglas Tsao^ Congrats on the progress in the quarter. Just one question for me. You spoke about sort of the feedback you're getting in terms of clinicians wanting to move away from steroids.

Obviously I presume payers will continue to sort of want that as a first line option. So I'm just curious from a reimbursement standpoint, how you potentially see that playing out? Do you think that physicians will just try steroids more briefly? Or do you think outright that ZORYVE can become first line therapy?

Todd Watanabe^ Sure. Yes. I think that's an important point probably to clarify. I think -- and Todd can comment on this too, but I think it's likely that we will continue to see a single step edit through a generic steroid to get to ZORYVE. The numbers that we were talking about on the call represent people who are already on a steroid and therefore have already met the step requirement, right?

So this issue of stepping through a topical steroid really is only relevant for the very small percentage of patients who are newly diagnosed, or who have not been on any treatment for quite

some period of time. Typically, the insurance companies will look at any treatment in the last six to 12 months, depending on the insurance company.

So what I think investors really need to focus on are the 16 million prescriptions out there already for topical steroids. Right? Those are all patients who have met the requirement for the step and the step is irrelevant. And that's where we think the growth opportunity is going to come. And Patrick, maybe you can talk a little bit more, as well about the paradigm of steroids in an acute treatment for a chronic disease and how ZORYVE fits into that picture.

Patrick Burnett^ Yes. I think that's one of the parts of the conversation that I think is going on right now is about what is the role that steroids have in the management of these diseases? And a lot of the conversation is about the chronic treatment of these chronic diseases. And the fact that in the absence of having nonsteroidals, steroids were trying to fill that gap even though they're not really well suited for chronic management of the diseases.

So I think this idea of having a steroid step through isn't really such a hurdle for patients for the reasons that Frank just said, which is that oftentimes when patients come in, they may get a steroid before it's realized that they're really going to have a need for a long-term management of the condition.

And that's the appropriate time anyway from a medical management perspective to shift them over to a nonsteroidal product like ZORYVE that will be able to kind of carry them the distance from there. So I don't really see that the utilization management criteria are too out of sync with clinical practice and how it's evolving right now.

Operator^ And I see there are no further questions in the queue at this time. I will turn the call back over to Mr. Frank Watanabe for any closing remarks.

Todd Watanabe^ Okay. Well I think we've covered everything. I just want to thank everyone again for making the time to call in for the earnings call. And we look forward to talking to you all again in the not-too-distant future when we have Q1 results. Thanks a lot.

Operator^ This concludes today's conference call. Thank you for your participation, and you may now disconnect.