

Arcutis Biotherapeutics, Inc. (Q2 2025 Earnings)
August 6, 2025

Corporate Speakers

- Brian Schoelkopf; Arcutis Biotherapeutics; Investor Relations
- Frank Watanabe; Arcutis Biotherapeutics; President and Chief Executive Officer
- Todd Edwards; Arcutis Biotherapeutics; Chief Commercial Officer
- Patrick Burnett; Arcutis Biotherapeutics; Chief Medical Officer
- Latha Vairavan; Arcutis Biotherapeutics; Chief Financial Officer

Participants

- Seamus Fernandez; Guggenheim Securities; Analyst
- Unidentified Participant; TD Cowen; Analyst
- Uy Ear; Mizuho; Analyst
- Lin Tsai; Jefferies; Analyst
- Judah Frommer; Morgan Stanley; Analyst
- Serge Belanger; Needham; Analyst
- Douglas Tsao; HC Wainwright; Managing Director
- Richard Law; Goldman Sachs; Analyst

PRESENTATION

Operator^ Good day. And thank you for standing by. Welcome to the Arcutis Biotherapeutics 2025 Second Quarter Financial Results Conference Call. (Operator Instructions)

Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your first speaker, Brian Schoelkopf, Head of Investor Relations.

Please go ahead.

Brian Schoelkopf^ Thank you, [Michelle]. Good afternoon, everyone. And thank you for joining us today to review our second 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^ Thanks, Brian. And thank you to everyone for joining us today.

I'm pleased to report that in the second quarter, we continued to see strong sales and demand growth with our ZORYVE franchise, demonstrating continued adoption by health care providers and patients and consistent execution by our commercial team.

During today's call we will review in detail the results for the quarter, but we'll also spend time talking in more depth about our plans to sustain our growth into the future including the next wave of growth for ZORYVE, how we intend to leverage our best-in-class development and commercialization capabilities to address the unmet urgent needs of patients living with immune-mediated dermatologic diseases and our capital allocation framework to enable this next growth phase.

Before I dive in, I want to thank the exceptional team at Arcutis that is dedicated to and instrumental in advancing our efforts to serve the needs of people living with serious skin diseases.

So on Slide 5, honing in on the second quarter, we saw another quarter of strong revenue growth as patients and clinicians continue to adopt ZORYVE for the treatment of a range of inflammatory dermatosis.

For the quarter, we reported net product revenues of \$81.5 million, representing 28% quarter-on-quarter growth and 164% growth compared to the same quarter 2024. This substantial sequential growth reflects the continuously increasing demand for ZORYVE with TRx volume increasing for all products.

In May, we received approval from the FDA for the use of ZORYVE foam 0.3% for the treatment of plaque psoriasis of the scalp and body, our fifth FDA approval for ZORYVE in the last three years.

We believe this new indication for our foam will provide an important and much-needed new treatment option for the over half of plaque psoriasis patients who have scalp involvement.

In the quarter, we continue to make progress against a core objective that is the progressive conversion of topical steroid prescriptions to ZORYVE.

We see growing evidence that dermatology clinicians are appreciating the risks associated with extended steroid use and as such, are increasing their use of alternative nonsteroid topical agents. We also saw strengthening in our business fundamentals in the second quarter.

As we continue to grow ZORYVE sales while remaining disciplined with our expense base, we are increasing our operating leverage. Latha will go into more detail on our operating results and improving cash burn profile.

As we progress towards reaching cash flow breakeven in 2026, we are rapidly approaching a point where we will have additional resources to invest in future growth. And today, we will begin to lay out our plans including the next wave of ZORYVE expansion, additional pipeline opportunities and our disciplined capital allocation strategy that underpins it all.

Okay.

Turning now to Slide 6.

We have been intently focused on clinical, regulatory and commercial execution for ZORYVE over the last several years as evidenced by our results. And so as I introduce our framework for near, medium and long-term growth today, I will start by saying that we will continue to see substantial opportunities for sales and profit expansion from our current ZORYVE indications and those in late-stage development.

While nonsteroidal topicals are making inroads in the treatment of immune-mediated inflammatory skin diseases, there is still a tremendous amount of potential conversion to be had.

As patients and prescribers continue to understand how ZORYVE can serve as the foundational long-term therapy for psoriasis, atopic dermatitis and seborrheic dermatitis, topical steroids will increasingly be reserved for acute treatment.

To dimensionalize the size of this opportunity, last year, over 69% of all topical prescriptions in our approved indications were written for steroids. So the progressive conversion from steroids will be a sustainable growth driver for ZORYVE for many years to come.

Our expected label expansion for pediatric atopic dermatitis and development efforts for infant AD, which Patrick will further detail shortly, will be another component of this continued growth.

Other commercial opportunities such as further access improvements and the development of the PCP and pediatric channel that we previously detailed will also support our continued momentum with ZORYVE. These cumulative near-term opportunities will power ZORYVE growth throughout 2025, 2026 and beyond.

Beyond our current ZORYVE portfolio, we see a next wave of growth being driven by effective and efficient life cycle management for the ZORYVE franchise. This has been enabled by the various formulations and concentrations available for ZORYVE, which has, in essence, create a Swiss Army knife for inflammatory skin conditions. Patrick will expand on our approach to ZORYVE life cycle management, but I will highlight that a core principle is to be data-driven and disciplined, matching investment to clinical promise and opportunity size.

Longer term, our current development pipeline shows promise in addressing areas of high unmet needs for these patients.

We will also continue to evaluate external sources of innovation based on our conviction that our core competencies gives us the ability to leverage the research and early development efforts of other companies and to drive those innovations through later stages of development, regulatory approval and commercialization.

We are at an exciting point at Arcutis, approaching profitability that will underwrite both the next stage of expansion for the ZORYVE franchise and subsequent waves of innovation. And while we are eager to apply our expertise in dermatological development and commercialization, I will again underscore that we will continue to be thoughtful and disciplined in our deployment of capital.

We will continue to be stringent in our internal capital allocation by being data-driven in our pipeline management decisions.

As you will hear from Patrick shortly in that vein, we have made the difficult decision to halt the development of ARQ-255 following the readout from our Phase Ib trial.

Finally, in the context of these promising opportunities for capital deployment, I will reaffirm that we are committed to generating positive free cash flow.

We remain on track to achieve this milestone with our current business in 2026.

It is our intention that future clinical development spend to advance our existing pipeline will be funded by cash flows from our ZORYVE franchise, although we do acknowledge that a potential acquisition of some external innovation might require incremental capital.

Okay.

On Slide 7, I want to take just a minute to expand on why we believe that pursuing further label expansion for ZORYVE is a smart investment and a judicious use of our capital.

First, as one of the most successful drug franchises of all time the story of HUMIRA's incredible success is well known.

But the details of how that success was achieved, in particular, the steady indication expansion for the franchise provides a sense of the power of a well-executed life cycle management program.

HUMIRA first launched in 2022 with initial indication in rheumatoid arthritis, which produced the majority of the brand's early revenues.

But as we can see in the chart on the left-hand side of the slide, it was not only the growth of that indication that powered HUMIRA's success, but also the consistent addition of new indications

and label expansions. And by the time HUMIRA reached its peak sales in 2022, AbbVie had added 11 indications for this drug and fully 68% of sales were derived from indications beyond rheumatoid arthritis.

A more recent and developing example of effective life cycle management can be found in Sanofi and Regeneron's Dupixent. Dupixent launched in 2017 with an initial indication of adult atopic dermatitis.

Since 2018, 10 additional indications for the brand have been approved.

While atopic dermatitis remains the most significant revenue driver, accounting for about 74% of sales as of 2024, approximately \$3.7 billion in sales was generated by these subsequently added indications such as asthma and nasal polyps.

The progressive expansion of our label for ZORYVE is not a new story either.

Since launching in adult plaque psoriasis in 2022, we've expanded to cover three diseases and won four label expansions. In the second quarter, the sales contribution from these new indications and label expansion exceeded two-thirds of our total sales. And it is our strong belief that continued pursuit of new patient populations who may benefit from ZORYVE will sustain the brand's growth.

And with that, let me turn it over to Todd to provide some more color on the quarter. Todd?

Todd Edwards^ Thank you, Frank.

I'm on Slide 9.

In the second quarter, we achieved \$81.5 million in net product revenue for ZORYVE, reflecting 164% growth year-over-year and sequential growth of 28% compared to the first quarter.

Importantly, growth during this period was driven by increased demand across all strengths and indications. highlighting the robust performance of the franchise and the continued adoption of ZORYVE across its approved indications.

The meaningful revenue expansion in the quarter was a result of strong volume growth supported by stable gross to net rates for ZYVE, driven by the high percentage of prescriptions being reimbursed. An additional factor driving product revenue growth in the quarter was the recovery of inventory levels in our distribution channels back to normal levels following a drawdown in the first quarter.

Looking ahead to the remainder of 2025, we anticipate steady sales growth driven by new indication launches, increased contribution from the PCP and pediatric channel through our partnership with COA and continued share gains in a sizable topical market, primarily coming from steroid conversion. That said, ZORYVE is not exempt from the seasonality that typically affects prescription topical products.

As a result, we anticipate a moderation in our sequential growth rate in the third quarter before returning to robust growth in the fourth quarter.

I'll provide additional detail on this shortly.

As shown on Slide 10, ZORYVE prescription volume reached a record high of 16,000 weekly scripts on a rolling 4-week average basis. The nearly 200,000 total prescriptions in the quarter reflect a year-over-year volume increase of 117% and a quarter-over-quarter increase of 13%. This strong performance is enabled by the substantial breadth of adoption across prescribers with over 18,000 health care providers have written prescriptions in the second quarter and 26,000 since launch. This quarterly figure represents a 7% increase in the number of total prescriptions quarter-over-quarter and nearly 70% increase year-over-year.

We continue to see an erosion of topical steroid share within the topical market.

In Q2 2025, branded nonsteroidal volume grew by 40% versus prior year, while topical steroid volume was effectively flat. ZORYVE is playing a key role in driving the shift as prescribers continue to appreciate its potential for sustained treatment of chronic inflammatory skin conditions compared to the intermittent use of that is appropriate with topical steroids.

We are in the early stages of launching ZORYVE foam 0.3% for patients with scalp and body psoriasis following FDA approval in May.

We expect this launch, along with the anticipated approval of ZORYVE cream 0.05% for patients aged two to five years old in October to drive further volume growth in the second half of this year.

While we continue to expect strong overall growth for ZORYVE in 2025 including in the third quarter, the pace of growth in Q3 will reflect the typical seasonality of the topical market. This is influenced by nonmedical factors such as summer vacations and medical factors including reduced flaring of inflammatory skin conditions during the summer months.

As a result, we anticipate some moderation of growth in Q3 before returning to a more robust trajectory in Q4.

Let's now turn to our recent approval for ZORYVE on Slide 11.

In May, we received FDA approval for ZORYVE foam 0.3% for the treatment of plaque psoriasis for scalp and body.

As Frank mentioned, more than half of plaque psoriasis patients have scalp involvement. Historically, these patients have managed their condition with a combination of topical steroids and other treatments, depending on plaque location, resulting in a frustrating polypharmacy approach. The ability to use a single product once daily across all affected areas offers a meaningful reduction in treatment burden.

ZORYVE foam 0.3% delivers reliable plaque clearance and rapid itch relief in a formulation specifically designed for hair-bearing areas and appropriate for use near the eyes and other sensitive areas.

We are confident this label expansion will drive incremental demand for ZORYVE, particularly as the foam displaces other treatment options for scalp psoriasis.

Since the foam formulation for Seb derm and psoriasis are on the same SKU across both indications, it will take additional time to accumulate sufficient longitudinal data to accurately parse out contributions by disease.

However, we have seen an acceleration in foam growth with a 9% increase in volume in the six weeks since launch compared to the prior six weeks.

As previously noted, our analysis indicates that clinicians who prescribe ZORYVE across multiple indications tend to generate significantly higher prescription volumes overall as they recognize the meaningful disease management benefits ZORYVE delivers for patients.

With the introduction of ZORYVE foam for this new indication, we expect this effect to compound further.

Moving to Slide 12. A long-standing objective at Arcutis has been to drive reimbursed prescriptions, not just any prescriptions as they directly impact top line revenue.

We continue to benefit from strong insurance coverage for ZORYVE across approved indications with approximately 80% of all prescriptions being reimbursed. This favorable coverage landscape supported the revenue growth achieved during the quarter with gross to net rates remaining stable.

We also made meaningful progress with Medicaid with well over half of all Medicaid recipients now having access to ZORYVE and the majority of covered lives only require a single step through a steroid. This advancement contributed to strong quarter-over-quarter unit growth from the Medicaid channel.

We remain actively engaged in negotiations with Medicare Part D plans and are committed to expand access for these patients even as payers continue to navigate financial disruptions due to the implementation of the Inflation Reduction Act. The IRA introduced changes to the Part D benefit structure including a shift in cost sharing responsibilities between CMS, Part D plans and manufacturers.

These changes are creating both operational and financial complexities for Part D plans as they work to update their systems, adjust risk models and align on formulary strategies. This environment has led to a more protracted process to cover decisions for all new pharmaceuticals.

Moving to Slide 13. The expanded utilization of ZORYVE in the primary care and pediatric setting remains a key component of our growth strategy, and we continue to make progress through our partnership with Kowa. From the outset, we recognize that the primary care selling cycle requires more frequent and sustained engagement to build familiarity. Many providers in this setting have limited exposure to topical nonsteroid treatments and tend to default to prescribing steroids. Kowa's field team continues to execute targeted high-frequency outreach to drive initial trial and ultimately, adoption of ZORYVE among these providers and their patients.

This process will further be supported by recent enhancements made to streamline the prescribing and fulfillment experience of these providers.

In the second quarter, we implemented a dedicated national pharmacy with improved capabilities for this channel. This pharmacy will play a pivotal role in appropriately helping offices navigate the fulfillment process that is often less familiar to primary care providers compared to dermatologists who are more accustomed to prescribing branded topicals.

The key advantage of this new dedicated pharmacy is its ability to integrate directly with EHR systems, enabling seamless incorporation of ZORYVE prescribing into existing workflows. Given the diversity and volume of patients in primary care setting, tools that reduce administrative burden and streamline access are instrumental in driving broader adoption.

I'm now on Slide 14. The future of ZORYVE is incredibly bright.

With multiple formulations and concentrations, we are equipping health care providers with the flexibility to meet patients where they are in their treatment journey by providing a treatment option suitable for long-term use and the ability to better support the management of chronic inflammatory skin conditions.

This versatility, combined with ZORYVE's well-established efficacy and safety profile continues to reinforce its position as the most prescribed brand topical across three major inflammatory skin conditions.

With that, I'll now turn the call over to Patrick for an update on R&D.

Patrick Burnett^ Thanks, Todd.

I'm on Slide 16.

In the quarter, as you come to expect from us, we made significant progress against our clinical and regulatory objectives as we received FDA approval for ZORYVE foam 0.3% for scalp and body plaque psoriasis, initiated our Phase II trial for ZORYVE cream 0.05% in infants with atopic dermatitis and submitted our IND application for ARQ-234 in atopic dermatitis.

Today I'll spend time describing our efforts in developing ZORYVE for pediatric AD patients, outlining our approach to ZORYVE life cycle management and give an update on ARQ-255.

First, I want to acknowledge the important milestone that our IND submission for ARQ-234 represents.

We continue to believe that CD200 receptor modulation has the potential to be a powerful mechanism for the control of atopic dermatitis and other inflammatory conditions.

We further believe that as a fusion protein with high selectivity for CD200, ARQ-234 has the potential to be a class-leading program. We look forward to sharing more detail on this program at a later date.

Turning now to Slide 17.

Unlike other inflammatory skin conditions, atopic dermatitis often presents at early ages for patients. Nearly 10 million children in the U.S. are impacted by atopic dermatitis with roughly 60% developing symptoms in their first year of life. AD presents unique challenges in these younger age groups, not only because the skin is more sensitive, but also because the condition often covers a greater percentage of their total body surface area compared to adolescents and adults.

Parents of these pediatric patients are highly sensitive to potential negative side effects of topical steroids. These concerns range from the impact of chronic steroid use on the child's growth and bone development to more immediate complications like application to the child's face or contact with the eyes and mouth can be difficult to control.

Given the size of the patient population and the need for safer and more tolerable therapeutic intervention, we've been enthusiastically pursuing label expansion for ZORYVE to younger ages of atopic dermatitis patients where we see a great fit for the ZORYVE clinical profile.

In February, we submitted our sNDA for ZORYVE cream 0.05% for the treatment of children aged two to five years old with atopic dermatitis, population of roughly 1.8 million patients. The submission was supported by data from the INTEGUMENT-PED Phase III trial, which demonstrated efficacy and a safe and tolerable profile in this age group, highlighted by 39% of children treated with ZORYVE achieving a 75% improvement in EASI score, also called an EASI-75, and this was done in just four weeks.

In June, we presented new results from the INTEGUMENT-OLE long-term open-label study that demonstrated children ages two to five who achieved disease clearance and switched to a proactive twice-weekly application of ZORYVE cream 0.5% were on average, able to maintain disease control for 238 days or nearly eight months without the need to return to daily dosing. And we believe that the potential to control AD without disease flares with less frequent dosing may be a particularly compelling benefit for patients in this age range and their caregivers and speaks to the differentiated profile of ZORYVE as a foundational treatment for chronic inflammatory skin conditions.

We look forward to our target PDUFA date for this application in October of this year.

We're also actively pursuing development of ZORYVE cream 0.05% in patients ages three to 24 months and enrolled the first patient in the INTEGUMENT infant trial for this population in June.

We're seeing brisk enrollment in the trial, which confirms our belief that amongst these young, vulnerable atopic dermatitis patients, there is an acute desire for alternative treatments to current therapies, most of which are topical corticosteroids. Pursuing these potential expansions into younger AD patient populations delivers on a core principle for Arcutis to deliver innovation that solves everyday challenges that significantly impact the lives of patients and their families.

Now moving on to Slide 18.

As Frank remarked at the beginning of this call pursuing new patient populations that may benefit from ZORYVE has been a core tenet of our clinical development strategy. This is evidenced by the four label expansions we have secured across plaque psoriasis, seborrheic dermatitis and atopic dermatitis following our initial approval in 2022.

We believe that there are additional skin diseases that may respond to and more patients who may benefit from ZORYVE. This belief is not only supported by our understanding of ZORYVE's broadly applicable anti-inflammatory and antipruritic properties, but also by our feedback we've received from health care providers in the field.

As part of our obligation to sponsor, our medical team monitors this feedback.

To date, we've identified more than 40 case reports from clinicians who have used ZORYVE in a multitude of other inflammatory dermatosis and see signs of efficacy. These clinicians have experienced the safe, tolerable, versatile and effective profile of ZORYVE in their psoriasis, AD and seb derm patients and have chosen to investigate novel applications of the therapy. These case reports are listed on the left side of the slide and include many diseases, which are not well managed by topical steroids and therefore, present a challenge for dermatology providers.

Our approach to assessing these potential opportunities is stepwise and resource efficient.

As indications of interest come to light, we'll engage in a collaborative research, conducting Phase II proof-of-concept studies where appropriate to evaluate the degree of response and understand potential safety and efficacy. Based on the results of these initial studies, our analysis of the addressable patient population for a given disease and feedback received by regulatory agencies, we may then identify additional indications for which a registrational trial conducted by Arcutis is a prudent investment.

We're already pursuing this strategy with efforts underway to begin enrolling Phase II studies in vitiligo and hidradenitis suppurativa, and we anticipate initiating additional Phase II proof-of-concept studies going forward. This evaluation of new indications and program planning will be comprehensive and evolve over time and each project will be carefully assessed relative to potential return on investment.

Our progress in this process is another topic that we plan to detail further at a future date.

Now moving on to Slide 19.

As Frank mentioned in his remarks and as you've heard throughout this call Arcutis is fortunate to have multiple opportunities for clinical investment to pave the way for our future growth.

As we evaluate our current and future portfolio of clinical programs, we will continue to be data-driven and apply a high bar for advancement.

In line with this rigorous portfolio management approach, we've announced today our decision to halt further development of ARQ-255 following our review of the results from our Phase Ib trial.

We've always known that the ARQ-255 program was a high-risk endeavor.

Multiple other topical JAK inhibitors had previously failed in alopecia areata, but preclinical studies suggested that our novel 4D technology might be able to overcome the challenges of treating alopecia areata topically. The study demonstrated a trend for positive efficacy in both the clinical endpoint of salt change from baseline and salt improvement to 50% or greater, suggesting that, in fact, 4D is able to deliver drug to the site of inflammation.

But unfortunately, the magnitude of improvement was not sufficiently large to justify a continuation of the program. Here, we show the efficacy data alongside that from other independent clinical trials conducted with oral JAK inhibitors in alopecia areata.

Although we were pleased to see the favorable trend that validates our topical formulation approach after extensive consideration of the potential profile relative to alternatives, we decided that this level of efficacy we observed with ARQ-255 would not be a meaningful addition to the treatment options for patients with alopecia areata.

We look forward to finding other opportunities outside of ARQ-255 to expand our pipeline and provide meaningful innovation in dermatology.

I want to thank the investigators, our advisers and the patients who participated in this program as well as the excellent Arcutis team that conducted a very well-run study. And with that, I'll turn it over to Latha.

Latha Vairavan^ Thank you, Patrick.

I want to start by reiterating the strength of this quarter.

Our improved operating leverage allowed the strong top line growth to translate to a reduction in cash burn and reemphasizes that our disciplined approach to capital allocation has us on a path to cash flow breakeven in 2026.

I'm on Slide 21, showing financial results both year-over-year and quarter-over-quarter for the second quarter of 2025.

As Todd has stated earlier, we generated net product revenues in the quarter of approximately \$81.5 million, which is up 164% from Q2 of 2024 and 28% from Q1 of this year. Cost of sales in the second quarter were \$7.5 million compared to \$3.5 million in 2024, primarily driven by increased ZORYVE sales volume.

Cost of sales decreased 15% sequentially versus the first quarter of 2025 despite increasing sales volume due to an expense recognized in the first quarter for the catch-up amortization of a \$10 million sales milestone owed to AstraZeneca for reaching \$250 million in cumulative net sales.

For the second quarter of 2025, our R&D expenses were \$19.5 million versus \$19.3 million for the corresponding period in 2024.

Our R&D spend has remained consistent year-on-year as decreased development costs for roflumilast in adult atopic dermatitis and plaque psoriasis were partially offset by an increase in development costs for pediatric atopic dermatitis.

SG&A expenses were \$69.2 million for the second quarter of '25 versus \$58.2 million in the same period last year. up 19% as we invested in our commercial organization to support our current and upcoming launches. Recall we expanded our sales force in the second half of 2024.

SG&A expenses were also up approximately 9% as compared to the first quarter of '25, primarily due to increased sales and marketing costs related to our launch in scalp and body psoriasis.

Net loss for the quarter decreased by \$36.4 million compared to the same period last year and \$9.2 million versus the first quarter of 2025.

While this rate of improvement in operating results will fluctuate across quarters in line with sales, it clearly demonstrates that we are making substantial progress towards reaching cash flow breakeven in 2026 and that the foundation of our business is strong and getting stronger.

Now I'm on Slide 22. You can see that we had cash and marketable securities of \$191.1 million on our balance sheet as of June 30, 2025, and we were slightly cash flow positive from operating activities this quarter. This positive net cash flow from operating activities of \$325,000 was due in part to our increased gross profit driven by our top line revenue growth, a highly encouraging signal of our progress towards cash flow positivity, but also in part due to timing changes in net working capital that reduced cash used in operations. This is a good example of the type of factors that lead to the quarter-to-quarter fluctuations I mentioned earlier and that we expect to see on occasion in the future.

We expect our quarterly cash burn to continue trending down as our revenues grow and we approach stable positive cash flow from operations sometime in 2026.

We have total debt of \$108 million and have the option to withdraw another \$100 million in whole or in part at our discretion through the middle of 2026, providing us with significantly enhanced flexibility. The success of 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'm going to hand it back to Frank for some closing remarks.

Frank Watanabe^ Thanks, Latha.

As you've heard throughout today's call we built a strong and sustainable foundation for our business and our prospects for continued near, medium and long-term growth at Arcutis are strong.

As we continue to execute our multifaceted plans to sustain this growth, we look forward to sharing updates on our progress. And to that end, we will be holding an R&D Day in the fourth quarter of this year to go into greater detail on several key aspects of our clinical development plans and corporate strategy.

And with that, we'll open up the call to Q&A.

QUESTIONS AND ANSWERS

Operator^ Our first question is going to come from the line of Seamus Fernandez with Guggenheim Securities.

Seamus Fernandez^ Congrats on the great quarter and reaching at least for this quarter, cash flow positivity.

A couple of questions here. Maybe just to start off, as we think about the sort of progression of revenue from second quarter to third quarter, it sounds like we should think about this as a little bit of a perhaps even a slightly down quarter? Or should we think about it more as a sort of flat progression or moderating growth as we think about third quarter?

And then, Frank, I think it's very obvious the opportunity to continue to really pursue the switch from topical steroids more broadly, especially considering the range of areas where topical steroids are utilized. But I wanted to just get a better sense of how far reaching you feel the opportunity is to move beyond the four initial indications here.

Obviously there's a number of indications that were listed on the slide on the R&D side. But you also mentioned potential business development pursuits moving forward beyond the existing pipeline. What do you feel would be kind of a good right fit for the company as you look beyond this? Is it to be able to scale the business with on-market assets? Or is it more to really release your R&D organization given the sort of clinical excellence that's been demonstrated so far?

Frank Watanabe^ Yes. So Seamus, maybe I'll answer your second question first, and then I'll ask Todd to address the question around revenue.

I think that -- from a clinical standpoint, it's pretty clear that ZORYVE has very broad applicability across a whole range of diseases, I think potentially even some non-inflammatory conditions. But they're not probably all worth us pursuing an indication for. I think we will look to generate data to inform the dermatology community where it's appropriate.

And then we'll look at those opportunities and determine is the market big enough? Is the magnitude of clinical improvement versus existing therapies big enough that it justifies pursuing an indication. And so we'll be very rigorous and selective in choosing those diseases where we think it's worth spending the money to do a full registrational program.

But I'm pretty confident that there are going to be other diseases that it makes sense for us to pursue an indication. particularly given how stringent insurance companies have become about the off-label reimbursement of drugs.

It's very different than it was 10 years ago even. So I think there's a lot of upside opportunity for us. There are a lot of steroid prescriptions for diseases other than our currently approved indications. And so we'll just need to be very rigorous and methodical in choosing which ones we just generate data on which ones we pursue an indication for.

Turning to the business development side, I would say that our primary focus is really on development stage assets Patrick and his team and Bethany and her team on the tech up side have, I think, proven that they are really outstanding, I would even say, best-in-class in dermatology and their ability to complete clinical development, regulatory approval. And then Todd and his team have shown how they can effectively operate commercially as well.

So we think that's probably the best area for us to focus on the -- in terms of creating value for shareholders. We are not a spec pharma company. I'm not interested in going around and just buying revenue and adding that to the pipeline. I don't think that's a good way for us to create shareholder value.

But leveraging the development expertise of this company, I think, is a great opportunity. And we continue to focus primarily on drugs where there is biological validation of the target.

So we're not taking on too much biologic risk. where there's a large unmet need and where we find an asset that is really differentiated from other assets, we're not going to be pursuing a bunch of me-too assets.

So hopefully, that addresses your question. And well again, we'll talk about this a lot more at the R&D Day. And then I'll turn it over to Todd to talk about Q3 and the rest of the year.

Todd Edwards^ Yes. Great. Thank you, Frank. And Seamus, we still anticipate sequential growth in the third quarter as we expect continued growth across all indications. The rate of

growth in the third quarter will be slightly moderated due to the seasonality that we spoke about. But nonetheless, we remain very optimistic about the growth.

I'll just frame it that we continue to want to see sustained momentum within this franchise and will in Q3 and beyond.

Operator^ Our next question is going to come from the line of Tyler Van Buren with TD Cowen.

Unidentified Participant^ This is [Yena] on for Tyler. I had a question about the Kowa partnership. And you guys also mentioned that you set up a national dedicated pharmacy. I was wondering what the early utilization of that looked like. And again, could you elaborate on the contribution of the Kowa partnership to date?

Todd Edwards^ Yes. This is Todd. Yes. Thank you for the question.

And as discussed before, we anticipated a slower adoption of ZORYVE in the primary care market versus the dermatology market due to the longer selling cycle that's required, also with primary care physicians not being as familiar with nonsteroidal topicals. And we are seeing that slower adoption of ZORYVE within the primary care market.

However, Kowa is taking the right actions to make certain that we have the right frequency on the right targets with the right messaging and also making certain that they continue to educate primary care physicians and other opportunities like peer-to-peer programs, speaker programs and such. Relative to the national pharmacy, we're seeing very positive signals with the early launch of that national pharmacy.

And as mentioned, it's critical that we provide a dedicated pharmacy that will appropriately enable and support the primary care physicians relative to the fulfillment process with ZORYVE. And once again, we're seeing positive signals with that and are encouraged by Kowa is continuing to adapt and execute on the right targets with the right frequency and what we expect from this national pharmacy.

Operator^ Our next question will come from the line of Uy with Mizuho.

Uy Ear^ Congrats on the quarter. So maybe just first question is, could you maybe just help us understand the gross to net dynamics in the quarter was better than what we expected, particularly for each of the individual products, if possible or just the foam?

Latha Vairavan^ Do you have additional questions? Do you want to finish them off?

Uy Ear^ No. No. That's fine. I'll follow up.

Latha Vairavan^ Okay. So in regards to gross to net, as Todd commented, we -- gross to net has been stable for the quarter and in the 50s. And beyond that, we haven't quite ever commented on the products. So I'm going to leave it at the 50s.

Frank Watanabe^ Gross to net is not changing very much anymore, and I wouldn't expect that it would.

Uy Ear^ Okay. And I guess in the press release, you guys commented on three patents that was allowed, I guess, in the quarter. Could you sort of elaborate on that?

Frank Watanabe^ We had -- yes, we had three additional patents that were issued in the quarter from the U.S. Patent Office. None of those extended the LOE for the product.

But I think they are further expand the strength of our IP portfolio. We now have 24 issued U.S. patents and many of those listed in the Orange Book. And I just think that it speaks to the further -- the continued strength of our intellectual property portfolio around ZORYVE.

Uy Ear^ Okay. And sorry, last question. You mentioned two studies, two Phase II studies that are ongoing. And I guess one of them is the atopic study in pediatric three months to two years old. What's the other one?

Patrick Burnett^ So we talked about initiation of a 3- to 24-month study in atopic dermatitis with ZORYVE, that's the 0.05%. That is a sponsored clinical trial that's part of a post-marketing commitment that we have in order to continue to step the age down that we are conducting as a sponsored registrational clinical trial.

The other two Phase II studies that we're talking about are collaborative research trials, which are being done to get an early understanding of the potential efficacy in two of these indications, which are not currently approved indications, but where we have seen some evidence of efficacy coming from case reports. And so that will give us a kind of quick and early understanding of what the efficacy might and safety might be in that disease state to help us to then make decisions on whether or not to pursue a registrational program for one of these indications.

Frank Watanabe^ And just to clarify, those Phase II studies are in HS and vitiligo, I believe both of them are posted on [clintrials.gov](https://www.clinicaltrials.gov) now.

Operator^ Our next question is going to come from the line of Andrew Tsai with Jefferies.

Lin Tsai^ Congrats on the execution. Maybe a bigger question.

Can you give us your latest and greatest thinking on how you're thinking about the peak sales opportunity across your three current indications and how that's changed compared to your original thinking?

Frank Watanabe^ So Andrew, we have not given peak sales guidance for quite some time. I think it was 2022 last time.

At that point, we had said that we thought that each one of the indications, i.e., psoriasis, AD and seb derm could be in the range of \$700 million to \$1.2 billion per indication.

I think we have not dramatically changed that view of the opportunity. If you just sit down and do some quick back of the envelope calculations, we're sitting at something like 2.5% market share in the total topical market.

If that grows to 10%, you're well north of \$1 billion. And I think that 10% of the topical market is very achievable and probably is a low bar given the clinical profile that we see and particularly if we expand beyond the three initial indications, as Patrick just mentioned.

What I will say is that we continue to evaluate this. And I think you can expect some further guidance from us in the future about what we think the peak sales potential is.

But clearly, we are really just scratching the surface in the total commercial opportunity for ZORYVE.

Lin Tsai^ Agreed. And then a follow-up to the last question on vitiligo and HS. Is it possible that we get initial data from the IST studies in 2026? Or is it sometime later? Just wanted to gauge your news flow.

Frank Watanabe^ Yes. I mean right now we're not putting out any expected timeline for those trials.

As we get engaged into our collaborative research that we're pursuing for these Phase II trials, we'll have a more clear understanding of what that might be. So we would expect to provide some guidance as we get further into them.

But at the current time, we're not able to give a milestone or expected timeline.

Operator^ Our next question will come from the line of Judah Frommer with Morgan Stanley.

Judah Frommer^ On the quarter. Just a couple for us.

I guess, first, we're hoping you can maybe elaborate a little bit on the pediatric opportunity in atopic dermatitis, kind of what penetration ramp could look like there relative to in adults given kind of potentially arguably greater unmet need or safety concerns there for those patients?

And then separately, I think this week, we saw a second joint status update on the Padagis litigation. Just curious if there was anything you could add there? Is the case just stayed and we're waiting for an update? Or was there more to that?

Frank Watanabe^ Yes. Patrick, do you want to maybe take the first of those questions?

Patrick Burnett^ Yes. We're really excited about the opportunity in 2- to 5-year-olds that's upcoming with the 0.05% when that's the approval that has a PDUFA in October. Out of the 9.6 million patients -- pediatric patients with AD, about 1.8 million of them are in this 2- to 5-year-old age range that are being topically treated. And so we were just at the Society for Pediatric

Dermatology meeting in Seattle and really got a very good understanding of just how important this age group is to them.

I think because many of these are kind of difficult to manage patients.

As I mentioned, this is a disease that comes on early in life, and there's a lot of avoidance of topical steroids from parents.

So what we're looking to be able to do is to present an option into these deeper age ranges. And 2- to 5-year-olds is the first step for us. And as we mentioned, we're getting started with the 3- to 24-month old trial as well with the same concentration. And I think it's just a very good fit between the need and the expectation of parents to be able to manage their kids without topical steroids and the profile that we've been able to show so far.

So we're really excited about the upcoming approval.

Frank Watanabe^ Yes. And Patrick and I were both just at the Society of Pediatric Derm two weeks ago. Do you want to maybe just give some color about the tenor of the conversations at SPD?

Patrick Burnett^ Yes. I mean there are conversations were about a very large patient flow in their offices for this age range because of the challenges of topical corticosteroid use. And it's common for a patient to be seen in a pediatrician's office, they might get one topical corticosteroid as their kind of start off. And then if that's not able to completely manage the disease, then they're looking to be referred oftentimes either to a pediatric dermatologist if one is available.

But dermatologists, it's very common for them, even if they are seen as adult dermatologists to be seeing patients down into the age of two and sometimes even younger than that. So not all of these patients are managed by pediatric derms.

But pediatric derms definitely represent kind of the core for education within this age group, and they influence a lot pediatrician prescribing and pediatrician openness to being able to use a new therapy.

So we think our contact points within both the pediatric dermatology community are really important. And that's what we were seeing when we were at the Society for Pediatric Dermatology, but also the adult dermatology health care providers are a really important point for managing these patients also.

Frank Watanabe^ And then just with regard to the Padagis case, recall that there is a requirement in the litigation stay that the two parties jointly provide periodic updates to the court. The first one of those updates has just recently been provided. those updates are confidential.

In fact, even I don't see them, but it was provided for in the stay. And I think the one relevant data point that all of us should be aware of was is that everyone agreed that the stay should and will remain in place.

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

Serge Belanger^ Congrats on a great quarter.

First question, regarding the 2Q performance, I think you mentioned that sales were up 28% quarter-over-quarter. I believe scripts were up 13%. So maybe just reconcile the difference. Was it just a bump up in gross to nets from Q1?

And I guess the follow-up to that is, I think you mentioned you expect gross to nets to be stable for the rest of the year. So should we expect script growth to be the main driver for sales over the remainder of 2025?

Second question, I think Todd talked a little bit about the issues regarding Medicare Part D. Can you remind us what part of the TAM Medicare Part D represents for ZORYVE? And when do you think you'll be in a position to kind of capture that opportunity and get coverage from those plants?

Frank Watanabe^ Todd, do you want to maybe address the bridge on sales?

Todd Edwards^ Yes, address the bridge on sales. The main driver of the product revenue growth over demand growth was a recovery in distribution inventory levels back to normal following a drawdown in the first quarter.

What I want to be clear about is that we did not see abnormal inventory stocking levels in the second quarter. This was simply recovery back to normal levels as a result of the drawdown in the first quarter.

In reference to gross to net, as mentioned and as Latha reinforced, we expect gross to net to be stable for the remainder of the year. So yes, that will -- the primary growth driver will be volume and demand.

We're very encouraged in what we see across the portfolio. We recently launched ZORYVE foam 0.3% for scalp and body psoriasis that will continue to be a growth driver. And then as Patrick mentioned, with the pending approval in October for ZORYVE 0.05% two to 5, we continue to be very optimistic and encouraged by future growth in our demand.

Frank Watanabe^ Yes. And then just with regard to Serge, your question around Part D, across the three diseases, keep in mind, let's say, roughly about half of those patients across our three indications are government pay, either Medicare or Medicaid. And the relative split between Medicare and Medicaid really varies by disease.

Atopic dermatitis is much more heavily Medicaid because of the age of the patients.

Seb derm is much more heavily Medicare because of the age of the patients.

And psoriasis is somewhere in between, although less psoriasis patients are government than with Seb derm or AD.

So I think in totality, again, it's about half are government.

We're rapidly penetrating into Medicaid, slightly less than half of that half is Medicare. Does that address your question around the Medicare piece?

Serge Belanger^ Yes. I guess the other part of that question was, when do you think you'll be in a position to start capturing that coverage?

Frank Watanabe^ Yes. That is hard to say because, unfortunately, it's completely outside of our control, right? As Todd mentioned, the dynamic that we're seeing is -- and you all probably have seen this if you cover the insurance companies, with the changes in the IRA that were adopted January one of this year, the insurance companies are losing a substantial amount of money on their Part D book of business and a number of them have had to issue earnings warnings even as a result of that. And that disruption then is leading them to be, I think, very conservative and to be looking at their businesses.

To the best of our knowledge, I don't think any new drugs have been added this year to the Medicare Part D formularies across all indications. So that tells you just sort of how perturbed they are. We don't know when things are going to settle out and they're going to start moving forward again.

We continue to have, I think, constructive dialogues with the Medicare Part D plans. But when your boat is sinking, the last thing you're thinking about is picking up new passengers. And I think that's a little bit how they feel right now. I expect it will stabilize.

We think Medicare is still an important opportunity for us and will contribute to our growth in the future. I just -- it's very difficult at this point for us to call the ball on what the timing would be for that.

Serge Belanger^ Okay. Maybe one last one. Obviously your sales force has executed well growing sales here in the second quarter. And it sounds like Kowa had -- still has little contribution so far.

So with the additional approvals coming up later this year, is there a case to be made to continue expanding your own sales force to continue executing well and growing the piece within the derm offices?

Frank Watanabe^ So I don't think we see or see at this point any need to expand in dermatology. We have a very well-sized dermatology sales force, and we have good coverage, good frequency on our dermatology targets.

What we will have to continue to evaluate is opportunities outside of dermatology and think about how we address those opportunities.

We felt that the Know partnership was a smart way, an economical way for us to access the primary care and pediatric opportunities. But at this point in the game, we don't have any plans for any further sales force expansions on the Arcutis sales force.

Operator^ Our next question is going to come from the line of Douglas Tsao with HC Wainwright.

Douglas Tsao^ Congrats on the progress.

I'm just curious, when we look at -- I think it's Slide 11, and you obviously -- as writers or as doctors write more for more indications, you sort of get a real economy of scale or sort of logarithmic effect in terms of the scripts that they're writing. How long does it typically take for docs to write for multiple scripts? Are they sort of coming at it sort of incrementally? And are there things that you can do or have started to do to sort of increase the indications that an individual doc is writing for?

Frank Watanabe^ Yes. Thank you for the question. Arcutis is in a very good position with ZORYVE. And what I mean by that is that with the recent launches that we've had with indications, the dermatology prescribers have already had experience with ZORYVE, whether it be with the cream 0.3% for psoriasis or the own formulation for seborrheic dermatitis. This drives rapid uptake relative to the other indications or formulations that we've launched.

And we do see that within the data that a good portion of our prescribing base has adopted the full formulary. This creates efficiencies with their prescribing, both with the patient, but also on the fulfillment side, given that's the same co-pay card, same pharmacy, same process.

So that it's a differentiation, excuse me, ZORYVE as an asset, meaning that across the different formulations and products, you can write the product relative to any duration time anywhere on the body.

We have a proven efficacy, proven safety. So this type of differentiation really compels the providers to continue to adopt the new formulations and indications we put into the market.

Douglas Tsao^ And I'm just curious, if I can, a follow-up just to the extent that some doctors might only still be writing for one indication, is it your sense that perhaps they don't have awareness of the breadth of the label? Or is it perhaps unique to their practice where they just might see sort of have a concentration into one of the indications?

Frank Watanabe^ Yes. Within our dermatology target universe, the dermatologists that have only adopted one indication is truly the exception. And usually, that's something that's unique to their practice or to their patient population.

We continue to engage with dermatologists, educate them on the ZORYVE differentiation and opportunity and expect that over time they will have adoption of the portfolio.

Operator^ Our next question comes from the line of Richard Law with Goldman Sachs.

Richard Law^ Congrats on the progress. A couple of questions from us.

So following up on the Medicare discussion, what drug classification would ZORYVE fall into in your Medicare coverage discussions or negotiations? Is it classified along with topical steroid? Or can you get your own separate classes of topical PDE for? And also, what is the progress in Medicaid over the last quarter?

Todd Edwards^ Relative to with regard to Medicare relative to the class, the market basket, if you will, we would be within the dermatology topical basket as how Medicare would position ZORYVE.

In reference to Medicaid, we've had exceptional success in expanding our Medicaid access. If you think about it, and as mentioned, more than half of Medicaid patients now have access to ZORYVE. And most often, that's only a single step through a steroid. And we continue to be steadfast in expanding that access, ensuring that Medicaid recipients continue to have an expanded access to ZORYVE.

Richard Law^ Okay. Just kind of follow-up on that.

So basically, is there a way to get a separate classes like a topical PDE4 or just the broad basket that you mentioned?

Todd Edwards^ Yes. It would be difficult to get just a PD4 class. They want to keep the topical products in the same market basket. And actually, that's advantageous for us given ZORYVE's differentiation, not only from an asset, but how we strategically price the product within the market.

So you take that strategic pricing within the market and you also take into consideration the average utilization of tubes per patient per year is two to three. We're a great value proposition to the Part D plans as well as the beneficiaries.

Richard Law^ I see. Great. And then just one more question. Any new thinking around the ex U.S. opportunity, especially in Europe based on how Opzelura is performing?

Frank Watanabe^ I would say at this point, no change. I think that Opzelura is really a distinct situation, especially because of the label they have in Europe and the lack of comparators for that indication in Europe.

I think for ZORYVE and some of the other advanced topical therapies, the reimbursement landscape in Europe is particularly challenging. And you lay on top of that some of the potential

domestic risks around MSN pricing, and we feel that the business case right now in Europe isn't compelling enough for us to pursue that.

Operator^ Thank you. And I would now like to hand the conference back over to Frank Watanabe for closing remarks.

Frank Watanabe^ Okay. Well as always, we appreciate all the great questions and appreciate you guys making the time to join us on the call today.

I know it's a very, very busy time of the year. So we look forward to talking to you all again in another quarter and hopefully putting up another great number next quarter. Thanks again.

Operator^ This concludes today's conference call. Thank you for participating.

You may now disconnect. Everyone, have a great day.