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Glaukos Corp. (GKOS)

Q1 2026 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Welcome to Glaukos Corporation's First Quarter 2026 Financial Results Conference Call. Copies of the company's press release and quarterly summary document, both issued after the market closed today, are available at www.glaukos.com. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] This call is being recorded and an archive replay will be available online in the Investor Relations section at www.glaukos.com.

I will now turn the call over to Chris Lewis, Vice President of Investor Relations and Corporate Affairs.

Chris Lewis

Vice President-Investor Relations & Corporate Affairs, Glaukos Corp.

Thank you, and good afternoon. Joining me today are Glaukos' Chairman and CEO, Tom Burns; President and COO, Joe Gilliam; and CFO, Alex Thurman. Similar to prior quarters, the company has posted a document on its Investor Relations website under the Financials and Filings Quarterly Results section titled Quarterly Summary. This document is designed to be read by investors before the regularly scheduled quarterly conference call. To ensure ample time and opportunities to address everyone's questions, we request that you limit yourself to one question and one follow-up. If you still have additional questions, you may get back into the queue.

Please note that all statements, other than statements of historical fact made on this call that address activities, events or developments we expect, believe or anticipate will or may occur in the future are forward-looking statements. These include statements about our plans, objectives, strategies and prospects regarding, among other things, our sales, products, pipeline technologies and clinical trials, US and international commercialization, market development efforts, product approvals, the efficacy of our current and future products, competitive market position, regulatory strategies, and reimbursement for our products, financial condition and results of operations, as well as the expected impact of general macroeconomic conditions bring more encouraging fluctuations on our business and operations.

These statements are based on current expectations about future events affecting us and are subject to risks, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Therefore, they may cause our actual results to differ materially from those expressed or implied by forward-looking statements. Please review today's press release and our recent SEC filings for more information about these risk factors. You'll find these documents in the Investor Relations section of our website at www.glaukos.com.

Finally, please note that during today's call, we will also discuss certain non-GAAP financial measures, including results on an adjusted basis. We believe these financial measures can facilitate a more complete analysis and greater transparency in the Glaukos' ongoing results of operations, particularly when comparing underlying results for period to period. Please refer to the tables in our earnings press release available in the Investor Relations section of our website for reconciliation of these measures to their most directly comparable GAAP financial measure.

With that, I will turn the call over to Glaukos' Chairman and CEO, Tom Burns.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

Okay. Thank you, Chris. Good afternoon, and thank you all for joining us. Today, Glaukos reported record first quarter consolidated net sales of \$150.6 million, up 41% on a reported basis and 39% on a constant currency basis versus the year ago quarter. As a result of our first quarter outperformance, we are raising our full year 2026 net sales guidance to \$620 million to \$635 million, compared to \$600 million to \$620 million previously.

Our first quarter results reflect strong execution across our global commercial and development priorities, highlighting the commitment of our teams, strength of our differentiated technology platforms, and our continued progression as an increasingly diversified leader in ophthalmology. Looking ahead, we believe we are well-positioned to sustain this momentum driven by two transformational growth drivers, including the continued advancement of the Interventional Glaucoma treatment paradigm with iDose TR and the launch of Epioxa, establishing a new standard in interventional keratoconus and rare diseases. Together, these compelling and durable market opportunities reinforce our confidence in delivering our best-in-class growth profile well into the next decade as we continue to invest in and advance our robust industry leading pipeline while remaining disciplined in capital allocation, focusing on ROI-driven investments to support our near-term objectives of continued operating leverage and cash flow breakeven.

Now, let's discuss our first quarter results in more detail. Within our US Glaucoma franchise, we delivered record first quarter net sales of \$93.5 million on strong year-over-year growth of 58%, driven by growing contributions from iDose TR, which generated sales of approximately \$54 million in the first quarter. iDose TR continues to deliver strong clinical outcomes that meaningfully improve patients' lives, driving strong physician interest and adoption.

From an execution standpoint, we remain focused on our key initiatives, including expanding our base of trained surgeons and active accounts, increasing utilization, broadening market access, scaling targeted commercial investments, and expanding body of clinical evidence. And the last point, iDose TR is supported by a robust and growing body of clinical evidence, demonstrating strong efficacy, safety and durability of effect. This now includes 22 peer reviewed publications, complemented by a broad portfolio of active Phase 4 studies across diverse real-world clinical settings, further reinforcing its consistent performance in real-world practice.

Importantly, iDose TR is serving as the foundation for a broader shift towards earlier interventional glaucoma care. Our efforts to educate surgeons and key opinion leaders globally are gaining traction, and helping to drive a steady evolution in the standard of care. This momentum was evident at recent major industry meetings, including AGS and ASCRS, where engagement and enthusiasm around interventional glaucoma and our novel therapies were notably strong and growing. To support these efforts, we continue to invest in our commercial organization and infrastructure to expand disease awareness and education, while enabling our customers to effectively adopt and operationalize interventional care into their clinical practice.

Moving on, our International Glaucoma franchise delivered record net sales of \$35.8 million on year-over-year growth of 23% on a reported basis, and 16% on a constant currency basis. The strong growth was once again broad-based as we continue to scale our international infrastructure and execute our plans to drive mix forward as a standard of care in each region and market – major markets in the world.

As previously discussed, we continue to expect new competitive product trialing headwinds in some of our major international markets as we progress through 2026, partially offset by growing contributions from iStent infinite, following its EU MDR certification and associated European commercial launch late last year. We also expect the currency tailwinds to abate going forward based on the current rate environment.

And finally, our Corneal Health franchise delivered net sales of \$21.3 million on year-over-year growth of 15%, including Photrexa, and very early Epioxa net sales of \$17.7 million. At the end of the first quarter, we are delighted to announce commercial availability of Epioxa, our novel, groundbreaking advancement in corneal cross-linking for the treatment of keratoconus, a rare, sight-threatening disease that is currently far too often underdiagnosed, undiagnosed and untreated. We believe Epioxa represents a transformative innovation in keratoconus care, offering an incision-free alternative to traditional corneal cross-linking procedures, as it does not require the removal of the corneal epithelium beyond the most layer of the front of the eye. This novel oxygen-enriched, topical therapeutic, bio-activated by UV light, is designed to reduce the pain associated with removal of the epithelium, streamline the procedure, and minimize recovery, all while delivering clinically meaningful outcomes and exceptional value to patients, providers and the healthcare system.

The response we've received from surgeons in the broader ophthalmic community since FDA approval and the more recent initial commercial launch activities has been very encouraging. As we've discussed, with the launch of Epioxa, we have redefined our go-to-market approach to better address this sight-threatening disease and truly expand patient care and access. Importantly, with this launch, we are substantially increasing our investments in patient awareness, education, and access while addressing the longstanding challenges of underdiagnosis and undertreatment that have affected this rare disease community.

As with all pharmaceutical launches, initial patient access will be gated by typical payer adoption headwinds and hurdles. But we've been encouraged by the progress we've made in short order through the early days of our launch. First, I'm proud to report that we have successfully established and continue to selectively expand a broad-reaching site-of-care network. Our acquired O2N systems are already actively deployed across locations serving roughly 65% of the US population, with the pipeline progressing through various approval processes that we expect will expand our treatment center reach to approximately 95%. Looking ahead, we will continue evolving this network to bring treatment access closer to patients as reimbursement and drug acquisition pathways become further established and streamlined.

Next, we continue to make considerable progress with payers to secure access pathways or policy coverage for Epioxa with several plans having already updated or are in the process of updating their policies to include this novel therapy. These efforts are translating to expanded access with pathways now established for more than 100 million covered commercial lives in the United States, including with four of the five largest payers reflecting encouraging initial receptivity of Epioxa's clinical value.

While we expect the pace of policy adoption to build over time, we remain focused on driving broader commercial – I'm sorry, broader coverage across both commercial payers and Medicaid programs to support more streamlined access pathways over time. Earlier this month, we achieved another important market access milestone as CMS assigned a product specific J-code for Epioxa, consistent with our expectations, and in response to our application. The new code, J2789, is scheduled to take effect on July 1, 2026, and we believe it will help streamline the reporting and reimbursement process for Epioxa among US payers over time. Until then, we anticipate Epioxa will be commercially available under a new technology miscellaneous J-code and anticipate measured adoption over this initial period until the permanent J-code is in place and solidified operationally by providers and our specialty pharmacy.

Beyond market access, we're proud to lead the way once again in forging a new path for interventional keratoconus by advancing a targeted marketing and DTC initiatives to drive awareness, education, and early detection, supported by greater optometric engagement and strengthened advocacy partnerships. Finally, we've

launched a copay assistance program for eligible patients and are operationalizing a specialty pharmacy partner network in support of Epioxa patients.

As you can see, we are very excited by the significant potential Epioxa offers to patients living with keratoconus. While Epioxa remains in the early stages of its launch, our teams are energized and executing with focus, and are encouraged by the solid progress we're making against our core launch priorities. Beyond Epioxa, we continue to advance a broad and differentiated clinical pipeline across our five novel therapeutic platforms, encompassing 13 publicly disclosed programs and additional undisclosed assets supported by a robust portfolio of active clinical and Phase 4 studies. This includes ongoing clinical trials for iDose TREX, iStent infinite in mild to moderate patients, and the PRESERFLO MicroShunt, an active Phase 2 trial for iLution Demodex Blepharitis, ongoing development for our iLink platform, including a planned market introduction of our KC screening device later this year, and our promising earlier stage retinal assets. Overall, we remain on track with our clinical timelines and encouraged by the progress across our complete portfolio.

In conclusion, at Glaukos, we're in the business of pioneering new marketplaces within ophthalmology for the benefit of patients. Our record first quarter performance highlights the strength of our strategy and execution as we continue evolving into an increasingly diversified ophthalmic leader with multiple transformational growth drivers in iDose TR and Epioxa, and advance our mission to transform vision therapies for the benefit of patients worldwide.

So with that, I'll open the call for questions. Operator?

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And our first question comes from the line of Tom Stephan with Stifel. Please go ahead.

Thomas M. Stephan

Analyst, Stifel, Nicolaus & Co., Inc.

Q

Great. Hey, guys. Thanks for the questions. Nice quarter. First one on Epioxa. Tom or Joe, maybe if you can talk about early findings, one, on sort of, how initial experiences in, sort of, the claims and prior auth processes are going? And two, what demand in the market looks like, sort of from an early utilization standpoint, maybe based on what you're seeing in the Epioxa patient portal? And then I'll have a quick follow-up.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Sure. Thanks, Tom. It's Joe, I'll start off there. I think Tom gave you some of the higher-level stats and the progress we're making with the Epioxa launch, both in terms of the two fundamental, I think foundational items, both our site-of-care network as well as the broader payer pathways. Underlying that, which I think you're asking a good question, is the process of making your way through that. Clearly, it's hard to judge too much on that until we get into the post J-code period, because at this point you're dealing with the miscellaneous code. So all systems around that, if you will, are by definition slower than normal as you adjudicate on a claim-by-claim basis.

But I will say that we've been very encouraged by those sites of care who've come online, as Tom referenced, and the patient flow that's coming from that and into our portal and the hub, as you say, and the leading indicator of what it can mean for the clinical demand associated with an Epi-on therapy like Epioxa. So as we make our

way through that and we see those claims get adjudicated, which we've seen positive claims get through the process, and also those procedures get done now. We're encouraged by I'll call the what is the leading indicator in terms of that funnel as it develops.

Thomas M. Stephan

Analyst, Stifel, Nicolaus & Co., Inc.

Q

Got it. That's great. And then follow-up just on iDose, really solid in the quarter, Joe, maybe just stick with you. Can you just talk about drivers of the strength? And it'd be great if you could maybe also discuss kind of Noridian and Novitas versus the remaining MACs and what you're seeing in kind of each of those two pools, if you will? Thanks.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah, absolutely. I think the most encouraging thing about the results of the first quarter was it was very broad based in terms of what drove that performance. It was continued expansion within the more established, I'll call it MACs. And you referenced Noridian and Novitas subset, I'll put First Coast in that as well, I'll come back to that. But now you start to see NGS in particular, turning on the early signs of Palmetto turning on, as well as we've more recently achieved a professional fee formally in that region.

And I think also encouraging was a real increase, certainly in the funnel into our hub associated with commercial and Medicare Advantage patient flow. So I think it was broad and consistent with what you would hope to expect in the context of our core initiatives. To put a finer point, I think on your question around Noridian and Novitas, typically I talk about that in the context of Noridian plus Novitas and First Coast is some of the earlier adopting MACs. And in the first quarter, that was down to about 73% of the overall region volumes, if you will, from 78% in the fourth quarter. And again, that's really because as they continue to grow, you might expect the adoption curves to be picking up even faster in areas like NGS and Palmetto to offset them.

Thomas M. Stephan

Analyst, Stifel, Nicolaus & Co., Inc.

Q

Got it. Congrats again. Thanks.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Sure.

Operator: Our next question comes from the line of Adam Maeder with Piper Sandler. Please go ahead.

Adam C. Maeder

Analyst, Piper Sandler & Co.

Q

Hey, good afternoon. Thank you for taking the questions and congrats on a great start to the year. The first one for me, I wanted to ask a modeling question. So nice Q1 top line beat, you raised the full year outlook by more than the Q1 outperformance. You've given a lot of great modeling color in the past. So, Joe, maybe for you or Alex, can you just kind of pull apart the updated guidance with iDose contribution versus the stent business versus Corneal Health? And as we think about Q2 in particular and as it relates to Epioxa, I would appreciate if you could give us a little bit of modeling help and then I had a follow-up. Thanks.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Sure, Adam. I'll dive in and I'll give at least some interrelated comments on that front. Then if folks have additional questions, we can dive a little bit deeper. But, as you said, it was a great start to the year with really each of our franchises exceeding expectations. And we made considerable progress across all those fronts, including within international glaucoma and iDose in particular. As a result, we were able to raise our guidance up to the \$620 million to \$635 million range. And as you think about that in your models by franchise, a handful of perspectives, first by franchise. On the international glaucoma side, I'd say really the dynamics here are somewhat unchanged. Obviously, we expect as we move forward here, some of the currency benefits that you heard Tom call out in the prepared remarks will wane. And so we do expect that going forward, we'll see sort of high-single-digit growth for the remainder of this year. Now, when you put all that together, that's going to translate into low-double-digit growth for the full year. But the remaining quarters, we would expect single digit growth in that franchise.

On the on the Corneal Health side, obviously, I think everybody knows there's a fair number of moving parts there. It was a strong first quarter, but we do continue to anticipate volatility associated with both the Photrexa to Epioxa transition, but also the temporary and permanent J-code transition over the course of call it Q2 and Q3. And so when you put all it together with the performance and what we're sort of seeing, we now expect kind of high-single-digit growth for this franchise for the entire year with some puts and takes in the individual quarters as we get there. And as you've heard me say in the past, we certainly expect to be exiting the fourth quarter with a pretty strong performance curve as we start to pull through Epioxa in a more meaningful way.

On the US glaucoma side. Again, another strong start to the year. We would adjust our views there, probably to be more in the, I'll call it the low 30% type growth for the full year. And that's really driven by still an ongoing view that going forward, we should expect kind of flattish non-iDose sales going forward until we've really been proven otherwise and continue sequential progress as we've been seeing with the iDose launch.

So you put all that together and I think as you said, we not only do we raise our overall guidance, but we raise it for each of our underlying franchises and the drivers.

I will add, just because you asked about it. I think for Q2 in particular, given there's a lot going on here and it's all good. But I want to make sure we've got it as dialed in as possible. That for the US glaucoma franchise, as I alluded to earlier, in Q2, I think we'd expect sort of flat non-iDose, and that continued to sequential iDose expansion. In interventional glaucoma, we expect the high single digits as we talked about as FX benefit wanes. And on the corneal side, I think as we said on the last call, we would expect in the second quarter to see a bit of a dip there on a year-over-year basis as we transition from Photrexa towards Epioxa.

Adam C. Maeder

Analyst, Piper Sandler & Co.

Q

Really appreciate all the color, Joe. And if I could just sneak in a follow-up. I wanted to ask about iDose, and we're reaching a point now where you have critical mass from the reimbursement standpoint. So Tom or Joe, can you just maybe talk about some of the new initiatives that you're going to start to put in place here? I think you've talked about growing the commercial team, potentially looking at direct to consumer as we kind of get into the latter part of the year. Would just love some incremental color for kind of the next chapter. Thanks again.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah, you're exactly right, Adam. We've always talked about it. You didn't want to put some of these things into place until you start to have a more solid foundation from a reimbursement standpoint. Certainly, what you're hearing in the context of our first quarter results and our guidance is increasing confidence in that foundation, both in terms of the five of the seven MACs that are now established professional fees and the teams driving incremental confidence, both on the reimbursement side as well as obviously, the clinical and commercial side. But also now increasingly, as we move forward here on the broader commercial Medicare Advantage.

So I think as we've talked about in the past, as we move forward here, it's about driving increased awareness for iDose, and interventional glaucoma, and teams that help drive that broader environment of both education of patients as well as the process to get them treated by an interventional procedure like iDose. So we have been making significant investments for some time now in more of our reimbursement and business teams that surround the traditional sales force, to really try to make sure that we can maximize both patient access and that broader awareness initiative.

So, I think you should expect to see more of that, certainly as we get our way into the second half of this year, and as we get closer to exiting the year and heading into next. Based upon this trajectory, we're going to feel, I think, a lot more confident and starting to make some of those more call it offensive investments.

Operator: Next question comes from the line of Larry Biegelsen with Wells Fargo. Please go ahead.

Larry Biegelsen
Analyst, Wells Fargo Securities LLC

Q

Hi. Good afternoon. Thanks for taking the question. I'll echo my congratulations here. Maybe one on iDose, one on Epioxa. Joe, if you could talk about how you've engaged with the MAC since the CAC meeting last year. And any updated thoughts on the likelihood of an LCD this year and the timing of those two RCTs you're running? And I had one follow up.

Joseph E. Gilliam
President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Larry, I'll start off at the beginning, and Tom can comment on the broader studies that we're doing especially with iDose here in a minute. So as we think about the engagement with the MACs, I'm not sure we have a particularly different strategy here. We've always engaged in an education process to make sure they understand our technologies, how they're utilized, the labels and indications for use around them. And we continue to do that. We continue to try and diagnose where we've got ongoing, I'll call it, less streamlined reimbursement in areas like CGS and WPS. And we continue to have momentum in some of those conversations.

So hopefully we're marching forward with those two MACs in a productive way that can drive professional fee establishment, similar to the other five larger MACs that have come before them. As it relates to the post-CAC conversation, LCD conversation. I mean, really no changes on this front since our last call, Larry. And we've talked about it. At this point, we've not seen any signs of an LCD and we continue to believe it would be premature at this stage of the clinical adoption curve. And having said that, obviously by nature these things can be unpredictable and on pace. So it certainly remains possible, even if we believe it's less probable at this point.

Thomas William Burns
Chairman & Chief Executive Officer, Glaukos Corp.

A

And I think to answer your question on Phase 4 studies, Larry, that we've contemplated actually, then enrolling for some time once we received NDA approval. We have done two major Phase 4 studies. The first would be iDose

plus cataract versus cataract surgery alone, to be able to demonstrate the incremental value of using iDose in combination with cataract surgery. And that study is actually fully enrolled, and we'll be following those patients over the course of this coming year. And we'll be looking to publish the data at regular intervals. And I think that will be a very powerful supplement to the data that we currently have on hand. Again, another 22 peer reviewed clinical trials.

And I think we were largely prescient in also during a study looking at iDose versus iDose plus infinite. Because I want to show the incremental value of these two different mechanisms of action to be able to lower intraocular pressure to supremely low target pressures, which will, by all evidence, be able to thwart the progression of glaucoma or a progression in glaucoma. I think with both of these in hand, I think it will be timely in case in any event in the future we're challenged by any MACs in using either combination modalities or procedural pharmaceuticals plus MIGS, or using iDose in combination with a cataract surgery.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

One other thing I'll just add, Larry, I think even at a minimum on this, these studies at times are referencing is important in the broader payer community. So, this is how you continue to expand that coverage irrespective of MACs and LCDs, etcetera, with the individual commercial players and Medicare Advantage plans to make sure that we're optimizing that access for our patients.

Larry Biegelsen

Analyst, Wells Fargo Securities LLC

Q

Thanks. And for my follow-up on Epioxa. Joe, I'm going to ask you kind of a more of a big picture question. I think from our past conversations, you've felt confident that Epioxa could return to peak Photrexa levels of roughly 18,000 to 19,000 eyes by the end of the decade. And if that's paid volume, that would be well, north of \$1 billion in revenue. So I guess my question is, you're still – how are you feeling about achieving that? And what is the ramp to that look like? Thank you.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Larry, I mean, I think I'll stop short of obviously making the longer term predictions formally and just say, I think we have been on record saying we view this as a potential billion dollar plus franchise. And the pace in which we get there we'll continue to monitor as we get into the actual true commercialization, especially as we get toward the second half of this year.

But I think part and parcel with that is I don't think we view it just in the context of where we've been with Photrexa on patient volumes. So we're making, the investments we're making, which are enormous, moving forward to drive increased awareness, and detection, and ultimately action and access in the hopes that we can treat quite frankly, far more than that.

We believe that there are more than the 18,000 to 19,000 eyes at any given time that should be getting diagnosed and treated. And so, from our standpoint, a lot of the DTC and the things that you've heard Tom reference, we'll be putting those investments towards hopefully growing this overall market from a volume perspective over that period of time and getting more and more of these patients treated. Thank you.

Larry Biegelsen

Analyst, Wells Fargo Securities LLC

Q

Thank you.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

A

And I would just add on that. If you think about what the possibilities are to build this marketplace over the planning period. And it's really important to be able to recognize what we have beyond this planning period. Certainly at the tail end of the planning period, and this would be the second generation customized algorithms that we have in place for the treatment of keratoconus. And they can't help with the market expanding if we show demonstrable changes in Kmax for these patients, and have the possibility of actually increasing their best corrected visual acuity by virtue of customized algorithms that we're going to be able to dispense and use on new patients with keratoconus.

So, I'm very bullish not only on the near term of all the different mechanisms we're putting in place to build the marketplace, but our possibility of having a second wind moving into the 2030s, which will increase our presence in this rare disease.

Larry Biegelsen

Analyst, Wells Fargo Securities LLC

Q

Thank you very much.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

A

Thanks, Larry.

Operator: Your next question comes from the line of Ryan Zimmerman with BTIG. Please go ahead.

Ryan Zimmerman

Analyst, BTIG LLC

Q

[indiscernible] (00:31:50) on strong start here. Just kind of dovetailing on some of the questions before, there's been obviously a lot of investor concern about these LCD risks. I know you just addressed it. But, Tom, I guess my question is around the existing body of evidence. I'm wondering if you could kind of talk about it, in contrast to the Phase 4 study, and remind us what percentage, now that we have quite a track record of iDose, what percentage are you seeing today, either in combination with cataract or with another MIGS in terms of the iDose usage? And if some of the studies already bear out evidence of combinatorial usage of iDose with other products or procedures, do you think that is sufficient or the Phase 4 study is really necessary to kind of refute any concerns there?

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

A

I'll let Joe start on, and I might add some color. Go ahead, Joe.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. I'll start on the – in the context of the trends that we've seen. Certainly I think they remain consistent, Ryan, with the past commentary, that relative percentage of the procedures done today where surgeons are treating glaucoma with iDose and at the same time, in conjunction with the cataract procedure, it's growing as expected,

given obviously Glaukos has already changed the standard of care for those patients. But at the same time, our efforts remain focused on that interventional glaucoma opportunity, and we continue to see rapid growth in the number of standalone procedures.

So, I would say that the majority of patients last year still saw a standalone iDose procedure, but the mix is certainly shifting towards a combination with cataract or in combination with another MIGS. As you might expect, because these physicians are trying to obviously do everything they can to slow the progression of a sight-threatening disease.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

A

And I would just say, based on the question that you have, that most of the Phase 4 studies we're doing as Joe has mentioned, are really for the payers and for moving into commercial payers and Medicare Advantage. I think surgeons in priority already have the confidence that putting iDose in combination with cataract surgery is going to yield an incremental effect. I think that you'll see that in any channel checks you do.

Likewise, the use of combination therapy of iDose plus an iStent infinite, surgeons will have high confidence that they're going to achieve incremental effect. So, the studies we're doing are less to be able to drive that portion of the market than more to validate surgeons' already existing confidence in using these technologies together.

Ryan Zimmerman

Analyst, BTIG LLC

Q

Understood. And then, maybe a question for Joe and Alex even, which is just, operating expense guidance and your thoughts on profitability. I mean, it's almost getting to a point where despite your best efforts, you will become profitable in kind of the next year. And I'm wondering kind of how you think about the ramp and sale, or, excuse me, the ramp and expenses needed for Epioxa commercialization, and kind of what that does or doesn't do to your timelines, or at least in our model, our timelines, the profitability?

Alex R. Thurman

Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

Hey, Ryan. It's Alex. I'll start. And I'll start with profitability. Again, just to reiterate what Tom had mentioned in his opening remarks, our near-term focus is in managing the business to do so on a cash flow breakeven and driving basically operating leverage within the P&L, which we're pleased to say we saw in the first quarter. And we're glad that that execution is happening.

But as we look ahead, to your point, we certainly can see with the commercial launches of iDose and Epioxa that we definitely have a fairly clean line of sight towards that pathway of profitability over the next few years. To your point, some of it will depend on the ramp of these commercial launches and the associated revenues that come with it. But as we continue to manage the business towards that cash flow breakeven, you'll see from an operating expense side that we continue to reinvest in the business, and reinvest in these commercial launches.

And we've talked about the fact that our operating expenses will grow this year, year-over-year. And we continue to feel that way. And I'll just give you some commentary now that as we did overachieve in the first quarter, Tom and I and Joe have talked about adding additional fuel to the fuselage in these commercial launches. So, you should see the operating expenses tick up slightly and moderate – modestly from what we talked about at the beginning of the year. But still in the high-teens, it's still showing that operating leverage overall as we progress throughout the year.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

I think, Ryan, the overall – when you hear Tom and I talking about the incremental spending from DTC or otherwise, it's important to note that a lot of that is by its very nature, discretionary. So as we look forward, you're thinking about making those investments alongside of the significant growth that we're achieving, and hopefully with the hopes of a return on investment that makes that certainly worth the incremental spend associated with it.

So, we'll be in a process here where we're continuing to evaluate the effectivity of those efforts and what that return looks like before diving in with two feet, if you will, to go full spend on DTC-related efforts. We've always been pretty disciplined in how we thought about those [indiscernible] (00:37:25).

Ryan Zimmerman

Analyst, BTIG LLC

Q

Okay. Appreciate it, guys. Thank you.

Operator: Your next question comes from the line of Allen Gong with JPMorgan. Please go ahead.

Allen Gong

Analyst, JPMorgan Securities LLC

Q

Thanks for the question. I wanted to start off with one actually on the core US Glaucoma business. I think iDose clearly had a really strong quarter. But underlying US Glaucoma also did quite a bit better than expected and grew at a healthy clip year-over-year, albeit also, as you know, bit of an easy comp, I believe. So, when I think about your forecasts, your reiteration for flat for 2Q and the year, what are you seeing that kind of supports that outlook? Is it just conservatism, or are there real challenges that you're seeing out in the market?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Allen, thanks for the question. I mean, you're right in the context that this was the second straight quarter where we've seen above the restoration of growth in that non-iDose remainder, or as you said, I think core US Glaucoma franchise. So, I think we've certainly seen signs of stabilization of the underlying market there. And I think that our teams are doing a great job in the – on the performance side within that now more stabilized market.

As we go forward, I think we're just not ready yet to make that call that that is I'll call it the new normal that we're operating in. It's been an encouraging two quarters. But if we look forward here, I think it's still safer for us and for investor expectations to be in that sort of more, I'll call it, flat year-over-year basis until we've proven otherwise on a sustained basis.

There are some things in there, obviously, and I think we've benefited a little bit in the quarter from some supply chain disruptions on the competition front. It's hard to measure that. I don't think it's material, but that should subside as we move forward here. So, I think we just want to play a couple more innings here of this on that side before we restate our view on guidance there.

Allen Gong

Analyst, JPMorgan Securities LLC

Q

Got it. And then, I guess a follow-up. Moving on to corneal health, you talked about how you've reached coverage of 65% of the US population with a line of sight to reaching 95%, I believe the number was. How quickly do you

think you can get to that 95%? Is that a target you think you can reach by the end of the year, or is it going to maybe slow down a little bit, now that you grabbed some of the low-hanging fruit? Thank you.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Thanks, Allen. In some ways, it's actually been accelerating. As you might imagine, once you announce commercial availability and the transition plan becomes more real, what we've seen is more of an acceleration than a deceleration on that front. Having said that, you also know that hospital systems and even certain other customers have longer cycles for bringing on new technologies and new drugs to the pharmacy network and the like. And so, I think we'll continue to make substantial progress here every month, and certainly hope that we're getting fair or close to that target in terms of realized sight care network by the end of the year.

Operator: And your next question comes from the line of David Roman with Goldman Sachs. Please go ahead.

David Roman

Analyst, Goldman Sachs & Co. LLC

Q

Thank you. Appreciate you taking the question. Maybe I could just start on Epioxa here. Could you maybe talk to us a little bit about some of the specific market development efforts that you have underway, and maybe you kind of break them into whether it's physician and practice education, patient assistance programs, and then engagement in education with payers?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Sure, David. It's Joe. On the Epioxa side, I think about it kind of as follows. So, I won't repeat what Tom's already said and we commented on. There's a foundational element that's first and foremost when you're kind of going through the stages of a launch. And that is that you get the site-of-care network established, affected, trained and everything ready there. The second layer of that is that you're engaging with the payers in a way to establish access pathways, and then ultimately from there further streamlining and optimizing those.

And then as you go alongside of that, you start to dial up, I'll call it, the more physician-related and even patient-related marketing efforts. But you don't want to do that too soon in that lifecycle until really the overall ecosystem is ready. So, a lot of where we're at right now is around the last part of what you said, which is making sure that as we're having success with the site-of-care network and on the patient side that the machinery in the middle is working as efficiently as possible to make sure that we're working things through the hub and through our specialty pharmacy, and we're providing that visibility to our customers and to our patients that our copay assistance programs are working as they're intended. And all the stuff that probably is a little less interesting to investors, but are – is critically important to the ultimate success here as we move forward.

And as I mentioned earlier in the call, we're really encouraged by that initial burst, if you will, of patients that are going in there. And now, we have to get through that process of trying to get them on therapy, which can be a lengthy one when you're dealing with that, a miscellaneous J-Code. And so, navigating that is paramount for us before we get to, obviously, the formal J-Code in the second half.

David Roman

Analyst, Goldman Sachs & Co. LLC

Q

Very helpful. Maybe just a follow-up here on iDose, and I know you talked a little bit about this. But could you just talk to some extent whether there was any contribution here from having the reimplement approval that came

early in the first quarter, to what extent that maybe giving physicians increased confidence implanting iDose? And how we should think longer term about the interplay between having the re-administration label as an iDose TREX?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. Well, I can confirm that we've now seen numerous successful re-administration procedures, as some of those earliest patients are getting out several years. It's not the predominant procedure being done. It's still a small fraction. But we've seen multiple surgeons do re-administration and do so successfully. We've seen payer policy updates occur and a lot of, I'll call it, general progress on that front.

So, I think we're encouraged. And this is sort of in line with what we always expected that as the benefits of the initial procedure start to wane, that both the patient and the provider are going to want to continue that therapy given the clear benefits to the patient. So, we're seeing that start to happen. And I think as we look out over the long run, certainly, re-administration becomes a much more material part of that overall mix. Every month and every quarter that we move forward here, it should be more and more relevant to what we're looking at. But out of the gate, we're encouraged by what we're seeing.

David Roman

Analyst, Goldman Sachs & Co. LLC

Q

All right. Great. Thanks for taking the questions.

Operator: Your next question comes from Richard Newitter with Truist Securities. Please go ahead.

Richard Newitter

Analyst, Truist Securities, Inc.

Q

Hi. Thanks for taking the questions. Congrats on the quarter. Just, I'm wondering if you could give us any kind of color on what's happened to the provider base as this transition to Epioxa is taking place? I'm not looking for you to necessarily give us a specific number of doctors or your installed base per se. But do you guys envision just a big concentration over the next few quarters in a small number of providers' hands to getting all of this refined and figured out from a consistency on the payment standpoint? Or is this potentially going to be broader and not as concentrated than maybe what I'm suggesting as we think through this? Just trying to get a sense for is it really a dramatically fewer number of doctors or is it going to be potentially broader than that?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

And I appreciate the question, Richard. I think – well, first, I think in terms of the definition of how you do concentrate, because I mean, I think, relative to our iDose user base, for example, inherently in keratoconus, even with Photrexa, you had a relatively concentrated group of centers and sites that were doing the procedures. Now, it won't surprise you, and I think, you know, that with Epioxa, it was our intent, obviously, to make sure that your initial site-of-care network is as concentrated as you can reasonably be to try and make sure you're close enough to the vast majority of the US population.

So inherently our wave 1, if you will, efforts have been very targeted around the country in that context. But I'll tell you, in some respects, our wave 1 efforts have gone maybe a little too well. And that's caused us to have to accelerate some investments to meet the needs of that customer base and their patients that are coming out of that.

So, there will always be earlier adopters than mid adopters in any launch and we'll see that here, obviously as part of Epioxa. But I'm not particularly concerned about any, significant concentration issues in any one or two or even 10 customers. I think it's going to be, measured much more in, hundreds of customers ultimately than it is in single digits.

Richard Newitter

Analyst, Truist Securities, Inc.

Q

Yeah. That's helpful. And then is there any one area where the spend that you're stepping up from a position of offense, clearly, is directed now that you've had some early learning experiences? In other words, where are the frictions most notable either to a doctor not wanting to do this, not wanting to buy Epioxa and move forward? Or is it more on the [ph] pull (00:48:00) side from the patients and the demand – the demand and awareness increase standpoint? Thanks.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. I would say it's actually maybe a bit more. So, if you think about this, whenever, there's always going to be conversations in education, both the sales force and the broader teams to make sure people understand what we're doing, why we're doing it, how we're doing it, as it relates to the Epioxa launch. And certainly, in the future, as we've talked about, there'll be a whole lot more of that spin oriented towards I'll call it more growth and DTC education related. Right now, in this moment where a lot of that spend is going, it shouldn't surprise you, it's much more in that initial lift, confidence, and process associated with claims prosecution and adjudications. It's about making sure that customers understand how it works that they're successfully seeking prior authorizations, that we're supporting that process where appropriate and compliant, and then ultimately getting those patients access to that care. So, a lot of it's much more in the machinery I'll call within the market access world than it is necessarily in marketing or even sales from that standpoint.

Richard Newitter

Analyst, Truist Securities, Inc.

Q

Got it. Thank you.

Operator: Your next question comes from the line of Mason Carrico with Stephens Incorporated. Please go ahead.

Q

Hey, this is [ph] Harrison (00:49:25) on for Mason. Thanks for taking the questions here. Would you be willing to provide some color on the utilization of the various cohorts of surgeons trained on iDose? Is there a portion of the surgeon base today that you would say has matured at this point with more stable utilization? Or are you still seeing pretty robust utilization growth across these older cohorts of surgeons too?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. [ph] Harrison (00:49:55), I'm not sure I would say that we're reaching stabilization, if you will, in any one cohort. I mean, if you think about it, even for some of the earliest adopters, there's still ongoing enhancements to how they think about Interventional Glaucoma, the amount of time they're spending on that versus other areas of

their practice. Let alone, as we talked about, coming into this year and again on this call, the movement from, I'll call it, the more traditional fee-for-service patient population into the commercial and Medicare Advantage world. So, I think we continue to see growth across both our more mature customer base as well as certainly with the addition of new surgeons and new practices throughout the country. So, we're still pretty early in that overall evolution curve, if you will, of the iDose launch.

Q

Got it. Yeah. That's helpful. And then second question here. Could you update us on the progress you've made this year from a commercial payer standpoint on iDose? I think in the middle of last year, you called out more than 50% of Medicare Advantage and commercial policies had a positive policy in place. Where does that percentage stand today?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. So, and I'm not sure it's changed a significant amount this past quarter. But just to put a line in the sand, sitting here today with iDose, we have about 99% of patients have an access pathway in the commercial and Medicare Advantage arena. To the point you made in your question, about 50% of those patients are in plans where there's a specific policy attached to it, and the remainder where there's silence and we're certainly seeing successful pull-through on that. I'll also add that in these, I call it the early days of the real efforts here, we're seeing a very, very high success rate in the context of the prior authorizations that are submitted for these patients across that landscape, which is what you'd expect given the statistics I just got done citing around the broader, patient access pathways.

Q

Great. Thanks for taking the questions.

Operator: Your next question comes from the line of David Saxon with Needham. Please go ahead.

David Saxon

Analyst, Needham & Co. LLC

Q

Great. Hey, guys. Thanks for taking my questions and congrats on the quarter. I wanted to start on the Specialty Pharmacy channel or with Orsini. So, I mean, I'd imagine the docs doing Epioxa were previously doing buy and bill with Photrexa. So, maybe new to Orsini. So, what's the feedback been from them in terms of process? And whether there's any friction in that kind of change of workflow?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. David, so I think that historically speaking with the mix, there were certainly those customers who preferred to buy and bill Photrexa, and those customers who acquired it through the pharmacy channel, in this case, on our case, Orsini. And that continues going forward. I think it will surprise you that certainly amongst our non-hospital based customers, the vast majority certainly out of the gate are choosing to access the drug via our specialty pharmacy. And so, that does mean some of them are doing this for the first time with our channel.

I think it's a little too early to comment specifically around that dynamic because again it's what I said earlier, when you're in the miscellaneous code environment, even with a, perfectly streamlined, I'll call it hub and specialty pharmacy process, the process to getting that access to the patient is much more elongated. And we've only had the drug on the market now for a month. So, from that standpoint, I think we're still in the early days of adjudicating those claims and getting access to the drug via the SP channel. But more to come on that. And we're certainly encouraged with the work that Orsini's been doing to make sure that they're in network with these various plans. And I think ultimately that's going to accrue to the benefit of our customers who choose that channel.

David Saxon

Analyst, Needham & Co. LLC

Q

Great. Thanks for that. And then maybe one for Alex, just on the gross margin. So, maybe remind us, what your expectations are for the year? And then, as we go through iDose and Epioxa looking into next year, kind of how we should think about gross margin potential? Thanks so much.

Alex R. Thurman

Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

You bet. Thanks, David. I mean, we saw 84% margin in the first quarter, which was up 120 basis points from last year. [indiscernible] (00:54:55) that was pleased to see that. In the last call, we – I gave a range for the year of an expectation of 84% to 86%. And sitting here today, we still continue to feel comfortable with that guidance range for the year, with expected accretion over the course of the year, as products like Epioxa become a greater share of the mix. And then to your point, looking forward in 2027, we'll comment more further when we get closer. But you would expect accretion, as these products continue to ramp.

David Saxon

Analyst, Needham & Co. LLC

Q

Great. Thank you.

Operator: Your next question comes from the line of Michael Sarcone with Jefferies. Please go ahead.

Michael Sarcone

Analyst, Jefferies LLC

Q

Hey. Good afternoon, and thanks for squeezing me in here. So, just a follow-up on the Epioxa, Specialty Pharmacy question. I mean, when you think about buy and bill, understanding that Specialty Pharmacy is coming first. Can you talk about, options that you may have or are evaluating to enable or efficiently enable buy and bill for Epioxa down the road?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah, Michael, I probably won't go too far into the details around that. But obviously, there's always an ongoing education process around from our reimbursement teams and the experts within that, as well as some of our site of care teams and the like, to make sure those customers understand how the buy and bill process will work, the key terms and conditions that we have in terms of our payment terms and things like that, to make sure that we've – that we can enable that where customers, ultimately choose to buy and bill the drug. Obviously, when they think about it from a business standpoint, that can be an attractive option to them when they've got the right building blocks in place to enable the buy and bill activity.

Michael Sarcone

Analyst, Jefferies LLC

Q

Got it. Thanks, Joe. And then just a quick follow-up on iDose TRIO. What's the latest and greatest there in terms of timelines and where we stand?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah. I'll be happy to address that, Michael. The, as we said before, we would complete and we have completed the clinical study for iDose TRIO. We'll monitor those patients over the course of this year. We plan to file by the end of this year, and we expect to be in position for targeted approval in the fourth quarter of 2027. So, we're hitting on all marks and all cylinders. And as we talked about before, when we did our human factors analysis, we saw a real strong preference for this new design on the order of 90%. So, we're encouraged by what we think we'll be able to bring to the marketplace and more encouraged by the ability to drive in-office use over time.

Michael Sarcone

Analyst, Jefferies LLC

Q

Great. Thank you.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

You're welcome.

Operator: Your next question comes from the line of Joanne Wuensch with Citi. Please go ahead.

Joanne K. Wuensch

Analyst, Citigroup Global Markets, Inc.

Q

Oh, hi. Can you hear me okay?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

We can.

Joanne K. Wuensch

Analyst, Citigroup Global Markets, Inc.

Q

Excellent. Let me do some of our due diligence on iDose. Physicians are still pushing back or are pushing back, maybe still is the wrong word, on the price tag of it. And honestly, I'm a little confused by that, since you do have the J-code and you do have the reimbursement in place. So, I'm sort of curious what your initial conversations are like and what the responses to that?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Yeah, Joanne. I think it's, I mean, you always have customers with varying views, but I'm not so sure that that's really as material of a driver today as it was when we launched it. Anytime you launch a pharmaceutical like we have with iDose or Epioxa, there's a period where you have to make sure that your customers understand the why and how, right? But at this point, sure, there will always be some of that. But for the vast majority of the

customers, and certainly, you can see with the results, we continue to add them and drive that forward. We can continue to overcome that challenge where it represents itself.

Joanne K. Wuensch

Analyst, Citigroup Global Markets, Inc.

Thank you, Joe.

Q

Operator: And your next question comes from the line of Steven Lichtman with William Blair. Please go ahead.

Steven Lichtman

Analyst, William Blair & Co. LLC

Thank you. Hi, guys. Just a couple quick ones on Epioxa. First, as it relates to the transition from Photrexa, are you still anticipating it to Photrexa to fully sunset by the end of 3Q? Or has there been any change in that plan?

Q

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

No change and because this is what we've communicated to our customers that we would expect in the third quarter to have that transition taking place. And ultimately, we will have Photrexa available in limited quantities through a different mechanism where their position may require an Epi-off based procedure thereafter. But I wouldn't call that out as a real material consideration for certainly the commercial aspects of it for you all. But for those physicians who seek ongoing access to Photrexa, we do have a pathway which we're going to continue to make it available to them.

A

Steven Lichtman

Analyst, William Blair & Co. LLC

Great. Thanks, Joe. And then obviously, we're at the beginning of the runway with Epioxa in the US. But just thinking longer-term, what is the potential for expansion of your platforms outside of the US, whether it's Photrexa or with Epioxa?

Q

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

Yeah. I think it's – it has to be much more selective. And it won't surprise you, Steven, that today's environment where you're navigating a combination of reference based pricing initiatives as well as other things in terms of payer dynamics and the like, there are certainly some markets internationally that can support the type of therapies that we're talking about with Epioxa and with iDose. But also we'll have to continue to evaluate that, as the landscape shifts that we bring successor generations of products forward and bring as much of this technology over time as we can internationally. But it's not something that at the moment I would be factoring in any material way into your models.

A

Steven Lichtman

Analyst, William Blair & Co. LLC

Got it. Thanks, Joe.

Q

Operator: Our final question comes from the line of Anthony Petrone with Mizuho Group. Please go ahead.

Anthony Petrone

Analyst, Mizuho Securities USA LLC



Congrats on the quarter. Maybe one on just keratoconus, just broadly. When you think about the disease state that it's just – it's underdiagnosed. You're getting most of these patients that come in with, stage 2 severity. Just thinking about the Epioxa opportunity. What is the really true TAM from a patient standpoint in terms of this disease state? I know it's, kind of considered an orphan disease. But I think the prevalence probably stretches to somewhere between 80,000 and 100,000 patients. So, what is the true TAM in terms of prevalence in the US? And what is the diagnostic pathway to get more patients into the funnel? Thanks.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.



Yeah. I think it's a great question in the context of, the exactly the why behind what we're trying to achieve here. So, and when you think about keratoconus and as a condition in where we've been, the 18,000 to 20,000 eyes that have been getting treated, we believe is likely going to be proven to be a fraction of what really should be getting caught, should be driven to detection and ultimately into therapy over time. I think our best estimates here suggest that there should be between 50,000 and 100,000 keratoconus eyes a year at a minimum that are getting diagnosed and treated with Epioxa and cross-linking. And but we're going to have to find that number out ourselves as we move forward with increased initiatives around awareness and detection and ultimately access that therapy.

But we do believe that over time that this could be proven to be more of a rarely diagnosed disease than a rare disease. But today it operates like a rare disease, and we're going to make those investments accordingly.

Anthony Petrone

Analyst, Mizuho Securities USA LLC



Thanks.

Operator: With no further questions in queue, I will now hand the call back over to Glaukos Corporation for closing remarks.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

Okay. I want to thank you all for your time and for your attention today. And thank you as well for your continued interest and support of Glaukos. Goodbye.

Operator: Thank you again for joining us today. This does conclude today's conference call. You may now disconnect.

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