29-Oct-2025

Glaukos Corp. (GKOS)

Q3 2025 Earnings Call

CORPORATE PARTICIPANTS

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

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

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

OTHER PARTICIPANTS

Thomas M. Stephan
Analyst, Stifel, Nicolaus & Co., Inc.

Adam C. Maeder
Analyst, Piper Sandler & Co.

Lawrence Biegelsen
Analyst, Wells Fargo Securities LLC

Ryan Zimmerman
Analyst, BTIG LLC

Allen Gong
Analyst, JPMorgan Securities LLC

David Roman
Analyst, Goldman Sachs & Co. LLC

Richard Newitter
Analyst, Truist Securities, Inc.

Mason Carrico
Analyst, Stephens, Inc.

David Saxon
Analyst, Needham & Co. LLC

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Michael Sarcone
Analyst, Jefferies LLC

Anthony Petrone
Analyst, Mizuho Securities USA LLC

Danielle Antalffy
Analyst, UBS Securities LLC

MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by. My name is Colby, and I'll be your conference operator today. At this time, I would like to welcome you to the Glaukos Corporation's Third Quarter 2025 Financial Results Conference Call. Copies of the company's press release and quarterly summary document, both issued after the market close today, are available at www.glaukos.com. All lines have been placed on mute to prevent any background noise. And after the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] Please note this call is being recorded and an archived 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 & 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 opportunity 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 facts 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 macro-economic conditions, including foreign currency 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 Investors 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 into Glaukos' ongoing results of operations, particularly when comparing underlying results from period to period. Please refer to the tables on our earnings press release available in the Investor Relations section of our website for a 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. Thanks, Chris. Good afternoon to everyone and thank you all for joining us today. In addition to discussing our record third quarter results today, we're also excited to provide an update on Epioxa, our groundbreaking advancement in corneal cross-linking for the treatment of keratoconus following the FDA approval that we announced last week.

Let's first start with the record quarter. Today, Glaukos reported record third quarter consolidated net sales of $133.5 million, up 38% on a reported basis or 37% on a constant currency basis versus a year ago quarter. As a result of our strong performance, we are raising our full year 2025 net sales guidance range to $490 million to $495 million compared to $480 million to $486 million previously.

Our third quarter record results reflect the sustained growth acceleration on our business driven by growing iDose TR adoption and utilization along with our broader Interventional Glaucoma, or IG, initiatives globally. Within our US Glaucoma franchise, we delivered record third quarter net sales of $80.8 million on strong year-over-year growth of 57%, driven by growing contributions from iDose TR, which generated sales of approximately $40 million in the third quarter.

iDose TR, a first-of-its-kind intracameral procedural pharmaceutical designed to continuously deliver glaucoma drug therapy for up to three years, continues to build commercial momentum supported by positive clinical outcomes and surgeon feedback that reaffirms our view that with the launch of iDose TR, we are pioneering a brand-new therapeutic category that has the potential to reshape glaucoma management as we know it today. Our teams continue to make great progress in the execution of our detailed launch plans for iDose TR, and we're encouraged with the continuing growing momentum.

Moving on, our International Glaucoma franchise delivered net sales of $29.4 million on a year-over-year growth of 20% on a reported basis and 17% on a constant currency basis. This strong growth was once again broad based as we continued to scale our international infrastructure and execute our plans to drive these forward as a standard of care in each region and major market in the world.

Last month, we were pleased to commence commercial launch activities for iStent infinite in our key European markets at the ESCRS Annual Meeting in Copenhagen. Surgeons' initial interest levels for iStent infinite were very high during the meeting, reaffirming our view that EU MDR certification for iStent infinite will help us not only maintain and grow our presence in Europe, but also advance and accelerate our broader IG initiatives globally in the years to come.

And finally, our Corneal Health franchise delivered net sales of $23.3 million on year-over-year growth of 13%, including Photrexa net sales of $20.3 million. As discussed previously, our third quarter results reflect the continued impact of Photrexa realized revenues as a result of our entry as a company into the Medicaid Drug Rebate Program or AMDRP (sic) [MDRP] (00:06:59).

Our record third quarter results reflect strong execution against our key strategic priorities and are a testament to our evolution into a more diversified ophthalmic leader with transformational growth drivers that span across multiple geographies and disease states as we advance the standard of care in glaucoma and rare disease with iDose TR and [indiscernible] (00:07:22) concept.

Beyond that, we continue to advance a robust pipeline that supports our long-term, best-in-class growth potential while remaining disciplined in capital allocation, focusing on ROI-driven investments and operational efficiency.

This quarter, we saw continued gross margin accretion and maintained a strong balance sheet with $278 million in cash and no debt.

Now, let's shift to our Corneal Health pipeline. As you know, last week, we were delighted to announce the FDA approval of Epioxa, a groundbreaking advancement in corneal cross-linking for the treatment of keratoconus, a rare sight threatening disease that is currently far too often undiagnosed and untreated. This approval marks a significant milestone for Glaukos and ushers in a new standard of care for keratoconus patients and practitioners with the first and only FDA-approved topical drug therapy that does not require removal of the corneal epithelium, the outermost layer of the front of the eye.

As a reminder, Epioxa utilizes a proprietary combination of an oxygen-enriched novel therapeutic that is bioactivated by UV light in an incision-free procedure. This is a result of more than a decade of research focused on slowing or halting the progression of keratoconus while significantly improving patient comfort and minimizing recovery time to provide a new way forward for patients afflicted with a sight-threatening rare disease.

The FDA approval is based on results from two prospective multi-center, double-masked Phase 3 pivotal trials that randomized a total of over 400 patients. Both trials successfully achieved their pre-specified primary efficacy endpoints and demonstrated favorable tolerability and safety profiles.

Keratoconus is a debilitating eye condition characterized by progressive thinning and weakening of the cornea that is often most aggressively advancing in patients under the age of 30. If left untreated, it can lead to loss of visual function and even blindness and is one of the leading causes of corneal transplants in the United States. Approximately 90% of cases of keratoconus are bilateral and as many as 20% of untreated keratoconus patients ultimately require a corneal transplant. Conventional keratoconus treatments such as eyeglasses or contact lenses address visual symptoms only and do not slow or halt underlying disease progression.

Before we discuss our plans for Epioxa, it's important to understand the historical journey of Photrexa, our first-generation cross-linking therapy that, unlike Epioxa, requires the removal of corneal epithelium. The FDA approval of Photrexa as an orphan drug was a major breakthrough back in 2016 as it became the first and only FDA-approved pharmaceutical therapy shown to slow or halt keratoconus progression.

Following our nearly $0.5 billion acquisition of Avedro in 2019, we have subsequently deployed several hundred million dollars in commercial and R&D investments to grow our Corneal Health franchise, driving new clinical trials, expanding our salesforce and commercial reach, strengthening market access capabilities, and enhancing patient education and support programs. These efforts have successfully resulted in Photrexa becoming the standard of care as excellent real-world outcomes have helped preserve visions for tens of thousands of patients.

While our disciplined commercial execution has delivered meaningful progress and our investments have made real impact on patients' lives for the past six years, the unfortunate reality is that the access to proper care still remains far too limited, evidenced by the fact that we are still only treating about 10,000 patients annually with Photrexa today. We estimate fewer than one in five actively diagnosed unstable keratoconus patients are getting access to Photrexa today and many more are never diagnosed at all, an unacceptable reality for patients that we must change moving forward.

To make matters worse, only 13% of treated patients are under the age of 18, which is when many patients are most vulnerable to significant disease progression and vision loss. Further, given the invasive nature and extended recovery associated with the current Photrexa procedure, many patients elect to delay or defer treatment. We estimate that as many as 40% of confirmed cases delay or decline Photrexa therapy, including

procedures involving treated patients [indiscernible] (00:23:55). This is simply not good enough for patients and we are determined to do better for this rare disease community.

Like other rare diseases, we believe there are several key factors contributing to why keratoconus remains too often undiagnosed and untreated today, including one, lack of awareness and an underdiagnosis. Two, misdiagnosis and a focus on managing symptoms rather than proactively treating the underlying disease. And three, a burdensome and lengthy patient journey marked with reimbursement hurdles and fragmented care pathways.

The FDA approval of Epioxa marks a pivotal moment, introducing the first incision-free treatment for keratoconus and offering a groundbreaking new therapy for patients. Just as important, it gives us the opportunity to reset and redefine our go-to-market approach to better address this sight-threatening disease and truly expand patient access.

With this approval, we plan to substantially increase our investments in patient awareness and access while addressing the long standing challenges of underdiagnosis and undertreatment that have affected this rare disease community. Our new approach includes significantly enhanced awareness, education and [indiscernible] (00:13:52) campaigns driven by increased engagements with the optometric community to established KC detection centers, the development of a handheld KC screening device, and expanded advocacy partnerships alongside new patient education efforts to identify and reach patients earlier.

To ensure patients move seamlessly from awareness to clinical diagnosis and treatment efficiently, we will establish a network of engaged ODs and MDs and committed Epioxa's sites of care that maintain the sense of urgency that these vulnerable patients deserve. In parallel, we will launch comprehensive patient services and support programs through our Patient Access Liaison teams to streamline care coordination, demystify the insurance approval process and advance cover decisions where possible. These efforts are designed to support patients and families at every stage, from awareness in diagnosis through ongoing treatment, making the entire journey as seamless, efficient and patient friendly as possible.

This approval is a culmination of unrelenting research, development and clinical efforts. And I want to thank our dedicated employees who have put in countless hours to make this approval a reality. We are also deeply grateful to the clinical investigators and participants in the clinical trials who played instrumental roles in bringing Epioxa to the United States.

Despite being a relatively young company, Glaukos has invested over $1 billion in R&D over the years to develop a robust pipeline focused on chronic and rare ophthalmic diseases. Our continued investment in R&D remains best in class, underscoring our commitment to going first and advancing the standard of care for ophthalmic patients worldwide into the future. We also just broke ground on a new 200,000-square foot research development and manufacturing facility in Huntsville, Alabama, to support long-term growth and innovation, including the eventual production of Epioxa.

As we hope you can see from our comments today, we are very excited by the significant potential Epioxa [indiscernible] (00:16:19) patients living with keratoconus and believe it will deliver an exceptional value to patients, providers and the healthcare system. We've had several meaningful and informative conversations with key members of the physician and patient advocacy communities regarding this value in relation to pricing. Our approach for Epioxa reflects our commitment to responsible innovation, balancing clinical value, cost effectiveness and patient access. These principles help inform our pricing decision, which also reflects the significant investments we've made thus far and those we plan to make going forward for this rare disease.

After several years of thorough and thoughtful evaluation, based on these factors and supported by a robust set of internal pharmaco-economic and published health, economic analysis, we have established a wholesale acquisition cost for Epioxa of $78,500, which represents a significantly lower price versus nearly all other rare disease drugs, including those within ophthalmology. This is particularly true when you consider that Epioxa is unique as a single administration therapy that is capable of slowing or halting disease progression in the vast majority of patients that are diagnosed with the sight-threatening disease.

We believe this not only provides a compelling value proposition for physicians and payers, but most importantly enables us to make a fundamentally different investment in patient and provider education and awareness to enable more patients over time to be properly diagnosed and treated at a younger age to preserve their needless loss of vision.

Going forward, we anticipate Epioxa will be commercially available in the first quarter of 2026 under a miscellaneous J-code, with a permanent J-code established by July 2026. As with all pharmaceutical launches, initial patient access will be gated by our site-of-care network deployment and typical payer adoption headwinds and hurdles. But we're investing in the infrastructure, teams and processes necessary to get Epioxa to as many patients as soon as possible in 2026 and beyond.

Given the significant advancement Epioxa represents and our commitment to ensuring patients gain access to state-of-the-art incision-free treatment for this rare, debilitating disease, we've made the decision to discontinue Photrexa commercial availability following a staged transition process in 2026. This transition will prioritize Epioxa as the primary treatment option, reflecting its safety, efficacy and superior patient experience. Photrexa will remain temporarily available for patients unable to access Epioxa due to coverage or geographic limitations. And we'll transition all remaining patients through dedicated support programs designed to minimize disruption and ensure continuity of care.

As we've discussed with the launch of Epioxa, a critical focus of ours is to improve patient access to the sight-saving keratoconus treatment. With that in mind, in addition to our new awareness campaign and patient support programs discussed earlier, we will also deploy a new financial co-pay assistance program for eligible patients and intend to have a comprehensive specialty pharma option available for customers at launch.

Our cross-functional teams have been hard at work putting these methodical plans together for several years now, and we are ready and excited to commence execution and make a difference in the lives of these keratoconus patients. The enthusiasm and energy for this new therapy and launch was palpable throughout our organization.

In summary, Epioxa represents not just a breakthrough in science, but a breakthrough in how we deliver on our promise to provide the best possible care to patients. Epioxa is more than a product. It's a reset moment and new way forward for keratoconus care. We're proud to lead the way once again in forging a new path to drive expanded patient access and enhanced treatment standards.

Finally, as discussed earlier, we are raising our 2025 revenue guidance to $490 million to $495 million versus $480 million to $486 million previously to reflect our third quarter outperformance and continued underlying momentum. We are also introducing a highly preliminary 2026 revenue guidance range of $600 million to $620 million. This preliminary outlook factors in our expectations as it relates to the continued commercial rollout for iDose TR, the surgical MIGS landscape, our International Glaucoma franchise, as well as our Corneal Health

franchise as we launch Epioxa and transition from Photrexa. We expect to refine this guidance range and provide additional commentary during our fourth quarter 2025 earnings call expected to be held in February 2026.

In conclusion, our record quarter highlights the strength of our strategy and execution as we continue evolving into a diversified [ph] product leader (00:21:55) with multiple growth drivers. iDose TR is already driving meaningful growth today and we expect Epioxa will begin to contribute in 2026 and beyond as our patient-oriented initiatives take hold. Combined with our robust pipeline that spans glaucoma, rare disease and retina in particular, along with our disciplined investment and strong balance sheet, we're well-positioned to sustain our growth momentum 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: Thank you. We will now begin the question-and-answer session. [Operator Instructions] Thank you. Your first question comes from the line of Tom Stephan from Stifel. Your line is open.

Thomas M. Stephan
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Great. Hey, guys. Thanks for taking the questions. I'll start off with iDose and I wanted to ask about the CAC meeting. Tom or Joe, maybe if you can discuss just the impetus or the rationale of the CAC maybe from what you have gathered in conversations with the MACs. And then maybe more importantly, talk to us about sort of what your views are on the potential outcomes here.

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

A

Sure. Hi, Tom, it's Joe. I'll start off. And as always, Tom can also add in the [indiscernible] (00:23:34) at the end here. I think that from a rationale perspective and maybe how we're viewing it from a macro standpoint is that we see this really as a step in the process of educating these MACs and really educating them on, number one, the significant unmet need that iDose meets for glaucoma patients as you all know. Two, and as importantly, the robust FDA and peer-reviewed Level 1 data evidence that supports its proper utilization in the care continuum. And three, ultimately really establishing the patient access that our glaucoma patients and physicians deserve around the product.

And clearly, if you think about this moving forward, you can make arguments both ways. And we've seen some of that play out obviously in the early commentary from the investor community. But in general, we're pretty confident that the considerable data behind iDose as an FDA-approved pharmaceutical, more high-quality evidence has been generated to support this pharmaceutical than virtually all of the glaucoma device solutions combined, including in at least 15 peer-reviewed publications, all this support and supported the FDA approval and the label that is, when you look at it, largely consistent with other pharmaceutical therapies for glaucoma.

So I think there's a handful of different paths that can emerge as we go forward. But I think what's most important is that for these MACs, they're taking a step to make sure they understand and are educated on what we already know, which is that iDose is a game-changing solution with a lot of evidence and data behind it to change the treatment paradigm associated with glaucoma patients here in the United States. So from that standpoint, we look

forward to having that engagement, and from them moving forward from a more educated basis to adjudicate the claims that come their way.

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

A

I'll just add, if I can, to Joe's. Let's talk about some of the data that we already have in hand. So we've got two Phase 3 clinical trials which you're all aware of [ph] to (00:25:40) establish the NDA submission and PMA approval with over 1,000 patients that are validating the use of iDose in standalone glaucoma patients. And then more importantly, I think we've been [ph] present (00:25:54) also as well as conducting a single arm prospective study in combination with cataract surgery, which showed demonstrably powerful decreases in their ocular pressure, 11.3 millimeters from pretreatment [ph] means (00:26:08).

We're conducting a prospective Level 1 study of iDose in combination with cataract versus cataract surgery alone. And we're also – I think we were smart in also conducting a study that we're in the process of enrolling today, which is iDose in combination with iStent infinite versus iStent infinite alone. And so we expect those studies will validate what we expect to see, which is incremental and cumulative advantage of using these different products, all of which should be conscribed and used under the current label [ph] of that provider (00:26:48).

Thomas M. Stephan
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Got it. That's great. Really appreciate that color. And then my follow-up is just on Epioxa, and congrats on approval. Maybe a quick two-parter. Can you just elaborate a bit on sort of your confidence in executing with this level of pricing just in terms of payer coverage and reimbursement? And then how should we be thinking about 2026 for corneal health just as we consider the moving parts with Epioxa ramping as well as Photrexa transitioning off? Thanks.

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

A

Sure. Thanks, Tom. I think as it relates to the coverage and continued access to or gaining access for Epioxa, the patients, I think like everything else, that's a process where there's education at the payer level around the benefits associated with this therapy and the real cost associated with the continued progression of the disease. And ultimately, as Tom mentioned, the – too often, these patients proceeding towards corneal transplants and other outcomes, let alone the continued impact from the visual impacts that keratoconus have on many of these patients. So I think we'll engage in that process as we go through it. We're confident, obviously, that we have a get – a best-in-class solution that works well for the patients afflicted with keratoconus. And so we look forward to engaging those conversations with the payer community.

As it relates to 2026, part of the reason why we decided to give the preliminary guidance for the year is to make sure that that was factored in at a macro level into the guidance and our expectation. You heard Tom mentioned some of these. But as you think about Epioxa rolling out over the course of the year, we have work to do to obviously establish the site of care network, the drug availability itself, timing in the first quarter, the reality of having a miscellaneous code throughout the first half of the year, the process of payers just updating the systems for the J-code in the second half of the year and alongside of that customers updating their contracts and generally what I'll call is the slow and methodical process of establishing proper payer coverage and patient access for any rare disease, Epioxa will be noticed not dissimilar. So, this is certainly one where we're expecting in the context of the way we think about the 2026 impact that we will come out of the gate crawling before we walk, before we jog as we exit 2026.

Operator: Your next question comes from the line of Adam Maeder from Piper Sandler. Your line is open.

Adam C. Maeder
Analyst, Piper Sandler & Co.

Q

Hi. Good afternoon. Thank you for taking the questions and congrats on the great quarter. Maybe just kind of piggybacking a little bit with [indiscernible] (00:29:44) the preliminary [indiscernible] (00:29:49) $620 million for next year, that's a little bit above consensus at the midpoint. And companies don't typically guide to [indiscernible] (00:29:58) to do so. And as we think about the different kind of components of that revenue range [indiscernible] (00:30:10-00:30:18) each of the segments, even if it's just as simple as [indiscernible] (00:30:22) different segments grow next year, that would be helpful. Thanks.

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

A

Sorry, Adam, you were breaking up pretty substantially, at least on our end throughout that. I believe that you were asking for more context or color around the guidance range for 2026 of $600 million to $620 million and probably pushing a bit for a bit more granularity around the constituent parts of that. So assuming that I'm correct on that...

Adam C. Maeder
Analyst, Piper Sandler & Co.

Q

That's correct, Joe.

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

A

I'll give you that answer, which is – okay, good. I think, as I mentioned before, we felt like it was prudent with what we were announcing in terms of the Epioxa approval, some of what Tom announced today, to make sure that we establish what I'll call as a highly preliminary view of 2026 and to really anchor ourselves around what we think entering into the year, where we're at here in October.

Our goal and our plan would be to provide more granular views by franchise during the fourth quarter call. But what I can say from a macro standpoint, we feel confident in this early range in that a variety of paths through each of the franchises, if you will, US Glaucoma, International Glaucoma and certainly the Corneal Health franchise will enable us to meet the expectations of that $600 million to $620 million range that we've established.

Adam C. Maeder
Analyst, Piper Sandler & Co.

Q

Understood. Thank you for the color there. And for the [ph] follow-up (00:31:52), I wanted to ask for just a little bit more color around iDose performance in the quarter. Really good numbers there. [indiscernible] (00:32:04) that MAC that onboarded in early August, just any color of how iDose is ramping as we head into Q4. And the second part of the question is really just around the utilization and kind of which patients are getting iDose, is this being done entirely in the standalone setting? How much is coming from combination with cataract, how much is with a second MIG? And thanks for the questions.

Thomas M. Stephan
Analyst, Stifel, Nicolaus & Co., Inc.

A

Yeah. Again, Adam, you're breaking up a little bit, but I think the question was largely around the iDose performance, dynamics associated with that in the quarter. And then a little bit more granularity on the breakdown of standalone versus combo cataract utilization.

So obviously, we announced in the quarter approximately $40 million of sales with iDose, a very nice step up from where we've been running in the second quarter, coming into the third. That I can was broadly in terms of what drove it, all of the MAC regions, if you will, contributed to that growth. As the growing early commercial and Med Advantage utilization was a part of that, we saw new doctors picking up. We saw some who had maybe been a part of early trying and trialing now having maybe received their payments for 2024 starting to get back into providing iDose as the therapeutic option for their patients.

So it was really high quality. And I would say, in terms of some of the contributions from – I couldn't hear you, but NGS obviously came online in August, very early, positive signs there. But realistically, the quarter itself looked very much like in terms of its mix, what we've seen in the second quarter where about 80% of the overall volumes were in the more established MAC regions, if you will, of Noridian, Novitas and First Coast. So the growth balance was across the board, but the weighting was still towards the more established regions in the country, which is not a huge surprise at this point. With that NGS announcement, you wouldn't really expect to start seeing the impact of that until at best kind of the later part of this quarter and really as you start moving into the next year.

As it relates to the mix on the standalone versus combo cataract, as you know, that's not something we directly track. We obviously are providing iDose TR for the benefit of patients afflicted with glaucoma and how surgeons utilize that in the combination with anything else, including as a part of a combination cataract procedure is not something that we know when it goes out the door.

Anecdotally, we know that those areas that have a little bit more established track record of reimbursement and, of professional fees, that the rate of utilization in combo cataract surgery is growing. That makes sense. Obviously, that's meeting the surgeon many times where they're already at, which is treating the cataract and trying to take care of the glaucoma disease in parallel.

So we are seeing some growth in that in terms of the – anecdotally of the overall mix, but it's largely in those regions where you have more established reimbursement than some of the other MACs where we're a little bit further behind.

Operator: Your next question comes from the line of Larry Biegelsen from Wells Fargo. Your line is open.

Lawrence Biegelsen

Analyst, Wells Fargo Securities LLC

Q

Good afternoon. Thanks for taking the question. I guess, Joe, I wanted to start with Epioxa. For those of us who have followed this a long time know that when Photrexa – when Avedro came out with the $3,000 or so ASP, there was some pushback. So you're obviously moving a lot higher here. So what data are you going to use with payers that gives you the confidence that commercial payers will cover it? And how are you thinking about the growth in 10,000 patients, I think you said earlier treated per year with Photrexa today, over time? Do you expect to grow that or could you actually lose some patients to off label corneal cross-linking treatments? And I had one follow-up.

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

Sure. I'll start, Larry, and others can comment as we go forward here. But for Epioxa, I think that first and foremost, and obviously the reset moment, as you heard Tom talk about, this is an education process, just like you'll recall to your point of having been around with Avedro back in the day as they first have reimbursement around keratoconus itself with Photrexa, is to remind the constituents that are out there, including the payer community, that this is a rare disease, that by definition you referenced it yourself when you're talking about 10,000 patients being treated.

In fact, that's an uber rare disease and pretty consistent with the type of treatment numbers, as we understand it, from indications or for other rare disease therapies in ophthalmology such as [indiscernible] (00:37:16) or TEPEZZA for thyroid eye disease.

So when you compare from a payer perspective the relative value of a single procedure that can slow or halt the disease progression of a condition like this, and you think about that patient population and the cost or the wholesale acquisition cost as Tom talked about, I think you're going to find it compares pretty favorably to the broader rare disease landscape, including that within ophthalmology.

I think more broadly than that, the conversation is one of education around what it takes to make sure that you're responsibly innovating in a category like this for rare disease. And then what you have to do to drive meaningful change in awareness, in diagnosis, in detection and in patient access, as you heard Tom talk about. This is a different way of looking at the situation, but was one that we had to look inwardly and ask ourselves what do we have to do to meaningfully change the outcomes that we're seeing in terms of too many patients not getting access to a sight-threatening therapy in the form of Photrexa. As we move forward Epioxa, that's exactly what we're committed to do.

Now, you asked about the 10,000 patients. I have no doubt that in the early days, as you're working your way through the inevitable payer hurdles and the various things you have to do to drive education and get access through each individual payer, they will face some headwinds there. But clearly, as we move forward, the whole reason for what we're doing is to meaningfully expand that number.

And you heard Tom referenced that we today believe we're treating one in every five patients who have uncontrolled or unstable keratoconus with Photrexa today. And so I hope that in the coming years, we'll put a meaningful dent in getting to what was, by definition, a uber rare disease with 10,000 patients to what would be merely considered a rare disease in the 50,000 patient range. And that's something that will be hard to work at, but it's not something that's going to be turned on overnight in 2026, for sure. But it's the reason because each one of those patients deserve to get access to an FDA-approved, incision-free topical therapy that can arrest or certainly dramatically slow the progression of that disease.

Lawrence Biegelsen
Analyst, Wells Fargo Securities LLC

Q

That's helpful. I guess just for my follow-up, it truly is related, I guess I'm just thinking ahead, as many people probably are, 2027, 2028, 2029, at $78,000 and 10,000 patients and I assume 90% bilaterally, the numbers get pretty big. Is there anything else? I mean, could you be doing 20,000 eyes in 2027, Joe? And should we be using an ASP of $78,000? Help us frame that beyond 2026 for hopefully obvious reasons. These are big numbers.

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

A

Yeah. Well, first, I think you have to do a blended average over time. I wouldn't do $78,500 your long-term model. Obviously, we are a member of the Medicaid Drug Rebate Program. We do provide that discounting for – that

patient population is a part of this. So when you think about a blended WACC, and we'll talk more about that as we actually get into making that drug available.

Certainly, I think we went far enough in terms of providing our view – our preliminary views on 2026. I'm not going to go that far, as you'd like, in terms of 2027 and beyond. I'll give you the bookend of what we're trying to target over a period of time in terms of meaningfully changing this for those patients.

And I would add that whatever you assume in our models over the course of the next several years, you should also assume requisite investments associated with what we're talking about here to make sure that we're actually driving the awareness, the education and the detection necessary to achieve those outcomes that you're talking about in 2027 and beyond.

Operator: Your next question comes from the line of Ryan Zimmerman from BTIG. Your line is open.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Great. Can you hear me okay?

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

A

We can, Ryan.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Okay, good. Yeah. Choppy earlier, but – so maybe for you, Joe, a little bit on iDose. In the absence of the CAC meeting and kind of the permutations that could come out of that, I'm wondering if you could talk a little bit about how you think about the ramp of iDose. And I asked that kind of in the context of 2026, and do we think of iDose following a similar progression in kind of a linear fashion through 2026 and beyond? Is there a point at which you see an inflection occurring where kind of the scales tip, if you will? I'm wondering if you could kind of speak to that and kind of how you guys think internally about the progression and adoption of iDose over time.

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

A

Yeah, Ryan. I think that the world we live in is obviously multi-dimensional relative to when we're building models or we're trying to do this. And there's a lot of varying puts and takes when you think about that. But what we've clearly established is plus or minus a pretty solid linear type of launch in its early days. I think it's hard to assess that without looking at the constituent parts of that. And as you said, in the context of 2026, we sit here today having put up $40 million of revenue in the third quarter with, as I said earlier, 80% of that volume coming from the Medicare regions that represent about 50% of covered lives.

So I think as we go forward, the CAC meeting, all the other education efforts that we're doing with these individual MACs to establish a proper and appropriate fee coverage moving forward, that simply getting the Medicare arena to the right place alone continues to leave us optimistic around what that means for 2026 and certainly beyond.

And that's before – I think you're touching on it a little bit, you start to think about that broader utilization that we're starting to see in some accounts across all patients who deserve to get access to iDose irrespective of what

insurance type they have, whether that's commercial, whether that's Medicare Advantage or certainly Medicare fee for service or other areas.

So as we make our way through and more and more folks get focused simply on treating the disease and less on the insurance type, I think that's when they're start – able to start focusing on really driving meaningful awareness in the standard-of-care shift that we think iDose represents for these patients' benefit. But until you get to that place where you got a little bit more stability, if you will, around that broader call it market access landscape, it's hard for physicians to really focus holistically on the clinical care continuum. But once you get there, I won't say, there'll be an inflection, but I think it's what underpins our bullish optimism of what iDose will mean for Glaukos, for our customers and for our patients, not just for 2026, but for the next decade as we continue to change the standard of care.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Okay. Just related to the CAC meeting, the agenda was posted, the questions were posted a couple of days ago. I don't want to leave witness here, Joe, and I don't know if you're going to comment on this, but I'm going to try anyway. And the questions kind of infer that the studies weren't long enough. And I don't know if you have a reaction to that. You kind of articulated this earlier, but is that your sense that you're going to be educating them on the robust kind of evidence, the totality of the data and that there is a misalignment in terms of understanding? Or do you feel like it's purely this is coming in with maybe a little more purpose given how fast this has kind of bubbled up, if you will, relative to the historical efforts we've seen in legacy MIGS? I'm just -- I'm trying to still understand kind of why this has happened as quickly as it did, so early in the launch cycle of iDose.

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

A

Yeah. I think part of what you're talking about and answer to the latter is that we've also been trying to aggressively educate and advocate on behalf of our customers. I think if you take a step back, Ryan, and you think about how much enthusiasm there is in the clinical community around iDose and what it means for the patients and the outcomes they're seeing, all the things that have led to the optimism that extends from that for you all in the investment community, that also leads to those physicians advocating to make sure that they're getting properly paid and the coverage associated with it. And I think a combination of that is probably what led them to want to ask the questions of the broader advisory committee to make sure they understand.

Anytime you go into one of those sessions, there's going to be questions within that that make sense in the context of the way we or our physician customers look at this and other questions that do not. And I think this preliminary question list reflects exactly that. There are some in there that you can understand, that – where they're trying to understand the overall fit of iDose into the treatment paradigm. And they want to ask that question of a group of network of experts, if you will. But there are others in there that clearly show they have not yet quite understood both the data of which there's a lot. And so I don't hold that against anyone. That's an education process that has to take place here in the coming weeks, months, if not years, if we continue to try to streamline that broader reimbursement coverage.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Thank You.

Operator: Your next question comes from Allen Gong from JPMorgan. Your line is open.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Thanks for the question. Just as a quick follow up to that, one question I do have is, you obviously won't get an LCD immediately after the CAC meeting. But should you get an LCD, what does that do to your coverage with the MACs that are currently holding out and the MACs that you're already working with, will that change your relationship with the MACs that don't have you on the [ph] profy (00:48:12) schedule yet? Will that accelerate that process or will you still have to wait to get on [ph] profy (00:48:16)?

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

A

Well, I think coverage and payment are two different things. And so from the standpoint that they attempt to appropriately value the procedural component associated with iDose, that process continues, ongoing. We continue to have constructive dialogue with each of the three remaining MACs out there. Clearly now, we have, with NGS being added, 70% of Medicare lives with established professional fees and a whole lot of work that's gone in behind that to understand how to value that in price. So I think that process continue to unfold.

What you're talking about in the kind of the way you asked it with LCDs and the like is much more around coverage determinations. And on that, I would just say that there are clearly scenarios that are positive for us, scenarios that present headwinds or areas where we have to educate them more fulsomely. But going into it, we don't have a bias either direction in that regard. We're just focused on making sure that we're educating them properly, that they understand what they're looking at in terms of iDose.

The one clear positive, I'll say, in any LCD that gets established is that alongside of that comes Medicare Advantage coverage policy as well. And so you do have to – oftentimes the, I'll call it, commercial carriers that are behind Medicare Advantage policies, they will wait until formal LCDs are established to force them into having policies of their own. And so you can argue that there's certainly some opportunity associated with that should the LCD ultimately emerge from this line of work.

Operator: Your next question comes from the line of David Roman from Goldman Sachs. Your line is open.

David Roman
Analyst, Goldman Sachs & Co. LLC

Q

Thank you. Good afternoon, everyone. I want to just to come back to the market development and education efforts around Epioxa. A lot of what you're laying out sounds like it actually more mirrors that of a more mass market disease and something that takes a lot of education. I don't know if it's direct-to-consumer. As I look across other sort of rare disease categories and I'm thinking more in the traditional pharmaceutical and biotech categories, there is a lot of investing around payer education and physician education, but maybe you could help us out just give a little bit more flavor of some of the specifics around the investments that you're making and how we see those show up and over what time period?

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

A

Yeah, David, it's Joe. So, I think counter to a little – I'll start macro and then I'll get a little more micro for your question. But from a macro perspective, what you think of in terms of large population base patient education is there's are the legacy, I'll call it, direct-to-patient advertising commercial that you see on broadband television

during various sporting events or whatever it may be that is there to help make sure there's awareness being driven.

What's different with rare disease is it's much more of a needle in a haystack [ph] texture sub (00:51:27). And so, that effort – those efforts around awareness and detection, mirror that of that broader disease state or mass market, as you said, but they're done in a much more targeted way to make sure that you're trying to find those patients who are most applicable based on where they're at in their own disease journey.

And so, a lot more of that happens in different forms, in different communities that are more digital in nature where folks are actively seeking out what's causing the change in their vision. It's important to take a step back here and remember that, you heard Tom say this, but when only 13% of patients are being treated under the age of 18 and we know the vast majority of damage is happening – or certainly starting to happen 4and accelerating in the teenage years and into the 20s and yet the vast majority of patients aren't getting access at that stage, you really have to redouble your efforts to find them much earlier in that journey based upon those early symptoms and the early things that could be signs of keratoconus to make sure that they're getting proper access to the detection and the various things that are necessary to, at least, diagnose them as a keratoconus suspect.

And that's a really big investment from a commercial and marketing standpoint. And it's not just DTC, although that's obviously an important part of any education thing. There's a lot in terms of what you do with your field organizations. And just to put that in context, a little more micro level, David, today, the majority or if not all of the treating physicians for Photrexa are in the MD community, but you're very much reliant upon the optometric community where the patients first present themselves most often with visual acuity issues. But there are 50,000 optometrists and numerous other opticians that serve a little bit as a primary care physician. So, how you get to driving education awareness in that community both visually as well as with your salesforce and other marketing-related activities is a pretty significant investment.

Now that part of it is really just the beginning in terms of driving awareness and education, if you will. You also have to then support, at anytime you have a needle in a haystack patient, and again, you heard Tom referenced in the prepared remarks, but these patients – think about the number of insurance plans that are out there. And when you're only treating 10,000 patients, every single time one of those patients presents themselves asking for access to Photrexa, not Epioxa, it's like this is the first time that that insurer has ever seen a claim because you're talking about 10,000 patients. There's 5,000 plans in United States.

So, to that point of really making sure you demystify the insurance process, that you support them along that way with proper education as you go through that and ultimately, to the extent qualify and provide them with assistance as they go through are all major, major investments for us.

Now, the last thing you have to think is how that turns on. We're going to have, and Alex can comment on this in the context of the broader P&L, we're going to have some of this happens right away. Some of it certainly picks up steam as we make our way into 2026 at the beginning. And then as we start to get the J-code established and our standard-of-care network up and running the second half, we'll try to elevate that up to, I'll call it, a full scale effort supporting those patients in that process, in their journey as we make our way and certainly as we exit 2026 and 2027.

David Roman
Analyst, Goldman Sachs & Co. LLC

Q

Great. I'll leave it there. Thank you.

Operator: Your next question comes from the line of Richard Newitter from Truist. Your line is open.

Richard Newitter
Analyst, Truist Securities, Inc.

Q

All right. Excuse me. Thank you for taking the questions. I may have missed it, but I just want to make sure I'm understanding the components of your updated 2025 guidance and kind of how we should be thinking about the areas for 4Q and what's implied there. Can you just run through the segments? I know you provided a prior outlook for Corneal Health, and I think it was flat to low-single-digit growth for the year. Could you just give us a sense of what we should be modeling for that business and what the trend should be in the kind of the iDose sequential trend?

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

A

Yeah, Richard, happy to. I haven't addressed it yet, obviously, other than us announcing the updated guidance range of $490 to $495 million. Yeah, I think, first putting in context, the performance thus far in 2025 and obviously highlighted with the results in the third quarter has really continued to exceed our internal forecast. And based upon that, we did raise our expectations for the year.

The biggest thing here in the fourth quarter is not new. We called it out on the last call and that is to take into consideration the expected headwinds that may phase our Corneal Health franchise in the fourth quarter as we and, more broadly, our patients and customers prepare for the transition from Photrexa to Epioxa.

Secondarily, I would say that the fourth quarter is a little bit more of an elevated or more difficult comp from a year-over-year growth perspective in our US and International Glaucoma franchises as you're thinking about and kind of looking at dialing that in relative to where we've been in the last couple of quarters.

As you think about the individual franchises within that, I would say that for International Glaucoma, the dynamics here really remain unchanged from what we've talked about previously. We expect low-double-digit growth in the fourth quarter based upon that slightly tougher comp that I mentioned. And really combining that with the continued sort of competitive launch headwinds that exists in several key markets. So, nothing new there.

On the Corneal Health side, I referenced and I think a little bit of it, you'll back into the expectations there. We do expect to see a fairly material year-over-year decline, and that's certainly implied in the guidance as we navigate that transition that I mentioned before. And we've already started to see some early signs of that emerge even here in October post the approval of Epioxa. And we've even seen patients now starting to come and ask about Epioxa in favor of the existing Photrexa therapy that may be offered to them.

On the US Glaucoma side, we expect growth in the mid-40% range year-over-year in the fourth quarter. As our non-iDose business continues its stance and everything else, continues to stabilize, we would expect in a low-single-digit decline in the fourth quarter. So continue on that that progress back to about a more stabilized situation post the LCDs that have impacted it – that part of the business earlier in the year.

And we do expect continued growth obviously in iDose TR, although you may find implied in the guidance, it's tempered a little bit sequentially versus the current trends just given many surgeons have pretty full cataract schedules throughout the remainder of the year. I think it's a little bit early to start seeing the benefit from the NGS, I'll call it, professional fee tailwind.

And again, in general, this quarter's a bit of a tougher year-over-year comps on the growth standpoint, but I think what you'll find is that it continues to be largely all systems go across the majority of our business with the one step back being really in the Corneal Health franchise as we transition there.

Richard Newitter

Analyst, Truist Securities, Inc.

Q

Okay. Thanks. And then maybe just a – two follow-ups. Consensus for iDose for 2026 is somewhere in the $220 million to $225 million range, I think. Anything you can express in terms of comfort or not kind of there just so we can benchmark ourselves as we put preliminary numbers out there. And then the second follow-up just on the trial timelines that you were talking about for combo cataract and MIGS plus iDose, can you just give us a sense as to when those that are going to read out and the ones that have read out, where they are?

Joseph E. Gilliam

President & Chief Operating Officer, Glaukos Corp.

A

So, I'll start and then I'll let Tom comment on the trials associated with iDose continue to be ongoing. Really, Richard, as I mentioned earlier, I think we're going to stay with the broader guidance that we've given for next year of $600 million to $620 million. We'll talk a bit more on the constituent parts of that on the fourth quarter call you referenced the consensus on iDose. Clearly, as we enter into next year, iDose is no longer the only, I'll call it, material variable that you all will be focused on in assessing. And so, I want to make sure that we talk about that in the same context, at the same time as we talk about our expectations for Epioxa in the Corneal franchise throughout the year.

What I had said based on the earlier question was if you think about the third quarter result, the $40 million we're at this point already [indiscernible] (01:00:42) on $160 million run rate based again largely on the continued progress within the three MACs that have established professional fee coverages entering the quarter, that being Novitas, Noridian and First Coast. So I feel good about the momentum in that part of the business and where it's heading and what that will mean for 2026. But we'll get more granular on the exact numbers as we set or update our guidance for the full year when we get to the fourth quarter call. Tom.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

A

Yeah. I'd be happy to answer the questions. We're looking in two pretty major level one based on our clinical studies and that's to look at iDose plus cataract versus cataract surgery alone, which we're currently enrolling. And as well, we're looking at a study that evaluates iDose plus infinite versus infinite alone.

And so, you can imagine the goals both those studies will be to validate and to show the incremental advantage of using iDose in combination with cataract surgery and certainly iDose in combination with infinite versus infinite alone. So, these are important studies as we go forward. And really, they're both currently under enrollment, it really will depend on when we choose to be able to show what [ph] kinds (01:01:59) of data we want to show. And so, I would probably prepare the investment community for a 2027 timeline, which would give us the ability to have, really, six months to a year of follow-up in each of these patients that we had published. And it may come as early as late 2026 if we choose to be able to terminate the study, or I should say, be able to look at these patients at earlier time points.

Typically, three months would be the earliest that I'd be able to publish. So, at such parameters to look at a late 2026 to 2027 with very, very important follow-up clinical data for the use of iDose.

Operator: Due to time allotted for the question-and-answer session, we please ask you to limit yourself to one question. Thank you. Your next question comes from the line of Mason Carrico from Stephens. Your line is open.

Mason Carrico
Analyst, Stephens, Inc.

Q

Hey, guys, thanks for fitting me in here. So, in the context of Epioxa pricing, could you just remind us how the bulk of Photrexa volumes are built today? You guys utilize a book-and-bill strategy with clinics, and if so, how much of your volumes rely on that?

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

A

Yeah, Mason. With Photrexa today, we offer both buy-and-bill acquisition options as well as specialty pharmacy. The specialty pharmacy option is something that we've really brought online primarily over the last couple of years, and that's been a growing percentage of the overall mix. But beyond that, I'm not prepared to disclose the exact mix between those. But I will say that specialty pharmacy has become an increasing material portion of the overall acquisition mix.

Operator: Your next question comes from the line of David Saxon from Needham & Co. Your line is open.

David Saxon
Analyst, Needham & Co. LLC

Q

Great. Yeah. Thanks, guys. Thanks for fitting me in. Yeah, just another one on Epioxa. So, can you just talk about the cadence of getting coverage by commercial payers in 2026? I mean, if Photrexa will be phased out next year, how much coverage do you think you can end the year with 2026 with? And then in terms of placing the new cross-linking machines for Epioxa, kind of what's the strategy there for either upgrading or trading out the current installed base? Thanks so much.

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

A

Yeah, David, I'll start with the – on the capital equipment in establishing the site-of-care network. Epioxa does require a new piece of capital equipment in O2n system that will be made available. We are already now, with the approval in hand, hard at work out in the – with customers to establish that changeover. As you might expect on – in the launch of this nature, we've got a variety of options for customers to acquire, to lease, and to swap out their existing equipment to make that the capital equipment component is not an impediment to them getting into providing Epioxa as a therapeutic solution.

For the payer coverage side2, you may recall on prior calls that we've been investing pretty heavily in this part of our organization alongside our field-based reimbursement. And that team is already hard at work similar to establishing our site of care. But in this case with the payers around direct education efforts, meetings and make sure they understand what we disclosed here today in terms the therapy, its benefit to patients, engaging with those in the medical community to make sure they're educated around that and ultimately try and establish that coverage.

I think on the positive side, this is not a the first launch in the category, and many payers already recognize that corneal cross-linking is the standard of care when it comes to arresting the progression of this sight-threatening disease. And from that standpoint, we need to educate them that on the patient benefits of which there are many,

as you heard Tom mention them during his remarks, as to the why behind the patient need to achieve access to Epioxa going forward.

So that process is already well underway. We'll provide updates as we make our way throughout the year, but it's a little bit premature for us to establish benchmarks in terms of payer coverage expectations. I'm optimistic that when we engage in the conversation around the benefits that we're providing to the patients that are at the end of this, that we'll move the needle as aggressively as we can with those payers to get that access going throughout the course of 2026.

Operator: Your next question comes from line of Joanne Wuensch from Citibank. Your line is open.

Joanne K. Wuensch
Analyst, Citigroup Global Markets, Inc.

Q

Thank you so much. I have so many questions, but I'm going to try and stick to my one, which is when you gave guidance for 2026, what is included in that for Epioxa and what is included for that for iDose? I'm just trying to piece it all together because at that ASP, those numbers can ramp really fast.

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

A

Yeah. Thanks, Joanne. And so, as I mentioned before, I think we want to make sure that we were establishing an overall range for 2026 in light of the Epioxa approval and announcement, and the number of moving parts. And for right now, I think I'll just leave it as what I said earlier that we're confident in that range and we're confident there's a variety of paths that should enable us to meet those expectations. We'll provide a lot more color on our fourth quarter call around individual constituent parts of that.

But you raise a totally valid and somewhat obvious point in that with the wholesale acquisition cost and what that means in terms of relative to that, implied in there is a material step down in the number of patients being treated with Epioxa in 2026 as we navigate all the things that I've already mentioned, including getting the standard-of-care network established, the miscellaneous code before establishing J-code, the time in which it takes to update the payers for that J-code in the second half. It'll be a journey through the year of really getting the foundation underneath us so that can be focused primarily on clinical care as we exit the year and head into 2027.

Operator: Your next question comes from the line of Michael Sarcone with Jefferies. Your line is open.

Michael Sarcone
Analyst, Jefferies LLC

Q

Hey, afternoon. And thanks for squeezing me in. I was just going to try to ask the MIGS case for iDose in a little different way. Joe, when you think about your internal modeling and what you're expecting for iDose maybe over the next three years, call it the midterm range, how do you think about the mix of iDose performed in the standalone setting versus combo cataract?

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

A

I think that's very surgeon specific. And if you look even at the adoption we've had now, our highest volume customers today do actually very little iDose in combination with cataract surgery. Clearly, as you make the

product available in that wider arena, the lower-hanging fruit for some surgeons who primarily focus on cataract surgery is for them to be doing it in combination.

And so, I think in the intermediate term, some of that "lower-hanging fruit" for that portion of the community could drive the mix a little bit closer toward – or a little bit more oriented towards the combo cataract setting. But certainly, as you get out into the 3, 5 and 10-year time horizon, the vast, vast majority of it is interventional in nature and standalone being the key driver of our long-term opportunity.

Operator: Your next question comes from the line of Anthony Petrone from Mizuho Group.

Anthony Petrone
Analyst, Mizuho Securities USA LLC

Q

Thanks. Maybe one on the follow-up discussion with FDA on iDose reapplication, as you mentioned in the prepared comments in the materials and the third quarter that those discussions are still ongoing. So, maybe just what is the latest there and when do you expect FDA to make some sort of announcement on the supplement for iDose reapplications? And what is really the read through of that element of the iDose story as we head into the CAC meeting on November 12? Thanks.

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

A

Yeah, I'll be happy to take the first part of that question. So, just to reiterate, the PDUFA date has already been established by the FDA. It will be January 28 of this coming year, 2026. And we expect then to get an answer to our appeals, to be able to have readministration of the iDose device.

As I said many, many times before, we take a belt-and-suspenders approach to this. The reason we have iDose TREX already in a clinical trial and moving forward is to have the ability for surgeons to have a de facto exchange product available when their current implantations of iDose come to term in three-plus years. And so, we think we're in great shape from that perspective. As I've said before, and I'll choose my words carefully here, we are hopeful, but we're not counting on the FDA giving us the [ph] nod to move forward was (01:12:27) on the readministration.

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

A

And as it relates to the -- I think the second part of your question on the CAC meeting and some of the considerations around there, it's actually I think a thoughtful question because it's important to think about iDose is an FDA-approved pharmaceutical with a label and its end use is pretty similar to topical PGAs and other glaucoma medications.

It's different than a medical device. And I say that because what matters in an FDA-approved pharmaceutical is what is the contraindications that are on with it. And the currently [ph] reimplantation (01:13:02) is the primary contraindication for iDose TR, it's not whether it's utilized in combination with cataract surgery, other MIGS devices or medications for that matter. Today, iDose TR is approved with an open label that's very similar to topical PGAs.

If indeed, as Tom was talking about, we were to achieve the PDUFA date around reimplantation, that would bring that to remove or at least modify that contraindication and certainly help us in terms of opening up that part of the market.

Anthony Petrone
Analyst, Mizuho Securities USA LLC

Q

Thank you.

Operator: Your next question comes from the line of Danielle Antalffy from UBS. Your line is open.

Danielle Antalffy
Analyst, UBS Securities LLC

Q

Hey, good afternoon, guys. Thanks so much for taking the question. I was at the AAO meeting a few weeks ago and I felt like the takeaway from [ph] that respect (01:14:03) they're looking for specific things, right. But was the focus on building out a standalone MIGS practices? I attended a lunch session that was focused on that, and I'm just curious about how you guys think the launch of iStent infinite into standalone is going, where you see standalone as a percent – I'm not asking iDose, right. I'm asking for the total MIGS patient population here, where you see standalone MIGS going over the next three to five years and what are the sort of logistical things with practices that you think need to happen in order to enable continued growth in that market? Thanks so much.

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

A

Yes, Danielle. I think it's a great question and a good one here as we are wrapping up this conversation. I mean, everything that we've been doing for a couple of years now and certainly as we are moving forward, is around driving that standard of care for Interventional Glaucoma and acting on behalf of these patients.

And so, from that standpoint, it doesn't surprise me, although I'm always happy to hear, that as you were doing your checks and rounds and at AAO that you heard that same thing, that any time you have a profound standard of care shift, there are logistical hurdles. But the first one you have to get through is the clinical component of this and the clinical buy in from the community.

And you've heard us say this before, but I'll reiterate it. We couldn't be more happy with the receptivity from the physician community around the need to act on behalf of these patients in an interventional way. And whether that tool is iDose, whether that tool is iStent infinite or any of the other things that might be a part of their toolkit, if you will, and trying to tackle this sight-threatening disease, it's encouraging to hear that they're – that they continue to sort of move forward.

But on the logistical side, it does change. It is changing the education of the optometry referral community. It's changing the scheduling blocks. It's changing the time and allocation of that time within their OR time, their surgery centers, and the like. There's a lot that goes into this over time. It's about establishing proper reimbursement and market access to the various tools that are there to treat patients the way you want to treat them as a surgeon or a physician.

So each one of these things play themselves out and none of them are overnight success stories. Each one of the things you make incremental progress every day, every week, every month and every year. And I think it's why when we look out over a 3, 5 or 10-year period, we're so optimistic about where this is all heading because it's all rooted in the right paradigm shift of clinical care.

The rest of it, we have to keep our head down to keep executing against that. And if we do that, you're talking about a market opportunity, as you've heard me say many times, that there are 21 million or 22 million eyes in the

United States with ocular hypertension or glaucoma, 12 million to 13 million of those eyes today are already being actively treated, maybe imperfectly, in the form of topical eye drops, but they're being treated.

You compare that to what we're talking about in the earlier days of combination cataract and MIGS where you had about 0.5 million eyes. So when we look at this over a prolonged period of time, we expect the vast majority of procedures, irrespective of the tool, to be done in that standalone and Interventional Glaucoma market [ph] sure lives (01:17:31) because of the relative size of those market opportunities and the clinical need for that.

Operator: Thank you. And with no further questions in queue, I would like to turn the conference back over to the company for closing remarks.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

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

Operator: This concludes today's conference call. You may now disconnect.