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Glaukos Corp. (GKOS)

Q2 2024 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Hello, and welcome to Glaukos Corporation's Second Quarter 2024 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 participants are currently in a listen-only mode. Later, we will conduct a question-and-answer session. [Operator Instructions] To 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 provide the investment community with a summarized and easily accessible reference document that details the key facts associated with the quarter, the state of the company's business objectives and strategies, and any forward statements or guidance we may make. This document is designed to be read by investors before the regularly scheduled quarterly conference call. As such, for this call, we will make brief prepared remarks and transition into a question-and-answer session. 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, 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, 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. Review today's press release and our recent SEC filing 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 into Glaukos's ongoing results of operations, particularly when comparing underlying results from period to period. Please refer to the tables in our earnings press release available on 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.

All right. Thanks, Chris. Good afternoon, and thank you, all, for joining us. Today, Glaukos reported record second quarter consolidated net sales of $95.7 million, up 19% on a reported basis and 20% on a constant currency basis versus the year-ago quarter. As a result of our strong performance, we are raising our full year 2024 net sales guidance range to $370 million to $376 million versus $357 million to $365 million previously.

Our second quarter record results were broad-based, with growth being driven by both our US and international glaucoma franchises, where we continue to accelerate efforts to expand access to interventional glaucoma tools for the benefit of physicians and patients. Our goal to advance and improve glaucoma care by driving earlier intervention continues to build momentum as we lead and work closely with surgeons and thought leaders globally to organically drive this broader evolution in the standard of care.

Within our US glaucoma franchise, we delivered record second quarter sales of $49.8 million on strong year-over-year growth of 26%, driven once again by strong growth within our overall iStent portfolio, led by iStent infinite, along with early but growing contributions from iDose TR. The utilization of iStent infinite for glaucoma patients that have failed medical and surgical therapy continues to expand as our ongoing clinical education efforts and an improving market access landscape takes hold.

Importantly, during the second quarter, five of the seven MACs issued draft MIGS LCDs that establish coverage for iStent infinite that is consistent with our original reconsideration request. We have actively supported industry efforts to encourage areas of improvement in these draft LCDs and look forward to their finalization as we expect it will be an important step in unlocking the remaining Medicare Advantage and commercial plan coverage for iStent infinite.

Turning to iDose TR. I'm pleased to report that we successfully advanced execution of our detailed launch plans for this first-of-its-kind intracameral procedural pharmaceutical that was designed to deliver glaucoma drug therapy for up to three years. Outcomes and feedbacks from early cases continue to be very positive and 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.

During the quarter, we successfully expanded access of iDose TR to all of our sales field personnel, while continuing to target those surgeons and facilities comfortable utilizing a miscellaneous drug code. In addition to our commercial efforts, the launch has been supported by growing set of clinical literature, now consisting of seven different peer-reviewed publications highlighting iDose TR as a transformative new treatment alternative for patients suffering with glaucoma and ocular hypertension.

As you know, a key element to the stage-gating of our iDose TR commercial launch is market access. As scheduled, a unique, permanent J-code for iDose TR, J7355, became effective earlier this month, on July 1, 2024. This now effective J-code is expected to increase patient access and will allow us to expand training plans to future waves of surgeons and facilities. We're also advancing efforts to secure professional fee coverage and payment with MACs, as well as establish commercial and Medicare Advantage coverage now that the permanent J-code is effective.

As noted in the past, we expect increase in adoption as reimbursement confidence is gained by our customers over the remainder of 2024, and more specifically, in the fourth quarter heading into 2025. Earlier this month, CMS issued their proposed 2025 facility fee and professional fee rules that, as drafted, largely maintain the 2024 reimbursement assignments and rates associated with our procedures. Finally, as promised, we've now engaged the FDA in a formal regulatory dialogue regarding the re-administration of iDose TR, and beyond that, remain on track to commence a Phase 3 clinical trial for iDose TREX, our next-generation iDose therapy by the end of 2024.

Moving on, our international glaucoma franchise delivered record sales of $26.1 million on year-over-year growth of 17% on a reported basis and 21% 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 MIGS forward as the standard of care in each region and major market in the world. During the quarter, we also finalized a new French CEPS agreement that provides for adjusted rebate tiers and successfully expanded the addressable patient population to reflect the growing adoption of iStent inject W in France. The net effect of this new agreement was favorable to our second quarter reported revenues and is expected to remain a tailwind for the remainder of 2024.

While we remain in the early stages of expanding our IG initiatives globally, our efforts are progressing well, evidenced by several recent international regulatory approvals, including for iStent inject W in China and standalone usage indication for iStent inject W in Japan, alongside the approvals of both iStent infinite and PRESERFLO in Brazil earlier this year. And finally, our Corneal Health franchise delivered sales of $19.8 million on 7% year-over-year growth, including Photrexa net sales of $16.7 million. As discussed last quarter, our second quarter results reflect the impact of Photrexa realized revenues as a result of our entry as a company into MDRP.

Shifting gears, we continue to prudently invest in and successfully advance our pipeline of novel promising platform technologies that we believe have the ability to significantly expand our addressable markets and fundamentally transform our company over time. This includes Epioxa, our next-generation corneal cross-linking therapy, for which we continue to progress towards data readout in the second half of this year for the second Phase 3 pivotal study supporting our NDA submission that remains on target for the end of 2024.

Beyond Epioxa, we also continue to make encouraging progress across our robust portfolio of clinical and preclinical programs focused in the areas of glaucoma, retina and rare disease, where our milestone targets and associated timelines remain on track and unchanged versus previous disclosures. We remain excited about the significant potential value that we believe our pipeline programs may create. At the same time, as we've discussed, we continue to prioritize the cadence of our investments as we strive to strike the right balance of risk-based spending and our capital position now and in the future.

On that front, during the second quarter, we opportunistically executed a transaction to exchange $230 million in principal amount, or 80% of our convertible senior notes, due 2027 for common stock, helping to further solidify our already strong capital position through a deleveraging and derisking of our balance sheet, as well as significant reduction in future cash interest expense. This convert, originally issued in June 2020 during the height of the pandemic, has proved to be a beneficial financial instrument that provided us with the financial flexibility to continue investing in our pipeline through COVID and other reimbursement-related uncertainties.

In conclusion, I'm pleased with the strong commercial development execution of our teams that have demonstrated so far this year. We look forward to continue to build upon the growing momentum in our business over the course of the coming quarters and years. Our foundation is strong and we are ideally positioned to continue transforming vision for the benefit of patients worldwide.

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

QUESTION AND ANSWER SECTION

Operator: All right. [Operator Instructions] Our first question comes from the line of Tom Stephan from Stifel. Please go ahead.

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

Q

Great. Hey, guys. Thanks for the questions and congrats on a nice quarter. Maybe I'll start with iDose. Any comments on 2Q 2024 sales contribution or instead maybe any color on the business growth in US glaucoma if you prefer to give that? And then, if you could also comment on 3Q trends you're seeing with the J-code now in place, that'd be fantastic.

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

A

All right. Thanks, Tom, and thanks for the comments. Not even a softball warmup before we dive into the iDose questions, but happy to start there and then we can take it further as you guys deem. I'll start with the overall US glaucoma performance. Obviously, Tom alluded to the strength there with growth once again accelerating in the second quarter to 26% on a year-over-year basis, and that was driven both by mid-teens growth yet again from our iStent portfolio and infinite standalone utilization in particular, alongside better-than-expected contributions from iDose TR.

I think the second part of your question, as we think about the third quarter with the J-code in place, and now we've kind of worked our way through the first month of that. I think it's important to say, I mean, obviously, we continue to be positive about the progress we're making with iDose launch in general, a ton of which happened in the second quarter, as we make our way through July that continues. In some respects, Q3, as we've said all along, is a bit of a – I'll call it, a reset moment as you had the J-code in place. And on the positive side, you'll have some accounts where their administration will now allow those first cases once the J-code has been established entering the quarter.

Frequently though, you also need to see that get billed and ultimately see reimbursement working before you'll fully open that up, and those same dynamics hold true for many of the accounts that did their first procedures on the miscellaneous code during the second quarter. So, I think as we make our way through here, you hope to continue knocking down those hurdles and really see that momentum build from where we were at certainly in the first half of the year.

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

Q

Got it. That's great. So, just as a quick follow up, if I dial in maybe 16%, 17% growth in the core US glaucoma business, I'm arriving at around, call it, $9 million of iDose. Is that fair? And then, my follow-up would just be, just on profitability. For breakeven, on a cash flow basis, is it some point in 2025 for total company maybe a reasonable target as we think about iDose accretion really starting to take hold in a more meaningful way? Thanks for taking the questions.

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

A

Yeah. Thanks, Tom. I'll start, and then I'll turn it over to Alex for the profitability side of that. I don't think the math that you did there, I know you're trying to do it on the fly as we're doing that guide. I don't think the math quite shakes out that way. So, you can redo that. I'm not going to comment and endorse a specific number on it other than just to reiterate what we said, when you kind of look at the overall growth profile of the business driven by mid-teens growth from iStent portfolio and the rest being larger than the expected contribution from iDose. Alex, you want to talk about profitability?

Alex Thurman
Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

Yeah. On profitability, Tom, it's obviously a great question and top of mind. And so, as we look forward, we've always said that the company would look at profitability in – on the other side of iDose, we're getting there. And to your point, you talked about 2025 and that's going to be a key year for us as far as iDose ramps up. Our goal internally, to be quite frank, is to get back to a place where we are getting to cash flow breakeven and then starting to generate cash as opposed to having a focus on profitability in the near-term. As Tom mentioned in his opening remarks, we've got a rich pipeline, there's a lot of value there, there's lots of investments to be made. But we really would like to get back to cash flow breakeven and then start to build up that cash flow over time, and I do think in 2025, we should start to see some of that occur.

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

Q

Got it. Okay.

Operator: Sorry, I'm going to cut you off a little bit, but our next question comes from the line of Larry Biegelsen from Wells Fargo. Please go ahead.

Larry Biegelsen
Analyst, Wells Fargo Securities LLC

Q

Hey. Good afternoon. Thanks for taking the question and congrats on a nice quarter here. Joe, if I look at the midpoint of the guidance range, it appears the growth rates are pretty similar in the first half and second half. Why wouldn't the growth be higher in the second half given the ramp of iDose? And I guess, is your commentary on the J-code earlier that iDose sales, you're not expecting to go up sequentially in Q3? Thanks.

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

A

Yeah. Thanks, Larry. A couple things to unpack there as it relates to the guidance and the seasonality. I mean, obviously, as you alluded to, we're super pleased with how the first half of 2024 shaped up, and I think we're able to raise our full year guidance by even more than the Q2 outperformance. As you look to translate that into, call it, our growing momentum into the second half, I want to point to a couple key things. First, the normal considerations around Q3 seasonality, which I'm happy to elaborate on more, and the FX headwinds that we called out as part of our press release.

You're also fairly aware of the continued impact of the MDRP as a headwind to our corneal franchise, with the most significant of that impact likely expected in the fourth quarter. When you think about iDose TR and the growing focus on our commercialization there, we want to be a little bit cautious that, as we clear the expected market access headwinds and hurdles, if you will, it may dampen some of the performance we've seen out of the stent portfolio in the first half as our sales organization leans further and further into, obviously, the iDose launch.

And the last thing really is kind of what I alluded to with Tom's question, which is the third quarter being a bit of a J-code transition quarter. It's really hard to pinpoint in such a small and precise period of time, Larry, when you're in a launch like this. The reality is that the sooner some of these things start to play their way through from a payment standpoint on the J-code in the quarter will accrue some more benefit in this quarter, but it's hard to nail that down in the context of such a precise period of time. All I can really say is that, as we look at the overall launch thus far, we're increasingly confident in where we're headed with this product and what it's going to mean certainly as we get into the fourth quarter and translate that into 2025 and beyond.

Larry Biegelsen
Analyst, Wells Fargo Securities LLC

Q

That's helpful. I hate to do this, but a math question, Joe, another way of looking at it. US glaucoma sales were up about $4 million to $5 million sequentially in Q2 last year and the year before. This year, US glaucoma sales are up about $8 million sequentially. Should we just assume the difference this year versus prior years is primarily iDose or roughly $3 million to $4 million sequential increase in iDose? Thanks for taking the question.

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

A

Yeah. Sure. I mean, I think there's a handful of ways that you could try to back into the specific number that's there. I think that where you're headed on that is probably closer to reality than I think the early math that was suggested before. But most importantly is that, we made significant progress in the second quarter with iDose and that's while having, obviously, the imposition of miscellaneous C-code in that environment there. So, again, that combined with the continued clinical feedback that we've been receiving really drives that confidence we've got and how that's been translated into the increased guidance that we gave today.

Larry Biegelsen
Analyst, Wells Fargo Securities LLC

Q

Thanks for taking the questions.

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

A

Thanks.

Operator: All right. Our next question comes from the line of Ryan Zimmerman from BTIG. Please go ahead.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Hey, guys. I'll keep the fastballs going and not give any softballs there. So, Tom, I want to ask about your conversations, your early feedback on the re-administration potential with iDose. Do you know at this point, whether you need a trial for that, kind of where do they stand on your existing data, [ph] they'd include (00:20:39) obviously, re-administration. Anything that you can kind of share with us at this point that maybe sets up your outlook on that potential?

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

A

Yeah. I'd be happy, Ryan. So, as you know, we've talked about we've submitted the reconsideration request. We'll begin an active dialogue with the FDA, which I presume will be over the next several months. They don't

have a statutory obligation to respond to us in a specific period of time. And so, they're not bound by typical impositions that we may go back and forth as we look at this over time.

I think, as I talked about before, it was kind of a late-stage in our mind the decision by the FDA to restrict us to a single administration. So, we didn't have the opportunity to make a more fulsome case at the tail end of the NDA adjudication prior to our successful approval. So, now we have that opportunity. So, the short answer is, no, we don't need any additional clinical trial information or clinical trial performance to be done. I think what we need to do and what we are doing is presenting the narrative on a compelling case, given the data that we've already been able to perform and have available, and I think we have a strong case. Having said that, we know that the, I'll call it, conservatism of the FDA, we suspect through the initial decision.

So, I have been conversing both investors and analysts to let's not get over our skis here. We're hopeful we may be able to make progress, but we're not counting it on. So, we'll make every successful effort to apply for re-administration of the iDose device, and what I've said before and I believe is that, we have a belt-and-suspenders approach here. If we're successful moving forward with iDose TREX, of which we're on track to begin the clinical trials by the end of the year, if you do the chronology, I suspect we'll be in a position to become a de facto device and a procedural pharmaceutical re-administration component for those patients that have served the full term of their initial iDose device. So, I like where we're at, I like how we're approaching this, I think we will make a strong case, and then we'll see. And I clearly will keep both you and the investment community informed once I've received a final decision from the FDA.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Okay. And then, my second question is just around what you're seeing today with adoption of iDose. And what I want to understand is, are you seeing competitive switches from DURYSTA? Are you seeing the adoption of iDose either before drops, after drops, before SLT? Can you just kind of talk about where iDose is shaping up in kind of that treatment paradigm? Thank you for taking the questions.

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

A

Yeah. Ryan, I'll start, and Tom may want to add color on this, too. From our standpoint, I think it's a little bit early to be making grand calls around exactly when and where it's being adopted, but I'll comment a little bit on where we expect it to be adopted. And from that standpoint, when you think about the label that exists with iDose, we would expect it to be a early option for intervention in standalone patients regardless of their disease severity going forward. And to your point, I think each surgeon will have a different view on the algorithm in which they deploy it, some will likely follow SLT, some will follow DURYSTA, some will put it in front of that. But I think, in general, what you're seeing with the overall interventional glaucoma shift is a mindset towards more proactive therapy for these patients and not relying on disease progression following years of increasing drop therapy. And I think all parties will benefit from that, and in particular, iDose TR and Glaukos.

Ryan Zimmerman
Analyst, BTIG LLC

Q

Thanks, guys.

Operator: Our next question comes from the line of Matthew O'Brien from Piper Sandler. Please go ahead.

Phillip Dantoin
Analyst, Piper Sandler & Co.

Q

Hey. This is Phil on for Matt. Thanks for taking our questions and congrats on the record quarter. Just for starters, I think Q1 saw 15 total implanting surgeons with about six weeks total of rollout. Any update on the implanting surgeon base in Q2? And just to keep the quick math train rolling here, I think we triangulated about just under one iDose per surgeon per week in Q1. Is that the right way to think about things especially in Q2?

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

A

Yeah. So, I think, Phil, what I would say there is that as we – pretty much everything with the launch has gone exactly as we planned and exactly as we told you we intended to execute. Of course, anything can happen, but so far so good from that standpoint. Across the board on the market access related items, we've seen the [ph] facility fee turn on (00:25:43) in Q2, the J-code in Q3. We're making professional fee progress, we saw the first of which to the schedules in the Noridian region come out this past quarter. So, the wheels of progress continue to grind on each of those fronts.

As you think about it from the commercial sales standpoint, we opened up our early access program, which is what you were referencing, when we had a planned sort of launch with the top 10 to 15 surgeons in the first quarter. We've opened that up to our entire US glaucoma sales force in the second quarter, as you heard Tom reference. And we saw a lot of progress as a part of that, as referenced or as seen in our – evidenced by our early results. You still have the headwind in practices that are comfortable with the gymnastics required with executing in the miscellaneous drug code. And so, I wouldn't underestimate that. And I just think that, taking a step beyond that in the context of how many surgeons have been trained and the average procedures per week, I think it's just a little premature for that. That's something that we'll start to get a much better handle on the trending of and decide how we communicate with that to you all as we kind of make our way through the year and start getting into 2025.

Phillip Dantoin
Analyst, Piper Sandler & Co.

Q

That makes sense. Thank you. And then, just my follow-up on iDose. As the excitement grows beyond it, call it, friends and family and the broader glaucoma – Glaukos user base, any competitive MIGS switches pulled over by iDose adoption from competitors and thoughts on maybe a core stent halo effect that you might see as iDose adoption grows?

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

A

Yeah. I mean, I think that in general, we've invested an awful lot of capital and time to generate an exceptional amount of data that surrounds all of our products. And whether that be the legacy iStent inject in combination cataract or iStent infinite now iDose, I think the totality of that portfolio is pretty compelling to practice as they think about the evolution of their care for these patients. And I certainly hope that we're benefiting from that, and as you referenced the sort of halo effect, the ability to treat patients, first and foremost, with iDose and ultimately as the disease progresses with iStent infinite is a pretty compelling value proposition that I think we're just now beginning to capitalize on.

Phillip Dantoin
Analyst, Piper Sandler & Co.

Q

Thanks so much.

Operator: All right. Our next question comes from the line of Allen Gong from JPMorgan. Please go ahead.

Q

Hi. This is actually [ph] Rohan (00:28:20) on for Allen. Thanks for taking our question. I was hoping that you could elaborate a bit more on what you meant by reset in third quarter. Obviously, I understand the J-code transition, but in light of that, when do you kind of expect to get to a full launch for iDose, and what are kind of expectations around run rate exiting 2024 into 2025?

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

A

Yeah, [ph] Rohan (00:28:45). It's Joe. I think, first I'll start with the elaboration on that. I think, a launch like this, there is rarely a single black-and-white event that creates the unlocking. I think, the J-code, as we've always alluded, is an important component of that. I think, as you get into the fourth quarter and you have the J-code with a published ASP, that's an important component of that. As the pro fees continue to be established and become more solidified, that's an important component of that. And I think as you continue to move forward, quite frankly, as I said earlier, we're going to have more accounts, I think, start to open up. We've already seen that where they're just more comfortable operating the J-code environment than a C-code. But they're still going to want to see a payment or two before they really allow the surgeons to run and do what they want clinically. So, you have to kind of overcome that first basic hurdle and establish reimbursement confidence, whether that's through the payment of the miscellaneous C-code, no claims are outstanding, or is the payment of the J-code as we get going.

Sitting here today, obviously, and for those folks who've done procedures on the month of July, they'll have just now been submitting those, and those things will start to be adjudicated and paid over the course of the quarter. And it gets very difficult for us to then translate how quickly that also translates into increased surgical volumes and clinical adoption based on the clinical merits of the product versus the – I'll call it, the reimbursement confidence piece. And that's why you've heard us consistently say that the third quarter is a positive step in the right direction, but it is a transition into what we think will translate into growing momentum in the fourth quarter going into 2025. I probably stopped short of quantifying that specifically, but as you think about your models and you're working on our guidance and what we've implied through the commentary for the third and fourth quarter, I think that starts to give you a sense of what that means for iDose as we exit the year and enter next.

Q

Great. Thank you.

Operator: Our next question comes from the line of Harrison Parsons from Stephens. Please go ahead.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Hi. Good afternoon. This is Harrison on for George, and thanks for taking the questions. I wanted to start on your guidance and specifically the domestic glaucoma revenue segment of that. I was wondering if for the remainder 2024, if the base stenting business we should expect that same mid-teens growth, and then whatever is incremental, that should be from iDose, is that the way should be thinking about it?

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

A

Well, Harrison, I think I might make a slight tweak to what you just said. I think it was asked a little bit earlier. One of the things that we're anticipating or at least preparing for as a part of providing guidance today is that, as our team increasingly focuses on the iDose TR commercialization, that could create some growth headwinds, if you will, relative to what we experienced in the first half in our broader portfolio in the US glaucoma. So, said in a different way, I think we've seen, obviously, a strong pattern emerge in the first half of mid-teens type growth in our stent portfolio, and I'm not sure that we're counting on that, obviously, as we make our way through to second half and the attention increasingly turns to iDose TR.

I do think I can provide a little bit more color in terms of the directional growth by franchise to healthier. I think, as we think about it for the full year and the revised guidance, I would expect the Corneal business to deliver low-single-digit growth for 2024, and I'd expect the international glaucoma business to continue along the strong trajectories had and to ultimately deliver low- to mid-teens growth for the year, reflecting the strong first half performance. And if you do that math, it implies US glaucoma year-over-year growth of sort of the high-20s to approaching nearly 30% on a year-over-year basis when it's all said and done for 2024.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Okay. Got it. Yeah. That's helpful. So, I wanted to move towards the sales force strategy. I know you've talked about a phased launch there. I know all of your reps are calling on surgeons now. But could you give any more color on how many surgeons each rep is going after? Is it just their top one or two? And I guess, what I'm really asking is, when are we going to be at a full sprint there with all of your sales force going out to all of their accounts?

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

A

Yeah. Sure. And every member of our sales team will find themselves in a slightly different part of their own trajectory as it relates to the launch. But the way I would characterize it is, what we said in the last call, you start off by enabling the first handful. For some, it's one or two, and for others, it's a couple more of surgeon targets, getting comfortable with that, getting the sea legs associated with launching a product like iDose. And then, ultimately, as we get into the third quarter, you start to open that up in waves. Again, I am – at this point, it's a little less focus on the exact number of surgeons that we're enabling with the sales force. And I think the unlocking, if you will, of it has a lot more to do with when they start to see the payment flow through of the J-code, and for those who've already done it under miscellaneous C-code environment, the C-code.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Great. Thanks for taking the questions.

Operator: Our next question comes from the line of Margaret Kaczor from William Blair. Please go ahead.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Hey, guys. Good afternoon and thanks for taking the questions. Yeah. I'm going to keep on the iDose trend at least for the first one. As we think about the number of accounts that have implanted iDose and the doc trainings

that you've done on the back end, you're sort of referencing the J-code and all these catalysts that should hopefully unlock more of those. I guess, A, do you expect a meaningful increase in implanters versus kind of what we saw in the Q2 case? And then, at what point do you hit a consistent quarter run rate for doc trainings or you've got kind of infinite capacity, no pun intended, where that can go?

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

A

Thanks, Margaret. I'm going to sound a little bit like a broken record I think here. But in many ways, the gating item here to that consistency, I'll call it, of the ramp and the number of doctors being trained in any given quarter, et cetera, is really based upon when we start to see the consistent, and recurring and predictable payment to the J-code. And we expect that in relatively short order [ph] or maybe clear (00:35:43). But from that standpoint, as you enter into the third quarter, it's a normal grinding of the process, if you will, as the MACs for example bring the J-code online, as they start to adjudicate these things and pay them in a more typical payment cycle as the account can count on.

At that point, administrators stop becoming the ones who are dictating access the product and it becomes adopted from the clinical side, and the things that we all know, the benefits that we all know exist for utilization of iDose TR. And that's the reason why I think, when you all do your surveys, you see such positive feedback from the surgeons who are thinking about it from a clinical standpoint and how they will adopt that. And I think as we get ourselves through the third quarter and certainly as we enter into the fourth quarter and exit the year, I think we're going to start to see a lot more clinical adoption versus, I'll call it, market access or reimbursement-related conservatism.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Okay. And then, I'll switch over then, because you guys – you keep referencing the success of that. Is it fair to assume that infinite still remains larger than iDose at this point or not? And then, as we think about what's driving that interest for infinite at this point, can you talk to types of accounts, number of accounts that have adopted and how – or what is in your guidance over the course of the year that's implied. Thanks.

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

A

Absolutely. I mean, I think first – absolutely, our stent portfolio and iStent infinite remain the dominant component of our overall portfolio. If you just think back to what I said earlier in the call, with mid-teens growth on a year-over-year basis, that – it just implies that it's, obviously, the largest chunk of our US glaucoma revenue base as it exists today. Now, I do expect and we all do expect that will shift pretty quickly here as iDose continues to ramp. But as we sit here today, infinite is still the largest contributor to the overall portfolio on the US glaucoma side.

What's driving it? I think, it's exactly what it's intended for. As we enter into this year and coverage was there and established in a much more predictable and recurring way, our customers start to focus on the intended use case of the product, which is for those patients who fail surgical medical therapy. And if you think about it, for those patients, it just makes sense to intervene first with infinite before moving on to more invasive procedures is what you'd want for your family member in the same situation. And I think as our sales force is able to have that clinical conversation with these customers, you see more and more adoption of our surgeons utilizing it exactly as it was intended.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Okay. Thank you, guys.

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

Q

Hey, guys, this is [ph] Joseph (00:38:49) on for David. Two questions, I guess, on the iDose and I'll just ask them together. In the quarter, gross margin improvement, how much of that was maybe driven by iDose? And then, looking just like towards the launch throughout the rest of the year, is there any plans on hiring on the back of the iDose launch? You had mentioned maybe that the broader portfolio could see some headwinds from [ph] the tension there (00:39:17). So, I was just wondering if that was contemplated in the plan.

Alex Thurman
Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

Okay. Hey, [ph] Joseph (00:39:26). It's Alex, and I'll take the first question on the margin. So, we did have a little bit of a modest year-over-year increase in margin. It fell within our expected range of 82% to 84%. And so, I wouldn't say iDose was a major driver of that. In fact, quite honestly, the iDose facility that we turned on tends to be right now a headwind to our margin as we intend to see these inefficiencies in manufacturing as you scale up production on these product launches. So, at this point, we expect to see the margin accretion continue to expand over the course of next year on the back of the iDose as it fully launches.

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

A

And as it relates to the sales force and hiring plans, I think we've always been consistent how we look at this and we're going to stay true to the same approach we've had for a long time now, which is we're always evaluating territories and opportunities where territories get to a scale that it makes sense to grow our salesforce. We have no plans as it stands here today to make wholesale changes to the size of the structure of our force, but I would expect that over time, organically we'll be adding folks to support the needs of the glaucoma business.

Q

Okay. Great. Yeah. That's all from us and congrats on the record quarter.

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

A

Thank you.

Alex Thurman
Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

Thank you.

Operator: Our next question comes from the line of Joanne Wuensch from Citibank. Please go ahead.

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

Q

Good afternoon and thanks for taking the question, and congrats on the quarter. I want to shift gears just a little bit to US MIGS. I'm curious what is going on there that's driving, let's call it, ex-FX 20-percent-plus kind of growth. And also, if my memory is correct, when you gave an initial 2024 revenue guidance, it was for that segment to be up low- to mid-teens. Seems like that may need to be updated or the second half [ph] really don't (00:41:27) have a problem. Thank you.

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

A

Yeah. Hi, Joanne. I'll start on the latter first. When we started the year, what we said or at least on the last call was that you should expect low- to mid-double-digit growth from that international business. And on this call today, I referenced low- to mid-teens growth. So, in fact, for the year, that does imply a step up in the overall growth profile. I can point to a couple things. You heard Tom reference, obviously, the French agreement.

But I think the biggest thing there continues to be the blocking and tackling of our teams across the markets out there. We're still in the relatively early innings of changing the standard of care in the combination cataract market in many of these areas. And we're just now starting to turn on new product introductions and approvals that you heard Tom reference, as well as beginning to follow that with increasing focus on the interventional glaucoma opportunity and standalone care of these patients proactively, just as we're doing here in the US.

So, I think we continue to be enthusiastic about the opportunity outside of the United States and into these international markets. Having said that, you've always got currency considerations there. We have competitive launches. We've been dealing with that for the last couple of years. We continue to see that now, and that takes time to work through as folks try and trial, and hopefully, ultimately come back to products they know and trust in the Glaukos portfolio. So, we feel confident about where we're headed with that franchise and I think the increased guidance in that area reflects that.

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

Q

Thank you for that. And the timeline for bringing iDose outside the United States, what would that be? And have a great evening.

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

A

Thanks, Joanne. Yeah. From an iDose standpoint, the first thing you do is get the approval in the United States, and that was the focus, and then from there, you shift your attention in our case to evaluating various markets internationally. That's a complex environment as you know in the context of the world where reference pricing and things like that exists. And so, I think we'll be cautious about how we approach iDose TR and the timing of any market entries outside the US for now, but we'll keep you updated as we continue to make progress on that evaluation.

Operator: Our next question comes from the line of Rich Newitter from Truist Securities. Please go ahead.

Richard Newitter
Analyst, Truist Securities, Inc.

Q

Hi. Excuse me. Thanks for taking the questions. Maybe just going back over the components of the bridge, the guidance range from old to new. You gave some color there. I just want to make sure I'm getting all the pieces correct. It sounds like international glaucoma has a bit of a call up. You just said low-double-digits to low- to mid-teens, and obviously, your US glaucoma is now high-20% to low-30%, and that's a call up, too. But it sounds like that you're getting some of the – maybe the incremental iDose contribution masked by commercial sales [ph] distraction (00:44:41), but time trade-off from the rest of the glaucoma portfolio. Is there anything else in there? Did I get the pieces right? Can you put any quantification around those?

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

A

Yeah. So, I think taking a step back, just to confirm the first part what you said, I think the punch line is in the revised guidance, it's guiding up on the international side, it's guiding up on the US glaucoma side. And from a macro standpoint, if you think about it, we beat the quarter I think by something like $7 million, and when you look at the midpoints, we raised our guidance by $12 million. And so, all of that is incremental as we think about the overall growth profile of the business.

From the corneal side, the low-single-digit is probably a tick down from where we were at on our prior call, all really related to our entry into the Medicaid Drug Rebate Program, which we've talked about on previous calls. I think, from a US standpoint, you largely captured that, that's right. What I said was, as you can imagine, our sales force is going to be increasing leading into the iDose TR launch. It's going to take an increasing amount of their time as they're turning on and training surgeons as we make our way through the second half. And while I hope this doesn't happen, we're preparing for financially in our guidance some dampening of the growth profile that we saw in the first half in our stent portfolio.

Richard Newitter
Analyst, Truist Securities, Inc.

Q

Got it. That's really helpful. And appreciate you're not giving us the specific iDose number for 2Q. But whatever that number is, call it, $4-whatever-million, whatever it may be. In an ideal world, if you were in our shoes, would you ideally like to see the consensus modeling roughly flattish kind of sequential, and then a big uptick in 4Q or spread it out a little bit? Slight uptick 3Q, major uptick 4Q. Can you just – any kind of directional help there, it might help calibrate consensus relative to where you might want it.

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

A

Yeah. I mean, I think it's a good question. So, if you just focus and zero in on seasonality, not with any specific product in mind, but just seasonality of the business. As you know, the underlying procedure demand tends to favor Q2 and Q4 over Q1 and Q3 in ophthalmology in general. In recent years, we've seen a sequential Q2 to Q3 step down of several million dollars. And I think we would expect that at least to be the starting trend line again this year as the – as you heard me say the relative next leg up from an iDose growth standpoint is likely to be weighted more towards Q4 as we've indicated for some time. As I also mentioned, it's really hard when you're – the way that the launch lines up to be quite so precise in the context of exactly what will occur with the third quarter versus the fourth. And so, I think from that standpoint, it makes sense for us to be a little bit conservative, while we're obviously planning for more optimistic outcome for the third quarter as well as clearly in the fourth.

Richard Newitter
Analyst, Truist Securities, Inc.

Q

Okay. Thanks. Congrats on the quarter.

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

A

Thank you.

Operator: Our next question comes from the line of Steve Lichtman from Oppenheimer. Please go ahead.

Steven Lichtman
Analyst, Oppenheimer & Co. Inc.

Q

Thank you. Evening, guys. Wanted to actually ask on, just on US Corneal Health, appreciate all of the full year guidance, how should we be thinking about that business after you anniversary the MDRP? Do you anticipate it picking up or do you have some device-related headwinds as we get closer to Epi-on? So, how do you think about that as we move past this?

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

A

Yeah. It's a good question, Steve. I think from the Corneal Health side, you set it up correctly. First thing you have to do is sunset some of the Medicaid Drug Rebate Program entry headwinds. Some of those could persist into 2025 as well as that adoption in the Medicaid arena continues to grow and the rebates grow alongside of them. But as we get past that from a, I'll call it, a gross-to-net adjustment standpoint, our expectation is that the underlying business, ex that dynamic, should be returning back to or exceeding the kind of growth that we've expected in the past from that franchise, so what you saw in 2023. Ultimately, a lot of the activities that we are doing and will do would be in anticipation of preparation for a very important launch on the Epioxa product as we exit 2025 and enter into 2026.

Steven Lichtman
Analyst, Oppenheimer & Co. Inc.

Q

Okay. That's helpful. And then, apologies if I missed it, but how are you thinking about OpEx growth now exiting here from 2Q for the year? Thanks.

Alex Thurman
Chief Financial Officer & Senior Vice President, Glaukos Corp.

A

Hey, Steve. It's Alex. I'll take the OpEx question. And again, our OpEx is trending along exactly how we were trying to guide it for the year. If you recall, we had said to expect OpEx to grow this year around 10% of a base of about $360 million from last year. That puts you at a full year OpEx around $400 million. Through the first half, we have spent $192 million. So, if you just sequentially take a little modest step up over the next two quarters, you can get to the $400 million and that's what we would expect for the year.

Steven Lichtman
Analyst, Oppenheimer & Co. Inc.

Q

Got it. Thank you, guys.

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

A

Thanks, Steve.

Operator: All right. And our last question comes from the line of Anthony Petrone from Mizuho. Please go ahead.

Anthony Petrone
Analyst, Mizuho Securities USA LLC

Q

Thanks. I'll stay on the iDose theme here. And first question would be on the strategy for the 20% Medicare Fee-For-Service patients out there, just doing some checks and there's a little bit of, obviously, sticker shock with the out-of-pocket for those patients in the instance where you have to use two stents. So, is there a balance sheet strategy to sort of close that doughnut hole in that 20% Medicare Fee-For-Service?

And then, just as we look out in terms of iDose getting into [indiscernible] (00:51:10) with its product launch, you mentioned potentially some sales force adds, the $400 million. But could there – is this a scenario once we get to 2025 and certainly into 2026, the sales force addition sort of level off and you really start to see that leverage benefit in the middle of the P&L, and is that sort of the right timeframe for that? Thanks.

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

A

Yeah. Thanks, Anthony. I think, first, let's take a step back, something I think we've talked about on prior calls around the payer landscape, and obviously, all of this was factored into the significant amount of work we did in arriving at the price point for iDose TR and looking at it from an access standpoint in that context. You have to break it down into the three constituent parts. For traditional Medicare Fee-For-Service, I think that's what you're referencing with the 20% comment. For those patients, the vast, vast majority of them actually have low to no out-of-pocket, because of secondary insurance coverage. So, from that standpoint, access for the vast majority of those patients really shouldn't be limited based upon the price point that you're talking about.

The second group that I'll focus on is the commercial payer – the commercial patient population. And for that, I think where you were referencing the balance, et cetera, we should expect that, yes, we will have a co-pay assistance program like all drug companies of similarly priced drugs to take that burden off the table for those patients that have commercial insurance. So, from that standpoint, the access to that will be gaited much more by the policies and coverage of those payers, and not so much the out-of-pocket dynamics that you're referencing.

The last group will be the Medicare Advantage. That's not unusual to us versus any other pharmaceutical or device companies out there, where a significant portion of those patients, both will be subject to the burden of policy restrictions as well as relatively high deductible plans. And for those patients, you tend to see them get treated more often than not in the later stage of the years when they actually even through their out-of-pocket maximums through other procedures earlier in the year. And so, we'd expect for that patient population to weight more towards the back half of any given fiscal year.

As it relates to the iDose sales force, I think maybe I want to clarify something there. When I talk about organic adds for us in there, I really do mean nothing wholesale. Ophthalmology in general and certainly surgical ophthalmology, there is quite a bit of leveragability in that. So, while we'll continue to be smart and prudent about supplementing that resource where it's needed throughout the country, we're not talking about something that scales infinitely or that overnight rapidly changes alongside the iDose launch. So, our expectation would be that, you would start to see the leverage, if you will, I think in the way you asked the question, sooner rather than later as it relates to the iDose and the launch in our sales force.

Anthony Petrone

Analyst, Mizuho Securities USA LLC

Q

Very helpful. Thank you.

Operator: All right. I would now like to turn it back over to our team at Glaukos for closing remarks.

Thomas William Burns

Chairman & Chief Executive Officer, Glaukos Corp.

Okay. I want to thank, everybody. Thank you, all, for your time and attention today, and thank you for your continued interest and support in Glaukos. Thanks and goodbye.

Operator: That concludes today's conference call. Have a pleasant day.