U.S. FDA Approval of Furoscix ReadyFlow | mannkind | July 24, 2026

Moderator:

Good morning and welcome to the mannkind Corporation conference call to discuss the US FDA approval of Furoscix ReadyFlow. As a reminder, this call is being recorded on July 24th, 2026 and will be made available for replay on the mannkind Corporation website shortly after this call for approximately 90 days. This call will contain forward-looking statements. Such forward-looking statements are subject to risk and uncertainties that may cause actual results to differ materially from these expectations. For further information on the company's risk factors, please see the form 10Q for the period ending March 31st, 2026, this morning's press release, and the slides prepared for this presentation. Joining us today from mannkind, our chief executive officer, Michael Castagna, and chief medical officer, Dr. Ajay Ahuja. I would now like to turn the conference call over to Mr. Castagna. Please go ahead, sir.

Michael Castagna, PharmD:

Thanks, Operator, and good morning everyone. Thank you for joining us on what is an exciting day for mannkind. Here's our agenda for this morning. I'll start with the approval and what it means, then I'll turn it over to Dr. Ajay Ahuja, our chief medical officer, to walk through a clinical overview of Furoscix ReadyFlow. After that, I'll come back and talk about our launch strategy and we'll open it up for Q&A. Let me start with the approval. As of yesterday, I'm proud to announce that the FDA has approved Furoscix ReadyFlow. This is a milestone we've been talking about since we announced the scPharma acquisition. It's now our third FDA approval in '26, starting with the Afrezza conversion dose update in Q1, the pediatric approval in Q2, and now this exciting opportunity with ReadyFlow autoinjector here in Q3.

For more than 60 years, furosemide has been the gold standard for treating fluid overload, yet administration has been limited to oral therapy or IV delivery in the hospital setting. The ReadyFlow approval opens up the potential to transform fluid overload by setting a new standard in this emerging new class called NODs, also known as non-oral diuretics delivered at home. We also announced a $50 million pipe financing led by Frazier Life Sciences, which will support the $45 million contingent value rate payment triggered by yesterday's approval. Furoscix ReadyFlow is the first and only IV equivalent diuretic delivered via an autoinjector. It takes a proven concept behind Furoscix and makes it quicker to administer and easier to use. We are moving from a five-hour wearable infusion to a full dose delivered in under 10 seconds while preserving the PKPD, that performance that clinicians expect from IV furosemide. Ajay will take you through the data, but the takeaway is simple, IV-equivalent performance in a simplified delivery format. We believe that simplicity can change the role Furoscix plays in practice. It may allow clinicians to consider treatment for more patients in more settings and potentially earlier in the fluid overload episode, whether that be before a hospital-based intervention becomes necessary or getting patients discharged earlier from the hospital. This is why we view Furoscix ReadyFlow as more than a device enhancement. We see it as an opportunity to broaden utilization and accelerate growth of the Furoscix franchise.

We fully expect to launch this in Q3 and are looking forward to helping a lot more patients who are suffering from fluid overload as we move forward. The opportunity to use Furoscix exists on both sides of hospitalization. We estimate there are approximately one million addressable fluid overload events in US each year. Many heart failure patients are managed with oral loop diuretics, and this works for the majority of time. But treatment effectiveness can decline during episodes of worsening congestion due to reduced absorption, reducing the effectiveness of not only the diuretic itself, but the other essential oral heart failure therapies further compounding an already challenging clinical situation. When this

happens, oral escalation is no longer enough. That is an important intervention window. Instead of waiting for the patient to progress toward hospital-based care, Furoscix gives clinicians a subcutaneous IV equivalent treatment that patients or caregivers can use at home. A second opportunity emerging within the new NOD category is earlier hospital discharge. Patients who are clinically stable but require continued diuresis may no longer need to remain in the hospital solely for IV therapy, creating a significant new opportunity for ReadyFlow.

The third opportunity we see is around preventing or reducing readmissions within 30 days post-discharge. Roughly 20 to 25% of patients may return home with residual congestion or experience a recurrence shortly thereafter discharge. Furoscix allows clinicians to extend IV equivalent exposure beyond the hospital and continue managing appropriate patients at home during that transition.

Furoscix is not tied to a single care setting or a single moment in the patient journey. It gives clinicians the opportunities to intervene earlier, support to transition to home, and manage fluid overload across a broader continuum of care. We believe Furoscix ReadyFlow's simplified administration can make these opportunities more practical and ultimately broaden where, when, and for whom clinicians consider Furoscix as this new NOD category is established. Heart failure and CKD are not only high risk conditions, they're also among the most expensive conditions for Medicare spending and take up a tremendous amount of resources in the hospital setting. In heart failure and CKD, direct medical costs are projected to exceed $100 billion by 2030. But the most important point is where much of that financial burden is created, when worsening congestion leads patients back into the ER and ultimately hospital-based care. Despite that, patients continue to cycle through the system. Approximately 25% of patients are hospitalized for heart failure and readmitted within 30 days. This current model is not only costly, but there's a gap between chronic oral diuretic therapy and hospital-based intervention. That is the economic context for Furoscix ReadyFlow. If clinicians can manage fluid overload events earlier and outside the hospital, the potential value extends beyond the treatment itself. It may mean a less disruptive care experience for patients while helping providers, payers, and health systems address one of the largest and most patient persistent cost drivers in heart failure and CKD.

Now here's a tailwind that I believe is still underappreciated. For years, the hospital readmissions reduction program placed financial accountability for excess readmissions primarily on hospitals. Beginning in '27, CMS is extending that accountability directly to cardiologists through the new ambulatory specialty model known as ASM. This matters for Furoscix because ASM rewards the exact behavior ReadyFlow is designed to support, identifying worsening congestion earlier, intervening in the outpatient setting, and helping patients avoid the hospital altogether. The timing is also highly favorable. ASM performance begins in '27, just as we are launching and scaling ReadyFlow. CMS is creating the incentive to intervene earlier and Furoscix ReadyFlow provides the tool to make that intervention practical. We believe that alignment can be a powerful catalyst for accelerated adoption beginning in '27. Before we move into the clinical overview, I'd like to introduce our chief medical officer, Dr. Ajay Ahuja, who joined us late last year.

Ajay is a cardiologist who brings more than 20 years of leadership across clinical development and medical affairs, where his work has spanned cardiometabolic and respiratory therapeutic areas. Before entering the industry, he completed his fellowship in cardiology and then served on the staff of Boston Children's Hospital for more than a decade. With that, I'll turn it over to Ajay to explain why ReadyFlow's profile is so meaningful for clinicians and patients.

Ajay Ahuja, MD:

Thank you, Mike, and good morning everyone. I'm pleased to walk you through the pivotal data that supported this approval. The pivotal PKPD study was a prospective randomized crossover study in 21

healthy adult volunteers comparing Furoscix ReadyFlow directly with IV furosemide. Each participant received both treatments separated by a three-day washout period, allowing each individual to serve as their own control. In one treatment arm, participants first received the 80 milligram dose of Furoscix ReadyFlow subcutaneously in just 5 to 10 seconds and after the washout period, they then received 80 milligrams of IV furosemide administered as two 40 milligram boluses two hours apart, consistent with FDA label. In the other treatment arm, participants first received IV furosemide and then after the washout period, they then received the Furoscix ReadyFlow autoinjector. It is also worth noting that this was a mature patient study population with the mean age of approximately 58 years and with the group's renal function spanning a wide range. That provides context as we evaluate the consistency of the pharmacokinetic and pharmacodynamic response.

The study met its primary pharmacokinetic endpoint. ReadyFlow achieved 107% bioavailability relative to IV furosemide, which falls within the goal 80% to 125% range for bioequivalence. This demonstrates that the subcutaneous administration delivers total furosemide exposure equivalent to IV therapy. And while the concentration profile was different as expected, the peak was lower and more gradual than IV. The overall exposure measured by area under the curve was still equivalent. The takeaway is straightforward. ReadyFlow provides IV equivalent drug exposure through a rapid subcutaneous administration. The study also successfully achieved its pharmacodynamic endpoints, demonstrating that this comparable drug exposure leads to the same diuretic effect.

ReadyFlow produced urine output equivalent to IV furosemide at 6, 8, and 12 hours with similar urinary sodium and potassium excretion. These are the measures that matter clinically, removing both fluid and sodium. Across each time point, ReadyFlow performed similar to IV furosemide. So the conclusion is clear, the 10 second subcutaneous administration preserved the pharmacodynamic performance of IV therapy. To summarize the safety findings, ReadyFlow was generally well tolerated. Injection site adverse events were mostly local symptoms and they were typically mild. And systemic adverse events were consistent with the established safety profile of oral and IV furosemide. Importantly, there were no discontinuations due to an adverse event. Taken together with the achievement of both the pharmacokinetic and pharmacodynamic endpoints, these results support a safety and tolerability profile consistent with what clinicians already know and expect from furosemide.

With that, I'll turn the call back over to Mike to talk about the launch strategy.

Michael Castagna, PharmD:

Thank you, Ajay. Now let me bridge to our launch strategy. The strategic opportunity here is straightforward. ReadyFlow materially reduces the treatment burden, which we believe can broaden the range of patients clinicians consider appropriate for Furoscix and support intervention earlier in a fluid overload journey of a patient. And that is not just our view. The feedback is very consistent. Patients immediately recognize the value of eliminating a five hour treatment experience. Clinicians describe ReadyFlow as a significant advancement. And patients tell us that a simpler option may reduce the hesitation they experience in calling their doctor when symptoms begin to worsen. Taken together, we believe ReadyFlow can expand not only who receives Furoscix, but also when in the patient journey treatment is considered.

We are prepared to move immediately from approval to activation. Our sales force is being trained and deployed over the next few weeks, supported by an integrated campaign designed to reach both healthcare professionals and patients across digital, field and point of care channels. We are excited about the new creative campaign our marketing team will be launching, and we will have a strong presence at several upcoming conferences.

I want to double click on the integrated delivery system network opportunity, because this is how we believe Furoscix can evolve from a product used by individual prescribers into a capability embedded across an entire health system. Our strategy is straightforward. First, establish. We are engaging more than 60 prioritized IDNs to build awareness and clinical confidence and ReadyFlow. We have another 20 to 40 teed up as the year progresses. Second, embed. We are working with those systems to incorporate Furoscix into early discharge, post-discharge and outpatient care heart failure pathways. And third, expand. We will then scale these pathways across more providers, patients, and sites of care. That progression from clinician adoption to pathway integration to system-wide use is what creates the growth opportunity ahead.

Once Furoscix becomes part of how an IDN manages fluid overload, the opportunity is no longer dependent on one physician making a treatment decision one patient at a time. It could become a more consistent and scalable part of the care model. And this strategy is increasingly aligned with where the healthcare system is going toward earlier intervention in the most appropriate care setting with greater accountability for avoidable hospitalizations. ReadyFlow gives us a simpler platform around which IDNs can begin to operationalize this new NOD category.

Let me close with this. Today marks an important inflection point for mankind. We have the first and only product to deliver an IV equivalent diuretic therapy through an autoinjector in under 10 seconds, helping establish us as a leader in this new class that I mentioned earlier. Today is also bigger than one product. We have now delivered the two major approvals we set out to accomplish this year, Afrezza Pediatrics and Furoscix ReadyFlow, while continued advanced nintedanib DPI towards important clinical milestone. We expect to receive top line results from our phase 1B study over the next few weeks. These accomplishments are intangible evidence that our strategy is working and that our transformation is into a more diversified growth-oriented company is well underway. More importantly, the Furoscix ReadyFlow approval gives patients another way to manage fluid overload outside the hospital with far less disruption to their daily life.

With that said, operator, I'll now turn our call over for Q&A.

Moderator:

At this time, if you would like to ask a question, please click on the raised hand button, which can be found on the black bar at the bottom of your screen. When it is your turn, you will receive a message on your screen from the host allowing you to talk, and then you will hear your name called. Please accept, unmute your audio, and then ask your question. As a reminder, we ask that you please only ask one question and one follow up.

Our first question today comes from Roanna Roots at Learing Partners. You may now unmute your line and ask your question. Thank you.

Roanna Roots:

Great. Morning everyone. So I have a couple questions. I thought it was interesting you were talking about engaging the prioritized IDNs and was curious what proportion of eligible patients does that represent? If you have any estimates about that for Furoscix. And curious also if you've already penetrated into some of those with the on-body infuser. How are you thinking about the autoinjector getting more traction there?

Michael Castagna, PharmD:

Great question. I think if I had to catalog how many heart failure hospitalizations are in those 60 centers, I think that's a little harder to crystallize right this second. I would just say they're the highest priority

centers, like places like Cleveland Clinic, NYU, Emory, just to give you some kind of brands that we're looking at to work with. Kaiser's in that list as well.

When you think about today, our IDM business just launched about January of last year and so today it makes up about 10% of our sales. Now, some of those doctors had migrated from using our direct patient portal into a more direct purchase within our institution. But ultimately that business has continued to grow through Q2 and we'll share more details on our next earnings call.

Roanna Roots:

Okay. Super helpful. And a quick follow up. How are you thinking about the proportion of patients that might switch from the on-boy infuser to the autoinjector initially in the launch of the autoinjector? And could you help us understand what's the balance of new patient starts versus switches that you expect more in the longer term for the auto-injector?

Michael Castagna, PharmD:

Yeah, I think the existing base of patients have been using the OBI, they're comfortable with the OBI. It's not a big push. Now remember, it's an acute use product, so there's not always a lot of refills on these prescriptions and those patients can convert over relatively quickly. It's really a systems conversion, I'll say, meaning a doctor's office decides, "Okay, going forward, this is what we're going to train on, this is how we're going to use it, and this is the one we're going to pick in the system." So that perspective on the new patients, I'll say, we expect 85% plus of new patients, maybe almost 100% to come in on the autoinjector. I think there is a subset of doctors that do feel like they want continuous infusion over five hours, whether that's because they haven't seen our data, they have no clinical experience, or they just believe maybe that smoother curve over five hours matters.

So there are doctors who've indicated they still want the OBI, and in the short term, we continue to make that available.

Roanna Roots:

Okay, great. I'll hop back in the queue.

Moderator:

Our next question today comes from Ben Burnett at Wells Fargo. Ben, you may now unmute your line and ask your question. Thank you.

Ben Burnett:

Hey, thank you. And congrats on the update. I wanted to ask, will there be any different pricing implications with the auto-injector relative to the infuser?

Michael Castagna, PharmD:

We expect comparable pricing to the OBI. That's the easy answer.

Ben Burnett:

Okay. Okay. And then just on the sales force, do you foresee needing to make any adjustments either now or in the future to the sales force?

Michael Castagna, PharmD:

So coming into the year, we made some adjustments to the sales force post-close of the SE acquisition, and then we expanded the key account manager team. So most of that infrastructure, all the disruption happened in Q1, and we really want a stable rest of the year in terms of call targets and relationships with the reps as well as vacancies. So I don't expect any major changes or expansions in the second half here. I think as we look at how sales continue to grow and we plan for '27, there's always opportunity to cover more physicians and nurse practitioners. Just to give you some color, there's about 60,000 targets between cardiologists, high treatment heart failure, as well as allied healthcare professionals with MPPAs. We target about 12,000 nephrologists and cardiologists. So there's definitely always room to shrink the sales territories, increase reach and frequency, and share voice. But I really want to continue to see the hospital IDNs expand and adopt. And I think that will just continue to build this compound effect size that we're looking for.

Ben Burnett:

Okay, that makes sense. Thank you.

Moderator:

Thank you. Our next question comes from Olivia Breyer at Cantor. Olivia, you may now unmute your line and ask your question. Thank you.

Olivia Breyer:

Hi, good morning. Yeah, congrats on the approval. Looking forward to the launch. Can you walk us through how the ReadyFlow changes the unit economics versus the OBI? And then I know the focus is around gross margins, but does the lower cost structure maybe change how you think about product sampling and investing in market access and commercial expansion for Furoscix more broadly? I know you touched on sales force, but even outside of that.

Michael Castagna, PharmD:

Great questions, Olivia. Great to hear from you. Thank you for joining us so early.

So ready flow, we previously communicated about a 70% reduction in potential cogs, and that's even becoming more severe as the Trump tariffs take effect here because of the on-body injector has many international components, unfortunately. So this couldn't have come at a better time in terms of the threats that come across society for tariffs, and ready-flow is completely made here in the US, so we're excited about that supply chain shift. So the economics will help free up some capacity. As we think about payers, majority of the use is Medicare and Medicaid, and they make decisions for 2027. Pretty much they can make improvements in formularies. They can't make negative changes per se. So we do expect today, probably 40% of our scripts that come in don't have a prior authorization. That is something we're really focused on now with payers, which is they've indicated they'll have comparable coverage to the own body infuser.

So we don't expect any major changes in current coverage rates, but we do want to see how do we continue to remove the burden of a physician, an office, a patient on either the copay issues, which have been really hard this year for patients, or the administration is just getting access to the patient quickly. So that is something we are focused on, especially as we go into '27. You hit the nail on the head on samples. We have pulled back samples this year that definitely impacted us a little bit, but the cost of those samples are incredible with all body infuser. Where with the autoinjector, the sample costs are dramatically reduced and we will have sampling available at launch.

Olivia Breyer:

Okay, very helpful, and then Mike, as you think about the peak sales opportunity here, how would you characterize the hospital discharge opportunity versus actual ER prevention and keeping patients out of the hospital altogether?

Michael Castagna, PharmD:

Yeah, I mean if you just did the TAM of this, call it 700,000 to a million hospitalizations a year, the average prescription is six to nine units, and you do the math on our net price, it's a $6 billion plus opportunity if everyone got treated effectively. So the market TAM is enormous, and so that to me is the biggest opportunity to transform healthcare and patient lives, and really, we were talking to Kayla the other day who described how patients come back for infections, and I'm like, yeah, that infection started in the hospital. When they were sitting there, you may have discharged them and two weeks later they pop back in for an infection. That's because they got sick in the hospital. So anything we can do to get these patients out of the hospital earlier is going to have a tremendous benefit to taxpayers and health systems and health plans, whether bedsores, infections, readmissions for congestion.

We just think there's a huge opportunity here, and while oral diuretics for the majority of patients work fine, they should, and this is meant to be acute in those really challenging situations. So if you ask me over the next five years, the hospital segment will become the largest followed by that physician community practice.

Olivia Breyer:

Okay, great. Thank you very much, and congrats again on the approval.

Michael Castagna, PharmD:

Thank you.

Moderator:

Thank you, our next question today comes from Gregory Renzer at Truist. You may now unmute your line and ask your question.

Gregory Renzer:

Great, thanks. Good morning, Mike and AJ. Let me add my congratulations on the approval as well. Mike, when it comes to the near term and the launch, I know you've said Furoscix should do about 110 to 120 million of revenue in 2026. I just wanted to ask with the ready flow now approved, how does that shape or provide some pieces for you to hit or get to that plan?

Michael Castagna, PharmD:

I think, Greg, I'm going to hold that question until we get to the earnings call in a few weeks because I think that gives us time now with the approval to kind of run through our own assumptions and make sure we're tight on that guidance here. So we'll come to that in the earnings call in a few weeks.

Gregory Renzer:

Yeah, great. That makes sense. Look forward to that, and then maybe just taking a step back of certainly FDA approval, but maybe just remind us or give us some color on how you're thinking about international expansion now that you have a Furoscix portfolio approved here and thinking about

growth externally. Are we thinking on a Fresa playbook? What are your thoughts on Furoscix XUS? Thanks so much and congrats again.

Michael Castagna, PharmD:

Thank you, Greg, and great to hear from you. The XUS opportunity as you look at international revenue of all companies, continues to grow and help on manufacturing efficiencies as well as price points, and so when you think about the autoinjector, it just does open up the opportunity, whether you think about health systems in the UK or Australia, Canada. One of the things we see in those health systems, and data just came out from another on-body infuser, showing a reduction in hospitalizations from 11 days to six days, and you kind of look at that and you say, "Wow, they're in the hospital for 11 days outside the US." In the US, it's six days. So yeah, just right off the top, we can probably get XUS discharges to be comparable to US. Right now, there's not a huge burden, I'll say, or cost driver to get people out of hospital in Europe and other countries.

But if they can free up beds by five, six days on these patients, I think there's a big market opportunity outside the US and the autoinjector really does lower the cogs to make that opportunity become real. So it's something we'll continue to assess and look at. We've had various discussions with different partners over the past 10 months, but what we'll do at the appropriate time we need is to get the autoinjector approved to really open up that aperture for that.

Moderator:

Thank you. Our next question comes from Brandon Folks at HC Wainwright. Brandon, you may now unmute your line and ask your question.

Brandon:

Hi, thanks for taking my question and congratulations on the approval. I just want to follow up on a few things earlier. Of those 60 RDNs, any color in terms of the breakdown between hospitals versus perhaps cardiology practices or outpatient clinics? Then Mike, I heard your comment about five years out in terms of market opportunity, but early on, do you envision the majority of new patients getting the autoinjector at hospital discharge or through a cardiologist? And if it's through the hospital, how should we think about the product launch Rampia or the conversion, either one? Is this going to be more akin to a hospital-based product or an outpatient cardiologist product initially? Thank you.

Michael Castagna, PharmD:

Great question, Brandon. I think when you look at the ecosystem today, the success of Furoscix has been built on the community practice. That's where the legacy targets have been in our Salesforce infrastructure and our marketing and sales efforts, and that's really helped the company and the brand to get to where it is, and that will be the fastest adoption of the autoinjector. A, because you can sample those places. B, that's where the unmet need is today that physicians see, and there's a lot of physicians who've written one or two scripts who now will expand this to more patients. So they're in our portal, they know our hub, they have some experience, but not a lot of experience, and so that's a big opportunity for faster adoption with an autoinjector because the autobody infuser is very simple. The team did a great job on this device and I think it will continue to be used.

But the autoinjector is similar to the Repatha autoinjector, which many of these customers use, and so it's the same platform from SHL. There's going to be a lot more comfort in just adopting an auto-injector, teaching an auto-injector, and prescribing an autoinjector in that setting where the on-body infusers, even Repatha used to have one, they were never widely adopted and they really struggled, and

so I do think you'll see that adoption happen quite quickly there. The IDNs, obviously the team has been working on them for a little over a year, and just to give you some color here, I'd love them to go faster. Every CEO and CFO in a hospital system, I was with a group last night. I mean they just talk about the cost of heart failure, the busy-ness in the ER is the burden that it puts on their staff. It's such a huge infrastructure category burn.

And they're all struggling with margins and reimbursement these days. So they want this tomorrow. The reality is you get to procurement, you get to contract, and you get to the lawyers and compliance and quality. It takes about eight to 12 months just to get one contract through a health system, and that's with us pushing. So it's not that we don't want to go faster. This is just the nature of the ecosystem of IDNs and health systems is it just takes longer than you want, and we just got to be patient, but the team's had a head start on this and those will become the biggest growth engines. Most of those contracts, I don't have all 60 in front of me, but I would say the large majority are with health systems like a Kaiser, like a Cleveland Clinic. We expect to bring NYU on shortly and others.

So Tower Health in Philly's been a huge adopter of Furoscix and such it gives you some color of we are seeing high quality institutions and a lot of great discussions happening. So I fully expect those IDNs will be on board, and there's just a lot of coordination from the quality department to the pharmacy, to the training of the staff, to discharge protocols, to the prior authorization to get that started so they get discharged with the product. So all that has to be lined up and the team is working really hard, but it just takes time, unfortunately.

Moderator:

Thank you. Our next question today comes from Un Jung at Wedbush Securities. You may now unmute your line and ask your question. Thank you.

Un Jung:

Hi, good morning. Congratulations on the approval and thank you very much for taking the question. So the first question, I just wanted to confirm if there is any requirement or plan to expand the label to include pediatric patient like it did with infuser, and second question is discharge. Well, I'm sure that's something that a lot of hospitals would like to see, and in addition to try to incorporate into the discharge protocol, do you have any evidence or do you expect to have any evidence that the use of Furoscix can help expedite discharge patient discharge? Thank you very much.

Michael Castagna, PharmD:

Sure. First of all, congrats on having the report out first thing this morning. You beat us by a few minutes, but that was fun to see. So thank you for your proactiveness. On the pediatric, good question there. It's not a large segment opportunity, unfortunately, but for those patients who need it, obviously it's a great opportunity and that's where the OBI is a unique situation with the bolus and continuous infusion. We are working on a 40 milligram autoinjector, and so

So, that we expect to file and launch in the future, and that will open up that pediatric market opportunity. So it's just the nature of the 80 milligrams all at once in pediatrics that gave the concern there, that being able to break that up with a 40 milligram and then another 40 if you need it is going to open up that pediatrics. So that's our plan is to refile that with the FDA and get it in that label that way.

Your next question was around discharge and data generation. So obviously that study coming out of Europe, while not applicable to the US, gave you the signal of what's possible. There is some additional data and some small studies that were ongoing that you will hear hopefully be presented at future conferences around this topic. But Ajay has been really working with some KOLs and we were waiting

for the autoinjector to kick off some real-world evidence generation here. And so we didn't want to start that a month or two before the approval. Let's get the approval. It makes it a lot easier to kick off those trials. So Ajay will be working full speed ahead to get those protocols off the ground and they'll implement it here in the second half.

Speaker 1:

Great. Thank you.

Moderator:

Thank you. Our next question today comes from Anthony Petrone at Mizuho Financial Group. Anthony, you may now unmute your line and ask your question.

Anthony Mizuho:

Thanks, and good morning and congrats here on a great milestone for the company. Maybe first on channel, on on-body infusor, just again, the recap of who's writing prescriptions today between nephrologists and cardiologists and what does that sort of push in the cardiology channel look like? How do we sort of track that going forward here? How many net new cardiologists should we be thinking one year out, two years out? And then commercial coverage, just milestones we should be looking for and what will prior authorization look like? I know in the study you had to step through an oral diuretic for three months. Is that something we'll probably see with the subcu formulation? Thanks.

Michael Castagna, PharmD:

On the OBI breakdown today, roughly 10% of our sales go through IDNs. That continues to fluctuate a little bit each quarter, but it's been growing. As we look at our prescribers today, if we took the community setting where majority of our sales efforts are, about 15% continues to be neph and growing and 85% is cardio. And so remember neph launched in Q2 of last year, so it's still in its early stages of launch, but we doubled down on the neph expansion this year. And I would tell you that that did pay off as we looked at May and June after a few months of that increased share of voice. We're seeing record number of prescribers, record doses come out of that segment, and we expect that to continue as the year progresses. So we're excited about the early leading indicators there in neph, but another quarter or two I think will solidify that growth trajectory. Thank you.

Moderator:

Thank you. Our final question today comes from Sahil Dhingra at RBCM. You may now unmute your line and ask your question. Thank you.

Sahil Padagni:

Hi, thanks and good morning. This is Sahil Padagni. Our congratulations on the approval. So my first question is on 2027 trajectory, recognizing that ReadyFlow will only have four months of contribution in 2026, how should we think about the full year 2027 Furoscix revenue opportunity? Is there a preliminary framework you can share on growth expectations once the autoinjector is fully ramped up?

Michael Castagna, PharmD:

I think let us get this off the ground. Let's understand the conversion that's happening over the next quarter or two. We obviously have a plan and some internal estimates, but we'd like to see how that

flows out in the real world. And then we don't give general guidance yet for '27, but I think that is something we will weigh as we progress into '27 and in terms of as the company grows, we get these products. It was very hard to give guidance this year. We just completed the acquisition. We had two FDA approvals and we were making those investments. So I think we will share some sentiment on the pediatric launch here on the Q2 call as well as the second half here. But I think in '27, that'll be later this year, early next year at JPMorgan.

Sahil Padagni:

Okay, thank you. That is helpful, Mike. And then my second question is one of your competitors, the SQ Innovation. So they recently presented RCT data showing four fewer hospital days with their subcutaneous furosemide, that's Lasix ONYU, versus standard IV care. And you mentioned on the Q1 call that you have trial results that should come out later this year looking at early discharge. Can you update us on the timing of that data and whether you believe you will need an RCT to compete effectively in the hospital discharge segment? Thank you.

Michael Castagna, PharmD:

I think on the Q2 earnings call, we'll have a little bit of an update there on the clinical section with a little bit double click down. Ajay's been working on a lot of great opportunities and we'll share a little more detail there in terms of what's coming. And some of these are internal institutional driven, not even company-sponsored events. And it's up to those institutions to ultimately publish and present the results. Some of them may not for competitive reasons. Some of them may want to for bragging rights. But we are aware of the data at least. And so we are excited by what we're seeing. I think in that European study you mentioned, the challenge when you talk to US customers is the average stay is about 5.5 days. And if you told them they could get a patient out in 1.5 days, i.e., a four-day reduction, they basically say that's not possible. These patients are not yet stable and there. So I think the data in Europe, while important and an early indicator what's possible for ex-US markets, it's not yet transferable to the US. I think what people in the US want to understand is can we shave a day or two off? I think that would be very meaningful. And we do have some clinicians really pushing that type of analysis and insight.

And the other flip side is we talk to payers, I think Anthony had a question on PAs and insurance. And that's one of our comments to payers is we're not looking to block competition or anything. We want all patients to have all options available. We think that's really important for patient choice. What's more important is that there's really not PAs for patients because if there's a prior auth and it comes in on a Friday, within two days, that patient's generally going to wind up in the ER and they're going to be stuck with a $20,000 bill.

So our real thing with insurance companies is just educating that this is an acute use product in a very difficult situation. And we want to minimize the friction for that patient and that journey in the hospital system. And when you talk to PBMs, they obviously care about cost, that's their job. When you talk to regional health plans, they have so much effort put into heart failure and readmissions and Medicare quality scores and HEDIS scores that there's a disconnect sometimes. And it's our job to help bridge that gap and expand that team, to call in the payers and make sure those health quality metrics are achieved because we think Furoscix will open up the window to help Medicare populations.

And this year I'd say on insurance is copays are definitely staying higher longer because not as many people are hitting their copay caps because some of the key drugs like Entresto went generic. And so that's A, the foundation's dried up in terms of funding sources and they're not hitting their cap as early. But that's another reason we want insurance companies to minimize the out-of-pocket costs because

they're getting the opposite effect they want, which is hospitalizations. So a lot of good things happening, a lot of great discussions with insurance companies. We've met with all the PBMs and we'll expect continued progress as the year progresses, getting ready for '27.

Sahil Padagni:

Thanks, Mike, and we look forward to the Q2 earnings call for more update. Thank you.

Moderator:

This concludes the question and answer portion of today's call. I will now hand the call back to Michael Castagna for closing remarks. Thank you.

Michael Castagna, PharmD:

Thank you. And thank you for everyone dialing in on such short notice. I want to thank the entire mannkind team who made today possible. Lots of hard work this year that no one ever really gets to see, but the team here at mannkind has delivered two major FDA opportunities that are transformative for the company. This milestone reflects your persistence, your expertise, and your commitment, and I just want to say thank you. We've delivered and now our focus will turn to fully launch execution mode to realize the opportunity ahead to help patients living with diabetes as well as heart failure and CKD. And hopefully soon we'll be able to talk about IPF. So really exciting time and thank you, operator, for everything. And we may now close the call.

Moderator:

This concludes today's call. We thank you for your participation. You may now disconnect at this time.