Mannkind Corporation Q2 2026 Earnings Call - August 5th, 2026

Operator (00:00:00):

Good afternoon and welcome to the MannKind Corporation Second Quarter 2026 Financial Results Earnings Call. As a reminder, this call is being recorded on August 5th, 2026 and will be 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 risks 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 ended June 30th, 2026, the earnings release, and the slides prepared for this presentation. Joining us today from MannKind, our Chief Executive Officer, Michael Castagna, and Chief Financial Officer Chris Prentiss. I'd now like to turn the conference over to Mr. Castagna. Please go ahead, sir.

Michael Castagna (00:01:00):

Thank you, operator. Good afternoon everyone. Thank you for joining us for our second quarter 2026 call. I'll start with some opening remarks, walk you through some business updates. Chris will talk about our financial results, and I'll close by giving a few closing statements here followed by Q&A. Let me start by saying how we transformed our company and our potential growth trajectory with the strategy we outlined back in Q1. We laid out three major catalysts this year, Afrezza pediatrics approval, opening an indication opportunity we have not had access to, FUROSCIX ReadyFlow, which we have a CVR around because of a meaningful contribution this will have to the important growth of this franchise. And finally, the Phase 1B readout in the Nintedanib DPI in patients with IPF and underlying lung disease. These three things contribute to a solid foundation as we close out 2026 and move into 2027.

(00:02:00):

Beyond the catalysts, Afrezza is off to a very strong start. Our top 20 key institutions have already written a prescription. Breakthrough T1D acknowledged the importance of this opportunity by funding a grant to go after insulin newly diagnosed patients. Furocix showed strong revenue growth with 43% growth just over Q1. And our phase two INFLO study is kicked off and underway with multiple shots on goal in front of us between TYVASO DPI, Ralinepag DPI, and now Nintedanib DPI, all focused on IPF disease. As we look at Q2 revenues, we grew 21% from Q1 26 to Q2 26. What's most important about this picture is when you double click down,

Michael Castagna (00:02:50):

... marketed products grew 27% quarter-over-quarter, where royalties declined 1% from Q1 to Q2. When you take out our collaboration service revenue, you can really see an underlying picture what's driving our growth quarter-to-quarter.

(00:03:07):

Now let me talk about our first tier revenue mix evolution as we look at the success of our diversification strategy that we laid out. When you take out that collaboration and service revenue, we grew 111% on marketed products year over year. This is obviously driven by the shift of Furoscix and you can see that the royalties remain a durable revenue stream for years to come, but the predominant revenue growth

of MannKind is being driven by marketed products and this crossed a threshold in Q2 from Q1 where our two marketed products now demonstrate faster growth and a higher percentage of our revenue over the royalties by themselves. The royalties provide a great strong base business as we go forward into our launch trajectories. Let me talk about the launch of Afrezza in pediatrics, which many of you have been asking us about.

(00:03:59):

Now that we're approved, this is the first alternative [to] mealtime injection in over a hundred years. This product is solving an unmet need and a challenge that parents and patients face when it comes to timing of administration and seeing the impact that insulin has on their sugars and their CGM. Seeing the ultra rapid effect of Afrezza, the earlier peak, and the tail coming off, allows patients to dose differently and treat their sugars in a way that they just cannot achieve with insulin pumps or injectable insulin. This is now backed by more than a decade of safety data on the market, clear commercial opportunity, and access at $35 opens up the door for many patients to start this therapy.

(00:04:43):

One of the main questions we get is, why do we believe Afrezza will be different in pediatrics than the adult segment? First, the top left, a concentrated, targetable, addressable market. When you think about the adult prescriber base, there's 60,000 adult prescribers that make up 80% of rapid acting scripts, which include a lot of type 2 patients. We pivoted over a year ago to type 1. The pediatric prescribers, or about a thousand prescribers, make up 80% and are predominantly institutional based.

(00:05:15):

Second, there's a connected patient-centric community. We see this online. We see it on Instagram. We see it in education and nurse educators. The adults, we only targeted prescribers. There was limited surround sound to patients. With the pediatric segment and the success we've had, we've seen noise come from caregivers, from CDEs, school nurses, influencers, and advocacy organizations across the board, driving a lot of demand and questions into the pediatric community.

(00:05:45):

Third, in the bottom left, a stronger clinical foundation and KOL support. When we launched with the adults, we had two studies published, and not a lot of top KOL support. As you look at pediatrics, we have some of the top world-renowned thought leaders talking about our data, talking about the unmet need, and the solutions that Afrezza can bring to pediatrics. This is followed by 10 years of safety on the market, new ADA guidelines, the INHALE-1 trial, as well as the INHALE-1st trial being done in the top 50, 60 centers across the US between all of our pediatric development.

(00:06:20):

And then finally is removing friction. We know access is a hurdle for any new launch, and we've basically taken the opportunity to take away all objections around access, FEV1, and providing point-of-care opportunities to make sure patients can have a frictionless, seamless experience when they go to start Afrezza.

(00:06:38):

The first eight weeks support these four pillars are driving a different uptake curve than adults. When I look at the names of the institutions on this slide, these are some of the top centers in the country that treat the biggest volume of patients. In fact, one in three of the top 100 pediatric rapid acting writers have already prescribed Afrezza. We had 20 priority counts and all 20 have written at least one

prescription since launch. We're really excited by these early metrics and we'll continue to keep you posted as we go forward.

(00:07:11):

And before I close on the pediatric launch, I want to talk about the media coverage has really helped convert early momentum. Over 200 markets in all 50 states, got episodes on CBS and ABC, as well as numerous articles highlighting the new innovation in pediatrics. This has signaled more demand from HCPs and patients in awareness than we expected.

(00:07:33):

And this media credibility is fueling real world engagement, social conversations, and pull through opportunities that we didn't have otherwise.

(00:07:41):

As I think about the roadmap to success, Afrezza's future includes additional product development, digital advancement, and external innovation. Today, we had updated, FDA-approved dose conversion in 2026. We have new guidelines support, and now we have the pediatric approval providing a foundation for global expansion and opportunity. As we looked at 2027, we expect to be able to introduce a two-unit cartridge, an Inhale IQ, which will be a Bluetooth connected device integrated with CGM.

(00:08:13):

And then as we approach 2028, we expect to be able to have high concentration formulations of Afrezza, which ultimately will enable higher doses and lower powder loads at the current doses, minimizing any cough opportunity and increase in cost-effectiveness as we get to higher doses in type 2.

(00:08:30):

Now let me bridge the FDA approval of the Furoscix autoinjector ReadyFlow. As we know, fluid overload across the patient journey is often something that happens at moments in time. The majority of patients can be stable on an oral diuretic at home. Oftentimes though, these patients will start to have fluid overload and edema. In the gut, it stops the absorption of not only the diuretic, but also the other meds that treat heart failure, causing a compound effect and worsening of this condition for patients. We often hope that Furoscix in the majority of our use today is in this early intervention stage in the community setting where we can hopefully prevent patients from going to the ER and progressing.

(00:09:11):

The opportunity we see tomorrow, especially with this ReadyFlow, is the post-hospital discharge, i.e., can we get patients out of the hospital sooner that are stable, or reduce readmissions to prevent the 30-day penalty that many hospitals get for not completely drying out patients before discharge? We see an opportunity here to increase intervention in the early stage, as well as start to continue to get post-discharge protocols across the top health systems in the US.

(00:09:38):

Since Q1, MannKind advanced several key Furoscix growth opportunities.

(00:09:46):

First, we highlight a limited hospital presence. We increased our IDN engagement in hospital systems to drive stronger hospital pull through. And as we see, our medical liaisons are engaging at the highest level on institution protocol development and discharge, as well as our key account managers working

with institutions in quality, purchasing, and pharmacy to drive continued contracts and growth opportunities across these IDNs. We saw 36% growth in Q2 over Q1.

(00:10:16):

Second, the team is really focused on trying to launch nephrology while continuing to deliver cardiology sales. We were able to separate those salesforce opportunities this year. We caused some disruption here in Q1, but you can start to see the impact of that effort here in Q2 with 67% growth in nephrology in Q2 over Q1 and a record number of prescribers.

(00:10:39):

The next is underfunded marketing spend. So we've made many changes to our marketing investments and you'll start to see those in the second half of this year as we prepare for the Furoscix ReadyFlow launch. We believe those investments will continue to accelerate growth as we close out '26 and position ourselves for 2027.

(00:11:01):

So what does ReadyFlow approval now mean? First, it's the only IV equivalent diuretic delivered via an autoinjector. This will be available in the next three weeks to key institutions and community prescribers. This will allow us to deliver treatment from a matter of hours to seconds. It's demonstrated equivalent urine output, sodium excretion, and potassium excretion to IV furosemide and healthy volunteers. The safety profile is consistent with oral and IV furosemide, and the symptom relief may begin in an hour or less. This is a really exciting opportunity to help patients prevent them from going into the hospital or hopefully getting them out of the hospital early or preventing those one in four patients from going back in.

(00:11:44):

The Furoscix ReadyFlow launch campaign is built to drive immediate awareness and adoption. And we're looking at field activation immediately along with integrated surround sound at the major health systems and opportunities where patients are showing up in these health systems as well as online with the prescribers and patients. We're excited to be present at these upcoming conferences in the fall. And we expect the awareness of Furoscix ReadyFlow to immediately take off in the coming weeks.

(00:12:12):

Now I'm going to bridge to nintedanib DPI. This is an exciting opportunity where we just had a quick update last week and we walked you through the totality of the program, and today I'm just going to give you a few key highlights. Number one, our positive Phase 1B study demonstrates safety and tolerability in patients with IPF. We saw no serious adverse events, no GI burden, no discontinuations due to safety, and no difference in spirometry parameters between placebo, which is an empty cartridge, and nintedanib DPI. Our Phase 2 study is underway, our first patient has been dosed, and we expect to continue to activate sites around the world and throughout 2026.

(00:12:56):

One of the things I want to highlight before we talk about the PK/PD is that Cmax is known to drive efficacy in pulmonary fibrosis. This means AUC is less of a driver in terms of nintedanib efficacy and hitting a peak threshold concentration matters more than total lung exposure. Beyond the peak, more exposure adds very little added benefit. And this is one of the challenges you have with oral delivered product is it's very hard to get high tissue levels in the lungs. We've known from our preclinical work that we can see significantly higher lung concentrations than plasma by targeting the lungs directly. So we believe that brief high peaks are sufficient with short bursts of high concentration to inhibit fibrotic

pathways is the data that's been generated out there today on nintedanib. Now as I move into our own program, let me talk about the data we have.

(00:13:50):

Our Phase 1a validated efficient deep-lung delivery of nintedanib DPI. We had rapid dose proportional exposure and a favorable safety profile in our healthy volunteer data. When you look at our Phase 1a study, significantly six to eight fold higher concentration on Cmax in our Phase 1 study compared to a study out there that's been published in nebulized treatment. When you look at the data on the right, our seven-day treatment shows you a dose proportional response when you zoom in on the key attribute here, we're looking at Cmax and AUC.

(00:14:30):

Now let me walk you through the data we just released last week. For those that didn't see it, this was the first inpatient study to assess safety, tolerability, and PK in patients with underlying IPF. This was a two cohort, multiple-ascending dose study where cohort 1 got two milligrams three times a day. And cohort 2 got four milligrams twice a day, delivered as two milligram cartridge, i.e., a patient took four cartridges a day in cohort 2. When you look at the baseline characteristics, the age was 73, the females were 37%, and the pulmonary function at baseline is consistent with you'd expect in this population with an FEV1 of almost two liters.

(00:15:11):

So in our Phase 1b study in patients with underlying IPF, we saw a clean safety profile with zero safety signals, zero bronchospasms, and zero discontinuations or down doses. This becomes a challenge when you think about discontinuations of oral therapy can be as high as 50%. This overall profile supports chronic use and de-risks our program as it advances into Phase 2.

(00:15:38):

Now let me double click down on the overall treatment adverse events, which was one of the questions we got post our call last week. And as you can see here, as previously stated, cough was about 39% in this trial, but there's no other single adverse event that really showed any concerns as we look at safety and tolerability in the placebo group or the active group.

(00:15:59):

So now let me double click down on the cough. There were no discontinuations and no serious adverse events. As I stated, 60% of patients had no cough post-inhalation and about 30% of patients had a mild cough. This mild cough is considered transient, does not progress over time, and basically is something that gets better with time as people use the product. So when you think about 90% of patients had very mild cough and none of these were severe. The cough typically happens with the first dose and does not worsen with time, and this is not a product that you're going to continue to increase the dose over time, so we do not expect the cough to change from this first seven days of treatment. There were over 450 doses administered over seven days in patients with IPF and not one patient had the dose reduce due to the powder load or the cough from the powder itself. We're really proud of these results and we're not surprised given that Technosphere powders have been studied in thousands of patients and we've seen very low single-digit discontinuations due to cough.

(00:16:59):

Now I'm going to turn it over to Chris for our financial results.

Chris Prentiss (00:17:05):

Thanks, Mike, and good afternoon everyone. Second quarter revenue was 109.4 million, up 43% year-over-year, and first half revenue reached 199.5 million up 29% over the first half revenue of 2025. At the product level, Afrezza generated 17 million in net sales. Once we are through the initial launch phase for the pediatric opportunity, we intend to provide separate visibility into adult and pediatric performance metrics. As you would expect, because the pediatric indication was approved on May 29th, the quarter included only a limited period of pediatric launch activity. Furoscix generated 22.2 million in net sales, an increase of 43% from the first quarter. This was driven by a 49% increase in units sold with the offset due to an increase in gross-to-net adjustments, which were 29% for the current quarter. As we acquired Furoscix in October 2025, we are not making prior year comparisons.

(00:18:15):

Our United Therapeutics revenue streams also continued to provide a meaningful contribution. Royalty revenue increased 4% over the second quarter of 2025 to 32.4 million while collaboration and services revenue increased 53% to 35 million. The increase in collaboration revenue was primarily attributable to a higher volume of products sold through to United Therapeutics, and to a lesser extent, price. In addition, we recognized 4.9 million of revenue associated with ralinepag DPI development milestones during the quarter. As we've noted previously, this revenue stream may fluctuate between periods depending on production scheduling at our Danbury facility across Afrezza, our development programs, and TYVASO DPI. Based on our production plans, we expect Q2 to be the highest quarter of manufacturing-related revenues with the annual revenues in line with the prior year. Overall, the quarter reflects increasing revenue diversification from our promoted commercial products relative to our stable base of UT related revenues.

(00:19:28):

Turning to the bottom line, for the second quarter of 2026, we reported a GAAP net loss of 19 million compared with GAAP net income of 700,000 in the prior year quarter. Our non-GAAP net loss was 2.7 million compared with non-GAAP net income of 13.9 million in the second quarter of 2025. The year-over-year change primarily reflects the planned investments to support Furoscix, including the ReadyFlow formulation, the pediatric Afrezza launch, investment in our MannKind 201 Development Program, and the incremental increase in our cost structure following the scPharma acquisition. As you review our non-GAAP adjusted net income, I'd like to call out two lines that are new this year. The first is the amortization of acquired intangible assets. This relates to our acquisition of the Furoscix On-Body Infusor, which is being amortized over its current expected useful life. Now that the autoinjector has been approved, we will begin to amortize this intangible asset in the third quarter, and on a full quarter basis will be approximately 2.2 million. It is important to note that the amortization of these intangible assets are non-cash, but we will see these expenses flow through our P&L for many years to come.

(00:20:56):

The other new item relates to the accounting for our contingent value right associated primarily with the recent auto-injector approval. We will pay out the 45 million CVR in Q3, and the balance of expense, approximately 16 million, will be recorded in the quarter. In conjunction with the autoinjector approval, we announced a $50 million pipe financing providing us pro forma cash position at quarter end of 161 million and giving us sufficient cash to pay the CVR and continuing to fully support our two launches and accelerate the development of our 201 program.

(00:21:39):

On the expense side, R&D expense was 18 million compared with 13.7 million in the prior year quarter. The increase was primarily attributable to development of the Furoscix ReadyFlow formulation, higher personnel costs following the scPharma acquisition, and increased development costs driven by our MannKind 201 program. SG&A expense was 58.3 million compared with 31.6 million in the prior year quarter. The increase primarily reflected the promotion and support of Furoscix, as well as the expansion of our field-based teams and activities to support the pediatric Afrezza and Furoscix ReadyFlow launches.

(00:22:25):

As we discussed last quarter, 2026 is a deliberate investment year. With both approvals now achieved, our focus has shifted from launch preparation to disciplined execution. We will continue to monitor performance, prioritize investments behind the opportunities showing the strongest returns, and appropriately managing our cost structure.

(00:22:50):

Before I hand it back to Mike, I want to mention that we'll be participating in the Wells Fargo Annual Healthcare Conference in Boston, as well as the Cantor Global Healthcare Conference and the HC Wainwright Global Investment Conference in New York. We look forward to engaging with many of you there.

(00:23:08):

With that, I'll turn the call back over to Mike.

Michael Castagna (00:23:12):

Thanks, Chris. Let me close with where this leaves us. I told you at the start of this year that three catalysts would define 2026 for MannKind, and we delivered on all three. Afrezza is approved in pediatrics and is launching well. Furoscix ReadyFlow is now approved and will be available by the end of this month. And nintedanib DPI showed positive results in Phase 1 with IPF patients, which validated our continued Phase 2 advancement and investment. Our job for the rest of this year is execution, and we have the team, the products, and the evidence to make it all happen. Before we take questions, a quick note on where our teams will be this week. First starting out, ADCES, which is the CD conference. And this fall, we'll have a presence at major heart failure and nephrology meetings, HFSA and ASN. And the last one I'd like to flag with you is ISPAD in November where our INHALE-1st pilot phase findings were selected for two oral presentations.

(00:24:14):

As the pediatric diabetes community's own meeting and having our newly diagnosed data presented there in a launch year is meaningful for how this therapy gets understood by the clinicians who will drive its use potentially around the world.

(00:24:28):

With that, operator, we'll now turn the call over for questions.

Operator (00:24:34):

Thank you. The floor is now open for questions. If you would like to ask a question, please click on the raise hand button, which can be found on the black bar at the bottom of your screen. When it is your turn, you'll 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 ask your question. If you have dialed in, please

select star nine to raise your hand and star six to unmute. We will wait one moment to allow the queue to form.

(00:25:05):

Our first question will come from Ben Burnett from Wells Fargo. You may now unmute your line and ask your question.

Ben Burnett (00:25:15):

Hey, thanks so much and congrats on the progress. I wanted to ask about Afrezza. You conveyed some good early momentum. I guess what proportion of scripts that you're seeing are coming through your cash program? And do you expect these patients will convert to more standard channels? And if so, when would you expect that?

Michael Castagna (00:25:36):

Thank you, Ben, and it's great to hear from you. When we look at all the scripts dispensed, we're still, because we got the hub and then we have some IQVIA data we're reconciling. But we are seeing a good portion go through as fully paid and we're seeing the other half at least go through as cash. It's too early to tell how quickly that will convert, but obviously we're pursuing prior authorizations and the appeals to make sure patients get it. And in parallel, we're also meeting with payers as we're trying to continue to increase cut cost and coverage for patients, especially as we go into '27. This program's going to go through the end of '26, and we'd hope by then we work through most of the payers to move forward there. So far, I can tell you our pediatric approval rates are consistent with the adult approval rates. And so that's one indicator what we're looking at. But otherwise, there is more than half going through as cash, but we expect many of those to convert to paid.

Operator (00:26:34):

Our next question comes from Olivia Saunders from Cantor. Please unmute your line and ask your question.

Olivia Saunders (00:26:41):

Hey, good afternoon guys. Thank you for the question. I know it's obviously very early in development still, but can you maybe help walk us through how you're thinking about the regulatory path forward for your IPF program? Obviously the ongoing Phase 2 will be a big part of that, but what feedback have you gotten maybe more recently from the FDA around what you'll need to get this to patients and whether there are things that you can do to help accelerate that path forward? And then as a follow-up, is PPF something that you guys are looking into at this point as you think about your long-term portfolio, just given how big of a market it is and how much R&D interest there seems to be around it right now?

Michael Castagna (00:27:23):

Thank you, Olivia and great questions. Obviously we're very excited about just the nintedanib IPF opportunity, but to your point, we will continue to look at IPF, PPF, ILD and all the indications related to nintedanib. We did meet the FDA last year as we finished up our Phase 1 to go to Phase 2. And we originally proposed a Phase 2/3 study because most of the time in starting these trials is site activations and we're trying to minimize that. And at that point, that's why we decided to do the Phase 1b to minimize any distraction related to the FDA feedback. They really wanted to know what the patterns look like in patients with IPF. We've now demonstrated that. We have submitted the Phase 2 protocol to

the FDA to open up potential US sites. And we'll have feedback on that in the fall. I think you've seen the FDA indicate probably one trial is probably all that will be required in addition to the Phase 2.

(00:28:16):

And that's our underlying assumption. But again, the FDA will have to confirm some of those. And I think depending on the significant effect size that we may or may not see, that's probably going to drive some of this other indication extrapolation discussions versus do you need additional studies. The pulmonary division is very different than the other divisions. And so I think it's still TBD, but we're going to learn, like you see on TYVASO DPI, as UT talks to the FDA, we'll learn things there. And there was indication extrapolation in DPI for ILD, and I think UT still needs to work through that

Michael Castagna (00:28:51):

... on Tyvaso DPI. So a lot of precedent setting around this set of patients and unmet need. And I think a lot of it with the FDA will determine the effect size and how much they understand this. But too early to tell, is it two trials, one trial, each indication, extrapolation? But our work and assumption is at least one trial for IPF and likely additional data generated in other target populations. But that's our working assumption. Will we do that in parallel to IPF? I think that's still TBD of how many bets we want to place simultaneously, but we want to make sure we establish the dosing here in phase two.

Operator (00:29:31):

Our next question will come from Roanna Ruiz from Leerink. Please unmute your line and ask your question.

Ryan (00:29:40):

Hey guys, you have Ryan on for Roanna. Thanks for taking our question and congrats on the quarter. Maybe going back to Afrezza, can you guys just help us understand the pace of script trends that you're seeing in the pediatric setting over the last month or two? As your reps spend more time in the field, are you seeing an acceleration of scripts or steady growth? And then just as we look out in couple quarters and years, how do you expect this mix of adult and pediatric scripts to trend? Thanks.

Michael Castagna (00:30:13):

Thank you, Ryan. What I'd say is in the first week or two, there was obviously a bolus of patients waiting for approval and we saw really fast submissions and getting those sites on board and our team getting out there to get them to use our reimbursement hub. I've been out there in the field. The excitement is palpable with the customers, the patients, the social media. And you saw, even though we had July 4th holidays and people on vacation, we've seen a nice, consistent, steady referral pattern into our reimbursement hub. The last two weeks, you're starting to see that build up with potential refills as well as momentum. So I expect continued momentum as the quarter and the months progress ahead. And we're also adding another call it 1,000 targets roughly in the pediatric community to our 70 reps who are selling Afrezza for adults. So they will now be kicking in here in August, and we'll actually be training them next week.

(00:31:10):

So I expect continued momentum building, but it is a nice steady group every week, and it has been growing the last few weeks as well. I think we hit our highest week a week and a half ago of the last eight weeks. So it is growing and we are hitting new peaks every week and that's exciting. And we think we're just getting started here. How that builds will be part of what we're looking for in terms of,

obviously you want to know how to build your models, but us too, right? We're making lots of investments here and we want to see how the refill patterns look, how's the adult coming in and where are these patients coming from? We just got research this morning. The good news is we're seeing significant number of patients are coming from MDI. They're using Afrezza full-time, probably 60, 70%.

(00:31:53):

And about a third are using it intermittently. And that means they may take a pump break, they may use it on top of their pump. But we are seeing a large percentage of people say they will use it full time, and a lot of good patient demand for it. So that's the overall picture I'd say for peds. Happy to dig in terms of output. Some of our biggest prescribers are asking every patient on every visit, "Do you want to try inhaled insulin?" And we've seen some people already, over 20, 30 patients already. On the adult side, I want to remind people, we pulled back resources this year on the adults. So obviously we see a little softness in Afrezza year over year. And that's related to really the top 10 prescribers had a disproportionate amount of decrease relative to the next 1,000. And so when you take away that top 10, you look at the underlying adult business, it does look like it hit a nadir here in Q2, Q3.

(00:32:44):

And that momentum in July did start to build back up with new patients growing almost 30% over the month of June. So I do think we'll start to see the compound in the second half of Afrezza adult and peds. And if you ask me personally, I think the peds response, the uptake, the number of patients coming in, the number of prescribers, the feedback, everything points to peds will continue to build momentum. And adults we want to hold steady and we believe the adult segment will grow with peds. And just to give you some color, sorry, we had roughly... It's on my notes page, sorry. We had roughly about 450 docs come in since launch that are new prescribers. And this is just one part of the data, not all the data, but on the conservative side. And of those, about 200 were peds and about 250 were adults.

(00:33:35):

So you're seeing more adults coming in with the peds approval and the confidence. And we had about 1800 writers of Afrezza since the June 1st launch. So we're seeing overall writing increase, we're seeing repeat writing increase, and we're seeing new writers increase. So that broad base of prescribing, I'll say, is what we're watching and seeing how much we can get depth and breadth of that audience.

Operator (00:33:58):

Our next question will come from Gregory Renza from Truist Securities. Please unmute your line and ask your question.

Anish (00:34:06):

Hey guys, it's Anish on for Greg. Congrats on the quarter and for taking our questions. Just first on the Afrezza peds share source with the previously quoted 23 to 37 peak share range, how much assumes conversion off pumps and pods versus capture of multiple daily injection patients? And second on the 201 registrational path for nintedanib DPI, what is the shortest credible route to approval? Does the study need to show FEC benefit on top of background anti-fibrotic therapy or non-inferiority to oral nintedanib? Thanks so much.

Michael Castagna (00:34:40):

Okay. I'll just keep building on the Afrezza theme and then I'll jump into 201. On the overall data, we would expect roughly half our patients to come from MDI and maybe 20, 30% to come off pumps or

added to pumps. And then the remaining 15, 20% be insulin naive patients. And so that's the segment that we're seeing some early data. We got almost maybe 20% of the naive trial enrolled already. And the two-unit cartridge is really going to be helpful for the naive setting. But I think in terms of MDI and pumps, that's the majority of our patients coming in today are patients coming from MDI or people wanting a pump break. And that's been some of the anecdotal feedback from doctors as they offer it to everybody. They didn't realize that people have burnout and that they're tired, and they'd love to be detached from something for a little while.

(00:35:27):

And it doesn't mean they're always going to use Afrezza full-time or a pump full-time. They're going to go back and forth realistically depending on their needs. So that gives you a breakdown of Afrezza. And I would say the research we just got in this morning reiterated that kind of breakdown of what we're seeing in our initial launch assumptions and how it's being used in the first six weeks, and how we expect to see that continue on. And also the research that came in reiterated, the 20, 30% share that we talked about previously. The doctors know that approval's there, they're continuing to indicate that's a real possibility. So we're continuing to remain bullish and excited here for what we see in the early days, but it'll take time to show these trends. The last thing I'll say on Afrezza is just some of the pharmacies are reporting and some of them are not reporting.

(00:36:11):

And so that noise will sort out and we'll continue to keep you updated, but we are working through that consistently as Wall Street may try to look at one data source, but not have the full data. On 201, that's an interesting question in terms of the fastest pathway. Having done a lot of biosimilars, my initial goal was to convince the FDA that a biosimilar-like pathway could be appropriate here, meaning a non-inferiority trial with indication extrapolation. I think we need to get the phase two data to show the effect size to alleviate any concerns that we would be putting this in a large population and not knowing, are you switching off stable Nintedanib to inhaled versus an add-on? And so I don't think the FDA has any clear guidance on what they prefer, but I think what they would like is an add-on design trial with placebo.

(00:37:02):

And the good news with the Jascayd launch, there's clearly going to be more patients to add on on top of background therapy, especially as we look at Tyvaso nebulizer. So I'm hopeful as we get to phase three, the ability to look at naive patients as well as add-on and enroll that trial quickly will happen. And that's our assumption. And then the size of the trial and the primary endpoints will be TBD. But that's really what I look at the IPF market as saying. If it was only nintedanib, and it had to be an add-on, it would be a hard study to enroll. But given the success of Jascayd and pirfenidone and Tyvaso nebulizer coming in, I'm excited about the phase three design here.

Operator (00:37:42):

Our next question comes from Brandon Folks from HC Wainwright. Please unmute your line and ask your question.

Brandon Folkes (00:37:49):

Hi, thanks for taking my question and congrats on all the progress recently. I'll just continue on the Afrezza theme. Understanding it's very early on. Any color on refills or prescribers writing repeat prescriptions? And then in terms of titration and equivalent dosing, you've generated good data there,

but is that resonating or well known with the peds prescribers right now? Or is there a similar learning curve to the adult launch, but this time you're doing it with the data in hand?

Michael Castagna (00:38:29):

We are seeing refills already in month two, so that's a good sign, but it's too early to tell how that builds. I think we're going to need another month or two of data to really look at those trends and the cash pay, and compare it to the IQVIA data. But the example, we did see almost a 50% jump in new to brand therapy just in June alone. We'll have July very shortly. So that's all positive. In terms of, if I think about how many docs wrote three or more scripts, over 30% of our customers have written three or more scripts from what we can see. And that number's probably being conservative because there's some duplication we're trying to eliminate. So we do see people already writing their second and third patient coming into our referral hub as well as in IQVIA data. So that's another exciting sign that we are seeing the repeat writing happen, let alone the refills. In terms of the learning curve, we tried to apply, as you saw, why do we think this is different from adults?

(00:39:25):

We don't want to make the same perceived objections in adults. And one of the things that came back today, for example, was cost. And we're charging $35, yet the perceived cost by the customers is in line with an insulin pump or injectable insulin. So the good news is they're not perceiving cost to be a barrier, which is one of the ones we hear in adults. And the other thing that's coming up is lung safety and lung testing. And so that's another one we want to continue to work through the system and make sure that those are not barriers. If you look at the top 20 institutions, two of them just wrote last week because it took them seven weeks to figure out how to get the lung function test embedded in their clinical practice. But that's done now and that continues to be less of a burden as we go forward.

(00:40:06):

And the dosing, I think that the change in the label brings people confidence on the conversion, because when you're talking about kids or adults and insulin, everyone's told if you dose too much, you go low and you don't do well. And so that dosing change is bringing people confidence to start with the appropriate dose and titrate up, but most importantly, start. And I think that's what that label change has gotten us. And that should result in less dropouts. And again, too early to tell that, but that's one of the things we'll be looking for.

Operator (00:40:33):

Our next question comes from Yun Zhong from Wedbush. Please unmute your line and ask your question.

Yun Zhong (00:40:44):

Good afternoon. Thank you very much for taking the questions and congratulations on the progress. So on the Afrezza pediatric launch, I wanted to ask about, you said one in three of the top 100 pediatric insulin providers, but what about [inaudible 01:30:10]? And have they not been reached or are they still trying to figure out maybe whether it's suitable for their patient or have they not received sufficient interest level from their patients? So if there is any additional information that you're able to provide, that would be very helpful. And on the ReadyFlow launch, I know that [inaudible 01:30:30] may not sounds like a big deal, but what needs to happen during that three weeks, and now that you are not able to launch immediately after the FDA approval? Thank you very much.

Michael Castagna (00:41:33):

Yeah. I think on the one third, these are the top 100 insulin writers. You could imagine it's very hard to get into these places. Many of them are in academic institutions. You have a lot of people taking summer vacations. And in some cases we have in-services scheduled in the month of August and September. So they're not always going to be there in the first 30 days. In many cases, we've been asked to come in ahead of our original in-service date and in-service to staff even earlier because of how many patients are coming and asking. So I'd say the other two-thirds, there's probably always going to be 10, 20% of docs who are never going to write. But the fact is we're just getting started here in the first eight weeks. I think we're pretty happy with one-third. I think that will continue to close the gap.

(00:42:12):

There's nothing specific that I would sit here and say today other than time of why the other two-thirds have not written. There's no major objections happening. And I think that's what's most important. I've been doing this for 10 years on Afrezza. I go out there with peds and people want to... They're not arguing why they shouldn't use it. They're trying to learn how to use it. And that's a very big difference in my experience from adults. They're asking the right questions. I can tell you, I did a dinner in a key part of the country. 15 providers showed up and they held me for three and a half hours of just discussion. And that was just their open time. They wanted to stay and continue to understand every nuance of this product over the last 10 years. So that's the level of detail people are getting into in a good way because they want to learn how to write it, how to prescribe it, how to titrate it, and how to really think about using it because it is so different than all the other insulins.

(00:42:57):

And so that's the good part about the peds that we're excited about is it's an audience that is more engaged, more open to change, and they are more progressive than the adults. And so far we are seeing that. On the ReadyFlow, unfortunately or fortunately, depending on what you want to look at, the supply chain is outsourced. Now, the good news is ReadyFlow's in the US versus the on-body infusers outside the US. And so that supply chain across the US just takes time to... We had to get the labels, we had to get the packaging, we had to get things printed. We got to fit in the queue of the outsourced providers. And all that's been lined up and the team is working tirelessly day and night to make sure we get there every day we can. But at this point, we've set the target.

(00:43:38):

We're training all the reps next week, the week of August 10th, and the following week they'll be out there promoting it and inventory should be there by the end of that week or the following Monday. So we'll be shipping drug in the month of August for all intents and purposes. And the product's made, so there's no worry so far that we have around is there manufacturing or anything like that. It's just really supply chain.

Operator (00:44:00):

Our next question comes from Anthony Petrone from Mizu Financial Group. Please unmute your line and ask the question.

Anthony Petrone (00:44:07):

Thanks. And congrats on all the progress this year. One on Afrezza and one on ReadyFlow. I think Mike, we talked about the additional doses at the upper end of the range for Afrezza, pediatric Afrezza. And maybe when will those be available? And once all of the cartridges are available, what do you think the mix will be in terms of dosing? And then how does that translate into gross margin contribution?

Because you have some pricing at the upper end of the range there with the larger dose cartridges. And then on ReadyFlow, the transition to subq from on body has a gross margin uplift. I'm just thinking as you go into 27 and we look at product gross margin specifically, when you have that higher mix to ReadyFlow, how should we think about product gross margin year over year from '26 to '27? Thanks. All right.

Michael Castagna (00:44:58):

I'll take the first one. I'll punt the second one to Chris. On the Afrezza doses, I would say that work on the high doses will take another 12 to 18 months realistically, and then we got to get that approved. We've submitted or in the process of submitting that requested FDA to understand and make sure we follow the bracketing approach we're looking for. On the smaller doses, the two unit, that work has already been done. It's already on stability and we've already asked FDA about it. So we feel pretty good about getting a smaller dose into the market, hopefully in 2027. And I think that's more important in the short term as we continue to get the pediatric market going. And even the adult market, I'd say more of the type one market, they're so used to thinking about half unit, one unit increments that a two unit cartridge really allows them to either start earlier in that honeymoon period when they're newly diagnosed, or to titrate between a 4 and an 8 to get to 6 or an 8 and a 12 to get to 10.

(00:45:52):

There are patients who just want to get that accurate. I don't think it's personally required, but you're changing a hundred years of habit, insulin sensitivity ratios and carb counting. And so they've been trained a certain way and we can either try to retrain all of society or we can try to fit into the model that they're used to. And I think the barrier to just fit into the model they're used to is going to make these incremental doses easier. I wouldn't expect a lot of change on gross margin between the different doses. It'll help on the fringes, but I think it's really going to help international. When I look at international markets, cost is a huge barrier. People are paying cash, and being able to continue to reduce the cost outside the US will only increase adoption there, but otherwise you're going to be limited to a very small population until we can get these higher doses into a single cartridge instead of two cartridges, because that literally costs them two to three times as much.

(00:46:43):

And so that will be a hindrance to global expansion. But in the US, the high doses in type twos will be an opportunity to continue to grow as the type two market wants to use Afrezza as well. So the high doses are important. They're not as important in the next 18 months, but they'll be there. Chris, I'll turn over you for the ReadyFlow and contribution.

Chris Prentiss (00:47:02):

Yeah. As we think about the Furoscix margin, our commentary has been that the margin increases by about 70% when we think about the transition from OBI to the ReadyFlow. And so as you start thinking about your model for 2027, you can start thinking about a large majority of that being the ReadyFlow. And so that will have a significant help for us. And the on body in reality will be impacted by tariffs that are soon coming into play. And so that difference between margin would be even exacerbated as we think about future periods.

Operator (00:47:44):

Our final question is coming from Douglas Miehm from RBC Capital Markets. Please unmute your line and ask your question.

Douglas Miehm (00:47:52):

Thank you. My question just has to do with Furoscix. And when you look at the first half of the year, the 38 million or so that you reported and achieving the guidance of 110 to 120, it implies around 75 million plus or minus a bit in the second half of the year. So roughly doubling or so the first half of the year. And with the launch occurring later in August, can you just walk us through the cadence and key assumptions that would give you confidence that the guidance range is achievable? Thank you.

Michael Castagna (00:48:37):

Thank you, Doug. I'd say a couple things on this topic. First, if you look at 2025, one third of the units came in the first half and two thirds of the units came into the second half of last year. I think that trend is probably what we expect until you start to see either smoothing in Medicare come in more aggressively, or there's some way to provide assistance, or we move more formularies to preferred status. That patient out-of-pocket cost in the first quarter or two as people close the donut hole is a major barrier to that earlier unit adoption. So you see the back half of the year as copays come down. There's a huge unmet need. Patients just can't afford it. And that's not the thing that Mannkind can change. It's not just our product, it's all brands. And the copay assistance foundations this year went away pretty much with the generics that came in on Entresto.

(00:49:28):

A lot of that assistance that was out there has gone away for these patients. And so the fact that we did hit roughly 35% of what we expect for the year in the first half, I think is great given some of the headwinds that are out there and the patient affordability. So if you just do that, your numbers are roughly directionally accurate of what we expect in the first half and second half. The only thing I'll add to it in terms of can we or can we not achieve that guidance range is the inventory is going to be shifting quite a bit over Q3 and Q4 between the autoinjector and the on body infuser. And so depending on how that conversion and how fast it happens, and those inventory buying patterns, that's going to drive a lot of that noise, I'll say in that range.

(00:50:07):

And so things look pretty good, but obviously the second half's got a large demand number in front of it. And based on history, we expect that we can achieve that demand. But the inventory part will also be another factor here we're driving towards. Thank you.

Operator (00:50:25):

There are no further questions. Back to Michael Castagna for closing remarks.

Michael Castagna (00:50:32):

Thank you everyone and great questions. It's somewhat refreshing our concern that we're all talking about Afrezza, but we're really excited about the pediatric launch opportunity we see in front of us. We're happy to hit all three milestones this year. These were amazing hard work on a lot of people and real big part of the future of the company. And I think Furoscix ReadyFlow, we're jazzed what that's going to do for patients and providers, and hopefully to launch trajectory there in the second half really is going to bring a lot of energy and momentum to the company. And I want to thank really the patients, the families, our investigators to do all of our trials. We couldn't be here without them. And our employees who honestly have worked night and day and weekends to make sure we got through the FDA and got these approval.

(00:51:12):

Now they're preparing for the launches. So a lot of people working a lot of long hours on your behalf and everything we discuss today starts and ends with everyone involved. So thank you to our employees and stakeholders. We look forward to updating you on our progress next quarter. We have three or four investor meetings between now and then. We'll continue to share updates on the launches and how things are progressing at those opportunities. So please dial in and listen and we're always available for questions if you want to reach out. Thank you, Operator. This ends today's call.

Operator (00:51:42):

That concludes today's call. You may now disconnect.