Mannkind Corporation Q3 2026 Earnings Call | November 5, 2026

Operator:

Good afternoon and welcome to the MannKind Corporation third quarter 2026 financial results earnings call. As a reminder, this call is being recorded on November 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 risks factors, please see form 10Q for the period ended September 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 call over to Mr. Castagna. Please go ahead, sir.

Michael Castagna:

Thank you, operator, and good afternoon everyone, and thank you for joining us for our third quarter 2026 earnings call. I'll start with our quarter highlights, then provide some business updates while Chris walks us through our financial results, and I'll provide some closing remarks.

Last quarter, I told you we had delivered all three catalysts we laid out for 2026. This quarter is about what comes next, moving from delivering catalysts to executing against them. Before we get into the quarter, I want to take a step back and look at how far MannKind has come. Five years ago, we were a company with roughly $75 million in revenue and one commercial product. Since then, we've grown revenue at a compound annual rate of more than 40%, and this year, we expect to be close to six times that size.

What I'm most proud of is how we've grown. We didn't get there on a single product or a single deal. First, our collaboration with United Therapeutics took off and Tyvaso DPI became a blockbuster built on our DPI technology, and its royalties and manufacturing revenue has funded our transformation. Then we used this foundation to expand our commercial business, and today, Furoscix and Afrezza are leading our growth. That growth is now reaching the bottom line. We expect record revenue in Q4 will drive us to profitability as we close out the year, and none of this reflects our pipeline or external business development opportunities that can drive faster inorganic growth. So today, MannKind isn't a single product story anymore. We're a diversified growth company with four FDA approved products, no near term IP cliffs or a concentrated risk on any one brand or therapeutic area.

Today, we have three value engines driving growth. Each one plays a different role. First, we hit the key milestones laid out this year and our commercial launches are growing nicely. Furoscix ReadyFlow is off to an exceptional start with rapid conversion from the on-body infuser and new patient growth, and the Afrezza pediatric launch is seeing strong early adoption. Second, our license agreement with United Therapeutics provides MannKind with cash flow that funds the development and will start to drop to the bottom line in 2027 and beyond. We anticipate $15 million in milestones from Ralinepag DPI in 2027. Third, our DPI platform provides upside. This is long-term value creation. Nintedanib DPI is our lung targeted approach to IPF treatment, and key clinical evidence investors should look for is the data readout we're anticipating in the first half of 2028. And with our out-licensed programs, Tyvaso DPI and Ralinepag DPI give us three potential payouts in the IPF.

Now, let me hit the exciting highlights for the quarter. Furoscix ReadyFlow was approved and by late October, roughly 75% of Furoscix shipments had moved to ReadyFlow, exceeding our internal expectations by several quarters. The marketing sales team did an amazing job and it tells you physicians and patients were eager for this product. The Afrezza Pediatric launch has exceeded all of our internal forecasts, including institutions and healthcare provider adoption, as well as our total prescriptions. In addition, average monthly new to brand prescriptions were up nearly 80% in Q3 compared with Q2. We're turning the brand to growth.

On the pipeline, we reported positive phase 1b results for nintedanib DPI. INFLO-1 demonstrate the safety and tolerability, especially around cough in patients with IPF. Several countries have now approved our new phase two protocol, enabling us to get clinical readout faster. And finally, we closed the $50 million private placement led by Frazier Life Sciences, which funded the $45 million CVR payment triggered by the ReadyFlow approval. This is a strong endorsement of our strategy from a high quality long-term investor.

Now, let's step back and look at the first nine months of the year. Total year-to-date revenue was $301 million, up 27% versus last year. Commercial product revenue from Afrezza and Furoscix more than doubled from 52 million to $112 million, up 116%, and royalties grew 8% to $103 million. The majority of our growth is now coming from products we promote, which will provide long-term sustainable revenue where we can bolt on other BD and pipeline opportunities to drive even faster growth in the coming years.

Yesterday, United Therapeutics put up excellent numbers for Tyvaso DPI, which returned to growth in the third quarter with $379 million in sales. On the call yesterday, they described stronger underlying demand, more consistent commercial execution, and increased adoption of higher dose cartridges. Importantly, UT also pointed to an improvement in referrals beginning in September with further benefits from its expanded commercial organization expected in the fourth quarter and well into 2027.

Our royalties were 37.5 million, up 16% versus Q2. As a sole manufacturer of Tyvaso DPI, we continue to benefit from both royalties and manufacturing revenue. This recurring cash flow funds our diversified growth strategy that investors will start to see in Q4, as we expect this quarter to be the best quarter in the history of MannKind. Now let me turn to business updates starting with Furoscix.

Furoscix ReadyFlow fundamentally took an administration that used to be measured by number of days in a hospital to seconds at home. This radical shift matters to patients and prescribers and will fundamentally transform how health systems think about managing fluid overload in the coming years, and I'll share with you some new market research we just conducted in a minute.

We began shipping ReadyFlow mid-September, and in six weeks, nearly 75% of the prescriptions have already converted to ReadyFlow. The majority of patients starting ReadyFlow are new to brand and more than 1600 prescribers have written their first prescription. These are all encouraging signs this early in the launch, and we expect to see faster growth for the balance of the quarter, and estimate Q4 sales should match the entire first half of 2027.

How big can Furoscix be? Our independent research we just conducted with LEK reinforces the opportunity across nearly every stage of the fluid overload journey. For patients, the value is treatment outside the hospital with easier access and a four [inaudible 00:07:36] out of pocket cost. For providers, it is another option to manage fluid overload supported by clearer patient selection and dosing guidance and evidence of value to health systems. For shareholders, the opportunity is broader adoption and long-term growth. The research points to roughly a million patients annually at each stage, with physicians indicating they would prescribe Furoscix to a significant share at each of these stages. To capture this opportunity, we're focused on three priorities, generating evidence and practical guidance

for physicians and IDNs, building awareness and expanding our reach in nephrology as well as IDNs, and simplifying patient access through hub and distribution improvements.

When you look back a year ago, we purchased SC Pharma where analysts had forecast peak sales of roughly $500 million, and today, with the ReadyFlow approval along with our incredible team leading us forward and the rapid adoption by prescribers, we are more excited than ever about the opportunity to help transform the management of fluid overload and the growth ahead.

Now let me turn to Afrezza. Afrezza generated 19.3 million in net revenue in the third quarter, up about 5% versus third quarter last year, and total prescriptions grew 17% sequentially. Pediatric patients now represent about one in four Afrezza prescriptions and the pediatric launch is now returning the brand to growth. I also want to be candid about our adult business, which has underperformed this year. There are three reasons why this is. First, turnover in our field team slowed activity with some of our key prescribers. Second, several new insulin pumps launched in type two diabetes, which created more competition for the same patients. And this was compounded by our third, which we can now look back and see Afrezza is promotionally responsive as our share of voice in adults was declined about 65% as we diverted our resources across the pediatric launch and nephrology to support Furoscix. As we look ahead to 2027, the opportunity to build on that early pediatric demand while re-energizing and focusing on the adult business will allow us to return the brand to growth.

The early adoption of the pediatric launch picture is strong. Four months in, Afrezza's share of the pediatric mealtime insulin prescriptions is more than double its share in adults. We never reached that share in the adult market, and in peds, we got there in a matter of months. Also, average monthly new to brand prescriptions for Afrezza are up nearly 80% versus the second quarter. In fact, Q3 alone came close to matching new patient starts for the entire first half. That's the trend we're focused on building upon.

Behind that foundation is in place is more than 2,000 pediatric patients who've been treated since launch with roughly 600 pediatric prescribers, and all 60 of our priority pediatric institutions have now prescribed Afrezza. We continue to see institutions adopt Afrezza and create back to school protocols as patients are now starting to return after having early success, and creating a flywheel that we hope will continue to drive further growth ahead. With that, I'll now turn over to Chris to discuss our financial results.

Chris Prentiss:

Thanks, Mike, and good afternoon everyone. Third quarter total revenue was 101.9 million, up 24% from 82.1 million in the third quarter of 2025. The headline this quarter is our continued diversification of our revenues. Commercial product revenue was 45 million with the addition of Furoscix roughly double the 22.3 million in the prior year quarter, making commercial products our largest source of revenue.

At the product level, Furoscix generated 22.4 million in net revenue. ReadyFlow shipments began in mid-September, and September was a record month for both prescribers and prescriptions. As Mike noted, demand shifted to ReadyFlow faster than we expected, and that pace tempered reported revenue in the quarter as patients and prescribers moved to ReadyFlow before the product was available for dispense. Additionally, based on launch inventories available, channel inventory was limited to just days. We estimate the transition reduced third quarter revenue by roughly three million.

With ReadyFlow now moving through the channel, we believe Furoscix will generate more revenue in the fourth quarter than it did in the entire first half of 2026. This is important as ReadyFlow has a meaningfully lower cost of goods than the on-body infuser, so the faster we convert, the faster that margin improvement flows through to the bottom line.

Afrezza generated 19.3 million in net revenue, up 5% year over year, with total prescriptions up roughly 17% from the second quarter driven by the pediatric launch. Because of our pediatric access program, which runs through the end of 2026, prescription growth is running ahead of revenue for now. That said, more than half of pediatric prescriptions are already being reimbursed by insurance, and converting the rest to paid coverage is a priority as

Chris Prentiss:

... we head into 2027. Our United Therapeutics revenue streams complement the growing contribution from our commercial portfolio and continued investment in our pipeline. Royalty revenue increased 12% to 37.5 million, driven by growth in Tyvaso DPI. Collaboration and services revenue was 19.4 million compared with 26.5 million in the prior year quarter. As a reminder, UT sets its order quantity on an annual basis. Thus, quarterly fluctuations are a reflection of the timing of deliveries within the year and not a change in anticipated annual order volume. We continue to estimate that collaboration and services revenue for the year will be consistent with the 2025 total.

Stepping back to the first nine months of the year, total revenue was 301.4 million, up 27% from 237. 0 million in the same period of 2025. Commercial product revenue was 120.9 million, up 90%. 406 contributed 60.1 million driving the growth in commercial revenue. Afrezza was in line with the prior year at 51.6 million, but the trend improved after the pediatric launch in June and the brand returned to growth in the third quarter. On the collaboration side, royalties grew 8% to 102.6 million, driven by continued growth in Tyvaso DPI and collaboration and services revenue of 77.9 million, which was in line with the prior year. These collaboration revenues have allowed us to build a diversified business. Two years ago, the majority of our revenue came from United Therapeutics. Today, commercial products are a growing share of a larger revenue base with a durable collaboration business underneath it.

Turning to the bottom line, gap net loss for the third quarter was 23.2 million compared with net income of 8.0 million in the third quarter of 2025. For the first nine months, gap net loss was 58.9 million compared with net income of 21.8 million in the prior year period. In terms of our 2026 results, a significant component of our gap loss was non-cash and tied to the scPharma acquisition. In the quarter, that included 11.6 million of expense related to the CVR and 5.2 million in amortization of acquired intangible assets. Year-to-date, those two items totaled 33.3 million.

As we've stated previously, 2026 was an investment year. It's not often a company of our size gets the opportunity to invest in two launches, as well as reach an important development milestone in our MNKD-201 program. Based on our progress to date in the current quarter, we expect a return to profitability in the fourth quarter on both a gap and a non-gap basis. And based on the product set we have today, we expect to be profitable in 2027 on an annual basis, while continuing to invest in the growth of our commercial products.

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

Michael Castagna:

Thanks, Chris. Let me turn to our pipeline, the third value engine I described at the start. Everything in our pipeline starts with Technosphere. Our technology is built for highly efficient delivery to the lung and it's proven. It's already used in two FDA-approved products, Afrezza and Tyvaso DPI. That's an advantage most companies developing lung therapy simply don't have. Why does that matter? Well, patients today face a trade-off. Oral therapies in IPF brings systemic side effects that cause many patients to stop treatment and nebulizers are a real burden in a chronic disease. Our platform is designed to avoid both. It's practical, it's portable, it's handheld, and takes seconds and no nebulizer set

up, cleaning or maintenance. When a patient may be on therapy for years, how a treatment fits in their daily life determines whether they stay on it in the long term.

IPF is a disease where we see a role for more than one approach, and our platform lets us pursue several of them that gives us three paths in the IPF. Tyvaso DPI through our UT license agreement is already a blockbuster approved in PH and PH-ILD with a future potential expansion opportunity in IPF as well as PPF. We remain excited about the growth and opportunity that has to help more patients than ever.

Nintedanib DPI, which is wholly owned by MannKind is a proven molecule now paired with demonstrated tolerability in IPF patients and a large global phase 2 study is now underway. Ralinepag DPI also partnered with UT as a next generation prostacyclin with multi-indication potential progressing towards IND. Three potential paths in IPF at different stages of development, all built around our platform, all point to meaningful upside ahead. Now, I want to focus on our nintedanib DPI, which brings me to our INFLO-2 Global Phase 2 trial. It's a 12-week placebo- controlled study of two doses in patients with IPF followed by a six-month open label extension. Based on what we learned in phase 1B, we streamlined the study to about 150 patients. We believe this will get us data faster and help inform our phase 3 program. We are starting to see countries approve our updated protocol and are now in the process of activating our 85 sites around the world. We expect a data readout in the first half of 2028.

Let me close with where this leaves us. We delivered on three catalysts in 2026 and we are more excited than ever about our growth ahead. I started today with three value engines and I want to end with them because each one has real momentum as we head into 2027. As Chris said, our commercial product revenue is growing led by Furoscix ReadyFlow conversion as well as the pediatric launch. Our UT license agreement will continue to provide an expanding revenue base that we estimate will provide more than $1 billion in revenue from 2027 through 2030. And our pipeline gives us long-term upside with three potential shots on goal for IPF.

Looking ahead, our upcoming milestones line up with the same three engines. First, we keep innovating on the products we already market. Next year, we expect approval of Afrezza two-unit cartridge, launch Inhale IQ, a connected Bluetooth device that will bring CGM integration for our Afrezza users. Beyond that, we're advancing Furoscix 40 mg autoinjector pen and a high concentration Afrezza that will bring us hopefully 16 and 20-unit cartridges and reduced powder per inhalation as we go forward. Each one strengthens our brands and gives prescribers and patients more reasons to choose them. Each of these milestones is an opportunity to create value as we move through 27 and into 28. This month we'll be in London for the UBS Global Biopharma Conference followed by the Jefferies Healthcare Conference. We're looking forward to continue the conversations with many of you over the next couple weeks.

And now with that said, operator, I'll open up for questions.

Operator:

Thank you. At this time, 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 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 ask your question. We will wait one moment to allow the queue to form.

Your first question comes from the line of Ben Bernard of Wells Fargo. Please unmute your audio and go ahead.

Ben Bernard:

Great, thanks so much. It looks like you're seeing an acceleration in Furoscix scripts, which is really interesting, if I understood that chart correctly. Just curious maybe if you could quantify that growth and also where is this coming from? Are these current Furoscix users that are now using Furoscix more, just given the ReadyFlow or are you seeing the ReadyFlow being adopted in new treatment settings?

Michael Castagna:

Ben, I think we lost you, but I think I got your questions.

So I think your first question was the growth in prescriptions is about 56% growth from post six weeks of launch versus the prior six weeks. So we feel pretty good about that growth and some of that growth was limited by the first inventory coming in was a little bit short-dated, so the next inventory that goes out the door next week has longer dating. These patients are new to brand, meaning they have no history in the last year of getting Furoscix, and we also saw a significant jump in prescribers coming from Nephrology as well as Cardiology prescribing for the first time Furoscix. So I think a lot of the growth is also coming from new prescribers in addition to new patients, and we attribute that to the increased share of voice on Neph as well as the continued focus here on Cardio.

Where we aren't seeing big growth is in the IDNs because we actually weren't really trying to ship ReadyFlow to them, so they're holding back some of the OBI business in terms of where it's going to ReadyFlow. But otherwise the growth is coming from new starts, new-to-brand patients, and new prescribers.

Ben Bernard:

Okay, that's fantastic. And if I could just also drill into the comments around profitability. I think you kind of touched on this throughout the call and at the end, but I just wanted to understand what the level of focus is on profitability going into next year as you think about spending on the pipeline. Should we be looking for a focus more on revenue growth or is profitability, is that a focus going forward?

Michael Castagna:

I'll pop it over to Chris.

Chris Prentiss:

Yeah, I would say the focus is still on driving revenue growth, right? We're still very early in the journey on both of our commercial launches, but I think the point is 2026 was the big investment year, and so 2027 is when we should pay that off through growth on revenues, a stable, I would say, investment on the expense side, which should lead to bottom line improvement and profitability on an annual basis, not necessarily in Q1.

Ben Bernard:

Okay, great. Thanks so much and congrats on the quarter.

Chris Prentiss:

Thank you.

Operator:

Thank you, Ben.

Your next question comes from Roanna Ruiz at Leerink Partners. Please unmute your line and ask your question.

Roanna Ruiz:

Yep, thanks. Afternoon, everyone. So follow up on the ReadyFlow question. I was curious if you're considering expanding the field force in the near term and possibly devoting more resources toward promotion to build on the momentum that you're seeing early out of the gate. And along that, are you thinking about any key launch metrics that you would want to watch that could trigger such investment?

Michael Castagna:

Yeah, I think we're waiting on two things that have now come to fruition. The first one is the L.E.K. Report coming in, giving us the roadmap of growth that we see in front of us. We felt pretty confident, but it was nice to see that, now really articulate out. There's obviously another hundred slides behind the one I showed. So we feel very good that there's a roadmap of data generation, Salesforce expansion, and idea and adoption that will play out over the next 6, 12, and 18 months.

The other part is the conversion of how fast ReadyFlow to OBI was going to come from OBI and how many new prescribers and new patients are coming in. I think the great news on all those metrics are the conversion happened faster than we expected, and I think the Salesforce did an amazing job there in the first six weeks. The second part is that expansion provides a lot more margin to the bottom line, which gives us a lot more flexibility because obviously there's a big cost benefit between the two products, and so we do expect to increase our share of voice and our Salesforce footprint going into 27.

Roanna Ruiz:

Yep, super helpful. And then, another question on Afrezza and the pediatric launch, I was curious, at

Roanna Ruiz:

At what point do you think the inflection in pediatrics could offset any possible pullback in the adult trajectory? And could you highlight any of the strategies or education efforts that you're pushing that are getting the most traction with pediatric prescribers of Afrezza?

Michael Castagna:

Yeah, I think on the adult side, we did several things this year that contributed a little bit to that decline, mainly around share of voice and reallocation of those resources in the field. And some of that decline was really driven by two top prescribers with the turnover in the field. And I would say that is all stabilized. It's now behind us. So I think as we look at Q3, Q4, we should continue to expect to see adult growth and that turned a corner going into next year.

On the pediatric side, we continue to hear new protocols being put into hospital systems, new hospital systems come on board, more deep depth of prescribing. I think just last week we had a record high in pediatric referrals into our hub. So, we feel like we're still in the beginning stages of this launch, and I think you'll see the adult return back to growth and that'll be compounded positively by peds.

Some of that'll be offset a little bit as we exit the $35 cash pay program this year. Going into next year, we do not intend to keep that. But the good news is half the pediatric prescribers were coming from non-targets, roughly. And what I mean by that is the social media work, the radio stations, the

conferences, the Instagram videos coming out from patients, that is continuing to drive a lot of demand and awareness out there. And, so it's exciting.

So I do believe everything we continue to see and hear and do is educate nurses, educating CD educators, as well as continuing to go deeper within the institutions that have adopted.

Roanna Ruiz:

Yep. Sounds good. Thanks.

Operator:

Your next question comes from the line of Andreas Argerides with Sharden. Please unmute your audio and go ahead with your question.

Andreas Argerides:

All right, fantastic. Congrats guys on the quarter. Thanks for taking our questions here. Regarding inflow, the roadmap puts that readout in '28 or later. Just curious what's driving that timeline for a 12-week study? What are the enrollment targets? And is there any interim look and beyond safety will you report FDC or other exploratory efficacy measures? And then I have one follow-up.

Michael Castagna:

Yeah, I think the number one thing, Andreas, is really the change in the protocol. Some of the countries, we were already in the middle of submitting the initial protocol and we decided to wait for those to get approved to modify the protocol. And in a couple countries, we didn't yet submit, so we waited till the final protocol was done, then we modified going from 220 patients to 150 patients.

And the good news is so far, I think we got four or five countries already approved on the new protocol. The rest are pending, but the new protocol is now in, I think everywhere. And so we also have a big meeting coming up next week with the FDA and that will help decide some of that timeline here, meaning if the FDA does agree to one of our requests, then we would add US sites to the trial and that'll pull the timeline even faster.

But, until we have that clarity rate, we're kind of sticking to the first half '28 as our expectation. And again, maybe that could be earlier if the FDA comes our way, or sometime that first half if it doesn't.

So, we feel pretty good about that. There will not be any interim analysis or resizing. It's really looking at safety tolerability with early reads on lung spirometry, FEV1, FEC type parameters. So, those will be the key attributes we'll be looking at and it'll be a [inaudible 00:29:57] borrowing part of the trial, so we'll be able to bolster up the control arm a little bit in terms of looking at that statistical support there.

Andreas Argerides:

All right, great. And just quickly on Ralinepeg DPI, you've got a milestone expected next year. What triggers that? I'm assuming it's some type of clinical development milestone.

And then beyond those, what are the economics, royalties, manufacturing revenue or both? And is it structured like Tyvaso DPI? So whatever you can explain on that. Thanks.

Michael Castagna:

Yeah, I think there's two things. The royalty is 10% just like Tyvaso, so that's clear. Manufacturing, UT has publicly indicated they intend to be the sole supplier of Ralinepeg and they've built that facility. I just

saw it a few weeks ago. It looks amazing. And that facility should be making commercial supplies of Ralinepeg when and if it's approved. Whether we're making the clinical supplies or they're making the clinical supplies, I think is still TBD, as they may want to do that in a new facility or they may need us to help get that done. So that's all still under discussions.

And, the milestones aren't disclosed around what they are, but they're obviously things that are in our control somewhat. But as long as this program's moving forward, we have reasonable confidence that those will come in the first half.

Andreas Argerides:

All right, appreciate it. I'll hop back in the queue and congrats on the quarter.

Michael Castagna:

Thank you.

Operator:

Our next question comes from Olivia Breyer at Cantor. Please go ahead with your question.

Olivia Breyer:

Hi, good afternoon. Thank you for the question. For Furoscix, how are you thinking about patient and specifically revenue growth from here, just given what you're seeing so far into the fourth quarter? Are you guys seeing a real-time inflection into October and November, or does that market still need to build before we really start to see more of a ramp up looking the next year?

Michael Castagna:

I think you heard our comments in that Q4 should be roughly equal plus or minus a little bit to the first half, and that puts you in the $38 million range. And so, I think we're pretty confident in that number and we're five weeks into the quarter, roughly four weeks. So let's see another few weeks. But the biggest thing was getting the new dated inventory in stock and out next week, because some doctors were either hesitant to prescribe or if the patient's going to pay the copay, they want to make sure they can use it beyond the next seven days.

So, I would just say that will help drive, I think, faster growth as we close out the quarter, but we're seeing it come from broader prescribing and broader adoption in NEF, and then we're going to open up IDNs a little bit more in the rest of the quarter so that again, we'll drive faster growth.

But so far, it's coming from a lot of good places and a lot of good execution on the front lines.

Olivia Breyer:

That's helpful. And then on inhaled nintedanib, maybe just a follow up there around how you plan to communicate whether you'll be incorporating US sites into that study. And I assume it'll take some time to get those sites up and running, if that does happen. So is the potentially faster enrollment with the addition of those sites, is it because there's a high level of enthusiasm for inhaled nintedanib type approaches or is it more just about adding additional capacity and sites there?

Michael Castagna:

Yeah, I think it's both, number one. We have an update at Jefferies as well as UBS, and so we'll be speaking about it there. And, we should know the FDA high level feedback by then. And so we'll be happy to share that once we have clarity as well.

But, the acceleration, I will tell you that the team did an incredible job here in the closeout of the phase one study where the US sites put a record number of patients in four to six weeks. Those are the same sites we want to get in the trial for phase two. They were very interested in participating, they were very happy with the tolerability, and we think that'll be great to have those sites on board plus another eight or 10 that we would add across the US. So, I think it's enthusiasm plus the expansion and the experience we already have with some of those sites and the speed at which they can enroll.

So, all that gives us a little bit of confidence on how fast the US will add to our success of getting this trial done quickly.

Olivia Breyer:

Okay, awesome. Thank you, Mike.

Michael Castagna:

Thank you.

Operator:

Your next question comes from the line of Gregory Renza at Truist Securities. Please go ahead.

Gregory Renza:

Hey guys, good afternoon. Congrats on the progress. Thanks for taking my question.

Mike, maybe just touching back to your mention on the collaboration side and the royalty growth, how should we think about the Tyvaso DPI royalty growth maybe separately from the manufacturing, the collaboration revs over the next few years? And, are any competitive developments altering or influencing your production plans, be it your capacity needs or expectations for that partner revenue stream?

And then I've got a follow-up. Thanks.

Michael Castagna:

Yeah, I think the good news is us and UT have been working pretty closely on the inventory. We're very comfortable with any increase in demand that we'll be able to supply. We get our orders a year in advance, we tweak them quarter to quarter on strengths and things like that, but otherwise we feel pretty good about the order volume for next year. I think that should be able to supply any upside cases in the market, and if we have to go higher, we will be prepared to do that.

And obviously with the settlement with Liquidia and UT's comments yesterday, we feel pretty confident Tyvaso DPI is going to do very well in Q4 as well as next year. So we'll be prepared to make sure we supply anything that comes our way on that one. And I think it just shows you also that this royalty is going to be pretty durable in the near term that we can see in even the midterm when you roll everything through. So we remain excited about manufacturing this for UT, but more importantly, helping the patients out there that will benefit from our technology.

Gregory Renza:

Got it. That makes sense. And as you and Chris talk about 2026 as an investment year, but also as you really executed on two important launches for the company, as you think about and you've been communicating even on the call today, your look externally or business development, how does this year inform the levels of what you're looking for and maybe your appetite for external business development, to maybe compliment the launches that are underway and also as you get to data inflow in 2028?

Michael Castagna:

Yeah, I think one of the key things we wanted to see, this is the first time in really ever mankind's history we were able to launch something from scratch in the case of ReadyFlow, and in the case of peds was a new indication that we could really launch from scratch.

And I think what we can see in our excitement is the capability of preparing for a launch, executing a launch, and seeing the results of that feel very positive in the first quarter here of where we are. That gives us confidence to look for other opportunities to bring in.

And on the BD side, each year the conferences and the agenda for people wanting to meet with us gets pretty large, and we find ourselves having to sift through a lot more ideas. And the other challenge is that there's a lot of things that come our way, but we got to make sure it's meaningful enough as we look out because if it's going to just do 20 to 40 million, that's not going to be enough for shareholders or our distraction.

We really need meaningful opportunities coming in front of us. And I think those are the types of ideas we'll be looking for. And we have plenty to execute now, but we're not against bringing in new ideas if they come our way.

So we continue to search is the short answer, and there's plenty of ideas and opportunities out there.

Gregory Renza:

Got it. Makes sense. Thanks again and congrats.

Michael Castagna:

Thank you.

Operator:

The next question comes from Brandon Folkes at HC Wainwright. Please go ahead with your question.

Brandon Folkes:

Hi, thanks for taking my question and congrats on the quarter. Maybe just firstly from me on Afrezza, can you talk about the pushes and pulls in getting pediatric patients onto paid scripts? Just, how different is the reimbursement cycle I guess here? Is it more similar to a new product launch or is it a lot smoother just given this was sort of a label expansion?

And then, as we move forward into 1Q of next year, do you envision those challenges

Brandon Folkes:

... increasing just with deductible resets, or do you make progress every quarter and you're able to improve as we begin 2027 from where we are today? Thank you.

Michael Castagna:

Thank you, Brandon. Great to hear from you. I think on the push, pull and peds, the first few months we could see some payers updated their criteria and knew the approval came and others had to follow. And so we have seen that if you look at May, June timeframe approval rates and we look at October, they've definitely gotten much better. I think the other thing we saw that was a little bit of a surprise is how many patients went into the community setting, meaning not our pharmacy network. And we're seeing pretty good approval rates out there on fully paid scripts coming from that segment. And so whether that's the doctor pushing the PA through or the patient using it, where when they came to us, we were filling for $35 first to get it out the door and then doing the PA. And in some cases, the patients are using it on top of a pump, so they're not in a rush to get the prior auth. They don't need the prescription right away. And in other cases, they were using it full time and they were anxious to get it covered.

So we see some of the delay in coverages around how they were using it, and then also our hub ability to execute to make sure they have all the information to submit the prior auth properly. And so all that I think is now working in the right way. We've expanded some of the resources there on the reimbursement support, and I think we'll continue to see that progress. The other thing that I'd say is going into next year and beyond, we've had several meetings with a lot of the payers around coverage of Afrezza and the cost benefit versus an insulin pump, for example. And I think we're hearing that we should be able to get criteria updated to at least be a single step, meaning you tried and failed the preferred injectable product as opposed to, in some cases we hear two or three steps of injectable products.

And honestly, they're all the same, so it's kind of unethical to make the patient fail the same drug three, four times. And so the nonprofits and the advocacy organizations are aware of that. The payers are responding to this request to at least minimize it to a single step. We're okay if the injectable insulin's first, it's cheaper, we get that. And so far that feedback seems to be positive. So I think as long as we keep getting those updated, that's going to continue to improve the approval rates that do come through and make it easier.

In terms of Q1, deductible resets are less of an issue for Afrezza than they are for Furoscix. And so on the Afrezza side, we ultimately see a Q1 dip more because people just fill an extra prescription at the end of the year as they go into the new year because they know they got new deductibles and they just try to maximize their insurance and their healthcare spending accounts. So I think that's a bigger driver in Q1. Commercial copays, we buy down to $35. Medicare has a small reset, but that's a smaller percent of our business. So I see less of an issue there on Afrezza. Maybe with the peds launch, we overcome some of those historical trends we'll find out.

Where Furoscix, that reset on Medicare is a big barrier to patients where they almost would rather go in the hospital than pay the out-of-pocket cost, which is unfortunate. And we're hoping ultimately CMS will issue some guidance here to help close that gap where that payers and health plans will start to see that that's driving up their costs, not shrinking their costs. But we do see patients trying to fill enough to carry them in the beginning of the year, but that is the phenomenon there for Furoscix. That's different than Afrezza.

Brandon Folkes:

Great, thank you very much.

Michael Castagna:

Thanks, Brandon.

Operator:

Your next question comes from the line of Yun Zhong at Wedbush. Your line is now open.

Yun Zhong:

Hi, good afternoon. Thank you very much for taking the questions. The first question is, do you have plan to maybe at some point break out sales from OBI versus autoinjector? And for those patients who have not transitioned, are there any specific reasons that they're not switching? I have a follow-up question on Afrezza, please.

Michael Castagna:

Yeah. Chris, on the OBI AI, I don't...

Chris Prentiss:

I think based on how quickly we're seeing patients and physicians both convert to the autoinjector, not sure it's going to be meaningful to have that breakout. There's probably a bit of both in Q4, but by the time you get into 2027, it looks like the vast majority will be on autoinjector.

Michael Castagna:

Yeah. And I think we'll have inventory through 27 on OBI, and at this point we probably will see 90% plus scripts in Q4 coming in before autoinjector. And then the institutions as they come online for January with the IDNs, that's probably where the remaining OBI is sitting. I was asking the field force, is there anything you're hearing of why a doctor would either write both products? Are they identifying a separate patient for OBI versus autoinjector? And I'm not hearing any cases of that. I'm not saying it's not happening, but there's no rationale. We're hearing from the field of, "Hey, a doctor would rather write this versus that or this patient type versus that."

I think the reason you're still seeing some OBI use today is either we haven't gotten to that office or gotten into service that office or they're part of the IDN direct purchase program. And again, we haven't allowed them to purchase any real Furoscix until October, and that was mainly because of the dating of the product. We want to minimize any returns in that dating, but we should be through that particular situation by next week.

Yun Zhong:

Okay, great. Very helpful. And then Afrezza, specifically related to adult patient, you say that it's a promotional sensitive and the reallocation of resources caused some decline, but you expect sales to rebound then. Is it through maybe adjusting resources or maybe related to your previous question [inaudible 00:45:01], do you have a plan to maybe make a little more investment to expand the size of the sales team to achieve higher revenues? Thank you very much.

Michael Castagna:

Yeah, two good questions. I think you will get there. The team is still working through this for 2027, but conceptually what I think you'll see is the Furoscix territories that sell that brand are quite large and we'd like to shrink those over time so that they have less travel distance, less state boundaries. And I believe that you'll see with the increased volumes and bringing nephrology into that particular audience, we had separated that out earlier this year. We've now added it back to the cardio team. So they're

calling on nef and cardio, and we think the Furoscix team can get there by expanding a little bit and covering both.

We would then have freed up some capacity on the Afrezza side where they can still target more of the peds and double down on the adult segment. We had pulled a lot of adult targets out of the pediatric, I mean out of the adult sales force to free up capacity. And I think that's an area where we still have a dedicated ped sales force and maybe dedicated adult sales force, and I think the team will look to see what's the best optimal framework for that next year. We think continuing to have pressure on peds is important and we think bringing more into that adult segment will be important as well. So I think you'll see more similar investment and capacity and a little bit increased investment on the Furoscix side.

Operator:

Thank you.

Michael Castagna:

Okay. Anything else?

Operator:

Your final question-

Michael Castagna:

Thank you.

Operator:

Your final question of today comes from Sahil Dhingra at RBC Capital Markets. Please go ahead. Your line is now open. Please go ahead with your question.

Michael Castagna:

Okay.

Operator:

There are no more questions at this time. I'd now like to turn the call over to Michael Castagna for closing remarks.

Michael Castagna:

Thank you for all your questions today. We know we had a few analysts drop off, probably went a little long and they had other calls as well, but we appreciate everyone joining us this afternoon. I'm really proud of what our team has accomplished this year. It's been a very busy year, many long hours, nights, and weekends, and I just want to thank all of our employees for the extra work that they've put in to get us to this point. And I think that you're seeing the hard work that got us to where we are on the launches, but there's still lots of work ahead of us going into '27. We look forward to updating our progress in the next quarter. We'll obviously expect to be meeting investors here in London in a few weeks and continue to update where we can on the FDA communications around inflow too. With that operator, we're going to close the call. Thank you.