United Therapeutics Corporation Q1 2025 Transcript

Operator: Good morning and welcome to the United Therapeutics Corporation First Quarter 2025 Corporate Update. My name is Dorwin [ph] and I will be your conference operator today. All participants on the call portion of this webcast will be in listen-only mode until the question-and-answer portion of this earnings call. [Operator Instructions] Please note, this call is being recorded. I would now like to turn the webcast over to Dewey Steadman, Head of Investor Relations at United Therapeutics.

Operator: Please go ahead.

Dewey Steadman: Thank you Dorwin [ph] and good morning. It is my pleasure to welcome you to the United Therapeutics Corporation first quarter 2025 corporate update webcast. Remarks today will include forward-looking statements representing our expectations or beliefs regarding future events. These statements involve risks and uncertainties that may cause actual results to differ materially. Our latest SEC filings, including Forms 10-K and 10-Q, contain additional information on these risks and uncertainties and we assume no obligation to update these forward-looking statements.

Dewey Steadman: Today's remarks may discuss the progress and results of clinical trials or other developments with respect to our products. These remarks are intended solely to educate investors and are not intended to serve as the basis for medical decision-making or to suggest that any products are safe and effective for any unapproved or investigational uses. Full prescribing information for those products are available on our website. Companying me on today's call are Dr. Martine Rothblatt, our Chairperson and Chief Executive Officer; Michael Benkowitz, our President and Chief Operating Officer; James Edgemond, our Chief Financial Officer and Treasurer; Dr. Leigh Peterson, our Executive Vice President of Product

Development and Xenotransplantation; and Pat Poisson, our Executive Vice President of Technical Operations.

Dewey Steadman: Our scientific, commercial and medical affairs team will present at the American Thoracic Society International Conference in San Francisco from May 16 to the 21st. And now I will turn the webcast over for Martine for an overview of our development pipeline and business activities. Martine?

Martine Rothblatt: Thank you Dewey and good morning everyone. We have slides available for reference and I encourage you to review those at your leisure. However, Mike and I will not speak directly to the slides. How often can a CEO report to their investors and stakeholders that we've had a record revenue quarter. For United Therapeutics, it has been 9 quarters out of the past 12. That reflects on the strong execution of our long-term vision to be a biotech leader with a relentless drive to deliver to patients with rare and underserved diseases, a broad array of solutions to help improve their lives.

Martine Rothblatt: Our solid foundation built by Tyvaso, Orenitram, Remodulin and Unituxin continues to grow revenue by double digits now for 11 quarters in a row. We expect this momentum to continue, led by Tyvaso and Tyvaso DPI with continued solid performance by our other commercial products. Moving to our innovation and revolution waves. We believe our record revenue performance can continue for the foreseeable future as we have entered a sustained period of clinical and regulatory events poised to propel our business forward.

Martine Rothblatt: We continue to grow our pipeline with 5 registration phase studies underway, a pending marketing application at the FDA and several new preclinical candidates, including 3 xeno organs that should be ready for clinical trials within a year. We also have other exciting innovations we will share later that we expect will keep our product portfolio

innovating for years to come. We're planning for the first transplant in our UKidney clinical study which we're calling the EXPAND study in the middle of this year. This will be followed by investigational new drug applications for the EXTEND study evaluating the UTHYMOKIDNEY and the EXPRESS study evaluating the UHeart.

Martine Rothblatt: Both of those INDs are expected to be submitted within the next year. We recently received positive feedback from the FDA on our UTHYMOKIDNEY program that gives us confidence to file INDs for both the UTHYMOKIDNEY and UHeart without conducting additional Baboon clinical studies. What makes United Therapeutics unlike any other biotech is that we've been able to accomplish this massive business growth and unparalleled pipeline productivity while maintaining strict financial discipline. We never spent more than 50% of prior year revenue on cash operating expenses.

Martine Rothblatt: And as a result, we have an industry-leading productivity per employee and more than $1 billion in annual operating cash flow. And we're deploying our capital thoughtfully and strategically to provide for a sustainable business in the years to come. In the past 6 quarters, we have touched on all 3 areas of our capital allocation philosophy across both our commercial and development portfolios. We've invested in CapEx to support our new Tyvaso DPI manufacturing facility and acquired additional real estate to support future commercial manufacturing needs.

Martine Rothblatt: We also commissioned the world's first clinical scale designated pathogen-free facility in Virginia and plan to complete 2 others in short order. On corporate development, we acquired IVIVA and Miromatrix to enhance our organ alternative development expertise and we've licensed in new technologies to support our small molecule business. And with all this, we still returned $1 billion to you, our shareholders, through an accelerated share repurchase program last year that was universally well received. We will continue to evaluate

all 3 core areas of our capital allocation philosophy on an ongoing basis and we plan to pursue multiple avenues of capital allocation in the future.

Martine Rothblatt: Our commercial business is extremely strong and growing. That, along with 5 registration studies underway, several important data reads in the next 18 months and revolutionary progress on revolutionary organ programs makes United Therapeutics a truly unique and compelling story. And I thank you, our stakeholders and shareholders for joining us on this journey. We're only just beginning. And with that, I'll now turn the call over to our President, Mike Benkowitz, who will give an overview of our spectacular commercial performance for the quarter.

Martine Rothblatt: Mike?

Michael Benkowitz: Thank you Martine and good morning everyone. Today we are pleased to report a strong start to the year with another quarter of record revenue at $794 million, representing 17% growth from the first quarter of 2024. driven by robust results for each of our treprostinil products. This quarter's performance is reflective of consistent patient demand where we continue to see very strong referrals, starts and patient shipments for all of our treprostinil products, Tyvaso, both DPI and nebulizer, Orenitram and Remodulin as well as Unituxin.

Michael Benkowitz: We continue to see growth in the number of treprostinil prescribers and increases in the depth of prescribing within practices as measured by writers with 3 or more patients. Overall, we believe these results demonstrate that treprostinil continues to be an important part of the treatment armamentarium for pulmonary hypertension even with new therapies reaching the market. Building on Martine's comments, we remain confident that Tyvaso DPI is positioned for sustained growth over the long term due to the convenience of the

device, its unlimited dosing potential, the thousands of prescribers and many, many thousands of patients experienced with the product since launch as well as the fact that there are no payer incentives to prefer an alternative product. Moreover, if positive, the TETON data in idiopathic pulmonary fibrosis which is expected soon, could shift Tyvaso use into a much larger market where we will have orphan drug exclusivity and rapidly position Tyvaso for continued long-term growth.

Michael Benkowitz: To wrap up, we couldn't be prouder of the unwavering effort of our dedicated team to deliver this outstanding performance and to provide therapies to our patients in need. And we believe that we are set up well to continue to execute throughout the remainder of the year and beyond. With that, I'll turn things back to Martine to run the Q&A session.

Martine Rothblatt: Thank you so much, Mike. That's an amazing report. Operator, can we have the first caller, please?

Operator: [Operator Instructions] The first question comes from Joseph Thome with TD Cowen.

Joseph Thome: On the quarter. Maybe will the UTHYMOKIDNEY program enroll the same target population as the 10-gene kidney program? And we saw the great progress, obviously, with Ms. Looney but then I did see that she did have to be explanted. So maybe if you could talk a little bit about what you learned from that experience and how you might apply that to the upcoming trial, that would be great.

Martine Rothblatt: Sure. Thank you for your question, Joe and thank you for the congrats. I'm going to assign that question to Dr. Leigh Peterson. She's in charge of all of our xenotransplantation activities. Dr. Peterson?

Leigh Peterson: Yes. Thanks for the call. And yes, we haven't completed our clinical protocol for our UTHYMOKIDNEY study yet. But yes, we do plan on enrolling a very similar, if not identical patient population into that study as what we're enrolling into the 10-gene xenokidney study. And yes, we learned an incredible amount. We're very, very grateful for Ms. Looney's participation through the EIND conducted by NYU. And we learned a lot.

Leigh Peterson: We learned a little bit more about tweaking the immunosuppression which is a little bit different than what's commonly done in allo transplantation. And we're looking forward to applying all of the learnings with regard to the immunosuppression and follow-up that we learned with her. So again, we're really, really grateful. We consider it definitely a positive experience and it's unfortunate that she did have the unrelated infection that required us to have to reduce the amount of immunosuppression that she was on which ultimately resulted in rejection.

Leigh Peterson: But again, it was an unrelated infection. And so learning how to manage that without having to reduce the immunosuppression quite as much is going to be key in the study.

Martine Rothblatt: Thank you so much, Dr. Peterson, for all of that great color on the progress that we're making both with the 10-gene kidney and with the UTHYMOKIDNEY and the -- and as we are now referring to the trials as the EXPAND trial for the 10-gene kidney which is now enrolling.

Operator: Our next question is from Jessica Fye with JPMorgan.

Jessica Fye: Congrats on the strong quarter. I was wondering if you could elaborate for Tyvaso on kind of the magnitude of year-over-year contribution to sales from the continued implementation of the Part D redesign. I think you guys had previously said that was kind of

mostly realized in '24. So I'm just curious the extent to which you're seeing that benefit again this year as the out-of-pocket cap is further reduced.

Martine Rothblatt: Yes. Thank you so much for that question and so nice to hear your voice this morning. If it's okay with you, I think the best person to address that question would be Michael Benkowitz. Mike?

Michael Benkowitz: Yes. Thanks, Martine. Thanks, Jess, for the question. Yes, I think if you're looking year-over-year, so Q1 of this year to Q1 last year, I mean, there's obviously a benefit, right? And I think we've talked about the last quarter. So we saw a step down in Q1 last year, continue to kind of step down into Q2 and Q3 and then kind of flatten out over the balance of the year. If I look at Q1 versus Q4, I would say like a modest benefit but then I think you also have to kind of counter -- on the flip side of that is with the manufacturers having to start to pick up part of the catastrophic on the back end of the Part D redesign, we had some obligations there.

Michael Benkowitz: Obviously, it was less because we have the phase-in. So I think -- I haven't looked at the math to see if those exactly cancel each other out. But I think by and large, they probably do. So I think any benefit is really, I think, very, very modest when looking at the results this quarter.

Martine Rothblatt: Great answer, Mike. fully nailed it and that queues us up for our next questioner. Operator, you can open up the line.

Operator: Yes. We have Roanna Ruiz with Leerink Partners with the next question.

Roanna Ruiz: So I was going to ask about Tyvaso DPI revenue growth specifically in 1Q. Could you help us understand just the general split of prescriber and patient demand driving growth

versus a little bit of price increase? And are there any gross to net impacts that we should think about for the product in 1Q or going forward?

Martine Rothblatt: Yes. Thanks, Roanna. Michael, again, would be totally on top of all of those numbers. So Mike, can you take that call?

Michael Benkowitz: Sure. Yes. So I think in terms of split between DPI and nebulizer, I think it's settled in at about 2/3, 1/3 in terms of new patient starts. We haven't really seen much variability from that really for several quarters now. So I think that mix persists. And it's great that we have both options, right? Because there just happen to be patients that tolerate a nebulizer better than they do a powder. And so we have an option for both patients.

Michael Benkowitz: So that's, I think, really great that we're able to provide those options to the patients. We did do a price increase at the beginning of the year on both products. I think it was the same amount for both in line with what we typically have done in the past. And then on the gross to net question, as we said on the call a couple of months ago, that largely played out in the fourth quarter. But for the additional, I think it's 1% obligation we have under the Part D redesign of the IRA that I mentioned in the answer to Jess's question, really no additional impact there that we observed in Q1.

Operator: We have Andreas Argyrides with Oppenheimer with the next question.

Andreas Argyrides: Let me also extend my congrats on a fantastic quarter here. Martine, you alluded to capital allocation considerations in your opening remarks and I think last time we left James out of the earnings call. So I wanted to make sure he gets the question here. But a successful share repurchase that was taking place last year. You have $5 billion in cash. There are a lot of things that are going on in the PAH space from a competitive landscape perspective.

Andreas Argyrides: How do you consider deploying capital, James, maybe you can elaborate deploying capital either for -- in terms of acquisitions to grow the business that way? Or -- and also, what are some of your thoughts around a repurchase going into a pretty significant catalyst from IPF and TETON.

Martine Rothblatt: Sure. Thanks for the questions, Andreas. I'm going to refer the capital allocation, the bulk of the capital allocation question to James and just giving him a few seconds here while I respond to one of the questions that you sliced in there about internal R&D and the competitiveness of the PAH space and whatnot. So we do, as mentioned in my introductory remarks, we spend about 50% of cash on various forms of internal R&D as well as SG&A, of course.

Martine Rothblatt: And a big part of that spending is, in fact, allocated to our core competencies in pulmonary hypertension and interstitial lung disease. So in that regard, as you know, we have these registration effort going on in -- with ralinepag and the outcome study as well as a lot of effort going toward pulmonary fibrosis with TETON 1, TETON 2, PPF, plus a lot of efforts that don't necessarily have any visibility because they are still in the lead product -- lead-in effort for the product and the preclinical. But we have alternative types of methods of dosing and variations on dosing. We have a once-daily Tyvaso dosing in preclinical development.

Martine Rothblatt: So all of these type of activities are continuing on our part. And as we've seen, since the first competition came in to us with, say, something like the Liquidia generic parenteral, I guess it was like 7 years ago or something. I really had no material effect whatsoever. There was quite a bit of concern about sotatercept. We did try to emphasize the fact that all signs were that it was much more complementary than anything else.

Martine Rothblatt: And in fact, in the year of rollout, it has proven to be exactly that, quite complementary. So we are constantly -- at UT, we are just relentless in improving our drugs, improving our drug delivery devices, like another example I'll just drop there. Our Remunity device is now virtually used by 100% of the patients. So that's pretty amazing to swap out a parenteral delivery device that has had many, many years in the clinic and in patients' hands and in essentially about 24 months or so to a virtually 100% swap out of that device.

Martine Rothblatt: We're now I'm preparing for yet a further upgrade of that one to what we call Remunity D9. You'll see similar types of evolution in our inhalation devices. And as mentioned, some of those developments will also allow us to -- even though I think that our 4 times a day dosing now is the easiest, the simplest, super effective as the data shows, loved by physicians and patients as the data shows. I think even there, you'll be able to see in the next few years that we'll be able to come out with new products that go for even once-a-day dosing.

Martine Rothblatt: So this is just endemic in the UT culture, what we call approve and then improve, approve and then improve and we're relentless about that. Everybody in the company, get something approved, then improve it. Get something approved, then improve it. And that's what we're doing on Tyvaso, too. Well, with that lead in, James, can you answer some of the more econometric financial aspects of the capital allocation question?

James Edgemond: Yes. Thank you, Martine. Andreas, thank you for the question and thank you for remembering the last call. As you know, we are committed to allocating capital wisely and we spend a lot of time internally talking about it. We want to do it in the best interest of our shareholders. And as you know, the first priority is deploying our internal -- our capital for internal research and development and commercial initiatives.

James Edgemond: As Martine just explained, there is a lot of -- and the highest priority around

spending for research and development. And if you look at the P&L this quarter, you'll see there was a milestone payment we made in research and development and outsized -- increased R&D kind of outsized for the quarter relative to prior quarters, just as we moved along and push along these initiatives that Martine talked about. And we also spend in our first pillar, a lot of capital on our manufacturing facilities. And as you know, we're building a new DPI manufacturing facility in Research Triangle Park, North Carolina that is well on its way.

James Edgemond: The second priority and consistent priority that we spend capital on is for our external corporate development. So we look for new opportunities for potential acquisitions, in-license opportunities, et cetera. And as Martine outlined in her opening remarks, over the last 1.5 years or so, we've actually touched on all these priorities or touched on these priorities relative to business and corporate development. So it is an area that's very active and we look for products that are complementary to our product -- existing products and platforms and tend to focus on rare diseases, things in cardiovascular and things where there are corridors have been different.

James Edgemond: So we want to look for opportunities where we can have a big impact and there's little products or competition at this point. And third, we do look, as Martine outlined, to return cash to shareholders. And as Martine talked about for 2024, we did the $1 billion share repurchase that was well received. So our capital allocation priorities and kind of waterfall is still the same. But as you can see, we've been very active in allocating capital across all 3 in the recent months and years.

James Edgemond: So thank you very much for remembering. Thank you for the question. And Martine, I'll turn it back to you.

Martine Rothblatt: Thank you, James. Thanks for such a great 360-degree coverage of that

topic.

Operator: Roger Song with Jefferies has the next question for us.

Roger Song: Congrats for the strong quarter. I think, Martine, you mentioned a couple of things related to the competitive landscape for PAH. Maybe just can you just qualitatively comment on the potential growth trajectory this year and next, given we have a couple of emerging competitor dynamic. If you can kind of understand you don't provide the revenue guidance but just qualitatively, the revenue growth trajectory for the rest of the year and the next will be helpful.

Martine Rothblatt: Of course, Roger, thank you for the question. But I right with you. I'm going to assign that question to Michael because he oversees so many of the core competencies that we have within UT relevant to the growth trajectory question. For a complex disease, like PAH and like ILD. Of course, it's very, very important to have a strong commercialization team, sales and marketing personnel, so-called specialized sales reps throughout the country.

Martine Rothblatt: But actually, it's just the foundation. And on top of that, there's like a superstructure that extends into global medical affairs and many other core competencies. And all of these, we have regional nurse specialists. Our drugs are complex and require almost always a drug device combination and there has to be training and how to use these things, working with the nurses, not to mention the entire payer universe.

Martine Rothblatt: So all of these things are relevant, Roger. And Mike is like a virtuoso conductor who's got all these different sections of the orchestra, all with the goal of providing a growth trajectory for our products that is second to none. And with that lead-in, Mike, can you provide some kind of deeper color on all of that?

Michael Benkowitz: Thanks, Martine and thanks for that introduction. I feel like I just won some kind of award. Yes, I think what we've been saying, I think, for the last couple of years and even as recently as the last call and to Martine's comments on this call is we expect to continue to grow revenues at double-digit growth with our existing portfolio heading into this year and next year. And then as I said in my opening remarks, if we have TETON, if that -- if that's positive, that gets us into an entirely new market where we have orphan exclusivity.

Michael Benkowitz: I didn't even touch on ralinepag which we're hoping would be commercialized around the same time frame and give us a best-in-class product within PAH. So despite the fact that it is -- PAH in particular, is becoming an increasingly competitive market, we still feel like we're extremely well positioned to grow in PAH. As I've said on prior calls, it's still only about 40% of PAH patients are on any kind of prostacyclin. So I think there's plenty of room for us to grow.

Michael Benkowitz: There's plenty of room for, I mean, even the competitive products within that class. So I think it's still -- prostacyclins, I think, are still woefully underprescribed within PAH. And with all of our efforts and all the teams that Martine mentioned, we're continuing to make progress there. It wasn't too long ago that we were saying it was only about 20% of patients in PAH were on prostacyclin. But I think through the efforts of our company, other companies, bringing new easier products to market such as Tyvaso DPI, we've been able to really expand the utilization of prostacyclins within PAH.

Michael Benkowitz: And then over in PH-ILD, obviously, it's still -- I still feel like we're just scratching the surface in terms of what the potential is there. I think with the expansion that we rolled out last year, I think we -- the team has done an amazing job in increasing our prescriber base as well as the depth of ILD physicians prescribing Tyvaso for pulmonary hypertension associated with ILD. I expect that to continue as we move into the balance of this year and even

heading into next year and beyond. So we -- I think we still have a lot of opportunity there.

Michael Benkowitz: So we remain very confident that we're going to meet these expectations of continuing to grow revenues at a double-digit clip with our existing portfolio.

Martine Rothblatt: Thank you so much, Mike. Operator, we're actually at the bottom of the hour but we'll take one last question.

Operator: We have our next question from Ash Verma with UBS.

Ash Verma: Congrats on the quarter. I have 2 questions. Just can you give us a sense of how much patient adds there have been in the last few quarters for Tyvaso? Is it more in line with the roughly 500-ish that you have had historically or more or less? Just wanted to understand like the volume growth dynamic for PAH and PH-ILD. And then secondly, for Insmed's upcoming data on TPIP, just what are you expecting this trial can show?

Ash Verma: And how do you think Tyvaso is competitive position against TPIP?

Martine Rothblatt: Okay. Mike, do you want to continue your role on that same topic?

Michael Benkowitz: Sure. Yes. I think with -- I think your first question was around patient adds for Tyvaso. Is that right? So yes, so going back about a year, 1.5 years, we really kind of moved away from the patient add metric due to, I think, just competitive confidentiality reasons. I think what we said about 1.5 years ago is if you look at the revenue, we've gotten to a point where I think the revenues are tracking pretty well with underlying demand.

Michael Benkowitz: And so I think you can kind of look at how the revenues are trending and really get a good sense of what's happening at the underlying demand level. In terms of the Insmed product, we'll see here in a few weeks when they unwind. And so it's hard for me to

sort of speculate on what the impact is going to be relative to Tyvaso without actually seeing any data but I think we're all going to find out here pretty quick. And then as Martine said in her answer to a prior question, we have some things that we're looking at in the preclinical setting and in our pipeline to potentially bring a once-daily inhaled product to market.

Martine Rothblatt: Yes. Thank you, Mike and thank you, Ash. I'm very skeptical that just copying treprostinil in a kind of a once-daily formulation is going to really provide comparably effective control of pulmonary hypertension. However, as Mike and I referred to earlier, we do have a once-daily NCE in our early development and the nature of our clinical development team and process as such that, that can actually move very, very rapidly from preclinical to registration phase. So not that I think it's necessary but I think all of you know that another big mantra at United Therapeutics is multiple shots on goal. That's why we have so many products for pulmonary hypertension.

Martine Rothblatt: As you saw from the data today, all of them are growing. I mean that's super, super cool, oral, parenteral, inhaled, nebulized DPI. I mean it's just like across the board. So we are constantly developing new products. And finally, I have not seen anything in -- since the company has begun developing products where some new one comes in and kind of steals the market. It actually has never happened. And the reason why is that when a product -- when a patient who has a life-threatening illness, is well managed on the medicine as the patients are well managed on United Therapeutics medicines in overwhelming numbers.

Martine Rothblatt: It is a very fraught and cautious and slow process to move those patients to some like [indiscernible] on the block that has not really been well proven in the clinic. And these are the reasons, the core reasons why Mike and I and the rest of the team can be so confident that United Therapeutics will continue to deliver the type of double-digit revenue growth year after year, the kind of record revenue growth that I reported in my introductory

remarks for many years to come. Operator, you can wrap up the call now.

Operator: Certainly. Thank you. Thank you for participating in today's United Therapeutics Corporation earnings webcast. A rebroadcast of this webcast will be available for replay for 1 week by visiting the Events and Presentations section of the United Therapeutics Investor Relations website at ir.unither.com. That is ir.unither.com. [Call ends abruptly]