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Q2 2010 United Therapeutics Earnings Conference Call

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PRESENTATION

Operator

Good morning. My name is Jonathan, and I will be your conference operator today. At this time, I would like to welcome everyone to the United Therapeutics Corporation's second quarter 2010 conference call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session.

(Operator instructions)

Remarks today concerning United Therapeutics will include forward-looking statements which represent United Therapeutics expectations or beliefs regarding future events based on current assumptions. United Therapeutics cautions that such statements involve risks and uncertainties that may cause actual results to differ materially from those in forward-looking statements. Consequently, all such forward-looking statements are qualified by the cautionary language and risk factors set forth in the United Therapeutics periodic and other reports filed with the SEC. There can be no assurance that the actual results, events, or developments referenced in such forward-looking statements will occur or be realized. United Therapeutics assumes no obligation to update these forward-looking statements to reflect actual results, changes in assumption, or changes in factors affecting such forward-looking statements. Thank you. Dr. Rothblatt, you may begin your conference.

Martine Rothblatt *United Therapeutics - Chairman & CEO*

Good morning everybody, and welcome to the United Therapeutics second quarter 2010 financial results conference call. I'm joined this morning by Dr. Roger Jeffs, our President and Chief Operating Officer; and Mr. John Ferrari, our Chief Financial Officer. Together the three of us will answer your questions after I start off with some introductory remarks.

The quarter has been a great one for us. Revenues for the second quarter were $137 million, up from $84 million in the second quarter of 2009. Net income for the second quarter of 2010 was $37.7 million, or $0.67 per basic share, compared to a modest net loss a year ago. So, the business is doing very well indeed. Our strong performance for this quarter, and indeed for the whole first half of 2010, has been highlighted by continued top line growth. These results, which were principally driven by the increase in demand for our therapies, affirmed that the patient base benefiting from our medicines is expanding along the entire range of the pulmonary arterial hypertension continuum. Indeed, that's been exactly our strategy in beginning with the parenteral therapies with Remodulin, expanding into the class III population with the inhaled treprostinil, and then with Adcirca being able to address the entire continuum of pulmonary hypertension class II, III, and IV patients. All of the therapies are experiencing substantial growth in their market segments, and have either achieved market leadership or are on their way to.

Starting with Remodulin, we remain overwhelmingly the therapy of choice for parental prostanoid therapy, having a clear majority of prescriptions and revenue market share compared to Flolan and its generic alternatives. In the inhaled market space, we are really excited to announce on this call that we are right on target to our goal of achieving 80% market share of inhaled prostanoids, because as of this call we now have crusted over 60% market share. This is especially significant when you consider we started from a dead halt nine months ago when we launched in September, and already six out of every ten patients using any form of inhaled prostanoid in the US are using our Tyvaso.

And then our goal for Adcirca is similarly right on track. There our goal is to achieve 80% market share by the time that REVATIO, the alternative PDE5 inhibitor goes off patent at the end of 2012. There too, we started from a debt start with its launch one year ago, and I'm just really impressed that one year later we're already at over 20% market share in the PDE5 space among pulmonary hypertension patients. So, just following that curve, I remain confident that Adcirca will become the treatment of choice along -- right on the schedule that we've projected it to be. We've -- for each of the individual products, we've had some either some slight variances from consensus with regard to -- let me start with GAAP earnings. We're aware that we're about 50% better than consensus, so I think a lot of that relates to people still understanding the -- the stock option structure accounting for that. But really great result on GAAP earnings per share.

In terms of Remodulin revenues, we are off about $3 million, off a couple million dollars on Tyvaso, and then up $2 million on Adcirca. So, these differences of $2 million or $3 million one way or the other are completely insignificant, given the level of revenues that we're talking about and the continued growth of patients in each of these three product lines. So with those introductory remarks behind me, let me now open up the lines and either myself, Dr. Jeffs, or John Ferrari will be glad to take your calls.

QUESTIONS AND ANSWERS

Operator

(Operator instructions)

Our first question comes from Salveen Kochnover from Collins Stewart. Your question please.

Laura Ekas ***Collins Stewart - Analyst***

Good morning. This is Laurie Ekas on behalf of Salveen. I was just wondering if you could give us some additional insight into -- or as to how we should think about the quarter-over-quarter increase in Remodulin sales, given that you took a price increase and that there was no inventory stocking in the first quarter? How should we think about the growth trajectory going forward from here?

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Yes, thanks for your question. I think you should think positively about the growth trajectory. Year-to-year we're looking at about 20% growth on Remodulin, and I think that's a reasonable sort of curve, looking forward. The total number of patients with pulmonary hypertension continues to grow.

Total spending in the hypertension market has a (inaudible) around 20%, so there's a lot of growth in the market. The vast majority of that growth is at the front end, with the patients who are being treated simply with oral therapies such as Adcirca. But for most of the patients, the condition is inexorably progressive, and the patients end up requiring parenteral therapy at the later stages of the conditions. And amongst the parenteral therapies, Remodulin is the clear choice of physicians throughout the country. It's got the very long half life, which is completely unique to it, and the greatest convenience. And finally, the physicians have the alternative modes of administration and delivery, whether subq or IV, which again gives a lot of flexibility to the patients. So, as these ever-growing numbers of pulmonary hypertension patients progress toward the latter stages of the disease, the numbers of patients on Remodulin are going to continue to increase. And that's what we've seen here, year over year. And I think you could continue to see it.

Now, it's interesting that there has been some little bit of cannibalization from Remodulin to Tyvaso. For example, as best as we can track, about 6% of our Tyvaso patients have actually come from Remodulin. This is not something that we encourage. In fact, it's something that a number of leading physicians caution against. But in the hands of the skilled physician, that transition for an appropriate patient can certainly be accomplished, and has been successfully accomplished. And for those patients, it's certainly a big sense of liberation going from a 24-hour a day therapy to a therapy that only takes eight minutes a day in the case of Tyvaso. Yet the fact that there's been such modest transition from

Remodulin to Tyvaso shows that that's not a very big factor affecting Remodulin's growth.

So, I think Remodulin is going to continue to grow. It's going to probably grow at the same rate that you've seen year-over-year. And it's interesting, it's in its eighth year and actually getting stronger and stronger. And if you ask me, Martine, what is the main reason why Remodulin continues to get stronger and stronger, it's because in the first few years of the drug, there was a lot of uncertainty on how to manage the site pain, which afflicts upwards of 90% of the patients who start the drug. And doctors don't want to hurt their patients. And so many people recoiled from subq. Dr. Jeffs led the brilliant effort to develop IV Remodulin, and very quickly we regathered all that steam with IV Remodulin. But in the intervening years, physicians figured out if you leave your subq needle in place beyond three days, the site pain for the great majority of patients greatly diminishes. And in some -- many patients, all but disappears. So, there has been an evolving practice of keeping the subq needle in place for upwards of three weeks, maybe a few more days.

And the long and short of it is the subq patient suffers site pain for two or three days, but for the rest of the month is pretty much free of the pain, and has the much greater freedom associated with subq. That has led to a situation where the majority of our Remodulin patients are now subq patients, which was a flip from -- at one point it was a majority IV. And that's continuing drive the aggressive growth of Remodulin into more and more of the pulmonary hypertension patient population.

Laura Ekas ***Collins Stewart - Analyst***

Okay, great.

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Next question?

Operator

Thank you, our next question comes from the line of Geoff Meacham from JPMorgan. Your question please.

Geoffrey Meacham ***JPMorgan - Analyst***

Yes, thanks. Thanks guys for taking the question. On Tyvaso, wondering Martine if you can talk about, or maybe Roger, the breakout of patients. I think last quarter you talked about de novo versus Ventavis switches versus Remodulin switches, and you just gave a number recently, or the 6% number. How does that distribution -- has that changed from 4Q last year to 1Q to 2Q?

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Yes, I'll start off answering the question and then invite Roger to provide some additional color. Things have -- the bottom line is things have not changed from the fourth quarter. The mix of patients is very similar to -- the mix we saw initially. And as mentioned in my introductory remarks, it's actually beginning to gain significant steam here in the second quarter and moving to the third quarter. Roughly speaking, about 10% of the patients come on to Tyvaso actually from parenteral therapies. Either Remodulin or Flolan or the other generic parenteral therapies. Maybe a tad less than 10%.

About 20% of the patients, maybe a little bit more than 20%, come on to our therapy from Ventavis, and then the majority, the large majority, around 70%, come on to our therapy after not really achieving the results desired with either oral or more commonly dual oral therapies. That is PDE5 plus an ETRA. So, that's pretty much as you recall the situation as we reported last year. The majority of patients are coming from the oral therapies rather than at the expense of Ventavis. And what I find really fascinating about that is it actually validates a thesis of our VP of strategic planning, Dr. Oster, who has actually long highlighted the fact that there is this huge population of patients on orals, upwards of 15,000 on PDE5s, maybe a little bit lesser number on ETRAs who -- only a small fraction of those patients are also on some form of prostacyclin therapy. And yes, those patients are overwhelmingly going to progress. And unfortunately, when there's no prostacyclin therapy that the patient wants to go on, all too often the patient ends up expiring without ever getting the benefits of prostacyclin therapy. And a lot of surveys have shown that to be a common end result with pulmonary hypertension.

What Dr. Oster's pointed out is the much greater convenience and efficacy, the safety associated with Tyvaso allows prostacyclin therapy to move upstream into this large patient population who are previously on orals. And indeed, that's exactly what we are seeing. Because to the best of our calculations, our achievement of 60% market share in the inhaled prostanoid space has come not so much at the expense of

Ventavis per se as it has come through moving upstream into patients who were previously treated on dual oral therapies. That's a very, very positive message for all concerned. And it's why my introductory remarks I said our revenue growth reflects our growth along the entire continuum of pulmonary arterial hypertension. Roger, would you like to add any color to those remarks?

Roger Jeffs ***United Therapeutics - President & COO***

No, I think that's a very eloquent response, Martine. The only thing I would add is that over time, the payer acceptance, and I would even say the payer preference for Tyvaso is emerging, and I think that continues to change the profile of patients started on Tyvaso versus Ventavis, which speaks to the share that we gained. So, I think it's an additive benefit to everything that you have said.

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Great. Thanks.

Geoffrey Meacham ***JPMorgan - Analyst***

Can I ask a follow-up or do you want me to get back in the queue?

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

I think you should get back in queue because -- there's a lot of people in line right now.

Geoffrey Meacham ***JPMorgan - Analyst***

Okay, thanks.

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Thanks.

Operator

Thank you. Our next question comes from the line of Michael Yee, from RBC Capital.

Michael Yee ***RBC Capital Markets - Analyst***

Hey, thanks Martine. A question on inventories. Were there any slight changes in inventory on Remodulin or Tyvaso? And then can you remind us how much inventory the wholesalers actually keep on hand, say weeks or days? Because based on our calculations, a couple days of change is even worth a few million of Remodulin, right? So that could impact things.

John Ferrari ***United Therapeutics - CFO***

This is John Ferarri. You are actually correct on the -- I guess change in patient days would have a change in potential revenues on it. For -- let me start with Remodulin. We did see a decline, a slight decline in the value of inventory held by US distributors at the end of June. But we saw a decline in the patient days held, probably about three or four days at the end of June. What -- by contract, they are supposed to hold approximately 30 days, patient days of inventory, at any point in time. So, Remodulin was around the contractual terms as we expected. Now for Tyvaso, we actually saw a significant decrease in both the dollar value of the inventory and the patient days held by our distributors for Tyvaso. So, we are working with the distributors to make sure that their ordering patterns are such that it complies with our contractual arrangements.

Michael Yee ***RBC Capital Markets - Analyst***

Great. Thanks, John.

John Ferrari ***United Therapeutics - CFO***

Thanks.

Martine Rothblatt ***United Therapeutics - Chairman & CEO***

Next question.

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