Theravance Biopharma
1Q 2017 Financial Results Conference Call

May 9, 2017 2:00 p.m. PT/5:00 p.m. ET

Set out below is the script that was used in the previously announced Theravance Biopharma, Inc. conference call held May 9, 2017 at 5:00 p.m. ET. We are furnishing this copy of prepared management remarks due to audio transmission issues outside of our control during the live conference call.

Alex Dobbin, Head of Investor Relations

Good afternoon, everyone, and thank you for joining our first quarter 2017 financial results conference call and webcast. With me on the call today are Rick Winningham, Chief Executive Officer; Renee Gala, Chief Financial Officer; and Brett Haumann, Chief Medical Officer. Following our prepared remarks, we will open the call for questions. A copy of the press release and the slides accompanying this call can be downloaded from our website, or you can call investor relations at 650-808-4045 and we'll be happy to assist you.

Before we get started, we would like to remind you that this conference call will contain forward-looking statements which involve certain risks and uncertainties including statements about our product pipeline, expected benefits of our products, the anticipated timing of trial results and regulatory filings, and expected financial results.

Information concerning factors that could cause results to differ materially from our forward-looking statements are described further in the Company's filings made with the Securities and Exchange Commission.

And now I would like to hand the call over to Rick Winningham. Rick?

Rick Winningham, Chief Executive Officer

Thanks, Alex. Good afternoon, everyone, and thank you for joining us.

2017 is shaping up as an extraordinary year of progress for Theravance Biopharma. Building on our accomplishments in 2016, we are continuing to make important clinical gains across all of our key programs, with multiple clinical milestones anticipated through the remainder of 2017 and 2018.

In our call today, we will provide an update on our key programs and near-term milestones. First I'll give an overview, and then Brett will share more color. Then, Renee will review our financial performance, and we'll open the call to questions.

- First, our Phase 1b study of TD-1473 in patients with moderate to severe ulcerative colitis is progressing, and we expect data in mid-2017. 1473 is designed to be selectively active, reducing inflammation in the intestinal wall while sparing the body from systemic immune suppression. In the Phase 1b study, we are looking for a meaningful reduction in disease activity in ulcerative colitis patients, and we want to achieve this without systemic immune suppression, consistent with the findings in Phase 1 healthy volunteers. Data from the Phase 1b study will inform our broader clinical development plans for this compound, including potential assessments in immune checkpoint inhibitor induced colitis and Crohn's disease.

- Second, we anticipate completing in the middle of this year the Phase 3 long-term safety study for revefenacin, our nebulized, once-daily long-acting muscarinic antagonist, or LAMA, for the treatment of COPD. This long-term safety study, combined with the two positive pivotal Phase 3 efficacy studies reported last October, is intended to support our NDA filing, which we expect to submit to the FDA in the fourth quarter of this year. We recently initiated a Phase 3b study of revefenacin in COPD patients with low peak inspiratory flow rate, or PIFR. These are patients who are not able to breathe in with sufficient force to effectively use handheld inhalers, and these patients exist at all levels of disease severity. Brett will elaborate shortly on a recent publication showing a relationship between low PIFR and reduced hospitalizations when these patients are discharged on nebulized therapy. Our Phase 3b study is designed specifically to evaluate the effect of revefenacin in this population of patients. The study is intended to support commercialization of revefenacin, and is not required for the NDA submission later this year. We expect results in the early part of 2018.

- TD-9855, a dual norepinephrine and serotonin reuptake inhibitor, or NSRI, is in a Phase 2a study in neurogenic orthostatic hypotension, or nOH. As we reported in February, we have seen encouraging patient responses in the single ascending dose portion of this study and, as a result, we have extended the duration of the study to allow for those patients who respond to continue dosing for up to 20 weeks, to test the durability of response. Sustained, durable response is important, because currently approved therapies have not demonstrated evidence of sustained long-term effect. Showing a durable response would represent a major therapeutic advance and a competitive advantage. We expect data from the extension study before the end of 2017. In parallel,

we plan to seek regulatory support for an orphan drug designation and an expedited development pathway, based on the encouraging patient responses seen to date in the Phase 2a study.

- Development of velusetrag is continuing on target. Velusetrag is partnered with Alfa Wassermann in certain ex-US geographies, and Alfa Wassermann has largely funded the Phase 2 program. We are completing a 200-patient Phase 2b study of velusetrag in both idiopathic and diabetic gastroparesis patients. Velusetrag has already shown a positive effect on gastric emptying in a Phase 2a study in gastroparesis and was granted Fast Track designation last year. We anticipate results from the Phase 2b study in gastroparesis in mid-2017.

With regard to VIBATIV, the current basis of our acute care sales infrastructure, we are advancing our commercial and label expansion strategies. The branded antibiotics space remains challenging, particularly due to the introduction of multiple suppliers of daptomycin last year. We expect pressure in the outpatient setting to recede in the second half of 2017 after the outpatient reimbursement price for generic daptomycin resets. Our ongoing Phase 3 study in primary bacteremia is progressing, and we expect data in 2018. If positive, the study would enable us to file an sNDA in this indication. Additionally, our recently completed patient registry study, or TOUR™, is providing valuable information about the use of VIBATIV in real-world clinical settings, including reports of positive clinical responses in patients with bacteremia, endocarditis, osteomyelitis, skin and respiratory infections.

With a strong cash position and a robust business model, we are moving forward with momentum across our pipeline of proprietary and partnered assets. In addition, GSK’s Closed Triple for

COPD represents an important strategic asset and a promising potential source of income for Theravance Biopharma. Looking ahead across an extensive set of milestones, we believe we are well-positioned to improve the lives of patients and create long-term value for our shareholders.

I'll now turn the call over to Brett for additional perspective. Brett?

Brett Haumann, Chief Medical Officer

Thanks, Rick.

I'll provide an overview of 4 of our key programs, all of which have clinical study readouts expected this year. Each program is the result of internal research and discovery, and we believe each could represent meaningfully differentiated therapeutic options for patients.

Firstly, in our JAK inhibitor program, the goal is to develop a highly differentiated treatment option for inflammatory bowel diseases, including ulcerative colitis, Crohn's disease and colitis associated with the use of immune checkpoint inhibitors.

We are developing JAK inhibitors that are designed to remain localized, and only act within the gut wall, thereby maximizing local anti-inflammatory efficacy and minimizing the systemic exposure that would otherwise lead to immunosuppression. Our approach has the potential to increase the therapeutic index by improving the safety profile seen with systemic JAK inhibitors and by increasing the potential to go to higher doses than could be achieved with systemic JAK inhibitors, to achieve even greater efficacy. It is also worth noting that our approach allows us to leverage the broad anti-inflammatory effect of a *pan*-JAK inhibitor by restricting its activity to the

diseased organ, in contrast to systemic JAK inhibitors that need to be more selective in order to reduce systemic toxicity.

As previously reported, we are conducting a small Phase 1b trial of 1473 in patients with active moderate to severe ulcerative colitis. The study is designed to assess the safety and tolerability of 1473 and the effect of 1473 on a range of relevant markers of inflammation in the colon, cellular changes and measures of endoscopic improvement, and clinical benefit, including changes in partial mayo score. We will also measure PK, to assess whether the systemic levels of 1473 in patients match the very low levels seen in healthy volunteers. The study has an adaptive design, which provides flexibility in dosing and yields the maximum amount of data for a study of this size. The collection of evidence from this novel Phase 1b study is intended to inform future development of 1473, including the potential to advance to more definitive induction and maintenance studies. We expect data from the Phase 1b study in mid-2017.

Now, moving on the revefenacin, as Rick briefly summarized, we recently initiated a study in approximately 200 GOLD 2, 3, and 4 COPD patients with low PIFR. This study is not required for filing, but rather is being conducted to better understand the needs of these patients and to support commercialization of revefenacin, if approved.

We believe that this patient group, many of whom have only moderate disease, may benefit particularly from the use of nebulized therapy, as opposed to handheld inhalers, because these patients are not able to inhale with enough force to benefit fully from handheld inhalers.

In this respect, the paper that Rick mentioned earlier is noteworthy. This retrospective study, published in the Annals of ATS by Loh et al, showed that more than half of patients who were

hospitalized for an exacerbation of COPD had low PIFR, and that in this group, rates of all cause readmission and COPD readmission were significantly lower for those patients who were discharged with nebulized therapy compared to inhaler therapy. In fact the results were stark: 50% of patients discharged on handheld inhaler therapy were readmitted within 30 days of discharge, compared to 0% for patients discharged on nebulized therapy. The average time to readmission for COPD in the handheld inhaler group was 27.5 days (less than a month) compared to 103 days (more than 3 months) for the nebulized group. The authors concluded that, quote, “incorporating measurement of Peak Inspiratory Flow in clinical practice is simple and beneficial”, endquote, and they went on to recommend, quote, “checking Peak Inspiratory Flow on both in- and outpatients to assess the need to switch from dry powder inhaler to other delivery devices or nebulized therapies”, endquote.

Indeed, PIFR is very easy to measure, requiring an inexpensive and readily available device, which means PIFR has the potential to become a powerful and accessible factor for physicians to consider as they determine the proper prescription for patients.

We and our partner Mylan are confident that there is a significant market need for a once-daily nebulized LAMA. If approved, revefenacin represents the first such therapy. Further, pivotal Phase 3 efficacy studies we reported last year showed the benefit of our once-a-day LAMA, both as a stand-alone agent and when added to existing COPD therapies including LABA and LABA/ICS.

Now, turning to TD-9855 in neurogenic orthostatic hypotension, or nOH. nOH is a disorder of the autonomic nervous system, characterized by the inability to regulate blood pressure when moving from a lying to a sitting or standing position. It's an orphan condition, affecting fewer than 200,000

patients in the US, and includes patients with multiple system atrophy, Parkinson's disease, and pure autonomic failure. The condition is very debilitating and confines patients to their beds, severely impacting mobility and quality of life.

Our objective with 9855 is to develop a treatment for nOH that can enhance blood pressure regulation, reduce patients' symptoms, and offer the potential for meaningful improvements in quality of life.

There are only limited treatment options available, and these require multiple doses during the day and carry the risk of rebound hypertension when patients lie down. These agents, midodrine and droxidopa, improve vascular tone by increasing levels of norepinephrine in the body. In contrast, 9855 is a reuptake inhibitor, prolonging the effect of the normal norepinephrine that is already present in the body.

9855 has a long half-life which supports the potential for once-daily dosing, and has demonstrated favorable tolerability in over 500 subjects dosed in other clinical trials to date.

Our Phase 2a proof of concept study in patients with nOH was initiated last year and was designed to evaluate postural changes in blood pressure, symptom reduction, and safety and tolerability, following single ascending doses.

Based on encouraging treatment responses in the majority of patients enrolled to date in the single ascending dose portion of the study, we chose to modify the study design, to allow those patients who respond to continue dosing once daily for up to 20 weeks. This study extension will allow us to assess the durability of the treatment effects of 9855, which could prove to be a

meaningful point of differentiation - particularly when one considers that droxidopa has not been able to demonstrate clinical effect beyond 2 weeks as reported in its label. We expect to report data from the extended Phase 2a study before the end of 2017. In parallel - as Rick mentioned - we plan to seek an orphan drug designation for 9855 in nOH, as well as an expedited development pathway.

Next, I'd like to speak about velusetrag, our oral 5HT4 agonist currently being evaluated in a Phase 2b trial in patients with idiopathic or diabetic gastroparesis. Gastroparesis is a serious condition of delayed gastric emptying, affecting nearly 6 million patients in the US, and for which there are very few treatment options. This program is partnered outside of the US with Alfa Wassermann, who has helped to shape the development strategy and paid for the majority of the costs in the Phase 2 program. As a reminder, Theravance Biopharma retains full commercial rights in the US, Japan, and certain other geographies.

Our earlier Phase 2a crossover study confirmed that velusetrag reduces gastric emptying time for patients with diabetic or idiopathic gastroparesis. The current study builds on this data to assess the effects of velusetrag on both gastric emptying time and the symptoms of gastroparesis. We were very pleased to have the FDA grant Fast Track designation for velusetrag in gastroparesis, a testament to its potential importance in treating a clinically important condition with limited alternative therapies. We expect results from our Phase 2b study in mid-2017, and assuming a positive outcome, will confer with our partner on next steps that could lead to a pivotal Phase 3 registration program.

Lastly, I would like to update you briefly on our NEP inhibitor program, where our goal is to develop a medicine that has broad potential to be combined with complementary mechanisms and to treat

chronic heart failure as well as other serious cardiovascular and renal diseases. We are evaluating both TD-0714 and TD-1439 in Phase 1 programs. Today, as reported in our press release, we are pleased to share that we have completed the multiple ascending dose study of 1439 in heathy volunteers, and the results are in line with what we saw in the single ascending dose study and supportive of our target product profile, specifically: 24-hour target engagement, non-renal clearance, and a favorable safety and tolerability profile. With these data, we now have two promising NEP inhibitors, each showing favorable results in Phase 1 studies in healthy volunteers, and we are currently evaluating next steps for these compounds in our NEP inhibitor program.

I'll now pass the call over to Renee to provide a financial update.

Renee Gala, Chief Financial Officer

Thank you, Brett.

Revenue for the first quarter of 2017 was $3.1 million, primarily related to U.S. net product sales of VIBATIV.

Research and development expenses for the first quarter of 2017 were $40.6 million as compared to $35.7 million for the same period in 2016. The increase in R&D expenses is primarily attributed to costs associated with the progression of our key programs. First quarter R&D expense includes $5.1 million in non-cash share-based compensation expense.

Selling, general and administrative expenses for the first quarter of 2017 were $20.8 million as compared to $23.6 million for the same period in 2016. The decrease in expense is due to a reduction in external costs and a decrease in non-cash share-based compensation expense. First quarter SG&A expense includes $5.2 million in non-cash share-based compensation expense.

Following our financing activities in 2016, we remain in a well-capitalized position with $540.7 million in cash, cash equivalents and marketable securities at the end of the first quarter. Completing our fund raising activities in 2016 enables the Company to fund multiple potential pipeline advancements in both 2017 and 2018, as we enter an incredibly catalyst rich period for the company.

Now turning to guidance, our 2017 financial guidance remains unchanged from the guidance we provided in February of this year. For the full year of 2017, we expect our operating loss, excluding non-cash share-based compensation, to be in the range of $195.0 million to $205.0 million.

As a reminder, our guidance does not include the impact of any potential new business development transactions, and we do not expect to receive milestones in 2017 related to existing collaborations.

Finally, I'll summarize our economic interests related to the GSK respiratory programs, as they represent an important potential source of income for Theravance Biopharma in the near and long-term. At the end of 2016, GSK submitted regulatory filings for the Closed Triple for COPD in both the US and the EU. Based on timelines provided publicly by GSK, we could expect approvals in both regions before the end of the year and could begin receiving cash flows related to this program as soon as early 2018. GSK will pay upward tiering royalties ranging from 6.5 to 10%

on world-wide net sales of the Closed Triple, and Theravance Biopharma holds an 85% economic interest in those future potential cash flows. In addition, GSK is responsible for all development and commercialization costs related to the Closed Triple with no costs being borne by Theravance Biopharma. This is important, because GSK continues to invest in clinical studies of the Closed Triple, including the Phase 3 IMPACT study in COPD, which is expected to read out later this year. This study in 10,000 patients with COPD is designed to assess the impact of the Closed Triple on exacerbations of COPD. In late 2016, GSK initiated the Phase 3 CAPTAIN study in asthma. This study is expected to read out in 2018, and, if positive, would be followed by regulatory filings, also in 2018. In addition, GSK recently released data from the Salford Lung Study of RELVAR, which contains two of the active ingredients of the Closed Triple. The findings in this study reinforce the value of once-daily therapy in patients suffering from asthma, which should have a positive impact on the future potential value of Closed Triple for Theravance Biopharma.

Now, I will turn the call back over to Rick.

Rick Winningham, Chief Executive Officer

Thanks, Renee.

As we progress into mid-2017, we are on track to deliver clinical results at every stage of development in our pipeline throughout the remainder of the year. From a personal perspective, very rarely in my career have I ever entered a year where I have Phase 1a, Phase 1b, Phase 2a, Phase 2b, Phase 3a, and Phase 3b studies, with a potential NDA approval and an NDA filing all anticipated to occur over a 12-month period of time. But, that's the opportunity that 2017 presents

for Theravance Biopharma. This unprecedented period for the Company underscores the depth and breadth of our portfolio, the productivity of our internal R&D engine, and our robust business model.

In summary, and if you reference the slide accompanying today's call, in 2017 we expect to achieve the following milestones:

- Data from the Phase 1b study of TD-1473 in ulcerative colitis.
- Data from the Phase 2b study of velusetrag in gastroparesis.
- Data from the Phase 3 12-month safety study of revenfenacin, followed by the planned NDA filing.
- Data from the Phase 2a study of TD-9855 in neurogenic orthostatic hypotension.
- Final data from the TOUR patient registry with VIBATIV.
- Data from the Phase 3b IMPACT study with the Closed Triple, and potential regulatory approval of the product in the US and EU for COPD.

And in 2018 we expect to achieve the following milestones:

- Data from the Phase 3b study of revefenacin (in patients with low peak inspiratory flow rate or PIFR) intended to support commercialization.
- Data from the Phase 3 registrational study of VIBATIV in bacteremia, followed by a planned sNDA submission in the US.
- The potential regulatory approval of revefenacin in the US for COPD.
- The potential to start earning income from the Closed Triple.

- And finally, data the Phase 3a CAPTAIN study of the Closed Triple in asthma patients, followed by potential regulatory submissions for asthma.

In closing, we are very proud of our entire team at Theravance Biopharma all of whom continue to drive our business forward. We believe that our programs represent valuable and differentiated product opportunities with the potential to have a meaningful impact on patients' lives, change how serious diseases are treated, and create long-term value for our shareholders.