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PRESENTATION

Operator

Greetings. Welcome to Verona First Quarter 2019 Earnings Conference Call. (Operator Instructions) Please note, this conference is being recorded. I will now turn the conference over to Stephanie Carrington, Investor Relations. Thank you. You may begin.

Stephanie Carrington *- ICR, LLC - SVP*

Thank you, operator. Good morning or afternoon depending on where you are. And welcome to today's call to review Verona Pharma's results for the 3 months ended March 31, 2019.

On this call, I am joined today by Jan-Anders Karlsson, Chief Executive Officer; and Piers Morgan, Chief Financial Officer. I trust that you have seen the press release that was issued this morning before market opened. It includes the results for the 3 months ended March 31, 2019, as well as the operational update. If you have not, the press release is also available on the Investor Relations portion of Verona Pharma's website.

On today's call, Jan-Anders will first provide a clinical development and business update for the first quarter 2019. Piers will then review the company's financial results for the first quarter ended March 31, 2019. We will then open the call to your questions and expect this call to last approximately 60 minutes. As a reminder, the conference call is being recorded, and will be available on Verona Pharma's Investor Relations website shortly following the conclusion of today's call.

During the call today, the team will be making forward-looking statements, and we remind you of the company's Safe Harbor language. All statements that do not relate to matters of historical facts should be considered forward-looking statements, including but not limited to, statements regarding ensifentrine as a potent bronchodilator and anti-inflammatory agent, the company's ability to provide a promising therapeutic effect through the delivery of ensifentrine, the timing of top line data from its ongoing clinical trials, the timing of that the end of Phase II meeting with the FDA and planned Phase II trial, changes in its clinical development plans based on additional data and the potential for certain formulations of ensifentrine to address larger markets, and the company's plan to explore these formulations in cystic fibrosis and asthma.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from the company's expectations implied by the forward-looking statements. Any such forward-looking statements represent management's estimates as of the date of this conference call. While the company may elect to update such forward-looking statements at some

point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. With that, I will now turn the line to Jan-Anders. Go ahead.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Thank you, Stephanie. It's a pleasure to have the opportunity to provide you with a clinical development and business update today.

Ensifentrine or RPL554 is a unique, first-in-class PDE3 and PDE4 inhibitor, which we believe will increase lung function, reduce symptoms and improve quality of life in the hundreds of thousands of patients with COPD in the U.S. alone that remain symptomatic despite current medications. Verona Pharma's global rights to ensifentrine, and we have granted patents in the U.S., EU, China and other major markets extending beyond 2035.

Before I go into the development events of ensifentrine in more detail, let me first point out that 2019 is a very important year for Verona Pharma with multiple value-creating clinical milestones, before our end of Phase II meeting with FDA and start of Phase III next year.

COPD is the third leading cause of death worldwide according to WHO, and almost twice as many patients die from COPD as from lung cancer. In the U.S. alone, over 15 million patients are diagnosed with COPD, current treatment provides some symptom relief, but there's no cure. Approximately, 2 million of these COPD patients are still uncontrolled and symptomatic despite being treated with 2 bronchodilators and an inhaled steroid. We believe that the ensifentrine, which is both a bronchodilator and anti-inflammatory agent in one molecule, once approved, will make a difference to the lives of many of these symptomatic patients.

Our clinical development program is designed to examine this novel COPD in order to evaluate efficacy, tolerability and dose to establish the optimal positioning in the COPD market. As announced today, we have initiated a Phase IIb, dose ranging study, evaluating nebulized ensifentrine as an add-on to treatment with a long-acting bronchodilator in patients with moderate to severe COPD. This 4-week randomized, double-blind parallel group dose ranging trial plans to enroll about 400 patients with moderate to severe COPD to evaluate the safety and efficacy of nebulized ensifentrine, when added on to inhaled tiotropium or Spiriva, a once-a-day antimuscarinic agent commonly used in COPD. Patients will receive twice daily dosing with 0.375 milligram, 0.75 milligram, 1.5 milligram, or 3 milligram nebulized ensifentrine or placebo. The trial will be performed at about 50 sites in the U.S. The primary endpoint of the trial is improvement in lung function with ensifentrine as measured by peak post expiratory volume in 1 second or FEV1 from 0 to 3 hours, a standard measure of lung function.

Key traditional endpoints include measurements of respiratory symptoms and quality of life via different patient reported outcome tools. We anticipate reporting data from this dose ranging Phase IIb study around year-end. The outcome of this trial is intended to inform the Phase III clinical development program in terms of dose selection, patient population, background therapy and clinical endpoints. Once we have the study report, our plan is to request an end of Phase II meeting with the U.S. FDA that we expect to take place in the first half of next year. At this meeting, we anticipate sharing the expanded data set and articulating our plans for Phase III development. Based on the totality of the information obtained with ensifentrine, we plan to conduct 2 pivotal Phase III trials, each of 6 months duration, and one of them safety expansion. We expect to conduct the studies in COPD patients, with (inaudible) patients with no background treatment or in patients using only one bronchodilator, and FEV1 to be an important endpoint for a broader label. We expect to start with 2 Phase III regulatory trials in 2020.

Separate and not necessarily as part of the pivotal Phase III program, we plan to conduct additional market positioning studies with severe patients with dual and triple therapy for physicians and payers.

Concurrently, we are advancing development of handheld inhaler formulation of ensifentrine in both dry powder and metered dose formulations to address the 80% or so of the COPD patients for just handheld devices for the treatment.

Turning to the Phase II clinical trial of the DPI or dry powder formulation of ensifentrine, that's underway. In early March, we reported positive interim, efficacy and safety data from part one of the 2-part Phase II clinical trial in 37 patients with moderate to severe COPD that receive a single dose of 1 of the 5 different dose range of ensifentrine between 150 and 6,000 microgram or placebo. The interim data showed the statistically significant and clinically meaningful increase in lung function as measured by FEV1 compared to placebo. Peak FEV1 increased from baseline in a

dose-dependent manner, average FEV1 0 to 12 hours, also showed a dose response and demonstrated durability of effect supporting a twice daily dosing regimen. The DPI formulation was well tolerated with an adverse event profile similar to placebo.

The second part of the Phase II trial in patients with moderate to severe COPD over 1 week of twice daily treatment is now ongoing, and we expect top line data in the third quarter of this year, which is earlier than previously indicated. We expect clinical trials with the MDI formulation to start later this month. Importantly, as we stated previously, we plan to seek a partner to support a late-stage development and commercialization of the DPI or MDI formulations to maximize the commercial potential of ensifentrine in such handheld devices.

As we advance towards pivotal trials, we are continuing to take steps to strengthen our team and the Board of Directors. Early in the first quarter of this year, Kathleen Rickard, MD, joined as Chief Medical Officer, and Tara Rheault, PhD, as Vice President of Research and Development Operations and Global Project Management. Dr. Martin Edwards joins the Board as a nonexecutive director in early April. He brings over 3 decades of development and business experience in the pharmaceutical and venture capital industries to our Board.

We want to highlight we continue to take steps to expand our intellectual property at stake, an important EU patent that was recently granted that provides intellectual property protection throughout Europe out to 2035 for a suspension formulation of ensifentrine suitable for nebulized administration. A correspondent patent has already been issued in the U.S.

Let me briefly mention also opportunities to ensifentrine in cystic fibrosis and asthma. As you may know, few if any effective anti-inflammatory treatments assist the patients with cystic fibrosis. Based on positive data from last year in CF patients, we are exploring opportunity to utilize ensifentrine's anti-inflammatory effects in patients with CF. Likewise, we have already shown that ensifentrine is affecting on asthma. While both CF and severe asthma are compelling clinical and commercial opportunities. Our focus right now is on nebulized ensifentrine for maintenance, treatment of COPD and for moving it into Phase III next year. We anticipate data readouts from 3 clinical trials over the next 3 quarters to a year. That will be important to a further development of ensifentrine. First, the nebulized formulation, we expect to report data from the most recently commenced 400-patient dose ranging Phase IIb study around year-end. The data from this study will provide guidance for end of Phase II meeting with FDA that we anticipate to take place in the first half of next year and followed by start of Phase III. For the DPI, positive, interim, efficacy and safety data with the dry powder formulation was reported in early March, and we expect data from the multi-dose study in the third quarter of this year. For the MDI or metered dose inhaler, the Phase II trial with this formation expected to start later this month and the readout in the first half of 2020, providing a top line data on an alternative handheld formulation.

I will now turn the call over to our CFO, Piers Morgan, to provide a financial overview. Yes, please.

Piers John Morgan - *Verona Pharma plc - CFO*

Thank you, Jan-Anders. Good day, everyone, and thank you for joining the call today. I will provide a brief recap of our financial position for the first quarter of 2019.

I'd like to refer you to the press release that we issued this morning, and which has also been filed as a 6-K with the SEC. This release includes audited financial results, inclusive of income, balance sheet and cash flow statement from the 3 months ended March 31, 2019.

Given that we are headquartered in the U.K., our financial results are in British pounds. We have the convenient translation to U.S. dollars using the noon buying rate of the Federal Reserve Bank of New York on March 29, 2019, which is GBP 1 Pound to $1.3032 for certain key figures.

Turning to the income statement. Our operating loss for the 3 months ended March 31, 2019, was GBP 7.8 million or $10.1 million compared to GBP 5.9 million for the first quarter of 2018. The loss after tax for the first quarter 2019 was GBP 5.4 million or $7.7 million compared to GBP 15.2 million for the prior year period. This represents a loss of 5.1p per diluted share or a loss of $0.536 per ADS for the first quarter ended March 31, 2019, and this compares to a loss of 14.5p per diluted share for the prior year.

The total comprehensive loss was calculated as follows. Research and development costs for the 3 months ended March 31, 2019, were GBP 5.9 million or $7.7 million, which is an increase of GBP 1.5 million compared to GBP 4.4 million for the prior year period. The cost of clinical trials increased

by GBP 1.3 million compared to previous year, reflecting 4 clinical trials of ensifentrine, even ongoing or in preparation in the 3 months ended March 31, 2019, compared to 1 trial in the 3 months ended March 31, 2018. In addition, spend on preclinical development also increased by GBP 0.2 million.

General and administrative costs for the 3 months ended March 31, 2019, were GBP 1.8 million or $2.4 million, which is an increase of GBP 0.3 million compared to the GBP 1.5 million in the first 3 months of 2018. The increase was primarily attributable to GBP 0.3 million increase in professional fees. Finance income for 3 months ended March 31, 2019, was GBP 1.9 million or $2.4 million, compared to GBP 0.2 million for the same period last year. The increase in finance income was primarily due to a decrease in the fair value of the warrant liability amounting to GBP 1.6 million during the 3 months ended March 31, 2019, which compares to an increase in the warrant liability during the 3 months ended March 31, 2018, an increase in liability in 2018 was recorded as a finance expense.

Finance expense was GBP 0.8 million for the 3 months ended March 31, 2019, and it's compared to an expense of GBP 10.3 million for the 3 months, March 31, 2018. The decrease was due to a decrease in the fair value of the warrant liability, which is recorded in finance income, compared to an increase in the value of the warrant liability during the 3 months ended March 31, 2018 of GBP 9 million.

In addition, there was the foreign exchange loss on cash and short-term investments of GBP 0.8 million compared to a loss of GBP 1.3 million in the 3 months ended March 31, 2018.

Taxation for the 3 months ended March 31, 2019, amounted to a credit of GBP 1.3 million or $1.7 million compared to a tax credit of GBP 0.8 million in the prior year. The credits are obtained at the rate of 14.5% of 230% of our qualifying research and development expenditure, and the increase in the credit amounts in 2019 were primarily attributable to the increased level of research and development expenditure in the first quarter of 2019 as compared to 2018, which was described earlier in this section of the call.

We ended the first quarter of 2019 with GBP 54.0 million or $70.4 million in cash, cash equivalents and short-term investments, which comprised cash deposits, which have maturity of more than 3 months. Our net cash used in operations for the 3 months ended March 31, 2019, was approximately GBP 9.9 million, or $12.9 million compared to GBP 6.2 million used in operations in the first 3 months of 2018. The cash used in operations reflects the expenditure on the progression of our clinical studies together with other preclinical and associated sporting activities as well as the expansion of our management team and other corporate purposes.

We expect that our existing cash, cash equivalent and short-term investments will more than enable us to fund our operating expenses and capital expenditure requirements through the end of our Phase IIb development of nebulized ensifentrine, for the maintenance treatment of COPD and our proof of concept studies with DPI and MDI formulations of ensifentrine for the treatment of COPD patients.

And with that, we would like to turn the call back to the operator and open it up for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is from Lucy Coddington with Jefferies.

Unidentified Analyst

Just 2 for me please. The first one, just in terms of the OpEx run rate for this year, would you say that this quarter's R&D spend and SC&J -- sorry, excuse me, SG&A is a good guide to the run rate for the rest of the year. I know the Phase IIb has only just started, but I believe there would have been some cost related to preparing for that ahead of this quarter. And then my second question just relates to the trails of the metered dose inhaler. Might we get some data for that this year, I believe, may be if you just confirm that.

Piers John Morgan - *Verona Pharma plc - CFO*

Yes. So thank you, Lucy for that. If I answer the first question on the OpEx, and whether that's a good proxy for the remaining quarters of this year. Yes. So obviously we don't forecast our expenditure, but looking at the level of studies, and the nature of the studies going on, I think your assumption is pretty reasonable. That's okay as an answer? I suppose so.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

And on the MDI. Yes. So we'll have data on the first single dose use as we have done in the dry powder study. And that will be in the second half of this year. And then the full data from the 1-week repeat dosing twice a day will come then in the first half of next year. So yes, we should have 2 data points for both formulations end of this year and then for the middle of next year.

Operator

Our next question is from Joon Lee with SunTrust.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Can you remind us what the background therapy was for your Phase IIb maintenance study, which I believe was dosed daily for 4 weeks. And the source of your confidence that the strong Phase IIa efficacy you're starting the smaller add-on to Spiriva will be maintained out to week 4. And I have a follow up after that.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes, that's a good start. Thank you, Joon. Yes. So the previous study was a very similar study from the patients parallel group 4 doses plus placebo, but in patients of moderate, severe COPD without any background treatment. So the difference this time is we have dropped the top dose, we add a lower dose, and we have a background treatment of once a day of Spiriva. So that's the difference. And then you asked what is the confidence that the activity will remain over a 4-week period? So the confidence is based on all the studies we have conducted to date in 800 patients, where we have repeatedly seen that the for a single dose after a week, after 4 weeks treatment irrespective of conditions, we have actually had a very reproducible data. So the expectation is of course that we also this time we'll see an effect of this maintain over the 4-week period if not improving, even.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Great. I'm looking forward looking to...

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

And as you say, we will also want to look at symptoms, which it takes a 4-week study to take a closer look at. So we're excited about that opportunity.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

And could you provide some color on what would be a good deal for you guys. There -- I could think of regional partnership or by indication. And then what would be the total cost of a Phase IIb program for something like this?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

We are talking about the MDI and DPI, I assume.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Yes.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

So yes. So that is different development path than for a nebulized drug. You are expected -- you can do it differently, but you're expected to do a 6-month study or a 12-month study in Phase III. But you would in many cases also ask if there is -- look at not the only lung function but also exacerbations. If that this the strategy then of course it's thousands of patients per arm and 12 months treatment. So it becomes a rather larger and longer study. On the back of such a study, of course, you would have -- if you would expect it be positive, you have a package that is much more compelling, and then you can, of course, compete in earlier lines of treatment, but that's where you need a very strong commercial organization to maximize the potential after that. And that's, of course, what we would look at.

Joon So Lee - *SunTrust Robinson Humphrey, Inc., Research Division - VP*

Okay. And the last question is do -- e-cigarettes are on the news a lot recently. Do e-cigarettes or vaping contribute to COPD as well? And do you think the size of -- the growing size of e-cigarette could materially impact the overall addressable market? I'm just curious.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

I think we have no hard facts, few studies, those studies state it may not be as innocent as it was initially portrayed. But I think we are not at the point where we understand if it contributes to more damage and COPD, for example, development in airway. I think it's too early. I don't think we need to look at expanding the number of patient, if it's growing on its own, especially, we're increasing (inaudible) and then especially if you look at China and India and other places. But it's not really reduced in U.S. or the West. I think there is a very large market opportunity already. And I think with a unique first-in-class drug in an area where there have very little innovation for many, many years, we think that it's a very compelling commercial opportunity. Actually those are for nebulized formulation and of course at the later stage with a partner for a larger DPI and MDI opportunity.

Operator

Our next question is from Liana Moussatos with Wedbush Securities.

Vasiliana Vireen Moussatos - *Wedbush Securities Inc., Research Division - MD of Equity Research*

Can you give us more market statistics for the Phase III targeted patient population? You mentioned 2 million that are inadequately treated with 2 bronchodilators and an inhaled corticosteroid. What percent of the overall COPD population is -- or not overall, of this population of 2 million or more severe would be the low-hanging commercial fruit? And your Phase IIb, sounds like you're testing it in a less serious population and just an add-on as a LABA and why the difference in population.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. Thank you very much. So the 2 million patients are the ones that are today treated with dual or triple therapy. And that out of those, we believe and from literature and from our own market research, that maybe 40% or so are still symptomatic and continued to deteriorate in lung function and, of course, symptoms. That would be some 800,000 patients that we think are all interested and in need of an additional therapy. There are not that many to choose from. Of course, not everybody is perhaps able to use a nebulizer or willing. But we do think that about 1/3 of moderate to severe COPD patients are actually already using chronically or maybe intermittently a nebulizer. So out of the 800,000, there will be a very significant part of those symptomatic patients that also are using maybe intermittently or maybe more consistently a nebulizer. So that would be 1 first target opportunity. I think it's also clear and we believe that doctors will use it in earlier lines of treatment. There is, of course, symptomatic patients already on a single treatment, and they are deteriorating. And some of them, we believe from our market research, don't -- will want to try a new mode of action, a bronchodilator anti-inflammatory like RPL554, ensifentrine, instead of going to a dual treatment. Of course, we need more studies to substantiate that. But we do think that there are compelling evidence so far that it will not only be used in the late stage, more obvious stage population but also in earlier lines of treatment. So that's just some numbers that we are considering based on literature and market research.

The other aspect you said, so why do only a IIb study on a single bronchodilator? So the reason for looking at this opportunity is going back to ICH guidelines, FDA guidance and competitor development of COPD products. They have achieved a broad label in principle for use in patients with COPD or for treatment of COPD patients while studying patients on no background treatment or maybe a single bronchodilator background treatment. So we believe that we would, at this point in time, if we had a similar background treatment in the Phase III study, as I was describing, we believe with positive data, we would also have an opportunity to have a broader label as said other compounds have achieved. And this would allow us, of course, to have a better opportunity for a successful Phase III program, the less background treatment and the more room for improvement that you allow the patients. I think that is the rationale. We have done one 400 Phase IIb patient study with no background treatment. We want to repeat it on a single Spiriva background treatment so that with FDA, we can have a good discussion on dose to take into Phase III on background treatment, on patient population and, of course, the totality of the Phase III pivotal program. And we believe with a new compound, a new mode of action that this will be an opportunity for broad label and to also use in the segment of patients that really need symptom improvement. Any of them in last line treatment but also some at earlier stages.

Operator

Our next question is from Tom Shrader with BTIG.

Thomas Eugene Shrader - *BTIG, LLC, Research Division - MD & Senior Biotechnology Equity Research Analyst*

A Phase III question. So you're saying 2 trials, no background, one background. Is that -- will those trials be 1 trial and no background and 1 trial with 1 background medication? Or are they both mixed?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

They -- as we look at -- this is our current thinking, which may change. But clearly, we believe that it will be better to mix the 2 populations in 2 trials. You have 2 replica trials. So yes, they like to see 2 trials that repeat or replicate the findings. So that's why we want to mix them in each study.

Thomas Eugene Shrader - *BTIG, LLC, Research Division - MD & Senior Biotechnology Equity Research Analyst*

Got it. And for the DPI, MDI, you started DPI a lot earlier. Is that the preferred format? Does it matter? Presumably you wouldn't be co-formulated as you're going to be used with once-a-day drug. Just is DPI what you most want to hit? Or does it not matter?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

I think there is no preference. We are interested in understanding if there's a difference because the DPI is, of course, particles in lactose in principle and a few other things. And for the MDI, it's a suspension formulation. And it is possible that you will see some PK or some other differences in the responses in COPD patients to either DPI or an MDI in this format. And that's what we wanted to understand and then, of course, pick the better one. I think there's no particular preference for the one or the other at this point in time. And we also, from a partnering perspective, wanted to make sure that we provide a broad opportunity for a potential partner to select what they think fits with their internal portfolio of drugs or if they have a particular preference for the one or the other.

Thomas Eugene Shrader - *BTIG, LLC, Research Division - MD & Senior Biotechnology Equity Research Analyst*

Okay. And then in this next Phase IIb trial, you say the primary endpoint is FEV1 at 0 to 3 hours, is that the morning dose? Is it the afternoon dose? Is it either? Just you have this remarkable effect on the afternoon dose. Can you capture that somehow?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. Thank you for observing that. I think the standard way of measuring it is after the morning dose. So in this case, we are choosing the morning dose. And one of the reasons is that it is very hard to keep patients up and dosing them 8:00 in the evening up to midnight or -- and then measuring up to midnight. And it also disturbs the trough value in the morning after. But I do think we want to understand it based on this study how to size the Phase III program and the proportion of patients with no background versus on a single background, and that's why we do study in this particular way. And I do agree that, of course, would expect that the evening dose may be at least as important, if not more, for patients that maybe have sleep problems, no FEV1 during the nights and some other difficulties that will, of course, manifest itself in the mornings and particularly difficult mornings for many of these COPD patients.

Thomas Eugene Shrader - *BTIG, LLC, Research Division - MD & Senior Biotechnology Equity Research Analyst*

And just to follow up. So is the only way to get that effect into the label -- would the only way, it would appear, would be kind of the shape of the curve over 24 hours, something like that?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. I think there are different way of measuring FEV1 and actually FDA has approved drugs, measured on peak and trough, and under the curve, at various time points. So I think we are intending to use some total of the experience in different settings, no background or some background, to find a time point that is relevant to patients, relevant to FDA and advantageous for ensifentrine.

Operator

Our next question is from Patrick Trucchio with Berenberg Capital Markets.

Patrick Ralph Trucchio - *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*

So first a follow-up on the Phase IIb study that was initiated today. Is this the first time a 0.375 milligram dose is being evaluated. And if so, how did you decide on that dose? And then more broadly, what made you decide on these 4 doses for the 4-week study?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. Patrick, the 4 doses, of course, is based on all the experience we have with ensifentrine in different situations and studies. And we have observed that there is a plateau of effect at the higher doses that we're using but also that the compound in longer trials seems to have a better effect than lower doses that we originally anticipated. So we choose to go down half a dose step -- half the dose compared to the lower previous dose and also to reduce from 6 to 3 milligrams with top dose. There is also, of course, a difficulty in the suspension formulation to move into homeopathic doses. But we do believe that these 4 doses will show a dose response curve that we will be able to discuss with the FDA and find an appropriate dose for ensifentrine in Phase III trials.

Patrick Ralph Trucchio - *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*

Jan, aside from the doses and the length of time, are there any other notable differences between the Phase II study in nebulized ensifentrine that read out earlier this year the 3-day study compared to the Phase IIb dose-ranging study, this 4-week study that was initiated today, in terms of endpoints or combination treatments that are included in the study?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. The very, I think, striking difference is, of course, this is a study now, the IIb study resulted on a single bronchodilator background on tiotropium once a day. The previous study, 3-day study, was of course through a parallel study, where all patients were given either placebo or 1 or 2 doses of ensifentrine on a background treatment of 2 bronchodilators. So that's the major difference because the issue in the first clinical pharmacology study was asking the question is there room for improvement in patients already on maximum bronchodilator therapy. And I think we answered that question even if the endpoints were not met on the morning of the first day and the third day, but certainly that was a 24-hour consistent improvement in the patients' lung function or in the (inaudible) So that was an important finding. But what we need for a Phase III program is a positioning where we answer that question to FDA, what is the optimal dose, what is the optimal background, and how do we size these studies for a successful Phase III program. And we believe that with the 2 Phase IIb studies, we will be able to answer that. The one we did on no background, and the one we're starting now with a background on a single bronchodilator. So I believe that -- yes. Yes, please go ahead.

Patrick Ralph Trucchio - *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*

Sorry, yes. Just one follow-up for me. So if the 4-week Phase IIb study meets expectations, meets the primary endpoint from both a regulatory and clinical response perspective, do you think this study will have more significance with global regulators and clinicians than the 3-day study that was conducted earlier this year?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

I think the 3-day study is an exploratory study, of relevance for the company and physicians maybe that are interested in the area. Regulatory authorities, as far as we understand it, are not looking at studies of shorter duration than a couple of weeks at least. So from that perspective, the most impactful studies is the one we did last year, the 4-week study, and this study. And they're both dose range-finding studies. And based on the 2, in conjunction, and the other data, of course, we have on the compound, I think we'll have a very good discussion with FDA on [-- as we move forward] at the end of Phase II meeting into the Phase III. And I think it's also important to recognize that again this is a new type of treatment. This is not a me-too drug. I think the uniqueness we hope will be recognized not only by physicians and KOLs but also by regulatory authorities as we move forward.

Operator

Our next question is from Adam Walsh with Stifel.

Neil Eric Carnahan - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Neil Carnahan on for Adam. With DPI interim data out and expectation for further data later on this year, can you walk us through your development plans for this formulation? Will results from that multidose study when paired with what you guys have seen for the nebulized formulation of ensifentrine provide us sufficient data set to move into pivotal studies for this larger patient population?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. So for the DPI, and it will be very similar for the MDI, the purpose of the first study is to find a dose range that is reasonable to work in. We have from the single dose, and we'll find it, of course, in a better way from the multiple 1-week dosing later this year. The next step is really to decide on which doses are most important to bring forward to a dose-ranging study and also to perform some more CMC work because we need to optimize both the dry powder and assume also for the MDI around the exact dose range that we think are most meaningful for larger dose range studies and also for potential commercialization later on. So there will be some CMC work before we continue with a better formulation and more suitable, and when you do the Phase IIb dose-ranging studies, as you know, you're expected to have a final formulation. So at that point, we think it would also be advantageous to have a partnership to help us to move that forward in the right way both -- not just on the CMC side but also on the clinical side.

Operator

(Operator Instructions) Our next question is from Ram Selvaraju with H.C. Wainwright.

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

This is Edward Marks on for Ram. Just looking at that end of Phase II meeting with the FDA, I'm wondering what sort of information you would need for that. It looked like you're going to be finishing up with some of the dosing at the end of 2019. Just wondering if you'd be able to have that meeting with preliminary information in the first quarter of 2020. Or would you need to read out that full trial before requesting that meeting?

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. Thank you. I think we expect to have a substantial body of the data available for the end of Phase II meeting. And of course, briefing book as you produce before that meeting, you will have to provide a summary of the totality of the data around ensifentrine. But of course for the clinical Phase III program, it really centers on the dose that we propose or that can be agreed with the FDA for the Phase III program and also the duration, the patients and the endpoints. And we believe that at this point in time early next year, we should have all the information necessary from our side to progress into these discussions with FDA.

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Excellent. And then just so next year, I imagine -- or it sounds like you'll have a lot of data to be able to present. But looking a little bit more on the short term, just wondering about what some of the most significant data you think will be presented at the American Thoracic Society in Dallas in a couple of weeks.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Yes. I think what's important is really that the data sets that we have developed around ensifentrine really confirms that it's a different mechanism of actions, that it seems to have different properties and qualities than the existing 2 classes of bronchodilators, not to mention the anti-inflammatory effect. And the data we will present supports this in terms of lung function and symptoms that we think are attractive, interesting and as we already

talked about in previous meetings that we think it sets it apart as an opportunity of the patients that need symptom improvement. Either they have no treatment, and of course many of them will get onto a generic treatment first, but also patients already on standard of care still are symptomatic, we believe ensifentrine really can provide an opportunity to these patients to have symptom improvement and improvement in quality of life. And we believe that's exactly what they are looking for and their physicians.

Operator

We have reached the end of our question-and-answer session. I will like to turn the call back over to Jan-Anders for closing remarks.

Jan-Anders Karlsson - *Verona Pharma plc - CEO & Executive Director*

Thank you. 2019 is an important year for Verona Pharma. We have multiple value-creating clinical milestones. Before the end of Phase II meeting with FDA and start of the regulatory trials with nebulized ensifentrine for COPD next year, we believe the broad set of data obtained with ensifentrine, including the ongoing Phase IIb study and our plan for regulatory Phase III trials, will improve our chances to attract a broad label and an attractive label for ensifentrine. We have multiple additional inflection points as we obtain the Phase II data with the DPI and MDI formulations, which have the potential to significantly increase the commercial attractiveness of ensifentrine as a standalone product and of course also as a partnered product.

Tomorrow, we'll be conducting investor and analyst R&D forum in London to provide insights into the unmet medical need and challenges for treating COPD as well as an update for the most recent clinical data on ensifentrine by our CMO, Kathy Rickard. The event will feature a panel of key opinion leaders in the field of COPD that will provide a clinician's perspective as well as COPD patients who will provide a patient's perspective on the disease. I hope you will be able to attend in person or listen to the webcast that will be made available after the meeting. Thank you, operator. This concludes today's call.

Operator

Thank you. This concludes today's conference. You may disconnect your lines at this time, and thank you for your participation.
