



MorphoSys AG

Q1 2019 Conference Call Transcript

May 8, 2019

The spoken word shall prevail.

**Dr. Sarah Fakh, Head of Corporate Communications & IR,
MorphoSys AG**

Good afternoon, good morning and welcome to our Q1 2019 conference call and webcast. My name is Sarah Fakh and the I'm Head of Corporate Communications & Investor Relations at MorphoSys.

Slide 2: Today on the Call

With me on the call today are Simon Moroney, our Chief Executive Officer, and Jens Holstein, our Chief Financial Officer.

Slide 3: Safe Harbor

Before we start, I would like to remind you that during this conference call, we will present and discuss certain forward-looking statements concerning the development of MorphoSys's core technologies, the progress of its current research and development programs and the initiation of additional programs. Should actual results differ from the company's assumptions, ensuing actions may differ from those anticipated. You are therefore cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof.

Slide 4: Agenda

In the presentation, Simon will start by giving you an operational review of the first quarter as well as an outlook for the rest of this year. After that, Jens will review the financial results of the first quarter of 2019. The presentation will last about 20 minutes.

After the presentation, we will all be available for your questions. You will find the slide deck for this presentation on our corporate website.

I would now like to hand over to Simon Moroney.

Dr. Simon Moroney, CEO, MorphoSys AG

Thank you Sarah, and also from me, a warm welcome to our Q1 call.

Slide 5: Operational Review Q1 2019 and Outlook 2019

We have made a very good start to the year 2019 with significant achievements in our proprietary as well as our partnered programs. I will go through the highlights in both areas, starting with the clinical programs from our Proprietary Development segment.

Slide 6: MOR208: Proprietary Antibody Against CD19

Our most advanced program is MOR208, the Fc-enhanced CD19 antibody in clinical development for B cell malignancies.

I'll start with L-MIND, our most important and advanced trial in terms of market proximity.

L-MIND is an open-label, single-arm phase 2 trial evaluating MOR208 plus lenalidomide in 81 patients with relapsed or refractory DLBCL, who are ineligible for high-dose chemotherapy and autologous stem cell transplantation. In December 2018, the last of the 81 patients enrolled in the study reached the twelfth and last month of follow-up according to the protocol.

We expect to have final results from the trial shortly and will present the data at the upcoming International Conference on Malignant Lymphoma in Lugano next month. We may publish headline data in advance, as soon as it is available.

In the meantime, we are on track with our plans to seek U.S. regulatory approval on the basis of the L-MIND study. Our submission to the FDA is ongoing and should be complete by year-end, which could, subject to review, allow for an approval in mid-2020.

In Europe, we are encouraged by discussions we have had with regulatory authorities on a potential path to approval in this region also based on L-MIND. We have had positive discussions with two European national authorities to assess the general level of acceptance of L-MIND and are currently seeking advice from the European Medicines Agency - EMA - on whether L-MIND can be used for a European submission. A successful outcome here could result in MOR208 being on the market in Europe earlier than previously assumed. On the basis of our current EMA interaction we expect to have a clearer picture of the way forward later in 2019 and will provide an update on this important topic as soon as we have clarity.

Independently of L-MIND, the phase 3 B-MIND trial of MOR208 is also ongoing. This study looks at MOR208 plus bendamustine versus rituximab plus bendamustine in patients with relapsed or refractory DLBCL who are ineligible for high-dose chemotherapy and autologous stem cell transplantation. In early March we announced an amendment of B-MIND that had been agreed with the FDA, namely the introduction of a biomarker-based, co-primary endpoint.

The scientific rationale for the amendment is based on our own pre-clinical data as well as published literature, which indicate that MOR208 might be particularly active in DLBCL patients who can be characterized by the presence of a certain biomarker that is present in roughly half the patient population addressed in this trial. We're filing patent applications on the biomarker and will disclose information about it when that's completed.

The pre-planned, event-driven interim analysis of B-MIND should take place in the second half of 2019. This interim analysis will inform our decision whether to continue with the original, all-comers trial of 330 patients, or whether to add a further 120 patients and focus on the biomarker-based, co-primary endpoint. In the first case, the study should be completed in the first quarter of 2020, in the second case, in the first quarter of 2021.

Discussions with the FDA regarding the assay validation procedures are expected to take place in the middle of this year.

The B-MIND biomarker amendment gives us an additional chance of a successful outcome to B-MIND, without compromising the trial's original design. Given that the interim analysis could lead to the paths forward I have just outlined, we will announce outcome and continuation of B-MIND as soon as the interim analysis has been done.

The third ongoing MOR208 trial is COSMOS. This exploratory study is looking at the safety of MOR208 in combination with either idelalisib or venetoclax in patients with CLL/SLL who have failed or become intolerant to prior treatment with ibrutinib. The treatment and observation of patients continued during Q1 2019 and we plan to present updated data at a medical conference towards the end of the year.

We have had a lot of inbound interest in our planned frontline DLBCL study of MOR208 and preparations are currently ongoing for the announced phase 1b trial, which will start later this year. Depending on the phase 1b data, the next step would be a pivotal phase 2/3 trial with roughly 800-900 patients, commencing in mid-2020.

As we move forward with our regulatory submission to the FDA of MOR208, we continue to build our commercial organization in the U.S. We have recruited all the main senior positions in support of our President, David Trexler, and are delighted with the excellent quality of management and high level of experience we have been able to attract. A key part of the U.S. organization is the medical affairs department: this currently comprises 10 people, many of whom have been engaging for several months with oncologists across the U.S. Overall, we are well on track to having the commercial team fully operational for an anticipated launch in mid-2020.

Lastly, I am very pleased to announce that MOR208 now has an International Nonproprietary Name - INN. The name is tafasitamab and we will transition our usage away from MOR208 to this name. Having an INN name is an important step in our current commercialization preparations.

Slide 7: MOR106: Proprietary Antibody Against IL-17C

I'll continue with MOR106, the antibody directed against IL-17C that is currently in clinical development for atopic dermatitis.

Just to remind you, we jointly discovered and developed the antibody with Galapagos, before signing an exclusive license agreement with Novartis in July of last year. Since the effective date of the agreement, all research, development, manufacturing and commercialization costs for MOR106 were assumed by Novartis. There are currently three studies ongoing for MOR106 and I would like to briefly update you on their status:

- **First:** Our ongoing phase 2 IGUANA trial in atopic dermatitis patients, which we started together with Galapagos in May 2018, is continuing patient enrollment and we expect completion of enrollment around the end of this year.
- **Second:** We started a phase 1 bridging study in the third quarter of last year, to evaluate the safety and efficacy of a subcutaneous formulation of MOR106 in healthy volunteers and atopic dermatitis patients and expect primary completion of this trial also by the end of the year.
- **Third:** In April, we announced the start of the phase 2 GECKO trial, which will enroll patients in the U.S. and Canada to evaluate the combination of MOR106 with topical corticosteroids. This IND-opening study extends the development program for MOR106 to the U.S. and Canada, complementing the ongoing clinical trials in Europe.

Further, the start of a Japanese ethno-bridging study together with Galapagos is planned for the second half of this year.

We see great potential for MOR106, which is, to the best of our knowledge, the first program against IL-17C in clinical development. While our initial focus is on atopic dermatitis, which is an area of enormous unmet medical need, under the terms of the agreement Novartis will explore the potential of MOR106 in additional indications other than atopic dermatitis.

Slide 8: MOR202: Proprietary Antibody Against CD38

Let me now turn to MOR202, our proprietary anti-CD38 antibody with opportunities in oncology and autoimmune diseases.

In the first quarter of 2019, our partner I-Mab Biopharma initiated two pivotal clinical trials of MOR202 in second and third line multiple myeloma in the Chinese region. Each of these trials, one phase 2 and one phase 3, could lead, if successful, to a Biologics License Application in China.

In the meantime, we continue preparations for a trial of MOR202 in a selected and as yet non-disclosed autoimmune disease. We are on track to start this trial in Q3 of this year at which time we will disclose the indication.

Slide 9: Partnered Discovery Programs - Tremfya® (Guselkumab)

I will turn now to our Partnered Discovery segment. Even though we're no longer actively seeking deals in this segment, it still is a substantial part of our overall value proposition. The segment comprises more than 100 programs currently in R&D, 24 of which are in clinical development. Our royalty participation in these promising drug programs will continue to serve MorphoSys well long into the future.

The most advanced product in this segment is Janssen's Tremfya®, which in July 2017 became the first drug based on our antibody technology to reach the market.

Sales of Tremfya® in the first quarter of 2019 reached 217 million USD, confirming that our royalty guidance of EUR 23 - 30 million is well within reach. Tremfya® is clearly an important asset for Janssen, and is being given the appropriate attention, both in commercialization and in further development. Janssen started clinical development in two additional indications in Q1 of 2019, namely:

- a phase 2a proof-of-concept study in ulcerative colitis, and
- a phase 1 trial in familial adenomatous polyposis, a genetically determined disease of the gut with a high prevalence to develop into colon cancer.

These new indications add to the ongoing ones, which include several forms of psoriasis, psoriatic arthritis, Crohn's disease and hidradenitis suppurativa. We are delighted to see such a broad clinical development program and are optimistic that Tremfya® can become a widely used drug, further supported by the recent FDA approval of the Tremfya® One-Press device in February of this year. This device allows a self-administration at home thereby offering a much more convenient administration for patients.

Slide 10: Our Pipeline

To conclude, at the end of the first quarter of 2019, the MorphoSys pipeline comprised overall 115 programs, from discovery to the market. These include one program already on the market, which is Tremfya® and 29 programs in various stages of clinical development. We expect a substantial amount of additional clinical data and potential milestones from several programs between now and year-end. As always, we have no control over what our pharma partners communicate, but we are confident that there are quite a few positive results to come. We believe many of these programs have the potential to be major value drivers for MorphoSys and we look forward to updating you on many of them in the future.

That concludes my operational review, I will now hand over to Jens for his wrap-up of the financials.

Jens Holstein, CFO, MorphoSys AG

Slide 11: Financials Q1 2019 and Guidance 2019

Thank you, Simon. Ladies and Gentlemen, also from my side a warm welcome to all of you.

As Simon already pointed out, we are very pleased with the developments and our performance in the first quarter of the year.

Let's now take a closer look at the most important financial figures of MorphoSys for the first quarter 2019.

Slide 12: Q1 2019: Consolidated Statement of Profit or Loss

I would like to start with our P&L statement on slide 12.

Group revenues totaled 13.5 million Euros, compared to revenues of 2.8 million Euros in the first quarter of 2018. This increase was driven by increasing Tremfya® royalties as well as by a milestone payment of 5 million U.S. dollars for MOR202 from I-Mab Biopharma following the start of the phase 2 clinical trial in March.

As in previous quarters, the contractual royalty reporting from Janssen for Tremfya® has not been received yet. Tremfya® royalties booked for Q1 2019 were estimated based on a public announcement made by Janssen/J&J. Final numbers can still vary slightly on the basis of foreign exchange effects.

Looking at expenses, our total operating expenses reached 37.3 million Euros. The expenses for research and development amounted to 24.7 million Euros. Selling expenses rose to 1.7 million Euros as compared to 0.8 million the year before. General and administrative expenses increased to 5.9 million Euros versus 3.9 million in Q1 2018.

Cost of sales for the first three months of 2019 amounted to 5.0 million Euros. This item consists of expenses related to services provided to partners such as Novartis or I-Mab. Those costs also included manufacturing costs for the expected market supply of MOR208, or tafasitamab, as the antibody is called from now on. In case of an approval, this material shall be partly used as drug product in 2020. In the first quarter of 2018, this cost item had not been used.

Earnings before interest and taxes amounted to minus 23.6 million Euros in Q1 2019, in comparison to minus 19.0 million Euros in the first quarter of 2018.

Our consolidated net loss after taxes amounted to 22.7 million Euros in Q1 2019, compared to a net loss after taxes of 19.5 million Euros in Q1 of the previous year. The earnings per share for Q1 2019 reached minus 72 Eurocents, after minus 67 Eurocents in Q1 of the previous year.

Slide 13: Segment Reporting Q1 2019

I am now on slide 13 to give you an overview of our segment reporting for Q1 2019:

In our Proprietary Development segment, in which we focus on the research and clinical development of our own drug candidates, we recorded revenues of 5.8 million Euros in the first quarter of 2019 as compared to 0.2 million Euros in Q1 of 2018. As mentioned earlier, this increase was mainly driven by a milestone payment of 5 million U.S. dollars from I-Mab for the start of a clinical trial of MOR202 in Taiwan.

Operating expenses amounted to 30.8 million Euros, as compared to 16.1 million Euros in Q1 2018. The main reason for this increase is our increasing investments for the development of our proprietary programs. Consequently, the EBIT of our proprietary development segment came in at minus 25.0 million Euros compared to minus 15.9 million Euros in the previous year.

In our Partnered Discovery segment, we apply our proprietary technology to discover new antibodies for third parties and benefit from our partners' development advancements through R&D funding, licensing fees, success-based milestone payments and royalties.

In the first quarter of 2019, revenues amounted to 7.8 million Euros as compared to 2.6 million Euros in Q1 2018. Consequently, the EBIT in our Partnered Discovery segment increased and amounted to 5.5 million Euros as compared to 0.6 million Euros in Q1 2018.

Slide 14: Consolidated Balance Sheet (IFRS) March 31, 2019

Moving on to the balance sheet on slide 14, as of March 31, 2019, we recorded total assets of 556.3 million Euros. This represents an increase of 17.5 million Euros compared to year-end 2018. The increase is a result of the application of the new IFRS 16 standard with respect to leases offset by the use of cash and cash equivalents for operations in the first quarter of 2019.

At the end of Q1, we had a cash position of 431.2 million Euros compared to 454.7 million Euros as of December 31, 2018. On the balance sheet, this cash position is reported under the following items: cash and cash equivalents; financial assets at fair value through profit or loss; and current and non-current other financial assets at amortized costs.

The number of shares issued totaled 31,839,572 at the end of Q1 2019, which is the same number as of year-end 2018.

Slide 15: Financial Guidance 2019

Before I conclude my section, I would like to re-affirm our financial guidance for full-year 2019, which was first communicated in March in connection with the presentation of our 2018 annual report. For 2019, we anticipate total Group revenues in the range of 43 to 50 million Euros. Thereof, we estimate Tremfya® royalties to be in the range of 23 to 30 million Euros at constant U.S. currency. We expect an EBIT in the range of minus 127 to minus 137 million Euros. Proprietary R&D expenses including technology development in 2019 are anticipated in a corridor of 95 to 105 million Euros.

Ladies and gentlemen, this concludes my review for the first quarter of 2019, and I'll now hand back to Sarah for the Q&A session.

Dr. Sarah Fakh, Head of Corporate Communications & IR, MorphoSys AG

Slide 16: Q&A

Thank you, Jens. We will now open the call for your questions.

Dr. Simon Moroney, CEO, MorphoSys AG

To wrap up, we're well on track to achieving or exceeding our goals for this year.

With MOR208, or tafasitamab as it's now called, based on all the data we've seen so far, we strongly believe we have a remarkable drug candidate. We'll report final data from the L-MIND trial within the next several weeks, and are well on track to complete our regulatory filing activities in the U.S. by year-end, as planned.

Buildup of the U.S. commercial organization also progresses according to our plan to be ready and fully operational for a launch in mid-2020. We look forward to keeping you apprised of our progress with this important expansion.

Our other proprietary programs, including MOR106 and MOR202 are also making good progress. With our solid financial position, MorphoSys is well equipped to execute its plans as outlined during the remainder of the year and beyond.

Dr. Sarah Fakh, Head of Corporate Communications & IR, MorphoSys AG

That concludes the call. If any of you would like to follow up, we are in the office for the remainder of the day. Thank you for your participation on the call and goodbye.