

August 26, 2020

# InDex Pharmaceuticals Holding AB (publ) interim report January - June 2020

# Focus on phase III preparations

"The commercial preparations have confirmed our belief in the potential of cobitolimod, where we estimate that the annual sales at a successful commercialisation can reach more than USD 1 billion," says Peter Zerhouni, CEO of InDex Pharmaceuticals.

## Period April - June 2020

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –15.6 (–17.7) million
- Result after tax amounted to SEK –15.6 (–17.7) million, corresponding to SEK –0.17 per share (–0.26) before and after dilution
- Cash flow from operating activities amounted to SEK –32.8 (–13.6) million

## Period January - June 2020

- Revenues amounted to SEK 0.0 (0.0) million
- Operating result amounted to SEK –39.6 (–34.9) million
- Result after tax amounted to SEK –39.6 (–34.9) million, corresponding to SEK –0.45 per share (–0.51) before and after dilution
- Cash flow from operating activities amounted to SEK –54.7 (–32.0) million
- Cash and cash equivalents at the end of the period amounted to SEK 70.6 (50.5) million
- Number of employees at the end of the period was 7 (7)
- Number of shares at the end of the period was 88,781,275

All comparative amounts in brackets refer to the outcome during the corresponding period 2019.

# Significant events during April - June 2020

- InDex received positive responses from FDA and EMA regarding phase III development of cobitolimod for the treatment of moderate to severe ulcerative colitis
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on Monday April 20, 2020.
  Board members Wenche Rolfsen (also chairman), Uli Hacksell, Lennart Hansson and Stig Lökke
  Pedersen were re-elected, and Marlene Forsell and Yilmaz Mahshid were elected as new ordinary
  board members

## Significant events after the reporting period

• No significant events have occurred after the end of the reporting period

#### Other events

• InDex announced that the successful results of the CONDUCT study will be presented orally at two leading medical conferences

#### **CEO** statement

Our focus remains on the phase III preparations with cobitolimod in ulcerative colitis. To assist, we have expanded our circle of medical advisors by setting up a North American advisory board. It is fantastic that we have succeeded to attract six of the top clinical experts in inflammatory bowel disease to support the continued development and positioning of cobitolimod with a focus on the US market. The group's first meeting in June clearly showed that they see a potential prominent role for cobitolimod in the future treatment of ulcerative colitis. We continue the work to finalize the phase III design and the associated financing. Contingent on how the Covid-19 pandemic evolves, we plan to start the study in the second quarter of 2021.

We have also had a US consultancy firm to detail the positioning as a complement to the market research we conducted during the first quarter of this year, which has provided us with a deeper understanding of the future market. The commercial preparations have confirmed our belief in the potential of cobitolimod, where we estimate that the annual sales at a successful commercialisation can reach more than USD 1 billion. More than 2 million people have ulcerative colitis in the US, Europe and Japan, and of these about 60 percent are estimated to suffer from moderate to severe ulcerative colitis. Approximately 55 percent of this group are considered to have left-sided colitis and more than half do not respond to conventional treatment and need other alternatives. With an assumed price in the US, Europe and Japan in line with the most recently launched products, it corresponds to an addressable market for moderate to severe left-sided ulcerative colitis of over USD 9 billion annually.

Since May, there have been several important news regarding competing development projects in phase III in ulcerative colitis. One project has been discontinued and others have reported less promising clinical results. Several of these drug candidates will probably not reach the market in the end. Cobitolimod has a completely different mechanism of action and safety profile than these substances, and for InDex the news mainly mean reduced future competition. It will also be very interesting to get more data from these studies that we can learn from for our own development.

Our phase IIb results from the CONDUCT study will be presented orally in October at two leading gastroenterology conferences; the UEGW in Europe and the ACG in the US. These events are great opportunities for us to further reach the international scientific community with the successful results, as well as potential partners and specialist investors.

It is very inspiring with the support from all our medical advisors. They point out cobitolimod's unique combination of efficacy and safety as well as the novel mechanism of action. I look forward to an eventful autumn for InDex with the continued phase III preparations.

## For more information:

Peter Zerhouni, CEO Phone: +46 8 122 038 50

E-mail: peter.zerhouni@indexpharma.com

The full report is attached as a PDF and is available on the company's website <a href="https://www.indexpharma.com/en/category/interim-reports/">https://www.indexpharma.com/en/category/interim-reports/</a>

#### **Publication**

This information is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication through the agency of the contact person set out above at 8:00 CET on August 26, 2020.

#### InDex Pharmaceuticals in brief

InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's lead asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe ulcerative colitis - a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in treatment of various immunological diseases.

InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm. Redeye AB with e-mail certifiedadviser@redeye.se and phone number +46 8 121 576 90 is the company's Certified Adviser. For more information, please visit www.indexpharma.com.