

February 25, 2021

# InDex Pharmaceuticals Holding AB (publ) year-end report 2020

## Financing secured for phase III development of cobitolimod

"With the equity financing secured until the next pivotal read-out of clinical data, it feels very inspiring to now advance cobitolimod into phase III, which is the final stage of development before application for market approval," says Peter Zerhouni, CEO of InDex Pharmaceuticals.

#### Period October - December 2020

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –10.1 (–25.6) million
- Result after tax amounted to SEK –10.1 (–25.6) million, corresponding to SEK –0.04 per share (–0.11) before and after dilution
- Cash flow from operating activities amounted to SEK -8.1 (-34.2) million

#### Period January - December 2020

- Revenues amounted to SEK 0.0 (0.1) million
- Operating result amounted to SEK –57.3 (–87.7) million
- Result after tax amounted to SEK –57.4 (–87.8) million, corresponding to SEK –0.24 per share (–0.45) before and after dilution
- Cash flow from operating activities amounted to SEK –70.7 (–85.1) million
- Cash and cash equivalents at the end of the period amounted to SEK 53.8 (126.8) 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 October - December 2020

• InDex announced the intention to carry out a fully guaranteed rights issue of approximately SEK 500 million to fund phase III development of cobitolimod

## Significant events after the reporting period

- An extraordinary general meeting was held in InDex on January 12, 2021
- The Board of Directors of InDex resolved on a fully guaranteed rights issue of approximately SEK 533 million
- InDex published a prospectus in connection with the fully guaranteed rights issue
- InDex's rights issue was oversubscribed and the company received approximately SEK 488 million net

#### Other events

- The Lancet Gastroenterology & Hepatology published the results of InDex's phase IIb study CONDUCT with cobitolimod and a positive independent expert commentary
- InDex hosted a virtual R&D day for investors, analysts and media

#### **CEO** statement

To finance phase III development of cobitolimod we have just completed a successful rights issue of approximately SEK 533 million. The subscription ratio amounted to as much as 153 percent and more than 99 percent was subscribed for by exercise of subscription rights. I would like to thank existing and new shareholders for the strong support in the rights issue, and extend a special welcome to HBM Healthcare Investments and Handelsbanken Funds as new large owners. These are two internationally recognized and successful life sciences specialists that have chosen to invest significant amounts, SEK 63.5 million and SEK 30 million respectively, which not only strengthens the ownership base, but also constitutes a strong validation of the potential of InDex.

The rights issue will primarily fund the important initial induction study in a sequential phase III program for left-sided moderate to severe ulcerative colitis. The results of this induction study will constitute a significant value inflection point and the remaining program can be optimised according to the outcome of the study.

We plan to start the study in the second quarter of 2021, subject to the Covid-19 pandemic, and we estimate that it will take 18 to 24 months to complete from initiation. Next step in our preparations is to finalize the agreement with the leading global contract research organisation that we have selected to conduct the study. The clinical study must then be approved by the authorities of each participating country.

It will be a global study with approximately 400 patients at a few hundred clinics. The primary endpoint, clinical remission, is to be measured at week 6. Apart from the dosing 250 mg  $\times$  2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, cobitolimod's excellent safety profile allows to also evaluate a higher dose, 500 mg  $\times$  2, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than what was observed in the CONDUCT study.

For those who want to know more about the phase III design, cobitolimod and ulcerative colitis, I highly recommend the webcast from the virtual R&D day which can be found on our website. The ulcerative colitis patient Jonas Eriksson gave a first-hand account of the problem that many patients do not respond to or experience severe side effects from current treatments. Two key opinion leaders within inflammatory bowel disease and Apex Healthcare Consulting, who has conducted market research on cobitolimod, also participated, as well as InDex's management.

InDex has a well-developed network of key opinion leaders and we established a North American advisory board in 2020. Recently, we have also formalized a European equivalent where several of the members have collaborated with InDex for a long time, and we have managed to attract a couple of new experts to the group as well.

Thanks to its outstanding combination of efficacy and safety, as well as the novel and unique mechanism of action, cobitolimod is positioned to be an essential part of the future treatment of ulcerative colitis and thereby improve the quality of life for patients suffering from the disease.

With the equity financing secured until the next pivotal read-out of clinical data, it feels very inspiring to now advance cobitolimod into phase III, which is the final stage of development before application for market approval.

## For more information:

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The full report is attached as a PDF and is available on the company's website <a href="https://www.indexpharma.com/en/investors/financial-reports-and-presentations/">https://www.indexpharma.com/en/investors/financial-reports-and-presentations/</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 February 25, 2021.

#### 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 the 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. Redeye AB with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90 is the Company's Certified Adviser. For more information, please visit <a href="https://www.indexpharma.com">www.indexpharma.com</a>.