November 25, 2020

# InDex Pharmaceuticals Holding AB (publ) interim report January – September 2020

## Phase III plan laid out

*"We have now laid out our plan for the phase III program with cobitolimod, which will form the basis for market approval, and we intend to finance the important initial induction study through a fully guaranteed rights issue of approximately SEK 500 million. In collaboration with the leading experts in the field we have arrived at a design that in an efficient manner will provide the basis to be able to draw firm conclusions regarding cobitolimod's efficacy and safety as well as solid ground for a successful future commercialisation," says Peter Zerhouni, CEO of InDex Pharmaceuticals.*

**Period July – September 2020**
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –7.7 (–27.2) million
- Result after tax amounted to SEK –7.7 (–27.2) million, corresponding to SEK –0.09 per share (–0.39) before and after dilution
- Cash flow from operating activities amounted to SEK –8.3 (–18.9) million

**Period January – September 2020**
- Revenues amounted to SEK 0.0 (0.1) million
- Operating result amounted to SEK –47.3 (–62.1) million
- Result after tax amounted to SEK –47.3 (–62.1) million, corresponding to SEK –0.53 per share (–0.90) before and after dilution
- Cash flow from operating activities amounted to SEK –63.1 (–50.9) million
- Cash and cash equivalents at the end of the period amounted to SEK 62.3 (117.6) 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 July – September 2020**
- No significant events have occurred during the period

**Significant events after the reporting period**
- InDex intends to carry out a fully guaranteed rights issue of approximately SEK 500 million to fund phase III development of cobitolimod

**Other events**
- The Lancet Gastroenterology and Hepatology published the results of InDex's phase IIb study CONDUCT with cobitolimod and a positive independent expert commentary

**CEO statement**

We have now laid out our plan for the phase III program with cobitolimod, which will form the basis for market approval, and we intend to finance the important initial induction study through a fully guaranteed rights issue of approximately SEK 500 million. It has been an intensive process since the regulatory authorities FDA and EMA endorsed the advancement of cobitolimod into phase III based on our previous positive study results and the significant medical need for new treatment options for patients suffering from ulcerative colitis. In collaboration with the leading experts in the field we have arrived at a design that in an efficient manner will provide the basis to be able to draw firm conclusions regarding cobitolimod's efficacy and safety as well as solid ground for a successful future commercialisation.

We are planning a sequential phase III program with two induction studies and a maintenance study with patients that have responded to cobitolimod as induction therapy. The first induction study, where the effect is measured at week 6, will include approximately 400 patients with moderate to severe left-sided ulcerative colitis. Apart from the dosing 250mg x 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 us to also evaluate a higher dose, 500mg x 2, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than the already competitive efficacy we observed in the CONDUCT study.

Based on the results of the first induction study, we then plan another induction study with the dose that shows the greatest efficacy. By reading out the results of the first induction study before the next study is started, we reduce the development risk of the program. Depending on the outcome of the induction studies and how the regulatory requirements develop, we will evaluate the possibility to apply for market approval based on only induction data. This could mean that cobitolimod can benefit patients more quickly.

To finance the important initial induction study and other operations, we are planning a fully guaranteed rights issue, for which we have already established interest from large existing shareholders like Linc and Fourth AP Fund to invest and Barclays Bank Ireland PLC and Carnegie Investment Bank AB to underwrite. The plan is to hold an extraordinarygeneral meeting in January 2021 and carry out the rights issue thereafter. It is our firm belief that it is strategically right to conduct the study on our own in order to create more value in cobitolimod and more shareholder value in InDex by taking cobitolimod closer to market approval.

Subject to how the Covid-19 pandemic evolves, we plan to start the first induction study in the second quarter of 2021 and expect to be able to report the results from the study within 18 to 24 months thereafter. It will be a global study including a few hundred clinics worldwide.

The successful results from the CONDUCT study were published in early October in The Lancet Gastroenterology and Hepatology, which is one of the highest ranked international medical journals within the field of gastroenterology. The journal also chose to publish an independent expert commentary that provides strong support for the potential of cobitolimod to become an essential part of the future treatment of ulcerative colitis, as many patients do not respond to or suffer severe side effects from current treatments. In October, the principal investigator of the study, Professor Atreya at the University of Erlangen-Nürnberg, also presented the results at the two leading gastroenterology conferences, UEGW and ACG. Furthermore, Professor Atreya won the award for best international abstract at ACG.

These external validations, together with the market research we have conducted, further strengthen our belief in the value of cobitolimod. With its outstanding combination of efficacy and safety as well as the novel and unique mechanism of action, we estimate that the global annual sales at a successful commercialisation can reach more than USD 1 billion.

On December 8, we will arrange an R&D day and tomorrow I will present the company at the Redeye Life Science Day. I hope you will have the opportunity to attend these virtual events. With the phase III plan, InDex is moving to the next level and I look forward with great enthusiasm to the continued journey.

**Conference call for investors, analysts and media**
A conference call on the company's interim report for Q3 2020 and description of the phase III program for cobitolimod and the financing of the important initial induction study will be held with CEO Peter Zerhouni on Wednesday November 25, 2020 at 11:00 (CET). During the conference call, which will be held in English, it will be possible to ask questions to the company. Questions can also be sent in by e-mail to info@indexpharma.com.

The conference call can be followed at https://tv.streamfabriken.com/index-pharmaceuticals

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The full report is attached as a PDF and is available on the company's website https://www.indexpharma.com/en/investors/financial-reports-and-presentations/

**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 November 25, 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.