August 25, 2017

InDex Pharmaceuticals Holding AB (publ) interim report January – June 2017

First patient enrolled in the CONDUCT study

Period April – June 2017
- Revenues amounted to SEK 0.0 (0.1) million
- Operating result amounted to SEK –15.4 (–9.6) million
- Result after tax amounted to SEK –15.2 (–10.5) million, corresponding to SEK –0.24 per share (–0.35) before and after dilution
- Cash flow from operating activities amounted to SEK –18.4 (–8.3) million

Period January – June 2017
- Revenues amounted to SEK 0.1 (0.1) million
- Operating result amounted to SEK –37.5 (–16.5) million
- Result after tax amounted to SEK –37.2 (–17.6) million, corresponding to SEK –0.60 per share (–0.58) before and after dilution
- Cash flow from operating activities amounted to SEK –37.5 (4.2) million
- Cash and cash equivalents at the end of the period amounted to SEK 155.7 (11.2) million
- Number of employees at the end of the period was 7 (8)
- Number of shares at the end of the period was 62,528,433

All comparative amounts in brackets refer to the outcome of InDex overall activities during the corresponding period 2016.

Significant events during April– June 2017
- InDex participated with two poster presentations at the Digestive Disease Week (DDW) 2017
- The Annual General Meeting in InDex Pharmaceuticals Holding AB was held on May 30, 2017
- The first patient was enrolled in the CONDUCT study

Significant events after the reporting period
- A new patent for cobitolimod was granted in Europe
- Orphan-drug designation for cobitolimod for pediatric ulcerative colitis was received in the US

"It was an important milestone when we enrolled the first patient in the CONDUCT study at the beginning of the summer. The money we raised in the IPO in 2016 is primarily used for this phase IIb study, and we are delivering according to plan," said Peter Zerhouni, CEO of InDex Pharmaceuticals.

CEO statement

It was an important milestone for InDex when we enrolled the first patient in the CONDUCT study with cobitolimod at the beginning of the summer. The money we raised in the IPO in 2016 is primarily used to fund this phase IIb study in moderate to severe active ulcerative colitis, and we are delivering according to plan. The objective is to have top line results from the study in the fourth quarter of 2018. The CONDUCT study will include 215 patients at 90 sites in 12 European countries. Currently the study is approved in 9 of the 12 countries. We expect that the patient recruitment will get under way more actively in September/October when all the countries and clinics should be up and running and the holiday season in Europe is over.

The CONDUCT study is designed to optimise the dosing of cobitolimod. The highest dose tested is almost ten times higher than the one tested in InDex's most recent clinical trial. One of the treatment groups also receives cobitolimod once a week, while it has only been given once a month in previous studies with promising results. The goal is that more frequent and higher doses will result in a substantially higher efficacy, while maintaining the compound's excellent safety profile, than in prior clinical studies with cobitolimod and also in comparison with what has been reported both for products on the market and other compounds in late stage clinical development.

In June, I attended the large BIO Convention in the US and met with many pharmaceutical companies that are potential future partners to InDex to update them on our progress. There is a continued great interest in new, more effective and safer treatment options in our therapeutic area. In this context, cobitolimod offers a novel and unique mechanism of action, meaning a new way to attack the disease that we are alone with.

From a lifecycle management perspective, an oral version of cobitolimod would be an attractive follow-on to the first-generation product, which is administered rectally in the form of a solution. To prepare cobitolimod for a long life on the market, we have therefore begun assessing the possibility to develop a capsule or tablet that is taken orally and releases cobitolimod in the intestine. Basic formulation work and a thorough development plan for an oral formulation will strengthen our position in future partnership discussions.

Recently, an additional method of use patent for cobitolimod was granted in Europe, which is in line with our strategy to establish a broad patent protection for the drug candidate. In addition, orphan-drug designation for cobitolimod for the treatment of pediatric ulcerative colitis was received in the US. However, children make up a very small fraction of the total number of patients with ulcerative colitis. The development of cobitolimod is currently only oriented towards the treatment of adult patients and no pediatric development is ongoing.

I look forward to a busy fall with a continued focus on the CONDUCT study.

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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 foremost asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe active 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 are traded on Nasdaq First North Stockholm. Redeye AB is the company's Certified Adviser. For more information, please visit www.indexpharma.com.