

May 30, 2017

# InDex Pharmaceuticals Holding AB (publ) interim report January - March 2017

## The CONDUCT study starts

### **Period January - March 2017**

- Revenues amounted to SEK 0.0 (0.0) million
- Operating result amounted to SEK –22.1 (–6.9) million
- Result after tax amounted to SEK –22.0 (–7.1) million, corresponding to SEK –0.35 per share (–0.23) before and after dilution
- Cash flow from operating activities amounted to SEK –19.1 (12.5) million
- Cash and cash equivalents at the end of the period amounted to SEK 174.1 (19.5) 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's overall activities during the corresponding period 2016.

## Significant events during January - March 2017

- The company has entered an agreement for services with a global contract research organization (CRO) for the implementation of the CONDUCT study
- InDex participated with two poster presentations at the annual congress of the European Crohn's and Colitis Organisation (ECCO)
- Johan Giléus was appointed as new Chief Financial Officer (CFO) from May 1, 2017
- A new patent covering 19 substances from the company's DIMS platform was granted in the US
- InDex hosted a well attended investigators' meeting for the CONDUCT study

## Significant events after the reporting period

• InDex participated with two poster presentations at the Digestive Disease Week (DDW)

"The work on the CONDUCT study is progressing according to plan and we will start treating patients during the second quarter of this year. Several clinics are now activated and ready to enroll patients," said Peter Zerhouni, CEO of InDex Pharmaceuticals.

### **CEO** statement

InDex's focus remains on the implementation of the phase IIb study CONDUCT with our lead drug candidate cobitolimod. The work is progressing according to plan and we will start treating patients during the second quarter of this year. Several clinics are now activated and ready to enroll patients.

The dose optimisation study will include 215 patients with moderate to severe active ulcerative colitis. The objective is that the last patient will enter the study in the fall of 2018 and that we thereby may have the main results from the study during the fourth quarter of 2018. Please read more about living with ulcerative colitis and the CONDUCT study in InDex's recently published annual report for 2016.

To conduct such a large clinical trial across 12 countries and 90 clinics is a complex project that requires careful preparation and involves hundreds of people with different competences. We have therefore chosen to collaborate with a leading global contract research organization (CRO) for the implementation of the study. They have people on the ground in all countries and in addition considerable experience from managing multinational clinical studies in inflammatory bowel disease. I can also note that the significant experience and expertise that we have internally at InDex regarding conducting clinical studies have contributed to the completion of the study preparations.

The study has been approved by the Medical Products Agencies in several countries and the application process is ongoing in the rest of the countries. In addition to the approval by the Medical Products Agency,

approval by an ethics committee is required in each country. In most countries, there is a central committee, but some countries require local approval for each clinic. We will have submitted applications to more than 40 ethics committees in 12 different languages. Before a clinic can be activated, we also need to have an agreement in place with the hospital, which amounts to quite an extensive administrative task given the number of clinics.

The logistics of the study is another area that is now in place. Study drug and sampling kits are sent to the clinics upon request and patient samples are sent from the clinics to a central laboratory in the Netherlands for analysis. Everything should arrive within one day and be shipped at a certain temperature, also from the most distant clinics in, for example, Russia and Ukraine.

However, the most important work is that performed by the clinics, and we attach great importance to keeping them engaged in the study and motivated to recruit patients. In March 2017, we therefore gathered the study teams from the clinics for an investigators' meeting in Stockholm, which was very successful. It was great to see the interest and commitment from the meeting participants.

I look very much forward to report on InDex's significant progress during the past year at the BIO Convention in San Diego, 19-22 June 2017. BIO is the pharmaceutical industry's largest networking event with some 16,000 representatives from drug development companies and larger pharmaceutical companies looking for innovative products for their portfolios.

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#### **Publication**

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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.