



# Interview with Matilda

## – about living with a stoma

### YOU ARE LIVING WITH A STOMA, WHAT IS A STOMA?

– Exactly, I have an ileostomy, there are some different types. Basically, it is a piece of the small intestine that is attached to the abdomen and the stool will thus come out through there and end up in the stoma bag that you have attached to your stomach.

### CAN YOU DESCRIBE YOUR DISEASE JOURNEY FROM WHEN YOU STARTED TO GET SYMPTOMS OF ULCERATIVE COLITIS TO THE POINT THAT YOU HAD A COLECTOMY AND GOT A STOMA?

– My symptoms started when I noticed blood in my stool when I was about to turn 15 years old. As we have the disease in my family, my mum understood pretty quickly what it could be and that it needed to be checked by a doctor. I had stomach pain on and off and my colon was bleeding. At first I did not have the constant need to always know where the nearest toilet is, which I know is the case for many others, but it did not stay under control, so I got a lot of different medications and treatments. Treatments that worked directly, kept the symptoms under control for a while until the next flare came and so on. About 2 years after my first symptoms, I had my most serious flare. I increased the dose of steroids myself, which is the medicine I hate the most because it never worked, but I felt I needed to do something. I could not keep much of the food, I had pain, I couldn't sleep, and then I also got fever. I was admitted to the hospital, received larger amounts of medications and we tested different treatments, but nothing showed improvement in my test values. I lived with my drip stand, had intestinal rest for 13 days, the fever remained, and I was generally exhausted to never be able to sleep properly and basically live inside the hospital toilet. With even higher fever one and a half months later it was decided to do an acute surgery, it was on a Saturday. At that point I was actually relieved that this would come to an end, that it finally would turn around. I woke up with a stoma after about 8 hours, directly named it Gunnar and since then I have just tried to get along with it as well as possible. I still treat my rectum for my UC, otherwise the whole colon is removed.

### WHAT WAS THE HARDEST THING ABOUT GETTING A STOMA?

– At that time, it was a relief, a solution and a way back to a life outside the hospital, but I remember that I did cry a bit under the covers. My thoughts were mainly regarding that I would not be able to wear my clothes, tight pants, dresses. Both prom dress and graduation dress were waiting within the two years it was said that I needed to have the stoma. That was probably the hardest thing for my 17-year-old way of thinking. I don't think I really reflected on what the stoma actually does.

### YOU TRIED MANY DIFFERENT TYPES OF MEDICATIONS BEFORE THE SURGERY, CAN YOU SHARE MORE ABOUT WHICH ONES AND IF YOU EXPERIENCED ANY SIDE EFFECTS?

– Now there is a risk that I do not remember all of them, I tested virtually everything that was on the market at that time. Asacol, azathioprine and Prednisolone were the ones I used the most. I also had medications for some side effects, for example because azathioprine affected the liver. In



short, a lot and large amounts of tablets. Then I also got Remicade intravenously. It helped the first round, but the second time it unfortunately did not have the same effect. Thereafter I tested Adacolumn and in the end a non-completed treatment with Humira. So far, I have not, what I know, had any serious side effects, which is a risk with many of these drugs. The thing that affected me the most was the steroids, my face got extremely swollen, which lasted for long periods and that was the most difficult part. The steroids also caused stretch marks, sore cheeks, sweating and thinner hair, but the swelling was the most obvious.

### WHAT DO YOU THINK ARE THE MOST IMPORTANT QUALITIES OF AN EFFECTIVE ULCERATIVE COLITIS TREATMENT?

– It's hard to say, the most important thing for me as a patient is that it works, that you can notice results, and that it does not cause serious side effects.

### HOW DO YOU LOOK AT THE FUTURE?

– I hope the research moves forward, at every level, both the causes of UC, preventive tools and effective treatments. The most important thing for us living with UC and/or a stoma is the general awareness. There is a need for increased awareness in society. It is usually people's ignorance that makes it difficult and hard.

**Name:** Matilda

**Age:** 23 years old

**Occupation:** Student

**Interests:** I love to hang out with my friends and big occasions. As much as I love to curl up on the couch and watch a good movie and eat something good.

**Diagnosis:** Ulcerative colitis

## 2018 in brief

- New mechanism of action data for cobitolimod was presented orally at the congress of the European Crohn's and Colitis Organisation (ECCO) in February, 2018. The abstract had been selected amongst the top 10 out of 1,366 submitted abstracts and was featured in the Highlights of ECCO'18 video.
- A new method of use patent for the drug candidate cobitolimod was issued by the Japan Patent Office in April, 2018.
- InDex hosted a Capital Markets Day in Stockholm in April, 2018 for investors, analysts and media.
- InDex announced in May, 2018 that the company has developed a novel formulation of its drug candidate cobitolimod for oral administration, with targeted delivery to the lower part of the gastrointestinal tract.
- InDex participated with two poster presentations at the Digestive Disease Week (DDW) in June, 2018.
- InDex announced in August, 2018 an updated timeline for the patient recruitment in the CONDUCT study.
- A post-hoc analysis of COLLECT study data was published in the October issue of the peer-reviewed journal Digestive and Liver Disease (DLD).
- InDex carried out a directed share issue to a small group of investors in October, 2018. InDex received proceeds of approximately SEK 37.5 million.

### CONSOLIDATED FINANCIAL SUMMARY

SEK million	2018	2017	2016	2015
Revenues	0.7	0.1	0.4	0.4
Operating loss	-82.4	-73.3	-39.5	-29.5
Result after tax	-82.3	-72.8	-41.3	-29.9
Result per share before and after dilution, SEK	-1.29	-1.16	-1.08	-0.99
Cash flow from operating activities	-79.5	-68.2	-31.9	-37.0
Cash and cash equivalents at year-end	83.0	125.1	193.2	7.0
Number of employees at year-end	7	7	7	8

Note: Result per share – Result after tax divided by average number of shares.

### FINANCIAL CALENDER

Interim report Q I 2019	May 6, 2019
Annual general meeting	May 6, 2019
Interim report Q II 2019	August 22, 2019
Interim report Q III 2019	November 27, 2019

## InDex 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 ulcerative colitis – a debilitating, chronic inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. 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.



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*The following definitions have been used in this annual report – "the company", "the group" or "InDex" for the operations conducted in InDex Pharmaceuticals Holding AB together with the subsidiaries InDex Pharmaceuticals AB and InDex Diagnostics AB.*

# Business overview

## Improve the life of patients with immunological diseases through the development of innovative drugs

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 ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

In addition, InDex has a broad portfolio of other DNA based ImmunoModulatory Sequences (DIMS) in discovery stage, with the potential to be used in the treatment of various immunological diseases.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon. InDex's clinical studies indicate that cobitolimod has a higher efficacy and a more favorable safety profile than what has been reported for the currently approved biological drugs in corresponding patient populations. Sales of biologics for treatment of ulcerative colitis amount to more than USD 5 billion a year<sup>1</sup>.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis. Cobitolimod has achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favorable safety profile. Data from four placebo-controlled clinical trials show that cobitolimod has statistically significant effects on those endpoints that are most relevant in this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively.

Based on the encouraging results from earlier studies InDex is now performing the phase IIb study CONDUCT to evaluate higher doses and dose frequencies than investigated in previous studies with cobitolimod. The goal of the study is to optimise the treatment and achieve substantially higher efficacy, while maintaining the compound's excellent safety profile. The CONDUCT study will include 215 patients with left-sided moderate to severe active ulcerative colitis at 90 sites in 12 countries. It is a randomised, double blind, placebo-controlled study for evaluating cobitolimod's efficacy and safety in inducing clinical remission compared to placebo. The dose optimisation study investigates three different dose strengths of cobitolimod and two different dose frequencies. The objective is to have top line results from the study during the first half of 2019.

Cobitolimod is also known as Kappaproct® and DIMS0150.

### Business Model

InDex develops compounds from pre-clinical through clinical phases, with the strategy to license the compounds to industry partners during late stage clinical development in order to reach the market. The company's revenues will consist of upfront and milestone payments from licensing agreements and royalty payments from third parties' sales of InDex's products.

### Vision

InDex's vision is to be an innovation driven company focused on bringing drugs from the DIMS platform for immune mediated conditions to market approval, alone or in collaboration with partners, starting with the lead drug candidate cobitolimod.

### Mission

InDex's mission is to significantly improve the lives of patients suffering from immunological disorders by providing effective and safe drugs for diseases with high unmet medical needs.

<sup>1</sup> Ulcerative Colitis Disease Coverage. Datamonitor Healthcare 2016.

# CEO statement

The intensive work with the CONDUCT study continued to characterise InDex's operations also in 2018. We will soon have enrolled all the patients in the phase IIb study with cobitolimod and are preparing to analyse the results, which will be a crucial milestone for the company. The aim is that higher dosing will result in a significantly higher effect than in previous clinical studies with cobitolimod and also compared to what has been reported for products on the market and those under development.

InDex works very actively with the CONDUCT study in close collaboration with the CRO that manages the day to day activities. Our main focus is on the patient recruitment where we are now getting close to the end. InDex's own personnel visited no less than 63 of the more than 90 participating clinics around Europe during 2018 in order to keep them engaged in the study and motivated to recruit patients. We constantly get confirmation that there is a positive interest in cobitolimod among the doctors during our visits, not least thanks to the new and unique mechanism of action. We are also continuously monitoring that the data base is complete and correctly entered, as well as preparing the process for unblinding and data analysis in order to be able to report the top line results as soon as possible after the last patient has been enrolled.

The CONDUCT study will include 215 patients with moderate to severe active ulcerative colitis. Due to a lower patient recruitment rate than expected, we were unable to report the top line results during 2018 as originally planned. No safety issues have been noted in the more than 150 patients that have already completed the study, which is very positive. In parallel to the CONDUCT study, InDex has also conducted further extensive preclinical safety studies with cobitolimod in preparation for phase III. These studies have also confirmed the good safety profile.

InDex is actively pursuing out-licensing of cobitolimod and are regularly attending the large partnering conferences in the US and Europe. The interest from the industry for new innovative drugs in inflammatory bowel disease remains high. The need to be able to combine treatment with multiple different drugs is discussed more and more. With its unique mechanism of action and good safety profile, cobitolimod is better suited for such an approach than most competing products under development and there are many in addition to InDex that are looking forward to the results of the CONDUCT study with great excitement.

New extensive data on cobitolimod's immunological mechanism of action was presented 2018 during the scientific program of the ECCO congress to an estimated audience of 4,000, including many investigators in the CONDUCT study, large pharmaceutical companies, and key opinion leaders within the therapeutic field with whom the major pharmaceutical companies consult for their transactions. Such positive exposure raises the profile of cobitolimod among potential partners and the abstract was also selected amongst the top 10 most interesting abstracts during the congress.

Other important news from 2018, that will also strengthen InDex's position in future partner discussions, is our successful development of a capsule to be taken orally and release cobitolimod in the colon. Additionally, the release profile can be adjusted to target other parts of the gastrointestinal tract which are inaccessible to the topical formulation currently evaluated in the CONDUCT study. An oral version would provide added patient convenience and broaden the potential therapeutic use of cobitolimod to also include other inflammatory bowel diseases such as Crohn's disease. InDex's life cycle management strategy for cobitolimod is to first launch the topical formulation. The oral formulation will be a follow-on product and the next stage of its development is contingent on the results of CONDUCT.

In addition to the clinical development of cobitolimod in ulcerative colitis, InDex is testing some selected DIMS candidates in models of other inflammatory diseases to broaden the portfolio. In 2016, InDex received a grant for this development from the innovation agency Vinnova and the work under this grant was completed in 2018. Positive signals were observed, and we are now investigating how we can confirm these early results with alternative and complementary methods in order to be able to select a DIMS substance for further development.

In the spring of 2018, we successfully hosted InDex's first Capital Markets Day. In addition to InDex's management, two internationally prominent professors in inflammatory bowel disease participated and gave their views on the medical need and cobitolimod's potential. The videos and presentation material from the day are available on InDex's website.

In October 2018, we carried out a directed share issue to a small group of reputable investors who had shown interest and the company received proceeds of approximately SEK 37.5 million. Through the transaction, the ownership base has been broadened with experienced and successful investors in Swedish drug development companies.

We look forward with confidence to the top line results of the CONDUCT study in the near future. With positive results, we will take a big step closer to our goal to make cobitolimod available to patients suffering from ulcerative colitis and who today lack treatment options with a satisfactory combination of efficacy and safety.

Peter Zerhouni, CEO



# Ulcerative colitis

## A chronic disease with high unmet medical need for new treatment options

### WHAT IS ULCERATIVE COLITIS?

Inflammatory bowel disease (IBD) refers to chronic inflammation of all or parts of the gastrointestinal tract, and primarily includes ulcerative colitis and Crohn's disease. Ulcerative colitis is limited to the colon and rectum. The disease causes long-lasting inflammation that gives ulceration in the innermost lining of the colon and rectum, and for many patients it is very debilitating to live with. Ulcerative colitis is characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. The disease can, despite lifelong medication, complicate the social life and make it impossible to work, as severe patients always need to be close to a toilet. Studies show that patients suffering from ulcerative colitis have a significantly lower quality of life than the general population<sup>1</sup>. In addition, patients suffering from ulcerative colitis have a significantly elevated risk of developing colon cancer.

### WHAT CAUSES ULCERATIVE COLITIS?

The underlying cause of ulcerative colitis is not known, nor is it known what triggers the disease to recur between its inactive and active forms. However, research strongly suggests that genetic susceptibility and environmental factors, together with an abnormal immune response, contribute to the development of the disease. Most commonly, the disease presents between 20 and 30 years of age. Typically, the course of ulcerative colitis is intermittent; periods of disease aggravation are followed by periods of remission (absence of symptoms). Almost half of the patients are estimated to have active disease at a given time<sup>2</sup>.

### HOW DOES THE SEVERITY OF ULCERATIVE COLITIS VARY?

Ulcerative colitis varies in severity based on the intensity of the symptoms, and about 30 percent of the patients have a mild form of the disease, about 50 percent of the patients have moderate ulcerative colitis and about 20 percent suffer from a severe form of the disease<sup>2</sup>. The extent of the inflammation of the colon may also differ and is usually divided into proctitis (only the rectum), left-sided colitis (from the rectum up into the first curve of the colon on the left side of the abdomen) and total colitis so-called pancoli-

tis (the whole colon is inflamed). The severity and extent of the inflammation are assessed by the physician looking inside the rectum and colon using an endoscope (endoscopy).

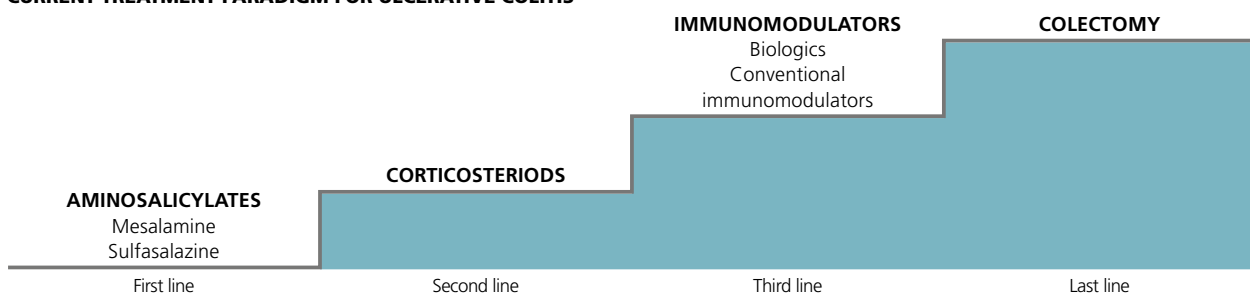
### HOW IS ULCERATIVE COLITIS TREATED TODAY?

You can never be cured from the disease and most patients need lifelong medication. The standard treatment for ulcerative colitis depends on the extent of the disease and how severe the symptoms are. The current first and second line treatment options for patients suffering from ulcerative colitis include aminosalicylates and corticosteroids. Corticosteroids are generally used to treat disease flare-ups and are not recommended for maintenance treatment due to the risks associated with long-term use. For patients suffering from moderate to severe relapse periods of ulcerative colitis, and do not respond to these treatments, the addition of conventional immunomodulators or biologics like TNF-alfa inhibitors or anti-integrins are often used. However, these third-line treatment options have several limitations in that the effect is often delayed and they are associated with known serious side effects. A substantial percentage of patients with moderate to severe ulcerative colitis will not respond to available therapies or will eventually develop tolerance to the treatment. Often, these patients require periods of medium to long-term hospitalisation. Colectomy, i.e. surgical removal of the colon, is the last option for patients with severe ulcerative colitis who do not respond to medical treatment. While colectomy is a potentially curative option in severe cases of ulcerative colitis, the operation entails risks of short and long-term complications such as infections, abdominal pain, and infertility. Treatment options for patients who do not respond to conventional or biological treatment are limited, and there is a high unmet medical need for new treatment options. Cobitolimod is under development as a safer and more efficacious alternative to the biological drugs in third line.

<sup>1</sup> <https://www.medscape.org/viewarticle/572039>

<sup>2</sup> IMS Health 2015 IBD disease insights webinar

### CURRENT TREATMENT PARADIGM FOR ULCERATIVE COLITIS





# Cobitolimod

## InDex's lead drug candidate

Cobitolimod is a potential new medication for patients with moderate to severe ulcerative colitis. Current treatment options have problems with side effects. In addition, a substantial percentage of the patients with moderate to severe ulcerative colitis does not respond to available therapies or will eventually develop tolerance to the treatment. For this patient group there is a high unmet medical need.

Cobitolimod can provide a local anti-inflammatory effect, which may lead to healing of the mucosa in the large intestine and relief of the clinical symptoms. Cobitolimod is planned to be positioned as a safer and more efficacious alternative to the biologics used today.

### HOW DOES COBITOLIMOD WORK?

The intestinal mucosa acts as a barrier to the outside world and constitutes an important part of the body's immune system. It is rich in immune cells that protect the body from disease organisms and harmful substances in the intestinal tract. A healthy intestinal mucosa responds to potential threats with a balanced immune response. However, an imbalance in the immune system of the intestinal mucosa can cause a vicious circle where the immune response is amplified and leads to chronic inflammation. In ulcerative colitis, an increased production of the cytokine interleukin (IL)-23 is seen, which stimulates the production of pro-inflammatory cytokines such as IL-1, TNF-alpha and IL-6, as well as IL-17, where IL-17 stimulates additional production of inflammatory mediators. One has also seen an increased proportion of inflammatory T helper 17 cells (Th17 cells)

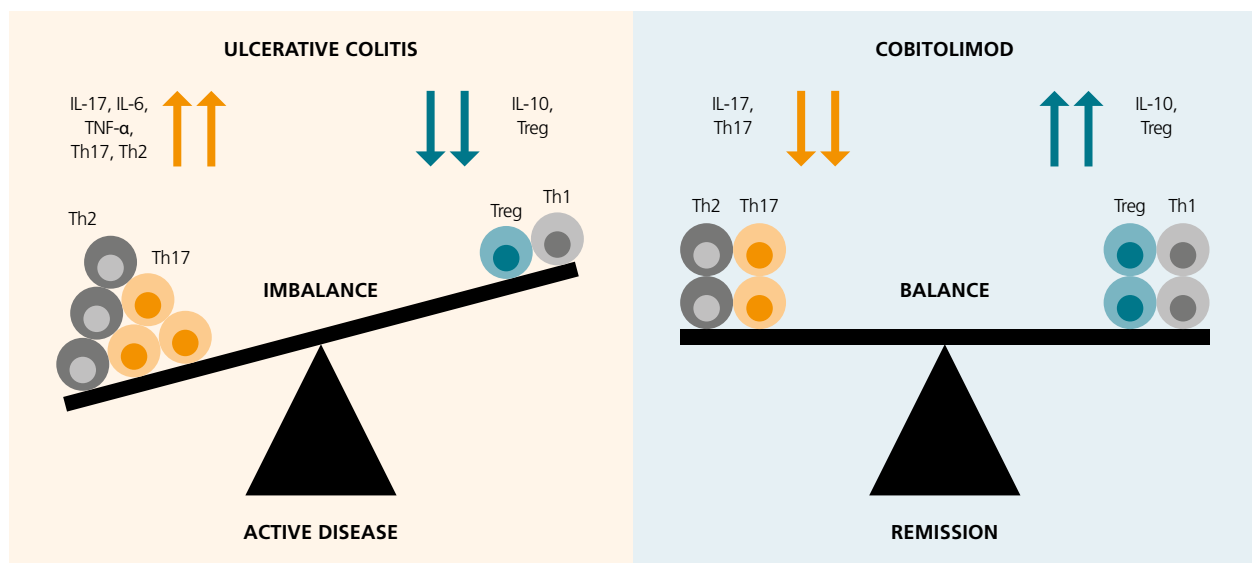
and Th2 cells, but a reduced number of regulatory T cells (Treg cells), creating an immunological imbalance in the intestinal mucosa.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist. TLR9 is a receptor that is expressed by certain immune cells and is the immune system's receptor for recognising DNA from bacteria and viruses. Cobitolimod is a synthetically manufactured oligonucleotide which by mimicking microbial DNA binds to TLR9 and can thereby modulate the immune system. Cobitolimod stimulates immune cells to produce beneficial anti-inflammatory cytokines like IL-10. At the same time cobitolimod decreases the production of inflammatory cytokines such as IL-17. By increasing the number of Treg cells and reducing the number of Th17 cells cobitolimod helps to restore the balance of the immune system. In this way, cobitolimod can provide a local anti-inflammatory effect, which may lead to healing of the mucosa in the large intestine and relief of the clinical symptoms in ulcerative colitis.

### POTENTIAL ADVANTAGES WITH COBITOLIMOD

In completed clinical trials with cobitolimod InDex has observed a higher efficacy than what has been reported for the approved biologics in corresponding patient populations with a comparatively very favourable safety profile. Cobitolimod is administered rectally directly to the inflamed colon with an enema, and has a very limited systemic absorption, which may contribute to a very favourable safety profile. The local administration can in addition provide a quick onset of action compared to systemically administered drugs.

### MECHANISM OF ACTION



In ulcerative colitis, there is an imbalance in the immune system leading to a chronic inflammation of the colon. Cobitolimod helps to restore the balance in the immune system by reducing the number of inflammatory Th17 cells and increasing the number of regulatory T cells, which reduces the inflammation in the colon

# The CONDUCT study

Based on the encouraging results from earlier studies, InDex is now performing a phase IIb study with cobitolimod to identify the dose regimen that provides the optimal efficacy of the treatment in patients with moderate to severe active ulcerative colitis. The goal of the study is, while maintaining the compound's favourable safety profile, to show a substantially higher efficacy than in prior studies and also in comparison with what has been reported for drugs on the market as well as compounds in late stage clinical development.

### WHAT DOES THE STUDY DESIGN LOOK LIKE?

The study will include 215 adult patients with left-sided moderate to severe active ulcerative colitis, randomly divided into four treatment arms receiving different dosages of cobitolimod and one arm receiving placebo. All patients will receive study medication in addition to standard of care treatment. The study is randomised, double blind, and placebo controlled. Clinical symptoms such as blood in stool, stool frequency, and mucosal healing will form the key efficacy variables and be included in the primary endpoint. The endpoints will be measured with the Mayo score, as advised by regulatory authorities, and other experts in the field. The primary endpoint will be measured six weeks after the patient received the first dose.

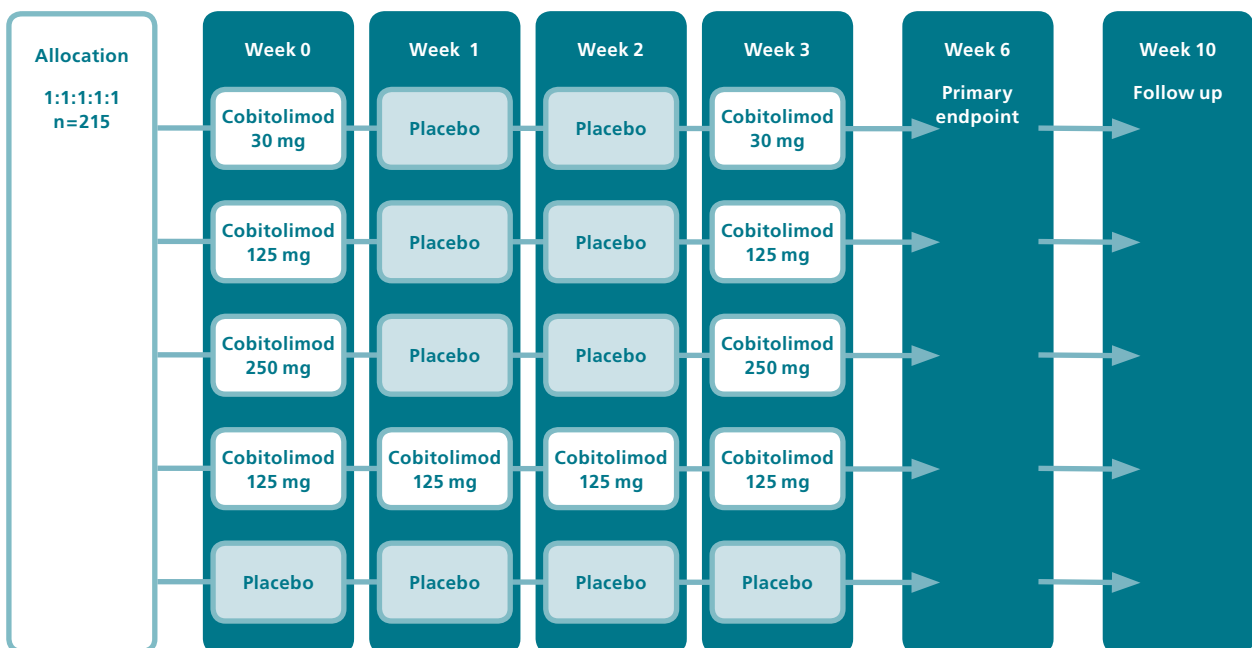
### WHERE IS THE STUDY CONDUCTED?

The study is carried out at approximately 90 clinics in 12 countries: the Czech Republic, France, Germany, Hungary, Italy, Poland, Romania, Russia, Serbia, Spain, Sweden and the Ukraine respectively. The first patient was enrolled into the study on June 21, 2017 and the objective is to have top line results from the study during the first half of 2019. InDex has entered an agreement for services with a contract research organisation (CRO) for the implementation of the CONDUCT study.

### WHAT HAPPENS AFTER THE CONDUCT STUDY?

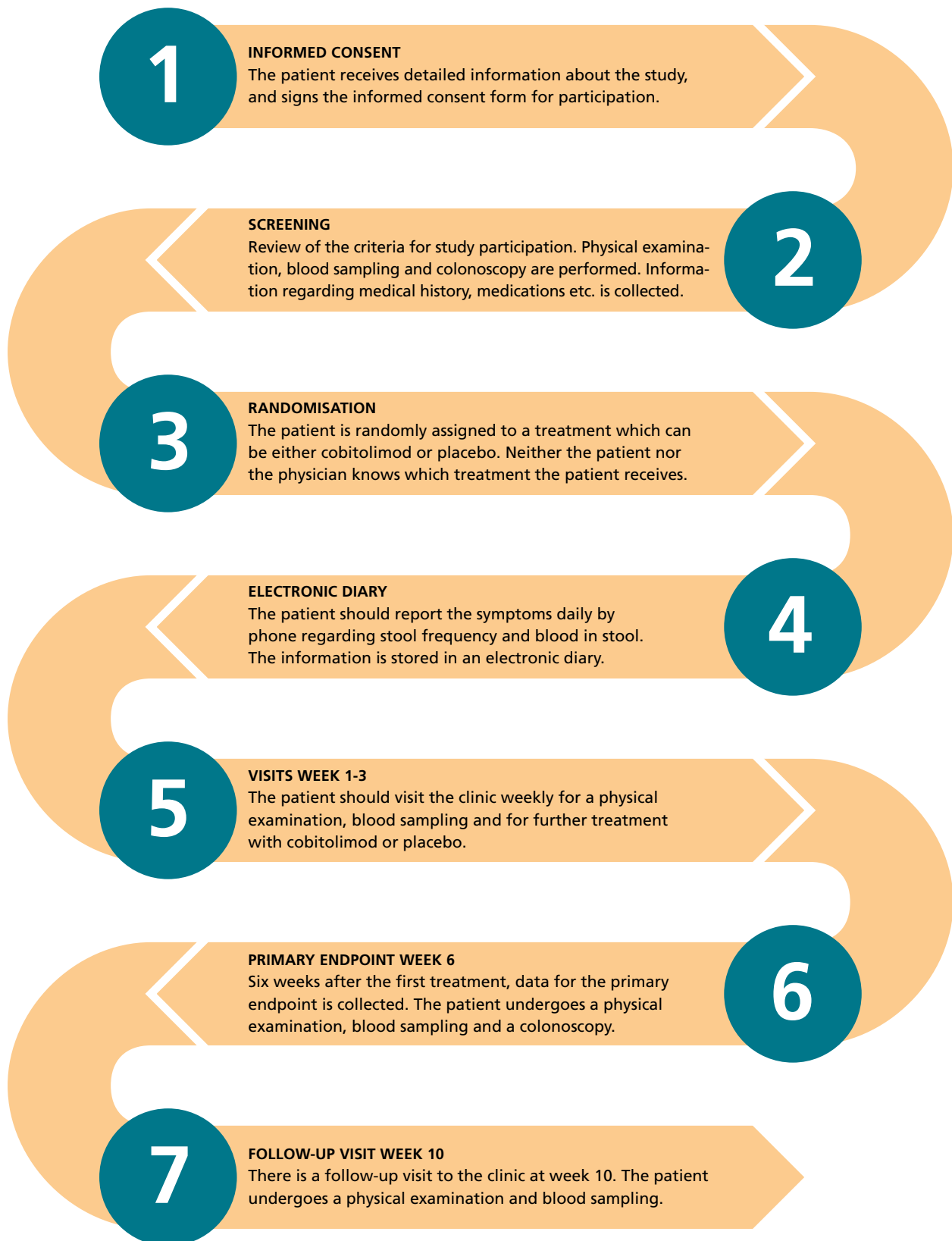
In parallel with the CONDUCT study, a phase III programme is being prepared to bring the substance to an approved product which can be launched on the market.

The design of the phase III program will be based on data from the CONDUCT study and in accordance with discussion with the regulatory authorities. In general, phase III programmes for moderate to severe ulcerative colitis consist of two shorter studies to induce remission in patients and a one year-long follow-up study. The goal is to confirm the overall efficacy and safety in a large patient population. The recently approved drugs have had approximately 1,000 patients in their respective phase III programmes as a basis for market approval in both the US and Europe. Preparatory work for commercialisation is generally done in parallel to phase III.



CONDUCT study design

# How does the CONDUCT study work from a patient perspective?



# How is the safety and quality ensured in the CONDUCT study?

## REPORTING OF ADVERSE EVENTS

The patients in the study should at each visit report if any unexpected events/adverse reactions have occurred since the last visit. The investigator is responsible for continuously registering and reporting any adverse events that may occur during the study.

If a serious adverse event occurs, the investigator must report this to the CRO company within 24 hours. Suspected unexpected serious adverse reactions should be reported as soon as possible to the respective health authorities and ethics committees according to national guidelines. A safety report with a summary of the reported adverse events shall be compiled once a year during the course of the study and submitted to the health authorities and ethics committees.

## DATA SAFETY MONITORING BOARD

Data Safety Monitoring Board (DSMB) is an independent safety committee of external experts that regularly review the safety reporting during a study. The DSMB can intervene and interrupt a clinical study if there is a suspicion that a treatment is not safe. The DSMB in the CONDUCT study consists of three independent experts in gastroenterology and biostatistics. They have had six meetings during the CONDUCT study and have each time recommended that the study should proceed according to plan since no safety issues have been noted amongst the patients.



## MONITORING

Monitoring is regularly performed at all participating clinics in the study as a quality control. During a monitoring visit, it is checked that the study protocol is complied with, that laws and regulations are followed, and that the data is correctly registered in the patient's case report form (CRF). The monitoring is performed by trained personnel, so-called Clinical Research Associates (CRAs) from the CRO.

## AUDIT

An audit is a systematic and independent review to verify that a clinical study has been carried out and reported correctly and in accordance with Good Clinical Practice (GCP) and current regulations. InDex has engaged independent external experts who have conducted audits at a number of selected clinics in the CONDUCT study. Additional audits can also be carried out by regulatory authorities and are then called inspections.

# What happens after the last patient has been enrolled in the CONDUCT study?

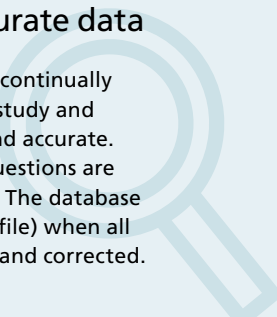
## Last patient in

Patients are continuously enrolled into the study. When the last patient has been enrolled, the study has achieved LPI (Last Patient In). The last patient should then undergo the study visits, examinations and sampling before data can be analysed.



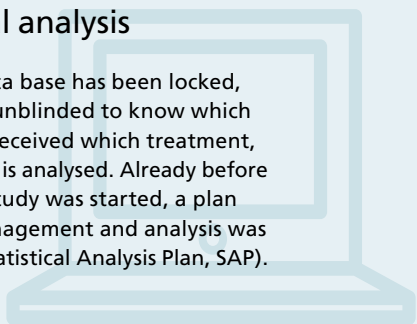
## Complete and accurate data

The database and CRF are continually reviewed throughout the study and ensured to be complete and accurate. In case of uncertainties, questions are asked to the investigators. The database is declared "clean" (Clean file) when all data is checked, complete and corrected.



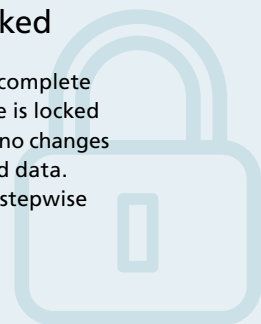
## Statistical analysis

Once the data base has been locked, the study is unblinded to know which patient has received which treatment, and the data is analysed. Already before the clinical study was started, a plan for data management and analysis was prepared (Statistical Analysis Plan, SAP).



## The data base is locked

When all data are checked, complete and corrected, the data base is locked (Data base lock). Thereafter, no changes can be made to the collected data. Data base lock can be done stepwise in a study.



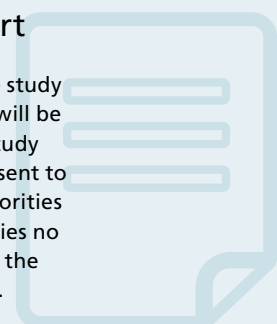
## Top line results

The top line results from the CONDUCT study are expected to be available during the first half of 2019. The top line results will be announced in a press release.



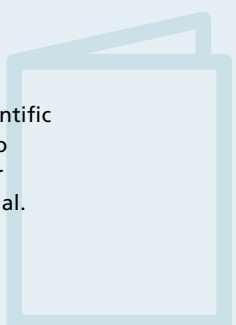
## Clinical study report

When all the results of the study have been analysed, they will be documented in a clinical study report. The report will be sent to the respective health authorities in the participating countries no later than 12 months after the study has been completed.



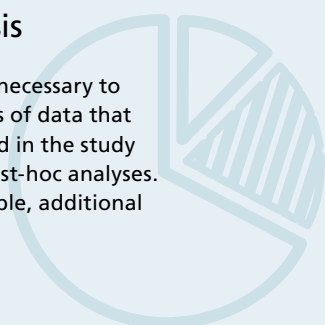
## Publication

The results of the study will be presented at international scientific congresses. The results will also be summarised in an article for publication in a scientific journal.



## Post hoc analysis

Sometimes it may be necessary to make further analyses of data that were not pre-specified in the study protocol, so-called post-hoc analyses. This can be, for example, additional subgroup analyses.



# Earlier studies with cobitolimod

Cobitolimod has achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favourable safety profile. Data from four placebo-controlled clinical trials show that cobitolimod has statistically significant effects on those endpoints that are deemed most relevant for the disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing. In addition, cobitolimod has in both preclinical toxicity studies and in clinical trials shown to have a very favourable safety profile. In addition to the placebo-controlled studies, a number of patients in Germany have been treated in a so-called compassionate use programme.

## THE COLLECT STUDY

InDex most recently completed study, COLLECT, was designed to further evaluate and confirm the efficacy and safety of cobitolimod for the treatment of moderate to severe active ulcerative colitis in patients who were not responding to conventional therapies. The patients were treated with cobitolimod or placebo in addition to their standard medication. All patients were treated with corticosteroids during the study. The patients were treated rectally, with two single 30 mg doses of cobitolimod, four weeks apart. They were then followed for 12 months without further treatment. In total, 131 patients were randomised at 38 centres in seven European countries.

Unexpectedly, a high proportion of the patients in the placebo group reached remission as defined by the primary endpoint (Rachmilewitz/CAI score  $\leq 4$ ) at week 12, and the study showed no difference between the two groups regarding this measure. However, this endpoint is no longer considered a relevant definition of remission by the regulatory authorities. Statistically significant improvement was however demonstrated in the cobitolimod-treated group compared to the placebo group for the secondary endpoints; patient reported remission (blood in stool = 0, number of stools/week  $< 35$ ) at week 4 and 8, registered remission (Rachmilewitz/CAI score of  $\leq 4$ , and an endoscopic Mayo score of 0 or 1) at week 4 and rate of colectomy by week 22.

These secondary endpoints were pre-specified in the protocol that describes all the details of the COLLECT study. The authorities are currently considering the symptoms of blood in stool, stool frequency, and mucosal healing (endoscopic remission), to be the most important endpoints to show clinical efficacy to achieve market approval. Remission based on these three variables combined into one endpoint, as endorsed by the US and European authorities, showed a statistically significant difference of 19 percent between the treatment groups at week 4 in terms of the proportion of patients reaching remission.

Those figures are better than for the approved biologics that have shown deltas of 9-12 percent in their phase III programmes<sup>1</sup>. The study results were published 2016 in the scientific journal "Journal of Crohn's and Colitis"<sup>2</sup>.

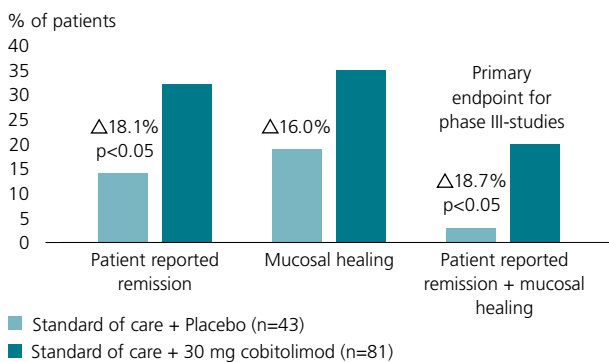
## ADDITIONAL CLINICAL STUDIES WITH COBITOLIMOD

Three clinical studies have been conducted with cobitolimod prior to the COLLECT study, see table below. In the first clinical study the "pilot study" with 11 patients, a positive effect of treatment with cobitolimod was observed, where both doses (3 mg and 30 mg) showed clinical benefits.

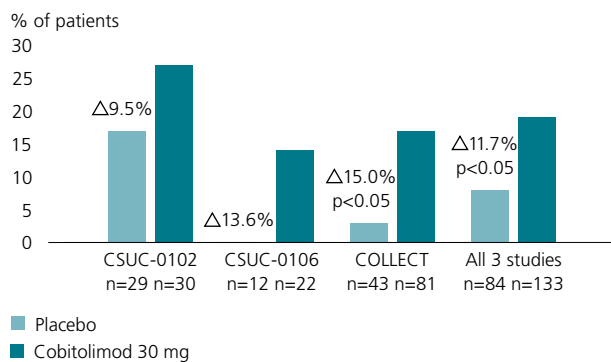
A subsequent study (CSUC-01/02) in 151 patients with mild to moderate ulcerative colitis evaluated single doses of 0.3 mg, 3 mg, 30 mg and 100 mg. In this study, conventional drugs, such as 5-ASA, were the only medications allowed for treatment of ulcerative colitis during the study period. Concomitant use of corticosteroids was an exclusion criterion in the study. The study showed that cobitolimod was well tolerated, with no serious side effects. Although statistical significance was not achieved, the study indicated that doses of 30 mg and 100 mg were more effective than 0.3 and 3 mg.

The subsequent study (CSUC-01/06) included 34 patients with moderate to severe active ulcerative colitis, who did not respond to corticosteroid therapy. Rectal administration

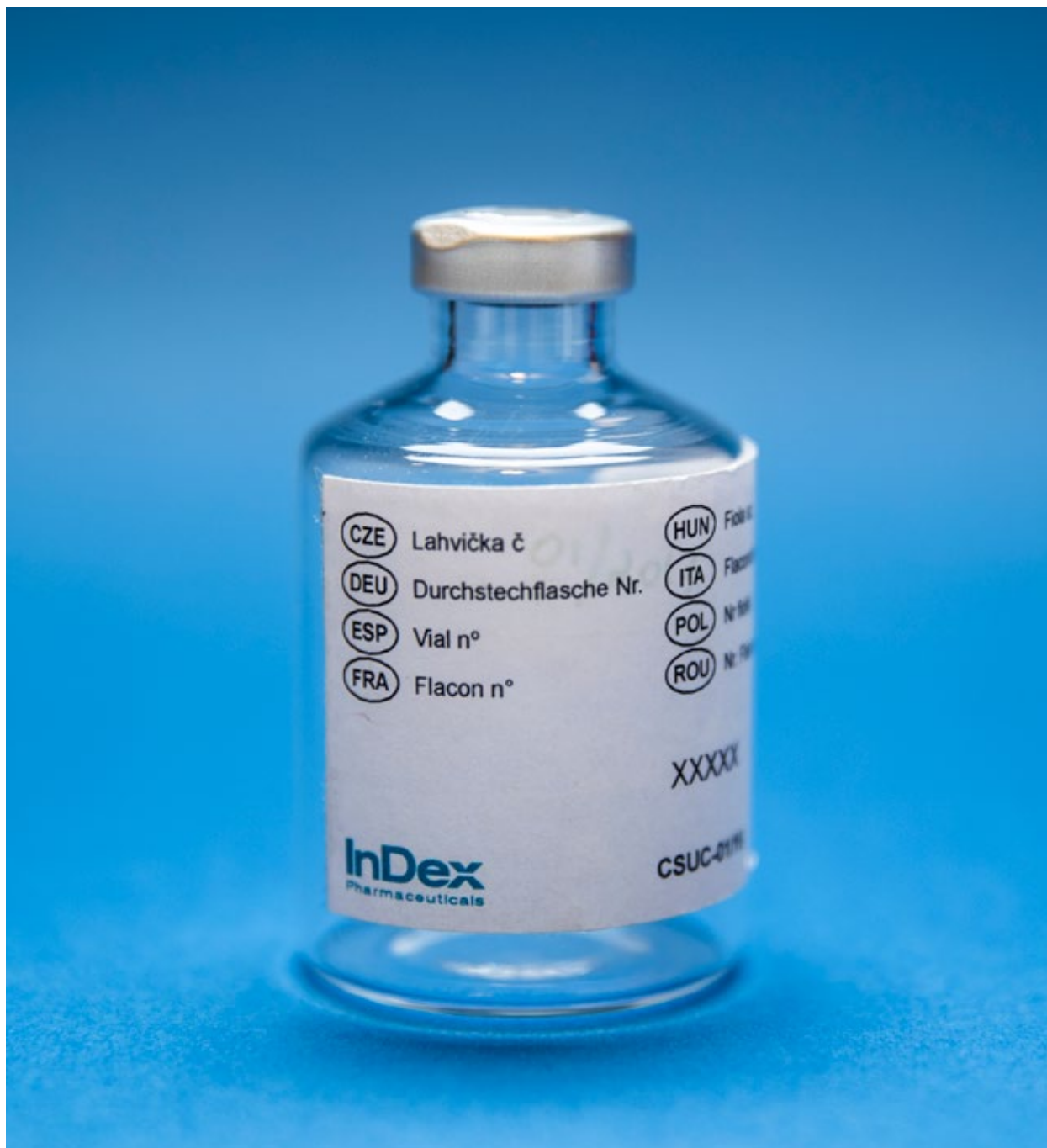
1 Geom Seog Seo et al. (2014) *World J Gastroenterol* 20(37): 13234-13238.  
2 Atreya et al. (2016) *Journal of Crohn's and Colitis*, 10(11): 1294-1302.



- Patient reported remission at week 4 defined as no blood in stool & stool frequency  $< 35$  per week
- Mucosal healing at week 4 defined as endoscopic Mayo score of 0 or 1



Meta analysis of three independent placebo-controlled clinical studies 4 weeks after one single dose of 30 mg cobitolimod show proof-of-concept. Clinical remission defined as Mayo score (or converted CAI for COLLECT)  $\leq 2$  with no subscores  $> 1$ .



of a single dose of cobitolimod 30 mg was found to be safe and well tolerated. A higher proportion of the patients achieved clinical remission in the cobitolimod group compared to the placebo group. This supports the hypothesis that cobitolimod can induce clinical response in patients with ulcerative colitis, although the study was too small to show statistical significance for the primary endpoint.

A meta-analysis of the three largest placebo-controlled studies with cobitolimod provides clinical proof of concept for cobitolimod in ulcerative colitis.

#### **COBITOLIMOD HAS SHOWN A VERY FAVOURABLE SAFETY PROFILE**

The experiences from the four completed clinical studies have shown that rectal administration of up to 100 mg of cobitolimod, as well as two doses of 30 mg four weeks apart is well tolerated. In previous completed studies,

249 patients with inflammatory bowel disease have been treated with cobitolimod without any relevant differences observed in the safety profile between the patients who received active substance and those who received placebo.

#### **CLINICAL STUDIES WITH COBITOLIMOD**

	Number of patients	Dose
COLLECT (CSUC-01/10)	131	2 x 30 mg
CSUC-01/06	34	1 x 30 mg
Dose study CSUC-01/02	151	1 x 0,3 mg-100 mg
Pilot HICS9801	11	1 x 30 mg
<i>Compassionate Use</i>	14	1-6 x 30 mg

*Summary table over clinical studies and compassionate use programme with cobitolimod.*

# Market overview

## Large and growing market for the treatment of ulcerative colitis

Today, about 0.2 percent of the population in developed countries has ulcerative colitis, which corresponds to more than 800,000 ulcerative colitis patients in Europe and more than 900,000 in the US<sup>1</sup>. Market research studies predict that the prevalence of ulcerative colitis will increase at an annual rate of 0.8 percent<sup>2</sup>. The total pharmaceutical market for ulcerative colitis was estimated in 2016 to approximately USD 6.3 billion and is expected to grow to about USD 8 billion in 2023<sup>2</sup>. Biological drugs represent the largest market segment in terms of value with annual sales in 2016 estimated to more than USD 5 billion<sup>2</sup>. Today, more than 200,000 ulcerative colitis patients are treated with biological drugs<sup>2</sup>. The US is the single largest pharmaceutical market for inflammatory bowel disease and represents more than 50 percent of the global market<sup>3</sup>.

### COBITOLIMOD'S MARKET POTENTIAL

With cobitolimod's unique mechanism of action, competitive efficacy and favourable safety profile, InDex sees a great market potential for the substance. The annual sales at a successful commercialisation are estimated to reach more than USD 1 billion, which is based on the forecasted sales of the most recently launched biologic, vedolizumab<sup>2</sup>.

InDex has conducted a first market research study for cobitolimod among doctors and patients in the US and the five largest European markets. A total of 65 physicians specialised in inflammatory bowel disease and 148 patients with ulcerative colitis participated in the study. The overall perception regarding cobitolimod's product profile was positive from both physicians and patients, and characteristics such as quick onset of action, efficacy and safety were highly valued. The result of this primary market research supports a future market acceptance and commercial potential for cobitolimod in both the US and Europe, provided that future clinical studies confirm the expected product profile.

### COMPETING THERAPIES ON THE MARKET

Since cobitolimod is under development for ulcerative colitis patients who are not responding to conventional therapy, the main competitors on the market today are the biological therapies, i.e. TNF-alpha inhibitors and anti-integrins. The TNF-alpha inhibitors; infliximab (marketed under the name Remicade and as biosimilars), adalimumab (marketed under the name Humira and as biosimilars) and golimumab (marketed under the name Simponi) together with the anti-integrin antibody vedolizumab (marketed under the name Entyvio) are the biological agents approved for treatment of ulcerative colitis today. The average price per patient for the above mentioned TNF-alpha inhibitors in the US and Europe range between USD 12,000 and USD 33,000 per year and for vedolizumab between USD 20,000 and USD 65,000 per year depending on the country and the dose<sup>4</sup>. A significant proportion of patients do not respond to these treatments and they have problems with tolerance and can cause serious side effects such as infections, malignancies and skin

disorders. For example, TNF-alpha inhibitors have long-term effects in only about 30 percent of the patients<sup>5</sup>. The biological substances are administered intravenously or subcutaneously, and need to reach a certain concentration in the blood before the substance can have its effect in the colon. This leads to a delayed onset of action, while locally administered therapies, such as cobitolimod, which directly reaches the site of inflammation potentially can induce a quicker relief of symptoms for the patients. Recently, the first JAK inhibitor was approved in Europe and the US, the tablet tofacitinib marketed under the name Xeljanz. However, tofacitinib did not show a better effect in its phase III program than the marketed biological drugs<sup>6</sup>. The product has also shown an increased risk of serious side effects such as severe infections, cancer, immune system disorders and gastrointestinal perforation.

### COMPETING THERAPIES IN LATE STAGE CLINICAL DEVELOPMENT

Several other companies conduct drug development in inflammatory bowel disease. Many of the drugs in pipeline for moderate to severe ulcerative colitis are new versions of anti-integrins (i.e. the same mechanism of action as vedolizumab). Cobitolimod has a new and unique mechanism of action. Other substances with new mechanism of actions for moderate to severe ulcerative colitis that are in phase III or which have applied for market approval are for example ozanimod (S1P receptor modulator developed by Receptos/Celgene) and ustekinumab (anti-IL-12/IL-23 antibody developed by Janssen). The patient population which these drugs seek to target is similar to cobitolimod, but their reported mechanism of actions are significantly different with none of them working through TLR9. The level of efficacy seen with cobitolimod in the COLLECT study is in line with what has been reported for the other substances in late clinical phase. The aim of the ongoing CONDUCT study is to provide a substantially higher efficacy with cobitolimod than what has been reported for the products on the market as well as for the substances in late stage clinical development, while maintaining its superior safety profile. Several of the compounds in pipeline for moderate to severe ulcerative colitis can cause serious side effects.

<sup>1</sup> www.ccfa.org

<sup>2</sup> Ulcerative Colitis Disease Coverage. Datamonitor Healthcare 2016.

<sup>3</sup> IMS Health 2015 IBD disease insights webinar

<sup>4</sup> www.firstreportnow.com; www.regione.calabria.it; rote-liste.de; gruposdetrabajo.sefh.es; Costing statement: ulcerative colitis. Implementing the NICE guidance on vedolizumab for treating moderately to severely active ulcerative colitis (TA 342). June 2015.

<sup>5</sup> Altwegg R et al. TNF Blocking Therapies and Immunomonitoring in Patients with Inflammatory Bowel Disease. Hindawi Publishing Corporation, Mediators of Inflammation, Volume 2014, Article ID 172821.

<sup>6</sup> Sandborn WJ et al Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2017 Aug 3;377(5):496-7.



**LICENSING AGREEMENTS AND ACQUISITIONS IN IBD**

There have been several significant transactions in the field of IBD the last years, demonstrating the medical need and

commercial opportunity for new therapies within the field. The table below summarises recent major licensing deals and acquisitions within the IBD space.

**LICENSING AGREEMENTS AND ACQUISITIONS IN IBD**

Date	Company	Partner	Substance	Completed clinical phase	Terms
April 2014	Nogra Pharma	Celgene	Mongersen	Phase II	USD 710M upfront + USD 1.9B in milestones + royalties
July 2015	Receptos	Celgene	Ozanimod	Phase II	USD 7.2B (acquisition)
December 2015	Galapagos	Gilead	Filgotinib	Phase II	USD 300M upfront + USD 425M equity investment + USD 1.35B milestones + tiered royalty starting at 20%
June 2016	Pfizer	Shire	SHP647	Phase II	USD 90M upfront + USD 460M in milestones + royalties
October 2016	MedImmune/ Astra Zeneca	Allergan	MEDI2070	Phase IIa	USD 250M upfront + USD 1.27B in milestones + royalties
February 2018	Theravance	Johnson & Johnson	TD-1473	Phase I	USD 100M upfront + USD 900M in milestones + royalties



# Business development and patents

## BUSINESS DEVELOPMENT

InDex is actively pursuing out-licensing of cobitolimod and prior to phase III, intends to partner with a large international pharmaceutical company that can contribute with financing as well as with expertise for the final development phase and eventual commercialisation of the product. With positive results from the CONDUCT study, the interest in cobitolimod from potential partners is expected to be very high and provide excellent opportunities for beneficial license agreements for InDex. Such agreements are expected to provide revenue through upfront and milestone payments as well as royalties.

Andrew Thompson has worked as Senior Business Development Advisor for InDex since 2015 and runs together with InDex's CEO and Business Development Manager the out-licensing activities. Andrew has extensive experience from the pharmaceutical industry with a background in marketing and sales in global pharmaceutical companies, but for the last 11 years he has worked in business development in mid-sized pharmaceutical companies and biotech companies. In this role, he has executed a significant number of international licensing agreements, primarily in the gastrointestinal area.

We took the opportunity to ask Andrew three short questions about business development at InDex.

### How does InDex work with business development?

InDex has established good contact with potential partners in the therapeutic areas of gastroenterology and inflammation, which we will intensify when the top line results from the phase IIb study CONDUCT become available. We regularly participate in the large partnering conferences in the US and Europe where interest for new innovative drugs in inflammatory bowel disease is high. InDex's CEO and myself, were for example, at the JP Morgan conference in San Francisco in January 2019 to update interested pharmaceutical companies on the development progress of cobitolimod. We have also prepared an electronic data room with all the relevant documentation on cobitolimod, while ensuring that we have access to relevant expertise within all necessary areas for a full due diligence.



Andrew Thompson, Senior Business Development Advisor.

### In your opinion, what makes cobitolimod an attractive asset for out-licensing?

Given the unmet medical need and shortcomings of the existing drugs to treat moderate to severe ulcerative colitis, whilst there are a number of on-going developments in the field, no product has yet achieved a satisfactory combination of efficacy and safety. Cobitolimod's fast onset of action, due to the topical route of administration, together with the excellent tolerability seen so far in clinical studies makes this a highly promising candidate for a company working in IBD. Cobitolimod is also potentially better suited than most competing products under development for combination therapy, i.e. concomitant treatment with several different drugs, due to its tolerability. Finally, in a first primary market research conducted in the US and the big five countries in the EU, the cobitolimod profile was scored highly by both patients and physicians.

### What is InDex looking for in a partner?

InDex is looking for a partner, that can complete the development of the product through phase III and market approval to full commercialisation, with a sales force calling on IBD centers and relevant specialists such as gastroenterologists. We want a partner that shares our goal which is to bring cobitolimod to patients suffering from this debilitating disease.

## PATENTS

InDex's policy is to protect its own proprietary position by seeking patent protection related to the company's proprietary technology, inventions and improvements that are important for its development and business operations. The company's patent portfolio covers use of cobitolimod in the treatment of various inflammatory diseases, composition-of-matter patents for other DIMS compounds and their methods of use, as well as the protection of the diagnostic kit DiBiCol.

The use of cobitolimod in treatment of patients afflicted with an inflammatory condition, such as ulcerative colitis, and that have a history of steroid use is covered by two granted patent families. This portfolio provides a broad method of use patent protection in the US, Europe, Japan, Canada and Australia until at least 2026, with the possibility of up to 5 years term extension after marketing approval. Furthermore, the use of cobitolimod for treatment of active ulcerative colitis in a patient that is refractory or responds insufficiently or is intolerant to anti-inflammatory therapy, with or without history of steroid use, is covered by a third patent family. This patent family has been granted in the US and Japan and is being prosecuted in Europe and Canada. It will protect cobitolimod until 2032 with the possibility of up to 5 years term extension after marketing approval.

In addition, further patent applications have been filed or are contemplated in the light of advances in the formulation and clinical development of cobitolimod, to provide exclusivity beyond the term of InDex's already granted patents. Cobitolimod will also be subject to data protection as a new chemical entity for ten years from marketing approval in Europe, eight years in Japan and five years in the US.

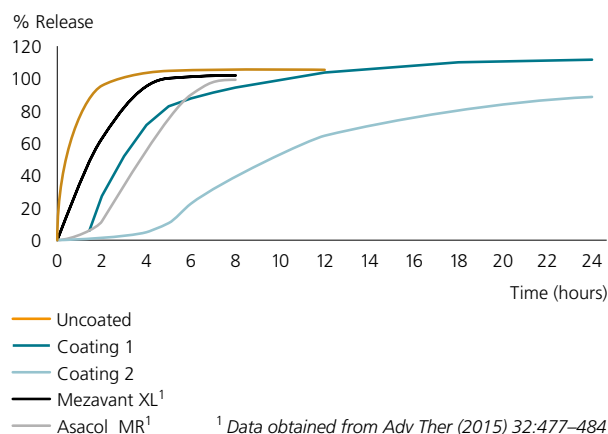
# Oral formulation of cobitolimod

InDex has developed a novel formulation of its lead drug candidate cobitolimod for oral administration, with targeted delivery to the lower part of the gastrointestinal tract. The capsule is a potential follow-on product to the topical formulation, which is currently being investigated in the CONDUCT study in patients with left-sided ulcerative colitis. An oral therapy makes it possible to deliver cobitolimod to parts of the gastrointestinal tract which are inaccessible to an enema and would be more convenient for the patients.

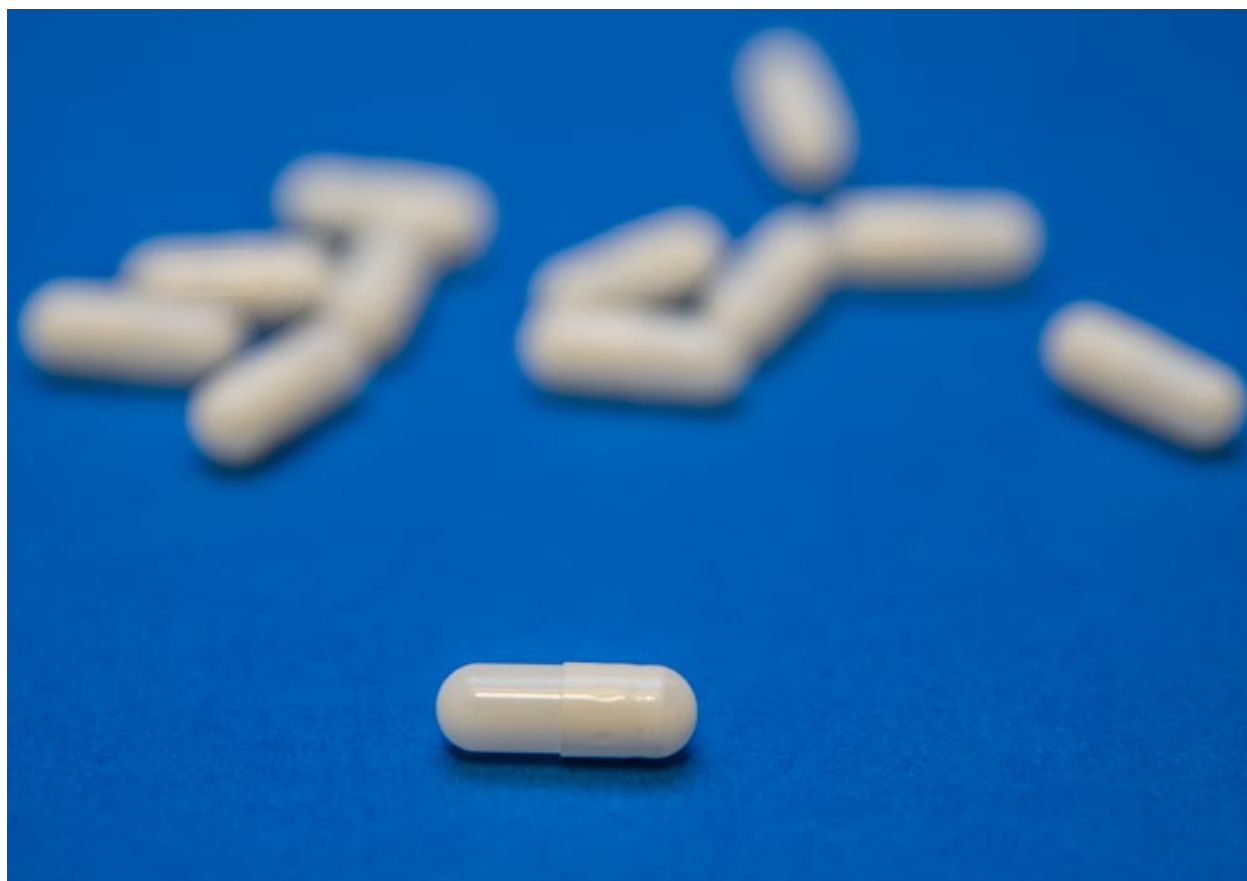
The oral formulation of cobitolimod consists of a core matrix in a capsule with a pH sensitive coating. Different parts of the gastrointestinal tract have different pH, and by using a coating that dissolves at a specific pH, one can direct the release of a substance to a specific part of the intestine. The capsule with cobitolimod is designed to initiate release of cobitolimod in the terminal ileum for controlled delivery to the colon.

The in vitro release profile for the capsule is similar to those reported for marketed oral mesalazine products for ulcerative colitis, with controlled release technologies such as Mezavant and Asacol. Additionally, the release profile can be adjusted to target other parts of the gastrointestinal tract, both by modifying the composition of the core matrix and the coating of the capsule.

This opens up the possibility to broaden the therapeutic use of cobitolimod to also include other inflammatory bowel diseases such as Crohn's disease, where the inflammation can be located higher up in the gastrointestinal tract. The oral formulation development also provides the opportunity to secure additional patent protection for cobitolimod.



Dissolution profile for cobitolimod compared to commercial mesalazine products



# DIMS compounds under development

InDex has besides cobitolimod a preclinical portfolio of more than 150 DNA-based ImmunoModulatory Sequences (DIMS). The DIMS candidates are oligonucleotides that differ in sequence composition and length, but are all TLR9 agonists. DIMS mimic bacterial DNA, without being harmful, and stimulate immune cells to produce beneficial anti-inflammatory cytokines that will help to dampen the inflammation. This opens up opportunities for the treatment of different inflammatory conditions, in which the immune responses are imbalanced. To capitalise on the substantial historical investments in the DIMS portfolio and to take advantage of

the expertise and experience built up during the development of cobitolimod in ulcerative colitis, InDex is testing a selected number of DIMS candidates, e.g. DIMS9054 and DIMS9059, in models of other inflammatory diseases. During 2016, InDex was awarded a grant of SEK 1.8 million for this development from the Swedish innovation agency Vinnova and the work under this grant was completed in 2018. Positive signals were observed, and InDex is now investigating how one can confirm these early results with alternative and complementary methods in order to be able to select a DIMS substance for further development.

PROGRAM	INDICATION	PRECLINICAL	PHASE I	PHASE II	PHASE III
COBITOLIMOD	MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS	▶			
DIMS 9059	INFLAMMATION	▶			
DIMS 9054	INFLAMMATION	▶			

## DiBiCol – an IBD diagnostic test

InDex has developed DiBiCol, which is a patented diagnostic method that helps to differentiate between ulcerative colitis and Crohn's disease. At the same time the test can either confirm IBD, or point to non-IBD such as the less severe condition Irritable Bowel Syndrome (IBS). Using traditional methods doctors sometimes have difficulties to give a definite diagnosis of patients with IBD. The two major forms of IBD, ulcerative colitis and Crohn's disease, share many symptoms and features. A substantial group of patients therefore fall into the category non-classified IBD, which is unfortunate since

treatment as well as surgical procedures differ between the diseases. In addition, it adds to the stress of the patient not knowing which disease he or she has. DiBiCol measures the expression of seven biomarker genes that are differently expressed in ulcerative colitis, Crohn's disease and non-IBD using a colonic biopsy. DiBiCol was introduced on the Swedish market in 2009, and has since been used in clinical routine practice. DiBiCol is not a focus area for InDex, and the service is not actively marketed.

# Organisation and the InDex team

InDex has a small number of employees with core competences and cooperates with experienced consultants within different areas of the development process. The plans are developed in close cooperation with key opinion leaders such as clinicians and scientists together with other experts such as Clinical Research Organisations (CROs) and Contract Manufacturing Organisations (CMOs), as well as through scientific advice from regulatory authorities and pricing authorities. InDex is using a so-called outsourcing model for its preclinical, clinical and pharmaceutical development work. Such a model provides a high degree of flexibility and utilises employees and other resources in a cost efficient way. InDex is selecting the most suitable CROs and CMOs to conduct trials and manufacturing of study drugs under the supervision of InDex.

As of December 31, 2018 InDex had seven full time employees. Three of the employees have Ph.D. degrees in immunology and inflammation. InDex has established cooperation with ten qualified consultants each specialised

in different areas, such as clinical trials, regulatory affairs, statistics, medicine, preclinical, manufacturing, business development and finance in order to ensure that the necessary competences and experiences are covered. The management has a strategy to involve all members of the team, regardless of employment status, to create a well-functioning team to meet the company's objectives. InDex's management and board of directors have together large and documented highly qualified international experience in the pharmaceutical industry. This covers the vast majority of the functions involved in the process to develop and commercialise new and innovative drugs.

To assist InDex in research and development the company is supported by highly experienced scientific advisors. Furthermore, InDex has engaged a panel of key opinion leaders within the gastrointestinal field to advise in medical questions related to the company's development portfolio, the design of InDex's clinical studies as well as the preparations of the interactions with relevant regulatory authorities.



*The InDex team*

# The share

InDex Pharmaceuticals Holding AB's share is listed on Nasdaq First North Stockholm since October 11, 2016 under the ticker symbol INDEX and with the ISIN code SE0008966295. The share is included in the Health Care segment.

## SHARE PRICE DEVELOPMENT AND TURNOVER OF SHARES

The share price as of December 28, 2018 was SEK 6.30 corresponding to a market cap of SEK 433 million. The highest share price paid on Nasdaq First North Stockholm during 2018 was SEK 8.58 and the lowest share price paid was SEK 4.29. During 2018, 8,963,127 shares were traded on Nasdaq First North Stockholm corresponding to a value of SEK 58.3 million.

## SHAREHOLDERS

InDex had as of December 28, 2018 2,617 shareholders according to Euroclear. The 10 largest shareholders in InDex held approximately 70 percent of the capital and the votes.

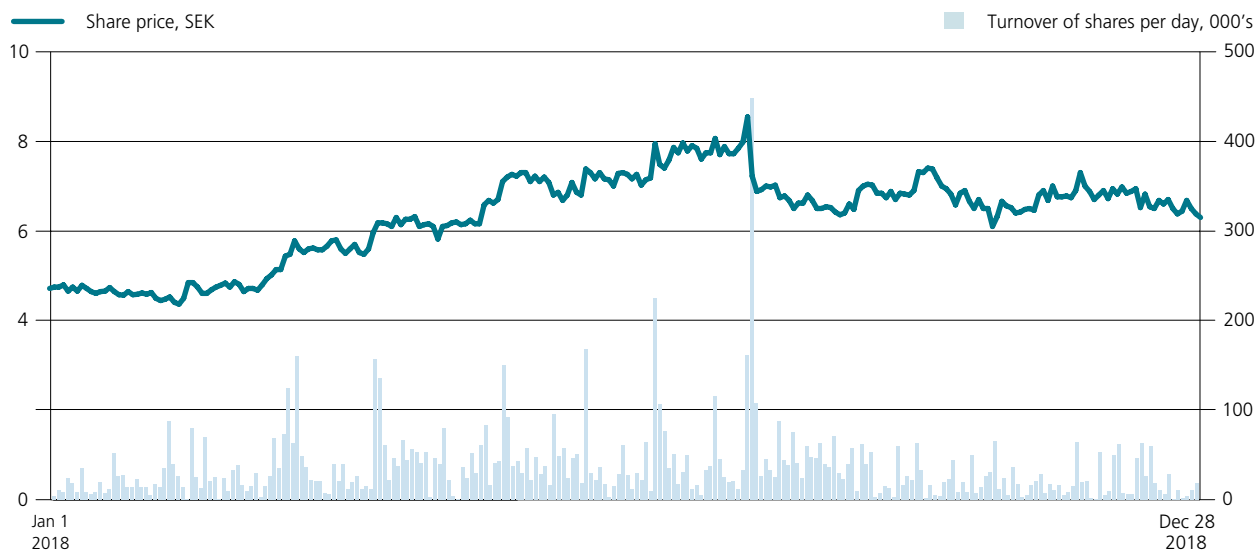
## CERTIFIED ADVISER

According to the rules of Nasdaq First North Stockholm a listed company needs to appoint a Certified Adviser to conduct certain surveillance tasks. Redeye AB is the company's Certified Adviser.

## LARGEST SHAREHOLDERS AS OF DECEMBER 28, 2018

	Number of shares	Percentage of capital and votes
SEB Venture Capital	14,657,241	21.3
Stiftelsen Industrifonden	12,900,272	18.8
NeoMed/N5	6,907,913	10.0
Staffan Rasiö	3,124,718	4.5
Linc AB	2,908,298	4.2
SEB Stiftelsen	1,785,714	2.6
SEB Life International	1,454,150	2.1
Skandinaviska Enskilda Banken S.A.	1,454,150	2.1
Avanza Pension	1,446,434	2.1
Ponderus Securities AB	1,348,996	2.0
Other	20,793,389	30.3
<b>Total</b>	<b>68,781,275</b>	<b>100.0</b>

## SHARE PRICE AND TURNOVER OF SHARES



**OWNERSHIP STRUCTURE BY SIZE OF HOLDINGS AS OF DECEMBER 28, 2018**

Holding	Number of shareholders	Number of shares	Percentage of capital and votes
1-500	377	63,396	0.1
501-1,000	812	634,329	0.9
1,001-5,000	982	2,400,095	3.5
5,001-10,000	215	1,655,203	2.4
10,001-15,000	63	814,326	1.2
15,001-20,000	36	666,070	1.0
20,001-	132	62,547,856	90.9
<b>Total</b>	<b>2,617</b>	<b>68,781,275</b>	<b>100.0</b>

**DEVELOPMENT OF SHARE CAPITAL**

Date	Transaction	Change in share capital	Total share capital	Number of new shares	Total number of shares	Paid in amount
Jun 27, 2016	Inception of the company	500,000	500,000	500,000	500,000	500,000
Sep 7, 2016	Split of shares	–	500,000	45,500,000	50,000,000	–
Sep 7, 2016	Share issue in-kind	601,345	1,101,345	60,134,466	110,134,466	–
Sep 7, 2016	Reduction of number of shares	–500,000	601,345	–50,000,000	60,134,466	–
Sep 7, 2016	Share issue	–	601,345	2	60,134,468	–
Sep 8, 2016	Reversed split of shares	–	601,345	–30,067,234	30,067,234	–
Oct 6, 2016	Share issue for pref. shares	52,685	654,030	2,634,279	32,701,513	52,685
Oct 6, 2016	Share issue	560,479	1,214,509	28,023,969	60,725,482	235,401,340
Oct 12, 2016	Share issue	14,305	1,228,814	715,250	61,440,732	6,008,100
Oct 25, 2016	Share issue	17,969	1,246,783	898,421	62,339,153	7,546,736
Nov 14, 2016	Share issue	1,895	1,248,678	94,725	62,433,878	795,690
Dec 29, 2016	Share issue in-kind	1,300	1,249,978	65,015	62,498,893	–
Jan 13, 2017	Share issue	591	1,250,569	29,540	62,528,433	248,136
Oct 23, 2018	Share issue	125,057	1,375,626	6,252,842	68,781,275	37,642,109

# Board of directors, senior management and auditors



## PROF. WENCHE ROLFSEN

Chairman since 2011.

*Born:* 1952.

*Current assignments:* Chairman of BioArctic. Board member of Swedish Match and Recipharm. In addition, partner in Serendipity Partners.

*Experience:* Managerial positions at Pharmacia and Quintiles, as well as board member of several listed companies. Former associate Professor in Pharmacology at Uppsala University.  
*Holdings:* Indirect holdings of 81,224 shares and direct holdings of 400,000 warrants 2016-2019.



## PROF. ULI HACKSELL

Board member since 2016.

*Born:* 1950.

*Current assignments:* Chairman of Cerecor and Adhera Therapeutics. CEO and board member of Medivir, as well as board member of Uppsala University and Beactica.

*Experience:* CEO and chairman of Cerecor, CEO of ACADIA Pharmaceuticals and managerial positions at Astra. Professor in organic chemistry at Uppsala University.  
*Holdings:* Direct holdings of 15,000 shares and 175,000 warrants 2016-2019.



## DR. LENNART HANSSON

Board member since 2011.

*Born:* 1956.

*Current assignments:* Chairman of Ignitus and Sixera Pharma, as well as board member of Medivir, Calliditas Therapeutics and Cinclus Pharma.

*Experience:* Former head of Life Science investments at Industrifonden, CEO of Arexis and managerial positions at AstraZeneca and Karolinska Development.  
*Holdings:* Indirect holdings of 30,000 shares.



## STIG LÖKKE PEDERSEN

Board member since 2012.

*Born:* 1961.

*Current assignments:* Chairman of Nuevolution, Modus Therapeutics, moksha8, Transmedica, and SSI-Diagnostics, as well as board member of Union Therapeutics, MSI, Skybrands and BroenLab.

*Experience:* Managerial positions at Lundbeck and Ciba-Geigy.  
*Holdings:* Indirect holdings of 23,809 shares and direct holdings of 175,000 warrants 2016-2019.



## ANDREAS PENNERVALL

Board member since 2016.

*Born:* 1974.

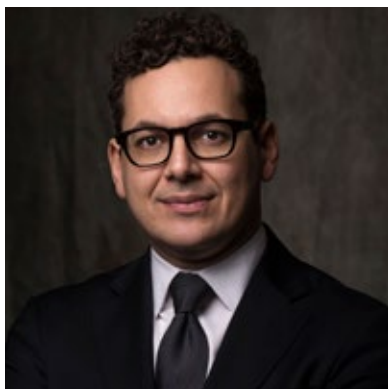
*Current assignments:* Board member of TSS Holding, Apica and Fairpoint Advisory.

*Experience:* Working as Investment Manager at SEB Venture Capital.  
*Holdings:* –.

## INDEPENDENCE

	In relation to		
	InDex	InDex's management	InDex's major shareholders
Prof. Wenche Rolfsen	●	●	●
Prof. Uli Hacksell	●	●	●
Dr. Lennart Hansson	●	●	–
Stig Lökke Pedersen	●	●	●
Andreas Pennervall	●	●	–



**PETER ZERHOUNI**

Chief Executive Officer (CEO)  
since 2015.

Board member of InDex Pharmaceuticals and InDex Diagnostics since 2017.

*Born:* 1972.

*Current assignments:* –.

*Experience:* CEO of Diamyd Medical and different positions at ING Bank in Amsterdam and Brussels.

*Holdings:* Direct holdings of 34,000 shares and 800,000 warrants 2016-2019.

**JOHAN GILÉUS**

Chief Financial Officer (CFO)  
since May 2017.

Board member of InDex Pharmaceuticals and InDex Diagnostics since 2017.

*Born:* 1965.

*Current assignments:* Board member of Gileus Consulting and Gileus Invest, as well as board member and chairman of the audit committee of Haldex.

*Experience:* Former Partner at Deloitte focusing on M&A, financial reporting and stock market issues.

*Holdings:* Direct holdings of 20,000 shares and 175,000 warrants 2016-2019.

**DR. THOMAS KNITTEL**

Chief Medical Officer (CMO)  
since 2012.

*Born:* 1962.

*Current assignments:* –.

*Experience:* More than 15 years of experience from clinical work within gastroenterology and managerial positions at Novo Nordisk, Harlan Laboratories and Develogen.

*Holdings:* Direct holdings of 15,000 shares and 175,000 warrants 2016-2019.

**PERNILLA SANDWALL**

Chief Operating Officer (COO)  
since 2012.

*Born:* 1963.

*Current assignments:* Board member of Innovativa Mindre Life Science företag (part of Läkemedelsindustri-föreningen).

*Experience:* Managerial positions within clinical operations at Merck (MSD).

*Holdings:* Direct Holdings of 25,000 shares and 350,000 warrants 2016-2019.

**AUDITORS**

PricewaterhouseCoopers AB with the authorised auditor Magnus Lagerberg as public accountant in charge since 2017.

*Note:* The years refer to InDex Pharmaceuticals AB as applicable.

*Holdings per December 31, 2018.*

# Directors' report

## InDex Pharmaceuticals Holding AB (publ) Corp. Reg. No. 559067-6820

The Board and the CEO of InDex Pharmaceuticals Holding AB hereby issue the annual report and the consolidated financial statements for 2018.

### INTRODUCTION

This annual report includes the group ("the group" or "InDex"), i.e. InDex Pharmaceuticals Holding AB, Corp. Reg. No 559067-6820, the subsidiaries InDex Pharmaceuticals AB, Corp. Reg. No. 556704-5140 and InDex Diagnostics AB, Corp. Reg. No. 556602-2751. The employees are employed, and the consultants are engaged, in the parent company or the subsidiary InDex Pharmaceuticals AB depending on the type of work performed. Invoicing of services between the group companies is based on utilisation. Revenues and direct costs for the diagnostic services (the diagnostic test DiBiCol) are accounted for in InDex Diagnostics AB.

The company's share is traded on Nasdaq First North Stockholm since October 11, 2016. Redeye AB is the company's Certified Adviser.

The operations are conducted at the so-called Gamma building, Karolinska Institute, with postal address Tomtebodavägen 23a, 171 77 Stockholm.

### BUSINESS OVERVIEW

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 ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

In addition, InDex has a broad portfolio of other DNA based ImmunoModulatory Sequences (DIMS) in discovery stage, with the potential to be used in the treatment of various immunological diseases.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon. InDex's clinical studies indicate that cobitolimod has a higher efficacy and a more favourable safety profile than what has been reported for the currently approved biological drugs in corresponding patient populations. Sales of biologics for treatment of ulcerative colitis amount to more than USD 5 billion per year.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis. Cobitolimod has achieved clinical proof-of-concept in moderate to severe

active ulcerative colitis, with a very favorable safety profile. Data from four placebo-controlled clinical trials show that cobitolimod has statistically significant effects on those endpoints that are most relevant for this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively.

Based on the encouraging results from earlier studies InDex is now performing the phase IIb study CONDUCT to evaluate higher doses and dose frequencies than investigated in previous studies with cobitolimod. The goal of the study is to optimise the treatment and achieve substantially higher efficacy, while maintaining the compound's excellent safety profile. The CONDUCT study will include 215 patients with left-sided moderate to severe active ulcerative colitis at 90 clinics in 12 countries. It is a randomised, double blind, placebo-controlled study for evaluating cobitolimod's efficacy and safety in inducing clinical remission compared to placebo. The dose optimisation study investigates three different dose strengths of cobitolimod and two different dose frequencies. The objective is to have top line results from the study during the first half of 2019.

Cobitolimod is also known as Kappaproct® and DIMS0150.

### SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

- New mechanism of action data for cobitolimod was presented orally at the congress of the European Crohn's and Colitis Organisation (ECCO), which was held in Vienna, Austria, on February 14-17, 2018. The abstract had been selected amongst the top 10 out of 1,366 submitted abstracts, and it was featured in the Highlights of ECCO'18 video. The video contains the most important scientific insights and take-home messages from the congress.
- InDex announced on March 28, 2018, that a new method of use patent for the drug candidate cobitolimod will be issued by the Japan Patent Office. The patent provides additional protection for treating chronic active ulcerative colitis in patients that are not responding or are intolerant to anti-inflammatory therapy, wherein cobitolimod is administered in combination with corticosteroid or glucocorticosteroids.
- InDex hosted a Capital Markets Day on April 25, 2018 for investors, analysts and media. The purpose of the Capital Markets Day was to provide an overview of ulcerative colitis and the drug candidate cobitolimod from a scientific and market perspective.
- InDex announced on May 4, 2018 that the company has developed a novel formulation of its drug candidate cobitolimod for oral administration, with targeted delivery to the lower part of the gastrointestinal tract. The oral formulation of cobitolimod is a potential follow-on product to the topical formulation, which is investigated in the CONDUCT study.
- The Annual General Meeting in InDex Pharmaceuticals Holding AB was held on May 24, 2018. Board members Wenche Rolfsen (also chairman), Uli Hacksell, Lennart

Hansson, Stig Lökke Pedersen and Andreas Pennervall were re-elected.

- InDex participated with two poster presentations at the Digestive Disease Week (DDW), which was held in Washington DC, US on June 2-5, 2018. DDW is the largest congress in the world within gastroenterology.
- InDex announced on August 9, 2018 an updated timeline for patient recruitment in the ongoing phase IIb study CONDUCT with the drug candidate cobitolimod. Top line results from the study are now expected in the first half of 2019 instead of in the fourth quarter of 2018 as previously communicated.
- InDex announced on October 19, 2018 that a post-hoc analysis of COLLECT study data has been published in the October issue of the peer-reviewed journal Digestive and Liver Disease (DLD). The paper presents the clinical effect of cobitolimod on patient-reported outcomes defined endpoints and in different patient subgroups defined by disease activity or anti-TNF therapy exposure.
- On October 23, 2018 InDex carried out a directed share issue to a small group of investors. InDex received proceeds of approximately SEK 37.5 million after transaction related costs for legal services and costs for registration and practical management.

#### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- No significant events have occurred after the end of the reporting period.

#### CORPORATE STRUCTURE

InDex Pharmaceuticals Holding AB was incepted on December 14, 2015 and was registered with the Swedish Companies Registration Office on June 27, 2016. At an Extra General Meeting held on August 25, 2016 it was resolved, and on September 7, 2016 an issue for non-cash consideration was registered at the Swedish Companies Registration Office, whereby the shareholders of InDex Pharmaceuticals AB transferred 99.76 percent (in December 2018 99.97 percent have been transferred) of the shares in the company in exchange for new shares in the new parent company, InDex Pharmaceuticals Holding AB. The intention is that also the remaining shares in InDex Pharmaceuticals AB will be exchanged for shares in the parent company.

With the support of valuations provided by two independent external parties, the Board attributed the shares in InDex Pharmaceuticals AB a total value of SEK 247.0 million, out of which the shares held by the parent company were reported in the balance sheet at the same value, as the remaining shares will be transferred alternatively compulsory acquired. A debt of SEK 0.1 million to the minority shareholders (the few shareholders that have not signed the share exchange agreement, representing 0.03 percent of total shares) have therefore been reported as of December 31, 2018. After registration of the various decisions taken as part of the formation of the new group, the share capital in InDex Pharmaceuticals Holding AB amounted to SEK 601,344.68, divided into 30,067,234 shares (after simultaneous withdrawal and consolidation of shares).

The Board has concluded that the restructuring described above has not in itself changed the business or the shareholder structure, why the consolidated financial statements have been prepared in accordance with the guidelines for acquisition under common control. In short this means that the consolidated financial statements are prepared as if InDex Pharmaceuticals AB is the acquiring company in the consolidated financial statements and, therefore, the assets and liabilities are reported at historical values. This further means that the comparative periods for InDex can be presented in the financial report for InDex where InDex Pharmaceuticals AB was the legal parent.

## FINANCIAL DEVELOPMENT

CONSOLIDATED FINANCIAL SUMMARY					
SEK million	2018	2017	2016	2015 *	2014 *
Revenues	0.7	0.1	0.4	0.4	45.2
Operating loss	-82.4	-73.3	-39.5	-29.5	-12.2
Result after tax	-82.3	-72.8	-41.3	-29.9	-10.4
Result per share before and after dilution, SEK	-1.29	-1.16	-1.08	-0.99	-
Cash flow from operating activities	-79.5	-68.2	-31.9	-37.0	-8.2
Cash and cash equivalents at the year-end	83.0	125.1	193.2	7.0	43.9
Average number of shares	63,692,156	62,527,366	38,110,575	30,067,234	-
Number of shares at the year-end	68,781,275	62,528,433	62,498,893	30,067,234	-

\* Information covering fiscal years 2014 and 2015 relates to the group where InDex Pharmaceuticals AB was the parent company.

Because of the nature of the business operations, there may be large fluctuations between different periods.

### Group

The revenues for 2018 amounted to SEK 0.7 million, which is an increase of SEK 0.6 million compared to the previous year. The increase is related to research grants received for projects completed during the year.

Operating expenses for 2018 amounted to SEK 83.1 million, which is an increase of SEK 9.7 million compared to the previous year. The increase is mainly attributable to higher costs for the ongoing phase IIb study. The costs during the period refer to costs for the ongoing phase IIb study and general operating expenses.

Costs for the personnel amounted to SEK 9.6 million during 2018, which is in line with the previous year.

Cash and cash equivalents as of December 31, 2018 amounted to SEK 83.0 million, which is SEK 42.1 million lower than December 31, 2017. InDex announced on October 23, 2018 that the Board, with support from the authorization granted by the annual general meeting on May 24, 2018, had resolved on a directed share issue of 6,252,842 shares to a small group of investors. The subscription price was SEK 6.02 per share, corresponding to a discount in line with market conditions of 7.7 percent to the 5-day volume weighted average price and 1.3 percent to the closing price. InDex received proceeds of approximately SEK 37.5 million after transaction related costs for legal services and costs for registration and practical management.

### Parent company

The revenues amounted to SEK 9.1 million during 2018 and consisted of invoicing of group wide expenses to the other companies within the group. The expenses amounted to SEK 14.4 million and consisted of personnel expenses in the parent company and other operating expenses relating to the administration of InDex. During 2018 the parent company provided a shareholder's contribution of SEK 40 million to the subsidiary InDex Pharmaceuticals AB. In accordance with InDex's valuation principles the shares in subsidiaries have simultaneously been written down with the same amount.

### THE BOARD AND CEO

The Board in InDex Pharmaceuticals Holding AB was elected at the Annual General Meeting on May 24, 2018 and consists of the chairman Wenche Rolfsen, Uli Hacksell, Lennart Hansson, Stig Lökke Pedersen and Andreas Pennervall.

Peter Zerhouni is CEO since April 1, 2015.

### RISKS AND UNCERTAINTIES

The business of the company can be affected by a number of risk factors. The ambition of the group is to establish a group wide risk management program that focuses on minimising potential negative effects on InDex's profit. The Board is ultimately responsible for identifying, managing and monitoring InDex's risks. The policy for identifying, management and monitoring of financial risks is decided by the Board and is subject to annual revisions. The Board has delegated the daily work regarding risk management to the CEO, who has delegated to the CFO. The Board may decide on temporary exemptions from the policy.

There is no guarantee that InDex's research and development will result in commercial success. There is no guarantee that InDex will develop products that can be patented, that granted patents can be retained, that future inventions will lead to patents, or that granted patents will provide sufficient protection for InDex's products.

There is no guarantee that InDex obtains necessary approvals to conduct the clinical trials that InDex would like to implement, or that the clinical trials conducted by InDex, independently or in collaboration with partners, will demonstrate sufficient safety and efficacy to obtain necessary regulatory approvals or that the trials will lead to drugs that can be sold on the market. It cannot be excluded that the regulatory approval process will require increased documentation and thereby increased costs and delays in projects or lead to projects being shut down.

Increased development costs and longer development time may mean that the risks of a project increase and that the compound's potential to successfully reach the commercial stage decreases or that the time for patent protected sales is reduced.

**EXPECTED FUTURE DEVELOPMENT**

The Board's estimate is that the main results from the CONDUCT study will be available during the first half of 2019.

The Board is reviewing the forecasted cash flow on an ongoing basis to determine InDex's capital requirements and resources required to conduct the business activities in accordance with the strategic direction decided by the Board.

It is the assessment of the Board that InDex has enough capital to finance the CONDUCT study until the main results are available and all other financial commitments that InDex has for the coming 12-month period.

InDex provides no financial forecast or similar forward looking statement.

**NON-FINANCIAL INFORMATION****Employees**

The number of employees at the end of the year was 7 (7) and the number of people closely associated with InDex through consultancy arrangements amount to 10 (10).

**Environment**

InDex is a small company and is therefore procuring services such as production of substance, drug production and preclinical and clinical trials services. InDex is cooperating with well-known partners and have rigorous oversight of permits, quality assurance and environmental obligations.

**Annual General Meeting in the parent company**

The Annual General Meeting of InDex Pharmaceuticals Holding AB will be held on May 6, 2019 at 5:00 p.m. (CET) at the company's premises, Tomtebodavägen 23a in Stockholm.

Shareholders who wish to attend the Annual General Meeting must be recorded in the share register maintained by Euroclear Sweden AB on April 29, 2019.

Shareholders who wish to attend the Annual General Meeting shall also give notice of attendance no later than April 29, 2019 at 5:00 p.m. (CET) by email to annika.lindmark@indexpharma.com or under postal address: InDex Pharmaceuticals Holding AB, Tomtebodavägen 23a, 171 77 Stockholm. The notice shall contain name, address and number of shares represented. If applicable, the number of assistants (maximum 2) shall be provided.

Shareholders that are represented by proxy shall provide the proxy to the agent. The proxy shall be provided to the company prior to the Annual General Meeting using the above-mentioned postal address. If the proxy is provided by a legal person a certified company certificate shall be attached.

**PROPOSED DISTRIBUTION OF EARNINGS****THE FOLLOWING RETAINED EARNINGS ARE AT THE DISPOSAL OF THE ANNUAL GENERAL MEETING**

SEK

Retained earnings	329,011,828
Net result	-45,369,754
	<b>283,642,074</b>

The Board's suggestion to be carried forward	283,642,074
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**THE BOARD'S OPINION REGARDING THE SUGGESTED DISTRIBUTION AND DIVIDEND POLICY**

The Board does not propose a dividend for 2018. The Board has no intention to propose a dividend until InDex can forecast long term profit and sustainable positive cash flow.

*Regarding the parent company's and the group's result and financial position the reader is referred to the pages overleaf presenting the income statement, balance sheet, statement of changes in equity, cash flow and associated notes. All amounts are presented in thousands of SEK unless stated otherwise.*

# Consolidated income statement

SEK 000's	Note	January 1, 2018- December 31, 2018	January 1, 2017- December 31, 2017
<b>Revenues</b>			
Net sales	4	128	113
Other income		612	–
<b>Total revenues</b>		<b>740</b>	<b>113</b>
<b>Operating expenses</b>			
Raw material and consumables	4	–560	–8,998
Other external expenses	5, 6	–78,981	–54,825
Personnel costs	6	–9,553	–9,594
Depreciations of tangible fixed assets	10	–11	–11
<b>Total expenses</b>		<b>–83,105</b>	<b>–73,428</b>
<b>Operating loss</b>		<b>–82,365</b>	<b>–73,315</b>
<b>Profit/loss from financial items</b>			
Financial income	7	156	1,340
Financial expenses	8	–106	–784
<b>Total</b>		<b>50</b>	<b>556</b>
<b>Earnings before tax</b>		<b>–82,315</b>	<b>–72,759</b>
Taxes for the period	9	–	–
<b>RESULT AFTER TAX</b>		<b>–82,315</b>	<b>–72,759</b>
<b>Attributable to:</b>			
Shareholders of the parent company		–82,315	–72,759
Non-controlling interest		–	–

# Consolidated balance sheet

SEK 000's	Note	December 31, 2018	December 31, 2017
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible fixed assets</i>			
Equipment, tools and installations	10	21	31
<b>Total tangible fixed assets</b>		<b>21</b>	<b>31</b>
<i>Financial assets</i>			
Other financial assets	12	1	1
<b>Total financial assets</b>		<b>1</b>	<b>1</b>
<b>Total fixed assets</b>		<b>22</b>	<b>32</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Accounts receivable		10	16
Other current receivables		1,480	848
Prepaid expenses and accrued income	13	482	921
<b>Total current receivables</b>		<b>1,972</b>	<b>1,785</b>
<b>Cash and cash equivalents</b>		<b>83,034</b>	<b>125,055</b>
<b>Total current assets</b>		<b>85,006</b>	<b>126,840</b>
<b>TOTAL ASSETS</b>		<b>85,028</b>	<b>126,872</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital		1,376	1,251
Additional paid in capital		254,930	217,581
Retained earnings, including loss for the year		-196,400	-114,085
<b>Attributable to shareholders of the parent company</b>		<b>59,906</b>	<b>104,747</b>
<b>Total equity</b>		<b>59,906</b>	<b>104,747</b>
<b>Current liabilities</b>			
Account payables		3,550	6,568
Other current liabilities		5,935	5,750
Accrued expenses and deferred income	14	15,637	9,807
<b>Total current liabilities</b>		<b>25,122</b>	<b>22,125</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>85,028</b>	<b>126,872</b>

# Consolidated statement of changes in equity

SEK 000's	Equity attributable to the shareholders of the parent company			
	Share capital	Additional paid in capital	Retained earnings, including loss for the year	Total equity attributable to the shareholders of the parent company
<b>Opening balance January 1, 2017</b>	<b>1,251</b>	<b>217,546</b>	<b>-41,326</b>	<b>177,471</b>
Net results			-72,759	-72,759
Issue of warrants		35		35
<b>Closing balance December 31, 2017</b>	<b>1,251</b>	<b>217,581</b>	<b>-114,085</b>	<b>104,747</b>

Share capital – 62,528,433 shares with a par value of SEK 0.02.

<b>Opening balance January 1, 2018</b>	<b>1,251</b>	<b>217,581</b>	<b>-114,085</b>	<b>104,747</b>
Net results			-82,315	-82,315
<i>Transactions with shareholders:</i>				
Issue of shares	125	37,517		37,642
Issue costs		-168		-168
<b>Closing balance December 31, 2018</b>	<b>1,376</b>	<b>254,930</b>	<b>-196,400</b>	<b>59,906</b>

Share capital – 68,781,275 shares with a par value of SEK 0.02.



# Consolidated cash flow

SEK 000's	Note	January 1, 2018- December 31, 2018	January 1, 2017- December 31, 2017
<b>Operating activities</b>			
Earnings before tax		-82,315	-72,759
<i>Adjustment for non-cash items:</i>			
Depreciations		11	11
Divestment of financial assets		-	27
Income tax paid		-	-
<b>Cash flow from operating activities before changes in working capital</b>		<b>-82,304</b>	<b>-72,721</b>
<b>Cash flow in working capital</b>			
Decrease(+)/Increase(-) of current receivables		-188	-574
Decrease(-)/Increase(+) of current liabilities		2,993	5,110
<b>Cash flow from operating activities</b>		<b>-78,499</b>	<b>-68,185</b>
<b>Cash flow from investment activities</b>			
Investments in tangible assets		-	-
<b>Cash flow from investment activities</b>		<b>-</b>	<b>-</b>
<b>Financing activities</b>			
Issue of shares		37,478	-
Issue of warrants		-	8
<b>Cash flow from financing activities</b>		<b>37,478</b>	<b>8</b>
<b>Cash flow for the year</b>		<b>-42,021</b>	<b>-68,177</b>
<b>Cash and cash equivalents at the beginning of the year</b>		<b>125,055</b>	<b>193,232</b>
<b>Currency translation difference in cash and cash equivalents</b>		<b>-</b>	<b>-</b>
<b>Cash and cash equivalents at the end of the year</b>	15	<b>83,034</b>	<b>125,055</b>

# Income statement parent company

SEK 000's	Note	January 1, 2018- December 31, 2018	January 1, 2017- December 31, 2017
<b>Revenues</b>			
Net sales	4	9,112	8,000
<b>Total revenues</b>		<b>9,112</b>	<b>8,000</b>
<b>Operating expenses</b>			
Other external expenses	4		
	5, 6	-9,194	-7,555
Personnel costs	6	-5,252	-5,107
<b>Total expenses</b>		<b>-14,446</b>	<b>-12,662</b>
<b>Operating loss</b>		<b>-5,334</b>	<b>-4,662</b>
<b>Net financial items</b>			
Write-down of financial assets	11	-40,000	-120,000
Financial expenses		-36	-1
<b>Total</b>		<b>-40,036</b>	<b>-120,001</b>
<b>Earnings before tax</b>		<b>-45,370</b>	<b>-124,663</b>
Taxes for the period	9	-	-
<b>RESULT AFTER TAX</b>		<b>-45,370</b>	<b>-124,663</b>

\* To reset the equity in the subsidiary InDex Pharmaceuticals AB, InDex Pharmaceuticals Holding AB provided a shareholder contribution of SEK 40 (120) million. A writedown of shares in subsidiaries was made simultaneously.

# Balance sheet parent company

SEK 000's	Note	December 31, 2018	December 31, 2017
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Financial fixed assets</i>			
Shares in subsidiaries	11	247,030	247,030
<b>Total financial fixed assets</b>		<b>247,030</b>	<b>247,030</b>
<b>Total fixed assets</b>		<b>247,030</b>	<b>247,030</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Intercompany receivables		351	176
Other receivables		15	–
Prepaid expenses and accrued income	13	353	455
<b>Total current receivables</b>		<b>719</b>	<b>631</b>
<b>Cash and cash equivalents</b>		<b>82,388</b>	<b>111,682</b>
<b>Total current assets</b>		<b>83,107</b>	<b>112,313</b>
<b>TOTAL ASSETS</b>		<b>330,137</b>	<b>359,343</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital		1,376	1,251
<b>Total restricted equity</b>		<b>1,376</b>	<b>1,251</b>
<i>Non-restricted equity</i>			
Share premium		500,647	463,294
Retained earnings		–171,635	–46,972
Net result		–45,370	–124,663
<b>Total non-restricted equity</b>		<b>283,642</b>	<b>291,659</b>
<b>Total equity</b>		<b>285,018</b>	<b>292,910</b>
<b>Current liabilities</b>			
Account payables		168	497
Intercompany liabilities		42,266	63,238
Other current liabilities		1,066	498
Accrued expenses and deferred income	14	1,619	2,200
<b>Total current liabilities</b>		<b>45,119</b>	<b>66,433</b>
<b>TOTAL EQUITY AND LIABILITES</b>		<b>330,137</b>	<b>359,343</b>

# Statement of change in equity parent company

SEK 000's	Restricted equity		Non-restricted equity		
	Share capital	Share premium	Retained earnings	Net result	Total equity
<b>Opening balance January 1, 2017</b>	<b>1,251</b>	<b>463,294</b>	<b>650</b>	<b>-47,622</b>	<b>417,573</b>
Disposition of last year's result			-47,622	47,622	-
Net result				-124,663	-124,663
<b>Closing balance December 31, 2017</b>	<b>1,251</b>	<b>463,294</b>	<b>-46,972</b>	<b>-124,663</b>	<b>292,910</b>

Share capital – 62,528,433 shares with a par value of SEK 0.02.

<b>Opening balance January 1, 2018</b>	<b>1,251</b>	<b>463,294</b>	<b>-46,972</b>	<b>-124,663</b>	<b>292,910</b>
Disposition of last year's result			-124,663	124,663	-
Net result				-45,370	-45,370
Issue of shares	125	37,517			37,642
Issue costs		-164			-164
<b>Closing balance December 31, 2018</b>	<b>1,376</b>	<b>500,647</b>	<b>-171,635</b>	<b>-45,370</b>	<b>285,018</b>

Share capital – 68,781,275 shares with a par value of SEK 0.02.

# Cash flow parent company

SEK 000's	Note	January 1, 2018- December 31, 2018	January 1, 2017- December 31, 2017
<b>Operating activities</b>			
Earnings before tax		-45,370	-124,663
<i>Adjustment for non-cash items:</i>			
Depreciations/write-down		40,000	120,000
Income tax paid		-	-
<b>Cash flow from operating activities before changes in working capital</b>		<b>-5,370</b>	<b>-4,663</b>
<b>Cash flow in working capital</b>			
Decrease(+)/Increase(-) of current receivables		-88	-58
Decrease(-)/Increase(+) of current liabilities		-21,314	48,017
<b>Cash flow from changes in working capital</b>		<b>-21,402</b>	<b>47,959</b>
<b>Cash flow from operating activities</b>		<b>-26,772</b>	<b>43,296</b>
<b>Cash flow from investment activities</b>			
Shareholders contribution		-40,000	-120,000
<b>Cash flow from investment activities</b>		<b>-40,000</b>	<b>-120,000</b>
<b>Financing activities</b>			
Issue of shares		37,478	-
<b>Cash flow from financing activities</b>		<b>37,478</b>	<b>-</b>
<b>Cash flow for the year</b>		<b>-29,294</b>	<b>-76,704</b>
<b>Cash and cash equivalents at the beginning of the year</b>		<b>111,682</b>	<b>188,386</b>
<b>Cash and cash equivalents at the end of the year</b>	15	<b>82,388</b>	<b>111,682</b>

# Notes

## NOTE 1 GENERAL INFORMATION

InDex Pharmaceuticals Holding AB (publ) Corp. Reg. No. 559067-6820 is a registered limited liability corporation in Sweden with its registered office in Stockholm. The address to the head office is Tomtebodavägen 23a, Stockholm. InDex Pharmaceuticals Holding AB, and its subsidiaries InDex Pharmaceuticals AB and InDex Diagnostics AB ("the group"), operations constitute research, clinical trials, development of technology and commercialisation of scientific discoveries within in the field of biomedicine.

## NOTE 2 ACCOUNTING AND VALUATION PRINCIPLES

The consolidated financial statements have been prepared in accordance with the Swedish Annual Accounts Act (1995:1554) and the Swedish Accounting Standards Board's BFNAR 2012:1 Annual report and consolidated financial statements ("K3").

### CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements cover the parent company, InDex Pharmaceuticals Holding AB and the entities the parent company directly or indirectly has control of (its subsidiaries). Control is the power to govern the operating policies of an entity to gain economic benefits from its activities. When assessing if a controlling interest exists, consideration should be made to financial instruments with a potential voting right and which without delay can be used or converted to equity instruments with voting right. Consideration should also be made if the company is able to govern the operations through an agent. Control is normally presumed to exist if the parent company owns, directly or indirectly, more than half of the voting power of an entity.

A subsidiary's net sales and expenses are included in the consolidated financial statements from the acquisition date and up to the date the parent company no longer has a controlling interest in the subsidiary.

The accounting principles applied by the subsidiary comply with the group's accounting principles. Intragroup transactions, intercompany receivables and payables and unrealised gains and losses related to group transactions, are eliminated in the preparation of the consolidated financial statements for the group.

### InDex Pharmaceuticals Holding AB's acquisition of InDex Pharmaceuticals AB in 2016

The Board has concluded that InDex Pharmaceuticals Holding AB's acquisition of InDex Pharmaceuticals AB has not changed the business or the shareholder structure, why the consolidated financial statements have been prepared in accordance with the guidelines for acquisition under common control.

In short, this means that the consolidated financial statements are prepared as if InDex Pharmaceuticals AB is the acquiring company in the consolidated financial statements and therefore assets and liabilities are reported at historical values. This means that the comparative periods for the group can be presented in the financial report for the group where InDex Pharmaceuticals AB is the legal parent.

### INCOME

Income is recognised at fair value of the consideration received or that will be received, less VAT, discounts, returns and similar deductions.

### Rendering of services

Income from rendering research services is recognised in the accounting period when the services are rendered.

### Interest income

Interest income is recognised over the term using the effective interest method. The effective interest rate is the rate that discounts estimated future cash payments during the fixed interest term equal to the carrying value of the receivable.

### LEASE AGREEMENT

Leases are classified as financial leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. Other lease agreements are classified as operational leases.

### The group as holder of lease agreements

The group does not hold any lease agreements that constitute financial leases. Lease payments under operating leases are expensed on a straight-line basis over the lease term unless another systematic approach better reflects the user's economic benefit over time. Consolidated operating leases comprise rental of premises.

### FOREIGN CURRENCY

The parent company's reporting currency is Swedish Kronor (SEK).

### Translation of foreign currency items

At each balance sheet date, monetary items in foreign currencies are translated at the closing day rate. Non-monetary items that are valued at historical cost in a foreign currency are not translated. Exchange differences are recognised in operating income or as a financial item based on the underlying business transaction in the period they are incurred.

### EMPLOYEE BENEFITS

Employee benefits which include salaries, bonuses, holiday pay, paid sick leave, etc. and pensions are recognised as the related service is rendered. Pensions and other post-employment benefits are classified as defined contribution or defined benefit plans. The group only has defined contribution pension plans. There are no other long-term benefits to employees.

**Defined contribution plans**

For defined contribution plans, the group pays fixed contributions to a separate, independent legal entity and has no obligation to pay additional fees. The group's profit is charged with costs as the benefits are earned, which normally coincides with the time when the premiums are paid.

**INCOME TAX**

The tax expense represents the sum of current tax and deferred tax.

**Current tax**

Current tax is calculated on the taxable profit for the period. Taxable profit differs from the result reported in the income statement as it is adjusted for non-taxable income and non-deductible expenses and for income and expenses that are taxable or deductible in other periods. The group's current tax is calculated using the tax rates in force on the balance sheet date.

**Deferred tax**

Deferred tax is recognised on temporary differences between the carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit. Deferred tax is recognised according to the so called balance-sheet method. Deferred tax liabilities are generally recognised for all taxable temporary differences, and deferred tax assets are generally recognised for all deductible temporary differences, to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilised.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries, except where the group can control the reversal of the temporary differences and it is not clear that the temporary difference will not reverse in the foreseeable future.

The valuation of deferred tax is based on how the company, on the balance sheet date, expects to recover the carrying value of the corresponding asset or settle the carrying amount of the corresponding liability. Deferred tax is calculated using tax rates and tax regulations that have been enacted by the balance sheet date.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same authority and the group intends to settle the tax by a net amount.

**Current and deferred tax for the period**

Current and deferred tax is recognised as an expense or income in the income statement, except when the tax relates to items recognised directly in equity. In such cases, also the tax is recognised directly in equity.

**TANGIBLE FIXED ASSETS**

If the difference in the consumption of significant components of a property, plant and equipment is considered essential, the asset is divided into these components.

Depreciation of property, plant and equipment is expensed so that the cost of the asset, possibly less

estimated residual value at the end of its useful life, is depreciated on a straight-line basis over its estimated useful life. Depreciation commences when property, plant and equipment can be put in use.

The useful lives of property, plant and equipment are estimated at:

**EQUIPMENT, TOOLS, FIXTURES AND FITTINGS:**

Equipment, tools, fixtures and fittings

5 years

Estimated useful lives and depreciation methods are reviewed if there are indications that the expected consumption has changed significantly compared with the estimation at the previous balance sheet date. When the company changes the assessment of useful lives, also the asset's possible residual value is reviewed. The effect of these changes is accounted for prospectively.

**Derecognition from the balance sheet**

The carrying amount of property, plant and equipment is derecognised upon disposal or sale, or when no future economic benefits are expected from the use or disposal/sale of the asset or component. The gain or loss that arises when property, plant and equipment or component is derecognised is the difference between what is possibly obtained, net of direct selling costs, and the asset's carrying value. The capital gain or loss that arises when property, plant and equipment or component is derecognised, is included in the income statement as other operating income or other operating expense.

**IMPAIRMENT OF TANGIBLE FIXED ASSETS**

At each balance sheet date the company analyses the carrying values of property, plant and equipment to determine whether there is any indication that those assets have declined in value. If so, the asset's recoverable amount is estimated in order to determine the value of any impairment loss. Where it is not possible to estimate the recoverable amount of an individual asset, the company estimates the recoverable amount for the cash-generating unit to which the asset belongs.

The recoverable amount is the higher of fair value less cost to sell and value in use. Fair value less cost to sell is the price which the company expects to receive in a sale between knowledgeable, independent parties and who have an interest in completing the transaction, less the costs that are directly attributable to the sale. When calculating the value in use estimated future cash flows are discounted to present value using a discount rate before tax that reflects the current market assessments of the time value of money and the risks associated with the asset. To calculate the future cash flows, the company has used the budget and forecasts for the next five years.

If the recoverable amount of an asset (or cash-generating unit) is determined at a value lower than the carrying amount, the carrying amount of the asset (or the cash-generating unit) is impaired to its recoverable amount. An impairment loss should be expensed immediately in the income statement.

At each balance sheet date, the group assesses whether the earlier impairment is no longer justified. If so, it is reversed partially or completely. When an impairment loss is reversed the asset's (the cash-generating units) carrying value increases. The carrying value after reversal of impairment loss must not exceed the carrying amount that would be determined if no impairment had been made of the asset (the cash-generating unit) in prior years. A reversal of an impairment is recognised in the income statement.

#### **PARTICIPATIONS IN GROUP COMPANIES**

The parent company's shares in group companies are recognised at cost less any impairment losses. Dividends from subsidiaries are recognised when the right to receive the dividend is deemed secure and can be measured reliably.

#### **FINANCIAL INSTRUMENTS**

A financial asset or financial liability is accounted for in the balance sheet when the group becomes a party to the instrument's contractual terms. A financial asset is derecognised from the balance sheet when the contractual right to cash flow from the asset terminates, is paid or when the group loses its control over the asset. A financial liability or part of a financial liability, is derecognised from the balance sheet when the contractual commitment is completed or in another way terminates.

At the initial accounting current assets and current liabilities are valued at cost. Long-term receivables and long-term liabilities are valued at the initial accounting at amortised cost. Borrowing costs are accrued as part of the loan's interest expense using the effective interest method.

After the initial accounting, current assets are valued at the lower of acquisition cost and net sales value as per the balance sheet date. Current liabilities are valued at nominal value

#### **Amortised cost**

Amortised cost is the amount at which the financial asset or the financial liability is measured at initial recognition minus principal payments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount and minus any reduction for impairment.

The effective interest rate is the rate that discounts estimated future cash receipts through the expected life to the net carrying amount of the financial asset or the financial liability on initial recognition.

#### **Impairment of financial assets**

At the end of each reporting period, financial assets are assessed for indicators of impairment. Examples of such indicators are significant financial difficulty of the borrower, breach of contract or that it is probable that the borrower will go bankrupt.

For financial assets measured at amortised cost, the amount of the impairment loss recognised is the difference between the asset's carrying amount and the present value of the estimated future cash flows by management. Discounting is done with an interest equal to the asset's original effective

interest rate. For assets with variable rate of interest on the balance sheet date, current interest rate is used.

#### **CASH AND CASH EQUIVALENTS**

Cash and cash equivalents include cash on hand and disposable balances at banks and other credit institutions and other short-term liquid investments which are easily converted into cash and are subject to an insignificant risk of changes in value. To be classified as cash and cash equivalents the duration may not exceed three months from the date of acquisition.

#### **CASH FLOW STATEMENT**

The cash flow statement shows the group's changes in cash and cash equivalents during the financial year. The cash flow statement has been prepared using the indirect method. The reported cash flow includes only transactions that involve deposits and payments.

#### **ACCOUNTING PRINCIPLES FOR THE PARENT COMPANY**

The parent company's accounting principles are consistent with the group's accounting principles.

### **NOTE 3 IMPORTANT ESTIMATIONS AND JUDGEMENTS**

To prepare the annual accounts and consolidated financial statements in accordance with K3, management needs to make estimates and judgments that affect the reported assets, liabilities, income and expenses. These estimates are based on historical experience as well as other factors deemed reasonable under the circumstances. Actual results may differ from these estimates if other estimates are made or other conditions exist. Estimates and judgements are reviewed on a regular basis. Changes in estimates are recognised in the period the change is made if the change affects only that period, or the period of the change and future periods if the change affects both current and future periods. The following accounting estimates and judgements have been applied, and can have a significant impact, in the preparation of these financial statements.

#### **Accrued costs for clinical trials**

At each balance sheet date management estimates the proportion of the coming milestone payments that have been accrued. The accrual for accrued costs is based on external parameters coupled with management's estimate of percentage of completion

#### **Impairment of participations in group companies**

Participations in subsidiaries are recognised at cost less any impairment losses. At each balance sheet date an assessment is made whether there are any indications that the value of shares in subsidiaries is lower than its carrying value. If there are indications, the asset's recoverable amount is calculated.



A write-down has been made during the year. No further indications of impairment losses have been identified by management.

#### Deferred tax assets

The group has determined that the future earnings and the timing thereof are not accurate enough to be able to evaluate and include deferred tax receivables attributable to loss reliefs. For further information please see note 9.

#### NOTE 4 INFORMATION ABOUT PROCUREMENT AND REVENUES WITHIN THE GROUP

	Group		Parent company	
	2018	2017	2018	2017
%				
Procurement	9.9	9.8	0.0	0.0
Revenues	98.6	98.6	100.0	100.0

All costs for group-wide functions such as the Board, management and premises are accounted for in the parent company, InDex Pharmaceuticals Holding AB.

Detailed analysis of the split of costs between the different companies within the group has been made and is regularly updated. This analysis supports the split of costs and the associated invoicing between the companies and are reported in the table above.

#### NOTE 5 LEASING

##### OPERATIONAL LEASING AGREEMENTS – LESSEE

The group is a lessee through operational leasing agreements for the premises rented. The total cost for the premises rented amounts to SEK 1,284 (1,303) thousand for the group and SEK 1,284 (1,303) thousand for the parent company. Minimum leasing fees for legally binding operational leasing agreements expire according to the following:

#### EXPIRATION DATE:

	Group		Parent company	
	2018	2017	2018	2017
Within a year	1,284	1,305	1,284	1,305
Later than one year but within five years	–	–	–	–
Later than five years	–	–	–	–
<b>Total</b>	<b>1,284</b>	<b>1,305</b>	<b>1,284</b>	<b>1,305</b>

#### NOTE 6 NUMBER OF EMPLOYEES AND EMPLOYEE REMUNERATION

##### AVERAGE NUMBER OF EMPLOYEES

	Group	
	2018	2017
<b>Parent company</b>		
Sweden	2	2
<b>Total parent company</b>	<b>2</b>	<b>2</b>
<b>Subsidiary</b>		
Sweden	5	5
<b>Total subsidiary</b>	<b>5</b>	<b>5</b>
<b>Total group</b>	<b>7</b>	<b>7</b>

##### COSTS FOR EMPLOYEES AND CONSULTANTS

2018	Salaries and other benefits	Social security cost	Pensions	Fees	Total
Parent company	3,142	1,143	945	3,219	<b>8,449</b>
Subsidiary	2,727	873	500	2,485	<b>6,585</b>
<b>Total group</b>	<b>5,869</b>	<b>2,016</b>	<b>1,445</b>	<b>5,704</b>	<b>15,034</b>

##### COSTS FOR EMPLOYEES AND CONSULTANTS

2017	Salaries and other benefits	Social security cost	Pensions	Fees	Total
Parent company	3,024	1,148	884	3,146	<b>8,202</b>
Subsidiary	2,777	894	529	3,030	<b>7,230</b>
<b>Total group</b>	<b>5,801</b>	<b>2,042</b>	<b>1,413</b>	<b>6,176</b>	<b>15,432</b>

#### BOARD AND MANAGEMENT

##### BOARD AND MANAGEMENT BY GENDER

	2018		2017	
	Board	Management	Board	Management
Male	4	3	4	3
Female	1	1	1	1
<b>Total</b>	<b>5</b>	<b>4</b>	<b>5</b>	<b>4</b>

##### SALARIES AND OTHER BENEFITS TO MANAGEMENT

2018	Salaries	Pensions	Fees	Total
CEO	2,008	575	–	<b>2,583</b>
Other members of management	1,167	493	2,144	<b>3,804</b>

**SALARIES AND OTHER BENEFITS TO MANAGEMENT**

2017	Salaries	Pensions	Fees	Total
CEO	1,868	553	–	<b>2,421</b>
Other members of management	1,153	331	2,460	<b>3,944</b>

Information above includes total remuneration from InDex. Other members of management include COO, CFO and CMO, whereof CFO and CMO are engaged through consultancy arrangements.

**SALARIES AND OTHER BENEFITS TO THE BOARD**

2018	Salaries	Pensions	Total
Wenche Rolfsen	400	–	<b>400</b>
Uli Hacksell	200	–	<b>200</b>
Lennart Hansson	200	–	<b>200</b>
Stig Lökke Pedersen	200	–	<b>200</b>
Andreas Pennervall	–	–	–

**SALARIES AND OTHER BENEFITS TO THE BOARD**

2017	Salaries/fees	Pensions	Total
Wenche Rolfsen	400	–	<b>400</b>
Uli Hacksell	200	–	<b>200</b>
Lennart Hansson	–	–	–
Stig Lökke Pedersen	200	–	<b>200</b>
Andreas Pennervall	–	–	–

Bonus to the CEO is included with SEK 302 (252) thousand in the amounts above.

**PENSIONS**

The group's cost for defined contribution plans, including wage tax, amounts to SEK 1 787 (1 745) thousand.

**NOTICE AND SEVERANCE PAY**

Between InDex and the CEO there is a mutual notice period of 6 months. No agreement including severance pay exists.

Between InDex and the other members of management there are mutual notice periods of 3 months. No agreement including severance pay exists.

**INCENTIVE PROGRAM**

At the Extraordinary General Meeting held on September 12, 2016 it was resolved to issue 3,250,000 warrants to be transferred to employees and other key persons within InDex. The warrants have an exercise price of SEK 19 per share and can be exercised in September 2019. Within this program, 3,237,500 warrants have been acquired at fair value by employees and other key persons in InDex.

The purpose of the incentive program is to be able to attract and retain key persons.

During 2017 the two former incentive programs have expired without any warrants being exercised.

**NUMBER OF WARRANTS**

	Group		Parent company	
	2018	2017	2018	2017
Opening balance	3,237,500	6,278,977	3,237,500	6,278,977
Granted during the year	–	175,000	–	175,000
Forfeited during the year	–	–	–	–
Redeemed during the year through divestment	–	–	–	–
Expired during the year	–	–3,216,477	–	–3,216,477
<b>Closing balance</b>	<b>3,237,500</b>	<b>3,237,500</b>	<b>3,237,500</b>	<b>3,237,500</b>
Average strike price per warrant	19.00	19.00	19.00	19.00

**NOTE 7 FINANCIAL INCOME**

	Group		Parent company	
	2018	2017	2018	2017
Interest income	0	0	0	0
Exchange differences	156	1,340	0	0
<b>Total</b>	<b>156</b>	<b>1,340</b>	<b>0</b>	<b>0</b>

**NOTE 8 FINANCIAL EXPENSES**

	Group		Parent company	
	2018	2017	2018	2017
Other	–63	–27	–	–
Interest expenses	–6	–40	0	0
Exchange differences	–37	–717	–36	–1
<b>Total</b>	<b>–106</b>	<b>–784</b>	<b>–36</b>	<b>–1</b>

**NOTE 9 TAXES**

	Group		Parent company	
	2018	2017	2018	2017
Other taxes	-	-	-	-
Deferred tax	-	-	-	-
<b>Total taxes</b>	-	-	-	-

**RECONCILIATION OF EFFECTIVE TAX RATE**

	Group		Parent company	
	2018	2017	2018	2017
Result before tax	-82,315	-72,759	-45,370	-124,663
Nominal tax rate (22%)	18,109	16,007	9,981	27,426
Tax effect non-deductible expenses	-30	-28	-8,802	-26,424
<i>Tax effect related to unrecognised deferred tax assets</i>				
Tax losses carried forward	-18,079	-15,979	-1,179	-1,002
<b>Tax cost for the year</b>	-	-	-	-

InDex is currently in a development phase whereby accounting as well as tax losses have been incurred. At the end of the fiscal year, due to the prudent principal and the existing uncertainties around future profits, no deferred tax receivables have been accounted for.

Tax losses carried forward amounts to SEK -5 180 thousand in InDex Pharmaceuticals Holding AB with no expiration date. Incurred loss for 2018 is estimated to provide an additional tax loss carried forward of SEK -5 359 (-4,554) thousand. If utilised against future revenues this would be valued at a total of SEK 2 319 (1 139) thousand.

Tax losses carried forward amounts to SEK -409 985 (-342 297) thousand in the subsidiary InDex Pharmaceuticals AB with no expiration date. Incurred loss for 2018 is estimated to provide an additional tax loss carried forward of SEK -76 562 (-67 721) thousand. If utilised against future revenues this would be valued to a total of SEK 107 040 (90 204) thousand.

**NOTE 10 EQUIPMENT, TOOLS AND INSTALLATIONS**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening acquisition value	1,129	1,129	-	-
Acquisitions	-	-	-	-
Divestments/scraping	-	-	-	-
<b>Closing acquisition value</b>	<b>1,129</b>	<b>1,129</b>	-	-
Opening depreciations according to plan	-1,098	-1,087	-	-
Divestments/scraping	-	-	-	-
Depreciations according to plan	-11	-11	-	-
<b>Closing accumulated depreciation according to plan</b>	<b>-1,109</b>	<b>-1,098</b>	-	-
<b>Carrying value according to plan</b>	<b>20</b>	<b>31</b>	-	-

**NOTE 11 SHARES IN SUBSIDIARIES**

	Parent company	
	Dec 31, 2018	Dec 31, 2017
Opening acquisition value	414,030	294,030
Shareholder contribution	40,000	120,000
<b>Closing accumulated acquisition value</b>	<b>454,030</b>	<b>414,030</b>
Opening accumulated write-downs	-167,000	-47,000
Write-down during the year	-40,000	-120,000
<b>Closing accumulated write-downs</b>	<b>-207,000</b>	<b>-167,000</b>
<b>Carrying value</b>	<b>247,030</b>	<b>247,030</b>

**DETAILS OF SHARES IN SUBSIDIARIES**

Company name	Dec 31, 2018			
	Capital	Votes	Number of shares	Carrying value
InDex Pharmaceuticals AB	100%	100%	60,281,586	247,030

Company name	Corp. Org. No.	Domicile	Equity
InDex Pharmaceuticals AB	556704-5140	Stockholm	21,921

**DETAILS OF SHARES IN SUBSIDIARIES**

Dec 31, 2017				
Company name	Capital	Votes	Number of shares	Carrying value
InDex Pharmaceuticals AB	100%	100%	60,281,586	247,030

Company name	Corp. Org. No.	Domicile	Equity
InDex Pharmaceuticals AB	556704-5140	Stockholm	59,052

**NOTE 12 OTHER LONG-TERM RECEIVABLES**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening acquisition value	1	1	–	–
<b>Closing accumulated acquisition value</b>	<b>1</b>	<b>1</b>	<b>–</b>	<b>–</b>
<b>Carrying value</b>	<b>1</b>	<b>1</b>	<b>–</b>	<b>–</b>

Note: Other long-term receivables refers to shares in Svenska Läkemedelsindustriföreningen.

**NOTE 13 PREPAID EXPENSES AND ACCRUED INCOME**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Prepaid rent	255	326	255	326
Prepaid insurance premium	145	367	33	28
Other items	82	228	65	100
<b>Total</b>	<b>482</b>	<b>921</b>	<b>353</b>	<b>454</b>

**NOTE 14 ACCRUED COSTS AND DEFERRED INCOME**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Accrued vacation salaries	1,258	1,440	773	995
Accrued social security charges	456	711	304	512
Accrued costs, clinical trials	12,628	6,764	–	–
Other items	1,295	892	542	693
<b>Total</b>	<b>15,637</b>	<b>9,807</b>	<b>1,619</b>	<b>2,200</b>

**NOTE 15 CASH AND CASH EQUIVALENTS**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Available funds at banks and credit institutions	83,034	125,055	82,388	111,682
<b>Total</b>	<b>83,034</b>	<b>125,055</b>	<b>82,388</b>	<b>111,682</b>

**NOTE 16 ACQUISITION OF SUBSIDIARIES**

InDex Pharmaceuticals Holding AB acquired on August 25, 2016 99.76% of the shares in InDex Pharmaceuticals AB through an issue in kind. The Board has concluded the restructuring described above has not in itself changed the business or the shareholder structure, why the consolidated financial statements have been prepared in accordance with the guidelines for acquisition under common control. As of December 31, 2018, 99.97 % of the shares have been transferred and the intention is that the remaining shares will be exchanged for shares in the parent company. A debt of SEK 64 thousand relating to the remaining shares has therefore been accounted for per December 31, 2018.

Elimination of shares in the subsidiary has been made against equity in the legal parent company InDex Pharmaceuticals Holding AB.

**NOTE 17 PLEDGED ASSETS**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Bank guarantee	50	50	50	50

**NOTE 18 CONTINGENT LIABILITIES**

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Contingent liabilities	None	None	None	None

**NOTE 19 PROPOSED DISTRIBUTION OF EARNINGS****THE FOLLOWING RETAINED EARNINGS ARE AT THE DISPOSAL OF THE ANNUAL GENERAL MEETING**

SEK	
Retained earnings	329,011,828
Net result	-45,369,754
	<b>283,642,074</b>
The Board's suggestion to be brought forward	283,642,074

**NOTE 20 RELATED PARTY TRANSACTIONS**

No related party transactions have occurred during 2017, aside from that a member of management has acquired warrants at fair value.

No related party transactions have occurred during 2018.

**NOTE 21 FINANCIAL RISK MANAGEMENT**

The business of the company can be affected by a number of risk factors. The ambition of the group is to establish a group wide risk management program that focuses on minimising potential negative effects on InDex's profit. The Board is ultimately responsible for identifying, managing and monitoring InDex's risks. The policy for identifying, management and monitoring of financial risks is decided by the Board and is subject to annual revisions. The Board has delegated the daily work regarding risk management to the CEO, who has delegated to the CFO. The Board may decide on temporary exceptions from the policy.

The following financial risks are InDex exposed to.

**LIQUIDITY AND FINANCING RISKS**

Liquidity and financing risks refer to the risk that InDex cannot finance its financial commitments as a result of insufficient capital resources or difficulties to raise additional capital or third party debt. InDex may also in the future need to raise additional capital. Both the size and timing of InDex's potential future capital requirements will depend on a number of factors, including opportunities to enter into collaboration or licensing agreements and the progress made in research and development projects. There is a risk that the required financing for the operations will not be available at the right time and at reasonable cost.

The company manages its liquidity and financing risks through cash flow forecasts together with a continuous evaluation of different financing options.

**CREDIT AND COUNTERPARTY RISKS**

Credit risks refer to the risk that a counterparty in a transaction causes InDex a loss by not fulfilling its contractual obligations. InDex is primarily exposed to a counterparty risk with one supplier due to the agreement entered into with PAREXEL in January 2017 covering the CONDUCT study with cobitolimod. In addition, InDex is exposed to the commercial bank where InDex liquidity is deposited. To mitigate the risk each key counterparty is analysed. The counterparty's financial position is assessed regularly to identify warning signals early on.

**RISK RELATED TO CAPITAL MANAGEMENT**

InDex's goal for managing its capital is to maintain InDex's ability to continue its operations to be able to generate reasonable returns to its shareholders and other stakeholders. The ability to forecast cash flows is of outmost importance for InDex coupled with the ability to secure additional external financing prior to that capital constraints emerge.

### CURRENCY RISKS

Currency risks refer to the risk that future cash outflows fluctuates due to movements in exchange rates. The exposure stems primarily from cash outflows in foreign currencies, so called transactional exposures. InDex's cash outflows are mainly in SEK and EUR and the bank deposits are primarily in SEK. InDex's finance policy allows InDex to use derivatives such as forward contracts, swaps and warrants. As of December 31, 2018 InDex has no derivatives.

### SENSITIVITY ANALYSIS

Based on this year's revenues and costs in different currencies, a movement of SEK against EUR with 1 percentage point would impact the groups operating result with approximately +/-SEK 0.6 million.

#### NOTE 22 RISK FACTORS

An investment in the shares of InDex is associated with risks. The business of the company can be affected by a number of factors which are not possible for InDex to control, either in part, or at all. These factors could have an adverse impact on the company's business, financial position and profits. Some of the risks are associated with the company, while other risks do not have any particular connection to the company. The risks are not described in any order of priority and this presentation is not intended to be exhaustive or complete. The company's future result may be significantly different from those anticipated in these forward-looking statements due to many different factors, including, but not limited to, the risks described below and elsewhere in this annual report.

### DRUG DEVELOPMENT

Generally, drug development is a complicated and capital intense process involving a substantial degree of risk. The research and development required for a drug is subject to risks such as delays in product development and/or costs becoming higher than expected or that the products do not have the anticipated effect or that they turn out to have unexpected and/or unwanted side effects.

There is a risk that the company will not be able to obtain necessary regulatory approvals and can delay or stop further product development and limit or prevent the commercial use of the products, which could have a material adverse effect on the company's business, financial position and profits in the future.

### PRECLINICAL AND CLINICAL STUDIES

Prior to launching a drug on the market, its safety and efficacy for treatment of patients with a certain disease must be ascertained by performing an extensive number of preclinical studies (evaluation of the drug candidate

in laboratory and animal studies) and clinical studies (patient studies).

The company currently has one drug development project in the clinical development phase, cobitolimod, and is performing a clinical phase IIb study (the so called CONDUCT study). The company's previous clinical studies of cobitolimod have not reached statistical significance in the primary endpoint of each study, but studies have indicated a clinical effect of the treatment which the company believes supports continued development. Results in previous clinical studies do not necessarily guarantee the corresponding results in future studies. Future studies of cobitolimod will entail changes, including changed doses and dose frequencies not previously studied.

The company cannot predict when planned clinical studies can start or be completed since the different factors that are crucial, such as approvals from authorities including ethics committees, the entering into agreements with e.g. clinics and access to patients are outside the company's control. Patient access refers to the participating clinics' ability to identify and include patients in the company's studies. Patient access is vital to how long a study will take. Accordingly, delays in completing the company's clinical studies could incur increased product development costs as well as delays in introducing the product on the market.

### PRODUCT LIABILITY AND INSURANCE

In the event the company's drugs or methods turn out (during current clinical studies or subsequent to obtaining approval and launching the product on the market) to cause illness, injury, disability or death, this could lead to compensation claims against the company from patients participating in clinical studies and patients using the products. If product liability claims are made against the company, the company may also be required to stop further sales of and prevent the use of its drugs and methods.

There is a risk that the applicable insurance policies will not provide sufficient coverage in the event of a product liability claim or any other claim against the company. There is also a risk that the company could fail to obtain or maintain adequate insurance coverage at acceptable terms in the future. Any and all uninsured losses could have a material adverse effect on the company's future business, financial position and profits.

### REGULATORY APPROVALS, LICENSES AND REGISTRATIONS WITH AUTHORITIES

In order to develop, manufacture, market and sell drugs, regulatory approvals or licenses must be obtained from, and registrations must be made with, relevant authorities in each geographic market where the company operates, which can be both time consuming and expensive. The authorities might make different assessments as regards e.g. the need for additional studies, interpretation of data from performed studies. The requirements for approvals may differ between authorities in different countries and the actual registration procedures may require extensive

work. Further, current rules and interpretations for drug approval may change in the future, which could adversely affect the company's ability to obtain the necessary regulatory approvals, which, in turn, could have a material adverse effect on the company's business, financial position and profits in the future.

Subsequent to the approval of a drug, the company will still be obliged to meet certain regulatory requirements, such as requirements for safety reporting and supervision of marketing of drugs. In the event the company fails to meet post-approval regulatory requirements, previously obtained regulatory approvals may be withdrawn. The company could also be subject to other sanctions, such as fines, operational restrictions or criminal sanctions.

#### **ENVIRONMENTAL SAFETY AND ETHICAL STANDARDS**

InDex's operations are subject to reporting requirements on safety, environmental regulations and will upon potential future market approval be subject to additional requirements. Should the company fail to comply with applicable laws and regulations in this regard, InDex could be subject to criminal sanctions and extensive damages or become obliged to cease or alter its activities. In addition, some of the company's employees could prove guilty of unethical or criminal conduct or conduct that would otherwise be in conflict with applicable laws and regulations, as well as internal guidelines. Such conduct would also damage the reputation of InDex. The corresponding conduct of partners could also have a material adverse effect.

#### **COMPETITION**

The pharmaceutical industry is a highly competitive industry characterised by global competition, rapid technological development and extensive investments. The company is facing competition from e.g. large pharmaceutical companies, including multinational companies, other companies active in the healthcare sector and universities. Some of the competitors have great financial resources and there is a risk that the company's competitors develop drugs similar to cobitolimod or alternative medicinal products which prove more successful than cobitolimod.

As of today, the company faces competition for cobitolimod from competing therapies approved for the treatment of ulcerative colitis, including generic products and biosimilars which are priced lower than the original medicinal products. Further, other companies are currently developing drugs that compete with or may compete with cobitolimod.

#### **LICENSE AND COLLABORATION AGREEMENTS**

InDex is dependent on license and collaboration agreements relating to the development and commercialisation of products on the markets covered by such agreements. Revenues from such license and collaboration agreements include, but are not limited to, upfront payments, licenses, royalties and milestone payments. Further, InDex may be entitled to compensation for its costs during different

stages of the collaboration. All revenues are dependent on that the product candidate in question is successfully developed and documented in order to reach the agreed milestones, as well as the product candidate is launched and sold on the market. The size of future revenues is uncertain and may vary significantly for a number of reasons, such as results from clinical studies, market approval, pricing of the product and marketing efforts. There is a risk that no collaboration agreements can be achieved or that collaboration partners fail to fulfil their undertakings. Failure of the establishment of license and collaboration agreements, or partners being unsuccessful in bringing a drug to market, may lead to reduced or absent revenue for InDex.

#### **COMMERCIALISATION, MARKET ACCEPTANCE AND DEPENDENCE ON REIMBURSEMENT SYSTEMS**

If a drug is approved, the risk that national or international sales do not meet expectations and that the product is not commercially successful remains. The level of market acceptance and sales of a drug depend on a number of factors, including product properties, clinical documentation and results, competing products, distribution channels, availability, price, subsidisation/reimbursement and sales and marketing efforts.

Cobitolimod is administered topically to the inflamed large intestine (colon) via the rectal route (rectum). There is a risk that the rectal route of administration may be perceived negatively in some markets, which could affect the commercialisation of the product and thereby have a material adverse effect.

Sales of prescription drugs is affected by the price set and obtained from the responsible authorities (such as the Dental and Pharmaceutical Benefits Agency in Sweden), from reimbursement payers and by healthcare payers, including insurance companies, hospitals and nationally responsible authorities. There is a risk that the price is lower than expected. The reimbursement rate that from time to time applies for a drug often depends on the value that the product is deemed to add for the patient and the healthcare system. There is a risk that the products do not qualify for subsidies from privately and publicly financed healthcare programs or that reimbursement is lower than expected, which e.g. may affect the market acceptance of the product or the operating margin. Reimbursement systems may also change from time to time, making it more difficult to predict the benefit and reimbursement that a prescription product may obtain. Various initiatives are in place in many countries to curb rising pharmaceutical costs, which could affect future sales margins and product sales for InDex and its potential partners. Such measures are expected to continue and could result in fewer reimbursement possibilities and lower reimbursement levels in some markets.

Several of the risks related to the commercialisation and sales of products as well as the reimbursement systems are outside the company's control.

**INTELLECTUAL PROPERTY RIGHTS, TRADE SECRETS AND KNOW-HOW**

The future success of the company is dependent on the company being able to protect its current and future intellectual property rights. The company's intellectual property rights are mainly protected through granted patents and patent applications. InDex only has method of use patents, but no composition of matter patent for cobitolimod. Generally, a method of use patent is deemed to give a more narrow protection compared to the protection given by a composition of matter patent. There is always a risk that the company's patents are challenged by third parties, which could result in the patents being declared null and void by a patent court, adversely affecting the company. Further, there is always a risk that the company's patents, trademarks and other intellectual property rights are intentionally or unintentionally infringed by third parties. In addition to being time consuming and thus disrupting the company's operations, patent infringements or challenges of intellectual property rights could entail considerable legal costs for defending the company's intellectual property rights. There is also a risk of the company unintentionally infringing intellectual property rights held by third parties, or wrongfully being alleged to do so, which also could entail considerable legal costs.

Patents are only granted for a limited period of time. After a patent has expired, there is a risk that the company's products are copied by third parties, adversely affecting the sale of the company's own products.

The company is also dependent on the protection of know-how and trade secrets, including information related to inventions for which patent applications have not yet been filed. Unlike patents and other intellectual property rights, know-how and trade secrets are not protected by exclusive rights by registration or similar. There is a risk that unauthorised disclosure or use of the company's know-how and trade secrets would render it impossible to obtain a patent or depriving the company of competitive advantages.

**DISPUTES AND LEGAL PROCEEDINGS**

Disputes, claims, investigations and legal proceedings might lead to InDex having to pay damages or cease certain operations. InDex may become involved in disputes as part of its normal business operations and risks being subject to legal claims concerning patents and licenses or other agreements. In addition, directors or employees may become subject to criminal investigations and criminal proceedings. Such disputes, claims, investigations and legal proceedings can be time consuming, disrupt normal operations, involve large claim amounts and result in considerable costs. Moreover, it can often be difficult to predict the outcome of complex disputes, claims, investigations and legal proceedings.

**DEPENDENCE ON KEY EMPLOYEES**

The company is dependent on its employees and consultants, especially on its senior management and other key individuals, and on its ability to recruit and retain highly qualified personnel. In the event a key employee would leave the company, this could have an adverse effect on the company's ongoing projects that leads to e.g. delays in product development. The company's ability to recruit and retain qualified personnel is crucial for its future success and growth.

**MANUFACTURERS AND SUPPLIERS**

The company engages external manufacturers (Contract Manufacturing Organisations, CMOs) and suppliers (e.g. Contract Research Organisations, CROs) for all of its required raw materials, active pharmaceutical ingredients and finished products for preclinical and clinical studies, the conducting of preclinical and clinical studies and other processes in development, but the company has no long-term agreements with any of these manufacturers and suppliers. There is a risk that current and future manufacturers or suppliers fail to deliver according to agreement, which could lead to delays and increased costs affecting the entire development project. None of the company's current manufacturers or suppliers are considered material in the sense that they cannot be replaced, but the company is dependent on such manufacturers and suppliers as changing manufacturers and suppliers might be both costly and time consuming. There is also no guarantee that the company will be able to find suitable manufacturers and suppliers offering the same quality and quantities on similar terms and conditions. Further, the company does not have any current contractual relationships for the manufacture of commercial supplies of any active pharmaceutical ingredients or product candidates if they are approved. There is a risk that the company will not find suitable manufacturers offering the required quality and quantities on terms and conditions satisfactory to the company.



# Signatures

The undersigned hereby assure that the consolidated financial statements and the annual report have been prepared in accordance with generally accepted accounting standards in Sweden, namely *Årsredovisningslagen* (Annual Accounts Act) (1995:1554) and *Bokföringsnämndens allmänna råd BFAR 2012:1 Årsredovisning och koncernredovisning ("K3")*, and they each provide a true and fair view of the group's and the parent company's financial position and earnings. The directors' report provides in addition a true and fair view of the group's and the parent company's operations, financial position and earnings and describe material risks and uncertainties faced by the parent company and the subsidiaries included in the group.

Stockholm April 1, 2019

Wenche Rolfsen  
*Chairman of the Board*

Uli Hacksell

Lennart Hansson

Stig Lökke Pedersen

Andreas Pennervall

Peter Zerhouni  
*CEO*

Our audit report was issued on April 1, 2019

PricewaterhouseCoopers AB

Magnus Lagerberg  
Authorised Public Accountant

This is an English translation of the Swedish annual report.  
In case of discrepancies between the English translation and the Swedish annual report,  
the Swedish annual report shall prevail.

# Auditor's report



To the general meeting of the shareholders of InDex Pharmaceuticals Holding AB, corporate identity number 559067-6820

## REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

### Opinions

We have audited the annual accounts and consolidated accounts of InDex Pharmaceuticals Holding AB for the year 2018. The annual accounts and consolidated accounts of the company are included on pages 26-51 in this document.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Other Information than the annual accounts and consolidated accounts

This document includes other information than the annual accounts and the consolidated accounts. The other information is included on pages 1-25 and 52-56. The Board of Directors and the Managing Director are responsible for the other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement

of this other information, we are required to report that fact. We have nothing to report in this regard.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website: [www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar). This description is part of the auditor's report.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of InDex Pharmaceuticals Holding AB for the year 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

**Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

**Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

**Auditor's responsibility**

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website [www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar). This description is part of the auditor's report.

Stockholm April 1, 2019  
PricewaterhouseCoopers AB

Magnus Lagerberg  
*Authorised Public Accountant*

# Corporate governance

## LEGISLATION AND ARTICLES OF ASSOCIATION

InDex is a Swedish public limited liability company and is governed by Swedish legislation, mainly the Swedish Companies Act (*Sw. Aktieföretagslagen (2005:551)*) and the Swedish Annual Accounts Act (*Sw. Årsredovisningslagen (1995:1554)*). The company is listed on Nasdaq First North Stockholm and apply the First North Rulebook. In addition to legislation and the First North Rulebook, the company's articles of association and its internal guidelines for corporate governance form the basis for the company's corporate governance. The articles of association, to be found on the company's website, contain e.g. the seat of the board of directors, the focus of the business activities, the limits for the share capital and number of shares and the conditions for participation at general meetings. The most recently adopted and registered articles of association were adopted at the extraordinary general meeting held on August 25, 2016.

## THE SWEDISH CODE OF CORPORATE GOVERNANCE

The Swedish Code of Corporate Governance (the "Code") defines a norm for good corporate governance at a higher level of ambition than the Swedish Companies Act's minimum requirements and applies to companies whose shares being traded on a regulated market in Sweden. Currently, the Code is not binding to companies whose shares are listed on First North; thus, the Code is not binding to the company. However, the Code is an important part of the company's internal guidelines for corporate governance.

## GENERAL MEETINGS

The shareholders' influence in the company is exercised at general meetings, which, in accordance with the Swedish Companies Act, is the company's highest decision-making body. As the company's highest decision-making body, the general meeting may resolve upon every issue for the company, not specifically reserved for another corporate body's exclusive competence. Thus, the general meeting has a sovereign role over the board of directors and the CEO. Notices, minutes and bulletines from general meetings are made available on the company's website.

At annual general meetings, which according to the Swedish Companies Act shall be held within six months from the end of each financial year, resolutions must be passed on adoption of the profit and loss account and balance sheet for the parent company and the group, allocation of the parent company's profit or loss, discharge from liability for the board of directors and the CEO, elections of members of the board of directors and auditor and on remuneration for the board of directors and the auditor. At general meetings, the shareholders also resolve on other key matters in the company, such as amending of the articles of association, any issue of new shares etc. If the board of directors considers there is reason to hold a general meeting before the next annual general meeting, or if an auditor of the company or owners of at least one-tenth of all shares in the company so demand in writing, the board must issue a notice to convene an extraordinary general meeting.

Notice to attend a general meeting shall, in accordance

with the company's articles of association, be made by announcement in the Swedish Official Gazette (*Sw. Post- och Inrikes Tidningar*) and by making the notice available on the company's website ([www.indexpharma.com](http://www.indexpharma.com)). At the same time as notice is made, it shall be announced in Dagens Industri that a notice has been made. Notice of a general meeting must be issued no earlier than six weeks and no later than two weeks before the meeting.

All shareholders who are registered directly in the company's share register, kept by Euroclear, five (5) weekdays prior to the general meeting (i.e. on the record date) and who notify the company of their intention to attend the general meeting no later than the date specified in the notice of the meeting shall be entitled to attend and vote at the general meeting, either in person or through a proxy. A shareholder may be accompanied by assistants at general meetings upon notification. Each shareholder of the company submitting a matter with sufficient foresight has the right to have the matter addressed at the general meeting.

To be able to determine who is entitled to participate and vote at general meetings, Euroclear shall, upon the request of the company, supply the company with a list of all holders of shares on the record date in connection with each general meeting. Shareholders who have their shares nominee-registered need to instruct the nominee to register the shares temporarily in the name of the shareholder in order to be entitled to attend and vote for their shares at general meetings (voting rights registration). Such registration must be completed no later than on the applicable record date and ceases to be in force once the record date has passed. Shareholders who have their shares directly registered on an account in the Euroclear system will automatically be included in the list of shareholders.

At the extraordinary general meeting held on September 12, 2016, it was resolved to establish a nomination committee and to adopt rules of procedure for the nomination committee. The main duties and responsibilities of the nomination committee are to propose candidates for the post of chairman and other members of the board of directors. The nomination committee also proposes fees and other remuneration to the members of the board of directors as well as makes proposals on the election and remuneration of the auditor.

According to the rules of procedure for the nomination committee, the nomination committee shall, as a main rule, consist of the chairman of the board of directors and four members appointed by each of the four, in terms of voting rights, largest shareholders. Should any of these shareholders waive their right to appoint a member, the right to appoint a member goes to the, in terms of voting rights, fifth largest shareholder etc. The nomination committee appoints a chairman. The chairman of the board of directors shall not be the chairman of the nomination committee. The members of the nomination committee and the shareholders who have appointed the members shall be announced no later than six months before the next annual general meeting. Should a member resign from the nomination committee before its work is completed, and the nomination committee considers it necessary to replace

him or her, a substitute shall be appointed by the same shareholder who appointed the member who resigned or, if this shareholder is no longer one of the four largest shareholders in terms of voting rights, by the largest shareholder in turn. If a shareholder that has appointed a member has substantially reduced its shareholding in the company, and the nomination committee does not consider it inappropriate taking into account any need for continuity for an upcoming general meeting, the member shall resign from the nomination committee and the nomination committee shall offer the largest shareholder not having appointed a member of the nomination committee to appoint a new member. The nomination committee's mandate period extends until the next annual general meeting or if necessary until a new nomination committee is appointed. The members of the nomination committee shall perform their duties and responsibilities in accordance with the Code.

The nomination committee before the annual general meeting 2019 has consisted of Jonas Jendi, chairman and appointed by Industrifonden, Filip Petersson appointed by SEB Venture Capital/SEB Stiftelsen, Pål Jensen appointed by NeoMed/N5, Bengt Julander appointed by Linc and Wenche Rolfsen, chairman of the Board.

#### BOARD OF DIRECTORS

Subsequent to the general meeting, the board of directors is the company's highest decision-making body. The board of directors is also the company's highest executive body and the company's representative. Further, the board of directors is, according to the Swedish Companies Act, responsible for the organisation of the company and management of the company's affairs and must regularly assess the company's and the group's financial position and ensure that the company's organisation is arranged so that the company's accounts, asset management, and finances in general are satisfactorily monitored. The chairman of the board of directors has a particular responsibility to preside over the work of the board of directors and to ensure that the board fulfils its statutory duties.

According to the company's articles of association, the board of directors shall consist of a minimum of three (3) and a maximum of ten (10) ordinary members, without deputy members. Members of the board are elected annually at an annual general meeting for the period until the next annual general meeting. There is no limit in time for how long a member may be on the board.

The company's board of directors is currently composed of Wenche Rolfsen (chairman), Lennart Hansson, Uli Hackzell, Stig Lökke Pedersen and Andreas Pennervall. Further information about the members of the board, can be found under the "Board of directors, senior management and auditors" section above.

The responsibilities of the board of directors include e.g. to set the company's overall goals and strategies, oversee major investments, ensure that there is a satisfactory process for monitoring the company's compliance with laws and other regulations relevant to the company's operations, as well as the compliance with internal guidelines. The responsibilities of the board of directors also include ensuring that the company's disclosure to the market and investors is transparent, correct, relevant and reliable and to appoint, evaluate and, if necessary, dismiss the company's CEO.

The board of directors has, in accordance with the Swedish Companies Act, adopted written rules of procedure for its work, which will be evaluated, updated and re-adopted annually. The board of directors meets

regularly in accordance with a program set out in the rules of procedure containing certain permanent items and certain items when necessary.

Provisions on the establishment of audit committees are found in the Swedish Companies Act. Provisions on the establishment of remuneration committees are found in the Code. In this respect, the provisions of the Swedish Companies Act only apply to companies whose shares are being traded on a regulated market, which does not include First North, and, as noted above in this section, the Code is not binding to the company. In light of the scope of the operations and the group's current size, it is the opinion of the company's board of directors that it is presently not justified to establish specific audit or remuneration committees. Instead, the board of directors believes that the responsibilities of the committees are best addressed within the board. It is the company's board of directors' responsibility to ensure transparency and control of the company's operations through reports and contacts with the company's auditor.

#### CEO AND OTHER MEMBERS OF MANAGEMENT

The company's CEO is, in accordance with the provisions of the Swedish Companies Act, responsible for the day-to-day management of the company in line with guidelines and instructions from the board of directors. Measures of an unusual nature or of great significance in view of the scope and nature of the company's operations are not considered as "day-to-day management" and should therefore, as a main rule, be prepared and presented to the board of directors for its decision. The CEO must also take any measures necessary to ensure that the company's accounts are maintained in accordance with applicable law and that its asset management is conducted satisfactorily. The CEO is subordinated to the board of directors, and the board of directors itself may also decide on matters that are a part of the day-to-day management. The work and role of the CEO as well as the allocation of duties between, on the one hand, the board of directors and, on the other, the CEO is established by written instructions (a so called "instruction for the CEO") by the board of directors and the board of directors continuously evaluates the work of the CEO.

#### INTERNAL CONTROL AND AUDIT

The company's board of directors is, according to the Swedish Companies Act, responsible for the organisation of the company and management of the company's affairs, must regularly assess the company's and the group's financial position and ensure that the company's organisation is arranged so that the company's accounts, asset management, and finances in general are satisfactorily monitored. The rules of procedure adopted by the board of directors for its work contains instructions for internal financial reporting, and all interim reports and press releases are published on the company's website upon publication.

Being a public company, the company must have at least one auditor for the review of the company's and the group's annual report and accounts as well as the management by its board of directors and CEO. The review must be as detailed and extensive as required by generally accepted auditing standards. The company's auditor is, according to the Swedish Companies Act, appointed by the general meeting. Thus, auditors of Swedish limited liability companies are given their assignment by, and are obliged to report to, the general meeting, and must not allow their work to be governed or influenced by the board of directors or the senior management.

# Glossary

**BIOLOGICAL DRUG**

A biological drug is a drug whose active substance has been produced in or purified from materials of biological origin.

**CLINICAL STUDY/TRIAL**

Is a study on healthy or ill people to investigate the effect and safety of a drug or treatment method.

**COLECTOMY**

A surgical procedure performed to remove the large intestine.

**COLONOSCOPY**

Examination of the large intestine using an endoscope.

**COMPASSIONATE USE**

A program under which an unapproved drug may be made available for humanitarian reasons.

**CRO (CONTRACT RESEARCH ORGANISATION)**

Contract research organisation.

**CROHN'S DISEASE**

Inflammatory disease that may occur throughout the whole gastrointestinal tract.

**CYTOKINES**

Cytokines are a group of proteins and peptides whose function is to carry chemical signals. They attach to specific receptors on the target cells and are produced only when needed. They have many different kinds of target cells. Some cytokines contribute to the immune system.

**DiBiCol**

Diagnostic test that can differentiate between ulcerative colitis, Crohn's disease and non-IBD.

**DIMS**

DNA-based ImmunoModulatory Sequence. Synthetically manufactured oligonucleotide that is immunomodulatory through binding to Toll-like receptor 9.

**ENDOSCOPY**

Endoscopy is a term for examinations in which a so-called endoscope is used. The doctor can see the inside of the body using the instrument.

**ENDPOINT**

How to measure the effect of a particular treatment.

**ENEMA**

Enema is a medical device with which a fluid is inserted into the large intestine through a tip by way of the rectum.

**FLARE**

A significant deterioration of a chronic but cyclical disease condition.

**GASTROENTEROLOGY**

Gastroenterology is the study of the digestive system and its disorders.

**INFLAMMATORY BOWEL DISEASE (IBD)**

Inflammatory bowel disease includes a number of conditions with inflammation of the digestive system, especially the intestine.

**INVESTIGATOR**

Physician participating in a clinical study.

**MECHANISM OF ACTION**

The way in which a treatment achieves the desired effect.

**ORAL FORMULATION**

A formulation of a drug taken by mouth.

**PLACEBO**

Inactive substance.

**PRECLINICAL DEVELOPMENT**

Laboratory tests and documentation of a drug candidate's characteristics in model systems.

**PROOF-OF-CONCEPT**

Concept validation in order to verify whether a particular method or idea works in practice.

**RECTAL ADMINISTRATION**

Administration through rectum.

**REMISSION**

Remission is a medical diagnostic term for when the symptoms have partially subsided or temporarily disappeared completely in chronic diseases.

**SAFETY PROFILE**

The side effects that a drug may cause.

**STOMA**

Stoma is a medical term for a surgical procedure in which an opening is placed on the front of the abdomen for the purpose of emptying the body's waste, such as stools.

**SUBCUTANEOUS INJECTION**

Injection under the skin.

**TOLL-LIKE RECEPTOR (TLR9)**

TLR9 is a member of the Toll-like receptor family and recognises DNA from bacteria and viruses.

**ULCERATIVE COLITIS (UC)**

Ulcerative colitis is an inflammation of the mucosa in the colon or rectum, which causes the bowel function to deteriorate.

# Pharmaceutical development in brief

## PRECLINICAL DEVELOPMENT

The preclinical studies evaluate the chemistry, toxicity and effects through appropriate laboratory trials and animal models. Once the preclinical requirements of the substance are fulfilled the substance may proceed to clinical development.

## CLINICAL DEVELOPMENT

The clinical development is typically conducted in four sequential phases where the prior phase needs to show promising results including safety in order to move into the next phase:

**Phase I:** Phase I trials are most often conducted in healthy volunteers, but may also be performed in patients with the targeted disease. The goal is to determine the safety of the medicinal product and how it is absorbed, distributed, metabolised in and excreted from the body.

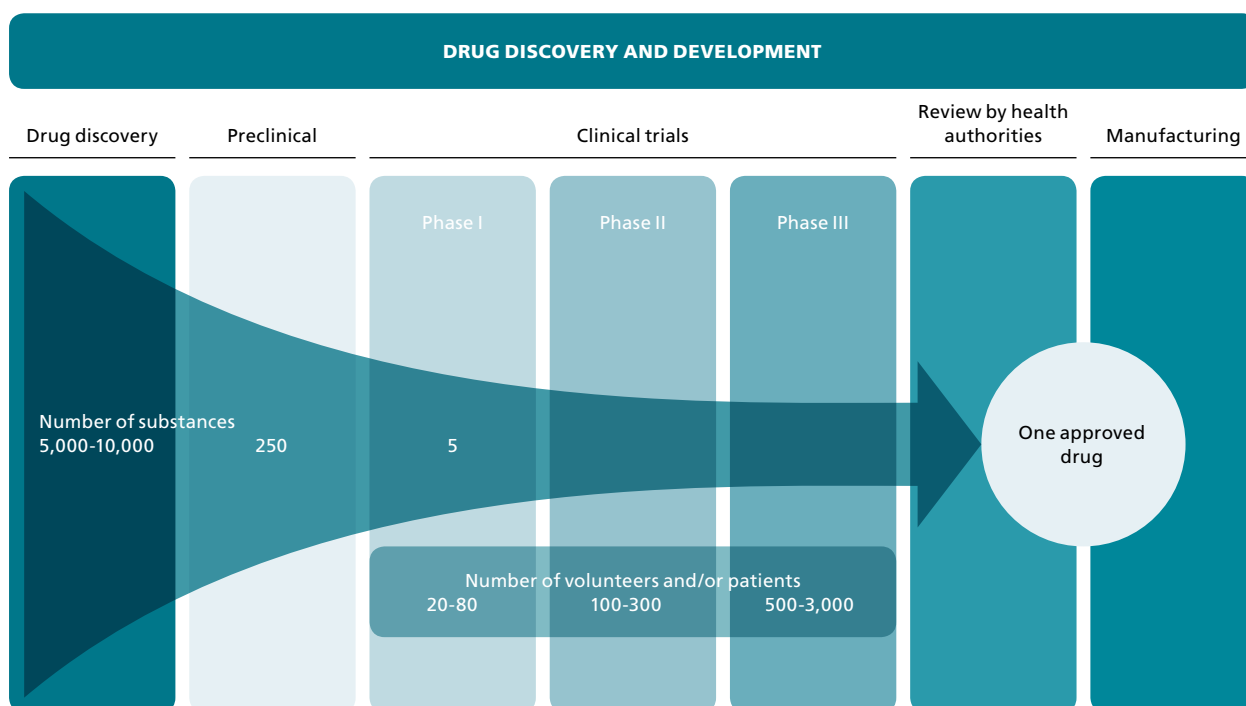
**Phase II:** Phase II trials are conducted in patients with the disease concerned, with the aim to establish an appropriate dosage for the phase III programme. The phase II studies also aim to obtain preliminary data on the efficacy of the substance. Safety is also carefully monitored. Phase II is usually divided into early phase (phase IIa) and late phase (phase IIb).

**Phase III:** Phase III trials, the basis for the marketing approval application, are conducted in patients to document statistically significant treatment efficacy, safety and tolerance. Sometimes different populations and different dosages are studied.

**Phase IV:** After the approval of a new medicinal product the development usually continues through so-called phase IV studies. More information from large groups of patients being treated for a long time is collected, whereby rare side effects may be discovered and further treatment effects can be evaluated. Sometimes efficacy and tolerance are compared between different medicinal products for a particular disease.

Development of medicinal products is thus a strictly regulated process, with many control steps along the way. During and after each phase the results are evaluated to decide if the development project will continue into the next stage. Approximately 10-20 percent of the substances that reach clinical development and begin a phase I study become an approved medicinal product<sup>1</sup>. The likelihood that the substance reaches the market generally increases the further into the development process the substance has come.

<sup>1</sup> Hay M, et al. vol 32,Nr 1, 2014, *Nature biotechnology*. Clinical development success rates for investigational drugs and David Taylor, *The Pharmaceutical Industry and the Future of Drug Development, in Pharmaceuticals in the Environment*, 2015, pp. 1-33.



The figure shows the drug development from the early substance to a final medicinal product.

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