

# InDex Pharmaceuticals Holding AB (publ)

**InDex**  
Pharmaceuticals

Interim report January-September 2021



## Ready to initiate patient recruitment in phase III study CONCLUDE

### PERIOD JULY-SEPTEMBER 2021

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –28.2 (–7.7) million
- Result after tax amounted to SEK –28.2 (–7.7) million, corresponding to SEK –0.05 per share (–0.03) before and after dilution
- Cash flow from operating activities amounted to SEK –26.5 (–8.3) million

### SIGNIFICANT EVENTS DURING THE QUARTER

- InDex received first regulatory approval from the Swedish MPA to start the phase III study CONCLUDE with cobitolimod
- InDex received FDA clearance to start the phase III study CONCLUDE

### SIGNIFICANT EVENTS AFTER THE QUARTER

- InDex got new patent for cobitolimod granted in the US
- InDex got new patent for cobitolimod granted in Canada

All comparative amounts in brackets refer to the outcome during the corresponding period 2020.

### PERIOD JANUARY-SEPTEMBER 2021

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –80.2 (–47.3) million
- Result after tax amounted to SEK –80.2 (–47.3) million, corresponding to SEK –0.16 per share (–0.20) before and after dilution
- Cash flow from operating activities amounted to SEK –80.1 (–63.1) million
- Cash and cash equivalents at the end of the period amounted to SEK 463.1 (62.3) million
- Number of employees at the end of the period was 8 (7)
- Number of shares at the end of the period was 532,687,650

### OTHER EVENTS

- InDex announced that the company will conduct a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden
- InDex announced that two new employees have been appointed in the clinical development organisation in preparation of the start of the phase III study CONCLUDE with cobitolimod

*“We have now several clinics activated in the phase III study CONCLUDE and look forward to enrol the first patient in the near term”, says Peter Zerhouni, CEO of InDex Pharmaceuticals. “It was quite dramatic in September when the FDA updated their safety warnings for JAK inhibitors as a class. It is a reminder that a product’s safety profile is very important.”*

InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company’s lead asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company’s shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm. Redeye AB is the company’s Certified Adviser (+46 8 121 576 90 or certifiedadviser@redeye.se).

# CEO statement



We have now several clinics activated in the phase III study CONCLUDE and look forward to enrol the first patient in the near term. We are pushing hard to get more and more clinics ready to enrol patients as we receive regulatory approval to start the study in the respective countries. We have already approval in the US, Sweden, Hungary, and France, and expect approval in several more countries in the coming weeks.

CONCLUDE is a global clinical study, which will include 440 participants to evaluate cobitolimod as a new treatment for patients with moderate to severe left-sided ulcerative colitis. The study will be conducted at several hundred clinics in over 30 countries.

The pandemic continues to affect the start-up of new clinical studies in that the clinics report resource constraints and a need to prioritize their regular care and to manage the backlog. Once our study is up and running, we expect to reach the planned patient recruitment rate.

There continues to be a lot of news coming out of the field of ulcerative colitis. It was quite dramatic in September when the FDA updated their safety warnings for JAK inhibitors as a class. The FDA added serious heart-related events, cancer, blood clots, and death to the already boxed warnings of JAK inhibitors. They also limited all approved uses to patients who have failed TNF blockers. FDA's decision firmly

positions the JAK inhibitors as a last line treatment in ulcerative colitis. It is a reminder that a product's safety profile is very important, and good news for cobitolimod that has demonstrated an excellent safety profile to date. Overall, the competitive landscape has clearly evolved in cobitolimod's favour over the last 18 months.

We recently got a new patent for cobitolimod granted in the US, which is the most important pharmaceutical market in the world. This new patent provides protection for the 250 mg dose, which was successful in the phase IIb study CONDUCT and is now included in phase III. The patent will provide an exclusivity period until May 2038, with the possibility of up to 5 years term extension after market approval. It is a good example of our IP strategy to build a thicket of patents around cobitolimod. We continue to file new patent applications 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.

I am excited that we are close to enrol the first patient in the phase III study and I hope you will tune in to our upcoming investor presentations at HC Andersen Capital today and Erik Penser Bank tomorrow.

Peter Zerhouni, CEO

# Business overview

## INTRODUCTION

InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's lead asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based Immuno-Modulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company's shares are traded on Nasdaq First North Growth Market Stockholm.

## COBITOLIMOD

Cobitolimod is a potential new medication for patients with moderate to severe ulcerative colitis. Ulcerative colitis is a chronic disease caused by inflammation of the colon. Today, about two million people in Europe and the United States suffer from ulcerative colitis, a disease that has a major impact on the patient's quality of life. Ulcerative colitis is characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss, and anemia. Patients also have a significant elevated risk of developing colon cancer. Most commonly, ulcerative colitis debuts between 15 and 30 years of age and most patients require lifelong medication. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms, and current therapies can cause serious side effects. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon.

Cobitolimod is a local treatment with a novel 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 is administered via the rectum using an enema allowing a rapid onset of action without systemic exposure and off-target effects.

Cobitolimod met the primary endpoint in the phase IIb study CONDUCT and demonstrated an outstanding combination of efficacy and safety. Data from four previous completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study. Given the outstanding combination of efficacy and safety, InDex is now advancing cobitolimod into phase III, which is the final stage of development before application for market approval.

Based on the sales of recently launched products, as well as the company's proprietary market research and analyses, including the addressable market described above, the annual global peak sales at a successful commercialisation of cobitolimod are estimated by the company to have the potential to reach more than USD 1 billion.

## THE MOST IMPORTANT ADVANTAGES WITH COBITOLIMOD



Illustrations: Freepik

**Phase III study – CONCLUDE**

Based on regulatory guidance InDex is planning a sequential phase III program with two induction studies and a one-year maintenance study with patients that have responded to cobitolimod as induction therapy.

The important initial induction study CONCLUDE will include 440 patients and the company estimates that it will take 18 to 24 months to complete from initiation. CONCLUDE is a randomised, double-blind, placebo-controlled, global phase III study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. The primary endpoint will be clinical remission at week 6. Apart from the dosing 250 mg x 2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, the phase III study will also evaluate a higher dose, 500 mg x 2, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than what was observed in the phase IIb study.

When a sufficient number of the participants in the study have been randomised and have eligible data for the primary endpoint, an interim analysis will be performed in a blinded fashion to select the best dose of cobitolimod and the other dose will be dropped. Following the blinded interim analysis, the additional patients to be randomised into the study will receive only the best dose of cobitolimod or placebo. Patients responding to cobitolimod in the induction study will be eligible to continue in a one-year maintenance study, where they will be treated with either cobitolimod or placebo.

InDex has entered into an agreement for services with the leading global clinical research organization (CRO) Parexel Biotech for the phase III study CONCLUDE. Parexel Biotech has considerable experience managing phase III studies in inflammatory bowel disease. Parexel Biotech was the CRO that InDex successfully collaborated with in the phase IIb study CONDUCT.

**Oral formulation of cobitolimod**

InDex has developed a prototype of a novel formulation of its lead drug candidate cobitolimod for oral administration, with targeted drug substance release or delivery to the lower part of the gastrointestinal tract and thus again avoiding systemic exposure. The capsule is a potential follow-on product to the current topical formulation. An oral therapy makes it possible to deliver cobitolimod to parts of the gastrointestinal tract which are inaccessible to an enema and could be more convenient for patients.

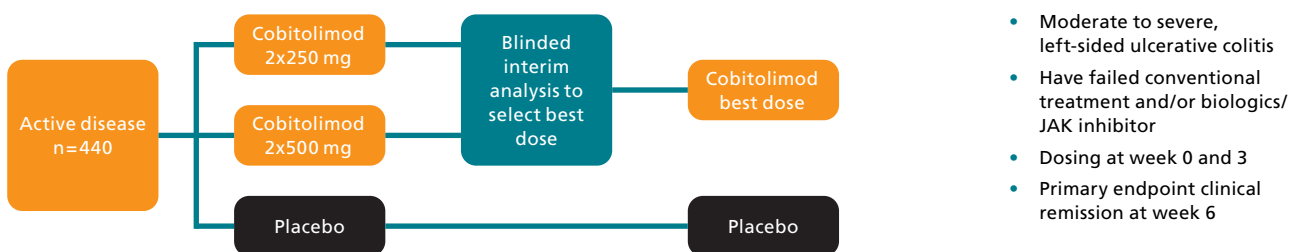
This opens the possibility to broaden the therapeutic use of cobitolimod to also include pancolitis and Crohn’s disease, where the inflammation can be located higher up in the gastrointestinal tract. The oral formulation development also provides the opportunity to secure additional patent protection for cobitolimod.

**OTHER DIMS**

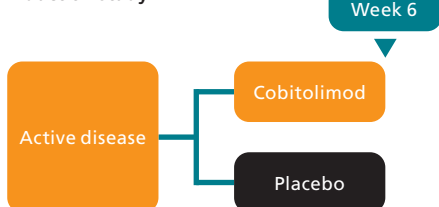
InDex has, besides cobitolimod, a preclinical portfolio of more than 150 DNA-based ImmunoModulatory Sequences (DIMS). The DIMS candidates are oligonucleotides that differ in sequence and length but are all TLR9 agonists. DIMS mimic bacterial DNA, without being harmful, and stimulate immune cells to produce beneficial anti-inflammatory cytokines that will help to dampen inflammation. This opens 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 in models of other inflammatory diseases. Positive signals have been observed, and InDex is now confirming these early results with alternative and complementary methods in order to be able to select a DIMS substance for further development.

**PHASE III DESIGN**

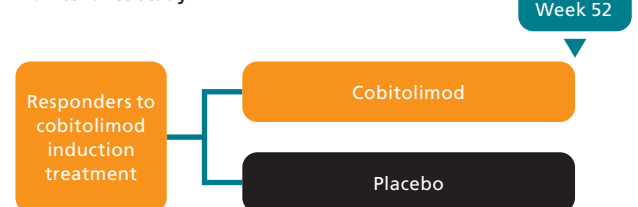
**Induction study 1 – adaptive design**



**Induction study 2**



**Maintenance study**





**SIGNIFICANT EVENTS DURING THE QUARTER**

- InDex announced on July 21, 2021 that the Swedish Medical Products Agency (MPA) has given approval to start the phase III clinical study CONCLUDE with cobitolimod in Sweden.
- InDex announced on August 24, 2021 that the U.S. Food and Drug Administration (FDA) has given clearance to start the phase III clinical study CONCLUDE with cobitolimod in the United States.

**SIGNIFICANT EVENTS AFTER THE QUARTER**

- InDex announced on November 9, 2021 that a new method of use patent for the drug candidate cobitolimod has been granted by the United States Patent and Trademark Office (USPTO). The patent provides protection for the use of certain dosage regimens of cobitolimod for treating inflammatory bowel disease, including the 250 mg dose which was successful in the phase IIb study CONDUCT.
- InDex announced on November 16, 2021 that a new method of use patent for the drug candidate cobitolimod has been granted by the Canadian Intellectual Property Office (CIPO). The patent provides additional protection for the use of certain dosage regimens of cobitolimod for treating chronic active ulcerative colitis in patients that are not responding or are intolerant to anti-inflammatory therapy.

**OTHER EVENTS**

- InDex announced on August 19, 2021 that the company will conduct a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden. The Swedish Medical Products Agency has given approval to start the study. The purpose of the study is to evaluate the systemic uptake of cobitolimod in local treatment of colonic inflammation. The study will include at least 6 patients with moderate to severe ulcerative colitis treated with doses of 500 mg of cobitolimod administered rectally.
- InDex announced on August 23, 2021 that two new employees have been appointed in the clinical development organisation in preparation of the start of the phase III study CONCLUDE with cobitolimod. Anders Bröijersén has joined InDex as Senior Medical Director Clinical Operations and Johan Levin as Project Manager Clinical Operations.



# Financial overview

## FINANCIAL SUMMARY FOR THE GROUP

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

### FINANCIAL DEVELOPMENT DURING JULY-SEPTEMBER 2021

Net sales for the period July to September 2021 amounted to SEK 0.0 (0.0) million. The net sales previous year were related to the sale of DiBiCol test kits up to September 30, 2020. Sale of DiBiCol test kits was then terminated.

Other operating income SEK 11.3 (0.3) million refers to grant received from Vinnova and foreign exchange gains of SEK 11.1 (0) million related to cash and cash equivalents in foreign currency. InDex purchased during the second quarter 2021 USD to be used for future payments related to signed contracts denominated in USD.

Operating expenses for the period amounted to SEK 39.5 (8.0) million. The increase is attributable to higher costs for phase III preparations.

The operating expenses during the period refer primarily to costs for phase III preparations and general operating expenses.

Costs for the personnel during the reporting period amounted to SEK 2.6 (2.4) million. The increase is partly related to general salary increases and an increase in number of employees.

### FINANCIAL DEVELOPMENT DURING JANUARY-SEPTEMBER 2021

Net sales for the period January to September 2021 amounted to SEK 0.0 (0.0) million. The net sales previous year were related to the sale of DiBiCol test kits up to September 30, 2020. Sale of DiBiCol test kits was then terminated.

Other operating income SEK 3.1 (0.3) million refers to grant received from Vinnova and foreign exchange gains (net) of SEK 2.7 (0) million related to cash and cash equivalents in foreign currency. InDex purchased during the second quarter 2021 USD to be used for future payments related to signed contracts denominated in USD.

Operating expenses for the period amounted to SEK 83.3 (47.6) million. The increase is attributable to higher costs for phase III preparations.

The operating expenses during the period refer primarily to costs for phase III preparations and general operating expenses.

Costs for the personnel during the reporting period amounted to SEK 8.0 (6.9) million. The increase is partly related to general salary increases and costs for recruitment of personnel.

Cash and cash equivalents as of September 30, 2021 amounted to SEK 463.1 million, which is SEK 409.3 million higher than as of December 31, 2020. The Swedish Companies Registration Office recorded the completed rights issue of 443,906,375 new shares on February 11, 2021. The subscription price was set to SEK 1.20. InDex received approximately SEK 488 million after deduction of the transaction related costs for financial and legal services and for costs for registration and practical management.

## FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

The covid-19 pandemic affects the healthcare systems and the investor sentiment globally and must be taken into account in the company's strategic planning. The Board, however, assess that there is no impact on the company's financial position as of September 30, 2021 due to events after the reporting period.

## EXPECTED FUTURE DEVELOPMENT

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 all financial commitments InDex has for the coming 12-month period.

InDex provides no financial forecast or similar forward-looking statement.

## PARENT COMPANY

The net sales amounted to SEK 7.1 (8.6) million during the period January to September 2021 and consisted of invoicing of group wide expenses to InDex Pharmaceuticals AB.

The operating expenses amounted to SEK 12.8 (12.9) million and consisted of personnel expenses and other operating expenses relating to the administration of InDex.

FINANCIAL SUMMARY						
SEK million	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Full year 2020	
Revenues	0.0	0.0	0.0	0.0	0.0	
Operating result	-28.2	-7.7	-80.2	-47.3	-57.3	
Result after tax	-28.2	-7.7	-80.2	-47.3	-57.4	
Earnings per share before and after dilution, SEK	-0.05	-0.03	-0.16	-0.20	-0.24	
Cash flow from operating activities	-26.5	-8.3	-80.1	-63.1	-70.7	
Cash and cash equivalents at the end of the period	463.1	62.3	463.1	62.3	53.8	

Note: Earnings per share – Net result divided by weighted number of shares (adjusted for the completed rights issue in February 2021).

# Other information

## EMPLOYEES

The number of employees at the end of the period was 8 (7).

## THE SHARE

The share is listed on Nasdaq First North Growth Market Stockholm since October 11, 2016.

### LARGEST SHAREHOLDERS PER SEPTEMBER 30, 2021

	Number of shares	Percentage of capital and votes, %
Linc AB	69,920,567	13.1
HBM Healthcare Investments	52,916,667	9.9
Fjärde AP-fonden	52,314,074	9.8
Handelsbanken Funds	25,000,000	4.7
Avanza Pension	22,432,876	4.2
SEB-Stiftelsen	19,047,617	3.6
SEB Life International	13,927,350	2.6
Bengt Thornberg, dödsbo	13,417,394	2.5
SEB Venture Capital	12,994,367	2.4
Stiftelsen Industrifonden	12,865,296	2.4
Nordnet Pensionsförsäkring	11,786,053	2.2
Staffan Rasjö	10,318,953	1.9
S-E-Bankens Utvecklingsstiftelse	10,000,000	1.9
Originat AB	7,000,000	1.3
Swedbank försäkring AB	6,286,367	1.2
Other	192,460,069	36.3
<b>Total</b>	<b>532,687,650</b>	<b>100.0</b>

## INCENTIVE PROGRAMMES

### LTIP 2020

At the annual general meeting held on April 20, 2020 it was resolved to issue 3,965,000 warrants to transfer to employees and other key persons within InDex. The warrants had an exercise price of SEK 20 per share and can be exercised during May-October 2023. The Board allocated in July 2020 958,388 warrants to employees and other key persons that were purchased for SEK 0.2522 per warrant. A total of 13 employees and other key persons were offered to subscribe for warrants and 12 of these individuals subscribed for their full allotment.

After the completed rights issue in February 2021 the exercise price and the number of shares that each warrant represents have been recalculated in accordance with the applicable terms. The new exercise price amounts to SEK 7.804 and each warrant entitles the holder to subscribe for 2.5627 shares. The remaining warrants have been terminated.

### LTIP 2021

At the annual general meeting held on June 3, 2021 it was resolved to issue 7,200,000 employee stock options to transfer to employees and other key persons within InDex. In addition, 2,262,240 warrants were issued to cover potential cash flow effects from social security costs arising from allotted employee stock options. The options have a strike price of SEK 4 per share and can be exercised during July-December 2024. In July 2021 the Board allocated 5,731,800 options to employees and other key persons free of charge. A total of 13 employees

and other key persons were offered and subsequently subscribed for their allotted employee stock options.

LTIP 2021 will be accounted for in accordance with IFRS 2 – *Share-based payments*. IFRS 2 stipulates that the employee stock options should be expensed as personnel costs over the vesting period. Personnel costs in accordance with IFRS 2 do not affect the company's cash flow. Social security costs will in accordance with UFR 7 be expensed in the income statement during the vesting period.

## REVIEW BY THE AUDITOR

This interim report has not been limited reviewed by the company's auditor.

## FINANCIAL CALENDER

Year-end report February 23, 2022

Stockholm, November 24, 2021

Peter Zerhouni, CEO

## FOR MORE INFORMATION, PLEASE CONTACT:

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The information in this interim report is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication by the contact person stated above on November 24, 2021 at 8:00 CET

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



# Condensed consolidated statement of total comprehensive income

SEKk	Note	Jul 1-Sep 30, 2021	Jul 1-Sep 30, 2020	Jan 1-Sep 30, 2021	Jan 1-Sep 30, 2020	Full year 2020
<b>Revenues</b>						
Net sales		–	5	–	31	35
Other operating income	5	11,308	308	3,096	308	380
<b>Total revenues</b>		<b>11,308</b>	<b>313</b>	<b>3,096</b>	<b>339</b>	<b>415</b>
<b>Operating expenses</b>						
Raw material and consumables		–4,338	–	–5,163	–14,937	–16,021
Other external expenses		–32,330	–5,281	–69,121	–24,892	–30,990
Personnel costs		–2,565	–2,401	–8,041	–6,890	–9,561
Depreciations/amortisations of tangible fixed assets and right-of-use assets		–301	–316	–935	–889	–1,192
Other operating expenses	5	–	–	–	–	–
<b>Total expenses</b>		<b>–39,534</b>	<b>–7,998</b>	<b>–83,260</b>	<b>–47,608</b>	<b>–57,764</b>
<b>Operating loss</b>		<b>–28,226</b>	<b>–7,685</b>	<b>–80,164</b>	<b>–47,269</b>	<b>–57,349</b>
<b>Result from financial investments</b>						
Financial income		–	–	–	–	46
Financial expenses		–22	–38	–77	–61	–115
<b>Financial items – net</b>		<b>–22</b>	<b>–38</b>	<b>–77</b>	<b>–61</b>	<b>–69</b>
<b>Earnings before tax</b>		<b>–28,248</b>	<b>–7,723</b>	<b>–80,241</b>	<b>–47,330</b>	<b>–57,418</b>
Taxes for the period		–	–	–	–	–
<b>LOSS FOR THE PERIOD</b>		<b>–28,248</b>	<b>–7,723</b>	<b>–80,241</b>	<b>–47,330</b>	<b>–57,418</b>

## Earnings per share, based on the net result attributable to the shareholders of the parent company:

SEK	Note	Jul 1-Sep 30, 2021	Jul 1-Sep 30, 2020	Jan 1-Sep 30, 2021	Jan 1-Sep 30, 2020	Full year 2020
Earnings per share before and after dilution *	7	–0.05	–0.03	–0.16	–0.20	–0.24

\* Adjusted for the completed rights issue in February 2021.

In the group there are no items reported in other comprehensive income. So total comprehensive income is consistent with profit/loss for the period. The profit/loss for the period and total comprehensive income are entirely attributable to the equity holders of the parent company.

# Condensed consolidated balance sheet

SEKK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible fixed assets</i>			
Equipment, tools and installations	688	832	818
<b>Total tangible fixed assets</b>	<b>688</b>	<b>832</b>	<b>818</b>
<b>Right-of-use assets</b>	<b>1,788</b>	<b>2,861</b>	<b>2,593</b>
<i>Financial assets</i>			
Other financial assets	1	1	1
<b>Total financial assets</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Total fixed assets</b>	<b>2,477</b>	<b>3,694</b>	<b>3,412</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Accounts receivable	–	–	–
Other current receivables	2,338	1,600	907
Prepaid expenses and accrued income	4,852	373	3,031
Cash and cash equivalents	463,089	62,252	53,834
<b>Total current receivables</b>	<b>470,279</b>	<b>64,225</b>	<b>57,772</b>
<b>Total current assets</b>	<b>470,279</b>	<b>64,225</b>	<b>57,772</b>
<b>TOTAL ASSETS</b>	<b>472,756</b>	<b>67,919</b>	<b>61,184</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	10,654	1,776	1,776
Additional paid-in capital	863,297	384,556	384,557
Retained earnings (including profit/loss for the period)	–417,246	–326,917	–337,005
<b>Total equity attributable to the shareholders of the parent company</b>	<b>456,705</b>	<b>59,415</b>	<b>49,328</b>
<b>Provisions</b>			
Other provisions	34	–	–
<b>Total provisions</b>	<b>34</b>	<b>–</b>	<b>–</b>
<b>Liabilities</b>			
<i>Non-current liabilities</i>			
Non-current lease liabilities	756	1,846	1,578
<b>Total non-current liabilities</b>	<b>756</b>	<b>1,846</b>	<b>1,578</b>
<i>Current liabilities</i>			
Current lease liabilities	801	768	763
Account payables	10,625	471	3,023
Other current liabilities	986	1,563	852
Accrued expenses and deferred income	2,849	3,856	5,640
<b>Total current liabilities</b>	<b>15,261</b>	<b>6,658</b>	<b>10,278</b>
<b>Total liabilities</b>	<b>16,051</b>	<b>8,504</b>	<b>11,856</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>472,756</b>	<b>67,919</b>	<b>61,184</b>

# Condensed consolidated statement of changes in equity

SEKK	Equity attributable to the equity holders of the parent company			
	Share capital	Additional paid in capital	Retained earnings, including loss for the period	Total equity
<b>Opening balance, January 1, 2020</b>	<b>1,776</b>	<b>384,314</b>	<b>-279,587</b>	<b>106,503</b>
Profit/loss for the period equal to total comprehensive income	-	-	-47,330	-47,330
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-47,330</b>	<b>-47,330</b>
<b>Transactions with shareholders of the parent company:</b>				
Issue of warrants	-	242	-	242
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>242</b>	<b>-</b>	<b>242</b>
<b>Closing balance, September 30, 2020</b>	<b>1,776</b>	<b>384,556</b>	<b>-326,917</b>	<b>59,415</b>
<b>Opening balance, January 1, 2020</b>	<b>1,776</b>	<b>384,314</b>	<b>-279,587</b>	<b>106,503</b>
Profit/loss for the period equal to total comprehensive income	-	-	-57,418	-57,418
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-57,418</b>	<b>-57,418</b>
<b>Transactions with shareholders of the parent company:</b>				
Issue of warrants	-	243	-	243
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>243</b>	<b>-</b>	<b>243</b>
<b>Closing balance, December 31, 2020</b>	<b>1,776</b>	<b>384,557</b>	<b>-337,005</b>	<b>49,328</b>
<b>Opening balance, January 1, 2021</b>	<b>1,776</b>	<b>384,557</b>	<b>-337,005</b>	<b>49,328</b>
Profit/loss for the period equal to total comprehensive income	-	-	-80,241	-80,241
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-80,241</b>	<b>-80,241</b>
<b>Transactions with shareholders of the parent company:</b>				
Issue of shares	8,878	523,809	-	532,687
Transaction costs	-	-45,192	-	-45,192
Value of the employees' employment	-	123	-	123
<b>Total transactions with shareholders of the parent company</b>	<b>8,878</b>	<b>478,740</b>	<b>-</b>	<b>487,495</b>
<b>Closing balance, September 30, 2021</b>	<b>10,654</b>	<b>863,297</b>	<b>417,246</b>	<b>456,705</b>

# Condensed consolidated cash flow

SEKk	Jul 1-Sep 30, 2021	Jul 1-Sep 30, 2020	Jan 1-Sep 30, 2021	Jan 1-Sep 30, 2020	Full year 2020
<b>Operating activities</b>					
Operating result	-28,226	7,685	-80,164	-47,269	-57,349
<i>Adjustments for non-cash items:</i>					
Depreciations/amortisations	301	316	935	889	1,192
Interest paid and received	-22	-38	-77	-61	-70
Income tax paid	-	-	-	-	-
Other adjustments	-10,907	-	-2,536	-	-
<b>Cash flow from operating activities before changes in working capital</b>	<b>-38,854</b>	<b>-7,407</b>	<b>-81,842</b>	<b>-46,441</b>	<b>-56,227</b>
<b>Changes in working capital</b>					
Decrease/Increase of current receivables	11,540	247	-3,252	-422	-2,117
Decrease/Increase of current liabilities	809	-1,171	4,983	-16,210	-12,306
<b>Cash flow from changes in working capital</b>	<b>12,349</b>	<b>-924</b>	<b>1,731</b>	<b>-16,632</b>	<b>-14,423</b>
<b>Cash flow from operating activities</b>	<b>-26,505</b>	<b>-8,331</b>	<b>-80,111</b>	<b>-63,073</b>	<b>-70,650</b>
<b>Investing activities</b>					
Investments in tangible assets	-	-8	-	-889	-909
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-8</b>	<b>-</b>	<b>-889</b>	<b>-909</b>
<b>Financing activities</b>					
Amortisation of lease liabilities	-260	-252	-822	-818	-1,639
Issues of shares, net after transaction costs	-	-	487,495	-	-
Issue of warrants	-	242	-	242	242
<b>Cash flow from financing activities</b>	<b>-260</b>	<b>-10</b>	<b>486,673</b>	<b>-576</b>	<b>-1,397</b>
<b>Cash flow for the period</b>	<b>-26,765</b>	<b>-8,349</b>	<b>406,562</b>	<b>-64,538</b>	<b>-72,956</b>
<b>Decrease/increase of cash and cash equivalents</b>					
Cash and cash equivalents at the beginning of the period	478,792	70,601	53,834	126,790	126,790
Currency translation difference in cash and cash equivalents	11,062	-	2,693	-	-
<b>Cash and cash equivalents at the end of the period</b>	<b>463,089</b>	<b>62,252</b>	<b>463,089</b>	<b>62,252</b>	<b>53,834</b>

# Statement of comprehensive income for the parent company

SEKk	Jul 1-Sep 30, 2021	Jul 1-Sep 30, 2020	Jan 1-Sep 30, 2021	Jan 1-Sep 30, 2020	Full year 2020
<b>Revenues</b>					
Net sales	1,482	2,771	7,144	8,614	11,265
<b>Total revenues</b>	<b>1,482</b>	<b>2,771</b>	<b>7,144</b>	<b>8,614</b>	<b>11,265</b>
<b>Operating expenses</b>					
Other external expenses	-2,496	-3,006	-7,868	-8,654	-11,485
Personnel costs	-1,510	-1,484	-4,783	-4,197	-5,754
Depreciations/amortisations of tangible fixed assets and right-of-use assets	-33	-45	-130	-59	-91
<b>Total expenses</b>	<b>-4,039</b>	<b>-4,535</b>	<b>-12,781</b>	<b>-12,910</b>	<b>-17,330</b>
<b>Operating loss</b>	<b>-2,557</b>	<b>-1,764</b>	<b>-5,637</b>	<b>-4,296</b>	<b>-6,065</b>
<b>Net financial items</b>					
Write-down of financial assets	-42	-	-100,042	-50,000	-50,000
Financial income	-	-	-	-	46
Financial costs	-	-3	-	-9	-6
<b>Total net financial items</b>	<b>-42</b>	<b>-3</b>	<b>-100,042</b>	<b>-50,009</b>	<b>-49,960</b>
<b>Profit or loss before tax</b>	<b>-2,599</b>	<b>-1,767</b>	<b>-105,679</b>	<b>-54,305</b>	<b>-56,025</b>
Taxes for the period	-	-	-	-	-
<b>PROFIT OR LOSS FOR THE PERIOD</b>	<b>-2,599</b>	<b>-1,767</b>	<b>-105,679</b>	<b>-54,305</b>	<b>-56,025</b>

In the parent company there are no items reported in other comprehensive income. So total comprehensive income is consistent with profit/loss for the period.



# Balance sheet for the parent company

SEKK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible fixed assets</i>			
Equipment, tools and installations	688	830	818
<b>Total tangible fixed assets</b>	<b>688</b>	<b>830</b>	<b>818</b>
<i>Financial assets</i>			
Shares in subsidiary	247,030	247,030	247,030
<b>Total financial assets</b>	<b>247,030</b>	<b>247,030</b>	<b>247,030</b>
<b>Total fixed assets</b>	<b>247,718</b>	<b>247,860</b>	<b>247,848</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Intercompany receivables	292,888	728	779
Other receivables	1,238	498	219
Prepaid expenses and accrued income	440	583	1,247
<b>Total current receivables</b>	<b>294,556</b>	<b>1,809</b>	<b>2,245</b>
Cash and cash equivalents	104,825	55,065	45,491
<b>Total current assets</b>	<b>399,391</b>	<b>56,874</b>	<b>47,736</b>
<b>TOTAL ASSETS</b>	<b>647,109</b>	<b>304,734</b>	<b>295,584</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	10,654	1,776	1,776
<b>Total restricted equity</b>	<b>10,654</b>	<b>1,776</b>	<b>1,776</b>
<i>Non-restricted equity</i>			
Share premium reserve	1,109,013	630,273	630,274
Retained earnings	-369,014	-312,989	-312,989
Profit or loss for the period	-105,679	-54,305	-56,025
<b>Total non-restricted equity</b>	<b>634,320</b>	<b>262,979</b>	<b>261,260</b>
<b>Total equity</b>	<b>644,974</b>	<b>264,755</b>	<b>263,036</b>
<b>Provisions</b>			
Other provisions	22	-	-
<b>Total provisions</b>	<b>22</b>	<b>-</b>	<b>-</b>
<b>Liabilities</b>			
<i>Current liabilities</i>			
Accounts payable	500	113	1,114
Intercompany liabilities	-	36,886	28,800
Other liabilities	313	1,125	323
Accrued expenses and deferred income	1,300	1,855	2,311
<b>Total current liabilities</b>	<b>2,113</b>	<b>39,979</b>	<b>32,548</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>647,109</b>	<b>304,734</b>	<b>295,584</b>

# Statement of change in equity parent company

SEKK	Restricted equity		Non-restricted equity		Total equity
	Share capital	Share premium	Retained earnings	Net result	
<b>Opening balance, January 1, 2020</b>	<b>1,776</b>	<b>630,031</b>	<b>-217,005</b>	<b>-95,984</b>	<b>318,818</b>
Disposition of last year's result	-	-	-95,984	95,984	-
Net results and total comprehensive income for the year	-	-	-	-54,305	-54,305
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-54,305</b>	<b>-54,305</b>
<b>Transactions with shareholders of the parent company:</b>					
Issue of warrants	-	242	-	-	242
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>242</b>	<b>-</b>	<b>-</b>	<b>242</b>
<b>Closing balance, September 30, 2020</b>	<b>1,776</b>	<b>630,273</b>	<b>-312,989</b>	<b>-54,305</b>	<b>264,755</b>
<b>Opening balance, January 1, 2020</b>	<b>1,776</b>	<b>630,031</b>	<b>-217,005</b>	<b>-95,984</b>	<b>318,818</b>
Disposition of last year's result	-	-	-95,984	95,984	-
Net results and total comprehensive income for the year	-	-	-	-56,025	-56,025
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-56,025</b>	<b>-56,025</b>
<b>Transactions with shareholders of the parent company:</b>					
Issue of warrants	-	243	-	-	243
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>243</b>	<b>-</b>	<b>-</b>	<b>243</b>
<b>Closing balance, December 31, 2020</b>	<b>1,776</b>	<b>630,274</b>	<b>-312,989</b>	<b>-56,025</b>	<b>263,036</b>
<b>Opening balance, January 1, 2021</b>	<b>1,776</b>	<b>630,274</b>	<b>-312,989</b>	<b>-56,025</b>	<b>263,036</b>
Disposition of last year's result	-	-	-56,025	56,025	-
Net results and total comprehensive income for the year	-	-	-	-105,679	-105,679
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-105,679</b>	<b>-105,679</b>
<b>Transactions with shareholders of the parent company:</b>					
Issue of shares	8,878	523,809	-	-	532,687
Transaction costs	-	-45,192	-	-	-45,192
Value of the employees' employment	-	123	-	-	123
<b>Total transactions with shareholders of the parent company</b>	<b>8,878</b>	<b>478,740</b>	<b>-</b>	<b>-</b>	<b>487,495</b>
<b>Closing balance, September 30, 2021</b>	<b>10,654</b>	<b>1,109,013</b>	<b>-369,014</b>	<b>-105,679</b>	<b>644,974</b>

# Statement of cash flow for the parent company

SEKK	Jul 1-Sep 30, 2021	Jul 1-Sep 30, 2020	Jan 1-Sep 30, 2021	Jan 1-Sep 30, 2020	Full year 2020
<b>Operating activities</b>					
Profit or loss before tax	-2,599	-1,767	-105,679	-54,305	-56,025
<i>Adjustments for non-cash items:</i>					
Write downs	42	-	100,042	50,000	50,000
Income tax paid	-	-	-	-	-
Depreciations/amortisations	33	45	130	59	91
Other adjustments	145	-	145	-	-
<b>Cash flow from operating activities before changes in working capital</b>	<b>-2,379</b>	<b>-1,722</b>	<b>-5,362</b>	<b>-4,246</b>	<b>-5,934</b>
<b>Changes in working capital</b>					
Changes in current receivables	-6,884	70	-292,321	-822	-1,258
Changes in current liabilities	23	-13,332	-30,435	-14,185	-21,616
<b>Cash flow from changes in working capital</b>	<b>-6,861</b>	<b>-13,262</b>	<b>-322,756</b>	<b>-15,007</b>	<b>-22,874</b>
<b>Cash flow from operating activities</b>	<b>-9,240</b>	<b>-14,984</b>	<b>-328,118</b>	<b>-19,253</b>	<b>-28,808</b>
<b>Investing activities</b>					
Shareholder's contribution	-42	-	-100,042	-50,000	-50,000
Investment of leases	-	-9	-	-889	-909
<b>Cash flow from investing activities</b>	<b>-42</b>	<b>-9</b>	<b>-100,042</b>	<b>-50,889</b>	<b>-50,909</b>
<b>Financing activities</b>					
Issues of shares, net after transaction costs	-	-	487,495	-	-
Issue of warrants	-	242	-	242	243
<b>Cash flow from financing activities</b>	<b>-</b>	<b>242</b>	<b>487,495</b>	<b>242</b>	<b>243</b>
<b>Cash flow for the period</b>	<b>-9,282</b>	<b>-14,751</b>	<b>59,334</b>	<b>-69,900</b>	<b>-79,474</b>
<b>Decrease/increase in cash and cash equivalents</b>					
Cash and cash equivalents at the beginning of the period	114,107	69,816	45,491	124,965	124,965
<b>Cash and cash equivalents at the end of the period</b>	<b>104,825</b>	<b>55,065</b>	<b>104,825</b>	<b>55,065</b>	<b>45,491</b>

# Development of parent company's share capital

SEK 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
Sep 23, 2019	Share issue	275,125	1,650,751	13,756,255	82,537,530	96,018,660
Oct 10, 2019	Share issue	124,874	1,775,625	6,243,745	88,781,275	43,581,340
Feb 11, 2021	Share issue	8,878,127	10,653,753	443,906,375	532,687,650	532,687,650

# Notes

## NOTE 1 GENERAL INFORMATION

This interim report includes the parent company InDex Pharmaceuticals Holding AB (publ), Corp. Reg. No. 559067-6820, the subsidiary InDex Pharmaceuticals AB and the sub-subsidiary InDex Diagnostics AB ('InDex', 'the company' or 'the group'). InDex Pharmaceuticals Holding AB (publ) is a parent company registered in Sweden with its registered office in Stockholm with the address Berzelius väg 13, 171 65 Solna, Sweden.

Unless otherwise stated, all amounts are in thousands of Swedish kronor (SEKK). Figures in parentheses refer to the comparative period.

## NOTE 2 ACCOUNTING POLICIES

InDex applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 *Interim Financial Reporting* and the *Annual Accounts Act*. The parent company prepares financial reports in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 *Accounting for Legal Entities* and the *Swedish Annual Accounts Act*.

Applied accounting principles and calculation methods are the same as in the annual report for 2020.

None of the IFRS or IFRIC interpretations that have yet to come into legal effect are expected to have any significant impact on InDex.

## NOTE 3 RISKS AND UNCERTAINTIES

### OPERATIONAL RISK

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 will obtain the necessary approvals to conduct the clinical trials that InDex would like to conduct, 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 pharmaceuticals 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.

## FINANCIAL RISK MANAGEMENT

InDex may also need to raise additional capital in the future. Both the size and timing of InDex's possible need for capital in the future depend on several factors, including the possibility of entering into collaboration or licensing arrangements and the progress made in research and development projects. There is a risk that the necessary financing of the operations is unavailable at the right time and at a reasonable cost.

For a detailed description of significant risks, refer to InDex's annual report for 2020. The annual report is available on the company's website.

## NOTE 4 IMPORTANT ESTIMATES AND JUDGEMENTS

The group makes estimates and assumptions about the future. The resulting accounting estimates will, by definition, rarely correspond to the actual results. The assumptions and other sources of estimation uncertainty where there is a significant risk of material adjustment to the carrying amounts of assets or liabilities within the next financial year are outlined below.

### (i) 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.

### (ii) Tax loss carry-forwards

Deferred tax assets related to loss carry-forwards or other future tax deductions are recognised to the extent it is probable that the deduction can be offset against future taxable profits. Since the group does not report positive results no deferred tax asset related to loss carry-forwards has yet been recognised.

### (iii) Estimates and assessments linked to development costs

An important assessment in financial reporting refers to the point in time for capitalizing pharmaceutical development costs. Based on the accounting policies set out under note 2 in the annual report for 2020, no pharmaceutical development costs meet the criteria for capitalisation and have therefore been expensed. Pharmaceutical development costs will be, at the earliest, capitalised after positive results have been achieved in phase III clinical trials or until registration studies have commenced. The reasons being that before that time, it is too uncertain whether the costs will generate future economic benefits and that financing of the asset's completion has not been secured.



**NOTE 5 OTHER OPERATING INCOME/OTHER OPERATING EXPENSES**

SEKk	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Jan-Sep 2021
Grants from Vinnova	35	121	246	402
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	–	11,062	2,693
<b>Other operating income</b>	<b>35</b>	<b>121</b>	<b>11,308</b>	<b>3,096</b>
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	–8,368	–	–
<b>Other operating expenses</b>	<b>–</b>	<b>–8,368</b>	<b>–</b>	<b>–</b>

SEKk	Jan-Mar 2020	Apr-Jun 2020	Jul-Sep 2020	Jan-Sep 2020	Oct-Dec 2020	Full year 2020
Grants from Vinnova	–	–	308	308	72	380
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	–	–	–	–	–
<b>Other operating income</b>	<b>–</b>	<b>–</b>	<b>308</b>	<b>308</b>	<b>72</b>	<b>380</b>
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	–	–	–	–	–
<b>Other operating expenses</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>

\* Revaluation of cash and cash equivalents at closing-day rate has been reported net in the accumulated period.

**NOTE 6 RELATED PARTY TRANSACTIONS**

No related party transactions have occurred from a group perspective.

InDex Pharmaceuticals Holding AB invoices InDex Pharmaceuticals AB for overall group functions.

**NOTE 7 EARNINGS PER SHARE**

Earnings per share is calculated by dividing the result for the period by the weighted average number of outstanding ordinary shares during the period.

InDex had potential ordinary shares in the form of warrants. However, these did not give rise to any dilution effect in 2020 or 2021 as a conversion to ordinary shares decreases loss per share.

SEK million	Jan-Sep 2021	Jan-Sep 2020	Full year 2020
Net result attributable to the equity shareholders of the parent company	–80.2	–47.3	–57.4
<b>Total:</b>	<b>–80.2</b>	<b>–47.3</b>	<b>–57.4</b>
<b>Weighted average number of shares (thousands)</b>	<b>487,749</b>	<b>236,750</b>	<b>236,750</b>
<b>Earnings per share, SEK</b>	<b>–0.16</b>	<b>–0.20</b>	<b>–0.24</b>