

InDex Pharmaceuticals Holding AB (publ)

InDex
Pharmaceuticals

Interim report
January-March 2019

The final phase of
the patient recruitment
in the CONDUCT study



PERIOD JANUARY-MARCH 2019

- Revenues amounted to SEK 0.0 (0.1) million
- Operating result amounted to SEK -17.2 (-18.8) million
- Result after tax amounted to SEK -17.2 (-18.7) million, corresponding to SEK -0.25 per share (-0.30) before and after dilution
- Cash flow from operating activities amounted to SEK -18.6 (-22.9) million
- Cash and cash equivalents at the end of the period amounted to SEK 64.4 (102.1) million
- Number of employees at the end of the period was 7 (7)
- Number of shares at the end of the period was 68,781,275

SIGNIFICANT EVENTS DURING JANUARY-MARCH 2019

- No significant events have occurred during the reporting period.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- InDex provided a status update on the patient recruitment in the CONDUCT study.

All comparative amounts in brackets refer to the outcome during the corresponding period 2018.

“With only 10 patients left to enrol we estimate that the patient recruitment will be completed during the month of June at the latest,” says Peter Zerhouni, CEO of InDex Pharmaceuticals.

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. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Stockholm. Redeye AB is the company's Certified Adviser (+46 8 121 576 90 or certifiedadviser@redeye.se).

CEO statement



We have now enrolled 205 patients, of the total 215 planned, in the phase IIb study CONDUCT evaluating the drug candidate cobitolimod. The patient recruitment has varied significantly on a monthly basis, with between 6 and 19 patients enrolled, which has made it challenging to predict the remaining recruitment time. April was an average month with 10 enrolled patients and with only 10 left to enrol we estimate that the patient recruitment will be completed during the month of June at the latest.

This represents a delay compared to the previously communicated timeline, which we informed of in a press release on April 11. The main reason for the lower recruitment rate is an increased competition for patients with moderate to severe ulcerative colitis from other studies. We however do well when comparing the recruitment rate in the CONDUCT study to the most recently completed phase III studies from global pharmaceutical companies such as Pfizer and Johnson & Johnson.

We continue to work very actively with the CONDUCT study and have regular direct contact with the more than 90 participating clinics around Europe. We constantly get confirmation that there is a positive interest in our study and cobitolimod among the doctors, not least thanks to the new and unique mechanism of action and the good safety profile.

As we approach the end of the patient recruitment, the focus is shifting more and more towards preparing the analysis of the top line results in order to be able to report them as soon as possible after the last patient has been enrolled. Also, within business development there are a lot of preparations ongoing ahead of the results becoming available. Next on the meeting program is the Digestive Disease Week in the US in mid-May, which is the largest medical congress in the world within gastroenterology and which all pharmaceutical companies within the field are attending.

In addition, we are intensifying preparations for phase III in order to shorten the time to market as much as we can by, for example, drafting study protocols and ensuring access to study drug. The CONDUCT results will be a crucial milestone for InDex and with positive data we will take a big step towards our goal to make cobitolimod available for these severely ill patients.

Today is InDex's Annual General Meeting and if you do not have the opportunity to attend, I will also present the company at the Introduce Investor Days on May 27 and at the Redeye Growth Day on June 10, both of which will be webcasted.

Peter Zerhouni, CEO

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 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.

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 approxi-

mately 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.

Cobitolimod is also known as Kappaproct® and DIMS0150.

SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

- No significant events have occurred during the reporting period.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- InDex provided on April 11, 2019 a status update on the patient recruitment in the CONDUCT study, with 197 patients, of the total 215 planned, then enrolled. The company estimates that the patient recruitment will be completed during the month of June at the latest, which represents a delay compared to the previously communicated timeline. The company will announce when the last patient has been enrolled in the study and the top line results are expected to be available within 8-10 weeks thereafter.

FINANCIAL SUMMARY FOR THE REPORTING PERIOD

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

Group

The revenues for the period January to March 2019 amounted to SEK 0.0 million, which is a decrease of SEK 0.1 million compared to the same period the previous year. The decrease is related to fewer DiBiCol test kits sold.

Operating expenses for the period amounted to SEK 17.3 million, which is a decrease of SEK 1.6 million compared to the same period the previous year. The decrease is mainly attributable to fewer patients enrolled in the ongoing phase IIb study compared to the same period the previous year. The costs during the period refer to costs for the ongoing phase IIb study and general operating expenses.

Costs for the personnel during the reporting period amounted to SEK 2.3 million, which is SEK 0.2 million less than for the same period the previous year.

Cash and cash equivalents as of March 31, 2019 amounted to SEK 64.4 million, which is SEK 18.6 million lower than December 31, 2018.

FINANCIAL SUMMARY

SEK millions	Jan-Mar 2019	Jan-Mar 2018	Full year 2018
Revenues	0.0	0.1	0.7
Operating result	-17.2	-18.8	-82.4
Result after tax	-17.2	-18.7	-82.3
Result per share before and after dilution, SEK	-0.25	-0.30	-1.29
Cash flow from operating activities	-18.6	-22.9	-79.5
Cash and cash equivalents at the end of the period	64.4	102.1	83.0

Note: Result per share – Net result divided by average number of shares.

Parent company

The revenues amounted to SEK 2.0 million during the period January-March 2019 and consisted of invoicing of group wide expenses to the other companies within the group.

The expenses amounted to SEK 3.1 million and consisted of personnel expenses and other operating expenses relating to the administration of InDex.

FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

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

EXPECTED FUTURE DEVELOPMENT

The Board estimates that the patient recruitment in the CONDUCT study will be completed during the month of June 2019 at the latest. The company will announce when the last patient has been enrolled in the study and the main results are expected to be available within 8-10 weeks thereafter.

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 time being.

InDex provides no financial forecast or similar forward looking statement.

EMPLOYEES

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

THE SHARE

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

LARGEST SHAREHOLDERS PER 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 Rasjö	3,124,718	4.5
Linc AB	2,908,298	4.2
Avanza Pension	1,928,939	2.8
SEB Stiftelsen	1,785,714	2.6
SEB Life International	1,454,150	2.1
Ponderus Securities AB	1,243,996	1.8
Skandinaviska Enskilda Banken S.A.	1,000,000	1.5
Other	20,870,034	30.4
Total	68,781,275	100.0

INCENTIVE PROGRAMMES

At the Extraordinary General Meeting held on September 12, 2016 it was resolved to issue 3,250,000 warrants to transfer 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 (3,237,500) warrants have been acquired at fair value by employees and other key persons in InDex.

REVIEW BY THE AUDITOR

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

FINANCIAL CALENDER

Annual General Meeting	May 6, 2019
Interim report Q2	August 22, 2019
Interim report Q3	November 27, 2019

Stockholm, May 6, 2019

Peter Zerhouni, CEO

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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 at 8:00 CET on May 6, 2019.

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.

Consolidated income statement

SEK 000's	Jan 1-Mar 31, 2019	Jan 1-Mar 31, 2018	Full year 2018
Revenues			
Net sales	35	54	128
Other income	–	–	612
Total revenues	35	54	740
Operating expenses			
Raw material and consumables	–2	–167	–560
Other external expenses	–14,957	–16,211	–72,981
Personnel costs	–2,290	–2,472	–9,553
Depreciations	–3	–3	–11
Total expenses	–17,252	–18,853	–83,105
Operating loss	–17,217	–18,799	–82,365
Profit/loss from financial items			
Financial income	0	50	156
Financial expenses	–4	–1	–42
Other	–	–	–64
Total	–4	49	50
Earnings before tax	–17,221	–18,750	–82,315
Taxes for the period	–	–	–
Net profit/loss for the period	–17,221	–18,750	–82,315
Loss per share, SEK (before and after dilution)	–0.25	–0.30	–1.29
Average number of shares	68,781,275	62,528,433	63,692,156
Number of shares at the end of the period	68,781,275	62,528,433	68,781,275

Consolidated balance sheet

SEK 000's	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
ASSETS			
Fixed assets			
<i>Intangible fixed assets</i>			
Patents, license and trademarks	–	–	–
<i>Tangible fixed assets</i>			
Equipment, tools and installations	19	29	21
Total fixed assets	19	29	21
Current assets			
<i>Current receivables</i>			
Accounts receivable	11	22	10
Other current receivables	1,501	3	1,482
Prepaid expenses and accrued income	484	965	481
Total current receivables	1,996	990	1,973
Cash and cash equivalents	64,395	102,148	83,034
Total current assets	66,391	103,138	85,007
TOTAL ASSETS	66,410	103,167	85,028
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	1,376	1,251	1,376
Total restricted equity	1,376	1,251	1,376
Non-restricted equity			
Retained earnings	58,530	103,496	140,845
Loss for the period	–17,221	–18,750	–82,315
Total non-restricted equity	41,309	84,746	58,530
Total equity	42,685	85,997	59,906
Current liabilities			
Accounts payables	4,990	1,769	3,552
Other liabilities	5,866	5,300	5,935
Accrued expenses and deferred income	12,869	10,101	15,635
Total current liabilities	23,725	17,170	25,122
TOTAL EQUITY AND LIABILITIES	66,410	103,167	85,028

Consolidated statement of changes in equity

SEK 000's	Share capital	Retained earnings	Net result
Opening balance, January 1, 2018	1,251	176,255	-72,759
Disposition of last year's result	-	-72,759	72,759
Net result	-	-	-18,750
Closing balance, March 31, 2018	1,251	103,496	-18,750
Opening balance, January 1, 2018	1,251	176,255	-72,759
Disposition of last year's result	-	-72,759	72,759
Issue of shares	125	37,517	-
Issue costs	-	-168	-
Net result	-	-	-82,315
Closing balance, December 31, 2018	1,376	140,845	-82,315
Opening balance, January 1, 2019	1,376	140,845	-82,315
Disposition of last year's result	-	-82,315	82,315
Net result	-	-	-17,221
Closing balance, March 31, 2019	1,376	58,530	-17,221

Consolidated cash flow

SEK 000's	Jan 1-Mar 31, 2019	Jan 1-Mar 31, 2018	Full year 2018
Operating activities			
Earnings before tax	-17,221	-18,750	-82,315
<i>Adjustments for non-cash items</i>			
Depreciations	3	3	11
Income tax paid	-	-	-
Cash flow from operating activities before changes in working capital	-17,218	-18,747	-82,304
Changes in working capital			
Changes in current receivables	-23	795	-188
Changes in current liabilities	-1,398	-4,955	2,993
Cash flow from changes in working capital	-1,421	-4,160	2,805
Cash flow from operating activities	-18,639	-22,907	-79,499
Investing activities			
Acquisition of tangible assets	-	-	-
Cash flow from investing activities	-	-	-
Financing activities			
Issues of shares	-	-	37,478
Cash flow from financing activities	-	-	37,478
Cash flow for the period	-18,639	-22,907	-42,021
Cash and cash equivalents at the beginning of the period	83,034	125,055	125,055
Cash and cash equivalents at the end of the period	64,395	102,148	83,034

Income statement parent company

SEK 000's	Jan 1-Mar 31, 2019	Jan 1-Mar 31, 2018	Full year 2018
Revenues			
Net sales	2,021	1,887	9,112
Total revenues	2,021	1,887	9,112
Operating expenses			
Other external expenses	-1,834	-1,589	-9,194
Personnel costs	-1,275	-1,313	-5,252
Total expenses	-3,109	-2,902	-14,446
Operating loss	-1,088	-1,015	-5,334
Net financial items			
Write-down of financial assets	-	-	-40,000
Financial costs	-4	-1	-36
Total	-4	-1	-40,036
Earnings before tax	-1,092	-1,016	-45,370
Taxes for the period	-	-	-
Net profit/loss for the period	-1,092	-1,016	-45,370

Balance sheet parent company

SEK 000's	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
ASSETS			
Fixed assets			
<i>Financial assets</i>			
Shares in subsidiary	247,030	247,030	247,030
Total fixed assets	247,030	247,030	247,030
Current assets			
<i>Current receivables</i>			
Other receivables	547	212	15
Intercompany receivables	390	2	351
Prepaid expenses and accrued income	409	564	353
Total current receivables	1,346	778	719
Cash and cash equivalents	63,284	101,767	82,388
Total current assets	64,630	102,545	83,107
TOTAL ASSETS	311,660	349,575	330,137
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	1,376	1,251	1,376
Total restricted equity	1,376	1,251	1,376
Non-restricted equity			
Retained earnings	283,642	291,659	329,012
Net result	-1,092	-1,016	-45,370
Total non-restricted equity	282,550	290,643	283,642
Total equity	283,926	291,894	285,018
Current liabilities			
Accounts payable	229	91	168
Intercompany liabilities	24,995	54,939	42,266
Other liabilities	965	939	1,066
Accrued expenses and deferred income	1,545	1,712	1,619
Total current liabilities	27,734	57,681	45,119
TOTAL EQUITY AND LIABILITIES	311,660	349,575	330,137

Statement of change in equity parent company

SEK 000's	Share capital	Retained earnings	Net result
Opening balance, January 1, 2018	1,251	416,322	-124,663
Disposition of last year's result	-	-124,663	124,663
Net result	-	-	-1,016
Closing balance, March 31, 2018	1,251	291,659	-1,016
Opening balance, January 1, 2018	1,251	416,322	-124,663
Disposition of last year's result	-	-124,663	124,663
Issue of shares	125	37,517	-
Issue costs	-	-164	-
Net result	-	-	-45,370
Closing balance, December 31, 2018	1,376	329,012	-45,370
Opening balance, January 1, 2019	1,376	329,012	-45,370
Disposition of last year's result	-	-45,370	45,370
Net result	-	-	-1,092
Closing balance, March 31, 2019	1,376	283,642	-1,092

Cash flow parent company

SEK 000's	Jan 1-Mar 31, 2019	Jan 1-Mar 31, 2018	Full year 2018
Operating activities			
Earnings before tax	-1,092	-1,016	-45,370
<i>Adjustments for non-cash items</i>			
Write downs	-	-	40,000
Income tax paid	-	-	-
Cash flow from operating activities before changes in working capital	-1,092	-1,016	-5,370
Changes in working capital			
Changes in current receivables	-627	-147	-88
Changes in current liabilities	-17,385	-8,752	-21,314
Cash flow from changes in working capital	-18,012	-8,899	-21,402
Cash flow from operating activities	-19,104	-9,915	-26,772
Investing activities			
Shareholder's contribution	-	-	-40,000
Cash flow from investing activities	-	-	-40,000
Financing activities			
Issues of shares	-	-	37,478
Cash flow from financing activities	-	-	37,478
Cash flow for the period	-19,104	-9,915	-29,294
Cash and cash equivalents at the beginning of the period	82,388	111,682	111,682
Cash and cash equivalents at the end of the period	63,284	101,767	82,388

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

Notes

NOTE 1 GENERAL INFORMATION

This interim report includes the parent company InDex Pharmaceuticals Holding AB (publ), Corp. Reg. No. 559067-6820 and the subsidiaries InDex Pharmaceuticals AB and InDex Diagnostics AB ("InDex", "the company" or "the group").

NOTE 2 ACCOUNTING PRINCIPLES

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and BFAR 2012:1 (K3). See also below under "Corporate Structure" for additional information about the completed legal restructuring.

The accounting policies adopted in this interim report are consistent with those of the 2018 annual report and should be read in conjunction with that annual report.

NOTE 3 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 noncash consideration was registered at the Swedish Companies Registration Office, whereby the shareholders of InDex Pharmaceuticals AB transferred 99.76 percent (in March 2019 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 compulsorily 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 March 31, 2019.

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.

NOTE 4 RISKS AND UNCERTAINTIES

OPERATIONAL RISKS

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 will 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 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.

For a more detailed description of the risk factors, please refer to the annual report for 2018, which is available on the company's web page.

NOTE 5 | IMPORTANT ESTIMATIONS AND JUDGEMENTS

The following areas have been identified as areas dependent of estimations and judgements, which can have significant impact on the financial statements: incurred costs for clinical trials, test for impairment of participation in group companies and deferred tax receivables.

For a more detailed description of important estimations and judgements, please refer to the annual report for 2018.

NOTE 6 | TRANSACTIONS WITH RELATED PARTIES

InDex Pharmaceuticals Holding AB invoices its subsidiaries for group wide services.