

Dicot AB (publ) 559006-3490

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## **Summary of Year-End Report 2022**

### Dicot AB (publ) 559006-3490

#### **FOURTH QUARTER 2022**

- Net sales amounted to KSEK 0 (0)
- Earnings after financial items amounted to KSEK -8,604 (-8,408)
- Earnings per share amounted to SEK -0.06 (-0.10)

## Significant events during the period

- On October 11, good results were reported from the ongoing preclinical toxicology studies, which show that the drug candidate LIB-01 has a good safety profile.
- Dicot announced on October 17 that a new patent application had been submitted. New patents provide 20 years of market exclusivity from the date of submitted application.
- On October 25, it was announced that parts of the manufacturing of the drug substance will be moved in order to decrease costs and reduce transportation. It is the extraction process that is being moved to South Africa where the starting material is already handled and where the company has established partners.
- Dicot held the first of two meetings with the Swedish Medical Products Agency on November 14 to prepare for an application to start LIB-01's clinical trials. The aim was to anchor the documentation that must be included in a clinical trial application.
- Dicot presented on November 15 the latest study of LIB-01's mechanism of action, showing that it differs from today's potency drugs such as Viagra. This means that LIB-01 can be assumed to represent a new generation of potency drugs.
- The board of Dicot decided on December 7, subject to subsequent approval at an extraordinary general meeting on January 9, 2023, to carry out a rights issue of SEK 54.8 million before issue costs, and two warrant programs in June and November 2023.

#### **FULL YEAR 2022**

- Net sales amounted to KSEK 0 (0)
- Earnings after financial items amounted to KSEK -31,756 (-27,175)
- Earnings per share amounted to SEK -0.26 (-0.42)

# Significant events after the period

- On January 4, 2023, Dicot entered an agreement with Clinical Trial Consultants AB (CTC) for conducting the clinical phase 1 studies intended to start in the middle of 2023.
- The extraordinary general meeting on January 9 approved the board's proposal to carry out a preferential rights issue, change the articles of association, and carry out a reduction of the share capital.
- On January 19, Thermo Fisher Scientific was contracted to perform GMP manufacturing of LIB-01 for the upcoming clinical studies, and on February 20 it was announced it had started.
- On January 23, it was announced that Dicot is moving forward with a patent application covering the new oral formulation for LIB-01 developed in 2022 and that will be used in the phase 1 clinical trials.
- On 31 January, it was announced that the rights issue was oversubscribed to 109.5%, meaning that no underwriting agreements needed to be invoked. Dicot received SEK 54.8 million before issue costs.
- On February 8, it was announced that 87% of the remuneration to issue guarantors is offset against new units instead of monetary compensation in a directed issue. The issue thus raised SEK 49.9 million in cash.
- Dicot's results from the latest study of LIB-01's mechanism of action were presented at the European Society for Sexual Medicine's annual congress on February 17.



### **Dicot AB in Brief**

Dicot is a pharmaceutical company developing the drug candidate LIB-01 into a new modern potency drug for the world market. The ambition is to create a drug that has longer duration of action and fewer side effects than those currently on the market. Dicot wants to change the way of treating erectile problems and improve quality of life for affected men and couples. The aim is to develop LIB-01 to become the first choice of drug when treating erectile dysfunction and premature ejaculation.

THE MOST WIDELY USED potency drugs today, such as Viagra and Cialis, come with some challenges and almost half of all those who try these drugs choose to discontinue treatment. Around 35% of users state that the drugs do not give the desired effect and many experience side effects and concerns about cardiovascular effect. In addition to requirements for planning, these drugs also have a short duration of action, which reduces spontaneity in the sex life.

**THE GLOBAL MARKET** in 2021 for erectile dysfunction drugs was worth SEK 44 billion and for premature ejaculation SEK 31 billion, totalling SEK 75 billion. Demand is growing strongly and is expected to increase by 7% and 9% respectively per year until 2026.

**THE NEED FOR NEW DRUGS IS VERIFIED** by medical experts in sexual medicine. Dr. Chris McMahon, former president of The International Society of Sexual Medicine, says "weekly treatments with proven efficacy, good safety profile and no significant side effects would be a game changer".

**DICOTS MAIN STRATEGY** is to develop LIB-01 under own auspices until clinical phase 2a study and thereafter, in partnership with larger established pharmaceutical companies, finance and develop LIB-01 further to a registered pharmaceutical on the world market.

**THE ACTIVE SUBSTANCE** in LIB-01 is a semi-synthetically produced molecule developed by the founder of Dicot,

Professor Jarl Wikberg, originating from a folk medicine use. Today, seeds are used as raw material and through an extraction process followed by a number of synthesis steps, substances in the seeds are converted into the active substance in LIB-01.

**CLINICAL PHASE 1 STUDIES** in humans are intended to begin in mid-2023 and reputable Clinical Trial Consultants AB has been contracted to conduct them. Within the ongoing preclinical development work, several effect studies have been performed in validated animal models which clearly demonstrate the effect of LIB-01. Toxicology studies carried out to date show that LIB-01 has a good safety profile and no side effects have been observed.

DICOT HAS CONTRACTED established partners for development and studies of LIB-01. Effect studies are carried out by Pelvipharm, a leading contract research organisation in France with validated models. Pelvipharm has worked with over 170 development projects, for example with Pfizer during the development of Viagra. Manufacturing of the drug substance and the oral formulation developed in 2022 is outsourced to established international drug manufacturers.

**THE COMPANY HAS A GLOBAL** and long-term IP strategy with granted patents and patent applications within three patent families. New patent applications were submitted in the last quarter of 2022 and the first quarter of 2023 which, as new granted patents, will provide patent protection until at least 2043.

### Statement from the CEO

During the last quarter of the year, Dicot continued to deliver according to plans and with a large focus on preparations for the start of studies in humans. When I sum up 2022, I conclude that it has been very eventful. We have made progress in the drug development and generated new results that all point in the same direction: we're onto something completely new. We have also advanced our positions in terms of IP and manufacturing, and we ended the year by initiating the rights issue in January which was oversubscribed to 110% and provided a substantial capital injection of approximately SEK 55 million before issue costs.

**THE DEVELOPMENT WORK** during the year has been aimed at preparing us for the phase 1 clinical studies that we intend to start in mid-2023. Last spring we had a major value-creating breakthrough; robust development work resulted in an oral formulation. Pharmacological studies also verified what we had previously seen – LIB-01 has a long-lasting effect. Later in 2022, we were also able to publish good results from ongoing toxicology programs. All these elements are important building blocks in our application to start the clinical studies.

**ONGOING STUDIES** on the mechanism of action of LIB-01 – i.e., how the drug affects the body to achieve the effect – show that our candidate's mechanism can be assumed to differ from the most common potency drugs, such as Viagra. This, together with the long-lasting effect, is a clear indication that LIB-01 may indeed represent a new generation of potency drugs.

**SEVERAL NEW PATENT OPPORTUNITIES** were identified at the beginning of the year. These are now protected as trade secrets until the right time to convert them into patent rights arises. The goal of the strategy is to secure the longest possible market exclusivity and revenue opportunity for LIB-01, and thereby increasing shareholder value. During the fourth quarter, we took one of these on to a new patent application and another patent application was prepared shortly thereafter.

**COMPANY COSTS** have been particularly under scrutiny this year, both short-term and long-term. For example, the extraction process during manufacturing has been moved to South Africa where the starting material is already handled, bringing major efficiency gains both immediately and in the future. The cost analysis was also important to optimize the capital requirement that formed the basis for the rights issue that was carried out in January 2023.

**2023 TOOK OFF** with a fantastic outcome of our rights issue, which was oversubscribed to 110% and provided a capital injection of approximately SEK 55 million gross before costs. In the beginning of the year, we also contracted CTC to conduct our phase 1 studies and Thermo Fisher Scientific has already started to manufacture the study drug to be used.

**MANY THANKS TO ALL** shareholders for the trust you place in us and welcome to a new year with Dicot that is likely to be the most eventful so far.

Elin Trampe, CEO Uppsala in February 2023



"New results all point in the same direction: we are onto something completely new."

## **Comments to the Report**

Dicot's development work regarding LIB-01 continues and follows the company's forecasts in terms of both cost and time. Operating expenses for the fourth quarter of KSEK 8,603 (8,412) are at the same level as the corresponding period last year. During the full year, the operating costs amounted to KSEK 31,843 (27,250), an increase compared to the previous year since the number of studies has increased as the project approaches the clinical studies that are intended to begin in mid-2023. Dicot has therefore during the year had higher external costs and hired more experts than last year. Manufacturing of drug substance and oral formulation has affected the external costs. The increase in personnel costs follows the number of employees. During the autumn, raw materials for the future production of clinical trial material for the clinical studies were acquired and stored to a value of KSEK 1,489 (0).

#### **Accounting principles**

The annual report is prepared in accordance with the Annual Accounts Act and BFNAR 2012:1 Annual report and consolidated accounts (K3).

The accounting principles are unchanged compared to the previous year.

For more information, please see Dicot's Annual Report from 2021.

### **Liquid Funds**

Cash and cash equivalents at the end of the period amounted to MSEK 9.4 (30.3).

### **Earnings per Share**

Earnings per share for the reporting period amounted to SEK -0.26 (-0.42) and for the period October – December to SEK -0.06 (-0.10).

#### The Stock

Dicot AB was listed on Spotlight Stock Market on June 20, 2018. As of December 31, 2022, the number of shares amounted to 137,103,020 and the share's closing price was SEK 0.336. The quota value was SEK 0.125.

### **Financing**

In June 2022, Dicot received SEK 10 million before issue costs of SEK 1 million through the warrants of series TO3 that were issued in autumn 2021. A total of 34,202,814 warrants were exercised, corresponding to

90 percent of outstanding warrants, at a subscription price of SEK 0.29 per share. The general development of the stock market during the spring of 2022 resulted in that the addition was lower than expected, despite the high subscription rate.

To ensure funding of the company's progress and the clinical phase 1 studies, the board decided in December 2022 to, subject to the approval of an extra general meeting, carry out a preferential rights issue in January 2023 which, if fully subscribed, would add SEK 54.8 million to Dicot before issue costs. The rights issue consisted of units containing shares and two series of warrants that may be exercised in June and November 2023, respectively.

It is within the board's and management's area of responsibility to continuously evaluate long-term working capital needs and financing alternatives. Dicot's main strategy is to develop LIB-01 under own auspice up to and including clinical phase 2a study and then, in partnership with major established pharmaceutical companies, finance and develop LIB-01 further to a registered drug on the world market. This strategy gives Dicot the opportunity to reach positive cash flows relatively early through so-called upfront payment already when signing agreements with partners. Depending on the outcome of warrant programs TO4 and TO5 and at what point in time partner agreements are signed, the need for additional working capital will be continuously evaluated and can be added through, for example, grant funding and targeted issues to collaboration partners or investors.

The board and management assess that Dicot with the warrant programs TO4 and TO5 covers the working capital needs for the next 12 months.

There are a total of seven ongoing incentive programs:

Option Program	Number of warrants (of which distributed)	Number of new shares	Increase in share capital	Strike price (SEK)	Time for share subscription
2018/2023	3,100	248,000	31,000	14.25	2018-05-08 – 2023-04-30
2019/2024	110,000 (80,000)	110,000	13,750	20.00	2019-07-03 – 2024-05-16
2020/2025	350,000 (250,000)	350,000	43,750	7.50	2020-06-11 – 2025-05-26
2021/2026 - board	350,000 (300,000)	350,000	43,750	4.10	2024-06-01 – 2026-06-01
2021/2026 - others	650,000 (450,000)	650,000	81,250	4.10	2024-06-01 – 2026-06-01
2022/2027 - board	700,000 (0)	700,000	87,500	0.91	2025-06-01 – 2027-06-01
2022/2027 - others	700,000 (0)	700,000	87,500	0.91	2025-06-01 – 2027-06-01
Total	2,863,100 (1,083,100)	3,108,000	388,500		

### **Annual General Meeting**

The annual general meeting will be held on 23 May 2023 at 10:00 in Uppsala. The annual report will be published on www.dicot.se no later than April 24 and it will also be available to the public at the company's office at S:t Olofsgatan 11A in Uppsala.

#### **Financial Calendar**

2023-05-19	Interim report January-March 2023
2023-05-17	
	Annual general meeting 2023
2023-08-24	Interim report January-June 2023
2023-11-09	Interim report January-September 2023

### **Proposal for Dividend**

The board proposes that no dividend is to be paid for the financial year of 2022.

#### **Auditor Review**

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

#### **Contact Information**

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Uppsala February 27, 2023

**Eva Sjökvist Saers** Chairman of the Board Fredrik Buch Board Member Mikael von Euler-Chelpin Board Member

Per-Göran Gillberg Board Member

**Lena Söderström**Board Member

Michael Zell Board Member

### **Income Statement**

KSEK	Oct - Dec 2022	Oct - Dec 2021	Jan - Dec 2022	Jan - Dec 2021
Net Sales				
Other operating income	32	4	120	79
Net sales	32	4	120	79
Operating expenses				
Other external expenses	-7,303	-7,215	-26,612	-23,851
Personnel	-1,266	-1,161	-5,053	-3,276
Depreciation	-2	-8	-8	-8
Other operating expenses	-32	-28	-170	-115
Operating expenses	-8,603	-8,412	-31,843	-27,250
Operating profit / loss	-8,571	-8,408	-31,723	-27,171
Profit / loss from financial items	-33	0	-33	-4
Earnings for the period	-8,604	-8,408	-31,756	-27,175

### **Balance Sheet**

KSEK Dec 31, 202	22	Dec 31, 2021
ASSETS		
Fixed assets		
Material assets	21	28
Total fixed assets	21	28
Current assets		
Inventories 1,4	89	0
Current receivables 1,4	85	1,412
Cash and bank balances 9,3	76	30,328
Total current assets 12,3	50	31,740
TOTAL ASSETS 12,3	71	31,768
EQUITY AND LIABILITIES		
Equity 5,3	58	28,351
Current liabilities 7,0	13	3,417
TOTAL EQUITY AND LIABILITIES 12,3	71	31,768

## **Cash Flow Statement in Summary**

KSEK	Jan-Dec 2022	Jan-Dec 2021
Cash flow from operating activities	-29,715	-25,866
Cash flow from investing activities	-	-
Cash flow from financing activities	8,763	35,867
Change in cash and cash equivalents	-20,952	10,001
Cash and cash equivalents at the start of the period	30,328	20,327
Cash and cash equivalents at the end of the period	9,376	30,328

## **Change in Equity**

KSEK	Share Capital	Share Premium Reserve	Other Non-Restricted Equity	Total Equity
0	5 450	50.005	22.224	40.000
Opening balance January 1, 2021	5,459	53,205	-39,004	19,660
Warrants program		9		9
Rights issue	7,404	33,011		40,415
Issue costs		-4,558		-4,558
Earnings for the period			-27,175	-27,175
Closing balance December 31, 2021	12,863	81,667	-66,179	28,351
Opening balance January 1, 2022	12,863	81,667	-66,179	28,351
Rights issue	4,275	5,643		9,918
Issue costs		-1,156		-1,156
Earnings for the period			-31,756	-31,756
Closing balance December 31, 2022	17,138	86,154	-97,935	5,358

## **Earnings per Share**

KSEK	Oct-Dec 2022	Oct-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
Earnings for the period	-8,604	-8,408	-31,756	-27,175
Number of shares at closing day	137,103,020	102,900,206	137,103,020	102,900,206
Average number of shares, before dilution	137,103,020	82,624,613	12, 235,879	64,133,066
Average number of shares, after dilution	138,216,120	101,502,994	121,348,979	69,324,987
Earnings per average number of shares, before and after dilution, SEK	-0.06	-0.10	-0.26	-0.42