# DICOT

**SUMMARY OF INTERIM REPORT**
**JANUARY - SEPTEMBER 2022**
Dicot AB (publ) 559006-3490

# Contents

# Summary of Interim Report

## January - September 2022

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## Overview January - September 2022

### THIRD QUARTER 2022

- Net sales amounts to **54 KSEK** *(0 KSEK)*
- Profit after financial items amounted to **-5,073 KSEK** *(-4,716 KSEK)*
- Earnings per share amounted to **-0.04 SEK** *(-0.07 SEK)*

### JANUARY - SEPTEMBER 2022

- Net sales amounts to **89 KSEK** *(30 KSEK)*
- Profit after financial items amounted to **-23,152 KSEK** *(-18,767 KSEK)*
- Earnings per share amounted to **-0.20 SEK** *(-0.32 SEK)*

## Significant events during the Third Quarter

- On July 1, payment was received from the warrants of series TO 3 that were subscribed for during June. Dicot received a net contribution of SEK 9.0 million.
- In July, Charlotta Gauffin assumed the role of Chief Scientific Officer (CSO) with the task of managing the development of the company's potency drug. Gauffin has over 20 years of experience in drug development, of which more than 15 years in clinical development.
- During the third quarter, evaluation and procurement of the CRO service for Dicot's phase 1 clinical trials began, i.e., the first human studies which are planned to start in mid-2023.

## Significant events after the end of the period

- On October 11, good results from the preclinical toxicology program with the drug candidate LIB-01 were reported. LIB-01 has so far shown to be well tolerated with a good safety profile and no signs of side effects have been seen in the animal studies.
- On October 17, Dicot announced that a new patent application has been submitted in accordance with the company´s IP-plan. It includes both new production methods and intermediates (various chemical compounds) during the manufacture of the drug substance.
- Late October, Dicot announced that parts of the manufacturing of the drug candidate are being moved to South Africa where the starting material is already being handled. It will lead to improved logistics, shorter lead times and reduced costs.

# About Dicot AB

**Dicot wants to drastically change the way of treating erectile dysfunctions and give affected men and couples an increased quality of life. Our vision is that LIB-01 will be the first choice of drug when treating erectile dysfunction and premature ejaculation.**

**THE GLOBAL MARKET** for erectile dysfunction drugs was worth 4.4 billion euros in 2021 and demand is growing rapidly. In major western markets, the number of pharmaceuticals sold has increased by 41% since 2018.[1]

**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% consider the treatments to lack the desired effect and many experience side effects and concerns about cardiovascular side effects.[2,3] These preparations also display a short duration time – 6 to 36 hours – which reduces sex life spontaneity.

**THE NEED FOR NEW TREATMENTS** is verified by medical experts within the field of sexual medicine. Dr. Chris McMahon, former president of The International Society of Sexual Medicine, says that ”weekly treatments with proven efficiency, good safety protocols and without significant side effects would be a game changer”.

**DICOT IS DEVELOPING A MODERN** potency drug that will treat erectile dysfunction and premature ejaculation better than existing pharmaceuticals, with significantly longer duration time and far fewer side effects. The goal is also for the drug to be applicable for a considerably larger treatment group than today’s pharmaceuticals.

**THE MAIN STRATEGY** is to develop LIB-01 through clinical phase 2 trials and then engage into strategic partnerships with established pharmaceutical companies to take the substance all the way to a registered drug on the world market.

**LIB-01 HAS BEEN DEVELOPED** based on traditional folk medicine usage of the root from the tree *Neobeguea Mahafalensis*, from which the founder of Dicot, Professor Jarl Wikberg, in his research managed to isolate previously unknown substances. Today, seeds are used as raw materials and through an extraction process followed by a number of synthesis steps, elements of the seeds are converted into the active substance in LIB-01.

[1] Analysis by IQVIA 2021 including the US, Great Britain, German, French and Nordic markets. [2] Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation, May 2012,Journal of Sexual Medicine 9(9):2361-9. [3] McMahon CN, Smith CJ, Shabsigh R. Treating erectile dysfunction when PDE5 inhibitors fail. BMJ 2006;332:589-92.

# Statement from the CEO

**During the third quarter, the development work has continued according to defined time frames and we are getting closer and closer to start of the phase 1 clinical trials. Procurement of a CRO for conducting clinical studies has also begun this eventful quarter. We recently reported on good results from toxicology studies, an important part of the authorities' assessment prior to the start of clinical studies in humans. We have also visited our partners in South Africa, which provided opportunity for in-depth dialogues to further develop our collaborations.**

*"The drug development has continued at full speed during the quarter. We are on schedule to start clinical trials mid next year"*

**MYSELF AND DICOT'S CSO**, Charlotta Gauffin, have recently returned from a very valuable trip to South Africa where we met with our partners. The active substance in LIB-01 is a semi-synthetically produced molecule with starting material from nature. It is seeds that undergo an extraction process followed by a number of synthesis steps. Everything starts in South Africa where our main partner Parceval with its experience and network, coordinates all activities connected to the raw material.

**IT IS CLEAR** that there is a great dedication from our partners. Meetings and site visits in South Africa have given us many insights to take forward to facilitate collaboration and for Dicot to make well-grounded decisions. One result of the good collaboration is that we now take the step to move the extraction process from Sweden to South Africa. By moving this part of the manufacturing, unnecessary transportation is avoided, it facilitates the coordination of activities and not least, reduces our costs.

**THE DRUG DEVELOPMENT** has continued at full speed during the quarter. We are on schedule to start clinical trials mid next year and now the procurement of a CRO to perform our clinical trials has begun. We have sent out application documents to leading research organizations that we consider to be innovative and modern and have been met with great international interest in working with our candidate. In addition to that, our toxicology program is also in full swing, and we have recently reported results showing that LIB-01 has a good safety profile and that no side effects have been identified so far.

**DURING THE MONTH OF JULY**, we had the privilege of presenting the results of our preclinical effect studies at the European Association of Urology, a scientific forum that we previously announced had selected our submitted abstract for presentation during its 2022-year congress.

**THE CAPITAL INJECTION** in July from the warrant program in the second quarter has enabled us to follow our set schedule and expenditure framework for both preclinical work and business development. At the same time, we are now working on securing funding for the upcoming phase 1 clinical trials.

**EVERY IMPORTANT INNOVATION** requires strong IP protection and we have now submitted the new patent application, that we announced before the summer we were working on. A new patent means market exclusivity until at least 2042 on a global market, which greatly increases the long-term value of LIB-01.

**THE THIRD QUARTER** of the year has been eventful, and it is with great pleasure that I see the commitment and drive of the Dicot team and our partners.

**Elin Trampe, CEO Dicot**
**Uppsala in October 2022**

# Comments to the Report

**During the third quarter, the preparations for the phase 1 clinical trials have run completely according to plan. To ensure a good and scalable flow of raw material and active substance, a stock of material covering the phase 1 trials has been built up. The operating costs for the third quarter amounting to 5 127 (4 716) KSEK are 9% higher than the corresponding period last year, which is in line with budgeted costs. The increase is explained by personnel costs in connection with the company going from one to two full-time employees. The total personnel costs are still deliberately low due to the majority of the resources that contribute to the development of the LIB-01 project are contracted when needed as part-time resources.**

**For the first nine months of the year, operating costs amounted to 23 241 (18 793) KSEK, an increase that reflects greater activity in preclinical studies and manufacturing of drug substance and oral formulation.**

**The company's cash in bank at the end of the period amounted to SEK 14.5 million (17.0).**

## Accounting Principle

The interim 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.

**See the company's annual report from 2021 for more information.**

## Liquid Funds

Cash and cash equivalents at the end of the period amounted to SEK 14.5 million (17.0). On the first of July, SEK 9.0 million was received, which constituted the net amount from the warrant program TO3.

## Earnings per Share

Earnings per share for the reporting period January-September amounted to SEK -0.20 (-0.32).

## The Stock

Dicot AB was listed on the Spotlight Stock Market on June 20, 2018. As of September 30, 2022, the number of shares amounted to 137 103 020 and the quota value per share to SEK 0.125.

The stock price as of September 30 was SEK 0.483, an increase of 0.6% compared to the beginning of the quarter. Trading in the share during the quarter was lower than during the same period last year, one reason being that a new issue was announced last year.

## Financing

The subscription program TO3, which was carried out in June, brought in SEK 9.0 million after issue costs through an issue of new shares. The disruptive macroeconomic effects in the external environment, reflected in the fact that the index for listed companies fell significantly during the spring, meant for Dicot´s part that the amount was lower than expected despite a subscription rate of 90%.

During the first quarter of 2023, the company will need additional working capital to start the phase 1 trials in mid-2023, which is in accordance with the plan that the company has communicated during the year.

The board and management are therefore working with various financing options to ensure continued operations in the short and long term. Tools available in the current development phase are primarily right issues and/or directed issues, but also partnerships, soft capital, outlicensing and other types of capital injections.

The authorization the board received at the annual general meeting to be able to decide on one or more occasions to increase the company's share capital by up to twenty percent of the registered share capital has not yet been used. The authorization may be used to issue shares, warrants and/or convertible loans, also with a deviation from the shareholders' pre-emptive right.

Dicot has four ongoing incentive programs in the form of warrants:

| Option program | Number of warrants | Exercise price (SEK) | Time for share subscription |
|---|---|---|---|
| 2018/2023 | 3 100 | 14,25 | 2018-05-08 – 2023-04-30 |
| 2019/2024 | 110 000 | 20,00 | 2019-07-03 – 2024-05-16 |
| 2020/2025 | 250 000 | 7,50 | 2020-06-05 – 2025-05-26 |
| 2021/2026 | 750 000 | 4,10 | 2024-06-01 – 2026-06-01 |

In addition to the above, the annual general meeting decided on two option programs with a term from 2022 to 2027. These options were signed by the company on May 31 but have not been transferred to the participants as of the balance sheet date.

## Financial Calendar

| | |
|---|---|
| Year-end Report 2022 | February 27, 2023 |
| Annual Report 2022 | Prel. week 17, 2023 |
| Interim Report Jan-March 2023 | May 9, 2023 |
| Annual General Meeting | May 23, 2023 |

## Auditor Review

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

## Contact Information

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Uppsala November 1, 2022

**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 | Jul - Sep 2022 | Jul - Sep 2021 | Jan - Sep 2022 | Jan - Sep 2021 | Full Year 2021 |
|---|---|---|---|---|---|
| **Net sales** | | | | | |
| Other operating income | 54 | 0 | 89 | 30 | 79 |
| **Net sales** | **54** | **0** | **89** | **30** | **79** |
| **Operating expenses** | | | | | |
| Other external expenses | –3 982 | –3 925 | –19 309 | –16 637 | –23 851 |
| Personnel | –1 073 | –784 | –3 788 | –2 115 | –3 276 |
| Depreciation | –2 | 0 | –6 | 0 | –8 |
| Other operating expenses | –70 | –7 | –138 | –41 | –115 |
| **Operating expenses** | **–5 127** | **–4 716** | **–23 241** | **–18 793** | **–27 250** |
| **Operating profit/loss** | **–5 073** | **–4 716** | **–23 152** | **–18 763** | **–27 171** |
| Profit/loss from financial items | 0 | 0 | 0 | –4 | –4 |
| **Earnings for the period** | **–5 073** | **–4 716** | **–23 152** | **–18 767** | **–27 175** |

# Balance Sheet

| KSEK | Sep 30, 2022 | Sep 30, 2021 | Dec 31, 2021 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Material assets | 23 | 36 | 28 |
| **Total fixed assets** | **23** | **36** | **28** |
| **Current assets** | | | |
| Inventories | 1 464 | 0 | 0 |
| Current receivables | 1 278 | 1 793 | 1 412 |
| Cash and bank balances | 14 513 | 17 026 | 30 328 |
| **Total current assets** | **17 255** | **18 819** | **31 740** |
| **TOTAL ASSETS** | **17 278** | **18 855** | **31 768** |
| **EQUITY AND LIABILITIES** | | | |
| Share capital | 14 168 | 16 929 | 28 351 |
| Current liabilities | 3 110 | 1 926 | 3 417 |
| **TOTAL EQUITY AND LIABILITIES** | **17 278** | **18 855** | **31 768** |

# Cash Flow Statement in Summary

| KSEK | Jan - Sep 2022 | Jan - Sep 2021 | Full Year 2021 |
|---|---|---|---|
| Cash flows from operating activities | –24 783 | –19 338 | –25 866 |
| Cash flow from investing activities | - | - | - |
| Cash flow from financing activities | 8 968 | 16 037 | 35 867 |
| **Change in cash and cash equivalents** | **–15 815** | **–3 301** | **10 001** |
| Cash and cash equivalents at the start of the period | 30 328 | 20 327 | 20 327 |
| **Cash and cash equivalents at the end of the period** | **14 513** | **17 026** | **30 328** |

# Change in Equity

| KSEK | Share Capital | Share Premium Reserve | Other non-Restricted Equity | Total Equity |
|---|---|---|---|---|
| Opening balance January 1, 2021 | 5 458 | 53 205 | –39 004 | 19 659 |
| Warrants program | - | 9 | | 9 |
| Rights issue | 2 646 | 14 709 | | 17 355 |
| Issue costs | | –1 327 | | –1 327 |
| Earnings for the period | | | –18 767 | –18 767 |
| **Closing balance Sep 30, 2021** | **8 104** | **66 596** | **–57 771** | **16 929** |
| Opening balance January 1, 2022 | 12 863 | 81 667 | –66 179 | 28 351 |
| Rights issue | 4 275 | 5 643 | | 9 918 |
| Issue costs | | –950 | | –950 |
| Earnings for the period | | | –23 152 | –23 152 |
| **Closing balance Sep 30, 2022** | **17 138** | **86 360** | **–89 331** | **14 168** |

# Earnings per Share

| | Jul - Sep 2022 | Jul - Sep 2021 | Jan - Sep 2022 | Jan - Sep 2021 | Full Year 2021 |
|---|---|---|---|---|---|
| Earning for the period, KSEK | –5 073 | –4 716 | –23 152 | –18 767 | –27 175 |
| Number of shares at closing day | 137 103 020 | 64 831 745 | 137 103 020 | 64 831 745 | 102 900 206 |
| Average number of shares, before dilution | 137 103 020 | 64 831 745 | 114 551 714 | 57 901 483 | 64 133 066 |
| Average number of shares, after dilution | 138 216 120 | 65 944 845 | 115 664 814 | 58 531 249 | 69 324 987 |
| Earnings per average number of shares before and after dilution, SEK | –0,04 | –0,07 | –0,20 | –0,32 | –0,42 |