DICOT

INTERIM REPORT JANUARY – SEPTEMBER 2023

Dicot AB (publ) 559006-3490

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Interim report January – September 2023

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Third quarter 2023

Net sales amounted to KSEK 0 (0)

The result after financial items amounted to KSEK -8,501 (-5,073)

Earnings per share amounted to SEK -0.01 (-0.04)

January – September 2023

Net sales amounted to KSEK 0 (0)

The result after financial items amounted to KSEK -28,496 (-23,152)

Earnings per share amounted to SEK -0.06 (-0.20)

Significant events in the third quarter

In August, Dicot received approvals from the Swedish Medical Products Agency and the Swedish Ethical Review Authority to initiate the Phase 1 clinical trial for the drug candidate LIB-01. The study is a placebo-controlled trial with its primary objective to assess the safety profile in humans.

The study commenced on August 25, with the first participants being dosed in early September. The study is being conducted at the Academic Hospital in Uppsala, where the company's clinical partner CTC has its hospital clinic.

In August, a new patent application was submitted, covering the oral formulation of the investigational drug currently used in the ongoing clinical study. This patent application is known as a provisional patent application, with the aim of obtaining an approved patent in the United States, that will be followed by an application to the Swedish Patent and Registration Office for the Swedish market and thereafter for other markets.

In September, an additional patent application was filed. This was an international patent application through the Patent Cooperation Treaty, which provides the opportunity for protection in 157 countries, offering indirect protection during the processing period. In addition to this, Dicot has submitted a fast track application for the key market, the United States. The patent application encompasses drug substances under development and their manufacturing methods.

Significant events after the reporting period

The subscription price for the exercise of TO5 warrants has been set at SEK 0.086 which corresponds to 70% of the stock's volume-weighted average price from October 13 to October 27.

The Sexual Medicine Society North America has selected Dicot's research findings as one of the agenda items at its annual congress in November. Sexual medicine expert Professor François Giuliano will present Dicot's preclinical program that underlies the potency drug candidate LIB-01.

Dicot in brief

The pharmaceutical company Dicot is developing the 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 available on the market today. This way, Dicot wants to drastically improve the treatment of erection problems and give affected men and couples a better intimate life. The goal is to make LIB-01 the first choice of treatment for erectile dysfunction and premature ejaculation.

LIB-01 is in phase 1 clinical trial, primarily aimed at assessing its safety profile in humans. Dicot has performed a robust preclinical program, where the effect of LIB-01 has been validated through several studies, and a favorable safety profile has been demonstrated in the toxicology studies.

Dicot's main strategy is to develop LIB-01 under own auspice up to and including a phase 2a clinical trial, and then, in partnership with major established pharmaceutical companies, finance and develop LIB-01 further into a registered drug on the world market. The global sales of drugs for erectile dysfunction is reported to be worth approximately SEK 50 billion in 2023 and for premature ejaculation approximately SEK 32 billion, totaling SEK 82 billion. Demand is growing rapidly and is expected to increase by over 50% from 2022 to 2029.

Given the frequently reported shortcomings of the currently available drugs, such as side effects, lack of efficacy and need of planning, they are used by far from everyone who has a need. It can therefore be assumed that the underlying market is many times larger than current sales figures reflect. The potential for new treatments with different mechanisms of action is therefore very large.

Dicot collaborates with world-leading partners for the development of LIB-01. Manufacturing is outsourced to established international pharmaceutical manufacturers such as Thermo Fisher Scientific and the company has a worldwide network of prominent experts in the field.

The active substance in LIB-01 is a semi-synthetically produced molecule based on 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. Simultaneously, studies are underway on an alternative method using cell culture for large-scale production of the starting material.

Dicot has a global and long-term IP strategy with granted patents in four patent families. In addition to already granted patents, an additional patent application has been submitted to provide IP protection until at least 2042.

Statement from the CEO

Quarter three. A quantum leap for Dicot. The Phase 1 study began as planned in August and is now in full swing. In November, dosing for the second part of the study, referred to as a MAD, will commence. Concurrently, many other important activities are underway to lead us into the future our hard work is aimed at. Strengthening our IP-protection, as we've done during this quarter, is one way to manage that future, but also to visualize the significant change that LIB-01 is set to bring.

Important events are taking place for Dicot here in Uppsala, undoubtedly. At a research clinic in the Academic Hospital in Uppsala, exactly 24 individuals have already been dosed in our clinical study to assist in evaluating the safety of LIB-01.

Simultaneously, we are looking towards the rest of the world and the future we envision for our candidate. A future where our commercial protection has been bolstered during this quarter through active management of the patent portfolio. At the end of September, an international patent application was submitted, covering 157 of the world's 195 countries. This is done through the so-called Patent Cooperation Treaty, which provides indirect protection also during the processing period. Although the USA is included in this PCT application, we have simultaneously submitted the same patent application directly to the United States Patent and Trademark Office via the fast-track Patent Prosecution Highway. This is intended to expedite the process in this crucial key market.

In the immediate future, we are about to dose participants in the second half of the Phase 1 study: our MAD. Instead of a single dose, participants receive multiple consecutive doses, followed by thorough safety checks, which is standard procedure for this type of study.

In November, our research findings will be presented at a scientific conference in the field of sexual medicine in San Diego. Renowned urologist Professor François Giuliano, who has been behind all our preclinical effect studies, will deliver the presentation, as he sees the potential of LIB-01 to make a significant difference. This provides an excellent opportunity to reach an international audience with our results.

And tomorrow November 1, the subscription period for TO5, our second warrant exercise this year, will commence. After an oversubscribed issue in January and a successful TO4 in June, we hope for continued strong engagement and trust from our investors.

Now that we have initiated our first in human study, my thoughts increasingly turn to all the men and couples we are working to assist. How relationships are strained today when intimate life doesn't function. How performance anxiety creates wounds in men's self-esteem, likely also in their partners.

My thoughts then shift into the future, to the point when we have developed a drug capable of helping those affected to reclaim their love life. When we can contribute to healing self-esteem, and sex is once again experienced as intimate, enjoyable, and spontaneous. Not until that happens will we decrease our efforts.

Elin Trampe
CEO Dicot
Uppsala, October 2023

"Important events are taking place for Dicot. At a research clinic in Uppsala, exactly 24 individuals have already been dosed."

Comments on the report

Dicot is a development company in pre-commercial phase and thus has no revenues yet. With the planned start of the clinical trial in the third quarter, Dicot's partner CTC, which is conducting the study, has initiated its work. This intensifies the development of the project and costs in the third quarter 8,682 KSEK (5,127) therefore increase by 3,555 KSEK compared to the same period last year when the company was in pre-clinical phase. The increase primarily pertains to the implementation of the clinical Phase 1 study.

Both the drug development of LIB-01 and the financial results are in line with the forecasts.

The equity amounted to SEK 44.5 million (14.2) at the end of the quarter.

Cash and cash equivalents

Liquid assets at the end of the period amounted to SEK 44.9 million (14.5).

Earnings per share

Earnings per share for the reporting period amounted to SEK -0.01 (-0.04).

The share

Dicot AB has been listed on Spotlight Stock Market since June 20, 2018. At the end of the period, the number of shares amounted to 625,147,346 and the share's closing price was SEK 0.148. The quota value was SEK 0.042.

Funding

In order to finance Dicot's clinical phase 1 study and ongoing operations, the Board of Directors decided in December 2022 to carry out a rights issue of units which, if fully subscribed, would initially provide Dicot with SEK 54.8 million before issue costs.

In January 2023, the issue was carried out, which was subscribed to 110% and provided Dicot with a net amount of SEK 50.1 million after issue costs, including set-off of guarantee compensation in a subsequent directed issue. The issues consisted of units containing shares and two series of warrants. The first series could be exercised in June 2023 and provided Dicot with gross proceeds of SEK 20.7 million after 83% subscription. The second series can be exercised in November 2023.

The share capital has been reduced during the first half of the year through transfer to the premium reserve in order to create a more purposeful capital structure.

To ensure Dicot's continued development and operations, the Board of Directors and management team continuously evaluate various financing options. This can be by obtaining capital from a future partner, a new share issue, grant financing or other types of capital contribution. The company also has the possibility to limit costs and commitments if necessary.

At the end of the quarter, Dicot has the following outstanding incentive programs:

Options program	Number of warrants (of which distributed)	Number of new shares	Increase in share capital	Strike price (SEK)	Time for share subscription
2019/2024	110,000 (80,000)	110,000	770	20.00	2019-07-03–2024-05-16
2020/2025	350,000 (250,000)	350,000	2,450	7.50	2020-06-11–2025-05-26
2021/2026 - board of directors	350,000 (300,000)	350,000	2,450	4.10	2024-06-01–2026-06-01
2021/2026 - others	650,000 (450,000)	650,000	4,550	4.10	2024-06-01–2026-06-01
2022/2027 - board of directors	700,000	700,000	4,900	0.91	2025-06-01–2027-06-01
2022/2027 - others	700,000	700,000	4,900	0.91	2025-06-01–2027-06-01
2023 TO5	225,229,530 (225,229,530)	225,229,530	1,576,607	0.086	2023-11-01–2023-11-15
Total	**228,089,530 (226,309,530)**	**228,089,530**	**1,596,627**		

Accounting principles

The annual report has been 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, see Dicot's annual report for 2022 https://www.dicot.se/investor-relations/finansiella-rapporter-och-emissioner/finansiella-rapporter/

Financial calendar

February 26, 2024	Year-End Report 2023
Week 15, 2024	Annual Report 2023
May 6, 2024	Annual General Meeting

Review by the auditor

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

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Uppsala October 31, 2023

Eva Sjökvist Saers
Chairman of the Board

Fredrik Buch
Board member

Mikael von Euler-Chelpin
Board member

Per-Göran Gillberg
Board member

Michael Zell
Board member

Jan-Eric Österlund
Board member

Income statement

KSEK	Jul-Sep 2023	Jul-Sep 2022	Jan-Sep 2023	Jan-Sep 2022	Full year 2022
OPERATING INCOME					
Other operating income	8	54	16	89	120
Operating income	**8**	**54**	**16**	**89**	**120**
OPERATING EXPENSES					
Other external expenses	-7,481	-3,982	-24,547	-19,309	-26,612
Personnel	-1,188	-1,073	-4,038	-3,788	-5,053
Depreciation	-2	-2	-6	-6	-8
Other operating expenses	-11	-70	-183	-138	-170
Operating expenses	**-8,682**	**-5,127**	**-28,774**	**-23,241**	**-31,843**
Operating profit/loss	**-8,674**	**-5,073**	**-28,758**	**-23,152**	**-31,723**
Financial net	173	0	262	0	-33
Earnings for the period	**-8,501**	**-5,073**	**-28,496**	**-23,152**	**-31,756**

Balance sheet

KSEK	Sep 30 2023	Sep 30 2022	Dec 31 2022
ASSETS			
Fixed assets			
Material assets	15	23	21
Total fixed assets	**15**	**23**	**21**
Current assets			
Inventories	2,686	1,464	1,489
Current receivables	2,537	1,278	1,485
Cash and bank balances	44,852	14,513	9,376
Total current assets	**50,075**	**17,255**	**12,350**
Total assets	**50,090**	**17,278**	**12,371**
EQUITY AND LIABILITIES			
Share capital	44,467	14,168	5,358
Current liabilities	5,623	3,110	7,013
Total equity and liabilities	**50,090**	**17,278**	**12,371**

Cash flow statement

KSEK	Jan-Sep 2023	Jan-Sep 2022	Full year 2022
Operating activities			
Earnings before financial items	-28,496	-23,152	-31,756
Adjustment for depreciation	6	4	8
Cashflow from operating activities before change in working capital	**-28,490**	**-23,148**	**-31,748**
Change in working capital			
Change in stock and work in progress	-1,196	-1,463	-1,489
Change in current receivables	-1,052	134	-70
Change in current liabilities	-1,391	-306	3,593
Cashflow from operating activities	**-32,129**	**-24,783**	**-29,714**
Investing activities			
Investments in material assets	-	-	-
Cash flow from investing activities	**0**	**0**	**0**
Financing activities			
Shares issues	67,605	8,968	8,763
Cash flow from financing activities	**67,605**	**8,968**	**8,763**
Change in cash and cash equivalents	**35,476**	**-15,815**	**-20,952**
Cash and cash equivalents at the start of the period	9,376	30,328	30,328
Cash and cash equivalents at the end of the period	44,852	14,513	9,376

Change in equity

KSEK	Share capital	Share premium reserve	Other non-restricted equity	Total equity
Opening balance January 1, 2022	12,863	81,667	-66,179	28,351
Rights issue, ongoing	4,275	5,643		9,918
Issue costs		-950		-950
Earnings for the period			-23,152	-23,152
Closing balance September 30, 2022	**17,138**	**86,360**	**-89,331**	**14,168**
Opening balance January 1, 2023	17,138	86,154	-97,934	5,358
Rights issue	34,276	20,565		54,841
Directed shares issue	1,096	4,124		5,220
Rights issue, TO4	1,314	19,337		20,651
Issue costs		-13,107		-13,107
Reduction of share capital	-49,448	49,448		-
Earnings for the period			-28,496	-28,496
Closing balance September 30, 2023	**4,376**	**166,521**	**-126,430**	**44,467**

Earnings per share

KSEK	Jul-Sep 2023	Jul-Sep 2022	Jan-Sep 2023	Jan-Sep 2022	Full year 2022
Earnings for the period	-8,501	-5,073	-28,496	-23,152	-31,756
Number of shares at closing day	625,147,346	137,103,020	625,147,346	137,103,020	137,103,020
Average number of shares, before dilution	625,147,346	137,103,020	472,761,872	114,551,714	120,235,879
Average number of shares, after dilution	851,486,876	114,551,714	665,735,097	115,664,814	121,348,979
Earnings per average number of shares before and after dilution, SEK	-0.01	-0.04	-0.06	-0.20	-0.26

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