



DexTech
Know-how in Translational Research

DexTech Medical AB
Interim report July 1 - September 30, 2022

By "Company" or "DexTech" is meant DexTech Medical AB with organization number 556664-6203.

Summary of the first quarter (2022-07-01 – 2022-09-30)

- Net sales amounted to MSEK 0,0 (0,0)
- Operating profit/loss amounted to MSEK -0,8 (-0,9)
- Earnings per share* SEK -0,04 (-0.06)
- Cash and cash equivalents at the end of the period amounted to MSEK 33,9 (35,5)

** Before and after dilution. Earnings per share: Profit for the period divided by the average number of shares 18,485,857. For the comparison period, the average number of shares was 14,920,478. Amounts in brackets refer to the corresponding period last year.*

CEO's comment

The application for a phase 1 clinical study regarding OsteoDex treatment of multiple myeloma, has now been approved by the Swedish Medical Products Agency and permission was announced on August 10, 2022. The study will include 20 patients with multiple myeloma and be conducted at approximately 4–5 hospital centers in Sweden and the rest of the Nordic region. It is expected to start no later than Q1 2023 and is expected to be completed in Q3 2024.

Principal investigator (PI) is Dr Katarina Uttervall, MD, PhD, Division of Hematology/HERM, Karolinska University Hospital, Huddinge. The main blood markers will be analyzed at the Central Laboratory, Karolinska University Hospital, NKS, Solna. The patients included have relapsed/treatment-resistant disease and have received 1–3 prior lines of therapy. The primary objective is to confirm safety and tolerability and as a secondary objective to determine treatment response documented by changes in the level of disease-related biomarkers. Documentation of quality of life will also be done (QoL scores).

Anders R Holmberg
CEO

Significant events during the interim period (July – September 2022)

DexTech announced on August 10, 2022 that the application for a phase 1 study regarding OsteoDex's effect on patients with multiple myeloma has been approved and granted permission by the Swedish Medicines Agency. The study will include 20 patients and will be conducted at 5 hospital centers in Sweden and Norway. The study is estimated to start during quarter 1 2023 at the latest and is estimated to be completed during quarter 3 2024.

DexTech announced on September 27, 2022 that the phase 1 study regarding OsteoDex's effect on patients with multiple myeloma will include 20 patients and be conducted at 4-5 hospitals in Sweden and other Nordic countries. Study is expected to start in Q1 2023 and be completed during Q4, 2024. Principal investigator (PI) is Dr Katarina Uttervall, MD, PhD, Division of Hematology/HERM, Karolinska University Hospital, Huddinge. The main blood markers will be analyzed at the Central Laboratory, Karolinska University Hospital, NKS, Solna. The study duration for each individual patient is 14 weeks, from screening to follow-up visits. Each patient will receive OsteoDex every two weeks, a maximum of 7 doses. Adult MM patients with recurrent/treatment-resistant disease, who received 1-3 previous lines of therapy, will be included. The primary objective is to confirm safety and tolerability. The secondary objective is to determine treatment response, change in the level of disease-related biomarkers, and documentation of quality of life (QoL scores).

Events after the end of the interim period

No events to report for the period after the end of the interim period.

Financial overview

	First Quarter	
	2022-07-01	2021-07-01
	2022-09-30	2021-09-30
Net sales, KSEK	–	–
Operating profit/loss, KSEK	-815	-945
Profit/loss before tax, SEK*	-0,04	-0,06
Cash flow from operating activities, KSEK	-668	-366
Cash flow from investing activities, KSEK	-943	-43
Cash flow from financing activities, KSEK	–	–
Cash flow for the year	-1 611	-409
<i>* before dilution</i>		
	2022-09-30	2022-06-30
Cash and cash equivalents, KSEK	33 862	35 473
Total assets, KSEK	38 283	39 589
Equity ratio, %	99	97

Results, The first quarter, July – September 2022

Turnover and earnings

The company had no sales during the first quarter. Operating profit amounted to MSEK -0,8 (-0,9). During the first quarter, costs of MSEK 0,9 (0,0) were capitalized for drug development and patents. Operating expenses amounted to MSEK 1,8 (1,0) and consist of personnel costs MSEK 0,2 (0,1), other external expenses MSEK 1,2 (0,3) and depreciation MSEK 0,4 (0,6). Other external costs include costs for patents MSEK 0,1 (0,1) and regulatory control MSEK 0,8 (-) regarding the phase IIb study. Profit after tax amounted to MSEK -0,8 (-0,9).

Liquidity and financing

Cash and cash equivalents at the end of the period amounted to MSEK 33,9 (35,5).

Cash flow for the period amounted to MSEK -1,6 (-0,4).

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Financing is done with equity. Equity at the end of the financial year amounted to MSEK 38,1 (38,9), corresponding to SEK 2.06 (2.10) per share. The equity / assets ratio was 99 (98) percent.

Working capital

During December 2021, DexTech carried out a rights issue that provided the Company with SEK 46.3 million before issue costs. DexTech received SEK 37.1 million net after issue costs of SEK 9.2 million. The rights issue in 2021 ensured continued operations until the end of 2024. The goal is for license revenues to finance operations thereafter.

Operations

DexTech Medical, org.no 556664-6203 based in Stockholm, develops drug candidates with application in urological oncology, primarily prostate cancer. The business began on August 9, 2004 and the Company was listed on the Spotlight Stock Market on June 19, 2014.

The company has a strong clinical foundation with valuable specialist expertise, from research laboratory and manufacturing to clinical oncology. Research and development are conducted cost-effectively through collaborations in a global network.

Based on a proprietary patented technology platform, GuaDex, the Company has developed four different drug candidates, OsteoDex, SomaDex, CatDex & GuaDex and a PSMA-binding conjugate, with patents / patent applications in several key markets.

- The company's main candidate, *OsteoDex*, for the treatment of skeletal metastases in castration-resistant prostate cancer, CRPC, has shown strong tumor-killing effect and potent inhibition of bone destruction after extensive preclinical studies. Following a successful phase I / IIa study in which the result shows high tolerability with only mild side effects and a clear effect in the highest dose group, a clinical phase IIb study (efficacy study) was initiated in autumn 2014. The complete clinical study report (CSR) from the phase IIb study for OsteoDex was completed in December 2018. The study conducted in Sweden, Finland, Estonia and Latvia included 55 well-defined patients with castration-resistant prostate cancer with skeletal metastases (mCRPC).
- *SomaDex* for the treatment of acromegaly, neuroendocrine tumors and palliative treatment for advanced prostate cancer. SomaDex is a drug candidate based on a body hormone, somatostatin for the treatment of acromegaly, neuroendocrine tumors and palliative therapy for advanced prostate cancer. SomaDex has undergone a Phase I clinical trial (in Sweden / Finland) and a Phase II pilot study in Mexico. The studies showed that SomaDex has few and mild side effects (phase I) and has a soothing effect (palliative) in advanced prostate cancer (pilot study).
- *CatDex & GuaDex*: GuaDex is the so-called. technology platform and is a charge-modified dextran molecule with tumor toxic properties (kills tumor cells) and is a development of CatDex.
- *PSMA-binding conjugate*, for target-specific treatment of mCRPC overexpressing PSMA (prostate-specific membrane antigen). The association is based on the platform, GuaDex.

DexTech's goal is to license the respective drug candidate by the latest phase II study. The technology platform, which can be likened to a "subway box" with multiple opportunities to build new molecules, can also be licensed.

The following parameters have been important for DexTech's positive development to date:

- modified generics with well-documented mechanisms of action that are patented, resulting in a lower risk of clinical development;
- early proof-of-concept data;
- strong clinical foundation with daily contact in clinical oncology;
- worked in networks, academically and commercially;
- minimized fixed costs

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- capital has been dedicated to drug development and patents.

Prostate cancer

- Prostate cancer is the most common form of cancer in men in the western world.
- About 25% of those with prostate cancer develop incurable castration-resistant prostate cancer (CRPC) with skeletal metastases.
- Today there are only a handful of approved drugs that can extend the life of these patients. All of these medicines have more or less serious side effects. Each of these drugs currently has, or is expected to achieve, sales of over \$ 1 billion annually, so-called block-busters.
- After a limited time, the CRPC becomes resistant to the respective drugs, which means that the need for new supplemental life-extending medicines is great.
- DexTech's main candidate, OsteoDex, has the potential to become such a complementary drug.

The Phase IIb study

The original study protocol with ID ODX-002 was approved by the Swedish and Danish Medicines Agency in October 2014 (a placebo-controlled randomized multicenter phase II trial) for OsteoDex for the treatment of castration-resistant prostate cancer with skeletal metastases (CRPC). On October 27, 2015, DexTech decided to change the study design and provide all study patients with active substance (OsteoDex). This is a result of discussions with the Swedish Medical Products Agency in Uppsala and advice from "BigPharma". The study design was changed to active treatment for all patients. DexTech thus gains faster knowledge of the tumor-inhibiting effect in relation to dose, the effect parameter demanded by prospective licensees. DexTech also obeyed patients' requests for access to active substance and thus did not have to risk randomization to the placebo group. A decision on approval of the new study protocol with ID ODX-003 was made by the Swedish Medical Products Agency in Uppsala on 28/2 2016.

The primary purpose of the Phase II study was to document the efficacy of OsteoDex in the treatment of CRPC. The study included 55 well-defined CRPC patients. Patients were divided between three treatment arms (blinded distribution, 3 escalating dose levels of OsteoDex). The treatment was given for 5 months where OsteoDex was administered every two weeks. The study was conducted in Sweden (Norrlands University Hospital in Umeå, Southern Hospital in Stockholm and University Hospital in Örebro), in Finland (Tampere University Hospital), in Estonia (East Tallin Central Hospital and Tartu University Hospital) and in Latvia (Riga East University Hospital and Daugavpils Regional Hospital). The first patient received his first treatment in September 2016 at Southern Hospital in Stockholm.

In connection with these changes, the company chose to change the study organization by recruiting Crown-CRO Oy as GCP responsible (good clinical practice) for the OsteoDex study. Crown-CRO Oy specializes in oncology studies in the Nordic and Baltic countries. Crown-CRO Oy replaces the company's former partner SynteractHCR.

In June 2018, the last patients in DexTech's Phase IIb study for OsteoDex were completed. The work was then focused on the completion of the formal study report.

In early October 2018, DexTech was able to present the first results of the completed Phase IIb study for Osteodex. The results met the primary objective of the protocol.

Parts of the results, previously announced, were presented at the BioEurope Conference in Copenhagen in November 2018 and received with great interest.

In December 2018, the full CRO report from the Phase IIb study for Osteodex was completed. Fifty percent of patients completed the treatment (5 months, dose every two weeks). Of these, 52% showed stable disease (improved / unchanged) in skeletal metastasis. 35% of patients completing the treatment received reduced tumor burden in the skeleton. Most of the patients who received a reduced tumor burden in the skeleton had been treated with, and no longer responded to, two or more of the currently available drugs (docetaxel, cabazitaxel, abiraterone, enzalutamide, radium-223 dichloride) before recruitment to the study. This finding is of great importance for the continued clinical development of OsteoDex as the current patient group represents a significant so-called. "unmet medical need". The results show that OsteoDex has a significant inhibitory effect on the vicious cycle

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in the skeleton, i.e. the biological process that drives this disease and thus also to shortened survival. More than 50% of patients showed markedly lowered levels of bone metabolism markers and a particularly marked decrease was noted in 67% of patients for marker CTX, which reflects bone degradation. The effect on this marker as well as other markers related to skeletal metastasis reflects the biological effect of the OsteoDex molecule. Tolerability was remarkably good with only a few side effects. No patients had to discontinue treatment due to side effects and no OsteoDex-related serious adverse events (SAEs) were noted. The three dose arms in the protocol exhibited equivalent treatment effect. The interpretation is that even the lower doses are sufficient to saturate the metastatic areas of the skeleton. The results met the primary objective of the protocol.

On October 14, 2019, DexTech reported promising follow-up results from the company's Phase IIb study on OsteoDex for the treatment of castration-resistant metastatic prostate cancer (mCRPC). Patients were followed for 24 months after end of OsteoDex treatment. The results as of October 14 2020 showed the following: 58 per cent of the patients with stable (unchanged) disease in skeletal metastasis at the end of treatment were alive; 48 per cent of the patients who discontinued the treatment or ended the treatment with progressive disease (progressive disease progression) were alive; 86 per cent of the patients who had objective response (reduction of existing skeletal metastases) were alive. The results indicate prolonged survival after OsteoDex treatment.

DexTech announced on June 12, 2020 that the randomized phase IIb study for the treatment of skeletal metastatic castration-resistant prostate cancer (mCRPC) had been completed, with 2-year follow-up results obtained from the last patients.

The primary endpoints of the study regarding markers for bone metabolism had been achieved. The majority of patients showed reduction in their skeletal markers in blood by the given treatment with OsteoDex. The treatment was very well tolerated (few and mild side effects) and good disease-inhibitory effect was seen even in the lowest doses. Objective responses were seen also in patients where the disease has progressed on treatments with several of currently available drugs for castration-resistant prostate cancer.

The study's secondary endpoints include overall survival 24 months after completion of treatment. Of the patients who responded to the treatment the median survival had not yet been achieved (> 27 months), compared with 14 months for the non-responders (significance, $p < 0.05$). The survival 2 years after the start of treatment was 65% for the patients who responded to the treatment, compared with 28% for the non-responders (significance, $p < 0.05$).

The results from the study were very positive and show that OsteoDex effectively slows down the tumor disease. Data regarding overall survival should be seen as an indication, as these data, for natural reasons, need to be confirmed in a much larger, so-called Phase III study.

None of the modern drugs is curative in castration-resistant prostate cancer and there is therefore a big unmet need for novel potent and well-tolerated drugs. OsteoDex has a clear potential to meet this need.

The continued clinical development of OsteoDex will be carried out by or together with a prospective licensee.

Extended preclinical program

OsteoDex has a mechanism of action against cancer cells that is general and therefore other cancers have also been investigated as possible indications in addition to mCRPC i.e., breast cancer, lung cancer and multiple myeloma.

Breast cancer

In November 2014, DexTech expanded the preclinical program with OsteoDex to include breast cancer. There are significant similarities between castration-resistant prostate cancer and advanced breast cancer regarding the tendency to metastasize to the skeleton. DexTech's preclinical studies to date have clearly shown that OsteoDex has promising potential for the treatment of this cancer as well. Through the Company's international network, extended preclinical studies are now being conducted regarding OsteoDex treatment for breast cancer. DexTech will own all rights to the data obtained. With further positive preclinical results, the Company will strengthen OsteoDex commercially in an out-licensing perspective. The value of the market for breast cancer drugs (total sales) in the US, Western Europe and Japan is estimated to be more than USD 15 billion in 2022 (Decision Resources

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2013). The expanded preclinical program is part of the company's strategy to show the potential of OsteoDex in addition to the indication of castration-resistant prostate cancer.

Lung cancer

DexTech has previously announced preclinical studies on the effect of OsteoDex on the most common form of lung cancer, so-called. non-small cell lung cancer (NSCLC). Conducted in vitro experiments at Karolinska Institutet, OsteoDex shows a robust cell killing effect in non-small cell lung cancer (NSCLC). The cell killing effect was found to be fully in par with that seen in castration-resistant prostate and breast cancer.

Lung cancer is divided into two main groups; non-small cell lung cancer and small cell lung cancer. About 80 percent of all lung cancer cases are non-small cell lung cancer (NSCLC), which in turn is divided into several subgroups. Globally, > 1.5 million people die from lung cancer annually and the vast majority of them die from the same. The lack of active and well tolerable drugs is striking.

Multiple Myeloma

DexTech has completed an extensive preclinical program regarding OsteoDex' effect on multiple myeloma. Conducted in vitro tests at Karolinska Institutet show that OsteoDex has a robust cell-killing effect on myeloma cells. The cell-killing effect has been shown to be superior in comparison with the standard preparation Melphalan.

MM is a form of blood cancer that starts in the bone marrow and causes the breakdown of the skeleton. The disease is incurable and the treatments that are currently available are used to slow the progression as much as possible. The treatments often have severe side effects.

The company sees OsteoDex as very promising for the treatment of MM and has therefore decided to conduct a phase 1 study regarding OsteoDex's effect on patients with multiple myeloma. This is based on OsteoDex's dual action mechanism, inhibition of bone-degrading cells and tumor cell toxicity, and with mild side effects, verified in clinical results.

On August 10, 2022, the Swedish Medicines Agency approved and granted permission to conduct the phase 1 study regarding OsteoDex's effect on patients with multiple myeloma. The study will include 20 patients and will be conducted at 5 hospital centers in Sweden and Norway. The study is estimated to start during quarter 1 2023 at the latest and is estimated to be completed during quarter 3 2024.

PSMA binding compound

In June 2016, DexTech filed a patent application for important innovation regarding diagnosis (so-called companion diagnostics) and target-specific treatment of prostate cancer.

It is well known that prostate cancer cells on their surface overexpress the protein PSMA (prostate-specific membrane antigen, i.e., PSMA is present in greater amount on the surface of the tumor cell). Extensive international research activity is underway to produce molecules that can bind specifically to PSMA and are thus used as carriers of cancer cell killing substances (radioactive isotopes, cytostatics etc.) for so-called target specific treatment of prostate cancer. Such molecules (including antibodies to PSMA) have been produced in several laboratories, but there are still challenges regarding production for clinical use, durability, patent protection, regulatory requirements, etc.

With the help of the company's technology platform, DexTech has now developed a new PSMA-binding association. The new substance has unique properties in that it has multiple PSMA-binding moieties and can carry a greater load of cell-killing substances than has been possible with PSMA-specific molecules produced so far. The production of the new substance can be relatively easily adapted to the company's GMP platform (i.e. manufacturing approved for clinical use). The current patent application complements and strengthens the company's other patents. DexTech intends to seek a development partner for the new drug candidate's pre-clinical / clinical development.

In June 2016, DexTech filed a patent application for an important innovation (patent family 4) regarding diagnosis (so-called companion diagnostics) and target-specific treatment of prostate cancer, PSMA.

In June 2018, this application was approved for a patent in Finland. In the fall of 2017, DexTech filed an international patent application (the so-called PCT application). Patents are now approved and granted in Europe.

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Patent

DexTech's patent portfolio includes four patent families containing approved patents and patent applications that provide good protection to the Company's drug candidates and the Company's technology platform. The portfolio has a geographical spread relevant to DexTech. The Company's four patent families / patent applications are strongly related, and each patent family is therefore relevant to all the Company's drug candidates and to the platform, GuaDex. Patent applications are filed in countries where there is advanced drug research and development and in the countries that constitute larger markets for pharmaceutical products.

Patent Family 1 - filed 1999

Patent Family 1 describes how the positively charged substance, CatDex, is selectively enriched in the tumor tissue, i.e. selectively relatively normal tissue.

Patent Family 1 includes approved patents in Australia, Canada, the United States, and Europe (registered in Belgium, Switzerland, Germany, France, United Kingdom, Italy and Sweden). The patent is valid until October 12, 2019.

Patent Family 2 filed in 2008

Patent Family 2, the GuaDex patent, a further development of Patent Family 1, describes its tumor cell killing properties against a variety of tumors, tumor cell cultures.

Patent Family 2 includes approved patents in China, Finland, Israel, USA, Mexico, Canada, Japan and Europe (registered in Switzerland, Germany, France, UK, Italy and Sweden). The patent is valid until March 6, 2028.

Patent Family 3 - filed in 2008

Patent Family 3, the OsteoDex patent, is a GuaDex molecule with a further component, a bisphosphonate, which has selectivity for the skeleton, i.e. where the metastasis is.

Patent family 3 includes approved patents in China, Japan, Canada, Israel, Mexico, Brazil and Europe (registered in Switzerland, Germany, France, UK, Italy and Sweden). The patent is valid until April 7, 2028.

Patent Family 4 - filed 2016

In June 2016, DexTech filed a patent application for an important innovation (patent family 4) regarding diagnosis (so-called companion diagnostics) and target-specific treatment of prostate cancer, PSMA. In June 2018, this application was approved for a patent in Finland. In the fall of 2017, DexTech filed an international patent application (the so-called PCT application). The application is approved, and patents have been granted in Europe. Patents are now approved and granted in Europe.

Outlook

DexTech's main drug candidate OsteoDex has a unique dual mode of action, tumor-specific denaturation and inhibition of bone resorbing cells (osteoclasts). OsteoDex has been studied in a clinical phase II study with good results. There are significant similarities between bone metastases from mCRPC and Multiple Myeloma, such as growth site, bone degradation and stimulation from osteoclasts.

These similarities have motivated DexTech's studies of the effects of OsteoDex on Multiple Myeloma. The company has in extensive preclinical studies conducted at Karolinska Institutet in Stockholm shown that OsteoDex has a very significant tumor cell killing effect that has been demonstrated on various Multiple Myeloma tumor cell lines. OsteoDex shows a strong effect even at low concentrations.

The project is now being further developed into clinical research and a formal protocol is being drawn up. On August 10, 2022, the Medical Products Agency approved and granted the application for a phase 1 study regarding OsteoDex's effect on patients with multiple myeloma. The study will include 20 patients and will be conducted at 5 hospital centers in Sweden and Norway. The study is estimated to start during quarter 1 2023 at the latest and is estimated to be completed during quarter 3 2024.

The intention is that the study will provide possible "proof of concept" and thereby further verify OsteoDex's great value as a potential cancer drug. The market for the new indication is estimated to

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be twice as large as that for mCRPC. The rights issue 2021 finances the Multiple Myelom study and ensures continued operation until the end of 2024.

The continued clinical development of OsteoDex will be carried out by or together with a prospective licensee.

Organisation

The Board consists of Chairman Andreas Segerros and Board members Per-Olov Asplund, Rolf Eriksson, Anders R Holmberg (CEO and founder) Sten Nilsson (founder) and Svante Wadman.

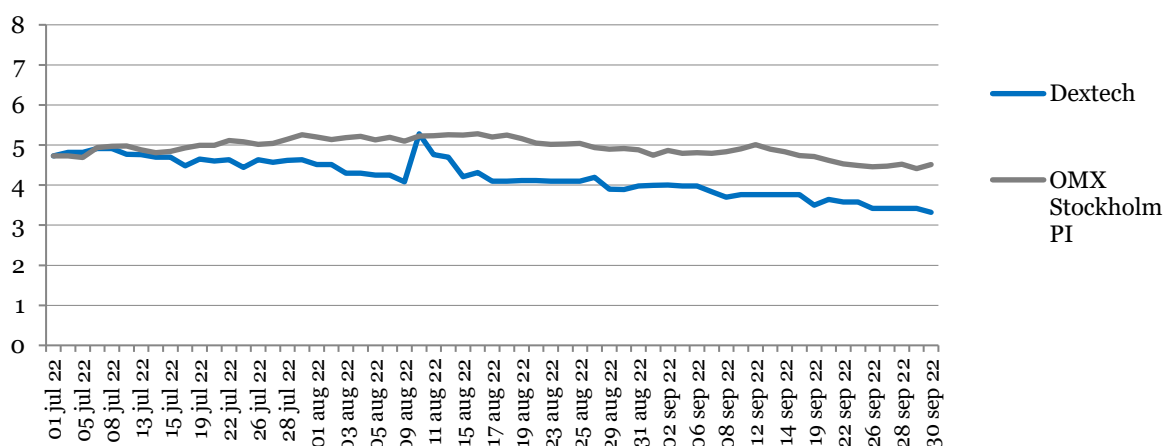
The share

The DexTech share was listed on the Spotlight Stock Market on June 19, 2014. Trading takes place under the name DEX.

The number of outstanding shares at the beginning and at the end of the interim period amounted to 18,485,857.

At the end of the financial year, the share price for DexTech Medical was SEK 3,32 and the reported equity per share was SEK 2,06. The market value was MSEK 61 373. The number of shareholders was 1 235.

Development of share price per share during the financial year 2022/2023



Related party transactions

Apart from the salary of the CEO and the fee to the CFO, there are no related party transactions to report.

Accounting principles

This 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 latest annual report.

Financial information

Annual General Meeting*	October 28, 2022
Half-year report 2022/2023	February 15, 2023
Q3-report 2022/2023	April 29, 2023
Year-end report 2022/2023	August 30, 2023

* The annual general meeting will be held in Stockholm on October 28, 2022.

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Contact

Anders Holmberg, CEO, +46 73 324 27 82
Gösta Lundgren, CFO, +46 70 710 47 88

This information is such information that DexTech Medical AB is required to disclose in accordance with the EU Market Abuse Regulation. The information was submitted for publication on October 27, 2022 through the care of the above contact persons.

This report is an in-house translation of the original report in Swedish

Stockholm October 27, 2022

DexTech Medical AB

Board of Directors

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

DexTech Medical AB
Dag Hammarskjölds Väg 34A, Uppsala
Mailing address:
Box 389, 751 06 Uppsala
www.dextechmedical.com

SUMMARY OF INCOME STATEMENTS

KSEK	First Quarter	
	2022-07-01	2021-07-01
	2022-09-30	2021-09-30
Net sales	-	-
Work performed by the company for its own use and capitalized	943	43
Operating expenses	-1 758	-988
Operating profit/loss	-815	-945
Profit/loss before tax	-815	-945
Tax	-	-
Net profit/loss	-815	-945
Earnings per share, SEK *	-0,04	-0,06
Average number of shares *	18 485 857	14 920 478

* Before and after dilution.

SUMMARY BALANCE SHEETS

KSEK	2022-09-30	2022-06-30
Assets		
Intangible assets	4 130	3 564
Financial assets	1	1
Receivables	290	551
Cash and cash equivalents	33 862	35 473
Total assets	38 283	39 589
Equity and liabilities		
Equity	38 062	38 878
Current liabilities	221	711
Total equity and liabilities	38 283	39 589

SUMMARY CASH FLOW ANALYSIS

KSEK	2022-07-01	2021-07-01
	2022-09-30	2021-09-30
Cash flow from operating activities	-668	-366
Cash flow from investing activities	-943	-43
Cash flow from financing activities	-	-
Cash flow for the period	-1 611	-409
Cash and cash equivalents at the beginning of the period	35 473	3 457
Cash and cash equivalents at the end of the period	33 862	3 047