



**DexTech**  
Know-how in Translational Research

DexTech Medical AB  
Interim report July 1 - September 30, 2019

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

### First Quarter Summary (July - September 2019)

- Net sales amounted to MSEK 0,0 (0,0)
- Operating profit/loss amounted to MSEK -2.0 (-1.9)
- Earnings per share \* SEK -0.13 (-0.13)
- Cash and cash equivalents at the end of the period amounted to MSEK 8,2 (0.0)

*\* Before and after dilution. Earnings per share: Profit for the period divided by the average number of shares 14,887,678. For the comparison period, the average number of shares was 14,752,833. Amounts in brackets refer to the corresponding period last year.*

### CEO's comment

In the beginning of October 2019, DexTech could present promising follow-up results from the company's Phase IIb study on OsteoDex for the treatment of advanced prostate cancer, castration-resistant metastatic prostate cancer (mCRPC), and patients are followed 24 months after discontinuing OsteoDex treatment. End point is information about whether the patient is alive or dead (dead / alive). The last patients will be reported in June 2020. The results as of October 14 show the following: of patients who had stable (unchanged) disease with skeletal metastasis at the end of treatment 58%, of patients who discontinued or discontinued treatment with progressive disease (progressive disease development) ) live 48%, and of patients who had objective skeletal metastases (reduction of existing skeletal metastases) at the end of treatment, 86% live. The results indicate prolonged survival after OsteoDex treatment.

The complete clinical study report (CSR) from the phase IIb study for OsteoDex was completed in December 2018 and the last patient was completed in June 2018. The study conducted in Sweden, Finland, Estonia and Latvia included 55 well-defined patients with castration-resistant prostate cancer with skeletal metastases ( mCRPC).

The results obtained show that OsteoDex acts as a brake medicine for metastatic castration-resistant prostate cancer. The OsteoDex treatment slowed down the course of the disease in the skeleton of the majority of patients who underwent the entire treatment (5 months) and the study also confirmed a very high tolerability.

During the summer of 2019, DexTech carried out a rights issue which in July 2019 brought the company SEK 9.2 million after issue costs. The rights issue amounted to SEK 10 million and the issue costs amounted to SEK 0.8 million. The rights issue was subscribed to approximately 318 percent of existing shareholders and the public at the end of June. The issue proceeds are mainly intended to be used to provide the company with a solid capital base and to finance licensing negotiations and to secure the company's continued research and development work.

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DexTech is now working confidently towards the company's primary goal of entering into an agreement with a licensee. In August 2019, DexTech added additional resources to the licensing work when collaboration began with the US company CYTO Consulting LLC, which focuses on prospective licensees in the US and China.

Anders R Holmberg  
CEO

### Significant events during the first quarter (July - September 2019)

- On July 1, 2019, it was announced that DexTech received SEK 10 million before issue costs through a heavily oversubscribed rights issue. The rights issue was subscribed to approximately 318 percent of existing shareholders and the public at the end of June. DexTech was thus raised approximately SEK 10 million before issue costs of approximately SEK 0.8 million.
- On August 15, 2019, DexTech announced a new collaboration regarding the US and China. The company has signed an agreement with CYTO Consulting LLC, Boston, USA where CYTO is assigned to assist DexTech in identifying and engaging with stakeholders primarily in the US but also in China regarding licensing of DexTech's research portfolio, in particular for OsteoDex, the company's drug candidate for the treatment of skeletal metastases. in advanced prostate cancer, so-called castration-resistant prostate cancer (mCRPC). CYTO is headquartered in the Boston area, which is a center for pharmaceutical / biotech operating companies. CYTO also has representation in Shanghai, China, and will assist DexTech in both China and the United States. Shanghai is a similar drug / biotech center in China. CYTO specializes in assisting life science companies that in various ways want to establish / sell their technology in the United States. The cooperation with CYTO is an important complement to the company's agreement with EY and further strengthens the licensing work in the US and China. The EY agreement concerns the identification of stakeholders to DexTech's research portfolio. Both the agreement with EY and CYTO are not exclusive and allow DexTech to further strengthen its resources if needed.

### Events after the end of the period

- On October 14, 2019, DexTech announced promising follow-up results from DexTech's Phase IIb study on OsteoDex for the treatment of advanced prostate cancer, castration-resistant metastatic prostate cancer (mCRPC), and patients are followed 24 months after discontinuing OsteoDex treatment. End point is information about whether the patient is alive or dead (dead / alive). The last patients are reported in June 2020. The results as of October 14 show the following: of the patients who had stable (unchanged) disease in skeletal metastasis at the end of treatment, 58%, of the patients who discontinued the treatment or ended the treatment with progressive disease ( progressive disease progression) lives 48%, and of the patients who had objective skeletal metastasis (reduction of existing skeletal metastases) at 86%. The results indicate prolonged survival after OsteoDex treatment.
- On October 17, 2019, the Annual General Meeting of DexTech was held. For further information on the decisions made, please refer to the press release published on October 17. The press release is available on DexTech's website ([www.dextechmedical.com](http://www.dextechmedical.com)).

## Economical overview

	First quarter	
	2019-07-01 2019-09-30	2018-07-01 2018-09-30
Net sales, KSEK	–	–
Operating profit/loss, KSEK	-2 004	-1 926
Profit/loss before tax, SEK*	-0,13	-0,13
Cash flow from operating activities, KSEK	-656	-893
Cash flow from investing activities, KSEK	-48	-620
Cash flow from financing activities, KSEK	8 937	–
<b>Cash flow for the period</b>	<b>8 233</b>	<b>-1 513</b>
<i>* before and after dilution</i>		
	2019-09-30	2019-06-30
Cash and cash equivalents, KSEK	8 244	11
Total assets, KSEK	19 177	12 372
Equity ratio, %	98	93

## Results, first quarter, July - September 2018

### Turnover and earnings

The company had no sales during the first quarter. Operating profit amounted to MSEK -2.0 (-1.9) million. During the first quarter, costs of MSEK 0.0 (0.6) were capitalized for drug development and patents. Operating expenses amounted to MSEK 2.1 (2.5) and consist of personnel costs MSEK 0.1 (0.1), other external expenses MSEK 0.6 (0.7) and depreciation MSEK 1.4 (1.7). Other external costs include costs for patents of MSEK 0.1. Profit after tax amounted to MSEK -2.0 (-1.9).

### Liquidity and financing

Cash and cash equivalents at the end of the period amounted to MSEK 8.2 (0.0). In July 2019, the company received SEK 10 million before issue costs of SEK 0.8 million after the full share issue in June. In August, the short-term loan of SEK 0.3 million was repaid to the company's principal owner.

Cash flow for the first quarter amounted to MSEK 8.2 (-1.5).

Financing is done with equity. Equity at the end of the period amounted to MSEK 18.8 (20.8), corresponding to SEK 1.26 (1.41) per share. The equity / assets ratio was 98 (93) percent.

### Working capital

During the summer of 2019, DexTech completed a rights issue that provided the company with SEK 9.2 million. The rights issue amounted to SEK 10 million and the issue costs amounted to SEK 0.8 million. The issue proceeds are mainly intended to be used to provide the company with a solid capital base and to finance licensing negotiations and to secure the company's continued research and development work. The rights issue ensures continued operation until the end of 2022. 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.

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- 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; kapital har dedikerats till läkemedelsutveckling och patent.

### 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

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Products Agency in Uppsala on 28/2 2016.

The primary purpose of the Phase II study is to document the efficacy of OsteoDex in the treatment of CRPC. The study includes 55 well-defined CRPC patients. Patients are divided between three treatment arms (blinded distribution, 3 rising dose levels of OsteoDex). The treatment is given for 5 months where OsteoDex is given every two weeks. The study is 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 Södersjukhuset 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 has 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 meet 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 in the skeleton, ie. 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) could be noted. The three dose arms in the protocol exhibit an equivalent treatment effect. The interpretation is that even the lower doses are sufficient to saturate the metastatic areas of the skeleton. The results well meet the primary objective of the protocol (primary objective).

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 are followed for 24 months after discontinuing OsteoDex treatment. End point is information about whether the patient is alive or dead (dead / alive). The last patients are reported in June 2020. The results as of October 14 show the following: of the patients who had stable (unchanged) disease in skeletal metastasis at the end of treatment, 58%, of the patients who discontinued the treatment or ended the treatment with progressive disease ( progressive disease progression) lives 48%, and of the patients who had objective skeletal metastasis (reduction of existing skeletal metastases) at 86%. The results indicate prolonged survival after OsteoDex treatment.

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

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### Extended preclinical program

#### 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 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. There is currently no curative treatment for metastatic lung cancer and the need for new active drugs is therefore very high.

### 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).

### 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

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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).

## Outlook

During the summer of 2019, DexTech carried out a rights issue which in July 2019 provided the company with SEK 9.2 million after issue costs. The rights issue amounted to SEK 10 million and the issue costs amounted to SEK 0.8 million. The issue proceeds are mainly intended to be used to provide the company with a solid capital base and to finance licensing negotiations and to secure the company's continued research and development work.

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

### Going concern

Research and development of new drugs is a capital-intensive business and as shown in the income statement, the Company has no revenue. The rights issue 2019 ensures continued operation until the end of 2022. The goal is for license revenues to finance operations thereafter.

## Organisation

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

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### 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 shares outstanding at the beginning of the interim period was 14,752,833. The rights issue was registered in July 2019 and the number of shares then increased by 167,645. The number of outstanding shares at the end of the interim period was 14,920,478.

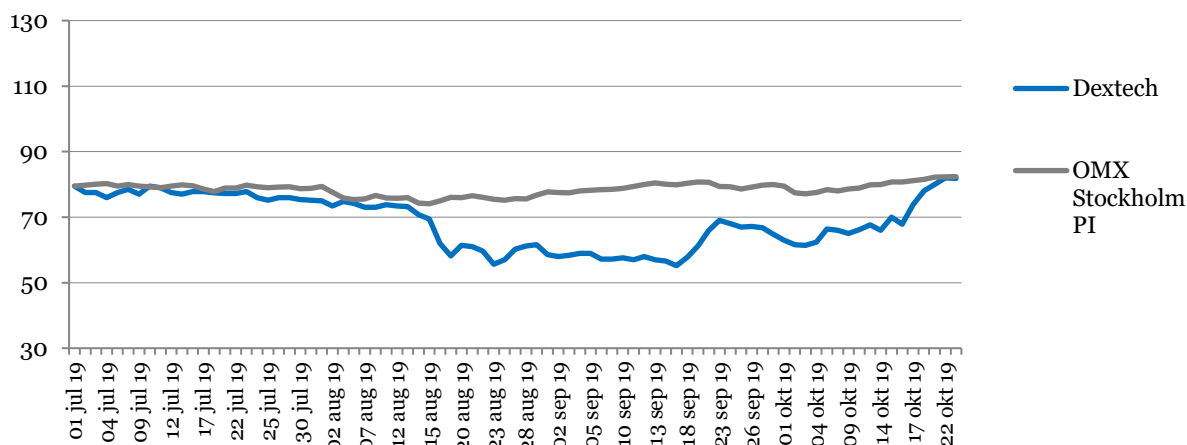
#### Completed rights issue

On May 28, 2019, the Extraordinary General Meeting of DexTech resolved to approve the Board's decision of May 9, 2019 to increase the Company's share capital by a maximum of SEK 7 544,025 through a new share issue of a maximum of SEK 167,645, each with a quota value of SEK 0.045 at a subscription price of 60.00 SEK per share. The new share issue was oversubscribed, and the company was given the entire issue amount of SEK 10,058,700 in July, with deduction for issue costs of SEK 821,332.

The rights issue increased the number of shares by 167,645. The total number of shares in the company then amounts to 14,920,478. The quota value is SEK 0.045.

At the end of the interim period, the share price for DexTech Medical was SEK 64.80 and the reported equity per share was SEK 1.26 after dilution from the rights issue. The market value was MSEK 967. The number of shareholders was 1,047.

Development of share price per share since July 1, 2019



### Related party transactions

In May 2019, DexTech received an interest-free loan of SEK 0.3 million from the company's chairman and principal owner, which was repaid after the subscription issue completed in July 2019. Apart from the aforementioned related party transaction, salary to the CEO and fees to the CFO, there are no related party transactions to report.

### Accounting principles

This year-end 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.



# DexTech Medical

## Financial information

Interim Report 2019/2020: January 31, 2020

Q3 Report 2019/2020: May 6, 2020

Year-end report 2019/2020: 28 August 2020

## Contact

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*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 24, 2019 through the care of the above contact persons.*

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

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

Stockholm October 24, 2019

DexTech Medical AB

Board of Directors

DexTech Medical AB

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# DexTech Medical

## SUMMARY OF INCOME STATEMENTS

KSEK	<i>First quarter</i>	
	2019-07-01	2018-07-01
	2019-09-30	2018-09-30
Net sales	-	-
Activated work for own account	49	620
Operating expenses	-2 053	-2 546
<b>Operating profit/loss</b>	<b>-2 004</b>	<b>-1 926</b>
<b>Profit/loss before tax</b>	<b>-2 004</b>	<b>-1 926</b>
Tax	-	-
<b>Net profit/loss</b>	<b>-2 004</b>	<b>-1 926</b>
Earnings per share, SEK *	-0,13	-0,13
Average number of shares, thousand *	14 887 678	14 752 833

## SUMMARY BALANCE SHEETS

KSEK	2019-09-30	2019-06-30
<b>Assets</b>		
Subscribed but unpaid capital	-	10 059
Intangible assets	10 660	11 989
Financial assets	1	1
Receivables	272	371
Cash and cash equivalents	8 244	11
<b>Total assets</b>	<b>19 177</b>	<b>12 372</b>
<b>Equity and liabilities</b>		
Equity	18 801	20 805
Current liabilities	376	1 626
<b>Total equity and liabilities</b>	<b>19 177</b>	<b>22 431</b>

## SUMMARY CASH FLOW ANALYSIS

KSEK	2019-07-01	2018-07-01
	2019-09-30	2018-09-30
Cash flow from operating activities	-656	-893
Cash flow from investing activities	-48	-620
Cash flow from financing activities	8 937	-
<b>Cash flow for the period</b>	<b>8 233</b>	<b>-1 513</b>
Cash and cash equivalents at the beginning of the year	11	3 648
<b>Cash and cash equivalents at the end of the period</b>	<b>8 244</b>	<b>2 135</b>