



Annual report 2019-07-01 - 2020-06-30 Dextech Medical AB Org.nr 556664-6203



DexTech is a Swedish research company specializing in urological oncology, primarily prostate cancer. DexTech develops drug candidates based on a modified carbohydrate molecule in combination with active substances, including generics. The substances have the potential to become new patented drugs that satisfy major needs in urological oncology. The company has a strong clinical foundation with valuable specialist expertise from research laboratory and manufacturing to clinical oncology. Through close international / national research and development cooperation with, among others, universities and hospitals, the development of the substances can be carried out cost-effectively. Prostate cancer is the most common form of cancer in men in the western world.

(This text is an in-house translation of the original Annual Report 2019-07-01 - 2020-06-30 in Swedish)



# **Management report**

The Board of Directors and the Managing Director of Dextech Medical AB (DexTech), org.no. 556664-6203, with its registered office in Stockholm, may hereby submit the annual report for the financial year 2019-07-01 - 2020-06-30. The company is a public company.

# **Operating activity**

DexTech conducts operations in medical research with the development of new drug candidates mainly in urological oncology, but also other cancer diseases and for non-malignant diseases. In addition to the technology platform GuaDex, DexTech has four drug candidates. OsteoDex for the treatment of skeletal metastases in castration-resistant prostate cancer (CRPC), SomaDex for the treatment of acromegaly, neuroendocrine tumours and palliative therapy in advanced prostate cancer, CatDex / GuaDex as an antibacterial agent, for example, for local treatment of urinary tract infections as well as PSMA-binding conjugates for target-specific treatment of CRPC. Anders R Holmberg and Sten Nilsson, both active at the Karolinska Institutet, founded DexTech in 2004.

# **Business concept and business model**

DexTech is a Swedish research company specializing in urological oncology, primarily prostate cancer. DexTech develops drug candidates based on a carbohydrate in combination with active substances including generics. The substances have the potential to become new drugs that satisfy major needs in urological oncology. The drug candidates must be licensed to the pharmaceutical industry no later than after Phase II. The licenses generate a one-time payment according to the usual payment model and then reimbursement for achieved development goals, so-called milestone compensation and future royalties on sales.

Through close international / national research and development cooperation, including universities and hospitals, the development of the substances can be carried out very cost-effectively.

# The cancer market globally

The global market for cancer drugs in 2018 is estimated to be SEK 7,200 billion

(https://www.tlv.se/lakemedel/lakemedelsmarknaden.html). The US dominates the world market with about 49 percent and Europe makes up about 22 percent. Africa, Asia and Australia together account for just over 16 percent, Japan constitutes just over eight percent of the world market and Latin America just over four percent of the world market.

Prostate cancer: Prostate cancer is the most common form of cancer in men in the Western world with a worldwide 1.3 million cases in 2018 (https://www.wcrf.org/dietandcancer/cancer-trends/prostate-cancer-statistics). In Sweden, prostate cancer is the most common form of cancer with 103 cases per 100,000 inhabitants.

About 1.75 million men are estimated to have prostate cancer in the seven largest pharmaceutical markets, the United States, the United Kingdom, Germany, France, Italy, Spain and Japan. About 20-25%, corresponding to just over 400,000 patients with prostate cancer, develop incurable so-called castration-resistant prostate cancer (CRPC) with skeletal metastases (Reference: The cancer market outlook).

### Castration Resistant Prostate Cancer (CRPC):

Twenty to 25% of patients develop CRPC, an incurable stage of prostate cancer where approximately 90% have skeletal metastases. Patients may have severe pain due to fractures, compression of the vertebrae and other skeletal symptoms. In general, skeletal pain is the most common form of cancer-related pain and can be difficult and debilitating in a majority of patients, with a pronounced negative effect on quality of life and mobility. Experienced clinics describe mCRPC as a skeletal disease. Over time, existing treatment has no effect and the patient dies of his illness. The median survival of mCRPC is only about 1 - 2 years (Reference: Kirby, M. Characterizing the castration-resistant prostate cancer population: a systematic review, The International Journal of Clinical Practice). Almost all patients who die from prostate cancer, today about every fourth patient, have castration-resistant disease. Today, only a few drugs are registered for life-prolonging treatment of castration-resistant prostate cancer: docetaxel (Taxotere) and cabazitaxel (Jevtana), both of which are so-called. cytostatics, and abiraterone (Zytiga), enzalutamide (Xtandi) and Radium-223 (Xofigo). Abiraterone and enzalutamide are hormonally active (inhibitors / blockers) while Radium-223 binds to areas of the skeleton where daughter tumors (metastases) are located and emit a local radioactive radiation effect. These five preparations have been shown to curb the tumor disease in most patients and extend survival by the order of 2.5 - 5 months.

All have more or less serious side effects and the patient's individual status determines which treatment can be used. All treatment of mCRPC patients aims to be disease-reducing and palliative, where treatment can at best extend the life of the patient. Each of these drugs has a relatively short duration of action when, after a limited period of time, all patients become resistant to the preparations. No curative drug is yet in sight and the need for new disease-reducing drugs is great ("unmet need").

Against this background, DexTech has developed a supplementary drug candidate that can be used when other drugs fail. Due to the large use of the five life-giving drugs and the fact that all of them eventually fail, the number of patients who remain without treatment is increasing. OsteoDex has shown potential for use in these patients.



Below is a brief description of breast and lung cancer to illustrate the importance of OsteoDex further potential indications;

#### Breast cancer

Breast cancer is the most common form of cancer among women with more than 2 million new cases in 2018 (https://www.wcrf.org/dietandcancer/cancer-trends/breast-cancer-statistics). For 2015, 9,362 women were diagnosed with breast cancer in Sweden (https://www.cancerfonden.se/om-cancer/om-brostcancer). In Western Europe, approximately 15–20 percent of breast cancer patients develop advanced breast cancer. In other parts of the world, this proportion is significantly higher due to late diagnosis. The treatment of metastatic breast cancer (Sweden) includes hormonal therapy, chemotherapy, antibody treatment and bisphosphonates. The optimal treatment is governed by the characteristics of the individual tumor (Reference: SweBCG, national guidelines for the treatment of breast cancer).

#### Lung 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, more than 1.5 million people suffer from lung cancer every year 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 (curative) treatment for metastatic lung cancer and the need for new active drugs is therefore very high.

A new drug with no more serious side effects that prolongs life, has all the potential to become a "blockbuster", i.e. a drug that sells for more than \$ 1 billion a year. DexTech's main candidate, OsteoDex, has the potential to become such a complementary drug.

#### DexTech's technology platform and drug candidates

DexTech uses dextran (a carbohydrate molecule) as a backbone in the design of new drug candidates. Active substances are coupled to dextran whereby the properties can be enhanced / altered so that the intended treatment effect becomes more effective while reducing side effects (lower toxicity). The biological half-life (degradation time) can be modulated and made more favorable depending on the application. The platform is protected by four applied / approved patent families (see page 7).

The drug candidates that the company is currently focusing on primarily relate to prostate cancer drugs. The company's main candidate, *OsteoDex*, for the treatment of skeletal metastases in castration-resistant prostate cancer, CRPC, has, after extensive preclinical studies, shown a strong tumor-killing effect and a potent inhibition of bone degradation.

Following a successful phase I / IIa study in which the result shows high tolerability with 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).

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 high tolerability of the patients for OsteoDex without serious side effects.

The Phase IIb study was terminated in June 2020 as 2-year follow-up results were obtained from the last patients. The follow-up results from the study were very positive and show that OsteoDex treatment can slow down the disease. The results show significantly longer survival for patients who responded to the treatment with a median survival longer than 27 months, compared with non-responding, with a median survival of 14 months (statistical significance, p <0.05). The survival 2 years after the start of the study is 65% for the patients who responded to the treatment, with slowing down or stabilization of the disease, compared with 28% for the non-responding (significance, p <0.05).

OsteoDex also has an application in skeletal cancer metastases from other types of cancer. E.g. breast cancer has a similar tendency as prostate cancer to spread to the skeleton.

DexTech's technology platform can be used for its own drug development, but can also be licensed for other specific applications. Licensing of the technology platform can be done to several different pharmaceutical companies, which creates new business opportunities for DexTech. The technology platform can be likened to a "Lego box" with multiple opportunities to build new molecules. The pipeline contains several substances with other properties and application areas that broaden DexTech's business opportunities.

DexTech's research, based on the technology platform, has so far resulted in four drug candidates, three with indications in oncology and a new anti-bacterial agent. In addition to DexTech's main candidate *OsteoDex*, there are the following drug candidates:

- 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 in advanced prostate cancer. SomaDex has undergone a Phase I clinical trial 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.

#### OsteoDex

OsteoDex is a unique bifunctional design, "tailored" for mCRPC, where two properties are contained in the same molecule:

- one inhibits bone-breaking cells (osteoclasts)
- the other a cytostatic drug, which kills tumor cells

When a patient has skeletal metastases, bone degradation and metastatic growth occur at the same site. Tumor cells and osteoclasts stimulate each other in a vicious circle. OsteoDex inhibits bone-degrading cells, thereby reducing tumor cell stimulation and simultaneously killing tumor cells. Where bone degradation occurs, bone minerals to which OsteoDex binds are highly bound and thus specifically enriched in bone metastasis / bone degradation areas. Regarding the ODX mechanism of action, ODX is perceived by the tumor cell as building blocks for its metabolism and is rapidly absorbed and enriched intracellular. Then, the tumor cell is rapidly killed by reactions with the cell's vital structures. The process can be likened to a Trojan horse.

OsteoDex has the potential to become another drug among the few that can affect the prognosis i.e. survival time with acceptable quality of life for patients with CRPC.

OsteoDex showed a good safety margin in toxicity studies, which has been confirmed in the phase I / IIa study. No serious side effects were noted and OsteoDex showed high tolerability (mild side effects).

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).

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

Two findings are considered particularly important, first that the tolerability of OsteoDex was confirmed with the absence of serious side effects, and that OsteoDex was able to reduce the skeletal tumor burden of patients who had received and failed (progressive) on treatment with 2-4 of the available disease-inhibiting drugs (cytostatic drugs). , i.e. Docetaxel / Jevtana; modern hormonally active drugs, i.e. Zytiga / Xtandi; Radium-223, i.e. Xofigo). These patients have few or no additional treatment options. This is a very important finding that meets the criteria for so-called "unmet need" in the treatment of metastatic castration-resistant prostate cancer (mCRPC) and is of significant importance for OsteoDex's continued clinical development towards registration / approval and also a heavy argument in licensing negotiations (with unmet need refers to "unmet medical needs").

Due to the great need for new drugs in mCRPC, the potential for OsteoDex is significant. In addition, unlike cytostatic drugs (e.g. docetaxel), OsteoDex has been found to have few and very mild side effects. The latter is important in the treatment of mCRPC (castration-resistant prostate cancer) as the patient is usually sensitive to treatment side effects. DexTech's preclinical OsteoDex studies (in vitro and in vivo) have also shown that OsteoDex has the potential for treating advanced breast cancer with skeletal metastases and the most common form of lung cancer.

#### OsteoDex, clinical results, phase I study

Following promising preclinical results with OsteoDex, a Phase I / IIa clinical trial was started in February 2012. The primary goal was to study tolerability and possible side effects. The study was a multicenter study conducted at the University Hospitals in Umeå and Lund and at the Södersjukhuset in Stockholm.

The study included 28 CRPC patients divided into 7 dose groups. Four patients in each dose group and with increasing dose.

The results show that OsteoDex has low toxicity with high tolerability. Only minor side effects have been noted. In the highest dose group, a strong effect on so-called bone markers in two of the total four patients. Bone markers often reflect the course of tumor disease. The results are a clear indication that OsteoDex at the appropriate dose has the expected effect.

Harrison Clinical Research-Synteract has been DexTech's CRO (Clinical Research Organization, study monitoring, etc., GCP, good clinical practice) during the study.

The results of DexTech's Phase I study on OsteoDex treatment of castration-resistant prostate cancer are the basis of the now completed phase II study.

# The Phase IIb study

The Swedish and Danish Medicines Agency approved the original study protocol with ID ODX-002 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 issued by the Swedish Medical 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 (Norrland University Hospital in Umeå, Södersjukhuset 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 on 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 need". The results show that OsteoDex has a significant inhibitory effect on the vicious cycle 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 lower 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 the 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).

In June 2020, DexTech's Phase IIb study of the drug candidate OsteoDex for the treatment of advanced prostate cancer, skeletal metastatic castration-resistant prostate cancer (mCRPC), was completed, with 2-year follow-up results obtained from the last patients.

The phase IIb study's primary endpoints regarding bone metabolism markers had been well achieved. A clear 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-inhibiting effect was seen even in the lowest doses. Slowing and regression of the disease was also seen in patients where the disease has progressed after treatment with several of the other available drugs for castration-resistant prostate cancer.

In the phase IIb study's secondary endpoints, there is overall survival that was studied through 24 months of follow-up after completion of treatment.

The follow-up results from the study were very positive and show that OsteoDex treatment can slow down the disease. The results show significantly longer survival for patients who responded to the treatment with a median survival longer than 27 months, compared with non-responding, with a median survival of 14 months (statistical significance, p <0.05). The survival 2 years after the start of the study is 65% for the patients who responded to the treatment, with slowing down or stabilization of the disease, compared with 28% for the non-responding (significance, p <0.05).

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

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.

#### Approved drugs against MCRPC 1

The competition for DexTech is made up of other pharmaceutical companies with the same business model, i.e. which involves licensing at the latest after the phase 2 study has been completed.

The pharmaceutical industry's portfolio for prostate cancer drug development is large with more than 400 candidates under active development. For patients with CRPC who have skeletal metastases, Taxotere (Sanofi) is the first choice in chemotherapy. Taxotere and Jevtana had total sales in 2016 of € 537 million (the figure also includes treatment of other cancers). Taxotere, like most cytostatic drugs, has many and severe side effects. Since Taxotere's patent protection expired in 2010, the drug has dropped significantly in sales to generics.

More new products have come to the market during this decade, including Zytiga (Janssen). Zytiga is highly priced in the US, about SEK 260,000 per treatment. Pricing in Sweden initially meant that many county councils did not use Zytiga, which underlines the importance of having a price as the market's chiefs, e.g. county council in Sweden, can accept. At present, Zytiga is now used by most county councils. In 2017, Zytiga achieved global sales of approx. \$ 2.5 billion. The indication for this drug is both pre-chemo (before docetaxcel) and post-chemo (after docetaxcel). Jevtana (Sanofi), was approved for sale in the US in June 2010 and in Europe in January 2011. In 2017, total sales of Jevtana totaled EUR 386 million. The indication for this medicine is post-chemo (after Taxotere).

Another new drug is Bayer's product Xofigo, a radioactive substance (Radium-223) active against CRPC. Bayer bought Xofigo from Norwegian Algeta in 2009 for USD 800 million and later the entire company for USD 2.9 billion. The product was approved by the FDA in May 2013 and EMA in December 2013. Xofigo is priced on a par with Zytiga and had sales of approx. 1 billion Euro for 2017. The indication for this drug is to be used both before and after chemotherapy (i.e. docetaxel).

Medivation / Astellas Pharma has recently launched Xtandi as a new drug for the treatment of CRPC. In August 2012, Xtandi was approved for sale in the United States and in June 2013, the drug was approved for sale in Europe. In 2017, total sales amounted to \$ 2.6 billion. The indication for this drug is both pre-chemo (before docetaxel) and post-chemo (after docetaxel). In 2010, Dendreon Provenge launched on the US market after FDA approval. The treatment is expensive and costs \$ 93,000 per treatment. In September 2013, Provenge was also approved for sale in the EU. In 2014, the total sales of the drug amounted to USD 300 million. Provenge is an immunotherapy in which patients' white blood cells are treated with the drug to make them immunologically more potent. Then they are reintroduced to the patient intravenously. The indication for this medicine is pre-chemo (before docetaxel). In 2017, Dendreon Pharmaceuticals sold proceeds to Chinese Sanpower for € 774 million.

Zometa (Novartis) is used in prostate cancer with skeletal metastases to delay skeletal-related events. Zometa belongs to the drug group bisphosphonates, which has its greatest application in the treatment of osteoporosis (osteoporosis). Zometa had annual global sales of approximately USD 1.5 billion in 2010 and 2011. In 2013, sales amounted to USD 600 million, a large decrease in sales as the preparation's patent expired and made free of generics. Zometa is the leading bisphosphonate drug in the indication prostate cancer with skeletal metastases, CRPC. Zometa has no effect on the tumor disease but delays skeletal-related events so-called. SRE, e.g. fractures. 1 Unless otherwise stated, each company's own sales figures come from each company.

#### Market Potential

The potential for OsteoDex is great as all life-extending drugs against mCRPC lose their effect over time and hence the need for new active drugs is great. OsteoDex has been shown to have a good effect even on patients who have failed on existing treatment.

The value of the five life-extending medicines' annual sales in 2018 (ref: annual reports for each company, Docetaxel (docetaxel) / Jevtana, Zytiga, Xtandi, Xofigo) amounted to approximately USD 10 billion. It also includes treatment of other cancers with docetaxel, but highlights the size of the mCRPC market for active drugs. The market is estimated at approximately \$ 13 billion by 2024. Growth is expected to be driven primarily by the increased incidence of prostate cancer, along with the launch of new products for the treatment.

There is a great need for new drugs that can extend life with relatively maintained quality of life for patients with CRPC. Today, only a few drugs are registered for this purpose. All have more or less serious side effects and the patient's individual status determines which treatment can be used. Each of these drugs has a relatively short duration of action when, after a limited time, the disease becomes resistant to the preparations and thus needs to be



replaced by one of the other preparations. Against this background, DexTech develops a supplement rather than a competing drug. Each of these drugs currently has, or is expected to achieve, sales in excess of \$ 1 billion annually, so-called. blockbusters. The CRPC market is expected to continue to grow in the future due to an aging population. For example, the great potential and interest in the CRPC market was confirmed in 2014 by Bayer acquiring Algeta for a purchase price of USD 2.9 billion and annual sales figures for existing active CRPC drugs (so-called blockbusters).

#### Manufacturing

DexTech has developed a GMP (good manufacturing practice) manufacturing process for its drug candidates. DexTech can present to prospective licensees a complete manufacturing method from bulk solution to finished vials all under GMP conditions.

Another advantage of the production of OsteoDex is the low cost of raw materials. All in all, a "simple" manufacturing at low cost is a competitive advantage that will have a positive effect on sales volumes and sales margins in a future market.

#### SomaDex

Somatostatin is a body hormone with many effects on humans. One effect is the effect of a natural "shutdown hormone", i.e. can turn off secretion of growth factors (proteins that stimulate growth) and various hormones e.g. growth hormone in acromegaly (pituitary tumor disease). Several tumor types express somatostatin receptors (recipient proteins for somatostatin) and including certain pituitary tumors, neuroendocrine tumors, and prostate cancer. For these reasons, somatostatin is of interest in the treatment of hormone-producing neuroendocrine tumors, growth hormone-producing pituitary tumors (acromegaly), and for palliative treatment of prostate cancer. Natural somatostatin is unstable (degrades quickly in the body) and therefore has very limited clinical utility. Synthetic somatostatin analogues are currently established drugs in the treatment of neuroendocrine tumors and acromegaly (Sandostatin®, Novartis).

With DexTech's technology platform, natural somatostatin has been stabilized (SomaDex) and obtained a new half-life of about 37 hours compared to about 3 minutes for natural somatostatin. This, together with the biological properties of somatostatin in SomaDex, provides high clinical utility. There is currently no synthetic somatostatin with the same properties as natural somatostatin.

Results from a clinical pilot study on CRPC patients with SomaDex as monotherapy show significant relief of symptoms and with improved function and better quality of life (EORTC QLQ-C30, quality of life questionnaire). Only minor side effects were noted.

SomaDex was licensed to TechSphere Corp. (Mexican Pharmaceutical Company) 2009. DexTech resumed the project in 2012 when TechSphere failed to fulfill its part in the licensing agreement (further development of SomaDex).

DexTech intends to identify a new license / development partner for SomaDex.

#### CatDex & GuaDex

CatDex is an electrostatically modified dextran molecule in preclinical phase. In a pilot study of patients with bladder cancer, CatDex was shown to accumulate with high preference in the tumor tissue (tumor cell specific) through its positive electrostatic charge (Patent 1 1998). CatDex has since been further developed (GuaDex, patent 2 2008) to have, in addition to tumor cell specificity, strong tumor cell killing properties. GuaDex is today the technology platform for new constructions / projects.

GuaDex has also been shown to have bactericidal properties. This is being investigated to identify possible new uses. The studies are conducted through the company's network in Mexico and focus on the treatment of urinary tract infections as well as oral antiseptics for dental procedures and the like.

#### 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).

# Marketing

As part of a conscious strategy to prepare for future licensing deals, DexTech has informed a large number of pharmaceutical companies about its operations, i.e. provided non-confidential information. This has in turn resulted in a number of confidentiality agreements where detailed and confidential information has been provided about OsteoDex. Today, several large pharmaceutical companies that have requested confidential information are following the development of OsteoDex. The Board considers that the strategy provides good conditions in the work to achieve a license agreement with a future licensing partner.

#### **Patent**

DexTech's inventions are protected by patents that give the Company exclusive rights. In other words, DexTech owns all patents and patent applications that have been filed since the Company was formed in 2004. 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. The patents usually run for 20 years but can in some cases be extended for up to 2 years for drugs. Through active management of the Company's patent portfolio, DexTech strives for a strong protection of future pharmaceutical products. This is further strengthened by the fact that the Company's total assets and rights are protected by clear agreements, strong patents and wise management of the knowledge that is published.

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

DexTech's patent portfolio is an important asset for the Company and a comprehensive patent portfolio prevents competitors from infringing on the Company's patented areas. The patents provide market exclusivity over the duration of the patent. Failed patents or patents that do not adequately protect the Company's business from competition run the risk of impairing the possibilities of obtaining a license agreement, which could adversely affect both profitability and the Company's value. The company's patent portfolio is managed by the patent office BOCO, Helsinki, Finland.

#### 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).

# Significant events during the financial year 2019/2020

On 1 July 2019, it was announced that DexTech had received SEK 10 million before issue costs through a
heavily oversubscribed rights issue. The rights issue was subscribed for by approximately 318 percent of existing



shareholders and the public at the end of June. DexTech thus received approximately SEK 10 million before issue costs of approximately SEK 0.8 million.

- On August 15, 2019, DexTech announced a new collaboration regarding the United States and China. The company has signed an agreement with CYTO Consulting LLC, Boston, USA where CYTO is commissioned to assist DexTech in identification and contacts with interested parties, primarily in the US but also in China, regarding licensing of DexTech's research portfolio, especially for OsteoDex, the company's drug candidate for 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 companies. CYTO also has representation in Shanghai, China, and will assist DexTech in both China and the United States. Shanghai is a similar center for pharmaceuticals / biotech in China. CYTO specializes in assisting life science companies that want to establish / sell their technology in the USA in various ways. The collaboration with CYTO will be an important complement to the company's agreement with EY and further strengthen the licensing work in the USA and China. The EY agreement refers to the identification of interested parties in DexTech's research portfolio. Both the agreement with EY and CYTO are not exclusive and give DexTech the opportunity to further strengthen its resources if necessary.
- On October 14, 2019, DexTech announced promising follow-up results from the DexTech Phase IIb study regarding OsteoDex for the treatment of advanced prostate cancer, castration-resistant metastatic prostate cancer (mCRPC), Patients are monitored 24 months after stopping OsteoDex treatment. End point is information about whether the patient is alive or has died (dead / alive). The last patients are reported in June 2020. The results as of October 14 show the following: of the patients who at the end of treatment had stable (unchanged) disease regarding the skeletal metastasis live 58%, of the patients who stopped the treatment or stopped the treatment with progressive disease (progressive disease development) 48% live, and of the patients who at the end of treatment had objective regression of skeletal metastases (reduction of existing skeletal metastases) live 86%. The results indicate prolonged survival after OsteoDex treatment.
- The company announced on June 12 that the randomized phase IIb study for the treatment of skeletal metastatic
  castration-resistant prostate cancer (mCRPC) had been terminated as a 2-year follow-up result was obtained
  from the last patients.
  - The primary endpoints of the study regarding markers for bone metabolism had well been achieved. A clear 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-inhibiting effect was seen even in the lowest doses. Slowing and regression of the disease was also seen in patients where the disease has progressed after treatment with several of the other available drugs for castration-resistant prostate cancer. The study's secondary endpoints include overall survival studied through 24 months of follow-up after completion of treatment. Of the patients who responded to the treatment, with slowing down or stabilization of the disease, the median survival has 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 the study is 65% for the patients who responded to the treatment, with slowing down or stabilization of the disease, 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 tumour 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 great need (unmet need) for new potent and well-tolerated drugs. OsteoDex has a clear potential to meet this need.

• The Corona pandemic has affected outlicensing work to such an extent that contacts with stakeholders are slower and meetings are limited to teleconferencing. Otherwise, the ongoing Corona pandemic has not affected DexTech as the costly clinical work has been completed.

#### Financial position and future capital requirements

To date, DexTech has been mainly financed by current shareholders. From the start in 2004, the company has raised SEK 73m in equity. In addition, capital was received from Signe and Olof Wallenius' foundation of SEK 350,000. In addition to these direct capital contributions, SEK 2.6 million was obtained through out-licensing of SomaDex in 2009 and in addition, many hours were invested in the various substances through DexTech's extensive national and international networks. In addition to a large network in Sweden, the company also has an extensive international network that contributes to cost-effective research and development. Work is often carried out as academic exchange projects such as postgraduate education, leading to a doctorate for the student.

In the fall of 2016, DexTech completed a rights issue that provided the company with SEK 15.3 million before issue costs of approximately SEK 0.8 million. The issue proceeds were primarily intended to be used to finance the completion of the company's Phase IIb study with OsteoDex, which ended on December 6, 2018. During the summer of 2019, DexTech implemented 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 goal is for license revenue to finance operations thereafter.

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

#### **Business Model**

Through licensing deals with strategic partners in the form of major pharmaceutical companies, DexTech is looking for partners who take on the financial and operational responsibility for the continued clinical development. The licenses generate a one-time payment according to the usual payment model and then reimbursement for achieved development goals, so-called. milestone compensation and future royalties on sales. Such partners have financial resources, experience in major clinical studies and established contacts with registration authorities. These partners will also in the future be responsible for the manufacture, marketing and sale of the registered drugs that may be the result of the development work. As part of a conscious strategy to prepare for future licensing deals, DexTech has informed a large number of pharmaceutical companies about its operations, i.e. provided non-confidential information. This in turn has resulted in a number of confidentiality agreements where detailed and confidential information has been provided about OsteoDex. Today, the development of OsteoDex is being followed by several large pharmaceutical companies that have requested confidential information. The value of a licensing business following a phase Ilb study where the result shows treatment effect that affects the patient's survival is deemed by the board to be significant.

The timing of signing a collaboration agreement with pharmaceutical companies is a business decision that is determined by costs, risk, competence needs and the value that another step in its own direction would add. Such collaboration agreements ensure that the projects are provided with knowledge and resources from large pharmaceutical companies at an early stage and DexTech avoids investing too large resources in a single project. It is in the Company's own interest to work without hesitation on security to minimize the time until the launch of medicines.

# **Overall objectives**

To secure OsteoDex's continued clinical development through partnership in 2020

- To continue the preclinical development of PSMA-Dex
- Developing CatDex / GuaDex for new indications
- To verify / develop widespread indication for OsteDex regarding breast cancer and lung cancer
  The company's primary goal is now to enter into an agreement with a licensee regarding OsteoDex. The stakeholders
  of OsteoDex consist of large organizations, which results in inertia regarding the time aspect of the negotiation
  process. This inertia, together with the large values that must be negotiated and regulated legally by both parties,
  means that it is time-consuming work that must be done before a license agreement is in place.

#### Outlook

During the summer of 2019, DexTech implemented 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.

#### The share

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

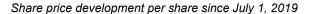
The number of shares outstanding at the beginning of the financial year was 14,752,833. The rights issue was registered in July 2019 and the number of shares then increased by 167,645. The number of outstanding shares at the end of the financial year was 14,920,478.

#### 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 financial year, the share price for DexTech Medical was SEK 49.00 and the reported equity per share was SEK 0.88 after dilution from the rights issue. The market value was MSEK 731. The number of shareholders was 1,085.







OMX Stockholm PI is an index that weighs together the value of all shares listed on the Stockholm Stock Exchange and shows an overall picture of the development on the stock exchange.

Largest shareholders as of June 30, 2020

Namn	Antal aktier	Andel av röster och kapital (%)
Svante Wadman (inklusive närstående)	3 969 369	26,60
Anders R Holmberg	1 563 227	10,48
Sten Nilsson	1 432 724	9,60
Donald Ericsson Fastigheter VI AB	1 124 750	7,54
Gösta Lundgren (inklusive närstående)	1 101 341	7,38
Hans Andersson (inklusive närstående)	1 063 676	7,13
Mats Ragnarsson Holmberg	440 000	2,95
Peter Kanekrans	383 329	2,57
Lennart Meurling	287 565	1,93
Övriga	3 554 497	23,82
Totalt	14 920 478	100,00

# Share capital development

Year	Event	Quota value	Increase in number of shares	Increase in share capital	Total number of shares	Total share capital	Paid including premium	Company value pre money
2004	Formation	100	1 000	100 000	1 000	100 000	100 000	0
2006	Right issue	100	1 100	110 000	2 100	210 000	860 000	781 818
2006	Right issue	100	234	23 400	2 334	233 400	750 000	6 730 769
2007	Right issue	100	123	12 300	2 457	245 700	2 500 000	47 439 024
2010	Stock split (100:1)	1	243 243	-	245 700	245 700	-	-
2010	Right issue	1	6 143	6 143	251 843	251 843	2 500 201	99 999 900
2011	Right issue	1	25 185	25 185	277 028	277 028	8 499 939	84 997 027
2013	Right issue	1	5 540	5 540	282 568	282 568	1 994 400	99 730 080
2014	Right issue	1,8	-	226 054	282 568	508 622	-	-
2014	Stock split 40:1	0,045	11 020 152	-	11 302 720	508 622	-	-
2014	Right issue	0,045	2 860 000	128 700	14 162 720	637 322	30 030 000	118 678 560
2016	Right issue	0,045	590 113	26 555	14 752 833	663 877	15 342 938	368 230 720
2019	Right issue	0,045	167 645	7 544	14 920 478	671 422	10 058 700	885 169 980



## Liquidity

The company has appointed the Sedermera Fondkommission as a liquidity guarantee (market maker) for its share in connection with the listing on Spotlight Stock Market. The purpose is to promote good liquidity in the share and to ensure a low spread between the buying and selling price in current trading. According to the agreement, Sedermera is to ensure a spread between the purchase and sale price of a maximum of 6 percent. On the buying and selling side, Sedermera will secure a volume equivalent to approximately SEK 5,000. The commitment was started in connection with the Company's listing on Spotlight Stock Market.

# 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.

# Significant risks and uncertainties

A number of risk factors can have a negative impact on DexTech's operations. It is therefore of great importance to consider relevant risks in addition to DexTech's growth opportunities. Risk factors are described below without mutual arrangement and without claim to be comprehensive.

# Industry- and company-related risks

#### Limited historical revenue

DexTech was founded in 2004 and has since conducted research and development with the aim of developing drug candidates that in clinical studies will develop into approved drugs. The company has not yet, either individually or through partners, launched any drug on the market and has no recurring revenue. The company has not conducted sales or generated any sales revenue from approved drugs. The limited revenues the Company has had so far come from a license agreement that the Company has repossessed.

DexTech is dependent on a positive outcome of the clinical studies that the Company is conducting or intends to carry out, as well as approval from authorities before the sale of the drug candidates can be initiated. There is a risk that DexTech's drug candidates will not exhibit sufficiently positive characteristics in the clinical trials and / or that government approval will be absent. If this is the case, it will pose a risk of missing the future launch of medicines and non-revenue.

#### Clinical studies

Before a drug can be launched on the market, safety and efficacy in treating humans must be ensured for each individual indication, as demonstrated by preclinical studies conducted on animals and clinical studies in humans. The pharmaceutical industry in general and clinical studies in particular are associated with great uncertainty and risks regarding delays and results in the studies. Outcomes from preclinical studies may not always be consistent with the results obtained in clinical trials. Results from early clinical studies also do not always match results in more extensive studies. If DexTech or its partners cannot, through clinical studies, sufficiently demonstrate that a drug is safe and effective, the Company may be adversely affected, which may result in failed approvals from authorities and thus non-commercialization and reduced or no cash flow. There is a risk that the collaborating partners who carry out the clinical trials may not maintain the clinical and regulatory quality required for future regulatory approval. There is also a risk that the authorities do not find that the clinical trial (s) that underlies an application for government approval is sufficient.

#### Side effects

There is a risk that patients who either participate in clinical studies with DexTech's drug candidates or otherwise come into contact with DexTech's drug candidates suffer from side effects. The consequences of such potential side effects may delay or stop the continued development of the product and limit or hinder the commercial use of the products and thus affect DexTech's sales, earnings and financial position. Another consequence is that DexTech may be sued by patients who may be suffering from side effects, whereby DexTech may become liable.

#### Partners

DexTech has collaborations with a number of partners. There is a risk that one or more of these will choose to terminate their cooperation with the Company, which could have a negative impact on the business. There is also a risk that DexTech's partners will not fully meet the quality requirements set by the Company. Similarly, establishing new business partners can be more costly and / or take longer than the Company estimates.

# Financing needs and capital

DexTech's commenced and planned clinical studies and development work entail considerable costs and the Company has no recurring revenue to date. There is a risk that the Company will not succeed in generating substantial and recurring revenue, which is why there is a risk that the Company will not achieve positive earnings in the future. Any delays in clinical trials may result in cash flow being generated later than planned. During the summer



of 2019, DexTech carried out a rights issue that ensures continued operations until the end of 2022. The goal is for license revenues to finance operations thereafter. The future capital requirement is also affected by whether DexTech can achieve partnership / co-financing. DexTech may need to raise additional capital in the future, depending on how much revenue the Company manages to generate in relation to its cost base. There is a risk that DexTech will not be able to raise additional capital, obtain partnerships or other co-financing or that such financing cannot be obtained on favorable terms for existing shareholders. This may mean that the development is temporarily halted or that DexTech is forced to operate at a lower rate than desired, which can lead to delayed or non-commercialization and revenue. This may have a negative impact on the Company's operations.

#### Manufacturers and suppliers

The company cooperates with suppliers and manufacturers. There is a risk that one or more of these will choose to terminate their cooperation with the Company, which could have a negative impact on the business. There is also a risk that current and / or future suppliers and manufacturers will not fully meet the quality requirements set by the Company or otherwise fully fulfil their obligations to DexTech. The company is to a certain extent dependent on its cooperation with other parties, both for the development of products and for the commercialization thereof. If existing collaborations work unsatisfactorily or are terminated, the Company may be forced to seek out other partners, which may be more costly and / or take longer than the Company estimates. Such a scenario could adversely affect the Company's operations and earnings.

#### Collaborations and outlicensing

DexTech is and will continue to be dependent on being able to find a licensing partner to carry out major clinical studies and / or in the marketing and sale of pharmaceuticals. In addition to the opportunities available for traditional out-licensing, DexTech's management evaluates various types of innovative forms of collaboration with major pharmaceutical companies and / or CRO partners. There is a risk that no agreements or collaborations will be reached or that such agreements may not be entered into on as favorable terms as the Company wishes or that partners do not fulfill their obligations in a successful manner. Lack of collaboration agreements or partners that do not succeed in their work to successfully launch drugs on the market, may result in reduced or no revenue for DexTech.

In connection with a licensing agreement, one-time payment, milestone payments and royalties on future sales are expected. Contradictory milestone payments may freeze for reasons that are contentious, or because intermediate goals are not met. Expected volume targets may be delayed or absent, whereby royalties may be delayed or completely absent.

### Authorization and registration

In order to be able to produce, market and sell medicines, permits must be obtained and registered with the relevant authority in each market, for example the Food and Drug Administration ("FDA") in the USA and the European Medicines Agency ("EMA") in Europe. In the event that DexTech or its potential partners fail to obtain the necessary permits and registrations from the authorities, the Company may be adversely affected in the form of reduced or missing revenue. The rules and interpretations currently in force may change in the future, which may affect the Company's ability to meet the requirements of various authorities. Permits and registrations can be withdrawn after the Company or its partners have received them. Thus, changes in rules and interpretations as well as revoked permits and registrations can also constitute future risk factors. In summary, government decisions may adversely affect DexTech's opportunities for revenue and the Company's financial position.

#### Key people, employees and consultants

DexTech's key personnel, employees and consultants have extensive expertise and long experience in the Company's business area. Loss of one or more persons can have negative consequences for the Company's operations and results. It is not possible to fully protect against unauthorized dissemination of information, which entails a risk that competitors will gain access to and benefit from the know-how developed by DexTech, which could be detrimental to the Company.

# Competitors

There is fierce competition in the pharmaceutical industry. There are many companies, universities and research institutions engaged in research and development of pharmaceuticals. Thus, there are several potential competitors to DexTech and its future partners. Some of the Company's competitors are multinational companies with large financial resources. If a competitor succeeds in developing and launching an effective and safe drug within the Company's business area, this could entail risks in the form of reduced sales opportunities. Furthermore, companies with global operations that currently work with related areas can decide to establish themselves within the Company's business area. Increased competition may have negative sales and earnings effects for the Company in the future.

## Patents and other intellectual property rights

DexTech is partly dependent on the ability to obtain and defend patents, other intellectual property rights and specific knowledge. Patent protection for medical and biotech companies can be uncertain and involve complicated legal and technical issues. Patents usually have to be applied for and maintained in several different jurisdictions. Patents, which form an important part of DexTech's assets, have a limited useful life.



There is a risk that existing and / or future patent portfolios and other intellectual property rights held by the Company will not constitute adequate commercial protection. If DexTech is forced to defend its patent rights against a competitor, this could entail significant costs, which could adversely affect DexTech's operations, earnings and financial position. Furthermore, there is always a risk in the type of business that the Company conducts that DexTech may or may allegedly infringe on patents held by third parties. Other operators' patents may also limit the possibility for one or more of the Company's future partners to freely use the affected drug or production method. Nor can it be ruled out that new patents in the area or new discoveries may affect the business. The uncertainty associated with patent protection means that the outcome of such disputes is difficult to predict. Negative outcomes of intellectual property disputes can result in lost protection, a prohibition on continuing to use the current right or the obligation to pay damages. The possibility of concluding important cooperation agreements can also be impaired. In addition, the costs of a possible dispute, even in the event of a DexTech advantage, could be significant, which could adversely affect the Company's earnings and financial position. The above could present difficulties or delays in the commercialization of future medicines and thus also difficulties in generating revenue.

DexTech is also to a certain extent dependent on know-how and corporate secrets, which are not protected by legislation in the same way as intellectual property rights. The company uses confidentiality agreements and thereby strives for far-reaching protection for sensitive information. However, it is not possible to fully protect against unauthorized dissemination of information, which entails a risk that competitors will gain access to and benefit from the know-how developed by DexTech, which could be detrimental to DexTech.

#### Development costs

In parallel with preclinical and clinical studies, DexTech will continue to conduct research and development regarding first and foremost drugs in urological oncology. Time and cost aspects in this area can be difficult to determine in advance with accuracy. This entails a risk that research and development work may become more costly and time-consuming than planned.

#### **Product Liability**

Given the nature of the business, it is relevant to take into account DexTech's product responsibility, which (regardless of the origin of the technology) arises as the Company develops and commercializes products. The company will need to review the insurance cover at each planned clinical trial and there will most likely, in every planned study, be limitations on the scope of the insurance cover and its amount limits. Therefore, there is a risk that the Company's insurance coverage may not fully cover any future legal requirements, which could adversely affect DexTech's operations and earnings. There is also a risk that suitable insurance cannot be obtained or received at an acceptable premium.

#### Economic development

DexTech's pharmaceutical development operations are affected by external factors such as supply and demand for pharmaceuticals, global economic trends, inflation and interest rate changes, which, among other things, affect the willingness to invest in potential licensing partners. This can have a negative impact on, among other things, operating costs, sales prices and share valuation.

#### Currency risk

Parts of DexTech's expenses are paid in various international currencies and some of DexTech's future sales revenue and costs may be included in international currencies. Exchange rates can change substantially, which could adversely affect the Company's costs and future revenues.

#### Political risk

The company is active in a large number of different countries in its research and development work, through collaborations, and intends to conduct global sales of medicines together with, or via, partners. Risks can arise from changes in laws, taxes, duties, exchange rates and other conditions for foreign companies. DexTech is also affected by political and economic uncertainties in these countries. The company may also be adversely affected by any domestic policy decisions. The above may have negative consequences for the Company's operations and earnings.

#### Pricing of medicines

DexTech's business model includes the licensing of medicines. In the event that drug pricing generally falls, there is a risk that this could adversely affect DexTech's earnings potential. Pricing for many drug types is determined in some countries at the government level. When a drug is launched, pricing may be regulated by authorities in several countries. The lower the pricing a drug receives, the lower revenue opportunities for DexTech. Thus, there is a risk that the pricing of drugs developed by DexTech may be lower than the Board of Directors of DexTech estimates.



# Equity-related risks

#### Price fluctuations and liquidity

There is a risk that the share price will undergo large variations in connection with an introduction to a marketplace. Exchange rate fluctuations can occur due to major changes in buying and selling volumes. Exchange rate fluctuations may adversely affect the Company's share price. Any operational setbacks can have a negative impact on the Company's valuation. The liquidity of the share affects the possibility of trading in the share at the desired time.

#### Psychological factors

The stock market in general and DexTech's share in particular may be affected by psychological factors. The company's share may be affected in the same way as all other shares that are regularly traded on different lists. Psychological factors and their effects on the share price are in many cases difficult to predict and may have a negative effect on DexTech's share price.

#### Dividend

DexTech has so far not paid any dividends. DexTech is in a development phase and any surpluses are planned to be invested in the Company's development. There is a risk that any future cash flows will fall below the Company's capital requirements or decide on future dividends.

#### Share sales from major shareholders, the board and senior executives

Board members, senior executives and major shareholders who hold shares in the Company see their shareholdings as a long-term investment. There is a risk that board members, senior executives and / or current shareholders who have previously signed a lock-up agreement will divest part or all of their holdings in the Company. This may adversely affect the Company's share price. There are currently no lock-up agreements.

#### Market

DexTech is listed on the Spotlight Stock Market. Spotlight Stock Market (formerly AktieTorget) is a subsidiary of ATS Finans AB, which is a securities company under the supervision of Finansinspektionen. Spotlight Stock Market operates a trading platform (MTF). Shares listed on the Spotlight Stock Market are not subject to as extensive regulations as the shares admitted to trading on regulated markets. Spotlight Stock Market has its own regulatory system, which is adapted for smaller companies and growth companies, to promote good investor protection. As a result of differences in the scope of the various regulations, an investment in shares traded on the Spotlight Stock Market may be riskier than an investment in shares traded on a regulated market.

# **Organisation**

The Board consists of Chairman Svante Wadman and members Sten Nilsson, Anders R Holmberg, Per Asplund and Rolf Eriksson. The Managing Director is Anders R Holmberg.

#### Key People

Sten Nilsson, (b.1948), MD, PhD, professor of oncology, is an internationally recognized authority in urological oncology. He has extensive experience in the design and implementation of early clinical studies, such as Algeta's Radium-223 studies, which subsequently led to the approval of a new drug, Xofigo.

Anders R Holmberg (b.1951), MD and chemical engineer, is a specialist in glycosylation chemistry with> 30 years of experience in this area including process development.

Marcela Márquez (b.1960), Professor of Biotechnology.

#### Scientific advice

DexTech has a large national and international network that contributes to cost-effective research and development. *Lennart Meurling*, associate professor of organic chemistry. Meurling has over 30 years of experience in senior positions in the pharmaceutical industry as well as pharmaceutical control in the healthcare industry. Meurling has been a shareholder in DexTech since 2006.

Marcela Márquez, professor of biotechnology. Marcela Márquez is married to Anders R Holmberg. Ulf Lerner, PhD, professor. Lerner is a leading specialist in bone and bone disease (Oral Cell Biology, Umeå University, Center for Bones and Arthritis Research, Institute of Medicine, University of Gothenburg). Meir Wilchek, Professor, Chemistry & Biophysics, The Weizmann Institute of Science, Israel. Wilcheck is a scientific adviser to DexTech.

#### Networks and collaborations

In addition to a large network in Sweden, the Company also has an extensive international network that contributes to cost-effective research and development. Work is often carried out as academic exchange projects eg. postgraduate education leading to the doctoral degree for the student.

#### Europe

- Helsinki University Hospital, Finland
- European Institute of Oncology, Milan, Italy
- Atlantic Bone Screen, Nantes, France



- · Steam current lab. Uppsala University, Sweden
- Pharmaplus Consultancy, The Netherlands
- University of Trás-os-Montes and Alto Douro, Vila Real, Portugal

#### Middle East / Asia

- King Feisal Research Center, Ryijad, Saudi Arabia
- The Weizmann Institute of Science, Israel
- · Shandong University Hospital, Shandong, China
- · Beijing University, Beijing, China

#### North America

- Memorial Sloan-Kettering Cancer Center (MSKCC), New York, USA
- UANL, Monterrey, Mexico
- UDEM / Mougerza Hospitals, Monterrey, Mexico
- TechSphere Corp. Mexico City, Mexico

#### South America

• Ipiranga University Hospital, Sao Paolo, Brazil

To conduct the Phase I / Ila study, Harrison Clinical Research, HCR, was hired as a CRO company. For the Phase IIb study, the Company has employed SynteractHCR Inc as a CRO company until 2015. With the change in the study design in early 2016, Crown-CRO Oy was appointed as GCP responsible (good clinical practice) for the OsteoDex study. For the production of substances for conducting the studies, the Company has engaged Biovian Ltd, Turku, Finland.

# **Economical overview**

	2019-07-01	2018-07-01	2017-07-01	2016-07-01	2015-07-01
SEK	2020-06-30	2019-06-30	2018-06-30	2017-06-30	2016-06-30
Net sales	_	_	_	_	460 732
Profit / loss after net financial items	-7 713 785	-8 355 606	-8 812 519	-7 875 821	-6 059 393
Earnings per share	-0,52	-0,57	-0,60	-0,60	-0,43
Cash and cash equivalents	6 091 442	11 283	3 647 994	13 340 544	8 355 197
Total assets	13 343 751	22 430 879	20 763 338	29 738 432	22 846 870
Equity ratio%	98	93	96	96	97
Cash flow from operating activities	-2 260 873	-1 372 791	-1 158 971	-939 111	-368 622
Cash flow from investing activities	-596 336	-2 263 921	-8 533 579	-8 602 816	-8 085 089
Cash flow from financing activities	_	_	_	14 527 274	-
Cash flow for the year	6 080 159	-3 636 712	-9 692 550	4 985 347	-8 453 711

# Proposal for appropriation of earnings

The Board of Directors proposes to the AGM the following appropriation of earnings:

Share Premium reserve	68 224 318
Profit or loss brought forward	-55 060 239
Profit/loss for the year	-7 713 785
	5 450 294
to be appropriated as follows:	
To be carried forward	5 450 294
	5 450 294

The result of the company's operations and the financial position at the end of the financial year are otherwise shown in subsequent income statements and balance sheets with accompanying notes.



# **Income Statement**

SEK	2019-07-01 2020-06-30	2018-07-01 2019-06-30
Net sales	-	-
Activated work for own account	596 336	2 263 921
•	596 336	2 263 921
Operating expenses		
Other external expenses	-1 975 438	-2 845 614
Cost for personnel	-718 192	-754 797
Depreciation and write-downs of tangible and intangible fixed assets	-5 616 348	-7 019 116
	-8 309 978	-10 619 527
Operating profit	-7 713 642	-8 355 606
Profit from financial items		
Interest costs and similar costs	-143	-
Profit before tax	-7 713 785	-8 355 606
Tax	-	-
Profit for the year	-7 713 785	-8 355 606



# **Balance Sheet**

SEK	Note	2020-06-30	2019-06-30
ASSETS			40.000.000
Subscribed but unpaid capital Fixed assets		-	10 058 700
Intangible assets			
Balanced expenditure for research and development and similar	4	0.450.074	44 000 004
Concessions, patents, licenses, trademarks and similar rights	5	6 458 671	11 380 801
Concessions, paterns, neerises, trademarks and similar rights	υ.	510 745 <b>6 969 416</b>	608 627 11 989 428
Financial assets		0 303 410	11 303 420
Other long-term holdings of securities	6	1 000	1 000
Total fixed assets	•	6 970 416	11 990 428
Current assets			
Current Receivables			
Other current receivables		30 253	59 738
Prepaid expenses and accrued income		251 640	310 730
		281 893	370 468
Cash and bank balances Total current assets		6 091 442 6 373 335	11 283 <b>381 751</b>
TOTAL ASSETS		13 343 751	22 430 879
TOTAL AGGETO		10 040 701	22 430 073
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		671 422	663 877
New issue under registration		-	7 545
Development fund	•	6 969 416	10 372 411
Unwanted and anythy		7 640 838	11 043 833
Unrestricted equity Share premium reserve		68 224 318	68 224 318
Profit or loss brought forward		-55 060 239	-50 107 628
Profit/loss for the year		-7 713 785	-8 355 606
	•	5 450 294	9 761 084
Total equity		13 091 132	20 804 917
Current liabilities			
Accounts payable		73 622	1 147 644
Other liabilities		28 105	331 180
Accrued expenses and deferred income  Total liabilities	-	150 892	147 138
TOTAL EQUITY AND LIABILITIES		252 619 13 343 751	1 625 962 22 430 879
TOTAL EQUIT AND LIABILITIES		13 343 /51	22 430 073



# Report on changes in equity

Equity 2020-06-30	671 422	0	6 969 416	68 224 318	-55 060 239	-7 713 785	13 091 132
Profit for the year						-7 713 785	-7 713 785
Transfer to development fund	d		-3 402 995		3 402 995		0
Transfer of previous year's result Rights issue*	7 545	-7 545			-8 355 606	8 355 606	0 0
Equity 2019-07-01	663 877	7 545	10 372 411	68 224 318	-50 107 628	-8 355 606	20 804 917
SEK	Share capital	registered capital	Develop- ment fund	Premium fund	Retained earnings	Profit/loss for the year	Total equity
		Not signed	_ <del>-</del>		-		
	Restricted equity			<u>Un</u>			

	Restricted capital			<u>Un</u>			
	Not signed						
	Share	registered	Develop-	Premium	Retained	Profit/loss	Total
SEK	capital	capital	ment fund	fund	earnings	for the year	equity
Equity 2018-07-01	663 877	-	11 988 553	58 994 495	-42 911 251	-8 812 519	19 923 155
Transfer of previous year's result					-8 812 519	8 812 519	0
Rights issue*		7 545		9 229 823			9 237 368
Transfer to development fur	nd		-1 616 142		1 616 142		0
Profit for the year						-8 355 606	-8 355 606
Equity 2019-06-30	663 877	7 545	10 372 411	68 224 318	-50 107 628	-8 355 606	20 804 917

<sup>\*</sup> The line for new share issues includes issue costs of SEK 821,332.

# **Cash Flow Analysis**

	Not	2019-07-01	2018-07-01
SEK	7	2020-06-30	2019-06-30
Operating activities			
Profit/loss after financial items		-7 713 785	-8 355 606
Adjustments for non-cash items		5 616 348	7 019 116
•	•	-2 097 437	-1 336 490
Income tax paid		-	-
Cash flow from operating activities before	•		
changes in working capital		-2 097 437	-1 336 490
Cash flow from changes in working capital			
Increase (-) / Decrease (+) of operating receivables		909 907	-822 079
Increase (+) / Decrease (-) of operating liabilities		-1 073 343	485 779
Cash flow from operating activities		-2 260 873	-1 672 790
Investment			
Acquisition of intangible fixed assets		-596 336	-2 263 921
Cash flow from investing activities		-596 336	-2 263 921
Financing activities			
Rights issue		10 058 700	-
New issue costs		-821 332	-
Borrowings		-	300 000
Repayment of loan		-300 000	-
Cash flow from financing activities	·	8 937 368	300 000
Cash flow for the year		6 080 159	-3 636 711
Cash and cash equivalents at the beginning of the year		11 283	3 647 994
Cash and cash equivalents at the end of the year		6 091 442	11 283



#### **Notes**

Amounts in SEK unless otherwise stated.

#### Note 1 Accounting principles

#### General accounting principles

The annual report has been prepared in accordance with the Swedish Annual Accounts Act and in accordance with the Swedish Accounting Standards Board's general advice BFNAR 2012: 1 annual report, K3. The accounting principles are unchanged compared to previous years.

#### Intangible assets

Expenditure on research, i.e. planned and systematic applicants for the purpose of obtaining new scientific or technical knowledge and insight are reported as costs when they arise.

When reporting expenditure on development, the capitalization model is applied. This means that expenditure incurred during the development phase is recognized as an asset when all of the following conditions are met:

- It is technically possible to complete the intangible fixed asset so that it can be used or sold.
- The intention is to complete the intangible fixed asset and to use or sell it.
- There are prerequisites for using or selling the intangible fixed assets.
- It is likely that the intangible fixed asset will generate future economic benefits.
- There are necessary and adequate technical, financial and other resources to complete the development and to use or sell the intangible fixed assets.
- The expenses attributable to the intangible fixed asset can be calculated reliably.

Internally accumulated intangible fixed assets are reported at cost less accumulated amortization and impairment losses.

The cost of an internally generated intangible fixed asset consists of all directly attributable expenses (eg materials and wages).

#### Other intangible assets

Other intangible fixed assets acquired are reported at cost less accumulated depreciation and impairment losses.

#### Impairment of intangible fixed assets

At each balance sheet date, it is assessed whether there is any indication that an asset's value is lower than its carrying amount. If such an indication exists, the asset's recoverable amount is calculated.

#### Financial assets and liabilities

Financial assets and liabilities are reported in accordance with Chapter 11 (Financial instruments valued on the basis of acquisition value) in BFNAR 2012: 1.

## Accounting in and removal from the balance sheet

A financial asset or financial liability is recognized in the balance sheet when the company becomes a party to the contractual terms of the instrument. A financial asset is removed from the balance sheet when it the contractual right to the cash flow from the asset has ceased or been regulated. The same applies when the risks and rewards associated with the holding are essentially transferred to another party and the company no longer has control over the financial asset. A financial debt is removed from the balance sheet when the agreed obligation has been fulfilled or terminated.

#### Valuation of financial assets

Financial assets are valued at acquisition value at initial recognition, including any transaction costs that are directly attributable to the acquisition of the asset.

#### Income

The inflow of financial benefits that the company has received or will receive on its own account is recognized as revenue. Revenue is measured at the fair value of what has been or will be received, less discounts.

#### Depreciation

Depreciation is applied on a straight-line basis over the asset's estimated useful life. Depreciation is recognized as an expense in the income statement.

#### Cash Flow Analysis

The cashflow statement is prepared according to indirect method. The reported cash flow only covers transactions that entail receipts or disbursements



# Note 2 Employees and personnel costs

	2019-07-01	2018-07-01
	2020-06-30	2019-06-30
The average number of employees		
Women	0	0
men	1	1
	1	1
Wages, allowances and social costs		
Salaries and other remuneration to the Board and CEO	600 000	600 000
Other social costs	61 260	98 160
	661 260	698 160

# Note 3 Depreciation and write-downs

Fixed assets are depreciated according to plan over the expected useful life.

The following depreciation percentages apply:

	2019-07-01	2018-07-01
	2020-06-30	2019-06-30
Intangible assets		
Concessions, patents, licenses, trademarks and balanced		
expenses.	20%	20%

# Note 4 Balanced expenditure on research and development work and similar work

	2020-06-30	2019-06-30
Accumulated acquisition values		
Accumulated acquisition value at the beginning of the year	50 330 584	48 390 259
Capitalization	416 988	1 940 325
Accumulated acquisition values at year-end	50 747 572	50 330 584
Accumulated depreciation		
Accumulated depreciation at the beginning of the year	-38 949 784	-32 231 897
Depreciations for the year	-5 339 117	-6 717 887
Outgoing accumulated depreciation	-44 288 901	-38 949 784
Closing balance	6 458 671	11 380 800

# Note 5 Concessions, patents, licenses, trademarks and similar rights

	2020-06-30	2019-06-30
Accumulated acquisition values		
Accumulated acquisition value at the beginning of the year	4 063 741	3 740 145
Purchase	179 348	323 596
Accumulated acquisition values at year-end	4 243 089	4 063 741
Accumulated depreciation		
Accumulated depreciation at the beginning of the year	-3 455 113	-3 153 884
Depreciations for the year	-277 231	-301 229
Outgoing accumulated depreciation	-3 732 344	-3 455 113
Closing balance	510 745	608 628



Note 6 Other long-term securities holdings	2020-06-30	2019-06-30
Shares in unlisted companies	1 000	1 000
	1 000	1 000
Note 7 Additional information for cash flow analysis		
	2019-07-01	2018-07-01
	2020-06-30	2019-06-30
Interest paid and dividends received		
Interest received	-	-
Interest paid	143	-
Adjustments for items that are not included in cash flo	w, etc.	
Depreciation and impairment of assets	5 616 348	7 019 116
	5 616 348	7 019 116

# Note 8 Significant events after the end of the financial year

No significant events after the end of the financial year can be reported.

# **Note 9 Definitions**

Equity per share

Adjusted equity in relation to the number of shares on the balance sheet date.

Cash and cash equivalents

Cash, bank balances and short-term investments with a remaining fixed term of less than three months from the balance sheet date.

Earnings per share

Profit for the year in relation to the average number of shares during the year. solidity

Adjusted equity in relation to total assets.



Stockholm, September 28, 2020

Svante Wadman Per Asplund Rolf Eriksson

Chairman

Sten Nilsson Anders Holmberg

Chief Executive Officer

# **Auditor**

Our Auditor's Report was submitted on September 3, 2020

KPMG AB

Per Hammar Authorized/Approved Public Accountant