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Biovica actively promotes the growing trend in healthcare for individualized treatment, with primary focus on patient survival and benefits to society.



## 2020/2021 IN BRIEF

### First quarter

- At the capital markets day in May 2020, Biovica announced its goal of achieving a 15 percent share of the total market potential in each market within three years of the launch.
- DiviTum®TKa acknowledged in two scientific journals.
- DiviTum®TKa mentioned in ASCO Educational Book.

## Second quarter

- Clinical validation prior to submitting the FDA application completed with positive results.
- Targeted new share issue generated approximately SEK 148 million. Several Swedish and international institutional investors, including the Second Swedish National Pension Fund (AP2), Coeli Asset Management and Lancelot Asset Management, participated.
- 510(k) application for DiviTum®TKa submitted to the FDA.
- Delay in the FDA review of the DiviTum®TKa application because of the decision to reallocate FDA resources due to the COVID-19 pandemic.

## Third quarter

- Four studies with DiviTum®TKa presented at San Antonio Breast Cancer Symposium.
- New study with DiviTum®TKa started in the UK and Sweden.
- New study with DiviTum®TKa started in Italy.
- FDA resumed its review of Biovica's 510(k) application for DiviTum<sup>®</sup>TKa.

### Fourth quarter

 PROMIX breast cancer study at Karolinska University Hospital, showing that testing for TKa levels during early treatment is prognostic for the long-term outcome of preoperative chemotherapy, published in the scientific journal, ESMO Open.

### Events after the end of the period

- Budget impact model showing large potential savings in the cost of care presented at ISPOR.
- Results reveal that DiviTum®TKa has prognostic and predictive capabilities for patients with metastatic skin cancer undergoing immunotherapy.

## Biovica in brief

Biovica develops and commercializes the blood-based biomarker assay, DiviTum\*TKa, to monitor and evaluate the effect of cancer treatments as a first step for women with metastatic breast cancer. In several clinical studies, DiviTum\*TKa has demonstrated its capabilities to early evaluate

therapy effectiveness. DiviTum\*TKa is also being developed as a prognostic tool for treatment outcome.

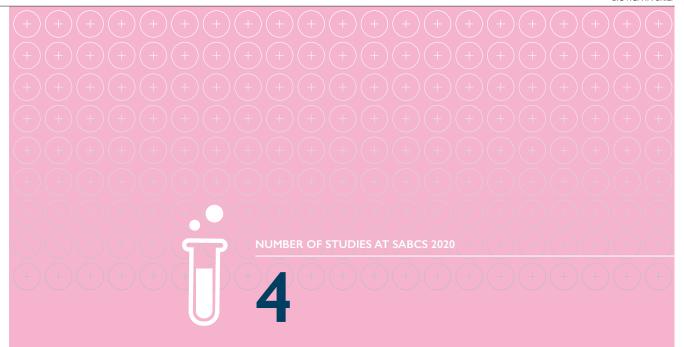
Biovica's partners and current customers are world-leading cancer institutes and pharmaceutical companies that are using DiviTum\*TKa in clinical studies. The potential lies in the large market for patient monitoring and future customers will be laboratories that perform testing for doctors who are treating cancer patients. DiviTum\*TKa has been developed on a standardized ELISA platform so that laboratories around the world can easily acquire and use it as part of their service offering.

Once the FDA grants market approval, the product will first be launched in the US market. It will then be launched in the five largest markets in Europe and the Nordic countries, thereafter, in Japan. DiviTum\*TKa has CE marking and it is registered with the Swedish Medical Products Agency. More long term, Biovica intends to establish DiviTum\*TKa in additional markets and for the treatment of other types of cancer and new targeted therapies.

Within three years of the launch of, Biovica expects to have achieved a market share of 15 percent of the market potential in the market where the assay is launched. Long term, Biovica's goal is to claim 50 percent of the share in the markets where DiviTum\*TKa is launched.

For the 2020/2021 financial year, sales amounted to SEK 2 million and the company had 20 employees. The head office, where R&D and production occurs, is located in Uppsala, Sweden. The company also has an office near Boston, USA.

Biovica's shares are traded on Nasdaq First North Premier Growth Market, Stockholm.





## Breast cancer

Breast cancer is usually expressed as a number on a scale of 0 through IV, depending on how large the tumor is and whether or not it has spread. Metastatic breast cancer is stage IV, which means that the original (primary) tumor has traveled through the blood or lymph system to form new tumors (metastases) in other organs or tissues of the body, typically in the skeleton, liver, brain or lungs.

Of those diagnosed for the first time with breast cancer, the cancer has already started to spread for three to five percent of them. Metastatic breast cancer is currently a chronic illness, requiring lifelong treatment, but only 22 percent live more than 5 years with the disease.

## DiviTum®TKa

DiviTum®TKa shows thymidine kinase activity (Tka), as a measure of cell proliferation, in serum or cell cultures. Thymidine kinase is an enzyme and in normal cells, the level is low. It rises, however, with cell division. Thymidine kinase is an enzyme and in normal cells, the level is low. It rises, however, with cell division. DiviTum®TKa is an assay for measuring cell proliferation and all that is required of the patient is a simple blood test.

## Biovica's history

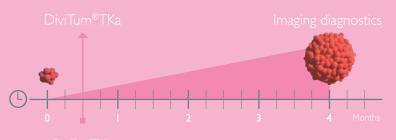
In 1982, researchers Simon Gronowitz and Claes Källander discovered the method for measuring thymidine kinase, which, in 2005, was patented as DiviTum®TKa.That same year, the first version of DiviTum®TKa received CE marking and the first clinical collaborations were initiated.

In 2013, Karolinska Institute published the first study with DiviTum®TKa and in the years that followed, important collaborations were set up with leading researchers at, for example, Dana Farber Cancer Institute, Washington University, IBCSG, BIG, Mayo Clinic and Johns Hopkins

Since 2016, the results from clinical studies with DiviTum®TKa have been presented each year at San Antonio Breast Cancer Symposium (SABCS), which is the world's largest breast cancer symposium.

Since 29 March 2017, Biovica's shares have been traded on Nasdaq First North

## DiviTum®TKa an early biomarker



DiviTum®TKa can quickly reveal whether or not treatment is effective





The initial focus on metastatic breast cancer facilitates a cost-effective launch of the assay in an area where there is a great need.



### MISSION

Biovica's mission is to establish DiviTum®TKa as a standard tool for monitoring treatment of metastatic breast cancer in the USA and Europe.

### VISION

Biovica's vision is treatment decisions with greater confidence, which will help give cancer patients a longer life with better life quality.

## STRATEGY

## - Initial focus on metastatic cancer in the USA

DiviTum®TKa has potential in many areas, but Biovica has chosen to initially focus its use as a tool for monitoring treatment of metastatic breast cancer, first launching the product in the US market, which is the world's largest and where there are high price levels.

## **BUSINESS CONCEPT**

To develop and commercialize blood-based biomarkers that improve monitoring and evaluation of modern cancer treatments.

## **BUSINESS MODEL**

Biovica's business model is based on three stages

- Good results from studies via leading partners
- 2. Launch through commercial partnerships
- Expansion into other markets and application areas

## FINANCIAL TARGETS

Within three years of the launch, Biovica expects to have achieved a market share of 15 percent of the market potential in the market where the assay is launched. Long term, Biovica's goal is to claim a 50 percent market share in the markets where DiviTum®TKa is launched.

## A financial year that brought us one step closer to realizing our vision of treatment decisions with greater confidence

For Biovica, the financial year was filled with a high level of activity preparing for the launch in the USA for the use of DiviTum®TKa to monitor treatment of metastatic breast cancer. To succeed with the upcoming launch, and more long term, realize our vision, we will rely on three main pillars: strong clinical evidence, social benefits through cost savings and strong commercial partners. During the financial year, we made progress in each of these areas.

# Strong clinical evidence is a prerequisite for inclusion in the care guidelines

To increase the clinical value of DiviTum®TKa for treating metastatic breast cancer, we continued our participation in clinical studies during the year and also initiated new ones. At present, DiviTum®TKa is included in six announced clinical studies on metastatic breast cancer. Each of these studies has been carefully chosen to both add and strengthen clinical data for the use of DiviTum®TKa for monitoring patients with metastatic breast cancer and evaluating treatment effect.

The high point of the year occurred in early December 2020, at the San Antonio Breast Cancer Symposium (SABCS), where DiviTum\*TKa was included in four posters based on the comprehensive SWOG study in the USA, the European multicenter prospective study (PYTHIA), the study conducted at Mayo Clinic (PROMISE), and a dosing study of palbociclib at Washington University School of Medicine in the USA.

Biovica supports studies like these to show DiviTum®TKa's clinical

accuracy and usefulness. Ultimately, all of it can result in the assay being included in both regional and national care guidelines.

## Clinical studies and social benefits in the form of cost savings provide the basis for reimbursement

In addition, clinical studies can provide the basis for pricing so that DiviTum®TKa can be included in reimbursement systems. To obtain reimbursement, oncologists and payers need to understand the value of the assay. One of our goals is for DiviTum®TKa to be included in at least one reimbursement system before the end of the year.

With that in mind, and to help influence payers' decisions, Biovica presented the results from one such budget impact model at the leading health economics and outcomes research conference, ISPOR in May 2021. It shows that the benefits of including DiviTum®TKa when monitoring hormone receptor positive metastatic breast cancer would primarily come from a reduction in futile therapy costs and other monitoring costs, such as imaging diag-

nostics. We are very happy that the results support our premise that the assay can help bring about significant improvements in healthcare efficiency.

## Strong commercial partners

Major cancer institutes are already important partners in our study collaborations and they could later become important commercial partners to us as well. Simultaneous to the FDA process, we are involved in discussions with future commercial partners who will be able to offer DiviTum®TKa analysis services. The first step is to sell DiviTum®TKa for Research Use Only (RUO). In June, we signed an agreement with a research laboratory in the USA and one in Europe, each of which will offer the assay to customers who are conducting clinical studies in order to, for example, develop new drugs.

Once we obtain FDA approval, which we expect during the third quarter of 2021, we intend to sign a similar agreement to jointly launch DiviTum\*TKa with a commercial partner, an oncology laboratory that has its own sales force and will be able to offer DiviTum\*TKa as an



Collaborating and sharing knowledge is becoming increasingly important, as well as being able to explain how the technology works and what it can do for us.

ANDERS
RYLANDER
CEO

additional service to its customers. In preparation for the launch, we have grown the organization both in the USA and Sweden. We also aim to launch DiviTum®TKa in one European country before the end of the year.

## Market potential

We estimate that the market potential in our initial markets - USA, EU-5 & Nordic countries and Japan – for using DiviTum®TKa for metastatic breast cancer at USD 400-700 million. It is important to keep in mind, however, that initially, we are only addressing about 1 percent of all the 43 million people who are living with cancer. The opportunities for wider use, into areas other than metastatic breast cancer, are therefore quite substantial. Our goal is to achieve a 15 percent market share within three years of having launched DiviTum®TKa in each market. Long term, our goal is to claim 50 percent of the market share in each market.

## Expansion to other indications

After the launch of DiviTum®TKa for metastatic breast cancer, we intend to

expand its use to other indications. Locally advanced cancer is a natural choice, since there are similar diagnostic needs. Locally advanced cancer adds another 30–40 percent market potential in existing markets.

During the financial year, we carried out a thorough analysis to identify additional indications that fit DiviTum\*TKa. By combining unmet clinical need, therapeutic fit, market potential and competitive situation, other indications that we identified besides locally advanced cancer breast cancer are metastatic malignant melanoma, castration-resistant prostate cancer (CRPC) and non-small cell lung cancer (NSCLC).

At the ASCO Annual Meeting during 4-8 June 2021, results from a new study at Karolinska University Hospital were presented. They show the prognostic and predictive capabilities of DiviTum®TKa for metastatic cutaneous melanoma patients undergoing immunotherapy. The study provides the first evidence that TKa measured in a simple plasma sample can be used for metastatic malignant melanoma to predict treatment response for patients who

are being treated with immune check point inhibitors. The results provide another strong indication that DiviTum®TKa has great potential beyond our initial area of metastatic breast cancer.

## We look to the future with great confidence

We completed yet another financial year that has brought us closer to realizing our vision of treatment decisions with greater confidence. And this could give cancer patients a longer life with better life quality. The first step towards realizing the enormous potential is a successful launch in the USA for use of DiviTum®TKa in treating metastatic breast cancer.

We are looking forward to the upcoming commercialization and soon being able to make a meaningful difference for patients with metastatic breast cancer. In summary, it has been an intensive year for Biovica. I'm excited and optimistic about the remainder of 2021 and all it holds.

Anders Rylander *CEO* 



## CDK 4/6 inhibitors

Cyclin-dependent kinases (CDKs) 4 and 6 play an important role in controlling an important phase in the cell cycle.
CDK4/6 inhibitors "shut down" these kinases and thereby slow down the cell cycle, which counteracts proliferation and inhibits the growth of cancer cells. Hormone receptor-positive breast cancer cells are sensitive to the anti-proliferative effects of CDK4/6 inhibitors, particularly in combination with endocrine therapy.

## THE VARIOUS STAGES OF BREAST CANCER

Breast cancer is divided into different stages: pre-stage (stage 0), stage II, stage III, and stage IV.

## Pre-stage – cancer in situ

The cancer has not spread past the area where it initially developed. This is a pre-stage to breast cancer. Most women do not experience any symptoms at all, but mammography can discover cancer in situ.

## Stage I – the cancer is growing in the breast

The cancerous tumor is growing and invading the milk duct or mammary gland, the adipose tissue or connective tissue of the breast. This means that the cancer has become invasive. It is typically difficult to detect the tumor through a breast self-exam, but it can be seen on a mammogram.

## Stage II – the cancer has spread to the lymph nodes

In this stage, the tumor can measure up to  $5\,$  cm. It may have spread to the lymph nodes under the arm on the same side as the breast cancer:

### Stage III – tumor measures more than 5 cm

In this stage, the tumor measures more than 5 cm or has invaded the skin or chest. It may also have become more extensive in the underarm lymph nodes.

## Stage IV – metastatic breast cancer – there are metastases in other parts of the body

The cancer cells have invaded blood vessels, enabling the disease to spread to other parts of the body and form new cancer tumors/metastases. This typically happens after the cancer tumor has existed in the breast for several years and when it has grown to a size of several centimeters. It might also take a shorter or longer period of time for the breast cancer to become metastatic.

Source: Bröstcancerförbundet



MARKET POTENTIAL FOR METASTATIC

400-700 USD MILLION PER

MARKET POTENTIAL FOR METASTATIC BREAST CANCER IN THE USA

755,000 TESTS PER YEAR

# Large clinical need and market potential

It is estimated that approximately 450,000 patients in the EU and the USA are currently living with metastatic breast cancer. Breast cancer is responsible for more than 40,000 deaths each year in the USA alone. These deaths happen because the disease has spread through the body and affected critical organs. If the cancer has spread, it is incurable. However, new treatments have been developed in recent years that extend the time that a patient can live with metastatic breast cancer. The number of available treatments has also risen.

For patients who are diagnosed with hormone receptor-positive breast cancer, the treatment outcome has primarily been improved through a combination of endocrine therapy and CDK 4/6 inhibitors that slow down the cell cycle, which counteracts proliferation and inhibits the growth of cancer cells. Approximately 80 percent of all breast cancer patients have hormone receptor positive cancer.

As more and better treatments become available, it becomes increasingly important for doctors to know, with greater certainty, when it is time to switch from one treatment to the next, or when to transition from endocrine treatment to cytostatic drugs/chemotherapy. Many patients do not respond to treatment or they develop resistance, which is difficult to discover without reliable tests. Furthermore, there is a great need for being able to more easily and quickly evaluate the effect of treatment. Besides that, many cancer treatments involve serious side effects and there are financial incentives because the treatments are expensive, costing more than USD 10,000 per patient

A number of tests and methods are run repeatedly and regularly to assess how the disease is progressing. In most instances, a single test will not provide a definitive answer, which is why many different tests are run repeatedly. Current diagnostic procedures are expensive, complicated and require time for monitoring, which is sub-optimal for the healthcare system and stressful for patients.

The initial target group for DiviTum\*TKa is women with hormone receptor positive spread breast cancer who are being treated with endocrine therapy. Each year in the USA alone, there are about 31,000 new patients for whom DiviTum\*TKa could be part of their treatment monitoring. Patients generally remain in this population for up to three lines of treatment, often for three years or longer.

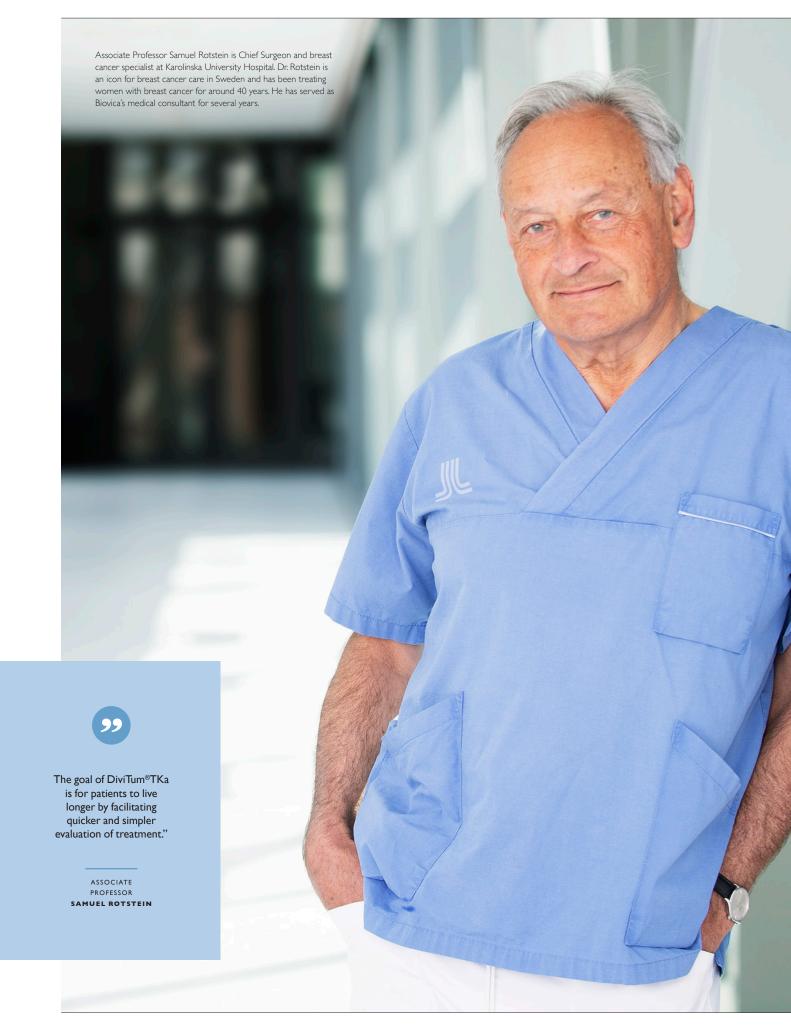
External advisors and oncologists suggest that a blood-based test such as DiviTum®TKa could be used as frequently as monthly early on during a treatment, and every three months thereafter. With testing frequency as suggested here, it corresponds to a market opportunity of 755,000 tests/year for metastatic breast cancer in the USA. Collaboration with leading researchers and payers has led to a better understanding of what is required as a basis for pricing DiviTum®TKa. Such opportunities will likely also grow as new treatments lengthen patient lives even more.

Biovica is supporting studies that substantiate DiviTum\*TKa's clinical accuracy and usefulness in order to create demand, a basis for pricing and getting DiviTum\*TKa included in reimbursement systems. Biovica's goal is to demonstrate that unnecessary treatment and/or continued treatment that is no longer effective can be avoided. Another aim is to show that it is possible to perform fewer diagnostic tests when using DiviTum\*TKa.

For hormone-receptor-positive breast cancer, Biovica estimates that the market potential is USD 400-700 million per year for DiviTum®TKa in the USA, EU-5, Nordic countries and Japan.









# DiviTum®TKa is simple, quick and precise

DiviTum®TKa is a dynamic biomarker test which, in several studies, has demonstrated its ability to provide answers about how a patient is responding to cancer treatment. Because all that is required of the patient is a simple blood sample, it is possible to, easily and frequently, evaluate the success of treatment over time and also learn whether the tumors are becoming resistant to the treatment.

Monitoring cancer with DiviTum®TKa is simple. The assay has been developed on a standardized ELISA platform for use in clinical laboratories. It is sold as a kit consisting of a reaction plate (96 wells) with reagents that have been optimized for ELISA applications.

The level of TK activity is closely correlated with the rate of cell proliferation, which makes TK monitoring

as a biomarker suitable for evaluating tumor aggressiveness and any slowing down of the cell cycle when a patient is treated with, for example, CDK 4/6 inhibitors.

Measuring TK activity with DiviTum®TKa provides a quick and precise evaluation of how a patient is responding to a particular type of cancer treatment. The information is clinically useful and it enables doctors to tailor and optimize treatment so that the patient gets the best possible outcome and unnecessary costs of care can be avoided.

The goal is to use DiviTum®TKa to prolong survival and raise the quality of life for patients. It can also lower healthcare costs by replacing expensive diagnostics and more quickly switching to a new treatment if the current one is ineffective.



## EXCERPT FROM INTERVIEW WITH ASSOCIATE PROFESSOR SAMUEL ROTSTEIN

"One problem is that patients are frequently over-treated. DiviTum®TKa can quickly evaluate which treatment is working for an individual patient, enabling us to avoid or delay the use of cytotoxics. The DiviTum®TKa assay would also likely facilitate a better and simpler evaluation of the treatment effect. In certain situations, it might even be possible to avoid taking a biopsy. Patients frequently also receive MRI scans. An MRI does not expose a patient to radiation. However, there are socio-economic reasons for avoiding them, because a single scan can cost as much as SEK 13,000."

The full interview is published in Biovica's Annual Report for 2019/2020

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# Well thought-out and detailed commercialization strategy

### Factors for a successful launch

- Informing and educating oncologists so that they understand the advantages and decide to use DiviTum®TKa because it offers more effective treatment.
- Results from clinical studies demonstrating the value of DiviTum®TKa.
- Inclusion in treatment guidelines.
- Inclusion in reimbursement systems from payers.
- Contracts with partners who provide analysis services and commercial channels.

The focus on metastatic breast cancer facilitates a cost-effective launch of the assay in an area where there is a great need. Launch will first take place in the USA, since the US market is the world's largest. The launch will be carried out together with partners that complement Biovica by providing a strong sales force and laboratories that can offer analysis services.

In September 2020, Biovica submitted its 510(k) application to the US Food and Drug Administration (FDA) in order to obtain market approval for the clinical use of DiviTum®TKa. Unfortunately though, the FDA needed to reallocate resources because of the COVID-19 pandemic, resulting in a delay of its review of Biovica's application. Biovica is pursuing its timetable of being able to launch DiviTum®TKa in the USA during 2021.

By entering into partnerships for sales of DiviTum®TKa analyses, Biovica will not need to set up its own sales force or laboratories, using ones that are already well established instead. In the USA, Biovica will be gathering documentation for reimbursement in the form of studies on the clinical and societal benefits via cost savings. It will also be formulating the marketing message to oncologists and patients. During the year, Biovica started growing its organization at the US office in Boston in preparation for the launch in the USA.

In collaboration with leading breast cancer researchers, many studies with

DiviTum\*TKa are being conducted to create demand and substantiate its usefulness. Biovica's collaborations with the laboratory divisions of major cancer institutes are also very important, in that they could later become important commercial partners to us. These collaborations have been expanded to include clinical laboratories and Biovica intends to widen them even more to include payers and integrated networks that have full responsibility for patient care and treatment costs.

### LAUNCH PLAN FOR THE USA

Once DiviTum®TKa has obtained market approval, Biovica has identified three important components for achieving commercial success.

- DiviTum<sup>®</sup>TKa must be widely available to oncologists.
- Inclusion in the treatment guidelines.
- Inclusion in reimbursement systems: coding, coverage and payment.

### Widely available to oncologists:

Both of the laboratories for the 71 cancer centers that are affiliated with National Cancer Institute (NCI), along with 20–30 important, independent oncological reference laboratories have been prioritized for Biovica's launch of DiviTum®TKa in the USA. Biovica is striving to ensure that the assay will be widely available via laboratories at these institutions. Service agreements with independent reference laboratories also open

up test availability for many other hospitals.

## Inclusion in the treatment guidelines:

There are strong links between treatment guidelines and inclusion in reimbursement systems for physicians' use. One important treatment guideline is National Comprehensive Cancer Network (NCCN). Its guidelines regularly review publications of clinical studies. Biovica's goal is to obtain strong results from studies showing DiviTum®TKa's accuracy and clinical usefulness, along with collaborating with researchers in order to quickly publish DiviTum®TKa results in prestigious scientific journals. The SWOG study is one important component of this strategy, since the NCCN assesses results from major, well-run studies.

## Reimbursement systems: Coding, coverage and payment:

Inclusion in treatment guidelines is an important part of making the test widely available. Biovica has conducted market studies in order to understand the requirements and path for inclusion in the US reimbursement systems. That requires an understanding and basis for pricing, along with the coding and coverage requirements. At the ISPOR conference in mid-May 2021, Biovica presented a budget impact model, which is an important puzzle piece for this endeavor. The model shows that there are potential savings of up to three times the cost of DiviTum®TKa.



### **USD MILLION PER YEAR**

Launch in the USA (1) will be followed by launch in Europe, primarily in the EU-5 (UK, Germany, Italy, Spain and France) and the Nordic countries (2). After that, Biovica will launch the product in Japan (3). These three markets have a total potential of USD 400-700 million per year for metastatic breast cancer. Besides that, there is additional potential elsewhere in the world.

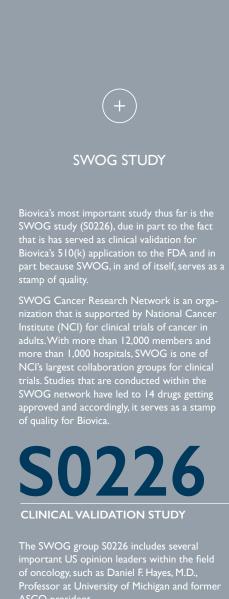
## Expansion beyond metastatic breast cancer in the USA

Expansion beyond metastatic breast cancer in the USA will occur by expanding into additional indication areas (see the next page), as well as geographic expansion.

Launch in the USA will be followed by launch in Europe, primarily in the EU-5 (UK, Germany, Italy, Spain and France) and the Nordic countries. After that, Biovica will launch the product in Japan.

These markets were selected on the basis of market analyses concluding that the prerequisites exist for establishing the product there. This is because the treatment protocol, payment systems and price levels are very similar to those in the US market. Expansion into new geographic areas will occur through collaborations with commercial partners.

Biovica expects that it will be able to reuse much of the data and resources generated for the US launch. In this way, reimbursement can, for example, be delegated to partners in Europe (where each country has its own system). Biovica can use partnership and licensing to quickly make the product available to patients in other markets than the initial three it will focus on.



**S0226** 

The SWOG group S0226 includes several important US opinion leaders within the field of oncology, such as Daniel F. Hayes, M.D., Professor at University of Michigan and former ASCO president.

S0226 study is a randomized phase III study for women with metastatic breast cancer who are being treated with endocrine therapy. Accordingly, this is the patient segment that will be covered by the initial area of use for DiviTum®TKa in the USA.



## Promising for other indications

A higher rate of cell growth applies to all types of cancers, and many cancers are treated with drugs that specifically target cell division. Biovica intends to expand the use of DiviTum\*TKa to some of these other indications after the launch for metastatic breast cancer.

During the last financial year, Biovica carried out a thorough analysis to identify additional indications that fit DiviTum\*TKa. By combining unmet clinical need, therapeutic fit, market potential and competitive situation, Biovica identified four focus indications: locally advanced breast cancer, metastatic malignant melanoma, castration-resistant prostate cancer (CRPC) and non-small cell lung cancer (NSCLC).

Locally advanced cancer is a natural choice, since there are similar diagnostic needs. Locally advanced cancer adds another 30–40 percent market potential in existing markets. DiviTum®TKa is being used in two studies on locally advanced breast cancer. In the PREDIX and Karolinska University Hospital,

DiviTum®TKa will be used to identify disease progression and response to CDK4/6i treatment for 180 patients.

The PROMIX study, which was published in March 2021 in the scientific journal, ESMO Open, showed that testing for TKa levels during early treatment is prognostic for the long-term outcome of preoperative chemotherapy and supports the use of DiviTum®TKa as a bloodbased alternative to the tissue-based Ki-67 biomarker. Samples from 125 breast cancer patients were collected pre-treatment, during therapy and at surgery.

Yet another example is the study on operable breast cancer (stage II-III) presented at the San Antonio Breast Cancer Symposium in December 2019. Results of the study indicated that DiviTum\*TKa is a strong prognostic marker for disease-free survival in local, operable breast cancer. The research group behind the study succeeded in showing prognostic effect for a large patient group (644 patients). Obtaining an early understanding of neo-adjuvant

treatment for locally advanced breast cancer would be very useful for improving the care for this category of patients.

Besides breast cancer, but also within the new focus indication for metastatic malignant melanoma, an initial pilot study with 124 patients was carried out together with Karolinska Institute and Karolinska University Hospital. Very promising was data presented at the 2021 ASCO Annual Meeting during 4-8 June 2021. Results reveal that DiviTum®TKa has prognostic and predictive capabilities for patients with metastatic skin cancer undergoing immunotherapy. The study provides the first evidence that TKa measured in a simple plasma sample can be used in metastatic malignant melanoma to predict outcome of patients treated with immune checkpoint inhibitors and provide information for better risk assessment before initiating treatment in this patient group. The full manuscript was submitted for review at the end of the financial year.



## CDx – attractive opportunity for developing new products

Companion Diagnostic (CDx) is a concept that has been firmly established in oncology for about 20 years. A companion diagnostic is a diagnostic test used as a companion to a therapeutic drug to determine its applicability to a specific person. It creates benefits to everyone involved. That means, besides patients, also payers, pharmaceutical companies and diagnostic companies.

As regards monitoring, there are few examples of successful CDx collaborations even though the FDA is demanding it so that treatment outcomes will improve. It thus creates a unique opportunity for Biovica to develop such, particularly since the company already has sales to some of the largest pharmaceutical companies in that area, as well as employees with unique experience in developing these types of products.

## Studies with impressive results

Dr. Cynthia Ma, MD, PhD, Professor of Medicine, is a medical oncologist at the Division of Medical Oncology, Washington University in St. Louis. In her daily work she rotates between patient care and scientific research including laboratory and clinical studies investigating biomarkers and targeted therapeutics for breast cancer. In 2016, Dr Ma's group published the first study to provide clinical evidence for DiviTum®TKa as a measure of the treatment effect of palbociclib in breast cancer.



Dr. Cynthia Ma is a medical oncologist at the Division of Medical Oncology, Washington University in St. Louis and she talks about her experience of DiviTum®TKa when treating metastatic breast cancer patients.

# Please tell us a bit about your "typical" metastatic breast cancer patient.

Patients with metastatic breast cancer are highly heterogeneous in regard to the clinical presentation and prognosis. Despite progress, metastatic breast cancer remains an incurable disease in the vast majority of patients. The goal of treatment in patients with metastatic breast cancer balances the need to prolong survival, reduce disease burden, and preserve quality of life. For hormone receptor positive disease, which represents the majority of breast cancer, hormonal therapy and targeted agents including inhibitors against CDK4/6, mTOR and PI3K are available and often preferred before considering chemotherapy which is more toxic. However, responses to these agents vary in individual patients. There is a constant need for disease monitoring in order to ensure that the treatment is efficacious.

## So, how do you decide to change between therapies?

We rely on tumor imaging studies such as CT scans, bone scans, MRI or PET scan. There are serum biomarkers, but none of them are fully reliable. As we do not have fully reliable surrogate biomarkers, imaging studies at regular intervals are often performed in the absence of symptomatic indications of progression/response. A blood test that could help us schedule imaging studies when needed is an unmet clinical need.

## Do patients mind coming in for imaging?

Patients don't complain about imaging studies on regular intervals as there are no alternatives. However imaging studies often expose patients to radiation, although small in quantities.

## What would be your ultimate wish to monitor these patients?

My ultimate wish is a blood test that has sufficient sensitivity and specificity that can help us to determine disease status accurately so we can order scans as needed.

## Aren't there blood tests available already?

There are tumor markers such as CA 27-29 and CA 15-3, but they are not perfect. Circulating tumor DNA (ctDNA) analysis has shown great promise but often expensive and not used to monitor disease clinically.

## Can you tell us about your research work with Biovica?

We started a study back in 2016 that provided the first proof of concept of DiviTum®TKa's ability to monitor treatment effect from palbociclib as a neo-adjuvant treatment in newly diagnosed breast cancer. I was impressed by the results. The study demonstrated a significant reduction in serum TK1 as early as two weeks following the start of palbociclib. The results paralleled to

changes in tumor Ki-67 and tumor thymidine kinase mRNA expression. The study provided impetus for future studies of DiviTum®TKa in the metastatic setting in patients receiving CDK 4/6 inhibitors for its ability to monitor treatment response.

# Can you talk about your ongoing study for an alternative dosing schedule for palbociclib in metastatic breast cancer and the role of Divi-Tum®TKa?

Yes, we are examining whether an alternative dosing schedule for palbociclib inhibits sTK1 and whether sTK1 dynamics predict the patient's response to palbociclib. We presented the study at the SABCS recently. The results are similar to those of the PYTHIA trial and imply that DiviTum®TKa is prognostic both at baseline and on treatment with CDK4/6 inhibitors. This is intriguing as there is not a test that predict CDK4/6 inhibitor efficacy in the clinic at this time.

# For doctors to adopt a test like DiviTum®TKa, what do you think is needed?

More studies including a larger sample size would be necessary to demonstrate the reliability of the assay as a prognostic marker and in monitoring disease status. Ultimately, prospective studies that demonstrate that patients' outcome are improved with this assay are needed. I think that DiviTum®TKa has this potential.

## There is a lot of clinical trial activity both with new therapeutics and new diagnostic tests for breast cancer patients. If you look forward 5-10 years, what sort of shifts do you see taking place in their care?

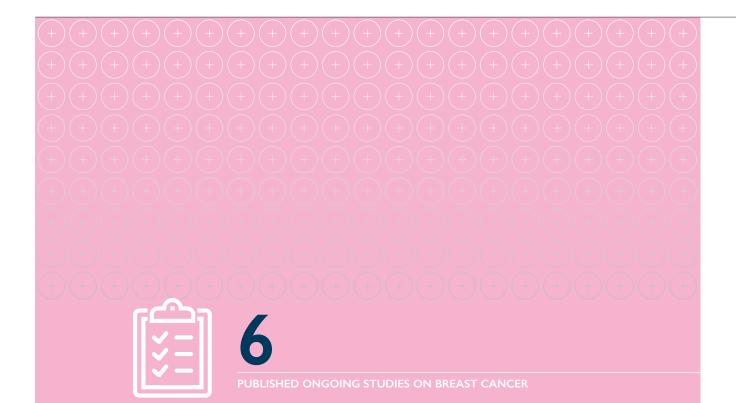
The Covid-19 pandemic has changed what can be done remotely, for example telehealth visits and in home monitoring. A blood test would be really helpful. With reliable blood markers, we could reduce scans when appropriate.



"My ultimate wish is a blood test that has sufficient sensitivity and specificity that can help us to determine disease status accurately so we can order scans as needed."

DR.







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PATIENTS PARTICIPATING IN ONGOING STUDIES WITH DiviTum®TKa



## Studies announced during the financial year

### TIRESIAS

In January 2021, DiviTum®TKa was selected to be included in the new prospective clinical study TIRESIAS, with the aim of investigating if DiviTum®TKa can be used to identify early resistance to treatment.TIRESIAS is a multi-center study that will collect samples from 150 patients with hormone receptor positive metastatic breast cancer who receive the first-line standard treatment: a CDK4/6 inhibitor and an aromatase inhibitor.The aim is to demonstrate that DiviTum®TKa can predict progression free survival and clinical benefit from samples taken as early as two weeks into treatment.

UK breast cancer study,
PDM-MBC (Personalized Disease Monitoring
in Metastatic Beast Cancer)

DiviTum®TKa was selected in November 2020 for inclusion in a new prospective UK breast cancer study of 100 women with hormone receptor positive metastatic breast cancer. The study, which is being led by researchers at Christie Hospital in Manchester, is investigating whether DiviTum®TKa can be used for disease monitoring during treatment with a CDK4/6 inhibitor and aromatase inhibitor. The hypothesis is that routine imaging can be delayed until predefined levels of biomarker progression is detected.

# The basis for a successful launch is favorable results from studies

Favorable results from clinical studies are a prerequisite for successful launch of a diagnostic product. Biovica has collaborations underway with world-leading cancer institutions and oncologists. In its collaborations with these partners, Biovica is able to create knowledge of, and demand for, the product. Favorable results from studies provide the basis for regulatory approval, reimbursement from payers, commercial partnerships and, ultimately, demand and sales.

DiviTum\*TKa is being used in several ongoing national and international, retrospective and prospective clinical studies. Each of these studies has been carefully chosen to both add and strengthen data that can support the use of DiviTum\*TKa for monitoring patients with metastatic breast cancer and as an effective tool for evaluating treatment effect.

At the present time, DiviTum®TKa is being used in six published ongoing studies on metastatic breast cancer.

- PYTHIA a study involving 100 patients to measure the development of resistance to CDK4/6 inhibitors
- Together with Johns Hopkins
  Biovica is conducting a study
  involving 100 patients to document
  biomarkers and measure the development of resistance to CDK4/6
  inhibitors.
- BioltaLEE a Phase IIIb study involving 287 patients receiving the CDK4/6 inhibitor ribociclib as first-line treatment. The study is being conducted by Novartis.
- PROMISE an investigative study at Mayo Clinic to evaluate the use of genomics in correlation with TKa. The study involves 63 patients and the interim results have been favorable.
- TIRESIAS a multi-center study that involving 150 patients who receive CDK4/6 inhibitor and an aromatase inhibitor as first-line treatment.
- UK breast cancer study PDM-MBC – a study to investigate whether DiviTum\*TKa can be used for monitoring treatment with a CDK4/6 inhibitor and an aromatase inhibitor.

## **ONGOING STUDIES IN BRIEF**

Study	Number of patients	Focus of the study
PYTHIA	121	Identification of resistance development
Johns Hopkins	100	Identification of resistance development
BioltaLEE	287	Progression monitoring
PROMISE	63	Investigative study with genomics
TIRESIAS (new)	150	Early identification of resistance
PDM-MBC (new)	100	Reducing the need for imaging diagnostics
TOTAL	821	

# High point of the year was four posters at SABCS

The high point of the year occurred in early December 2020, at the San Antonio Breast Cancer Symposium (SABCS), where DiviTum®TKa was included in four posters based on the comprehensive SWOG study in the USA, the European multi-center prospective study (PYTHIA), the study conducted at Mayo Clinic (PROMISE), and a dosing study of palbociclib at Washington University School of Medicine in the USA. In addition, results from the breast cancer study PROMIX at Karolinska University Hospital were published in the scientific journal, ESMO Open in March 2021.

In all of the studies presented at SABCS, DiviTum®TKa was used to monitor the treatment response of women with metastatic breast cancer. The studies showed that in various ways, DiviTum®TKa can be used as a dynamic, non-invasive biomarker for patients with metastatic breast cancer who are being treated with endocrine therapy and/or CDK 4/6 inhibitors. The drugs included in the study represent standard treatment in the USA.

### DiviTum®TKa in four posters at SABCS

• The SWOG study, S0226, revealed impressive data on progression free survival and overall survival. Furthermore, the results support that DiviTum®TKa can predict benefit from metastatic breast cancer therapy. The study, which analyzed more than 1,700 samples from more than 400 patients is the largest to date that is evaluating DiviTum®TKa for prognostic and serial monitoring of metastatic breast cancer. The study provides the basis for clinical validation of DiviTum®TKa in the 510(k) application submitted to the FDA.

- The PYTHIA study is the first prospective study where DiviTum®TKa was evaluated as an early predictor of treatment efficacy for women with metastatic breast cancer. This European multi-center study was sponsored by the International Breast Cancer Study Group (IBCSG) and conducted in collaboration with Breast International Group (BIG), with financial support from Pfizer. Biovica financed the collection and analysis of samples. The study indicates that, after just two weeks of treatment, DiviTum®TKa can evaluate the effect of endocrine therapy and a CDK 4/6 inhibitor.
- The PROMISE study evaluates the use of genomics in correlation with TKa to improve monitoring of breast cancer treatment. The interim results show that DiviTum\*TKa has a potential predictive capacity when used in this way. The study involves a total of 250 patients and it is being conducted by Mayo Clinic. The interim results presented at SABCS involved 32 patients.
- Dosing study supports
  DiviTum®TKa as an early and
  effective tool in treatment monitoring and predicting response to
  the CDK 4/6 inhibitor palbociclib.
  During serial monitoring a rise in
  TKa was a predictor of disease progression more than three months
  prior to imaging progression.

The PROMIX study shows that TKa levels early in a treatment can predict the long-term result of preoperative cytotoxic drugs at that DiviTum\*TKa could be a blood-based alternative to the biopsy-based biomarker Ki-67.

Samples from 125 breast cancer patients were collected pre-treatment, during therapy and at surgery.

During the financial year, several summary articles were published about DiviTum®TKa in the area of breast cancer. The scientific journals, British Journal of Cancer, Scientific Reports (publishers of Nature) and Biomarkers in Medicine have each published articles on DiviTum®TKa results and using biomarkers for evaluating the treatment effect of CDK4/6 inhibitor. The authors conclude that DiviTum®TKa has the potential to become a prognostic biomarker for early detection of treatment resistance in patients with metastatic breast cancer.

Also during the financial year, the ASCO Educational Book 2020 highlighted DiviTum®TKa as a potential solution for addressing unmet needs as regards monitoring the treatment effect of CDK4/6 inhibitors. American Society of Clinical Oncology (ASCO) is the world's leading professional cancer organization, with around 45,000 members who are doctors, oncologists or others members of the oncology care team. Each year, ASCO publishes an educational book on important topics in the field of oncology.

Thus far, 15 scientific articles from clinical studies on breast cancer have been published covering 1,800 breast cancer patients. Through these studies, it has been documented that DiviTum\*TKa can measure cell proliferation and be used as a prognostic tool for patient survival and for monitoring treatment effort for patients with breast cancer. In total, 26 articles have been published over a wide spectrum of cancer forms.



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In May 2020,
DiviTum®TKa was
highlighted in the 2020
ASCO Educational
Book as a possible
solution for addressing
unmet needs as
regards monitoring
the treatment effect of
CDK4/6 inhibitors.

"These preliminary results highlight the potential for serum TK1 activity to act as a noninvasive biomarker for CDK4/6 inhibitor target engagement"."

THE AUTHORS

Dana-Farber Cancer Institute,
MD Anderson and others

2,000

PATIENTS THUS FAR HAVE PARTICIPATED
IN PUBLISHED STUDIES WITH DiviTum®TK2



# DiviTum®TKa can give meaningful information on virtually every patient

Dr Luca Malorni, MD, PhD, is a medical oncologist and Director of the Translational Research Unit of the Hospital of Prato, a regional cancer center for the Tuscany area.



Dr. Luca Malorni serves as a senior medical oncologist at the Hospital of Prato, Italy, where he is Director of the Translational Research Unit. He has a specific interest in hormone receptor positive breast cancer and endocrine resistance.

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The beauty of DiviTum®TKa is that it only requires blood for analysis.That is what convinced us."

DR.
LUCA MALORNI

# You have been responsible for many studies including DiviTumTKa, but how did you first come in contact with the test?

We have a long standing and exciting collaboration with Biovica that all started in 2014 when we met Biovica in San Antonio at SABCS (San Antonio Breast Cancer Symposium). We were approached by Biovica and as we have a strong interest in biomarkers and therapeutic strategies, we got interested in DiviTum<sup>®</sup>TKa. Already in the summer of 2015 we started our first pilot trial. It was a small study, but with intriguing results that convinced us to deepen our understanding. Since then, we have extended our collaboration and have now been working six years with DiviTum®TKa in various studies, providing interesting data for clinical utility of the assay.

# You have several collaborations with diagnostics and pharmaceutical companies, is there anything special in this collaboration?

At Prato, we are collaborating a lot internationally. We have many academic collaborations within international frameworks of the breast cancer community like the International Breast Cancer Study Group (IBCSG) and the Breast International Group (BIG), but we also collaborate with pharmaceutical and diagnostic companies, small and big. So, we have many collaborations, but the collaboration with Biovica has been unique. We truly appreciate Biovica's approach to our collaboration. Biovica does not act as a regular company selling a product, but as a company that understands its product, how the product fits the user and how it can make lives better. This is not always the case in companies we meet. Of course, we are all here to make the lives of patients better, but you can tell that this is a very strong focus in the mind of Biovica. So, our collaboration is not like a traditional company and academia, it's more in line with academia and academia

### What about the DiviTum®TKa test itself?

What interested us is the clear and simple concept. Cell proliferation has always been in focus in breast cancer and a lot can be captured with tumor cell proliferation, but so far assays have been done with tissue samples. The beauty of DiviTum®TKa is that it only requires blood for analysis. That is what convinced us. The limitation of other assays is the sample itself; using old samples might not give adequate information and new fresh biopsies can be complicated to collect. So, the first and most important point is that from blood you can have information on tumor proliferation.

## The liquid biopsy test market has evolved, aren't there other viable alternatives?

Yes, it has evolved, but this is still the only blood test that gives this kind of information. There are tests evolving which use circulating tumor DNA, but they will not give information on tumor proliferation. Using for example ctDNA can give you a lot of information, but often not every patient will have an interpretable result, and, most importantly, the information you get may not be so important clinically. The DiviTum®TKa blood test can give meaningful information on virtually every patient that is interpretable and usable. You always get a result.

# You have done many studies during these six years using DiviTum®TKa, are there any you specifically want to highlight?

It is rather the flow throughout the years that I would like to highlight. We started from the concept that tumor proliferation is important for the response to endocrine treatment. We knew from studies in the neoadjuvant setting, before surgery, that changes in tumor proliferation - measured by the standard marker Ki-67-can predict hormone sensitivity. We shifted this concept to the metastatic setting where the use of Ki-67 is limited, and a more dynamic measure of tumor proliferation is very useful. If it works in the neoadjuvant setting, it must work in the metastatic setting.

## How did it work out?

We wanted to see if there was a correlation not only to base line TKa and outcome, but also, if early changes during treatment could give an idea on future response. That seemed to be the case in our small pilot study, but it was also confirmed in a larger follow up study we performed. I must also say that I was very happy to see the SWOG results presented at SABCS in December 2020. They started from the same concept as us, in a large population, and confirmed that tumor proliferation measured by DiviTum®TKa can give prognostic and predictive information in patients with HR+, HER2- breast cancer receiving hormone therapy.

## From that you moved on to CDK4/6 inhibitors.

Yes, this is our latest development. We have looked for mechanisms of resistance to CDK4/6 inhibitors and led a multi-center study called TREnd that involved patients with metastatic breast cancer that received the CDK4/6 inhibitor palbociclib. We tested the hypothesis that DiviTum®TKa could be a useful biomarker in this setting, and indeed it was. We found that dynamic changes in the first cycle of treatment could identify patients that would not respond to treatment. Patients that did not have a decrease in TKa had a very bad outcome.

## That sounds very similar to the PYTHIA trial.

Yes, I was the Principal Investigator in a study lead by IBCSG and BIG - the PYTHIA study (Palbociclib in molecularly characterized ER-positive/HER2-negative metastatic breast cancer) – designed to investigate new biomarkers where we included DiviTum®TKa.The results were presented in San Antonio in December 2020 and completely confirmed our hypothesis; Patients that do not show a drop in DiviTum®TKa activity, do very poorly. But the most striking and interesting result was that this could be seen only after 15 days of treatment. That means that in just 15 days you could probably identify a group of patients that have intrinsic resistance, who have a high likelihood not to be helped by the treatment. This information could be very helpful. Perhaps you should escalate intensity of treatment or try other treatments to overcome resistance. Of course, we need to learn a lot more, in more trials, but this has been the most interesting result so far.

## Perhaps the BioltaLEE study will give more guidance?

We will hopefully get more data from BioltaLEEa phase IIIb study in postmenopausal women receiving letrozole plus ribociclib as first-line treatment. It is similar to PYTHIA, however in a much larger, and less pre-treated population. With this study the picture will be complete, and we will hopefully have proof to support the concept that the assay is prognostically very useful not only in the second and third-line setting (like seen in TREnd and PYTHIA) but also in the first-line setting. We can already say that the assay is useful to stratify patients across many treatment lines and that, whenever you use the assay for whatever treatment (hormonal therapy alone or in combination with CDK4/6 inhibitors), this assay could be helpful clinically. This makes the assay very interesting for the management of metastatic breast cancer.

## Could DiviTum®TKa be used in other areas outside breast cancer?

Potentially, as a dynamic biomarker any tumor type could be investigated because when you use a dynamic biomarker, you see what happens during treatment and tumors that respond to therapy decrease or stop proliferating. There might be issues with some types of treatment that may interfere with the assay, but potentially, it may be used anywhere, in any cancer, but perhaps specifically in cancers where Ki-67 is used, and proliferation has a proven prognostic role. But, of course, it would have to be investigated further.

## Neoadjuvant treatment

Preliminary cancer treatment (chemotherapy, radiation therapy, hormone therapy, immunotherapy, hyperthermia, etc.) that precedes a second, necessary form of treatment.

# Strong protection that goes beyond strong patents

Biovica feels that intellectual property rights are a cornerstone for successful commercialization and thereby value creation. Biovica has strong patent protection, having been granted patents in all markets were the company applied for one. At present, Biovica has patents in 49 countries.

The patents for DiviTum®TKa expire in 2026 and 2031 for the two different patent families, which cover two different technology platforms,

ELISA and PCR. Both platforms measure TK and the correlation between them is high.

During the development of DiviTum®TKa, Biovica accumulated considerable know-how that would make it difficult for others to copy DiviTum®TKa. Even after the patents expire, Biovica expects that it will retain strong protection since neither the manufacturing process nor compilation of the test is disclosed in

the patent specification. The risk that Biovica's technology is copied is further lowered by the fact that Biovica does not share this type of knowledge with any production partners.

In most countries, clinical documentation is also required for successful commercialization of a diagnostic test. Demonstrating that a copied product works as well as DiviTum\*TKa would be a difficult and costly task.



## Sustainability

Biovica's sustainability report is closely aligned with our vision of treatment decisions with greater confidence, which will help give cancer patients a longer life with better life quality. The core of our operations, and our most important contribution to sustainable development, is making safer, more efficient diagnostics available to cancer patients.

### **KEY VALUES**

Biovica actively strives to continually improve its company culture. Biovica's key values clearly capture the principles that provide the foundation for our organization and its culture along with how the company makes decisions and how we interact with each other, our customers, owners, partners and other stakeholders.

**Respect** – We treat our colleagues and customers with respect. We listen and appreciate each other's perspectives.

**Solution-oriented** – We identify problems and propose solutions.

Purpose-driven – We are delivering on our goals that have been formulated based on the purpose that drives

**Team player** – We work as a team, supporting each other to become successful.

## DEDICATED EMPLOYEES ARE THE KEY TO SUCCESS

Employee commitment, initiative and motivation to perform contribute to Biovica's success. The company culture fosters dedication and entrepreneurial spirit. We also have a decentralized organizational structure where all employees contribute to the end results. Biovica's employees work as a team to achieve the vision of treatment decisions with greater certainty, which will help give cancer patients a longer life with better life quality.

Biovica has 20 employees in three countries with different assigned tasks and areas of responsibility. All Biovica employees have the same ultimate mission however, which is establishing DiviTum®TKa as a standard tool

for monitoring the treatment of metastatic breast cancer.

Commitment and clarity are values that permeate the entire organization. At Biovica, we want every employee to feel proud of their contribution to the company's success. Biovica strives for equality, sustainability and to provide a healthy work environment where every employee is able to perform, develop and thrive. Our future growth and success require that we continually work with our brand and strengthen our reputation as an attractive employer.

Biovica has operations in three countries, but most are employed in Sweden. At present, we have two employees working in the USA and two in Denmark. Of the total number of employees, 45 percent are women and 55 percent are men. Biovica strives to achieve and maintain an even gender balance at the company.

Over the last few years, employee turnover and absence due to illness have been at low, sustainable levels at Biovica. The results from our employee satisfaction surveys also indicate that our employees enjoy their work.

### Focus areas in 2020/2021

During the 2020/2021 financial year, Biovica has focused on several important areas aimed at preserving our attractive reputation as employer and ensuring the company's continued growth and success. Biovica has continued to work with its focus areas, which are the work environment, skill development and self-leadership.

## An attractive workplace

Biovica expects a lot from its employees and they, in turn, can expect a lot from Biovica. Over the last few years, Biovica has invested in benefits and incentives that provide employees with more security and higher quality of life. Biovica's employees have salary options for making higher pension provisions, subsidized fitness memberships, wellness programs and fun team-building activities.



### SUSTAINABILTY FFFORTS

Biovica has initiated sustainability efforts based on the 17 UN Sustainable Development Goals In total, Biovica has focused on five of these goals, which represent the areas where Biovica can contribute most and make a difference.



By offering DiviTum®TKa, Biovica helps improve the health of women suffering from metastatic breast cancer. Our vision is to improve the quality of life for cancer patients, with a longer survival.



Biovica believes that all people have equal worth, regardless of, for example, their gender or ethnicity. These values govern both how the company recruits and interacts with employees and stakeholders alike.



As an employer, Biovica strives to provide a good work environment, with opportunities for development and with attractive terms.



Biovica's innovative technology will help lower the reliance on other technologies that have a negative impact on both health and the environment. By replacing such technologies with monitoring of cancer treatments, Biovica helps reduce travel for patients, along with their exposure to radiation, which is beneficial to both health and the environment.



Biovica strives to minimize negative impact on the environment. Biovica does this by packaging efficiently and using as much environmentally-friendly and recyclable material as possible.

Besides that, efficient packaging helps lower the environmental impact of transports. Furthermore, Biovica considers the environmental aspects of employee business trips. Unnecessary travel should be avoided and priority given to more environmentally friendly travel options whenever possible.

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## Biovica shares

Biovica's shares became listed on Nasdaq First North Growth Market Stockholm on 27 March 2017 and are included in the First North All-Share SEK index and the First North Health Care PI index.

Biovica has two share classes: Class A shares (3 votes each) and Class B shares (1 vote each). Registered share capital is SEK 1,884,891.47 allocated across 28,573,372 shares of which 6,623,170 are Class A shares and 21,650,202 are Class B shares. The quotient value is SEK 0.07 per share.

## Nasdaq First North and Certified Adviser

First North Growth Market is an alternative marketplace for Nordic growth companies that is designed primarily for small and medium-sized companies. It does not have the same legal status as a regulated market and the regulations are somewhat less extensive than those that apply to the stock exchange's larger marketplaces.

All companies whose shares are traded on First North Growth Market have a Certified Adviser who monitors that the company complies with First North Growth Market's regulations for providing information to the market and investors.

FNCA Sweden AB is the appointed Certified Adviser.

Phone: +46 8 528 00 399, E-mail: info@fnca.se

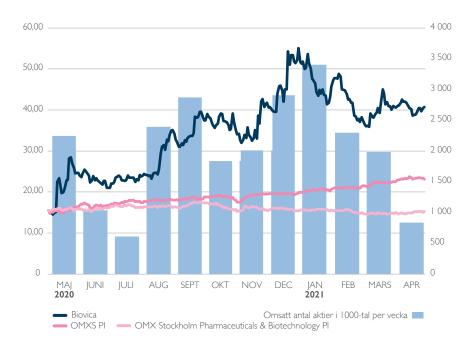
### TRADING INFORMATION

Ticker symbol on Nasdaq First North Stockholm: BIOVIC B ISIN code: SE0008613731 LEI code: 549300VADE1VRR555N78 The shares are registered by Euroclear Sweden AB.

#### SHARE PRICE GROWTH

During the financial year, the price of the Biovica share increased **163 percent**, compared to the First North All-Share index, which increased 74 percent during that same period. The highest price paid was SEK 55 on 2020-12-28 and the lowest was SEK 14.45 on 2020-05-06.

On 30 April 2021, the listed price for shares in Biovica was SEK 40.70, corresponding to market capitalization of **SEK 1,157 million.** 



## THE TEN LARGEST OWNERS AS OF 30 APRIL 2020

Name	Number of class	Share of capital, %	Share of votes, %
Anders Rylander	3,955,396	13.92	26.76
Avanza Pension	1,999,699	7.04	4.82
Gunnar Rylander	1,503,297	5.29	8.11
Coeli	1,446,806	5.09	3.47
Lancelot Asset Management AB	800,000	2.82	1.92
Nordnet Pension Insurance	682,986	2.40	1.65
Henrik Osvald	624,106	2.20	1.50
LYM Consulting AB	493,810	1.74	1.19
Lars Erik Holmqvist	480,630	1.69	1.16
Second Swedish National Pension Fund (AP2)	475,000	1.67	1.14
Total, 10 largest owners	12,461,730	43.85	51.72
Other shareholders	15,956,642	56.15	48.28
Total number of shares	28,418,372	100.00	100.00

Source: Euroclear & Holdings

## SHARE-RELATED INCENTIVE PROGRAMS

Biovica has four ongoing incentive programs The table below provides an overview of the content of each program.

Program	То	Class B shares Subse	cription price	Option price	Subscription period	Share capital increase	Number of class B shares
TO4	Board of Directors	150,000	19.50	0.94	25 March 2022 – 25 August 2023	10,000.00	150,000
TO5	employees	170,000	17.16	1.23	25 March 2021 – 25 August 2022	11,333.33	170,000
TO6	employees	173,000	45.14	3.31	25 March 2022 – 25 August 2023	11,533.33	173,000
TO7	Board of Directors	200,000	45.14	3.31	25 March 2022 – 25 August 2023	13,333.33	200,000
						46,200.00	693,000

## **GROWTH OF SHARE CAPITAL OVER TIME**

The table below shows the historical growth of Biovica's share capital 2008 until the present time.

		Number of	class			
Registration date	Event	Change	Total	Share capital (SEK)	Total	Quotient value
2021-01-28	Share subscription due to warrants	145,000	28,418,372	9,666.67	1,894,558.11	0.07
2020-08-25	New share issue	4,700,000	28,273,372	313,333.33	1,884,891.45	0.07
2019-05-07	New share issue	6,000,000	23,573,372	400,000.00	1,571,558.12	0.07
2017-04-06	New share issue	4,800,000	17,573,372	319,999.99	1,171,558.12	0.07
2016-07-29	New share issue	2,300,000	12,773,372	153,333.33	851,558.12	0.07
2016-07-29	New share issue	690,000	10,473,372	46,000.00	698,224.79	0.07
2016-07-29	New share issue	465,875	9,783,372	31,058.33	652,224.79	0.07
2016-05-24	New share issue	931,747	9,317,497	62,116.47	621,166.46	0.07
2016-04-28	Split 1:15	7,826,700	8,385,750	-	559,050.00	0.07
2016-04-19	New share issue	6,346	559,050	6,346.00	559,050.00	1.00
2016-01-12	New share issue	50,625	552,704	50,625.00	552,704.00	1.00
2015-06-08	New share issue	61,150	502,079	61,150.00	502,079.00	1.00
2015-05-15	Exchange of convertibles	54,080	440,929	54,080.00	440,929.00	1.00
2015-05-15	Decrease in share capital	-12,500	386,849	-12,500.00	386,849.00	1.00
2014-08-14	New share issue	82,893	399,349	82,893.00	399,349.00	1.00
2014-07-07	Decrease in share capital	-12,500	316,456	-12,500.00	316,456.00	1.00
2013-09-25	New share issue	45,987	328,956	45,987.00	328,956.00	1.00
2012-07-16	Decrease in share capital	-	282,969	-25,000.00	282,969.00	1.00
2012-07-16	New share issue	25,000	282,969	25,000.00	307,969.00	1.09
2012-07-05	Bonus issue	-	257,969	25,000.00	282,969.00	1.10
2012-07-05	Decrease in share capital	-25,000	257,969	-25,000.00	257,969.00	1.00
2011-06-01	New share issue	3,906	282,969	3,906.00	282,969.00	1.00
2011-06-01	New share issue	39,063	279,063	39,063.00	279,063.00	1.00
2010-06-09	New share issue	50,000	240,000	50,000.00	240,000.00	1.00
2009-11-06	New share issue	30,000	190,000	30,000.00	190,000.00	1.00
2009-02-24	New share issue	60,000	160,000	60,000.00	160,000.00	1.00
2009-02-24	Split 1:100	99,000	100,000	-	100,000.00	1.00
2008-12-29	New formation	1,000	1,000	100,000.00	100,000.00	100.00



## Corporate governance report

Good corporate governance is about ensuring that companies are managed in a way that is as efficient for shareholders as possible. Corporate governance at Biovica is based on Swedish Law, primarily the Swedish Companies Act, Annual Accounts Act and the Swedish Corporate Governance Code (the Code). Biovica stock is traded on Nasdag First North Premier Growth Market and accordingly, Biovica complies with the applicable legislation, Nasdaq First North Nordic's rules and regulations and statements issued by the Swedish Securities Council on good practice in the Swedish securities market. During the 2020/2021 financial year, Biovica did not have any departures from the Code.

#### **AGM**

The AGM is Biovica's highest decision-making body. The Annual General Meeting is held each year within six months of the end of the financial year. The Annual General Meeting shall be held within six months after the end of the previous financial year in order to, among other things, present and adopt the statutory financial statements and reports, appropriate earnings and resolve to discharge the members of the Board from liability. All shareholders registered in the shareholders' register who have announced their intent to participate by the date specified in notice of the AGM are entitled to participate in the meeting and exercise their voting rights. A shareholder who would like to have a particular matter dealt with at the AGM must, well in advance of the AGM, submit their request to the AGM, using the

address published on the company's website. The Board of Directors may also, beyond the AGM, summon shareholders to extraordinary general meetings. Biovica's Articles of Incorporation do not contain any limitations on how many votes each shareholder may exercises at the AGM.

### Resolutions at the 2020 AGM included:

- The following Board members were reelected:
   Lars Holmqvist, Maria Holmlund,
   Ulf Jungnelius, Henrik Osvald, Anders
   Rylander and Jesper Söderqvist. The AGM also resolved to elect Annika Carlsson Berg and Marie-Louise Fjällskog as new members of the Board of Directors.
   Lars Holmqvist was elected as the Chairman of the Board.
- Grant Thornton Sweden AB was re-elected as the company's auditor. Authorized Public Accountant, Stéphanie Ljungberg, will continue as the auditor-in-charge.
- Guidelines for remuneration to senior executives. The guidelines were unchanged from last year.
- Resolution on granting the Board of Directors the authority to issue new shares for a maximum amount equal to 20% of the current number of shares.
- A warrant scheme for staff of 220,000 warrants.
- A warrant scheme for members of the Board of Directors of 200,000 warrants.

### Major shareholder

Anders Rylander is Biovica's largest share-holder with 13.92 % of the capital and 26.76% of the votes.

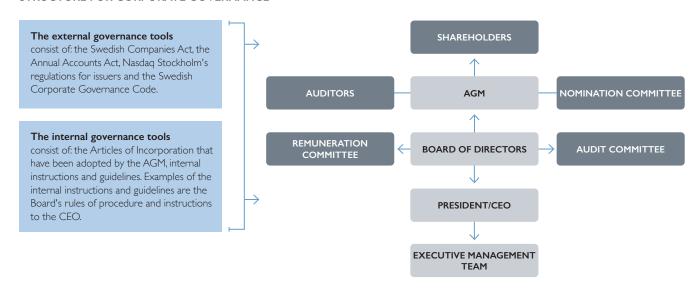
#### **Nomination Committee**

The Nomination Committee is responsible for submitting proposals on who should serve as chairman for general meetings of shareholders, candidates for Board members, including the Chairman of the Board, fees and other remuneration to each Board member, along with remuneration for committee work, as well as the election of, and remuneration to, external auditors.

For the period up until the 2021 AGM, the Nomination Committee consists of: Anna Rylander Eklund, appointed by the Rylander family, Mikael Petersson, appointed by Coeli and Lars Holmqvist, Chairman of the Board at Biovica.

No remuneration is paid to the members of the Nomination Committee. The Nomination Committee is entitled to request compensation from the company for reasonable costs that are necessary for the committee to carry out its assigned tasks. The mandate period for the Nomination Committee extends until a new Nomination Committee is announced. In conjunction with the Nomination Committee's work and for the purpose of own improvement efforts, the Board of Directors conducts an evaluation each year of its work and efficiency. The results of that evaluation are distributed to the Nomination Committee.

## STRUCTURE FOR CORPORATE GOVERNANCE



### **BOARD MEMBERS AND THEIR INDEPENDENCE**

Name	Position	Elected	Independent in relation to the company and Group management	Independent in relation to major shareholders	Attendance at Board meetings	Attendance at Committee meetings
Lars Holmqvist	Chairman	2019	Yes	Yes	20/21	3/3
Annika Carlsson Berg	Board member	2020	Yes	Yes	8/10	
Marie-Louise Fjällskog	Board member	2020	Yes	Yes	10/10	
Maria Holmlund	Board member	2016	Yes	Yes	21/21	5/5
Ulf Jungnelius	Board member	2014	Yes	Yes	20/21	
Jesper Söderqvist	Board member	2013	Yes	Yes	21/21	5/5
Henrik Osvald	Board member	2019	Yes	Yes	21/21	3/3
Anders Rylander	Board member, CEO	2010	No	No	21/21	

### Composition of the Board of Directors

Biovica's Articles of Incorporation stipulate that the company must have at least three Board members and at most ten Board members. At the 2020 AGM, a total of eight Board members were appointed: three women and five men. Lars Holmqvist, Annika Carlsson Berg, Marie-Louise Fjällskog, Maria Holmlund, Ulf Jungnelius, Henrik Osvald, Anders Rylander and Jesper Söderqvist. Lars Holmqvist was elected as the new Chairman of the Board. The CEO is always a member of the Board of Directors and is always present at Board meetings. Cecilia Driving EVP CFO at Biovica serves as secretary for the Board of Directors.

All Board members (except for Anders Rylander) are independent in relation to the Company, its management and major shareholders. Biovica is thus in compliance with the requirements issued by Nasdaq Stockholm and with the Code as regards the independence of Board members.

## The work done by the Board and Board evaluation

The Board has the ultimate responsibility for directing the company's operations between the Annual General Meetings. The Board makes decisions on issues relating to the company's strategic direction, financing, major investments, acquisitions, divestments, organizational issues, incentive principles and important policies. The work done by the Board is regulated by, among others, the Swedish Companies Act, the Articles of Incorporation, the rules of procedure that the Board has adopted and the Board's instructions to the CEO. The rules of procedure clarify each Board member's responsibilities, in particular the Chairman's, as well as allocation of responsibilities between the Board of Directors and CEO along with the CEO's authorities. Those authorities have also been clarified in more detail in the instructions to the CEO. The rules of procedure also state, at an overall level, the subject areas that the Board of Directors shall cover

and work with during the year, along with how time should be allocated to the various components of their work.

The Board reviewed its rules of procedure during 2020, along with instructions to the CEO and reporting instructions. It also evaluated the work done by the CEO. During the year, the Board set up two committees: a Remuneration Committee consisting of Maria Holmlund, Chair, and Jesper Söderqvist; and an Audit Committee consisting of Henrik Osvald, Chair, and Lars Holmqvist. During the 2020/2021 financial year, the Board held 21 meetings where the minutes were taken.

### Evaluation of the Board

An external, systematic evaluation of the work done by the Board of Directors was carried out during spring 2021. As part of the evaluation, Board members gave feedback on the Board's working methods, Board material, their own efforts and views on the efforts of other Board members. The purpose of it all is to develop the work done by the Board and provide the Nomination Committee with information relevant to its work and decisions.

## Responsibilities of the Remuneration Committee

The Remuneration Committee is responsible for preparing matters and/or materials for decisions having to do with the following:

 Providing the Board with proposals on remuneration guidelines and other employment terms for the CEO and other senior executives (in accordance with the rules stipulated in the Swedish Companies Act). This occurs at the first ordinary Board meeting of the financial year. This includes policies on such things as salary, benefits and other employment terms for Biovica's senior executives. Examples are policies on bonus and incentive programs for the short and long term, pensions, basic salary and other employment terms. • The Committee also makes a proposal for the CEO's salary and other benefits.

## Responsibilities of the Audit Committee

The Audit Committee is responsible for monitoring corporate governance issues and how they are applied. It reviews the company's risk management routines, as well as its management and control of the financial reporting.

By maintaining a continuous dialog with the company's auditors and the accounting/ finance function, the Committee shall ensure that both internal and external auditors fulfill the stipulated requirements and that there are relevant policies and governing documents in place. They also discuss with auditors the scope and focus of audit work. Each year, the Audit Committee prepares an audit plan and defines joint issues that the audit should focus on. The Audit Committee evaluates the audit work and approves any additional services that the company has engaged from the external auditors. The Committee also assists the Nomination Committee by making a proposal for the company's selected auditor, along with the fees for that work.

The Chair of the Audit Committee is responsible for keeping the entire Board continuously informed about the Committee's work and, as needed, referring any matters to the Board for a decision.

Although the Audit Committee is able to have in-depth discussions with the company's auditors, this does not replace the meetings that the auditors otherwise have with the entire Board of Directors. Such meetings take place at least once per year, typically in conjunction with the annual report.

## CEO and Group management

The CEO is responsible for the ongoing administration and running of the company's business. Allocation of work between the Board and the CEO is detailed in the company's rules of procedure for the Board and instructions to the CEO. The CEO keeps the

Board continuously informed about the company's operations, performance and financial position through, among others, monthly reports. The CEO is also responsible for preparing reports and compiling information for Board meetings, along with presenting that information at Board meetings.

Anders Rylander is the President and CEO of Biovica and the other members of the management team are: Cecilia Driving, EVP CFO, Otti Bengtsson Gref, VP R&D, Tomas Andersson, VP Operations, Joakim Arwidson, VP Regulatory and QA, Robert Dann, SVP Marketing and US Business, Helle Fisker, VP Commercial and Henrik Winther, SVP Business Development.

## Remuneration and employment terms Board of Directors

At the AGM on 27 August 2020, it was resolved that a fee of SEK 150,000 would be paid to each member of the Board who is not an employee of the company and that the fee paid to the Chairman of the Board would be SEK 400,000. For the 2020/2021 financial year, remuneration to the Board of Directors totaled SEK 1,300,000.

## CEO and Group management

Biovica shall offer a market-competitive total compensation package such that it is possible to recruit and retain talent for its executive management team. Compensation shall consist of fixed salary, performance-based remuneration, share savings programs, pension and other remuneration. Together, it comprises an individual's total compensation package.

Fixed salary, which is reviewed each year, shall reflect the individual's areas of responsibility and experience. Performance-based remuneration is based on the individual achieving certain qualitative and quantitative targets. For senior executives, the variable portion of compensation may not exceed 40 percent of fixed salary.

The Board of Directors decides on the remuneration policy for the CEO and Group management team. The policy in place as of the date of this annual report has been designed in accordance with the

guidelines for remuneration to the CEO and Group management that were adopted by the AGM. Individual remuneration to the CEO is proposed by the Remuneration Committee and approved by the Board of Directors. For other members of the Group management team, individual remuneration is proposed by the CEO and approved by the Board.

Details on the total remuneration and other remuneration that has been granted, directly or indirectly, by the Company to its senior executives is provided in Note 10. The Company has not granted any loans to its senior executives.

## Auditors

The company's auditor is appointed at the AGM. During the year, the auditor meets with the Board of Directors at various times to present their findings based on the audit of the financial statements and internal controls, ensuring that the requirements of a listed company have been met. For the 2020/2021 financial year, Grant Thornton Sweden AB was appointed as the company's auditor, with Stéphanie Ljungberg as the auditor-in-charge. The company's auditor met with the Audit Committee/Board of Directors on three occasions to present the findings and conclusions from their audits.

## Internal control and risk management

The Board of Directors is responsible for internal control at Biovica. For financial reporting, internal control and risk management is a process that has been designed by the Board aimed at providing them, management and others within the organization with reasonable assurance about the reliability of external financial reporting and that it has been prepared in accordance with generally accepted accounting principles, applicable laws & regulations and the requirements for listed companies.

## Control environment

The internal control environment is based on allocation of responsibilities and authorities among the members of the Board of Directors, Board committees, the CEO and

other senior executives. The most important components of Biovica's control environment are documented in the rules of procedure for the Board, instructions to the CEO, policies and other governance documents.

### Control activities

Appropriate control activities are a prerequisite for managing the significant risks associated with internal control. In order to safeguard its internal control, Biovica has both automated, system-based controls and manual controls, such as reconciliations and physical inventory counts. Financial analyses of the company's results, along with follow-up on plans and forecasts, supplement the controls and provide an overall confirmation of the quality of reporting. This is monitored continuously throughout the year via reports to the Board and at both Audit Committee meetings and Board meetings.

## Internal audit

Biovica has set up a governance and internal control system and activities are carried out at various levels of the company regularly to ensure compliance. Based on that, the Board has assessed that, at the present time, there is no need for setting up a special audit function. The Board reconsiders this decision each year.

### Information and communication

The company's governing documents in the form of policies, guidelines and manuals on both internal and external communication are regularly updated and communicated via such things as meetings and other relevant company-internal channels. Biovica's information policy governs communication with external partners, which specifies the guidelines on how information is made public. The aim of the policy is to ensure that the company fully and completely fulfills its information obligations in accordance with the applicable laws and regulations.

## **BOARD CALENDAR**

QI	Q2	Q3	<b>Q</b> 4
MAY-JULY	AUGUST-OCTOBER	NOVEMBER-JANUARY	FEBRUARY-APRIL
Board report/CEO evaluation	Strategy meeting     Annual General Meeting (AGM)     Meeting following election	• Policies	• Budget
Year-end report     Annual report	Annual General Meeting (AGM)     Q1 Interim report	• Q2 Interim report	• Q3 Interim report

## Board of Directors

Biovica's Board of Directors consists of eight ordinary members elected by the AGM, including the Chairman of the Board, who have been elected for the period until the next Annual General Meeting.









LARS HOLMQVIST	LARS	HOI	LMQ	/IST
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**ANNIKA** 

**MARIE-LOUISE** 

MARIA HOLMLUND

	z mo riozrigyio.	CARLSSON BERG	FJÄLLSKOG, MD, PhD	.,
Born	1959	1963	1964	1956
Ordinary member	Chairman of the Board since 2019	Board member since 2020	Board member since 2020	Board member since 2016
Citizenship	Swedish	Swedish	Swedish	Swedish
Education/ background	Executive MBA from INSEAD France. Previously Senior Advisor for healthcare at Bain Capital. Senior management roles in pharmaceutical and medtech companies including: Agilent, Dako, Applied Biosystems Inc. and Medtronic Europe Sarl.	Annika Carlsson Berg has more than 35 years of experience in the pharmaceutical, biotech, Life Sciences and diagnostics industry, of which, 24 years have been in executive positions. Annika is Global Vice President of Quality Assurance & Regulatory Affairs at the Immuno-Diagnostic Division of Thermo Fisher Scientific. Her prior positions were Global Vice President of Quality Assurance, Regulatory Affairs and Medical Affairs at Agilent Technologies, Global Vice President of QA/RA at GE Healthcare and Section Manager at Pfizer. Annika is an analytical chemist and she holds a licentiate's degree in analytical chemistry.	Marie-Louise is an MD, having received here degree in medicine from Uppsala University and she became Associate Professor of Oncology in 2008. Marie-Louise has more than 25 years of experience in clinical oncology, translational research, and drug development. Prior experience includes leading positions at Novartis Institute for Biomedical Research (NIBR), Merus and Infinity Pharmaceuticals.	B.A. in chemistry and biology from Uppsala University and Gothenburg University. M.Sc. from University of North Carolina. More than 30 years of experience working in the field of Life Science and diagnostics. Senior positions in marketing at several major international diagnostic companies.
Current assignments	Board member at: Lundbeck Fonden A/S, H Lundbeck A/S, ALK-Abelló A/S, Naga Uk TopCo and Vitrolife AB.	Global Vice President of Quality Assurance & Regulatory Affairs at the ImmunoDiagnostic Division of Thermo	Chief Medical Officer at Sensei Biotherapeutics in Boston, USA. Board members	Board member at Prolight Diagnostics AB (publ)

Fisher Scientific.

Lytix Biopharma AS.

Holding in the

Directly and indirectly 523,630 Class B 25,000 TO7 shares, 50,000 TO4 and 50,000 TO7

25,000 TO7

9,750 Class B shares, 25,000 TO4 and 25,000 TO7

Independent in relation to the Company, its management and major shareholders.

Yes

Yes

Yes

Yes









**ULF JUNGNELIUS,** MD

HENRIK OSVALD ANDERS RYLANDER

JESPER SÖDERQVIST, PhD

Born	1951	1959	1970	1966
Ordinary member	Board member since 2014	Board member since 2019	Board member since 2010 and CEO since 2011	Board member since 2013
Citizenship	Swedish	Swedish	Swedish	Swedish
Education/ background	Oncology Specialist with diploma from Karolinska Institute, along with clinical experience from Radiumhemmet in Stockholm.  Dr. Jungnelius has extensive experience in international clinical research & development in the field of oncology. He has held executive positions at several international companies such as Eli Lilly, Pfizer, Takeda and Celgene.	Henrik is CEO at Primas Invest AB and has a portfolio of investments in, for example, the life science sector. He has experience as an entrepreneur and CEO working with distribution and retail. He has also successfully built up major international operations.	M.Sc. in mechanical engineering with focus on industrial economics from KTH Royal Institute of Technology. Previously Senior Manager at Accenture, CTO for ICA AB and founder of Axholmen (consultancy firm).	M.Sc.Eng. from KTH Royal Institute of Technology. Ph.D. in Physics from KTH Royal Institute of Technology and CERN. Previously CEO at Arcoma, Vice President for Elekta AB's neuroscience division, General Manager for mammography at Philips Healthcare and CEO at Sectra Mamea.
Current assignments	CEO at Isofol Medical AB, Board member at Oncopeptides AB, Ryvu Therapeutics and Monocl AB.	Henrik is CEO and a member of the Board of Directors at Primas Invest AB.	Board member at Arinvest AB and Anders Rylander Investment AB.	Jesper Söderqvist is CEO of Boule Diagnostics AB, Board member of Arcoma AB, as well as Board member and CEO of Dekatria AB.
Holding in the company	25,000 TO4 and 25,000 TO7	Directly and indirectly 624,106 Class B shares, 25,000 TO4 and 25,000 TO7	Indirectly 3,575,640 Class A shares, 379,756 Class B shares, 20,000 TO5 and 20,000 TO6	Directly and indirectly 41,085 Class A shares and 38,200 Class B shares, 25,000 TO4 and 25,000 TO7
Independent in relation to the Company, its management and major shareholders.	Yes	Yes	Anders Rylander is (via companies and related parties) Biovica's largest shareholder.	Yes

## Senior executives

Biovica's executive management team consists of the President/CEO and seven additional senior executives. There are five men and three women on the executive management team.







For five years in a row, it achieved

growth in the range of 50- 100 per-

cent by introducing two to three new

20 years. Before Tomas Joined Diovision, he was Head of Supply Chain at Olink Proteomics, a company that works with last ten years, he has held the position of VP Quality and Regulatory at Modical Solutions, a molecular



specifically with bone densitometry, fluoroscopy and C-frames. During the

Hermes Medical Solutions, a molecular

imaging company that focuses on

applications used in oncology and

	ANDERS RYLANDER	CECILIA DRIVING	TOMAS ANDERSSON	JOAKIM ARWIDSON
Born	1970	1971	1960	1968
Position	President/CEO	EVP and CFO since 2016	VP Operations since 2020	VP RA / QA since 2021
Education/ background	M.Sc. in mechanical engineering with focus on industrial economics from KTH Royal Institute of Technology. Previously Senior Manager at Accenture, CTO for ICA AB and founder of Axholmen (consultancy firm).	Master of Laws and B.Sc. in business administration from Stockholm University. Cecilia has experience working in the fields of Life Sciences, IT, telecommunications and research as CFO and Corporate Counsel. She also has experience working with listed companies, in private equity and with both privately owned and state-owned companies.	Tomas has a university degree in medical laboratory technology and more then 30 years of experience in the Life Sciences field, working with everything from production and logistics, to process development, introduction of new products and quality control. He has been employed in leading positions at Biacore, GE Healthcare and Doxa over the last	Joakim has a bachelor's degree in computer and electrical engineering from the Institute of Technology at Linköping University (LiTH). He has more than 25 years of experience in QA/RA experience in the Life Sciences field working with development, production, market introduction and market follow-up in North America, Europe and Asia. He has worked

		products per year.	theranostics.
Board member at Arinvest AB and	Board member at Ovzon AB.	-	_

Current assignments Holding in the company Indirectly 3,575,640 Class A shares, 20,000 TO5 20,000 Class B shares, 20,000 TO5 and 20,000 TO6 20,000 TO6

and 20,000 TO6



Holding in the 20,000 Class B shares, 20,000 TO6 company







20,000 TO5 and 20,000 TO6

	ROBERT DANN	OTTI BENGTSSON GREF	HELLE FISKER	HENRIK WINTHER
Born	1962	1968	1969	1966
Position	SVP Marketing and US Business since 2020	VP R&D since 2020	VP Commercial since 2021	SVP Business Development since 2020
Education/ background	Robert Dann has and MA in Russian Civilization from University of Chicago and an MBA from Columbia University. He has more than 20 years of experience working in the healthcare industry in a variety of roles, including country manager, head of global launches and strategy formulation. He has worked with cancer care, pharmaceuticals, diagnostics and artificial intelligence at AstraZeneca, GE Healthcare and IBM Watson Health. Robert has been influential in the market launch of several revolutionary products in the healthcare industry.	Licentiate of Medical Science degree in immunology from Uppsala University. Executive MBA from MGruppen. She has more than 20 years of experience working with research, product development and production in both academia and industry. Otti has held several management positions in both development and production at Thermo Fischer and she has extensive experience in product development of in vitro diagnostics. Most recently, Otti worked as R&D Director at Cavidi AB developing, manufacturing and marketing HIV molecular diagnostics.	Helle has an MSc Eng in Biotechnology from the Technical University of Denmark (DTU) specializing in immunology and an Executive MBA from Copenhagen Business School. During the last 20 years, she has held a variety of sales and marketing positions at oncology and cancer diagnostic companies and was influential in implementing several global product launches and commercial strategies for such companies as GSK, Dako (now Agilent) and Leica Biosystems, as well as introducing new products in the European markets for small and medium-sized companies, examples of which are ViroGates and Visiopharm. Before joining Biovica, Helle worked as a strategy and marketing consultant on assignments for such clients as Sysmex, Diaceutics, Tieto and Pathcore, working with advanced nuclear, genetic and digital cancer diagnostics and oncology.	Henrik was Associate Professor in Anatomy, Physiology and Cell Biology at University of Copenhagen prior to taking employment at the diagnostics company, Dako, which was later acquired by Agilent. Henrik held several executive management positions at Dako. He was the R&D Director prior to taking over as Business Area Manager for Companion Diagnostics. Under his management, the business area experienced tenfold growth in both revenue and number of employees. At Agilent, Henrik was appointed Vice President and General Manager of the Companion Diagnostics Division. Prior to joining Biovica, Henrik worked at SVP Business Development at the Swedish diagnostics company, Immunovia.
Current assignments	-	-	-	Board member at SAGA Diagnostics AB.

20,000 TO5 and 20,000 TO6

# Auditor's statement on the corporate governance report

To the AGM of Biovica International AB, CIN 556774-6150

# Assignment and allocation of responsibilities

We have reviewed the corporate governance report for the financial year 2020-05-01 – 2021-04-30 on pages 31–37. The Board of Directors is responsible for the corporate governance report and for ensuring that it has been prepared in accordance with the Annual Accounts Act. Our responsibility is to express an opinion on the corporate governance report based on our review.

#### Focus and scope of the review

Our review has been conducted in accordance with RevU 16, Auditor's Review of the Corporate Governance Report. This means that we planned and conducted the review with the aim of assessing, with a reasonable degree of assurance, whether the corporate governance report is free from material misstatement. It involves reviewing a selection of the supporting documents for information in the corporate governance

report. We believe that the review has provided us with sufficient basis for our opinions.

#### **Opinions**

A corporate governance statement has been prepared. It is consistent with the annual accounts and consolidated accounts, as well as in accordance with the Annual Accounts Act.

Uppsala, 30 June 2021

Grant Thornton Sweden AB

Stéphanie Ljungberg

Authorized Public Accountant



# Directors' report 2020-05-01-2021-04-30

The Board of Directors and CEO of Biovica International AB (publ), Biovica, CIN 556774-6150, hereby present the annual report and consolidated financial statements for the financial year 1 May 2020 through 30 April 2021. The annual report will be put forth for adoption at the AGM on 31 August 2021. The company's Class B shares are listed on Nasdaq First North Premier Growth Market, ticker symbol BIOVIC and the company is domiciled in Uppsala, Sweden. The annual report has been prepared in SEK and in accordance with International Financial Reporting Standards (IFRS) that have been adopted by the EU.

#### General information about the business

Biovica International AB is the Parent Company of a Group that was established in 2009, with the goal of developing and producing a biomarker assay that measures cell proliferation for the benefit of cancer patients and healthcare providers. The company's head office is in Uppsala, Sweden and it also has an office in the USA in Boston.

#### Vision

Helping bring about treatment decisions with greater confidence so that cancer patients get the best possible treatment from day one.

#### Financial targets

Within three years of the launch of DiviTum®TKa, Biovica expects to have achieved a market share of 15 percent of the total market potential in the market where the assay is launched. The product will first be launched in the US market during the latter part of 2021, followed by the five largest markets in Europe and the Nordic countries. The first launch in Europe is expected to take place in 2022. After that, further geographic expansion will occur, with an initial focus on the Japanese market. Long term, Biovica's goal is to claim 50 percent of the share in the markets where we launchDiviTum®TKa.

#### Significant events during the 2020/2021 financial year

In August of 2020, a targeted new share issue of 4,700,000 Class B shares at SEK 31.50 per share was carried out, raising SEK 148 million in capital prior to issue costs. Several Swedish and international institutional investors participated in the targeted new share issue, including the Second Swedish National Pension Fund (AP2), Coeli Asset Management and Lancelot Asset Management.

In September of 2020, Biovica submitted the 510(k) application for market approval to the US Food and Drug Administration, FDA. Biovica then became directly impacted by the pandemic when, at the end of October 2020, the FDA announced that it had paused its review of Biovica's 510(k) application. However, the FDA resumed its review of Biovica's application at the end of January. It will, however, take a bit longer than normal for the review to be completed. This has resulted in a delay of the launch by one business quarter. The FDA announced that it is not adhering to the normal MDUFA schedule (90 days) for review because of the increased workload it has had stemming from the pandemic. Risk of further delay in obtaining approval from the FDA remains. However, management has assessed that approval should be granted before the end of the third quarter.

#### Results from a major study presented at San Antonio Breast Cancer Conference 2020

A major study with the cancer research network, SWOG, has provided additional confirmation of DiviTum®TKa's monitoring capabilities for patients with metastatic breast cancer. The study, S0226, also revealed impressive data on progression free survival and overall survival. Furthermore, the results support that DiviTum®TKa can predict benefit from metastatic breast cancer therapy.

Positive DiviTum®TKa results from a clinical study at University of Nebraska Medical Center and Washington University School of Medicine, USA. The study supports the use of DiviTum®TKa for monitoring treatment effect and predicting response to the CDK 4/6 inhibitor palbociclib.

The PYTHIA study is the first prospective study where DiviTum®TKa was evaluated as an early predictor of treatment efficacy for women with metastatic breast cancer. The study was conducted in collaboration with Breast International Group (BIG). Publication

Results from the breast cancer study PROMIX at Karolinska University Hospital were published in the scientific journal, ESMO Open. The study showed that testing for TKa levels during early treatment is prognostic for the long-term outcome of preoperative chemotherapy.

#### New studies

TIRESIAS is a multi-center study that will collect samples from 150 patients with hormone receptor positive metastatic breast cancer who receive the first-line standard treatment: a CDK4/6 inhibitor and an aromatase inhibitor. The aim is to demonstrate that DiviTum®TKa can predict progression free survival and clinical benefit from samples taken as early as two weeks into treatment.

DiviTum®TKa has been selected for inclusion in a new British prospective study of women with hormone receptor positive metastatic breast cancer. The aim of including DiviTum®TKa in the study is to investigate if this marker can be used for disease monitoring during treatment with a CDK4/6 inhibitor, which in combination with an aromatase inhibitor is considered standard of care for this subgroup of patients.

Two new warrant schemes were added during the year. The TO6 scheme comprises 220,000 warrants and was set up for employees. In total, 173,000 warrants were subscribed for and the remainder were canceled. The second new scheme, TO7 was set up for the Board of Directors and all of the 200,000

warrants were subscribed for. Within the scope of the TO3 scheme, a total of 145,000 Class B shares were subscribed for during the year and the remaining 55,000 warrants that were not distributed have been canceled. A DiviTum®TKa budget impact model for calculating the potential savings in the cost of care was developed during the year and presented at the leading health economics and outcomes research conference, ISPOR 2021 in May. New healthcare interventions often add to the total cost of care. But for DiviTum®TKa, the opposite is true and the model shows that there are potential savings of up to three times the cost of DiviTum®TKa.

In preparation for the launch in Europe, a new employee has been recruited as Commercial Director Europe and the recruitment process is underway for a Commercial Director for the USA.

#### Market and events

There continues to be great interest in DiviTum\*TKa, which is evidenced by the company having added new customers in the research market during the year and the multiple research collaborations that are in place.

## Financial performance *Profit (loss)*

Net sales for 2020/2021 amounted to SEK 2,077 (1,671) thousand. Sales are solely to customers in the research market. The company reported a loss for the year of SEK -39,483 (-30,318) thousand. The net loss for the year exceeds that of the previous year due to higher costs associated with growing the size of the organization and commercialization activities. Other external costs and employee benefit expenses increased by SEK 7,290 (7,053) thousand compared to last year and for the 2020/2021 financial year amounted to SEK 42,550 (35,260) thousand. The results for the year are lower than the budget that was presented for the 2020/2021 financial year. This is attributable to the delay in the FDA's review of our 510(k) application, causing us to delay growth of the organization in the USA.

#### R&D work

R&D work has progressed according to plan. The capitalized costs for R&D work during the year amounted to SEK 3,560 (7,035) thousand, which corresponds to 7 (18) percent of the Group's total operating expenses, see Note 13.

#### Cash flow

Cash flow from operating activities was SEK -34,409 (-24,782) thousand and total cash flow for the year was SEK 104,692 (23,946) thousand. The positive cash flow for the year results from having raised capital of SEK 148 million at the beginning of the financial year.

#### Investments

The acquisition of intangible assets for the year amounted to SEK 3,560 (7,035) thousand, of which 100 percent was capitalized both this year and last year. Capitalized development expenditure primarily consists of personnel expenses associated with development of the biomarker assay that monitors cell proliferation by measuring thymidine kinase (TK) activity, The amount of property, plant and equipment acquired during the year (in the form of equipment) for SEK 0 (0) thousand.

#### Financial position

The closing amount for cash & cash equivalents on 30 April 2021 was SEK 145,364 (40,777) thousand. At the end of August 2020, a targeted new share issue of 4,700,000 Class B shares at SEK 31.50 per share was carried out, raising SEK 148 million in capital prior to issue costs. See Note 21 for more information. The company's senior executives and Board of Directors have thus concluded that there is adequate working capital to cover the company's need, according to the adopted budget, for at least the next 24 months, without factoring in the expected increase in sales.

Equity at the end of the period was SEK 182,661 (78,217) thousand and the equity ratio was 95 (87) percent. No dividends have been proposed for the 2020/2021 financial year.

#### Parent Company

The figures reported for the Parent Company are essentially the same as those reported for the Group. The aforementioned comments thus also apply to the Parent Company. Operations have been run on a small scale in the US sudsidary, Biovica Inc., during the financial year.

#### The work of the Board

At the 2020 AGM, a total of eight Board members were elected: Lars Holmqvist, Annika Carlsson Berg, Marie-Louise Fjällskog, Maria Holmlund, Ulf Jungnelius, Henrik Osvald, Anders Rylander and Jesper Söderqvist. Lars Holmqvist was elected as the new Chairman of the Board. During the year, the Board held 21 meetings and it also set up two committees. Biovica thus now has a Remuneration Committee and an Audit Committee. The Board dealt with such matters as financing and financial reporting. The Board is responsible for the company's organization and administration, along with continuously assessing the company's financial situation. The Board has adopted a written rules of procedure document which regulates such things as Board meetings, matters to be submitted to the Board, financial reports and instructions to the CEO.

#### Corporate governance report

The corporate governance report is prepared separately and presented on pages 31-38 of the annual report.

#### **Employees**

The average number of employees is 20 (17) of which 9 (8) women.

#### Sustainability

See the separate section on Biovica's sustainability work on page 27 of the annual report.

#### Share and share capital

The company has both Class A shares (each worth 3 votes) and Class B shares (each worth 1 vote). The company has registered share capital of SEK 1,894,558.13 allocated between 6,542,860 Class A shares and 21,875,512 Class B shares. The quotient value is SEK 0.07 per share. During the year, (464,664) 289,914 Class A shares were converted to Class B shares in accordance with what has been stipulated in the Articles of Incorporation. This may occur at the end of each quarter until there are no longer any Class A shares registered.

#### Major shareholders

Anders Rylander, CEO and member of Biovica's Board of Directors owns approximately 14% of Biovica's shares, which corresponds to approximately 27% of the votes in the Biovica.

#### Related party transactions

During the period, the company, represented by parties related to the main owner and board member, Anders Rylander, leased office facilities to the Parent Company. The total fee for rent paid was SEK 198 thousand. Transactions were in accordance with market-based terms and conditions.

## Significant events after the end of the period

Because of the COVID-19 pandemic, review of such things as 510(k) applications by the FDA is taking longer than normal. There is uncertainty about whether this could lead to further delays for Biovica's FDA application.

#### **Expected future development**

Biovica's business plan aims to launch DiviTum\*TKa in the clinical market for monitoring metastatic breast cancer. The initial launch will occur in the US market as soon as market approval is granted by the FDA, which is expected during the third quarter of 2021. After that, DiviTum\*TKa will be launched in selected markets in Europe starting in 2022

Biovica's strategy is to sign agreements with commercial labs in the USA that have their own sales forces and will be able to offer the assay as a service to their end customers. During the pandemic, however, these potential partners have focused much of their attention and resources on COVID-19 testing. Because of that, negotiations on commercial partnerships have also been delayed.

However, progress with vaccinations in the USA has been successful, leading us to conclude that a return to normal is imminent. The extraordinary priority that COVID-19 testing has had will soon diminish, thereby freeing up time and resources for commercial discussions in other areas. This will increase Biovica's opportunities for signing commercial partnership agreements.

#### Significant risks and uncertainties

In general, the Group's risks can be grouped into two categories,

which are operational risks related to business activities and risks related to financing activities. The Board is responsible for ensuring that the Group manages its risks in the right way and that there is compliance with the established principles for financial reporting and internal control.

In Note 3 of this annual report, Biovica lists the company's main risks and explains which measures are in place to mitigate those risks. Below is a summary of the risks.

#### Regulatory risk

A risk in the process for obtaining FDA approval is an incorrect understanding by the Company of the FDA's requirements, which could result in the approval becoming delayed. Biovica has been proactive in its efforts to obtain FDA approval and reduce the risks of a delay. We have, for example, engaged in a pre-submission process and submitted a supplement containing our questions to the FDA. The feedback on that has given us a clear understanding of what the application must contain (and what must be substantiated) so that we will gain approval. A supplement with our questions concerning clinical validation has also been submitted to the FDA. Further delay in our commercialization schedule would require us to test our intangible assets for impairment, which could possibly result in a write-down of their value. There is a good margin on the year's impairment testing.

## Financing and inadequate working capital

There is also a risk that Biovica will not succeed in attracting the capital it requires for implementing its business plan. If that were to happen, Biovica would adjust its business plan to prioritize other applications or delay the launch, which would then lower the potential gains and benefits for owners.

#### **Employees**

Biovica is highly dependent on key employees. There is a risk of the company's projects becoming delayed or not being able to complete them if these key employees leave the company or, for some other reason, are unable to perform their assigned tasks.

#### Effects of COVID-19

During the first half of the year, the COVID-19 pandemic only had a marginal impact on Biovica's operations. Biovica then became directly impacted by the pandemic when, at the end of October 2020, the FDA announced that it had paused its review of Biovica's 510(k) application. However, the FDA resumed its review of Biovica's application at the end of January. It will, however, take a bit longer than normal for the review to be completed. This has resulted in a delay of the launch by one business quarter. Risk of further delay in obtaining approval from the FDA remains. At present, the risks associated with the pandemic remain, including the risk of a delay of commercial activities, potential disruptions in supply chains, the health of our employees and financial stability of our customers and suppliers. The Board is actively monitoring the situation and is prepared take action if any of those risks were to materialize.

#### **R&D** activities

Biovica develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. Biovica's DiviTum®TKa measures cell proliferation rate and clinical studies have shown that it can quickly reveal whether treatment is effective. Nearly half of Biovica's employees work in the R&D department.

#### **Environmental impact**

Biovica does not run any environmentally hazardous activities requiring a permit or obligation to report in accordance with the Swedish Environmental Code.

#### Dividends

The Board proposes that no dividends shall be paid for the 2020/2021 financial year.

#### MULTI-YEAR COMPARISON FOR THE GROUP

All amounts are in SEK thousands, unless otherwise stated	2020/2021	2019/2020	2018/2019	2017/2018	2016/2017
Net sales	2,077	1,671	3,005	2,723	632
Operating profit (loss)	-40,181	-29,816	-21,718	-17,956	-14,690
Profit (loss) for the period	-39,483	-30,318	-21,556	-18,010	-14,715
Cash and cash equivalents	145,364	40,777	16,831	42,127	65,469
Equity	182,661	78,217	52,097	73,713	91,664
Total assets	192,650	90,259	60,859	80,771	97,202
Equity ratio, %	95	87	86	91	94
Number of employees	20	17	16	14	8
Number of shares at the end of the period	28,418,372	23,573,372	17,573,372	17,573,372	17,573,372

#### **Definitions**

Equity ratio = adjusted equity as a percentage of total assets

#### MULTI-YEAR COMPARISON FOR THE PARENT COMPANY

2020/2021	2019/2020	2018/2019	2017/2018	2016/2017
2,077	1,671	3,005	2,723	632
-41,907	-30,312	-21,886	-17,894	-14,839
-40,004	-30,571	-21,606	-17,935	-14,848
142,920	39,642	15,779	42,069	65,410
182,061	78,117	52,005	73,611	91,546
189,748	86,292	59,972	80,376	97,184
96	91	86	91	94
19	16	16	14	8
28,418,372	23,573,372	17,573,372	17,573,372	17,573,372
	2,077 -41,907 -40,004 142,920 182,061 189,748 96 19	2,077	2,077     1,671     3,005       -41,907     -30,312     -21,886       -40,004     -30,571     -21,606       142,920     39,642     15,779       182,061     78,117     52,005       189,748     86,292     59,972       96     91     86       19     16     16	2,077     1,671     3,005     2,723       -41,907     -30,312     -21,886     -17,894       -40,004     -30,571     -21,606     -17,935       142,920     39,642     15,779     42,069       182,061     78,117     52,005     73,611       189,748     86,292     59,972     80,376       96     91     86     91       19     16     16     14

#### PROPOSAL FOR APPROPRIATION OF FUNDS

The Board proposes that the available funds of SEK 153,518,841 are appropriated as follows:

accumulated losses	-145,235,961
share premium reserve	338,758,474
loss for the year	-40,003,672
Retained funds at year-end	153,518,841
Amount to be carried forward	153,518,841

For further information on the company's profit (loss) and financial position, please see the accompanying income statements, balance sheets and supplementary disclosures.

#### KEY PERFORMANCE INDICATORS FOR THE GROUP

SEK thousands	2020/2021	2019/2020	2018/2019	2017/2018
Net sales	2,077	1,671	3,005	2,723
Operating profit (loss)	-40,181	-29,816	-21,718	-17,956
Profit (loss) for the year	-39,483	-30,318	-21,556	-18,010
Capitalized R&D costs	3,560	7,035	6,464	6,596
Capitalized R&D expenditure as a percentage of operating expenses	-8	-20	-22	-26
Earnings per share, before dilution	-1.39	-1.29	-1.23	-1.02
Earnings per share, after dilution	-1.36	-1.29	-1.23	-1.02
Cash and cash equivalents at the end of the period	145,364	40,777	16,831	42,127
Cash flow from operating activities	-34,409	-24,782	-17,966	-14,882
Cash flow for the period	104,692	23,926	-25,295	-23,342
Equity	182,661	78,217	52,097	73,713
Equity per share	6.43	3.32	2.96	4.19
Equity ratio (%)	95	87	86	91
Average number of employees	20	17	16	14

The Group was established in 2009 by setting up the subsidiary company, Biovica Services AB. There is now also a subsidiary, Biovica Inc., in the USA, see Note 18.

#### ALTERNATIVE KEY PERFORMANCE INDICATORS

Of the KPIs presented above, the only one that is obligatory to report, and which is defined in accordance with IFRS is: Earnings per share, before and after dilution. For the other KPIs, the following are in accordance with IFRS presentation requirements: Profit (loss) for the year, Cash & cash equivalents at the end of the period, Cash flow for the period and Equity.

KPIs	Definition	Reason for using alternative KPIs, which are not defined in accordance with IFRS. $ \\$
Net sales	Income from goods sold	Shows the demand for the product.
Operating profit (loss)	Profit (loss) before financial items and tax.	Operating profit (loss) is an indication of the company's earnings generated from ordinary operations.
Earnings per share, before and after dilution	Profit (loss) divided by the weighted average number of shares during the period, before and after dilution.	
Cash & cash equivalents and short-term investments	Bank balances and short-term investments.	
Cash flow from operating activities	Cash flow before the cash flow from investing activities and financing activities.	
Cash flow for the period	Change in cash & cash equivalents for the period not including the effect from unrealized exchange gains and losses.	
Equity per share	Equity divided by the number of shares at the end of the period.	Management uses this KPI to monitor the value of equity per share.
Equity ratio	Equity as a percentage of total assets.	Management uses this KPI because it provides an indication of the company's financial stability.
Average number of employees	The average number of employees is calculated as the average of worked hours during the period divided by normal working hours for the period.	

# Consolidated income statement and statement of comprehensive income

SEK thousands	Note	May-April 2020/2021	May-April 2019/2020
Net sales	5, 6	2,077	1,671
Other operating income	8	3,241	1,215
Work performed by the company and capitalized		3,560	7,035
		8,878	9,921
Materials cost		-367	-220
Other external costs	9	-15,332	-15,386
Employee benefit expenses	10	-27,218	-19,874
Depreciation/amortization of property, plant and equipment and intangible assets		-6,142	-4,170
Other expenses			-86
Operating profit (loss)		-40,181	-29,816
Financial income		855	_
Financial expenses		-60	-443
Profit (loss) before tax		-39,386	-30,259
Tax expense	12	-96	-59
Profit (loss) for the year		-39,483	-30,318
Earnings per share			
Earnings per share, before dilution (SEK)		-1.39	-1.29
Average number of shares, before dilution		28,418,372	23,573,372
Earnings per share, after dilution (SEK)		-1.36	-1.29
Average number of shares, after dilution		29,111,372	24,218,372
Consolidated statement of comprehensive income			
Profit (loss) for the year		-39,483	-30,318
Items that may be subsequently reclassified to profit and loss			
Exchange rate differences, foreign net investments		-	-
Other comprehensive income for the year		_	_
Comprehensive income for the year (loss)		-39,483	-30,318

# Consolidated statement of financial position

SEK thousands	Note	2021-04-30	2020-04-30
ASSETS			
Intangible assets			
Capitalized expenditure for R&D	13	37,476	37,296
Patents	14	4,393	5,370
		41,869	42,666
Property, plant and equipment			
Machinery, equipment, tools, fixtures and fittings	15	704	1,234
Right-of-use assets	16	2,312	3,313
		3,017	4,546
Financial assets			
Deferred tax asset	17	499	743
		499	743
Total fixed assets		45,384	47,955
Inventories		527	397
Current receivables			
Accounts receivable		222	_
Other receivables		629	547
Prepaid expenses and accrued income		524	582
repair or polices and accided medine		32.	002
Cash & cash equivalents including short-term investments	27, 28	145,364	40,777
Total current assets		147,266	42,303
TOTAL ASSETS		192,650	90,259
EQUITY	21	1.005	1.570
Share capital	21	1,895	1,572
Other contributed capital		338,758	195,133
Retained earnings (losses), including loss for the year		-157,992 <b>182,661</b>	-118,487 <b>78,217</b>
Total equity		102,001	70,217
LIABILITIES			
Lease liabilities	16	934	2,272
Deferred tax liability	17	460	709
Total non-current liabilities		1,394	2,981
Lease liabilities	16	1,486	1,182
Advance payments from customers		1,213	3,521
Accounts payable		1,085	1,007
Current tax liabilities		154	500
Other liabilities		634	624
Accrued expenses and deferred income		4,023	2,228
Total current liabilities		8,595	9,061
TOTAL EQUITY AND LIABILITIES		192,650	90,259

# Consolidated statement of changes in equity

SEK thousands	Share capital	Other contrib- uted capital	Reserves	Retained earnings	Profit (loss) for the year	Total equity
Opening balance, I May 2019	1,172	133,776	_	-61,295	-21,556	52,097
Appropriation in accordance AGM decision				-21,556	21,556	-
Reclassification		5,074		-5,074		-
New share issue	400	53,246				53,646
Issue costs		3,036				3,036
Adjustment due to change in accounting policy				-246		-246
Translation differences			2			2
Profit (loss) for the year					-30,318	-30,318
Closing balance, 30 April 2020	1,572	195,132	2	-88,171	-30,318	78,217
Appropriation in accordance AGM decision				-30,318	30,318	-
New share issue	313	147,737				148,050
Issue costs		-7,151				-7,151
Warrants scheme	10	3,040				3,050
Translation differences			-22			-22
Profit (loss) for the year					-39,483	-39,483
Closing balance, 30 April 2021	1,895	338,758	-20	-118,488	-39,483	182,661

# Consolidated statement of cash flows

SEK thousands	Note	May-April 2020/2021	May-April 2019/2020
Profit (loss) before tax		-39,386	-30,259
Depreciation/amortization of property, plant and equipment and intangible assets		6,142	4,170
Other non-cash items	24	146	-349
Income tax paid		-447	-150
Change in current receivables		-351	1,646
Change in current liabilities		-384	111
Change in inventories		-129	49
Cash flow from operating activities		-34,409	-24,782
Investments in intangible assets		-3,560	-7,035
Cash flow from investing activities		-3,560	-7,035
New share issue		143,949	56,682
Amortization of lease liabilities		-1,288	-940
Cash flow from financing activities		142,661	55,742
Cash flow for the year		104,692	23,926
Cash and cash equivalents at the beginning of the year		40,777	16,832
Translation difference		-105	19
Cash and cash equivalents at the end of the year		145,364	40,777

# Parent Company income statement

SEK thousands	Note	May-April 2020/2021	May-April 2019/2020
Net sales	5, 6	2,077	1,671
Work performed by the company and capitalized		3,560	7,035
Other operating income	8	2,071	972
		7,708	9,677
Goods for resale		-367	-220
Other external costs	7, 9, 11, 16	-22,119	-18,991
Employee benefit expenses	10	-22,243	-17,849
Depreciation/amortization of property, plant and equipment and intangible assets		-4,887	-2,843
Other operating expenses			-86
Operating profit (loss)		-41,907	-30,312
Other interest income and similar items		759	97
Interest expenses and similar items		-1	-356
Profit (loss) after financial items		-41,150	-30,571
Appropriations		1,146	_
Profit (loss) before tax		-40,004	-30,571
Income tax	12	_	-
Profit (loss) for the year		-40,004	-30,571

The Parent Company's statement of comprehensive income is consistent with profit or loss for the year.

# Parent Company balance sheet

SEK thousands	Note	2021-04-30	2020-04-30
ASSETS			
Intangible assets			
Capitalized expenditure for R&D	13	37,476	37,296
Patents	14	4,393	5,370
Property, plant and equipment			
Machinery, equipment, tools, fixtures and fittings	15	704	1,234
Financial assets			1,20
	10	100	100
Participations in Group companies	18 19	108	108
Receivables from Group companies	20	1,999	985
Prepaid expenses and accrued income  Total fixed assets	20	44,790	45,148
Inventories		527	397
Current receivables			
Accounts receivable		222	-
Other receivables		629	547
Prepaid expenses and accrued income		659	558
Cash & cash equivalents and short-term investments	27, 28	142,920	39,642
Total current assets		144,958	41,144
TOTAL ASSETS		189,748	86,292
EQUITY			
Restricted equity			
Share capital	21, 22	1,895	1,572
·	21, 22	27,211	25,170
Fund for development expenditure  Total postricted equity		29,105	26,741
Total restricted equity		27,103	20,741
Non-restricted equity			
Share premium reserve		338,758	195,133
Capitalized gain or loss		-145,798	-113,187
Profit (loss) for the year		-40,004	-30,571
Total non-restricted equity		152,956	51,375
Total equity		182,061	78,117
LIABILITIES			
Prepayments from customers and prepaid grants		1,213	3,521
Accounts payable		1,086	1,004
Liability to Group companies		1,087	476
Current tax liabilities		80	420
Other liabilities		634	624
Accrued expenses and deferred income		3,587	2,131
Total current liabilities		7,687	8,176

# Parent Company statement of changes in equity

SEK thousands		Fund for develop- nent expenditure	Share premium reserve	Retained earnings	Profit (loss) for the year	Total equity
Opening balance, I May 2019	1,172	18,135	133,439	-79,134	-21,606	52,005
Appropriation in accordance AGM decision				-21,606	21,606	-
Capitalized development expenditure						
for the year	7,035		-7,035		-	
Reclassification			5,411	-5,411		-
New share issue	400		56,282			56,682
Profit (loss) for the year					-30,571	-30,571
Closing balance, 30 April 2020	1,572	25,170	195,132	-113,186	-30,571	78,117
Opening balance, I May 2020	1,572	25,170	195,132	-113,186	-30,571	78,117
Appropriation in accordance AGM decision				-30,571	30,571	-
Capitalized development expenditure						
for the year	2,041		-2,041		_	
New share issue	313		147,737			148,050
Issue costs			-7,151			-7,151
Warrants scheme	10		3,040			3,050
Profit (loss) for the year					-40,004	-40,004
Closing balance, 31 April 2021	1,895	27,211	338,758	-145,798	-40,004	182,061

# Parent Company statement of cash flows

SEK thousands	May-April 2020/2021	May-April 2019/2020
Profit (loss) before tax	-40,004	-30,571
Depreciation/amortization of property, plant and equipment and intangible assets	4,887	2,843
Income tax paid	-340	-259
Change in current receivables	-406	2,649
Change in current liabilities	-149	468
Change in inventories	-129	49
Cash flow from operating activities	-36,142	-24,822
Investing activities		
Investments in intangible assets	-3,560	-7,035
Investments in financial assets	-969	-964
Cash flow from investing activities	-4,528	-7,998
Financing activities		
New share issue	143,949	56,682
Cash flow from financing activities	143,949	56,682
Cash flow for the year	103,278	23,862
Cash and cash equivalents at the beginning of the year	39,642	15,779
Cash and cash equivalents at the end of the year	142,920	39,642

# Supplementary disclosures

#### **NOTE I GENERAL INFORMATION**

Biovica International AB (Biovica) is the Parent Company for the Group and it is a public limited liability company with registered office in Uppsala, Sweden. The head office and its primarily place of establishment is: Dag Hammarskjölds väg 54B, 752 37 Uppsala, Sweden. Biovica's shares are traded on Nasdaq First North Premier Growth Market in Stockholm.

### NOTE 2 SIGNIFICANT ACCOUNTING AND VALUATION PRINCIPLES

The consolidated financial statements have been prepared in accordance with the Swedish Annual Accounts Act and RFR I Supplementary Accounting Rules for Groups and the International Financial Reporting Standards (IFRS) that have been adopted by the EU. The financial statements have been prepared under the assumption that the Group runs its operations in accordance with the going concern principle.

The consolidated financial statements for the reporting period that ended on 30 April 2021 (including comparison figures) were approved by the Board on 30 June 2021.

The Parent Company applies the same accounting policies as the Group, except for the items presented in the section called "Parent Company accounting policies".

#### Valuation and classification

Assets and liabilities are reported at historical cost, except for financial assets and financial liabilities, which are measured at amortized cost. Short-term investments (funds) are measured at fair value via profit of loss.

#### Functional currency and reporting currency

The Parent Company's functional currency is SEK, which is also the reporting currency for the Parent Company and the Group. Accordingly, the financial statements are presented in SEK. All amounts, unless otherwise stated, are rounded to the nearest thousand.

#### Assessments and estimates in the financial statements

In preparing the financial statements, the executive management team must make assessments and estimates that affect both the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. The actual outcome may deviate from these estimates and assessments.

Estimates and assessments are regularly reviewed. A change in estimates and assumptions is reported in the period when the change is made if it only impacts that period. Otherwise, it is reported in the period when the change is made *and* in future periods if it impact both the current period and future periods.

Assessments and estimates that have a significant impact on the financial statements and which could lead to material adjustments in future financial statements are described in more detail in Note 4.

#### Significant accounting policies

This note details the significant accounting policies that have been applied during preparation of the consolidated financial statements. Unless otherwise stated, these policies have been applied consistently for all years presented in the report. The consolidated financial statements cover Biovica International AB and its subsidiaries.

#### (i) Changes in accounting policies resulting from new or revised IFRS

None of the standards that entered into force in 2020 have impacted the annual report for 2020.

#### (ii) New IFRS that have not yet been applied

None of the other IFRS or IFRIC interpretations that have yet to enter into force are expected to have a significant impact on the Group.

#### Consolidated financial statements

Subsidiaries are all companies in which the Group has a controlling interest. The Group has a controlling interest over a company when it is exposed to, or entitled to a variable return from, its holding in the company and it is able to affect such return via its controlling interest over the company. Subsidiaries are included in the consolidated financial statements as of the date when the controlling interest has been transferred to the Group. Subsidiaries are removed from the consolidated financial statements as of the date when the Group no longer has a controlling interest.

The acquisition method is used for reporting the Group's business combinations. The purchase price (cost of the transaction) for acquisition of a subsidiary consists of the fair values, at the acquisition date, of assets, liabilities (incurred or assumed), and equity instruments issued by the Group; It also includes the fair value of all assets and liabilities resulting from an agreement on contingent consideration. Identifiable acquired assets, assumed liabilities and assumed liabilities from a business combination are initially measured at fair value on the acquisition date. The costs associated with acquisitions are expensed as incurred. Intra-Group transactions, balance sheet items and unrealized gains/ losses on transactions between Group companies are eliminated. The accounting policies for subsidiaries have, in some instances, been revised to ensure that they are consistent with the Group's policies.

#### Segment reporting

The Group's operations consist of development, manufacturing and sales of blood analysis products. The Group's organizational structure is by function as follows: production, sales & marketing, administration and R&D. The Group is considered to be a single unit, where all of its sub-components are integrated and dependent upon each other. Biovica's highest decision-making body monitors the consolidated income statement and statement of comprehensive income. More information is provided in Note 6, Segment reporting.

#### Consolidation principles and business combinations

#### (i) Subsidiaries

Subsidiaries are companies where the Parent Company has a controlling interest. Controlling interest involves a direct or indirect right to design a company's financial or operating strategies in order to obtain financial benefits. The financial statements of subsidiaries are included in the consolidated financial statements as of the acquisition date and up until the date when a controlling interest no longer exists.

#### ${\it (ii)}\ Transactions\ eliminated\ upon\ consolidation$

All intra-Group receivables and payables, income or expenses and unrealized gains or losses that arise from transactions between Group companies are eliminated in full when preparing the consolidated financial statements. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that no write-down requirement exists

#### Foreign currency

#### (i) Transactions in foreign currency

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the transaction date. The functional currency is the currency used in the main financial environments where the company runs its operations. Monetary assets and liabilities denominated in foreign currency are converted to the functional currency at the exchange rate prevailing on the closing date. Exchange rate differences that arise upon translation are reported in profit or loss. Non-monetary assets and liabilities that are reported at historical cost are translated at the exchange rate prevailing at the time of the transaction.

Non-monetary assets and liabilities that are reported at fair value are translated to the functional currency at the rate prevailing on the date when measurement at fair value occurred. Exchange rate fluctuations associated with receivables and liabilities from operations are reported in operating profit or loss, and those stemming from financing activities are reported in net financial items.

#### (ii) Financial statements of foreign operations

Assets and liabilities from foreign operations, including goodwill and other consolidated surpluses and deficits, are translated from the foreign operation's functional currency to the Group's reporting currency, SEK, at the closing day rate. Income and expenses from foreign operations are translated to SEK using an average exchange rate that is an approximation of the currency exchange rate at the time of each transaction. Translation differences arising from currency translation of foreign operations are reported in other comprehensive income and accumulated in a separate component of equity, referred to as translation reserve. When selling a foreign operation, the cumulative translation differences attributable to the business are realized, reclassifying them from the translation reserve in equity, to profit or loss for the year. In instances where there has been a divestiture, but a controlling interest remains, the proportionate share of accumulated translation differences is transferred from other comprehensive income to holdings without a controlling interest.

#### Revenue from contracts with customers

Revenue from contracts with customers is recognized when the performance obligation has been fulfilled and control over the goods or services has been transferred to the customer. This assessment shall occur from the customer's perspective, taking into consideration such things as transfer of ownership and risks, the customer's acceptance, physical access and the right to invoice. An assessment must also be made of whether control has been transferred at a specific point in time, or over time. Most of Biovica's agreements with customers pertain to product sales. The products are regarded as separate and distinct performance obligations. Revenue is recognized at a specific point in time (when control of the goods or services has been transferred to the customer). The contract terms and conditions may vary but typically, transfer of control and thus revenue recognition occurs at the time of delivery.

# Agreements with customers where the performance obligation has not yet been fulfilled

Biovica does not have any agreements with customers that extend beyond one year, which is why the simplification rule has been applied. It means that disclosures do not need to be made on the scope of agreements with customers where the performance obligation has not yet been fulfilled.

#### Reporting of government grants

Government grants are reported at fair value when there is reasonable certainty that the terms associated with the grant can be met and accordingly, that the grant will be paid. Grants that have been received to cover expenses are reported under the heading "other income" in the same period that the expenses arise. Grants attributable to an asset

reduce the asset's value in the balance sheet. Grants that have been received, but for which the terms have not yet been met are reported in *Prepayments from customers and research grants*.

#### Financial income and expenses

Financial income consists of interest earned on cash & cash equivalents. Interest income on financial instruments is reported using the effective interest method. The effective interest rate is the interest rate that discounts the estimated future cash flows of a financial instrument, during the expected duration, to the financial asset's or liability's reported net value. When making the calculation, all payments made and received between the parties to the contract are considered that are a part of the effective interest, transaction costs and all other premiums and discounts. Financial expenses consist of interest on loans. Borrowing costs are recognized in profit or loss using the effective interest method except to the extent that they are directly attributable to the purchase, design or production of an asset that takes a considerable amount of time to complete for its intended use or sale (such costs are instead included in the cost of acquisition for the asset).

Foreign exchange gains and losses attributable to assets and liabilities associated with financing activities are reported net.

#### Taxes

Income taxes consist of current tax and deferred tax. Income taxes are reported in profit or loss for the year, except when the underlying transaction is recognized in other comprehensive income or in equity, whereby the associated tax effect is also reported in other comprehensive income or in equity.

Current tax is the tax to be paid or refunded for the current year. It also includes adjustments to current tax that are attributable to prior periods.

Deferred tax is calculated in accordance with the balance sheet method based on temporary differences between the tax base and carrying amounts of assets and liabilities. Temporary differences are not taken into consideration for consolidated goodwill, nor for differences arising upon initial recognition of assets and liabilities that are not business combinations, which, at the time of transaction, impact neither reported profit nor taxable profit. Consideration is neither given to temporary differences attributable to participations in subsidiaries and associated companies that are not expected to be reversed in the near future. The measurement of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled.

Deferred tax is calculated using the tax rates and legislation in effect or decided as of the closing date.

Deferred tax assets relating to deductible temporary differences and loss carryforwards are only reported to the extent that it is probable that they will be utilized.

#### Financial instruments

Financial instruments reported in the balance sheet include, on the asset side, cash & cash equivalents, short-term investments, accounts receivable, securities holdings and loan receivables. On the liability side, they include accounts payable.

#### Recognition and derecognition in the balance sheet

Financial assets and liabilities are reported in Biovica's balance sheet when the company becomes party to the instrument's contractual terms. An asset (receivable) is recognized in Biovica's balance sheet when there is a contractual obligation for the counterparty to pay, even if the invoice has not yet been sent. Accounts receivable are recognized in the balance sheet when the invoice has been sent. A liability is recognized in Biovica's balance sheet when there is a contractual obligation for the counterparty to pay, even if the invoice has not yet been sent. Accounts payable are recognized when the invoice has been received. A financial asset is removed from the balance sheet when the rights in

the contract are realized, mature, or when Biovica loses control over them. The same applies to a portion of a financial asset. A financial liability is removed from the balance sheet when the obligations have been settled, canceled or in some other manner extinguished. The same applies to a portion of a financial liability. Financial assets and liabilities are offset and reported at a net sum in the balance sheet, only when there is a legally enforceable right to offset the amounts and an intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

#### Measurement at initial recognition

All financial instruments are initially measured at fair value plus or minus transaction costs. However, for financial instruments that are, on an ongoing basis, measured at fair value through profit or loss, the transaction costs are instead expensed as incurred. Accounts receivable (without a significant financing component) are initially measured at the transaction amount that is established in accordance with IFRS 15.

#### Classification and subsequent measurement of financial assets

At initial recognition, a financial asset is classified as having been measured at amortized cost, fair value through other comprehensive income (debt instrument investment), fair value through other comprehensive income (own capital investment), or fair value through profit or loss. Below is a description of how the Group has classified its various holdings of financial assets:

#### Financial assets

All financial assets are measured at amortized cost except short-term investments, which are measured at fair value through profit or loss. This is because they are held in accordance with a business model for which the goal is to obtain the contractual cash flows. Furthermore, the cash flows from these assets consist solely of payments of principal amounts and interest.

#### Classification and subsequent measurement of financial liabilities

Financial liabilities are classified as measured at amortized cost or at fair value through profit or loss. All other financial liabilities are measured at amortized cost using the effective interest method.

#### Impairment of financial assets

At the end of each reporting period, the Group assesses whether there is any objective evidence of a write-down requirement because a financial asset or group of financial assets has become impaired. Impairment loss on a financial asset or group of financial assets is only recognized if there is objective evidence of a write-down requirement due to one or more events having occurred subsequent to initial recognition of the asset and it has a significant impact on the expected future cash flows of the financial asset, which can be reliably measured.

#### Property, plant and equipment

#### (i) Owned assets

Property, plant and equipment is reported by the Group at cost less accumulated depreciation and any impairment losses. Cost includes all costs necessary to bring the asset to working condition for its intended use. The accounting policies for impairment are explained below. Property, plant and equipment consists of various items, with specific useful lives, that are treated as separate components of PPE.

The carrying amount of an item of PPE is removed from the statement of financial position upon disposal/retirement or when no future economic benefits are expected to be derived from its use or disposal/retirement of the asset.

Gains or losses arising from the sale or disposal of an asset consist of the difference between the selling price and the asset's carrying amount less direct selling costs. Gains and losses are reported as other operating income/expenses.

#### (ii) Additional expenses

Additional expenses are added to the cost of acquisition only if it is probable that the future economic benefits associated with the asset will flow to the company and the cost of acquisition can be calculated reliably. All other additional expenses are expensed as incurred. An additional expense is added to the cost of acquisition if the expense is associated with the replacement of identified components or parts of such. Even in cases where a new component is created, the expenses are added to the cost of acquisition. Any non-depreciated carrying amount on replaced components or parts of components are disposed of, and expensed, in conjunction with the replacement. Repairs are expensed as incurred.

#### (iii) Depreciation principles

Depreciation is on a straight-line basis over the asset's estimated useful life. Land, however, is not depreciated. Leased assets are also depreciated over the estimated useful life or, if shorter, over the agreed term of the lease

The Group applies component depreciation, which means that the estimated useful life of the component is the basis for depreciation.

The following estimated useful lives are applied:

- plant and machinery: 5 years
- equipment, tools, fixtures and fittings: 5 years

At each year-end closing, the depreciation methods, residual values and estimated useful lives are reviewed and if necessary, revised.

#### Leased assets

The Group primarily leases premises and cars. The term of lease agreements for premises currently varies between 60-90 months, including likely extension periods. Cars are typically leased for 36 months. Leased assets may not be used as collateral for loans. In some instances, an extension is possible, see below for more information.

A right-of-use agreement is reported as an asset and corresponding liability as of the date when the leased asset is available to the Group. Lease payments are divided into amortization of the liability and interest expense. The interest expense for each period is calculated using the annuity method. Right-of-use assets are depreciated on a straight-line basis over the useful life. Assets and liabilities attributable to leasing are initially measured at fair value.

Lease liabilities include the present value of the following payments:

- regular fixed payments,
- variable fees that are based on an index or a price,
- residual value guarantees that the lessee expects will need to be paid to the lessor and.
- purchase options that are likely to be exercised at the end of the lease term

Payments are discounted to present value using the interest rate implicit in the lease, or, if that cannot be established, using the marginal lending rate.

- present value of future payments at the initial valuation of the lease liability,
- payments made on or before the lease commencement date, such as higher initial payment,
- direct costs and restoration costs

Payments attributable to short-term agreements or leases for which the underlying asset is of low value are expensed in the income statement. Short-term agreements are those with a term that does not exceed 12 months. Management has assessed that agreements where the underlying asset is of low value pertain to simple machinery and office equipment.

The lease term consists of the non-cancellable portion of the lease plus possible extension options if, at inception of the lease, it is reasonably certain that they will be exercised.

#### Intangible assets

#### Research and development

Expenditure for research that is for the purpose of gaining new scientific or technical knowledge is expensed as incurred. Expenditure for development (where the research results or other knowledge is used to achieve new or improved products or processes) is recognized as an intangible fixed asset in the statement of financial position if the product or process is technically or commercially usable and the company has adequate resources for monitoring the development and thereafter using or selling the intangible asset.

Development expenditure that is directly attributable to development and testing of identifiable and unique products that the Group controls, are recognized as intangible assets when the following criteria have been met:

- i. it is technically feasible to complete the product so that it can be used
- ii. the company's intention is to complete the product and either use it or sell it,
- iii. the prerequisites exist for being able to use or sell the product,
- iv. it is probable that the future economic benefits that are attributable to the asset will flow to the company,
- v. there are adequate technical, economic and other resources for completing development and being able to use or sell the asset, and
- vi. expenditure attributable to the product and its development can be calculated in a reliable way.

Directly attributable expenditure that is capitalized as part of the cost of the asset includes expenditure for employees and materials, along with a reasonable portion of the indirect costs. With capitalization, consideration is given to the portion of expenditure recognized as revenue against received/expected grants. Capitalized development expenditure is reported as intangible assets and amortized as of the date when the asset is ready for use.

Other expenditure for development is expensed as incurred and recognized in profit or loss for the year. In the statement of financial position, development expenditure is recognized at cost less accumulated amortization and any impairment losses.

#### Additional expenses

Additional expenses for capitalized intangible assets are recognized as an asset in the statement of financial position only if they increase the future economic benefits associated with the specific asset that they relate to. All other expenditure is expensed as incurred.

#### **Patents**

Patents are recognized at the cost of acquisition and they are amortized on a straight-line basis over their estimated useful lives. Amortization is over a 10-year period. The estimated useful life is assessed based on the legal life of the patent.

#### Amortization

Amortization is on a straight-line basis over the estimated useful life of the intangible asset, provided that the estimated useful life is not indefinite. Estimated lives are reviewed, and if necessary revised, at least once per year. Intangible assets with an indefinite useful life or which are not yet ready for use (such as development projects) are tested for impairment annually, or sooner, if indications arise that indicate that the asset in question has decreased in value. Intangible assets with a finite useful life are amortized as of the date when they are available for use. The estimated useful life for capitalized development expenditure is 10 years.

#### Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of acquisition for inventories is measured using the FIFO method and it includes expenses associated with the acquisition of inventory assets, along with transportation costs for bringing them to their current location and condition. For manufactured goods and work-in-progress, the cost of acquisition includes a reasonable share of the indirect costs based on normal capacity.

Net realizable value is comprised of the estimated selling price in the day-to-day operations, after deduction of estimated costs for completion and for achieving a sale.

Inventories consist of the following categories: Raw materials and supplies, WIP goods, finished goods and merchandise.

Manufacturing is primarily based on orders and forecasts that are updated each month. Accordingly, the level of obsolescence is insignificant for the company's inventory of finished goods. Whenever there is a replacement of components, the remaining inventory is written down when the replacement occurs. Obsolescence of spare parts is assessed each quarter by analyzing the inventory turnover rate.

#### Impairment

The Group's reported assets are assessed at each closing date to determine whether there is any indication of impairment, which is a requirement for proprietary assets that have not yet been completed. Impairment testing is done at least once per year at the year-end closing by calculating the net present value (NPV). NPV is calculated on forecasted cash flows using a discounted cash flow model. Decisions on whether or not to capitalize expenditure on development projects are made by the company's Board of Directors based on documentation and support provided by the Audit Committee. The decision is based on whether it is possible to implement the project using existing or future resources and on whether conclusion of the project and launch is expected to occur in the foreseeable future.

IAS 36 is applied for impairment of assets other than: financial assets that are reported in accordance with IAS 9, available-for-sale assets and disposal groups that are reported in accordance with IFRS 5, inventories and deferred tax assets. For the exempted assets listed above, the carrying amount is assessed in accordance with the applicable reporting standard.

#### (I) Impairment of property, plant and equipment and intangible assets

The recoverable amount of an asset is calculated whenever there is any indication of impairment. For goodwill, other intangible assets with indefinite useful lives and intangible assets that are not yet ready for use, the recoverable amount is calculated annually, regardless of whether there is any indication of a decrease in value or not. If it is not possible to associate essentially independent cash flows with a specific asset, and its fair value less selling costs cannot be used, the assets will then be grouped for testing of impairment at the lowest level where it is possible to identify essentially independent cash flows. That level is referred to as the cash-generating unit.

An impairment loss is recognized when the carrying amount of an asset, or cash-generating unit (or group of units) exceeds the recoverable amount. Impairment losses are recognized in profit or loss for the year. When a write-down requirement has been identified for a cash-generating unit (or group of units), the amount of the impairment loss is first allocated to goodwill. After that, a proportional write-down is made to the other assets belonging to the cash-generating unit (or, if applicable, the group of units).

The recoverable amount equals fair value less selling costs or the value-in-use, whichever is higher. When calculating value-in-use, future cash flows are discounted using a rate that considers the market's assessment of risk-free interest along with the risk associated with the specific asset.

#### (ii) Impairment of financial assets

The Group's financial assets meet the requirements for use of the expected credit loss model. Impairment of cash and cash equivalents is assessed as immaterial.

The Group applies the simplified approach for calculating expected credit losses. With this approach, expected credit losses during the asset's entire life are used as the point of departure for accounts receivable. To calculate expected credit losses, accounts receivable are grouped based on the number of days that payment is overdue. The expected credit loss levels are based on customer payment history and loss history in recent years.

#### (iii) Reversal of impairment

Impairment on assets that fall within the scope of IAS 36 is reversed if there is both an indication that the need for impairment no longer exists and there has been a change in the assumptions that formed the basis for the calculation of the recoverable amount. However, impairment losses on goodwill are never reversed. A reversal is only made to the extent that the asset's carrying amount after reversal does not exceed the carrying amount that would have been reported (less depreciation, where applicable) if no write-down had been made. Impairment losses on loan receivables and accounts receivable that are reported at amortized cost are reversed if the previous reasons for the write-downs no longer exist and full payment from the customer is expected to be received.

#### Equity

#### Share capital

Ordinary shares are classified as share capital. The company has both Class A and Class B shares. See Note 21 for more information.

#### Issue costs

Transaction costs directly attributable to a new issue of ordinary shares or options are recognized, net after tax, in equity as a deduction from the emission proceeds.

#### Earnings per share

The calculation of earnings per share is based on the Group's profit (loss) for the year attributable to the Parent Company's owners and using the weighted average number of shares outstanding during the year.

When calculating earnings per share after dilution, earnings and the average number of shares are adjusted to take into account the effects of dilutive potential ordinary shares such as stock options Dilution from options affects the number of shares and arises only when the exercise price is lower than the market price.

#### **Employee benefits**

#### (i) Defined-contribution pension plans

Defined-contribution pension plans are those where the company's obligation is limited to the fees it has committed to paying. For these types of plans, the size of the employee's pension depends on the fees paid by the company to the plan (or to an insurance company) and the return on capital generated by those funds. Consequently, it is the employee who carries the risk that the compensation will be lower than expected, as well as the investment risk, i.e. that the invested assets will be insufficient for providing the expected benefits. The company's obligations regarding fees for defined contribution plans are reported as an expense in profit or loss for the year at the rate they are earned by the employees performing services for the company during the period.

#### (ii) Defined benefit pension plans

The Group has no defined benefit pension plans, except for plans involving several employers, which, however, are reported as defined contribution pension plans in accordance with IAS 19 due to the absence of required data for calculating the defined benefit obligation.

#### (iii) Warrant schemes

The Group has warrant schemes for employees and the Board of Directors, see Note 23.

#### (iv) Termination benefits

Costs for remuneration in connection with termination of employment are only reported if the company has committed to following a detailed plan for early termination of the employment and the company has no realistic way of canceling that obligation.

When compensation is given as an offer to encourage voluntary resignation, a cost is reported if it is probable that the offer will be accepted and the number of employees who will accept the offer can be reliably estimated.

#### (v) Short-term benefits

Short-term benefits to employees are calculated without discounting and reported as an expense when the related services have been provided. A provision is reported for the expected cost of bonus payments when the Group has a current legal or informal obligation to make such payments as a result of services provided by employees and the obligation can be calculated reliably.

#### **Provisions**

A provision differs from other liabilities in that there is uncertainty about when payment may be required, as well as the amount required to settle the obligation. A provision is recognized in the statement of financial position when there is an existing legal or informal obligation as a result of an event that has occurred, and it is probable that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount can be made.

Provisions are made for an amount that is the best estimate of what is required to settle the existing obligation as of the closing date. In instances where the timing of the payment is significant, provisions are calculated by discounting the expected future cash flow at an interest rate (before tax) that reflects current market assessments of the time value of money and, if applicable, the risks associated with the claim.

#### (i) Guarantees/warranties

A provision for guarantees/warranties is reported when underlying products are sold. The provision is based on historical data on guarantees and a weighting of possible outcomes in relation to the probabilities with which the outcomes are associated.

#### Contingent liabilities

A contingent liability is recognized when there is a possible commitment that arises from events occurring and whose occurrence is only confirmed by one or more uncertain future events or when there is an obligation that is not reported as a liability or provision due to the fact that it is unlikely that an outflow of resources will be required.

#### Parent Company accounting policies

The Parent Company's annual report has been prepared in accordance with the Annual Accounts Act (1995:1554) and RFR 2 Accounting for Legal Entities, issued by the Swedish Financial Reporting Board. The interpretations pertaining to listed companies that have been issued by the Swedish Financial Reporting Board have also been applied. The application of RFR 2 means that in the annual report for the legal entity, the Parent Company applies all of the IFRS adopted by the EU and the interpretations, to the extent possible without deviating from what is stipulated in the Annual Accounts Act, the Pension Obligations Vesting Act and with consideration given to the relationship between accounting and taxation. The recommendation states which exceptions from, and additions to, IFRS should be made.

# (i) Differences between the Group's and the Parent Company's accounting policies

Differences between the Group's and the Parent Company's accounting policies are presented below. The accounting policies presented below for the Parent Company have been applied consistently in all periods presented in the Parent Company's financial statements.

#### (ii) Classification and presentation

For the Parent Company, both an income statement and statement of other comprehensive income are provided. For the Group, these two reports are what comprises the consolidated statement of comprehensive income.

Furthermore, for the Parent Company, the names of its reports are "balance sheet" and "statement of cash flows". The corresponding reports for the Group are called "consolidated statement of financial position" and "consolidated statement of cash flows". For the Parent Company, the income statement and balance sheet have been presented in accordance with the Annual Accounts Act. However, the statement of other comprehensive income and statement of changes in equity have been prepared in accordance with IAS 1 Presentation of Financial Statements and the statement of cash flows has been prepared in accordance with IAS 7 Statement of Cash Flows.

Differences between the consolidated financial statements and the Parent Company's income statement and balance sheet primarily pertain to reporting of financial income and expenses, fixed assets, equity and the fund for development expenditure. Also, provisions are reported as a separate heading in the Parent Company's balance sheet.

#### (iii) Subsidiaries

Shares in subsidiaries are reported in the Parent Company according to the cost method. This means that transaction costs are included in the carrying amount of holdings in subsidiaries. In the consolidated financial statements, transaction costs are reported directly in profit or loss as incurred.

#### (iv) Group contributions and shareholder contributions

The Parent Company thus reports both Group contributions paid and received as appropriations. Shareholder contributions made are reported as an increase in the value of shares and participations. An assessment is then made as to whether there is a need to record an impairment loss on the value of shares and participations in question.

#### (v) Leased assets

In the Parent Company, all leases are reported in accordance with the rules for operating leases.

#### (vi) Borrowing costs

In the Parent Company, borrowing costs are reported in profit or loss in the period they arise. No borrowing costs are capitalized on assets.

#### (vii) Taxes

In the Parent Company's balance sheet, untaxed reserves are reported without allocation between equity and deferred tax liability (which is done for the Group). Likewise, in the Parent Company's income statement, there is no allocation of a portion of the appropriations to deferred tax expense.

#### (viii) Fund for development expenditure

Capitalized costs for development work are recognized in the Parent Company financial statements as part of equity in the fund for development expenditure, which reduces non-restricted equity.

## NOTE 3 FINANCIAL RISK MANAGEMENT AND CAPITAL RISK

#### Financial risk management

The Group's business activities are associated with a variety of financial risks: market risk (including currency risk and interest rate risk on cash flows), credit risk and liquidity risk. The Group's overall risk management policy, which has been established by the Board, is to strive for minimal adverse effects on financial results and financial position.

#### Market risk

#### Currency risks

The Group has operations both domestically (in Sweden) and internationally, which means that there is exposure to fluctuations in different currencies, particularly USD and EUR. Currency risk arises through future business transactions and reported assets and liabilities. Given the current scope of the company's operations, its net exposure to foreign currencies is limited. Accordingly, it has not adopted a policy for hedging the exposure. If the SEK had weakened/strengthened by 10 percent, holding all other variables constant, the recalculated profit (loss) after tax as of 30 April 2021 would have been SEK 5 (5) thousand lower/higher, primarily due to gains and losses arising from recalculation of current receivables and liabilities. The corresponding effect on the Parent Company would be SEK 5 (5) thousand. Recalculation effects from operations in the US subsidiary, Biovica Inc. are still at such a low level that they have little impact on Biovica's reporting in SEK thousands.

#### Interest rate risk on cash flows

Interest rate risk is the risk that the value of financial instruments will fluctuate due to changes in market interest rates. The Group currently only has interest-bearing financial assets in the form of bank balances. Calculated on the basis of financial interest-bearing assets and liabilities with variable interest as of April 30, 2021, a change in the market interest rate of one percentage point would affect the Group's and the Parent Company's earnings by SEK 125 (116) thousand.

#### Credit risk

Credit risk is the risk that a party to a transaction involving a financial instrument is unable to fulfill its obligation. The maximum exposure to credit risks associated with financial assets amounted to SEK 222 (0) thousand on April 30, 2021. The corresponding figure for the Parent Company was SEK 222 (0) thousand.

#### Liquidity risk

Caution in managing liquidity risk involves holding sufficient liquid funds or agreed credit facilities in order to be able to run the business. Based on the business plan, the company has liquid funds sufficient for running the business beyond the next 24 months. The maturity structure for the Group's financial liabilities is presented below.

		Between 3 months and I year	Between I and 2 years	Between 2 and 5 years	More than 5 years
Accounts payable	1,085	-	-	-	-
Accrued liabilities	4,023	-	-	-	-
	5,108	0	0	0	0

#### Managing capital risks

The Group's goals pertaining to capital structure (defined as equity), are to ensure that the company is able to run its operations in order to generate returns for its shareholders and value to other stakeholders, along with ensuring that the capital structure is optimal with regard to the cost of the capital. Dividends to shareholders, redemption of shares, issuance of new shares or sale of assets are examples of measures that the company can use to adjust the capital structure.

#### The Group's debt/equity ratio

SEK thousands	2020/2021	2019/2020
Total interest-bearing liabilities	934	2,272
Less: interest-bearing assets	145,364	40,777
	144,430	38,505
Net debt-equity ratio	79	49

#### Net debt-equity ratio

Net debt divided by equity.

### NOTE 4 IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

Described below are the most important assumptions about the future, and other significant sources of uncertainty in estimates as of the closing date that entail a significant risk of needing to make material adjustments to the carrying amounts of assets and liabilities during the next financial year.

The most significant uncertainty is associated with intangible assets. Capitalization of intangible assets only occurs when all of the criteria listed in Note 2, Intangible assets, have been met. Impairment testing is based on a review of the recoverable amount, which is assessed based on the value-in-use of the asset concerned. The company's senior executives calculate future cash flows based on internal business plans and forecasts.

This also involves making estimates on such things as discount rates and future rates of growth that extend beyond adopted budgets and forecasts. The carrying amount of the Group's intangible assets amounts to SEK 41,869 (42,666) thousand, of which SEK 37,476 (37,296) thousand is capitalized development expenditure and SEK 4,393 (5,370) is patents.

Changes in the assumptions and assessments made by the senior executives in conjunction with demarcation between research and development projects, as well as changes in assumptions and assessments made when testing for impairment, could result in a write-down requirement on the intangible assets, which, in turn, could have a significant impact on the company's earnings and financial position.

#### Internal development expenditure for research and development

Assessment is required for making the allocation between the research and development phases in new development projects of diagnostic tests. Assessments must also be made when deciding whether the requirements for capitalizing development expenditure have been met. After capitalization occurs, management monitors that the accounting requirements for development costs are still being met, along with whether there is any indication of impairment to the capitalized expenditure. Should the situation arise whereby the company's financing is not secured, it could result in a write-down requirement on the intangible assets. Management continuously evaluates that the financing is secured.

#### Growth and gross margin

The recoverable amount is based on a calculation of the value-in-use by using cash flow forecasts based on budgets that have been approved by the Board of Directors, along with forecasts that stretch over the life of the company's patents. The forecasts are based on the business plan for 2021/2022. Gross margin is calculated based on the product calculation.

#### WACC (weighted average cost of capital)

WACC represents a weighted average of the risk that both owners and the financial market are prepared to take in order to finance operations. When calculating the WACC, consideration is given to the fact that operations have been financed via both debt and equity. The cost of equity is based on expectations of a certain return on invested capital in the financial market. The cost of debt capital is based on borrowing costs in the financial market. The WACC rate corresponds to the Group's assessed average cost of capital and it is primarily set using the Group's yield requirement. Added to that is an estimation of the market's assessment of risk. Changes between the years in the WACC rate are attributable to such things as changes in the level of debt.

#### Impairment of non-financial assets

In order to assess impairment, management calculates the recoverable amount for each cash-generating unit based on expected future cash flows. It then uses a suitable rate to discount those cash flows to present value. There is uncertainty in assumptions about future operating profit and establishing a suitable discount rate.

#### Useful life of depreciable assets

At each closing date, management reviews its assessments of the useful life that has been established for each category of depreciable assets, taking into consideration how long the Group expects to use those assets. There is uncertainty in these assessments because of the demand and market acceptance.

#### **NOTE 5 NET SALES**

All net sales are sales at a particular point in time. No sales are reported as sales over time. Net sales are distributed across the following lines of business for the Group and Parent Company:

	2020/2021	2019/2020
Goods	2,077	1,671
	2,077	1,671

Net sales are distributed across the following geographic markets for the Group and Parent Company:

	2020/2021	2019/2020
Sweden	299	-
EU, excl. Sweden	531	397
USA	1,247	1,249
Asia	-	25
	2,077	1,671

#### **NOTE 6 SEGMENT REPORTING**

Operating segments are reported in a manner consistent with internal reporting provided to the chief operating decision maker. The chief operating decision maker is the function that is responsible for allocating resources and assessing the operating segments' performance. In the Group, this function has been identified as the senior management team, which consists of six people including the CEO. Senior management has determined that the Group, as a whole, is a single segment based on the information that the Board and senior management together use as the basis for allocating resources and evaluating performance. All of the fixed assets are located in Sweden. The Group's net sales consist of the sale of goods and services, all of which is invoiced from Sweden. Customers are primarily in the USA. The Group has three customers that account for ten percent or more of the company's revenue.

#### **NOTE 7 INTRA-GROUP PURCHASES AND SALES**

Biovica International AB purchases sales support and other services from its subsidiary, Biovica Inc. During the year, such services were purchased for an amount of SEK 7,123 thousand.

#### **NOTE 8 OTHER OPERATING INCOME**

	The G	iroup	Parent C	Parent Company		
	2020/2021	2019/2020	2020/2021	2019/2020		
Grants	1,843	972	1,843	972		
Sales of securities	-	-	-	-		
Gain on disposal of fixed assets	1	-	-	-		
Foreign exchange gains/losses	228	-	228	-		
Other remuneration and income	1,169	243	-	-		
	3,241	1,215	2,071	972		

The grants have been received from BIOVALID, which is a Horizon 2020 project (Phase II). Grants have also been received for sick leave expenses. The income from grants to projects is recognized at the rate that the associated project is completed.

#### **NOTE 9 AUDIT EXPENSES**

	The G	iroup	Parent Company	
	2020/2021	2019/2020	2020/2021	2019/2020
Grant Thornton Sweden AB				
Audit assignment	-370	-415	-370	-400
Audit activities besides the audit assignment	-	-2	-	-2
Tax advice	-	-	-	-
	-370	-417	-370	-402

Audit refers to the statutory audit of the annual report and accounts, along with the Board's and CEO management. It also includes other work that the company's auditor deems necessary, advice and other assistance resulting from observations made during the audit or execution of other such tasks. Everything else is other services.

NOTE 10 NUMBER OF EMPLOYEES, GENDER DISTRI-BUTION, EMPLOYEE BENEFIT EXPENSES AND REMUNERATION TO SENIOR EXECU-TIVES

	The Group		Parent Company	
	2020/2021	2019/2020	2020/2021	2019/2020
Average number of employees				
Women	9	8	9	8
Men	- 11	9	10	8
	20	17	19	16
Gender distribution, senior executives				
Women	3	2	3	2
Men	5	5	5	5
	8	7	8	7
Gender distribution, Board of Directors				
Women	3	2	3	1
Men	5	5	5	5
	8	7	8	6
Employee benefit expenses				
Salaries and other benefits to the Board of Directors	1,150	950	1,150	950
Salaries and other benefits to the CEO	1,583	1,318	1,583	1,318
Salaries and other ben- efits to other senior executives (7 people)	5,524	4,589	5,524	4,589
Salaries and other benefits to other employees	12,465	7,219	7,990	5,399
Social security contributions	3,989	3,537	3,627	3,537
Pension expenses for the Board and CEO	366	340	366	340
Pension expenses for other senior executives	785	903	785	903
Pension expenses for other employees	726	371	726	371
Total salaries, other benefits, social security contribu- tions and pension contributions	24 500	10.220	21.752	17.407
contributions	26,589	19,228	21,752	17,407

#### Remuneration to the Board of the Parent Company

	2020/2021	2019/2020
Lars Holmqvist, Chairman of the Board	400	400
Maria Holmlund	150	150
Ulf Jungnelius	150	150
Jesper Söderqvist	150	150
Henrik Osvald	150	150
Helena Fjällskog	75	-
Annika Berg	75	-
Anders Rylander*	-	-
	1,150	1,000

\* Anders Rylander is employed as the CEO of Biovica and therefore does not receive any Board fees.

As of I January 2019, the Group has had employees from the Parent Company working in Boston, Massachusetts. Employee benefit expenses for Biovica's US subsidiary amount to SEK 4,975 (1,821) thousand, which is comprised of salary and social security contributions, but not pension expenses (which are paid by the Parent Company). There are no agreements on severance pay. For the CEO, the notice period is six months.

#### **NOTE II TRANSACTIONS WITH RELATED PARTIES**

During the year, the company, represented by parties related to the main owner and board member, Anders Rylander, leased office facilities to the Parent Company. The total fee for rent paid was SEK 198 (198) thousand. Pricing was in accordance with the arm's length principle.

#### **NOTE 12 TAX EXPENSE**

The Group	2020/2021	2019/2020
Profit (loss) before tax	-39,386	-30,259
Tax according to the applicable tax rate	8,429	6,475
Tax effect of non-capitalized loss carryforwards	-8,588	-6,295
Tax effect of non-deductible expenses	-164	-239
Tax effect of non-taxable income	191	-
Effect of foreign tax rates	36	-
Reported tax	-96	-59
The tax expenses is comprised of the following:		
Current tax expense	-104	-70
Deferred tax revenue		
-Change in temporary differences	8	11
Tax expense	-96	-59
Deferred tax revenue reported in other comprehensive income	8	11

Parent Company	2020/2021	2019/2020
Profit (loss) before tax	-40,004	-30,571
Tax according to the applicable tax rate	8,561	6,542
Tax effect of non-capitalized loss carryforwards	-8,588	-6,295
Tax effect of non-deductible expenses	-163	-247
Tax effect of non-taxable income	191	-
Reported tax	0	0

Note 17 contains information on deferred tax assets.

New tax rules entered into force on 1 January 2019. The tax rate will be lowered in a two-step process and it amounts to 21.4 percent for fiscal years starting on 1 January 2019 or later. After that, it is lowered to 20.6 percent for fiscal years starting on 1 January 2021 or later.

#### NOTE 13 CAPITALIZED EXPENDITURE FOR DEVELOP-MENT AND SIMILAR WORK

Group and Parent Company	2021-04-30	2020-04-30
Opening cost	45,733	38,698
Capitalized expenditure	3,560	7,035
Closing accumulated cost	49,293	45,733
Opening amortization	-8,436	-7,138
Amortization for the year	-3,380	-1,299
Closing accumulated amortization	-11,817	-8,436
Closing carrying amount	37,476	37,296

In addition, SEK 4,200 (1,320) thousand was expensed for R&D during the year.

#### **NOTE 14 PATENTS**

Group and Parent Company	2021-04-30	2020-04-30
Opening cost	9,896	9,896
Closing accumulated cost	9,896	9,896
Opening amortization	-4,526	-3,549
Amortization for the year	-977	-977
Closing accumulated amortization	-5,503	-4,526
Closing carrying amount	4,393	5,370

# NOTE 15 MACHINERY, EQUIPMENT, TOOLS, FIXTURES AND FITTINGS

	The Group		Parent C	ompany
	2021-04-30	2020-04-30	2021-04-30	2020-04-30
Opening cost	3,162	4,279	3,162	3,162
Purchases	-	-	-	-
Reclassification	-	-1,116	-	-
Closing accumulated cost	3,162	3,162	3,162	3,162
Opening depreciation	-1,929	-1361	-1,929	-1,361
Depreciation for the year	-529	-567	-529	-567
Closing accumulated depreciation	-2,459	-1,929	-2,458	-1,929
Closing carrying amount	704	1,234	704	1,234

#### **NOTE 16 LEASING**

The Group has lease agreements that are primarily for premises and cars. Leases where the underlying asset is of low value pertain to office equipment and amount to SEK 15 (17) thousand for the year. The Group does not have any short-term leases. Total cash flow for leasing amounts to SEK 1,288 (940) thousand. Interest expense on lease liability for the year amounts to SEK 58 (87) thousand.

The Group	2021-04-30	2020-04-30
Opening cost	4,640	3,618
Purchases	385	
Reclassification	-	1,022
Sales/disposals	-190	
Closing accumulated cost	4,835	4,640
Opening amortization	-1,328	
Sales/disposals for the year	61	
Amortization for the year	-1,255	-1,328
Closing accumulated amortization	-2,523	-1,328
Closing carrying amount	2,312	3,313
Right-of-use assets		
	2021-04-30	2020-04-30
Premises	1,476	2,547
Cars	836	766
	2,312	3,313
Depreciation of right-of-use assets	2021-04-30	2020-04-30
Premises	-1,071	-1,07
Cars	-184	-257
	-1,255	-1,328
The present value of liabilities associated with	h right-of-use ass	sets is:
	2021-04-30	2020-04-30
Within I year	1,486	1,182
Between I-5 years	934	2,272
More than 5 years	-	
	2,420	3,453
The Parent Company's leasing costs Leases where the company is lessee Expensed lease payments for the year:		
		2019/2020
Parent Company	2020/2021	2017/2020
Parent Company Total leasing costs	1,763	1,696

Leased office space and rental of office equipment are classified as operating leases. Most of the leasing costs are attributable to rental of office space via operating leases. The leasing agreements run without special restrictions with an option for extension.

#### **NOTE 17 DEFERRED TAX ASSET**

The Group has tax loss carryforwards that may be utilized against taxable profits in the future. The company reports a deferred tax asset when it is probable that taxable profits will be generated, Capitalization of deferred tax would result in a deferred tax asset of SEK 25 million as of 2021-04-30. However, the company's executive management team has concluded that the prerequisites do not yet exist for reporting a deferred tax asset. As of 30 April 2021, the Group's tax loss carryforwards amounted to SEK 122,227 (82,096) thousand.

The deferred tax asset is attributable to right-of-use agreements.

-			
Det	erred	tax	asset

	2021-04-30	2020-04-30
Opening cost	743	-
Change for the year	-225	743
Effect due to change in tax rate	-19	-
Closing carrying amount	499	743
Deferred tax liability		
	2021-04-30	2020-04-30
Opening cost	708	-
Change for the year	-230	708
Effect due to change in tax rate	-18	-
Closing carrying amount	460	708

#### **NOTE 18 GROUP COMPANIES**

	2021-04-30	2020-04-30
Opening cost	108	108
Closing accumulated cost	108	108
Closing carrying amount	108	108

Name/Registered office	Registered office	CIN	Number of shares	Share %	Carrying amount (SEK)
Biovica Services AB	Uppsala	556781-8454	1,000	100%	100,000
Biovica Inc.	Delaware, USA	30-1045327	100	100%	8,236

	Equity (SEK)	Profit/loss (SEK)	
Biovica Services AB	448,069	-74	
Biovica Inc	438,502	434,730	

#### **NOTE 19 RECEIVABLES FROM GROUP COMPANIES**

2021-04-30	2020-04-30
985	-
-	985
1,281	-
-267	-
1,999	985
1,999	985
	- 1,281 -267 <b>1,999</b>

#### **NOTE 20 PREPAID LEASE PAYMENTS,** PARENT COMPANY

#### Prepaid lease payments

	2021-04-30	2020-04-30
Opening cost	198	176
Additional receivables,		
higher initial payment	-	22
Closing accumulated cost	198	198
Opening amortization	-43	-
Amortization for the year	-45	-43
Closing accumulated amortization	-88	-43
Closing carrying amount	110	155

#### **NOTE 21 SHARES**

Biovica has issued both Class A shares (each worth 3 votes) and Class B shares (each worth 1 vote). As of 30 April 2021 there was a total of 28,418,372 shares; of which 6,623,170 Class A shares and 21,795,202 Class B shares. The Class A shares are unlisted and the Class B shares are listed on First North Premier. Share capital amounted to SEK 1,894,558.13 and the quotient value per share is SEK 0.07. The total number of votes amounted to 41,664,712.

#### Reclassification of shares

At the end of each quarter, class A shareholders are offered the opportunity of reclassifying their shares to B shares. During the year, a total of 464,664 Class A shares were reclassified. Prior to reclassification, the total number of votes was 37,588,420 and after reclassification the total was 41,664.712 votes.

2021-04-30	Class A shares	Class B shares	Total
Before reclassification	7,007,524	16,565,848	23,573,372
Issue	-	4,700,000	4,700,000
Subscription due to warrants	-	145,000	145,000
Reclassification	-464,664	464,664	0
After reclassification	6,542,860	21,875,512	28,418,372

#### **NOTE 22 SHARE PREMIUM RESERVE**

The amount received for issued shares over and above the quotient value (share premium) is included in the item Share premium reserve, after a deduction for registration fees and other similar fees, as well as a deduction for applicable tax benefits. The costs for new share issue that have been reported directly in equity amounted to SEK 7,151 (3,036) thousand.

Share premium has also been reported for the issue of share capital pertaining to share-related remuneration to employees, see Note 23.

#### **NOTE 23 WARRANTS**

Biovica has four outstanding warrant schemes. The warrants were transferred following market valuation in accordance with the Black & Scholes pricing model. A market-based price is used for receipt and payment of warrants. Included in the TO6 warrant scheme for employees is one employee in USA, who was offered 20,000 employee stock options.

Within the scope of the TO3 scheme, a total of 145,000 Class B shares were subscribed for during the year and the remaining 55,000 warrants that were not distributed have been canceled. For TO5, a total of 100,000 warrants were canceled during the year and for TO6, the corresponding number is 47,000. After cancellation and subscription, the number remaining is shown in the table, below.

Program	То	Class B shares	Subscription price	Warrant price	Subscription period	Share capital increase	Number of class B shares
TO4	Board of Directors	150,000	19.50	0.94	25 March 2022 – 25 August 2023	10,000.00	150,000
TO5	employees	170,000	17.16	1.23	25 March 2021 – 25 August 2022	11,333.33	170,000
TO6	employees	173,000	45.14	3.31	25 March 2022 – 25 August 2023	11,533.33	173,000
TO7	Board of Directors	200,000	45.14	3.31	25 March 2022 – 25 August 2023	13,333.33	200,000
						46,200.00	693,000

#### NOTE 24 NON-CASH ITEMS

	The G	iroup	Parent Company		
	2021-04-30 2020-04-30		2021-04-30	2020-04-30	
Leasing	0	-349	0	0	
Currency effects	146	0	0	0	
Depreciation/amorti-					
zation	6,142	4,170	4,887	2,843	
	6,288	3,821	4,887	2,843	

#### **NOTE 25 PLEDGED ASSETS**

	2021-04-30	2020-04-30
Pledged assets	None	None

#### **NOTE 26 CONTINGENT LIABILITIES**

	2021-04-30	2020-04-30
Contingent liabilities	None	None

#### **NOTE 27 CASH AND CASH EQUIVALENTS**

	The Group		Parent Company	
	2021-04-30	2020-04-30	2021-04-30	2020-04-30
Bank balances	145,351	40,767	142,908	39,632
Short-term invest- ments	12	10	12	10
	145,364	40,777	142,920	39,642

#### **NOTE 28 FINANCIAL ASSETS AND LIABILITIES**

The accounting policies contain a description of each category of financial assets and liabilities, the accounting policy for each and how they are measured. The carrying amounts for financial assets and liabilities, by category, is as follows:

#### Amortized cost 2020/ 2021, SEK thousands

#### Financial assets

	The Group	Parent Company
	2020/2021	2020/2021
Accounts receivable	222	222
Other current receivables	629	629
Accrued income	99	99
Cash and cash equivalents	145,351	142,908
Total financial assets	146,302	143,858

#### Other financial liabilities

	2020/2021	2020/2021
Other non-current liabilities	934	-
Accounts payable	1,085	1,086
Intra-Group accounts payable	-	1,087
Accrued expenses and deferred income	4,023	3,587
Other current liabilities	634	634
Total financial assets	6,676	6,393

#### Amortized cost 2019/ 2020, SEK thousands

#### Financial assets

	The Group	Parent Company
	2019/2020	2019/2020
Other current receivables	547	547
Accrued income	168	168
Cash and cash equivalents	31,231	30,096
Short-term investments	9,546	9,546
Total financial assets	41,492	40,357

#### Other financial liabilities

	2019/2020	2019/2020
Other non-current liabilities	2,727	-
Accounts payable	1,007	1,004
Intra-Group accounts payable	-	476
Accrued expenses and deferred income	2,228	2,131
Other current liabilities	624	624
Total financial assets	6,130	4,235

#### Loan receivables and accounts receivable

The Group's operations generate accounts receivable, which, historically, have not totaled significant amounts. Historically, there have not been any bad debt losses on accounts receivable either. Cash & cash equivalents primarily consists of bank balances and short-term investments in SEK. As of the closing date, there were no receivables that needed to be written down. The fair value of the Group's loan receivables and accounts receivable is in all material respects consistent with the carrying amounts.

#### Borrowings and accounts payable

The Group does not have any interest-bearing liabilities. The maturity structure for financial liabilities is provided in Note 3. The Group has not provided any security for any of the financial liabilities. The fair value of the Group's financial liabilities is in all material respects consistent with the carrying amounts.

#### **NOTE 29 FINANCIAL INSTRUMENTS AT FAIR VALUE**

Information on financial instruments at fair value:

Group and Parent Company

	2020/2021		2019/2019	
	Carrying amount	Value change recognized	Carrying amount	Value change recognized
Available-for-sale financial assets	12,493	890	9,546	-331

The financial assets stated above consist of investments in funds. For financial instruments that are listed, the quoted prices are used for measurement at fair value (Level 1).

#### NOTE 30 SIGNIFICANT EVENTS AFTER THE FINAN-CIAL YEAR-END

Because of the COVID-19 pandemic, review of such things as 510(k) applications by the FDA is taking longer than normal. There is uncertainty about whether this could lead to further delays for Biovica's FDA application.

# The Board of Directors' and CEO's assurance

The consolidated income statement and balance sheet will be brought forth at the Annual General Meeting on 31 August 2021 for adoption.

The Board of Directors and CEO affirm that the consolidated accounts have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU and that they provide a true and fair view of the Group's financial position and results.

The Parent Company's financial statements been prepared in accordance with generally accepted accounting policies and they provide a true and fair view of the Parent Company's financial position and results. The Board of Directors' report for the Group and parent company provides a true and fair overview of the Group's and Parent Company's operations, financial position and results and also describes material risks and uncertainties faced by the parent company and the companies that comprise the Group.

Uppsala, 30 June 2021

Lars Holmqvist Annika Carlsson Berg
Chairman of the Board Board member

Marie-Louise Fjällskog Maria Holmlund
Board member Board member

Jarl Ulf JungneliusHenrik OsvaldBoard memberBoard member

Anders Rylander Jesper Söderqvist

\*President/CEO, Board member Board member

Our audit report was issued on 30 June 2021

Grant Thornton Sweden AB

Stéphanie Ljungberg

Authorized Public Accountant

# Audit report

To the AGM of Biovica International AB (publ), CIN 556774-6150

### REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

#### **Opinions**

We have conducted an audit of the annual accounts and consolidated accounts for Biovica International AB (publ) for the financial year 2020-05-01-- 2021-04-30. The company's annual accounts and consolidated accounts are provided on pages 40-64 of this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and in all material respects, give a true and fair view of the Parent Company's financial position as at 30 December 2021 and of its financial performance and cash flow for the year in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and in all material respects, give a true and fair view of the Group's financial position as at 30 December 2021 and of its financial performance and cash flow for the year in accordance with the International Financial Reporting Standards (IFRS) that have been adopted by the EU. The Directors' report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the Parent Company and the Group.

#### Basis for opinions

We conducted the audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing practices in Sweden. Our responsibility as per these standards is described in the section, Auditor's responsibility. We are independent of the Parent Company and the Group in accordance with the auditor's oath in Sweden and have otherwise fulfilled our ethical responsibilities under these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Other information besides what is shown in the financial statements and consolidated financial statements

This document also contains other information than the annual report and consolidated financial statements, which is presented on pages 1-39 and page 67. The Board of Directors and CEO are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated. If we, based on the work performed concerning this informa-

tion, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in that regard.

#### The Board of Directors' and CEO's responsibilities

The Board of Directors and CEO are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and CEO are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, the Board of Directors and CEO are responsible for the assessment of the company's and the Group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the CEO intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

#### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the CEO.

- conclude on the appropriateness of the Board of Directors' and the CEO's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts.
   We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

## REPORT ON OTHER REQUIREMENTS IN ACCORDANCE WITH LEGISLATION AND OTHER REGULATIONS

#### **Opinions**

In addition to our audit of the annual report and consolidated financial statements, we have performed an audit of the Board's and CEO's administration of Biovica International AB (publ) for the financial year 2020-05-01 -- 2021-04-30 and the proposed appropriation of the profit or loss.

We recommend that the Annual General Meeting appropriate the profit in accordance with the proposal in the Directors' Report and discharge to the members of the Board of Directors and the CEO from liability for the financial year.

#### Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the Parent Company and the Group in accordance with the auditor's oath in Sweden and have otherwise fulfilled our ethical responsibilities under these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### The Board of Directors' and CEO's responsibilities

The Board of Directors for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the Parent Company's and the Group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the Group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The CEO shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the CEO in any material respect:

- has undertaken any action or been guilty of any omission, which could give rise to liability to the Company, or
- in any other way acted in contravention of the Swedish Companies Act or the Articles of Association.

Our goal regarding the audit of the proposed appropriation of the profit or loss, and thus our statement on this, is to, with a reasonable degree of certainty, assess whether the proposal is consistent with the Swedish Companies Act.

Reasonable certainty is a high degree of certainty, but no guarantee that an audit performed in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that could give rise to a liability to the Company or that a proposal for the appropriation of the profit or loss is not consistent with the Swedish Companies Act.

As part of an audit in accordance with generally accepted accounting standards in Sweden, we use professional judgment apply professional skepticism throughout the entire audit. The audit of the administration and the proposed appropriation of the profit or loss is primarily based on the audit of the financial statements. We decide what additional procedures to perform based on our professional judgment, and having considered both risks and materiality. It means that we focus the audit on such measures, areas and conditions that are essential for operations and where deviations or transgressions would significantly impact the company's situation. We review and test decisions, supporting documentation for decisions, measures taken and other factors that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board's proposed appropriation of the profit or loss, we examined whether the proposal is consistent with the Companies Act.

Uppsala, 30 June 2021

Grant Thornton Sweden AB

Stéphanie Ljungberg

Authorized Public Accountant



#### SHAREHOLDER INFORMATION

ANNUAL GENERAL MEETING (AGM)
The Annual General Meeting for the 2020/2021 financial year will be held on 31 August 2021, via postal voting. Notice of the AGM will be published in Post- och Inrikes Tidningar (gazette) and in SvD (newspaper). The Board of Directors proposes that no dividends shall be distributed to shareholders.

#### NOMINATION COMMITTEE

The Nomination Committee has been appointed in accordance with the AGM guidelines

#### **FUTURE REPORTING DATES:**

AGM	I August 2021
Interim Report for Q1: May-July 2021/2022	31 August 2021
Interim Report for Q2: August-October 2021/2022	I December 2021
Interim Report for Q3: November-January 2021/ 2022	15 March 2022
Interim Report for Q4: May-July 2021/2022	16 June 2022

#### FOR MORE INFORMATION, PLEASE CONTACT:

Anders Rylander, CEO

Cecilia Driving, EVP CFO

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