

BIOVICA INTERNATIONAL AB

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# BIOVICA

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**BEST POSSIBLE  
TREATMENT FROM DAY ONE**

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**ANNUAL REPORT  
2018/2019**

# This is Biovica

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**Biovica** develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. DiviTum® measures thymidine kinase activity (TKA), which indicates the cell proliferation rate and clinical studies have shown that it can quickly reveal whether treatment is effective.

**Biovica** is a biotechnology company with research and development, production facilities and head office in Uppsala, Sweden. It also has an office in Boston, USA. Our current customers are in the research market and they are pharmaceutical companies and CROs (Contract Research Organizations) that conduct clinical studies in conjunction with creating new treatments. Our future customers will be laboratories that perform analyses for doctors who are treating patients.

**Biovica** has its registered office in Sweden and it is listed on Nasdaq First North Premier Stockholm. For the 2018/2019 financial year, sales amounted to SEK 3 million and the company had 17 employees.

6 **BILLION SEK**  
Market potential in  
USA and Europe

9/17  
Ongoing  
Published studies

912  
Patients in  
ongoing studies

### THE YEAR IN FIGURES

The Group, SEK thousands	2018/2019	2017/2018	2016/2017
Net sales	3,005	2,723	632
Operating loss	-21,718	-17,956	-14,690
Net profit (loss) for the year	-21,556	-18,010	-14,715
Capitalized R&D expenditure	6,464	6,596	5,075
Capitalized R&D expenditure as a percentage of operating expenses	-22	-26	-27
Earnings per share, basic	-1.23	-1.02	-0.84
Earnings per share, after dilution	-1.18	-1.00	-0.80
Cash and cash equivalents at the end of the period	16,831	42,127	65,469
Cash flow from operating activities	-17,966	-14,882	-10,746
Cash flow for the period	-25,295	-23,342	64,541
Equity	52,097	73,713	91,664
Equity per share	2.96	4.19	5.22
Equity ratio (%)	86	91	94
Average number of employees	16	14	8

This is a translation of an original document in Swedish. In the event of any discrepancy between this translation and the original Swedish document, the original Swedish document shall prevail.



# Large market and clinical need

**DiviTum®** is a biomarker test that makes it possible to monitor cancer treatment within just 2-4 weeks after initiating the treatment. With a simple blood sample, it is possible to evaluate the success of treatment over time and also detect whether the tumors are becoming resistant to the treatment.



## Structured commercialization strategy

- FDA application, reimbursement, guidelines and partners for commercialization 2020/2021.
- Successful commercialization for use in treating breast cancer will create opportunities for business deals with major diagnostic platform providers.



## Milestones for 2019/2020

- More results from clinical studies will be presented during 2019 and 2020.
- FDA 510(k) submission in 2019 with expected approval during the first half of 2020.
- Commercial sales partnerships for the research market (2019) and clinical market (2020).



## Innovative and patented diagnostic technology

This unique technology quickly shows whether or not the treatment is effective (just 2-4 weeks after having started treatment, rather than 2-4 months required with traditional imaging diagnostics). The patents for DiviTum® expire in 2026 and 2031.



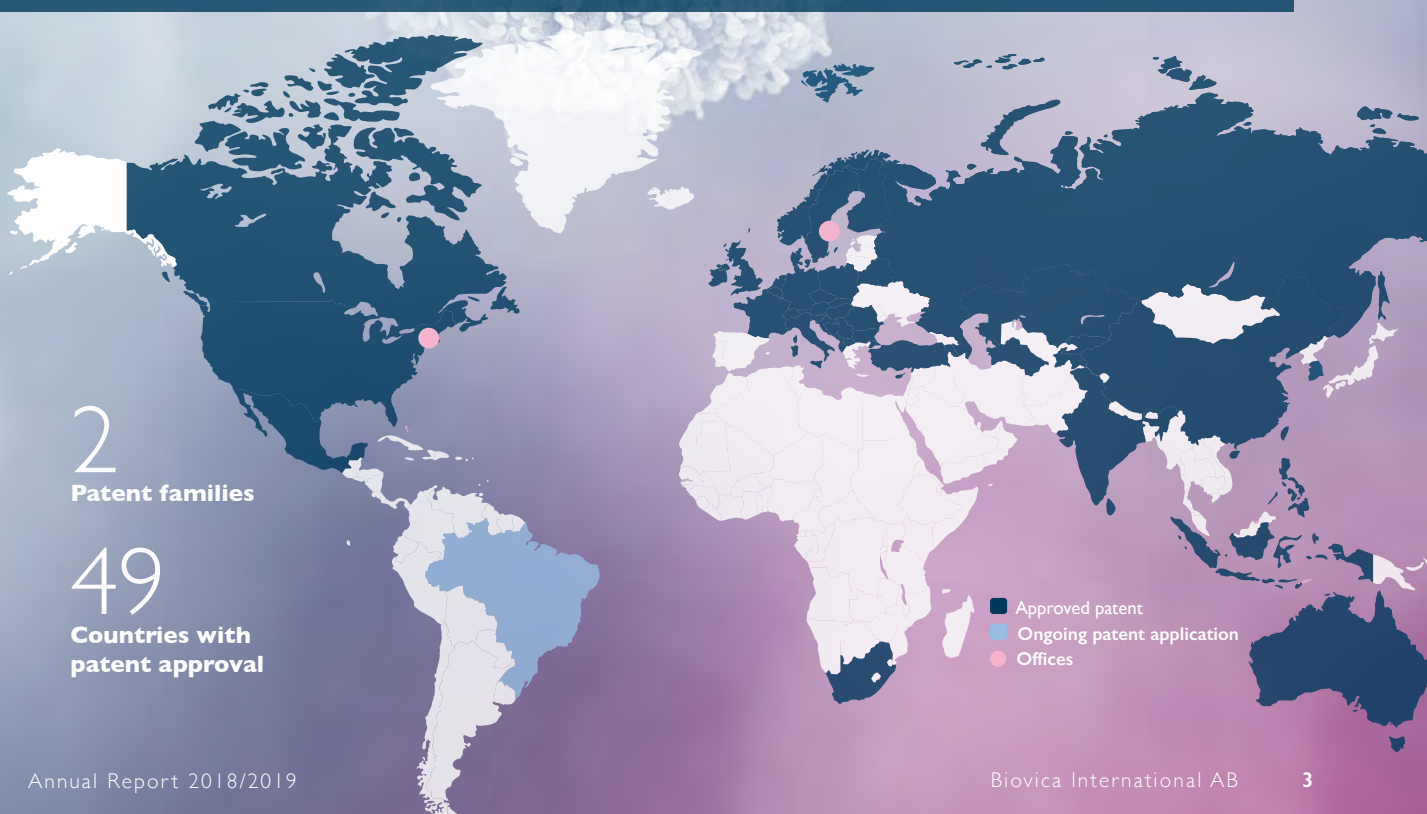
## Meets a large clinical need: "How aggressive is the cancer? Is the treatment effective?"

- Up to 80% of breast cancer patients do not respond to the selected treatment.
- It is estimated that 450,000 patients in EU and USA have metastatic breast cancer.
- The market potential is SEK 6 billion per year for DiviTum® for treating patients with metastatic breast cancer in the EU and USA.



## Strong results from studies with DiviTum®

- 6 published articles in scientific journals show that DiviTum® is able to measure the cell proliferation rate and that it also provides a good prognosis and risk assessment for patients with breast cancer. In total, 17 articles have been published over a wide spectrum of cancer forms.
- An additional 9 studies are ongoing with world-leading institutions and oncologists to further verify the ability of DiviTum® to evaluate treatment effect.



## CEO's comments

The 2018/2019 financial year was a very successful year for Biovica and we achieved several important milestones. It has been particularly satisfying to see the results from our clinical studies, which continue to be positive, and this certainly boosts our confidence as we prepare for commercialization.

### Strong results from clinical studies show the value of DiviTum®

The results from our ongoing studies with breast cancer show that DiviTum® provides valuable information as a diagnostic tool. The results are very promising, showing that DiviTum® can more quickly provide answers on whether or not a treatment is working. The test meets a very large unmet need in the market, generating benefits to both patients and society.

### DiviTum® meets the FDA's requirements and is in the validation phase

Commercialization efforts are progressing as planned. We are engaged in a proactive dialog with the FDA to ensure that our product meets their requirements. We have also developed DiviTum® so that it performs in accordance with the FDA's guidelines. That development process has been concluded and we are now in the validation phase. This involves conducting studies where the results show that DiviTum® is a reliable test for measuring cell division activity in cancer tumors and that it adds new valuable information. Our goal is to complete the clinical validation work by the end of the year and including it in our application for FDA approval.

### New market study confirms the market potential.

Early in 2019, we commissioned a study of the US and European markets. It showed that DiviTum® satisfies an unmet need and that our earlier assessment of the market potential of SEK 6 billion per year is realistic based on a scenario where DiviTum® becomes a standard part of treating patients with metastatic breast cancer in the EU and USA.

The total market potential for DiviTum® should, however, be much larger since it

can likely be used to evaluate other treatments and forms of cancer. That still needs to be documented, but our clinical study program will continue delivering new results in several studies aimed at gathering even more knowledge that oncologists can benefit from when using DiviTum® to evaluate the treatment of their patients.

During the year, we presented the results from studies at the following conferences: EFECT study at ASCO and Palbociclib resistance in cell cultures at San Antonio Breast Cancer Symposium, together with, for example, Prato Hospital in Italy. A scientific article was published in the European Journal of Cancer called "Prognostic role of serum thymidine kinase 1 activity in patients with hormone receptor positive metastatic breast cancer: analysis of the randomised phase III EFECT trial."

### Reimbursement and commercial partnerships

Once DiviTum® obtains regulatory approval in USA and Europe, the product will be marketed for clinical use. In order to achieve a truly successful launch and real breakthrough in the market, DiviTum® needs to be part of treatment guidelines. Contracts also need to be made regarding reimbursement between the treatment clinics and reimbursers. There are different solutions in each market and although efforts are already underway, the work will intensify as soon as we have FDA approval. The same applies to our work in setting up partners for selling the product.

Sales in the research market continue. Our agreement with IBL America increases our resources in that area and it is expected to result in higher revenue from the research market. Sales to the research market should also result in opportunities for creating new applications for the product.

### The targeted new share issue gave us a capital injection of SEK 60 million before issue costs.

In March, we implemented a new share issue for a total of SEK 60 million. The reason for deviating from shareholders' preemptive rights was the desire to broaden our ownership base, adding more Swedish and international institutional investors. The Board and main owners were in agreement that this was the best opportunity for acquiring capital on favorable terms. The capital will primarily be used to finance preparations for the FDA 510(k) submission for market approval in USA. It will also be used to support our efforts associated with reimbursement and for our sales & marketing activities in USA and Europe. The price per share was established on market terms via an accelerated book building process.

### Future prospects

In summary, Biovica has made much progress towards establishing DiviTum® in the market for clinical use and thereby making sure that cancer patients get more individualized treatment with better outcomes. Our next important milestone will be obtaining FDA approval and establishing DiviTum® as a standard tool for monitoring the treatment of metastatic breast cancer. After that, we will focus our efforts on establishing DiviTum® as a monitoring tool for other forms of metastatic cancer.

We've come a long way towards realizing our vision of offering the best possible treatment to cancer patients from day one!

**Anders Rylander**  
CEO



⊕ "We've put the prerequisites in place for taking DiviTum® to market and finally capitalizing on the enormous benefits of the product to patients, society and investors."

ANDERS RYLANDER  
CEO Biovica



## IMPORTANT EVENTS DURING THE 2018/2019 FINANCIAL YEAR:

### Results from studies

- At ASCO 2018, results from the EFFECT study with DiviTum® were presented (poster). During spring 2019, a full-length article was published in the European Journal of Cancer. The study involved 244 patients and it documented the effect of treatment over time using DiviTum®.
- The results of DiviTum® were presented (poster) at San Antonio Breast Cancer Symposium, in December 2018. The study provides us with both understanding and knowledge of the effects of palbociclib treatment at the cel-

lular level. It is also documentation that the effect of palbociclib can be measured with DiviTum® and that it is directly related to treatment outcome.

- In April 2019, results from the TReND study with DiviTum® were presented (poster) at AACR. This study shows that DiviTum® is able to evaluate the effect of palbociclib treatment for women with metastatic breast cancer.

### Product development, production and regulatory approval

- Developed a new version of DiviTum® that meets FDA requirements.
- The production process has been updated to meet FDA requirements.
- Biovica received positive feedback from the FDA on Supplement I. It means that we now have confirmation that the analytical validation will be carried out in a way that meets FDA requirements so that the product obtains 510k approval.

### Commercialization

- Biovica set up an office in Boston, Massachusetts.
- Lars Holmqvist was elected as the Chairman of the Board at an extraordinary general meeting in March 2019.
- Biovica started off the new financial year with a targeted new share issue to Swedish and international institutional investors that generated capital of SEK 60 million. The capital will primarily be used to finance preparations for the FDA 510(k) submission for market approval in USA. It will also be used to support our efforts associated with reimbursement for DiviTum®.

## VISION

### Best possible treatment from day one

Biovica's vision is that DiviTum® will help give cancer patients a longer life with better quality of life. Quick, accurate results on how a patient is responding to a particular cancer treatment help oncologists individualize it and make sure that patients get the best possible treatment from day one.

## BUSINESS CONCEPT

Biovica develops and commercializes blood-based diagnostic tests with biomarkers that improve monitoring and evaluation of modern cancer treatments. Through collaboration with world-leading cancer institutes and pharmaceutical companies, Biovica actively promotes the growing trend in healthcare for personalized treatment, with primary focus on patient survival and benefits to society.



## BUSINESS MODEL

**Development, manufacturing and sales:** DiviTum® is manufactured by Biovica in Uppsala, Sweden. The product is sold as a kit consisting of a reaction plate (96 wells) with reagents that have been optimized for ELISA applications.

**Customers:** Current customers are primarily researchers who use the test to study various treatment alternatives in pre-clinical and clinical studies. For use in clinical practice, Biovica's kit will be sold to laboratories and used to analyze blood samples from cancer patients who are undergoing treatment. DiviTum® 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.

**Success factors:** Biovica must inform and educate oncologists who are treating patients with metastatic breast cancer so that the doctors will consider using DiviTum® because it offers more effective monitoring of treatment.



## STRATEGY

Biovica shall pursue continual innovation and development within the company, thereby constantly improving the technology to generate a better basis for choosing the best cancer treatment

### Qualitative clinical studies and evidence on the benefits to society

Biovica's strategy is to gradually and successfully commercialize DiviTum® for use in treating breast cancer in USA and Europe. The next milestone will be widening its use for monitoring other forms of cancer and sales in other markets around the world.

### Focus on metastatic breast cancer

Biovica's focus is on entering the diagnostics market for metastatic breast cancer in USA and Europe. New areas and applications will be added after that.

The goal is for the product to be available for clinical use (at the end of) 2020. For that to happen, we must first obtain regulatory approval in each market.

### Establishing DiviTum® in treatment guidelines

In order to sell larger volumes of DiviTum®, Biovica must ensure that the product becomes part of the guidelines for cancer treatment. In other words, it must be incorporated into the treatment guidelines of various leading organizations. It must also be included in the reimbursement system of each market.

Biovica will thus submit applications to both NCCN and ASCO. They are two of the most important organizations issuing guidelines on use of biomarkers for metastatic breast cancer. Biovica anticipates that it will be able to use the results from both concluded and ongoing studies in its application.

In USA, there are several organizations involved in the reimbursement process. Biovica will concentrate efforts on gaining support from each of them. To succeed with that, we must have clinical studies confirming the benefits of DiviTum®.

Lastly, we need a sales organization for reaching out to customers and patients. Biovica is not planning on building its own sales organization to cover the main markets. Instead, it will sign agreements with companies that already have established sales channels for supplying customers with DiviTum®. Such companies include laboratories, diagnostics companies and distributors.



### GOALS FOR 2020

Biovica's goal is to establish DiviTum® as a standard tool for monitoring treatment of metastatic breast cancer in Europe and USA. Important milestones during the coming year are:

- 1. Publishing results** in accordance with an established strategy from ongoing clinical study programs.
- 2. Obtaining regulatory approval** in USA and registering DiviTum® in accordance with the EU IVD Directive.
- 3. The test is included in treatment guidelines and reimbursement systems** in both USA and the major European markets.
- 4. Agreement** with a commercial partner.

In the long term, Biovica intends to establish DiviTum® for the treatment of other types of cancer and new targeted therapies.



# Market overview

## Market introduction

One important prerequisite for getting an IVD (In Vitro Diagnostic) product launched is obtaining regulatory approval. That must occur before marketing and selling the product in each market is allowed.

The following are also required for successful marketing and sales of the product:

- It must be included in the national treatment guidelines of each country
- It must be included in the reimbursement system of each country

## Success factors

All clinical studies are carried out in collaboration with leading oncologists and they provide scientific evidence that DiviTum® offers clinical and societal value, along with higher quality of life for patients.

## Sales and distribution

Once it has obtained regulatory approval, Biovica intends to launch DiviTum® kits to customers in USA

and Europe. The company plans on conducting sales via commercial partners who have established sales channels that are appropriate for the product and each market.

After the product has been established for use in treating breast cancer, Biovica intends to offer it for treatment of other types of cancer and in other geographic markets besides USA and Europe. Furthermore, the product has potential for use in treatment of other diseases outside the cancer area, such as viral infections and autoimmune diseases.

In order to sell larger volumes of DiviTum®, Biovica must ensure that DiviTum® becomes part of the guidelines for cancer treatment. In other words, it must be incorporated into the treatment guidelines of various leading organizations. It must also be included in the reimbursement system of each market.

Biovica will thus submit applications to both NCCN and ASCO. They are two of the most important organizations issuing guidelines in USA on use of biomarkers for metastatic breast cancer. In Europe, the market is more frag-

mented. ESMO, European Society for Medical Oncology, is one of the important organizations that issues guidelines. Each European country also has its own national guidelines.

Commercial success also depends on DiviTum® being included in the reimbursement systems of each market.

The patents for DiviTum® expire in 2026 and 2031 for the two different platforms. However, Biovica still expects to have strong protection even after the patents expire. That is based on the fact that neither the manufacturing process nor compilation of the test is revealed in the patents. In developing DiviTum®, Biovica has accumulated a vast amount of proprietary information and know-how which will make it difficult for others to copy DiviTum®.

## Long-term opportunities

Biovica intends to expand into other patient groups and geographic markets. There are also plans for introducing DiviTum® for use in treating other forms of cancer and autoimmune diseases.



### Market size and potential

In January 2019, Biovica commissioned a study of the US and European markets in order to gain more knowledge of our most important markets. It showed that DiviTum® satisfies an unmet need and that our earlier assessment of the market potential of SEK 6 billion per year is reasonable based on a scenario where DiviTum® becomes a standard part of the recommended treatment of patients with metastatic breast cancer in Europe and USA. Calculations on the size of the market were based on the estimated number of patients in the markets of USA and Europe, along with interviews with oncologists and reimbursers about test frequency and willingness to pay for the test.

The calculations show a market potential of approximately SEK 6 billion per year. However, Biovica's assessment is that the total market potential is significantly larger, since the test can be used to evaluate the effect of treatment for other types of cancer than metastatic breast cancer. This has been confirmed in several clinical studies that have been published on, for example, lung cancer and gastro-intestinal cancer.

### Customers

DiviTum® will primarily be sold to laboratories that perform analyses for doctors who are treating patients. Oncologists will primarily be the ones who decide whether to use DiviTum® and they will then order analyses from the laboratories who are our customers.

### Market growth

Once regulatory approval has been obtained, Biovica will be able to start marketing its test in the market. In order to create demand in the clinical market, our assessment is that ample results from studies must first be generated and presented so that DiviTum® can start being included in national treatment guidelines. Prices can be negotiated after that. The process for all of

this is different in each country and region. Biovica has started the work and processes for being included in the reimbursement systems of our most important markets.

### Trends

The number of patients with metastatic cancer is still increasing for most forms of cancer. In only a few instances have treatments been identified for stopping the trend and lowering the number of cancer cases. The HPV vaccine is one example, where the rate of cervical cancer has declined as a result. But, until more effective cancer prevention solutions have been found, the trend of an increasing rate of cancer will prevail.

### Driving forces

Doctors have expressed a great need for better tools that will help them monitor the progress of a chosen form of treatment. As more and more drugs are launched in the market, the complexity of treatment decisions will increase. One of the only ways to avoid exposing patients to ineffective treatments and unnecessary side effects is via quick feedback on whether the chosen treatment is working. It now takes between 2-4 months before such feedback on tumor growth is available with the diagnostic tools available today. With DiviTum®, however, such answers can be available within 2-4 weeks.

### Market access

The goal is for the product to be available for clinical use in USA and Europe during 2020. For that to happen, we must first obtain regulatory approval in each market.

Commercial success depends on DiviTum® becoming part of the guidelines for cancer treatment. In other words, it must be incorporated into the treatment guidelines of various leading organizations. It must also be included in the reimbursement system of each market.

Biovica will thus be submitting applications to both NCCN and ASCO. They are two of the most important organizations issuing guidelines in USA on use of biomarkers for metastatic breast cancer. In Europe, the market is more fragmented. ESMO, European Society for Medical Oncology, is one of the important organizations that issues guidelines. Each European country also has its own national guidelines.

In USA, there are several organizations involved in the reimbursement process. Biovica will concentrate efforts on gaining support from each of them. To succeed with that, we must have clinical studies confirming the benefits of DiviTum®.

Lastly, we need a sales organization for reaching out to customers and patients.

Biovica's plan is to sign agreements with companies that have established sales channels for supplying customers with DiviTum®. Such companies include laboratories, diagnostics companies and distributors.

More long term, Biovica intends to capitalize on the knowledge and network it has built up by developing DiviTum® for other applications. In other words, opportunities exist for widening the scope of operations by developing, validating and globally commercializing other diagnostic methods based on Real Time Assay technology for patient classification, early detection of the progression of disease and how the patient is responding to treatment.

### Copies and patent protection

The patents for DiviTum® expire in 2026 and 2031 for the two different platforms. However, Biovica still expects to have strong protection even after the patents expire. That is based on the fact that neither the manufacturing process nor compilation of the test is revealed in the patents. In developing DiviTum®, Biovica has accumulated a vast amount of proprietary information and know-how, which will make it difficult for others to copy DiviTum®.

+ “We still have a desperate need for biomarkers to identify tumors that are most likely to benefit from these novel approaches”

PROFESSOR HOPE RUGO,  
UCSF<sup>1</sup>

1) <http://www.ascopost.com/issues/november-1-2014/novel-agents-may-address-endocrine-therapy-resistance/#.XJC07xmDMOY.email>

# Cancer in brief

## What is cancer?

Cancer is a collective term for many types of diseases that can arise in various parts of the body. The symptoms of each type of cancer vary significantly, as do the chances of survival and the type of treatment. They all have one thing in common, however: They arise because one or more cells have become abnormal and are now growing uncontrollably in the body. And when that happens a cancer tumor, or several cancer tumors may form. Cancer tumors can obstruct or prevent the body from functioning as it should.

## Cell division – a complicated process

The body is comprised of many billions of cells. For example, skin is made up of skin cells and the liver is made up of liver cells. The cells need to divide so that there can be new cell growth. Old, damaged cells are thus replaced in this way. This is how the body grows and functions. Cell division varies depending on the type of cell it is. For example, certain types of blood-building cells divide every 24 hours, while liver cells divide approximately once per month. And certain cells, like nerve cells, divide even less often.

Cells duplicate or copy their DNA right before they divide. After that, they divide and become two cells.

Most of the time, cell division is regulated, but sometimes the mechanism for this does not work. For instance, something might have become damaged inside the cell, changing its structure. Altered cells that keep dividing can lead to cancer.

## From cell change to cancer

Cancer cells have certain typical characteristics:

- They stop doing what they are supposed to.
- They no longer cooperate with the surrounding environment.
- They grow uncontrollably.
- They don't die when they should, making room for new cells.
- They can invade neighboring tissue and after a while, spread to other parts of the body.

“Cell changes” mean that cells in a certain part of the body are behaving abnormally due to damage in their DNA. Cell changes often cease, however, before leading to cancer. But, if they persist and keep dividing, there is a risk of new damage to their DNA. And, every time new damage arises, the cells behave even more abnormally. Eventually, there is so much damage to the DNA that the cells become cancer cells.

Cancer cells that grow in volume form a nodule called a cancer tumor. There are

though, some forms of cancer where tumors do not arise, such as leukemia. But leukemia cells still cause damage by suppressing the production of normal blood cells.

The time it takes to develop cancer varies, depending on several factors. One such factor is where the cancer first started in the body. Sometimes, many years can pass between the first DNA damage that occurs and discovery of the cancer. In other cases, the process is more rapid.

## Cancer develops in different phases

The progression of cancer is typically categorized as pre-cancerous and four additional stages:

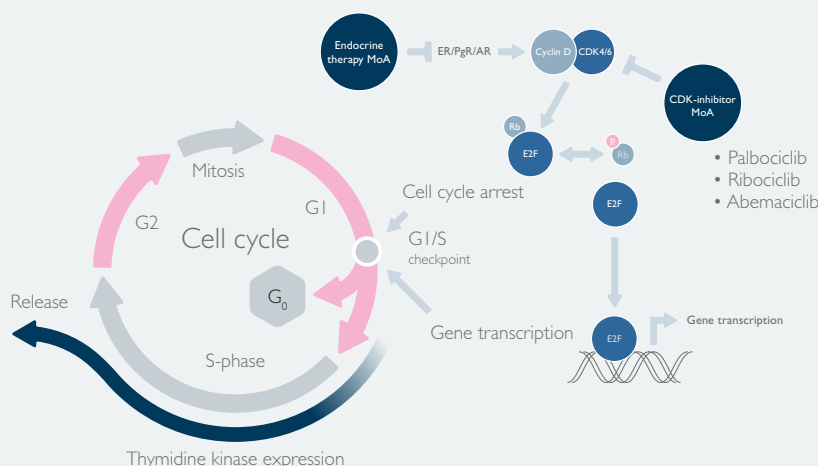
- Pre-cancerous, hyperplasia
- Stage I, dysplasia
- Stage II, cancer in situ.
- Stage III, invasive cancer
- Stage IV, metastatic cancer.

## Breast cancer – the most common form of cancer in women

Breast cancer is the second most common form of cancer in the world and it accounts for 11.6% of the 18.1 million cancer cases each year. Breast cancer is the most commonly diagnosed cancer in women, making up 24.2% or about 1 in 4 of all

## CELL CYCLE

Cell cycle is the process of cell division. Most of the cells in the body are in a dormant stage (i.e. not growing). For cells that are dormant, the level of TK activity is very low. With cell division, a cell goes through several phases. During the synthesis phase (S phase) the cell is preparing to divide so that it can copy its DNA. In order to do that, it must produce specific proteins required for DNA synthesis. Thymidine kinase is one such protein and the level of it is subject to cell cycle regulation. There is a low level of TK late in the G1 phase, but it increases throughout the S phase and up until the G2 phase.





new cancer cases diagnosed in women worldwide.<sup>1</sup> It is the most common cause of cancer fatality in women and globally, there were 630,000 deaths due to breast cancer in 2018 and more than 200,000 fatalities in Europe and USA in that same year.<sup>2</sup> Places with the highest rates of cancer are Australia, New Zealand, northern and southern Europe and North America.<sup>1</sup>

Despite the high incidence and number of deaths due to breast cancer, there are treatment alternatives that offer much better results and quality of life. For early stage breast cancer, the treatment is surgery, with or without radiation, chemotherapy and subsequent endocrine therapy. HR+ (hormone receptor positive) treatment therapy may also include adjuvant endocrine therapy or chemotherapy with trastuzumab<sup>3</sup>. For local tumors, the 5-year survival rate is 99% and when the cancer has spread to nearby lymph nodes, the 5-year survival rate is still quite high, at 85%. Despite significant improvements with treatment alternatives and results, the 5-year survival rate is much lower for patients with metastatic breast cancer, at just 27%.<sup>4</sup>

### Metastatic breast cancer

Although just 6% of patients have an initial diagnosis of metastatic breast cancer, more than 20% of patients with an initial diagnosis of a lower stage of cancer will develop metastatic cancer.<sup>5</sup> Effective, life-prolonging treatment is crucial to these patients, since metastatic cancer is currently incurable.

The primary goal in treating metastatic breast cancer is a longer life, and higher quality of life for patients battling the disease. Many therapies are available for

metastatic cancer, but the choice is based on tumor status, prior treatments and drug preference. For HR+ tumors (hormone-receptor-positive), which account for 78% of metastatic breast cancer, endocrine therapy provides the basis for treatment.<sup>5,6</sup>

Even with all the new treatments, the 5-year survival rate for women with metastatic cancer reveals that most of them do not respond positively to the selected treatment.

Individual tumors may be resistant to a particular type of treatment, or become resistant over time. In such cases, the cancer tumor will continue to grow, even though treatment is being administered.

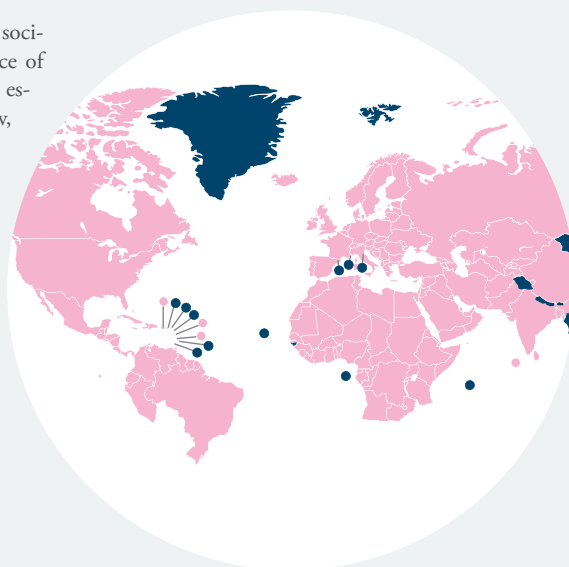
There is also great value in being able to limit or entirely avoid ineffective treatments. Incorrect treatment actually increases the risk of cell proliferation and unnecessary side effects, which worsens the prognosis for future treatment options.<sup>7</sup> It currently takes 3–4 months to evaluate the effectiveness of a treatment using imaging techniques or invasive methods.

In order to generate benefits to society in the form of cost savings, choice of a suitable and effective treatment is essential. Furthermore, the cost of new, more effective therapies is also much higher than with older pharmaceuticals, which again stresses the importance of only being prescribed treatments that actually work. In USA for example, a single cycle (4

weeks) of palbociclib treatment costs more than USD 12,000 compared to around USD 20 for one month of treatment with tamoxifen. In healthcare systems with strict budget limitations, or for patients who are financing treatment themselves, it is even more important to ensure that expensive treatments are only used for patients who will definitely benefit from them, thereby limiting the financial burden or costs to society.<sup>8</sup> Doctors may resist prescribing expensive, modern drugs, particularly in markets with public healthcare systems financed by taxpayers, particularly when they are unsure about whether the patient will actually respond.<sup>9</sup> Patients run the risk of being denied the most effective treatment and thereby a less successful outcome for these patients.

### CANCER AND WOMEN

- Breast cancer
- Other cancer



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# DiviTum®

DiviTum® is an innovative biomarker assay developed with the aim to monitor and predict outcome in cancer treatment of solid tumors.

DiviTum® measures the activity of thymidine kinase (TK) in serum or cell cultures. In normal cells, TK activity is very low. It rises, however, with increased cell division. Because the level of TK activity is closely correlated to cell growth, monitoring it as a biomarker is suitable when evaluating the tumor cell proliferation rate and aggressiveness, along with the effect of drugs designed to inhibit the cell cycle. Measuring TK activity provides clinically useful information on the tumor cell proliferation rate and ag-

gressiveness. DiviTum® is simple to use. All that's required is an ordinary blood sample. It has been developed on a standardized ELISA platform for use in laboratories. By quickly and reliably being able to determine if a drug is effective, treatment can thereby be tailored and optimized. DiviTum® has potential to prolong the survival time and raise the quality of life. It can also possibly lower healthcare costs by replacing expensive, ineffective tests and quickly evaluate treatment methods.







## DIVITUM® CAN EVALUATE THE EFFECT OF CDK INHIBITOR TREATMENT

CDK inhibitors and endocrine therapy is the standard, first-choice treatment for women with metastatic HR+ breast cancer in USA and most European countries. But, it is both expensive and has many side effects. At present, no suitable biomarker exists that can help in making decisions with this type of treatment.

However, the results from clinical studies with DiviTum® show that it can be used for early detection of patients who are resistant to CDK inhibitor treatment. This is how DiviTum® can help prevent exposing women to unnecessary side effects while also reducing the high cost of ineffective treatments. Ultimately it can lead to a higher quality of life and survival rate for patients.

# Cancer diagnostics

*What are the diagnostic methods currently being used for cancer treatment?*

## Imaging diagnostics – the current standard

The most common method for evaluating cancer treatment is imaging diagnostics. An image prior to treatment is compared to one taken a few months into the treatment, where tumor size provides an indication of how the patient is responding to treatment. The disadvantage of this method is that several months must pass before there can be any follow-up.

DiviTum® measures the cell proliferation rate, which is what leads to a larger tumor volume. An advantage of DiviTum® is that it can quickly provide information on changes in the cell proliferation rate. Studies have shown that with DiviTum®, it is possible to observe significant reductions in the cell proliferation rate just two weeks after starting treatment.

## Biopsies

A biopsy involves extracting tumor cells using a needle. The tissue can then be analyzed, providing important information about the patient's cancer, which is needed in order to select the right treatment.

One of the most frequently used tests in clinical procedures for measuring cell division is Ki67. It is carried out on cells that have been extracted from the tumor via a biopsy. Ki-67 is included in the treatment guidelines and reimbursement systems of many markets. It is widely used by oncologists for initial diagnosis of patients. The information from a biopsy is often critical when selecting the type of treatment.

It is necessary to take a biopsy with Ki-67, which is why it is a less common diagnostic tool for metastatic cancer and treatment monitoring. This is a problem associated with biopsies in general.

## Blood-based test

There are several blood-based biomarker tests being used that can provide more information on different types of cancer diseases. For breast cancer, for example, CA 15-3 and CEA are biomarkers currently being used. They have been approved by the FDA and incorporated into the NCCN and ASCO treatment guidelines. They are also included in the reimbursement systems of many markets, including USA.

It is important to point out, however, that CA 15-3 and CEA are only recom-

mended in combination with other diagnostic and monitoring examinations. There is a need for better biomarkers in the area, which was revealed in the market analysis commissioned by Biovica.

In several studies, it has been shown that DiviTum® is able to provide early information on treatment response for patients with, for example, metastatic breast cancer. It has been shown that, compared to CA 15-3, DiviTum® has higher precision in predicting outcomes.

CDK inhibitors and adjuvant endocrine therapy is the standard, first-choice treatment for women with metastatic HR+ breast cancer in USA and most European countries. But, it is both expensive and has many side effects. At present, no suitable biomarker exists that can help in making decisions with this type of treatment.

The results from clinical studies with DiviTum® show that it can be used for early detection of patients who are resistant to CDK inhibitor treatment. This is how DiviTum® can help prevent exposing women to unnecessary side effects while also reducing the high costs of ineffective treatments. Ultimately it can lead to a higher quality of life and survival rate for patients.



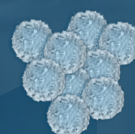


## IMAGING DIAGNOSTICS

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Imaging  
diagnostics



DiviTum<sup>®</sup>



# Published studies

Biovica collaborates globally with leading cancer researchers, medical institutes and pharmaceutical companies to provide strong pre-clinical and clinical evidence of the effectiveness of DiviTum®.

Studies have been conducted with more than 1,000 patients (early-stage to metastatic breast cancer) where DiviTum® has successfully been used to assess TK activity as a monitoring tool for treatment response. Through these studies, it has been documented that TK activity can be measured and used as a prognostic tool for patient survival and for monitoring the effect

of ongoing treatment. These conclusions have been supported in the results from clinical studies that have been conducted.

Thus far, DiviTum® has been studied in 17 clinical studies, of which 8 in breast cancer. Overall, more than 1,000 patients were involved in these studies. Most of the patients had metastatic breast cancer (n = 845). Some though, had early stage cancer (n = 211). The studies were conducted in collaboration with world-leading oncologists and medical institutes in several countries including USA, Sweden, Italy, Belgium, Canada, Israel and China.

In these clinical studies, it was shown that TK activity could be measured and used as a prognostic tool for tumor cell proliferation rate and aggressiveness, as well as the overall survival rate of patients. Its potential has

also been substantiated as a monitoring tool for obtaining early evidence of treatment response and resistance to chemotherapy, endocrine therapy and CDK inhibitors for patients with metastatic breast cancer.

In particular, the results from the 8 studies on breast cancer showed that:

1. Measurement of TK activity has the potential for meeting the large demand for a quick and accurate monitoring and prognostic tool for metastatic breast cancer. It can provide doctors and patients with a careful assessment that is non-invasive and which provides results much faster and easier than with current biomarkers and imaging diagnostics.
2. When TK activity is measured frequently and early during treatment, a patient who is not responding can potentially be switched

## SCIENTIFIC ARTICLES WITH DiviTum®

### BREAST CANCER

**McCartney A, Biagioni C, Schiavon G, et al.**

Prognostic role of serum thymidine kinase I activity in patients with hormone receptor-positive metastatic breast cancer: Analysis of the randomised phase III Evaluation of Faslodex versus Exemestane Clinical Trial (EFFECT). *European Journal of Cancer* 2019; 114: 55-66

**Bonechi M, Galardi F, Biagioni C, et al.**

Plasma thymidine kinase-I activity predicts outcome in patients with hormone receptor positive and HER2 negative metastatic breast cancer treated with endocrine therapy. *Oncotarget* 2018; Mar; 9 (23): 16389-16399.

**Bagegni N, Thomas S, Liu N, et al.**

Serum thymidine kinase I activity as a pharmacodynamic marker of cyclin-dependent kinase 4/6 inhibition in patients with early-stage breast cancer receiving neoadjuvant palbociclib. *Breast Cancer Res and Treat.* 2017; Nov 21; 19(1):123.

**Bjohle J, Bergqvist J, Gronowitz JS, et al.**

Serum thymidine kinase activity compared with CA 15-3 in locally advanced and metastatic breast cancer within a randomized trial. *Breast Cancer Res and Treat* 2013; 139(3):751-8.

**Nisman B, Kadouri L, Allweis T, et al.**

Increased proliferative background in healthy women with BRCA1/2 haploinsufficiency is associated with high risk for breast cancer: Cancer Epidemiol Biomarkers Prev. 2013; Nov; 22(11):2110-5.

**Nisman B, Allweis T, Kadouri L, et al.**

Serum thymidine kinase I activity in breast cancer. *Cancer Biomark.* 2010; 7(2):65-72.

### LUNG CANCER

**Nisman B, Nechushtan H, Biran H, et al.**

Serum Thymidine Kinase I Activity in the Prognosis and Monitoring of Chemotherapy in Lung Cancer Patients. *J Thorac Oncol* 2014; Oct; 9(10):1568-1572.

**Korkmaz T, Seber S, Okutur K, et al.**

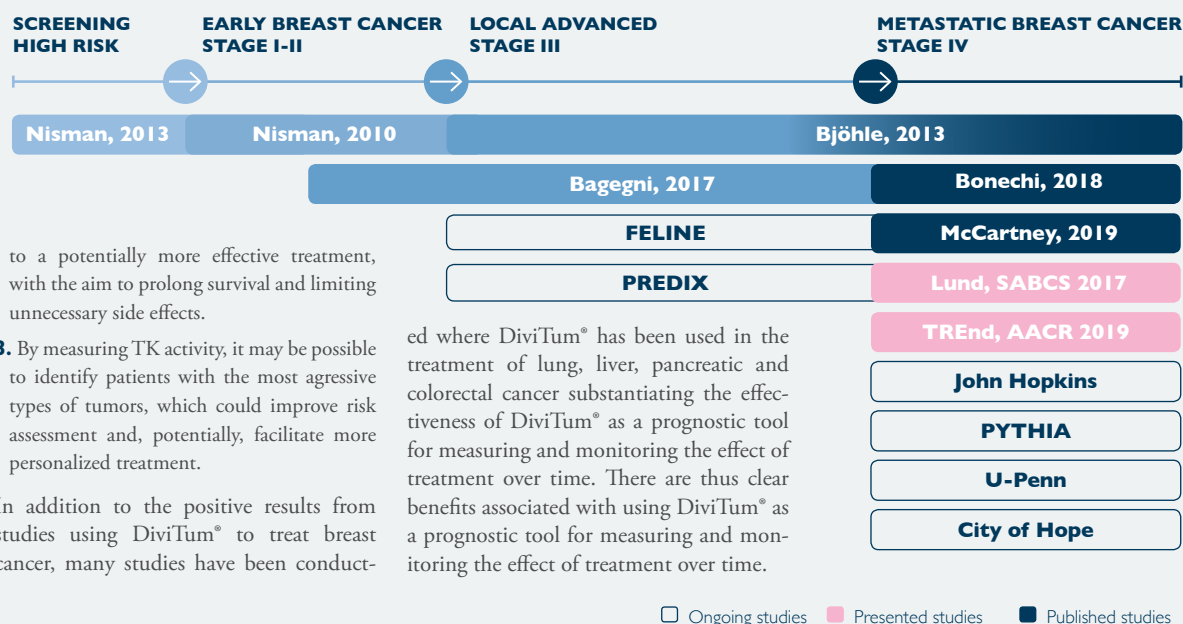
Serum thymidine kinase I levels correlates with FDG uptake and prognosis in patients with non small cell lung cancer. *Biomarkers* 2013; Feb; 18(1):88-94.

### PANCREATIC CANCER

**Felix K, Hinz U, Dobiasch S, Hackert T, et al.**

Preoperative Serum Thymidine Kinase Activity as Novel Monitoring, Prognostic, and Predictive Biomarker in Pancreatic Cancer. *Pancreas.* 2017; Nov 16.





## BREAST CANCER AND COLORECTAL CANCER

**Bolayirli M, Papila C, Korkmaz G, et al.**

Serum thymidine kinase I activity in solid tumor (breast and colorectal cancer) patients treated with adjuvant chemotherapy.

*J Clin Lab Anal.* 2013; May;27(3):220-6.

## KIDNEY CANCER

**Nisman B, Appelbaum L, Yutkin V, et al.**

Serum Thymidine Kinase I Activity Following Nephrectomy for Renal Cell Carcinoma and Radiofrequency Ablation of Metastases to Lung and Liver.

*Anticancer Res.* 2016; Apr;36(4):1791-7.

**Nisman B, Yutkin V, Nechushtan H, et al.**

Circulating Tumor M2 pyruvate kinase and thymidine kinase I are potential predictors for disease recurrence in renal cell carcinoma after nephrectomy.

*Urology.* 76 (2), 513. e1-e6, 2010.

## BLOOD CANCER

**Stelmach P, Blonski JZ, Wawrzyniak E, et al.**

Prognostic value of thymidine kinase activity in patients with chronic lymphocytic leukemia.

*Postepy Hig Med Dosw.* 2016; 70(0):1321-1330.

**Bacovsky J, Myslivecek M, Minarik, et al.**

Analysis of thymidine kinase serum levels by novel method DiviTum™ in multiple myeloma and monoclonal gammopathy of undetermined significance – comparison with imaging methods 99mTc-MIBI scintigraphy and 18F-FDG PET/CT.

*Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub.* 2015; Mar;159(1):135-8.

**Procházka V, Faber E, Raida L, et al.**

High baseline serum thymidine kinase I level predicts unfavorable outcome in patients with follicular lymphoma.

*Leuk Lymphoma* 2012; Jul;53(7):1306-10.

**Rivkina A, Vitols G, Murovska M, et al.**

Identifying the stage of new CLL patients using TK, ZAP-70, CD38 levels.

*Exp. Oncology* 2011; 33(2), 99-103.

## METHOD

**Nisman B, Allweis T, Kadouri L, et al.**

Comparison of diagnostic and prognostic performance of two assays measuring thymidine kinase I activity in serum of breast cancer patients.

*Clin Chem Lab Med.* 2013; 51(2):439-47.

## Ongoing studies

Several ongoing studies are further evaluating serum TK activity as a marker of response to endocrine treatment or CDK inhibitors in breast cancer and other indications. A number of other studies and collaborations are also being planned to further investigate the potential of DiviTum®.

DiviTum® is repeatedly mentioned and documented in many international and national studies on metastatic breast cancer, which is Biovica's first commercial application. Biovica has 8 ongoing clinical breast cancer studies. The company is also involved in an ongoing study on lung and gastrointestinal cancer.

At SABCS 2017, a study by Lund University was presented. It involved 142 patients with metastatic breast cancer and its purpose was to measure the treatment effect of 3 types of standard treatment.

At AACR 2019, the results of DiviTum® from the TREnd study were presented. The study shows that DiviTum® is able to evaluate the effect of palbociclib treatment for 45 patients with metastatic breast cancer.

Together with Johns Hopkins, Biovica is conducting a study involving 100 patients to measure drug resistance development, including CDK 4/6 inhibitor.

PYTHIA is a study that is being conducted by BIG and IBCSG involving 120 stage IV patients to measure the treatment effect of targeted therapy.

Together with University of Pennsylvania, Biovica is conducting a pilot study involving 28 stage IV patients to measure the effect of combination treatment with chemotherapy and targeted therapy.

FELINE is a study that is being conducted by University of Kansas involving 120 stage III patients aimed at measuring the effect of targeted therapy and correlation with other biomarkers.

Together with City of Hope, Biovica is conducting a pilot study involving 18 patients to measure the effect of two new cancer drugs.

PREDIX is a study that is being conducted by Karolinska Institutet involving 200 stage III patients to measure the effect of targeted therapy and the survival rate.

Biovica has also started collaborating with WntResearch to identify patients with colon cancer who could benefit from Foxy-5 treatment. A Phase II study will be conducted with these patients to investigate the potential of using DiviTum® to supplement Foxy-5 and potentially become a Companion Diagnostic (CDx) to the drug.

Study	Stage	Number of patients	Endpoints	2018	2019	2020
Lund	IV	142	TK activity prognosis for PFS and OS, correlation to Ki-67	Presented @ SABCS 2017		
TREnd	IV	45	Can TK evaluate the effect of palbociclib	Presented @ AACR 2019		
PYTHIA	IV	120	TK activity to measure the effect of targeted drugs			
PREDIX	III	200	TK for targeted drug responses and survival			
Johns Hopkins	IV	100	Biomarkers for resistance to targeted drugs			
UPenn	IV	28	Pilot chemo and targeted drugs			
City of Hope	IV	18	Pilot two targeted drugs			
FELINE	III	120	TK for targeted drug responses and correlation with other biomarkers			
Dana-Farber	IV	139	TK for targeted drug responses	Presented @ AACR 2017		
9 studies	III-IV	912				





# Collaboration with Key Opinion Leaders (KOLs)

Since 2011, Biovica has been successfully working to achieve its vision by collaborating with several world-leading oncologists and research groups. In total thus far, 17 scientific articles and clinical studies have

been published. Biovica has also won several prestigious awards and research grants, including Horizon 2020 (Phase II). The company collaborates with leading partners in healthcare and academia. Our

partners are primarily oncologists who are conducting clinical studies, presenting the results of studies at conferences and developing treatment guidelines aimed at improving care for patients with breast cancer.

Institute/partner	KOL (Key Opinion Leaders)	Study	Stage	#Pat
Hadassah and Hebrew University Medical Centre, Jerusalem, Israel	Benjamin Nisman	BRCA	High risk	80
Hadassah and Hebrew University Medical Centre, Jerusalem, Israel	Benjamin Nisman	BC early	I,II	161
Karolinska Institute, Sweden	Thomas Hatscheck, Jonas Bergh	TEX	III, IV	287
Washington University School of Medicine Mayo Clinic Baylor College of Medicine, USA	Cynthia Ma Matthew Goetz Matt Ellis	WU in St. Louis	II, III	48
Hospital of Prato, Prato, Italy	Luca Malorni	Pilot Prato	IV	31
Hospital of Prato, Prato, Italy AstraZeneca, Cambridge, UK Institut Jules Bordet, Belgium Northwestern University, Chicago, USA British Columbia Cancer Agency, Canada	Luca Malorni, Angelo di Leo Gaia Schiavon Martine Piccart William J. Gradishar Stephen Chia	EFFECT	IV	244
Lund University, Sweden	Anna-Maria Larsson, Lisa Rydén	Lund	IV	142
Hospital of Prato, Prato, Italy	Angelo di Leo, Luca Malorni	TREnd	IV	45
IBCSG, BIG	Luca Malorni	PYTHIA	IV	120
Karolinska Institute, Sweden	Thomas Hatscheck	PREDIX	III	200
Johns Hopkins, Baltimore, USA	Vered Stearns	Johns Hopkins	IV	100
University of Pennsylvania, USA	Amy Clark	UPenn	IV	28
City of Hope, Los Angeles, USA	Yuan Yuan	CoH	IV	18
Kansas University, USA	Qamar Khan	FELINE	III	120
Dana-Farber Cancer Institute, Boston, USA	Geoffrey Shapiro	Dana-Farber	IV	139

## 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. We work as a team to achieve our vision of every cancer patient getting the best possible treatment from day one.

Biovica has 17 employees in two countries with different assigned tasks and areas of responsibility. However, each employee at Biovica is working towards the same end goal, where every cancer patient gets the best possible treatment from day one. Commitment and clarity are values that permeate the entire organization, where the goal is for each employee to feel proud of Biovica and his or her contribution to the company's success. Biovica strives to have equality, sustainability and a healthy work environment where every employee is given the opportunity to perform, develop and thrive. Our future growth and success requires that we continually work with our brand and strengthening our reputation as

an attractive employer. Biovica has operations in two countries, but most are employed in Sweden. At present, we have just one employee working abroad (in USA). Of the total number of employees, 44 percent are women and 56 percent are men. Biovica strives to maintain an even gender balance at the company. Over the last few years, employee turnover and absence due to illness has been low. Our surveys also indicate that Biovica's employees enjoy their work.

### Focus areas in 2018/2019

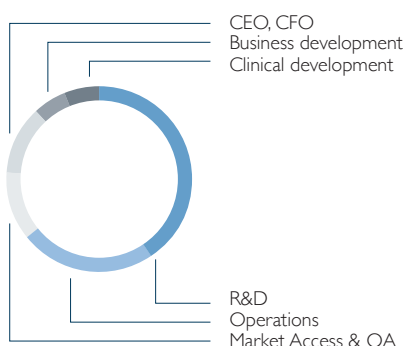
During the 2018/2019 financial year, Biovica has focused on several important areas aimed at preserving our attractive

reputation as employer and ensuring the company's continued growth and success. The focus areas we've worked with include improvements to the work environment, skill development and self-leadership.

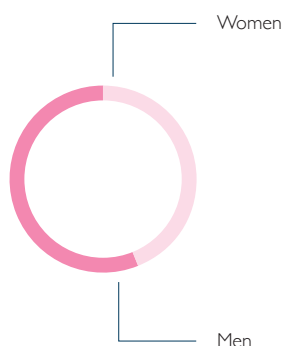
### An attractive workplace

We expect a lot from our employees and they expect a lot from us! Accordingly, over the last few years, we've invested in benefits and incentives that provide our employees with more security and higher quality of life. They have salary options for making higher pension provisions, subsidized fitness memberships, wellness programs and fun team-building activities.

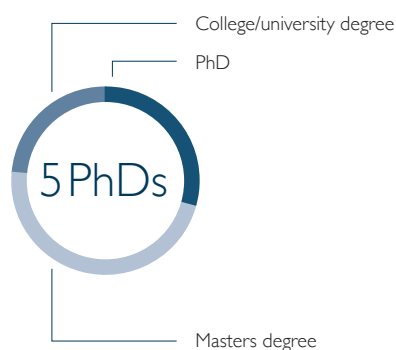
### DISTRIBUTION BY FUNCTION



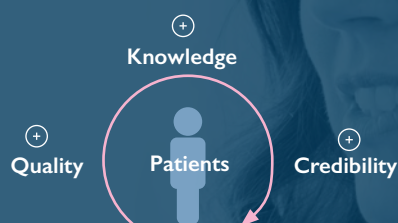
### GENDER DISTRIBUTION



### LEVEL OF EDUCATION







#### KEY VALUES

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

**Quality:** Biovica's customers should feel secure when they use our products. Quality prevails throughout the entire product development and production processes.

**Knowledge:** Biovica and its representatives should always behave ethically, professionally and factually. We should always be one step ahead, proactively striving to get it

right from the start, minimizing risks and meeting deadlines. Biovica shall always comply with laws and regulations, use the best possible technology and deliver the best solution with the highest possible quality.

**Credibility:** Credibility is based on mutual respect and understanding. All of us contribute to our success and credibility. Biovica believes that

each and every one of its employees is making a valuable contribution. We respect, trust and collaborate with each other to achieve good results. Our efforts to develop the organization include the well-being of our employees. We want them to enjoy their work, have fun, thrive and show appreciation for each person's value and contribution.

#### CORNERSTONES OF BIOVICA

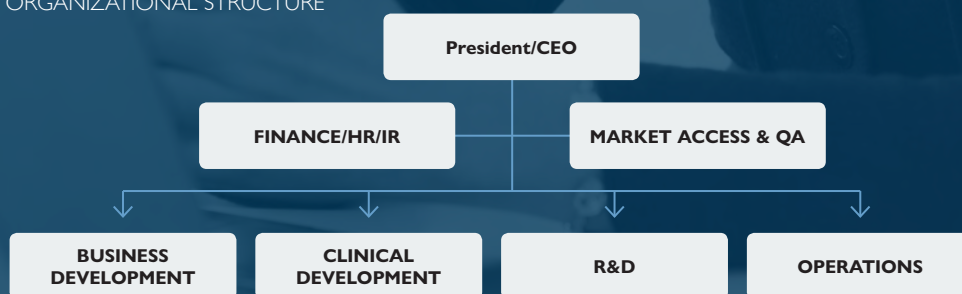
**Respect** – We treat our colleagues and customers the same way we want to be treated

**Solution-oriented** – Focus on solutions instead of problems

**Working towards the right goals** (goal-oriented) – We keep our promises

**Positive reinforcement** – support and a positive attitude

#### ORGANIZATIONAL STRUCTURE



# Biovica Share

## Shares

Biovica's shares have been traded on Nasdaq First North Stockholm since 29 March 2017 under the ticker symbol, BIOVIC B. On 4 March 2019, the shares were re-listed on Nasdaq First North Premier Stockholm.

First North Premier is Nasdaq Europe's growth market. It operates parallel to the main market but with less regulated listing requirements and ongoing disclosure rules. Each company listed on First North Premier has a Certified Adviser, CA, with responsibility for ensuring that the company meets those rules and requirements. Biovica's Certified Advisor is FNCA AB. First North companies are traded in the same trading system as companies listed on the Nasdaq main market.

As of 30 April 2019, Biovica's total number of shares amounted to 17,573,372 and its share capital amounted to 1,171,558.13 allocated among 7,297,438 Class A shares (each worth 3 votes) and 10,275,934 Class B shares (each worth 1 vote). The quotient value of Biovica's shares is SEK 0.07 per share. The total number of votes amounted

to 32,168,248. Biovica has approximately 1,300 shareholders.

## Dividends policy

Biovica has not adopted a dividends policy.

## Warrants

Biovica has four warrant schemes. The warrant scheme decided on 27 January 2014 (TO1) is for members of the Board of Directors. The warrant scheme consists of 13,000 warrants, which, after a 1:15 split, entitled each warrant holder to subscribe for 15 new class B shares.

For the warrant scheme decided at the extraordinary general meeting on 24 January 2017 (TO2), all of the warrants were transferred to Biovica's employees.

At the AGM on 30 August 2018, it was decided to set up an additional warrant scheme for employees (TO3).

At the extraordinary general meeting on 20 March 2019, it was decided to set up a warrant scheme for members of the Board of Directors (TO4).

## Reclassification of shares

Biovica's Class A shares may be converted to Class B shares at the end of each quarter during the year, in accordance with Section 7 of the Articles of Incorporation. During the year, Biovica shares were converted on four occasions. In total, 953,969 Class A shares were converted to Class B shares during the year.

## WARRANTS

Program	To	Class B shares	Subscription price	Warrant-price	Subscription period	Share capital increase	Number of class B shares
TO1	Board of Directors	13,000*	250.00*	10.20*	7 July 2014 – 30 June 2019	13,650.00	195,000
TO2	employees	200,000	25.00	0.54	29 March 2017 - 30 March 2020	13,333.33	200,000
TO3	employees	200,000	21.90	0.44	30 March 2020 - 25 August 2021	13,333.33	200,000
TO4	Board of Directors	175,000	19.50	0.94	25 March 2022 - 25 August 2023	11,666.67	175,000
<b>Total</b>							<b>770,000</b>

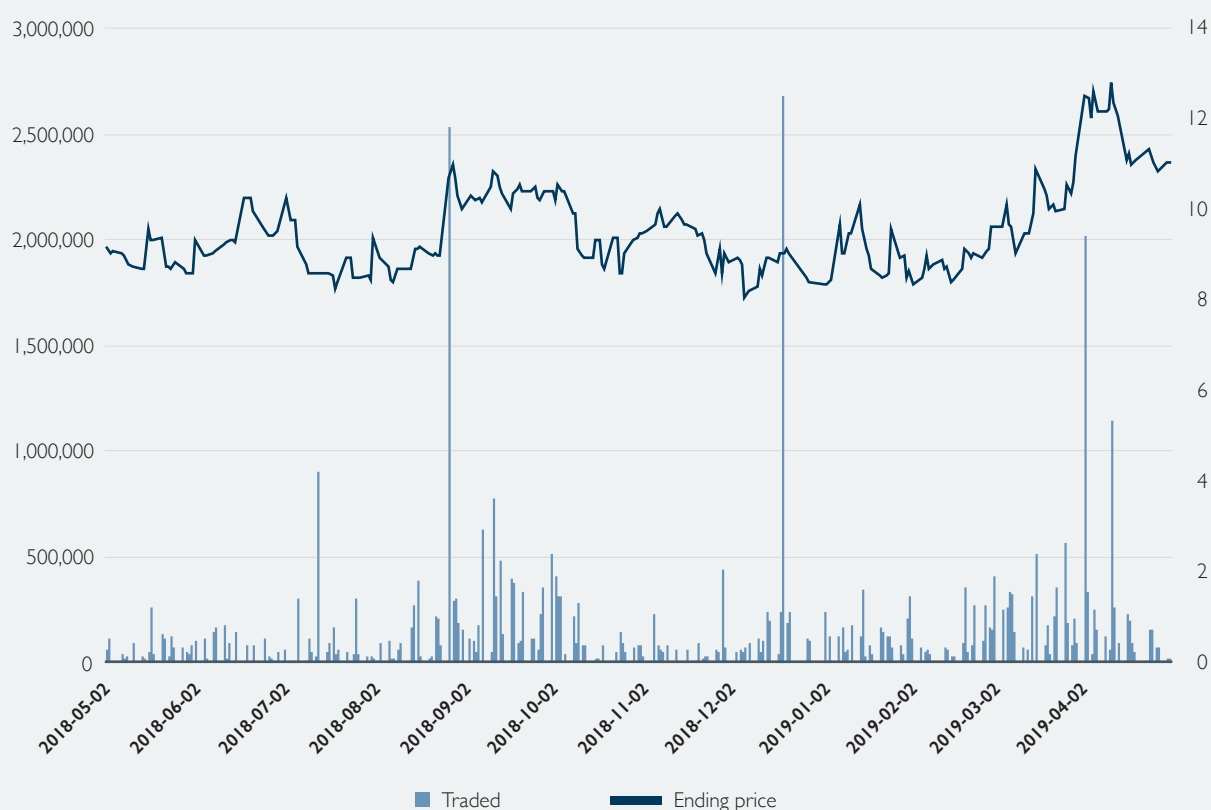




## THE TEN LARGEST OWNERS AS OF 29 MARCH 2018

Name	Class A shares	Class B shares	Number of shares	Number of votes
Anders Rylander via company	3,575,640	360,956	22.40	33.78
Gunnar Rylander	931,185	52,112	5.60	8.67
Avanza Pension		743,447	4.23	2.26
LYM Consulting AB		493,810	2.81	1.50
Kristina Gronowitz	411,660		2.34	3.76
Lars Holmqvist, directly and via company		410,630	2.34	1.25
Nordnet Pensionsförsäkring		388,711	2.21	1.18
Danica Pension		322,900	1.84	0.98
Mats Danielsson, directly and via company	244,025	62,000	1.74	2.42
Per Stålhandske		291,723	1.66	0.89
<b>Total, 10 largest owners</b>	<b>5,162,510</b>	<b>3,126,289</b>	<b>47.17</b>	<b>56.70</b>
<b>Other owners</b>	<b>2,464,928</b>	<b>6,819,645</b>	<b>52.83</b>	<b>43.30</b>
<b>Total number of shares</b>	<b>7,627,438</b>	<b>9,945,934</b>	<b>100.00</b>	<b>100.00</b>

## BIOVICA SHARE TREND

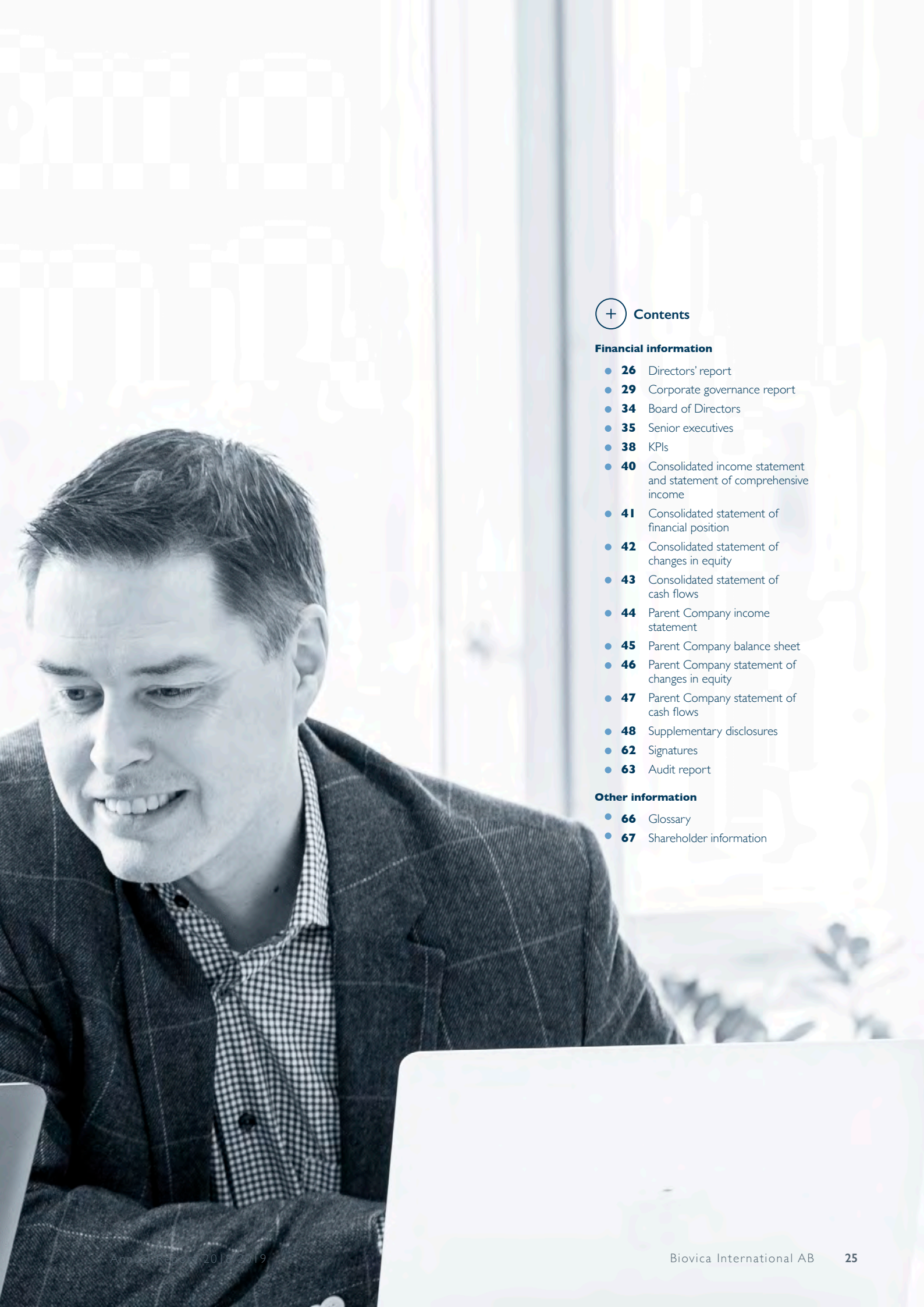




# ANNUAL REPORT 2018/2019







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# Directors' report for 2018/2019

The Board of Directors and CEO of Biovica International AB (publ), Biovica, hereby present the annual report and consolidated financial statements for the financial year 1 May 2018 through 30 April 2019. The company's registered office is in Uppsala, Sweden and its corporate identity number is 556774-6150.

The Board of Directors and CEO of Biovica International AB (publ), Biovica, hereby present the annual report and consolidated financial statements for the financial year 1 May 2018 through 30 April 2019. The company's registered office is in Uppsala, Sweden and its corporate identity number is 556774-6150.

## GENERAL INFORMATION ABOUT THE BUSINESS

Biovica develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. Biovica's DiviTum® technology measures cell proliferation rate and clinical studies have shown that it can quickly reveal whether treatment is effective. Biovica's vision is a future where every patient receives the best possible therapy from the very first day of treatment. Biovica plans to launch DiviTum® in the year ahead for use in treating breast cancer.

## SIGNIFICANT EVENTS AND CIRCUMSTANCES

The company's B shares have been listed on Nasdaq First North since 29 March 2017. Since 4 March 2019, the company has been listed on Nasdaq First North Premier, Stockholm.

## SIGNIFICANT EVENTS DURING THE FINANCIAL YEAR

Additional patent applications were approved during the year and now, the only country of 49 in total where the company is still awaiting approval is Brazil.

Discussions with the FDA continued via a supplement explaining how the test will be validated analytically. Efforts are now underway to implement the analytical validation in accordance with the FDA's requirements. The goal is to submit the FDA application during 2019.

During the financial year, studies involving the company's product, DiviTum®, were presented with positive results. At the ASCO (American Society of Clinical Oncology) conference in June 2018, results

from the EFECT study (244 patients involved) were presented. The study showed that with DiviTum®, it was possible to evaluate whether tumors were resistant to the standard treatment (endocrine) that was being administered (an article on this was also published in European Journal of Cancer).

In December 2018, results from a study were presented at the San Antonio Breast Cancer Symposium where data on cells revealed that it is possible to follow up treatment effect using DiviTum®.

At the American Association for Cancer Research conference in April 2019, data was presented from the TREnd study.

Collaboration on a study is also underway with WntResearch. The aim is to investigate whether DiviTum® can be successfully used to identify patients with a high risk of recurrence and who, accordingly, should be treated with Foxy-5, a drug developed by WntResearch, to lower the risk of that happening.

As of mid-April, IBL America is a new distributor in USA for the research market. Via this collaboration, Biovica seeks to increase its sales capacity in that area.

During the year, operations and an office were set up in Boston, Massachusetts. This is part of the preparations for the launch DiviTum® and closer proximity to our largest market.

## COMMENTS ON CONSOLIDATED INCOME STATEMENT

### Operating income

Net sales for the 2018/2019 financial year increased by 10 percent and were SEK 3,005 (2,723) thousand. This was generated from sales of the DiviTum® kit to the research market.

### Operating costs and profit (loss) for the year

The company reported a loss for the year of SEK -21,556 (-18,010) thousand. The net loss for the year exceeds that of the previous year due to higher costs associ-

ated with growing the size of the organization, setting up operations in USA and a high level of activity in development projects. Other external costs and employee benefit expenses increased by SEK 4,209 thousand compared to last year and for the 2018/2019 financial year amounted to SEK 28,207 thousand. The results for the year are in accordance with expectations and the budget that was presented for the 2018/2019 financial year.

## R&D work

R&D work has progressed according to plan. The capitalized costs for R&D work during the year amounted to SEK 6,464 (6,596) thousand, which corresponds to 20 (24) percent of the Group's total operating expenses.

## COMMENTS ON THE GROUP'S FINANCIAL POSITION

### Investments

The acquisition of intangible assets for the year amounted to SEK 6,464 (6,596) thousand, of which 100 percent was capitalized both this year and last year. The capitalized development expenditure is primarily attributable to employee benefit expenses associated with development of the ELISA and RTA projects (two different platforms for measuring TK). The carrying amount is reduced by the amount equivalent to the portion of development expenditure funded via decided and paid grants. Of the year's investment in capitalized expenditure for development costs, SEK 0 (0) was covered by grants.

Property, plant and equipment was acquired during the year (in the form of equipment) for SEK 864 (1,989) thousand.

## COMMENTS ON CONSOLIDATED CASH FLOW

Cash flow from operating activities was SEK -17,966 (-14,882) thousand and total cash flow for the year was SEK -25,295 (-23,342) thousand. The negative cash flow is attributable to the fact that the company is still developing its product and

organization, along with investments that were made during the year.

### **CASH & CASH EQUIVALENTS AND FINANCIAL POSITION FOR THE GROUP**

The closing amount for cash & cash equivalents on 30 April 2019 was SEK 16,831 (42,127) thousand. Early in May 2019, the company implemented a targeted new share issue that generated SEK 60 million, see Note 25 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 12 months.

Equity at the end of the period was SEK 52,097 (73,713) thousand and the equity ratio was 86 (91) percent.

### **COMMENTS ON THE PARENT COMPANY'S INCOME STATEMENT, BALANCE SHEET, STATEMENT OF CASH FLOWS AND CASH & CASH EQUIVALENTS**

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. Small-scale operations got underway towards the end of the financial year in Biovica's US subsidiary, Biovica Inc.

### **MAJOR OWNERS AND SIGNIFICANT CHANGES IN THE OWNERSHIP STRUCTURE**

Anders Rylander, CEO and member of Biovica's Board of Directors owns 22 % (via company) of Biovica's shares, which corresponds to 34 % of the votes in the Company.

### **SHARES**

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 1,171,558.13 allocated between 7,297,438 Class A shares and 10,275,934 Class B shares. The quotient value is SEK 0.07 per share. During the

year, 953,969 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.

### **FUTURE EXPECTATIONS, MATERIAL RISKS AND UNCERTAINTIES**

The focus of Biovica's business plan is to launch DiviTum® in the clinical market as a supplementary diagnostic test for evaluating how a patient is responding to cancer treatment drugs. DiviTum® is in the early stage of commercialization. It is expected to be introduced for the intended application, metastatic breast cancer, in the US and European markets in 2020.

The risks associated with the company's operations fell during the year because new, positive results from studies on breast cancer were released, supporting and confirming early studies. More results will be presented during the year ahead on both ongoing and planned studies. There are many potential areas of application besides breast cancer for use of DiviTum®, which further adds to the potential. 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. 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.

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.

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.

### **R&D ACTIVITIES**

Biovica develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. Biovica's DiviTum® technology measures cell proliferation rate and clinical studies have shown that it can quickly reveal whether treatment is effective. Biovica's vision is a future where every patient receives the best possible therapy from the very first day of treatment. Biovica collaborates with world-leading cancer institutes and pharmaceutical companies to develop next-generation cancer therapies. Nearly half of Biovica's employees work in the R&D department.

### **EMPLOYEES**

The average number of employees is 16 (14) of which 7 (7) women.

### **INCENTIVE PROGRAMS**

Detailed information on the company's outstanding warrant schemes is provided in Note 18, below.

### **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 2018/2019 financial year.

## MULTI-YEAR COMPARISON FOR THE GROUP

All amounts are in SEK thousands, unless otherwise stated	2018/2019	2017/2018	2016/2017	2015/2016
Net sales	3,005	2,723	632	2,432
Operating profit (loss)	-21,718	-17,956	-14,690	-4,617
Profit (loss) for the period	-21,556	-18,010	-14,715	-5,049
Cash and cash equivalents	16,831	42,127	65,469	928
Equity	52,097	73,713	91,664	24,943
Total assets	60,859	80,771	97,202	28,387
Equity ratio, %	86	91	94	88
Number of employees	16	14	8	5
Number of shares at the end of the period	17,573,372	17,573,372	17,573,372	559,050

### Definitions

Equity ratio = adjusted equity as a percentage of total assets

## MULTI-YEAR COMPARISON FOR THE PARENT COMPANY

All amounts are in SEK thousands, unless otherwise stated	2018/2019	2017/2018	2016/2017	2015/2016	2015/2016
Net sales	3,005	2,723	632	2,432	459
Operating profit (loss)	-21,886	-17,894	-14,839	-5,533	-6,498
Profit (loss) for the period	-21,606	-17,935	-14,848	-5,965	-7,043
Cash and cash equivalents	15,779	42,069	65,410	867	1,047
Equity	52,005	73,611	91,546	24,545	8,316
Total assets	59,972	80,376	97,184	28,733	17,760
Equity ratio, %	87	93	94	85	47
Number of employees	16	14	8	5	5
Number of shares at the end of the period	17,573,372	17,573,372	17,573,372	559,050	399,349

## PROPOSAL FOR APPROPRIATION OF FUNDS

The Board proposes that the available funds of SEK 32,698,918 are appropriated as follows:

accumulated losses	-66,074,987
share premium reserve	120,379,628
loss for the year	-21,605,723
<b>Retained funds at year-end</b>	<b>32,698,918</b>
Amount to be carried forward	32,698,918

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



# Corporate governance report

The aim of Biovica's corporate governance activities is to create value for shareholders via active risk management and a healthy company culture. Since its IPO in 2017, Biovica has prioritized ongoing efforts to ensure that it has well-functioning governance, control and monitoring. This corporate governance report has been prepared in accordance with Chapter 6, Section 6 of the Annual Accounts Act and the Swedish Corporate Governance Code (the Code).

## COMPLIANCE WITH THE SWEDISH CORPORATE GOVERNANCE CODE.

Biovica's shares are traded on Nasdaq First North Premier, which means that Biovica must apply the Swedish Corporate Governance Code (the Code). It is based on the principle of "comply or explain", which means that the company must apply the Code, or, explain any reasons for departure. During the 2018/2019 financial year, Biovica did not have any departures from the Code.

## ARTICLES OF INCORPORATION

Biovica's Articles of Incorporation, upon which the Company's operations are based,

state the Company's name, the Board's registered office, the objective of its business activities, details on the Company's share & share capital and items dealt with at the AGM. The Articles of Incorporation does not stipulate limits on how many votes each shareholder is entitled to exercise at AGMs, nor does it contain requirements on appointing or dismissing Board members or making changes to the Articles of Incorporation. The Articles of Incorporation are published at: <http://biovica.com/governance/bolagsordning/>.

## GOVERNANCE MODEL

Biovica International AB, CIN: 556774-6150, (Biovica) is a Swedish public limited liability company. Its shares are traded on Nasdaq First North Premier Stockholm. The company's head office is located on Uppsala, Sweden. The Corporate Governance Report is part of the company's Directors' Report. Corporate Governance at Biovica is split between external and internal governance tools and it is aligned with Swedish law, Nasdaq Stockholm's regulations for issuers, the Swedish Corporate Governance Code (the Code) and the company's own internal rules and regulations.

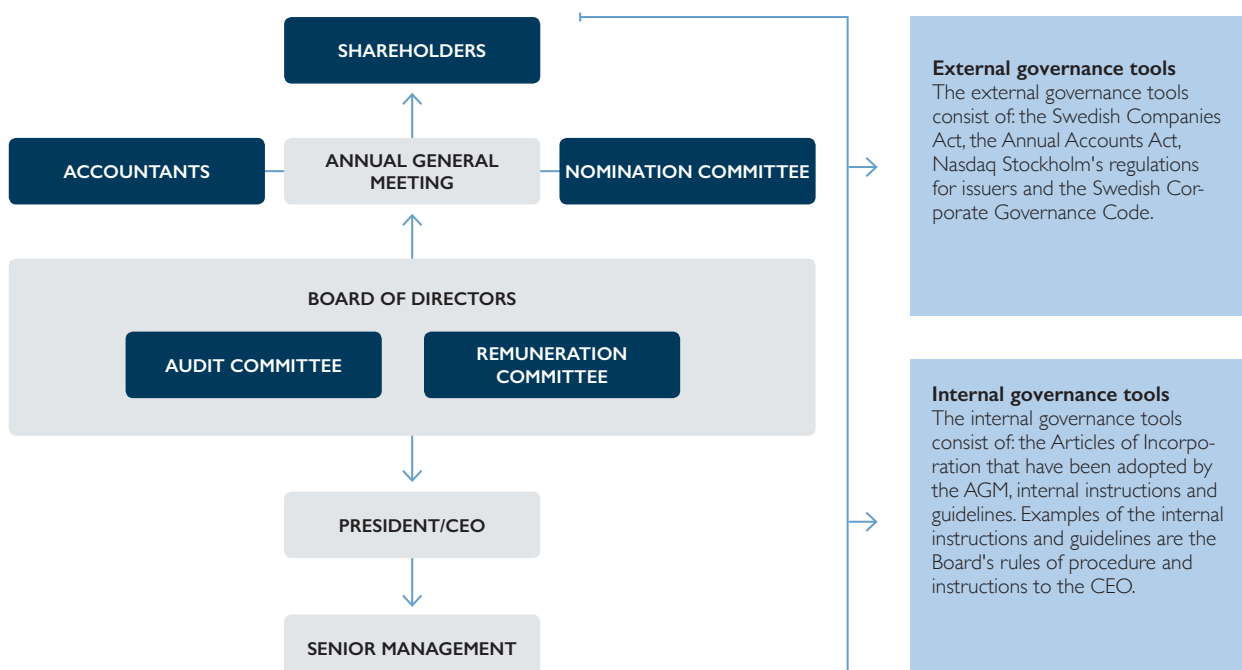
## EXTERNAL GOVERNANCE TOOLS

The external governance tools provide the framework for corporate governance at Biovica. The external governance tools consist of: the Swedish Companies Act, the Annual Accounts Act, Nasdaq Stockholm's regulations for issuers and the Swedish Corporate Governance Code. During the 2018/2019 financial year, Biovica did not have any departures from the Code.

## INTERNAL GOVERNANCE TOOLS

The internal governance tools consist of: the Articles of Incorporation that have been adopted by the AGM, internal instructions and guidelines. Examples of the internal instructions and guidelines are the Board's rules of procedure and instructions to the CEO. The Board has also adopted several policies, such as an information policy, which provide guidance on how internal efforts shall be governed and controlled. In addition to that, Biovica has a handbook for how financial reporting at the company shall be done.

## STRUCTURE FOR CORPORATE GOVERNANCE



## BIOVICA'S SHARE AND SHAREHOLDERS

As of 30 April 2019, Biovica's total number of shares amounted to 17,573,372 and its share capital amounted to SEK 1,171,558.13 allocated among 7,297,438 Class A shares (each worth 3 votes) and 10,275,934 Class B shares (each worth 1 vote). The quotient value of Biovica's shares is SEK 0.07 per share. The total number of votes amounted to 32,168,248. According to ownership information maintained by Euroclear Sweden AB, the ten largest owners of Biovica owned 57 percent of the votes and 47 percent of the shares in the company. Swedish owners had a 66 percent ownership share. Biovica's largest shareholder, Anders Rylander, CEO and member of Biovica's Board of Directors owns 22% (via company) of Biovica's shares, which corresponds to 34% of the votes in the Company. All other significant relationships between Biovica and the Company's largest shareholder, to the extent the Company is aware, are described in Notes 10 and 11. The Board of Directors does not have any knowledge of any other shareholder agreements on voting rights or other rights. Authority has been issued by the AGM to the Board to decide on issuance of new shares for a maximum of 10% of the current number of shares.

## ANNUAL GENERAL MEETING

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. At the AGM, the balance sheet and income statement as well as the consolidated balance sheet and consolidated income statement are presented and decisions are made on, among other things, appropriation of the company's earnings, election of and remuneration to Board members and auditor, and other matters that are dealt with at the AGM in accordance with law. 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 the 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.

## Resolutions at the 2018 AGM include:

- that the funds available for appropriation of SEK 60,768,811 shall be carried forward
- that each Director shall be paid a fee of SEK 125,000 and that the Chairman of the Board shall be paid a fee of SEK 200,000
- to re-elect the following Board members: Göran Brorsson (Chairman), Maria Holmlund, Ulf Jungnelius, Anders Rylander and Jesper Söderqvist.
- to reelect Grant Thornton Sweden AB as the company's auditor, with Stéphanie Ljungberg as the auditor in charge
- guidelines on remuneration to senior executives
- the process for appointing a nomination committee along with the work instructions that it should follow
- on granting the Board of Directors the authority to issue new shares for a maximum amount equal to 10% of the current number of shares
- a warrant scheme for staff of 200,000 warrants

Through to the date of issuance of the annual report, two extraordinary general meetings were held:

## Resolutions at the extraordinary general meeting on 20 March 2019 include:

- that the Chairman of the Board would be paid a fee of SEK 200,000 through to the next AGM
- to elect Lars Holmqvist as the new Chairman of the Board.
- a warrant scheme for the Board of Directors of 175,000 warrants

## Resolutions at the extraordinary general meeting on 2 May 2019 include:

- a targeted new share issue of 6,000,000 Class B shares at SEK 10 per share

## ANNUAL GENERAL MEETING 2019

The AGM for the 2018/2019 financial year will be held on 29 August 2019 at 4 p.m. The location is Hubben, Dag Hammarskjölds väg 38 in Uppsala, Sweden. Registration will begin at 3:30 p.m.

Shareholders who are registered in the shareholders' register maintained by Euroclear Sweden AB by Friday 23 August 2019 and who have notified the company of their intent to participate by 4:00 p.m. on that same date, are entitled to participate in the AGM.

## Important dates associated with the AGM for the 2018/2019 financial year are:

- 23 August 2019 – reconciliation date for participation in the AGM
- 23 August 2019 – last day to notify the company of intent to participate in the AGM
- 29 August 2019 – 3:30 p.m. registration of attendance at the AGM begins
- 29 August 2019 – 4:00 p.m. start of the AGM

## Board proposals for resolutions at the 2019 AGM:

The Board of Directors proposes that no dividends shall be distributed to shareholders for the 2018/2019 financial year.

## NOMINATION COMMITTEE

The Nomination Committee is responsible for ensuring that each member of Biovica's Board of Directors has knowledge and experience that is relevant for being able to make a contribution that enhances Biovica's performance over time in the best possible way. The Nomination Committee monitors the Board's efforts based on the Board evaluation that is carried out once per year, what is stipulated in the Code, and having considered Biovica's needs and the views from other owners. The Nomination Committee then presents a proposal to the AGM on the number of Board members, the composition of the Board and fees to be paid to the Board of Directors. The Nomination Committee is also responsible for presenting a proposal on the person to serve as Chairman of the Board of Directors and Chairman of the AGM, along with the auditors and their remuneration. The Nomination Committee's proposals are published in the notice of the AGM. Motivation for its proposals is published on Biovica's website in conjunction with issuing the notice of the AGM.

In accordance with the Code, Biovica adopted an instruction for the Nomination Committee at the 2018 AGM. It stipulates that the Nomination Committee shall consist of three members. These members shall be appointed by the Company's two largest shareholders (in terms of number of votes) based on information in the shareholders' register maintained by Euroclear as of 31 December the year before the AGM. They shall be summoned by the Chairman of the Board and given the opportunity each appoint one member to the Nomination Committee. Chairman of the Nomina-

tion Committee shall be appointed by the member who is the largest shareholder (in terms of the number of votes). The Chairman of the Board shall not serve as Chairman of the Nomination Committee. Members of the Nomination Committee that will be proposed at the 2019 AGM were presented on Biovica's website in February 2019. Members of the Nomination Committee may not receive any remuneration for their work on the committee.

**Members of the Nomination Committee that will be proposed at 2019 AGM are:**

- Gunnar Rylander, Chairman of the Nomination Committee (appointed by Anders Rylander)
- Leif Glantz (appointed by LYM Consulting AB)
- Lars Holmqvist, Chairman of the Board

**BOARD OF DIRECTORS**

Biovica's Board of Directors is the second highest decision-making body after the Annual General Meeting. The Board of Directors has overall responsibility for creating long-term value for shareholders and other stakeholders. Together with management, the Board is responsible for the company's overall strategy and it strives to ensure that the company manages its risks well and has good internal controls.

**Members of the Board of Directors**

Biovica's Articles of Association stipulate that the company must have at least three

board members and at most ten board members. Board members must contribute expertise and experience that is beneficial to Biovica's development. Biovica's Board of Directors currently consists of five ordinary members (one woman and four men). All of the members were reelected at the 2018 AGM to serve during the period of time through to the 2019 AGM. Both Anders Rylander, President and CEO of Biovica and the CFO, Cecilia Driving, attend every Board meeting. Cecilia Driving serves as secretary at each Board meeting. Other senior executives participate as needed to present on specific issues.

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.

Please see pages xx-xx of the annual report for a presentation of each of the Board members.

**The work done by the Board and Board evaluation**

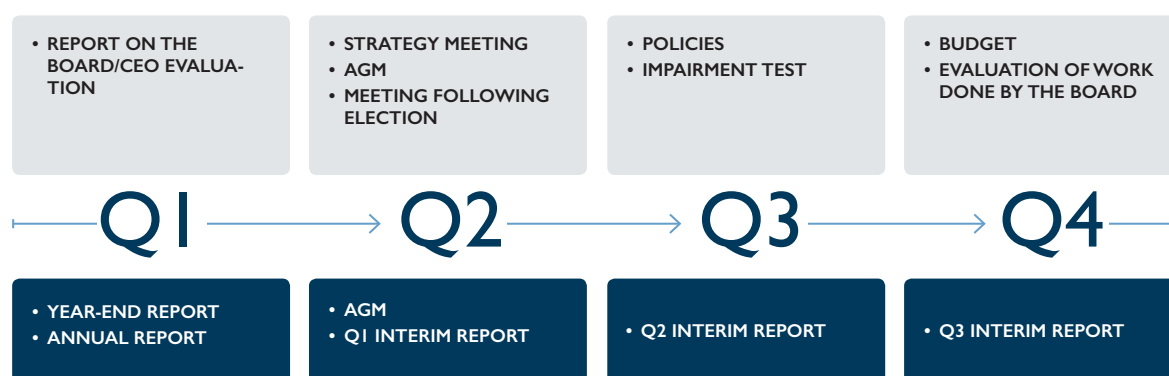
The Board's responsibilities and its tasks are regulated in the Swedish Companies Act, Biovica's Articles of Incorporation and in the Board's rules of procedure, which are revised each year and adopted at each Board meeting following election. The Rules of Procedure regulate such things as the Board's functions and allocation of work between Board members and the

CEO. The Board is responsible for continually monitoring the company's strategic direction, financial performance, its methods, processes and controls to ensure that operations function optimally.

The Board shall also participate in, and help ensure that the company's financial reporting and internal controls are of high quality. It is also responsible for evaluating the company based on the established financial targets and guidelines for senior executives. Other responsibilities of the Board are to continually evaluate performance of the CEO and participate in the annual audit carried out by Grant Thornton AB, with Stéphanie Ljungberg as the auditor-in-charge. The Chairman of the Board, who is elected at the AGM, has special responsibility for managing the work done by the Board and for ensuring that such work is well-organized and conducted in an efficient manner. Board meetings are planned by the Chairman and CEO, jointly. The Board convenes in accordance with a set schedule of meetings for the year.

Beyond that, the Board may hold additional meetings to deal with specific matters. Besides their interaction in conjunction with Board meetings, the Chairman of the Board and CEO maintain an ongoing dialog on management of the company. During the 2018/2019 financial year, the Board held 17 meetings (along with a strategy day with management). Seven of those were physical meetings, eight were per capulam and two were phone conferences. At regular Board meetings, the Board deals

**BOARD TASKS AND EVENTS**





with ordinary reports from the CEO. The Board goes over the interim reports at its Board meetings in August, December, March and June.

The Chairman of the Board is responsible for ensuring that the Board members evaluate the work that they have done each year. Evaluation covers the Board's work process, compilation of the Board and its expertise. Evaluation is partly in form of a survey and partly by interviewing the Board members. The work done by the Board is presented to the Nomination Committee.

#### Remuneration to the Board of Directors

The fees paid and other remuneration to Board members is decided at the AGM. At the AGM on 30 August 2018, it was decided that each Director (who is not employed by the company) shall be paid a fee of SEK 125,000 and that the Chairman of the Board shall be paid a fee of SEK 200,000. Total remuneration for the Board and Committee work for the 2018/2019 financial year amounted to SEK 575,000.

#### AUDIT COMMITTEE

The entire Board of Directors serves as the company's Audit Committee. The primary responsibility of the Audit Committee is to ensure the quality of the company's financial reporting, which covers internal controls, a review of the important accounting and valuation policies and also a review of the Company's external reports. The Audit Committee evaluates the audit effort and assists the Nomination Committee in making proposals for selection of auditor and remuneration for the audit work. The Audit Committee also decides on which other services, beyond the audit, to procure from the Company's auditor.

#### REMUNERATION COMMITTEE

The entire Board of Directors serves as the company's Remuneration Committee. The Remuneration Committee's main responsibility is to propose the salary, other benefits and employment terms for the CEO. It is also responsible for proposing principles for remuneration and employment terms for other members of the executive management team. Furthermore, it makes proposals for incentive programs.

The Remuneration Committee shall ensure that there is compliance with the established guidelines for remuneration to senior executives.

#### ACCOUNTANTS

The auditor is responsible for auditing Biovica's annual report and financial statements, along with the administration of the company. Subsequent to the end of each financial year, the auditor submits an audit report and Group audit report to the AGM. The external audit of Biovica's financial statements and all of its subsidiaries that are subject to audit are carried out in accordance with International Standards on Auditing and generally accepted auditing practice in Sweden. Biovica's auditor is elected at the AGM based on a proposal by the Nomination Committee. At the 2018 AGM, Grant Thornton was elected as the company's auditor, with Stéphanie Ljungberg as the auditor-in-charge. On behalf of the Board, the company's auditor also conducts a review of at least one interim report per year. The auditors meet with the entire Board each year, both with, and without, senior executives being present.

#### BOARD MEMBERS AND THEIR INDEPENDENCE

Name	Role in the company	Year elected to Board	Attendance	Fee	Independence to the Board's management	Independence to major shareholders
Lars Holmqvist	Chairman of the Board	2019	3/3	200,000	Yes	Yes
Göran Brorsson	Chairman of the Board	2013	14/14	116,667	Yes	Yes
Mats Danielsson	Board member	2010	3/3	-	Yes	Yes
Maria Holmlund	Board member	2016	17/17	125,000	Yes	Yes
Ulf Jungnelius	Board member	2014	14/17	125,000	Yes	Yes
Jesper Söderqvist	Board member	2013	17/17	125,000	Yes	Yes
Anders Rylander	Board member and CEO	2010	17/17	-	No	No

\* Mats Danielsson declined reelection at the AGM on 30 August 2018.

\*\* At the extraordinary general meeting on 20 March 2019, Lars Holmqvist was elected as Chairman of the Board, replacing Göran Brorsson, who, wanting to decrease his workload, asked that he be replaced as Chairman of the Board for Biovica.



# Board of Directors



## **LARS HOLMQVIST (1959)** *Chairman of the Board since 2019*

**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.

**Current assignments:** Board member at: Lundbeck Fonden A/S, H Lundbeck A/S, ALK-Abelló A/S, Tecan AG, BPL Plc-UK and Vitrolife AB.

**Holding in the company:** 410,630 Class B shares, 50,000 warrants (TO4)

## **ULF JUNGNELIUS, MD (1951)** *Board member since 2014*

**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.

**Current assignments:** Chairman of the Board at Isofol Medical AB. Board member at: Oncopeptides AB and Monocl AB.

**Holding in the company:** 25,000 warrants (TO4)

## **JESPER SÖDERQVIST, PH.D (1966)** *Board member since 2013*

**Education/background:** M.Sc.Eng. from KTH Royal Institute of Technology. Ph.D. in Physics from KTH Royal Institute of Technology and CERN. Previously Vice President for Elekta AB's neuroscience division, General Manager for mammography at Philips Healthcare and CEO at Sectra Mamea.

**Current assignments:** Jesper Söderqvist is CEO of Arcoma AB. He is also a Board member and CEO of Dekatria AB.

**Holding in the company:** Directly and indirectly: 41,085 Class A shares and 38,200 Class B shares, 3,000 warrants (TO2), 25,000 warrants (TO4)

## **ANDERS RYLANDER (1970)** *Board member since 2010 and CEO*

**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).

**Current assignments:** Chairman of the Board at: Springcap Invest AB, Idrottsinfrastruktur i Danderyd AB, Konstgräs DaGy AB. Board member at: Arinvest AB, Citerus AB and Anders Rylander Investment AB.

**Holding in the company:** Indirectly: 3,575,640 Class A shares, 368,956 Class B shares

## **MARIA HOLMLUND (1956)** *Board member since 2016*

**Education/background:** B.A. in chemistry and biology from Uppsala University and Gothenburg University. M.Sc. from University of North Carolina. Maria has 30 years of experience working in the field of life license and diagnostics. She has held senior positions in marketing at several major international diagnostic companies.

**Current assignments:** Board member and CEO at Prolight Diagnostics AB (publ). Board member at Idégaraget AB.

**Holding in the company:** 9,750 Class B shares, 25,000 warrants (TO4)





# Senior executives

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



## ANDERS RYLANDER (1970) CEO since 2010

See the information in the previous section on the Board of Directors.

## CECILIA DRIVING (1971) CFO since 2016

**Education/background:** Master of Laws and B.Sc. in business administration from Stockholm University. Cecilia has experience working in the fields of life science, 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.

**Current assignments:** Chairman of the Board at Adom AB.

**Holding in the company:** 10,000 Class B shares, 20,000 warrants (TO2), 20,000 warrants (TO3)

## KARIN MATTSSON, PH.D. (1970) R&D Director since 2017

**Education/background:** Ph.D. in cell and tumor biology from Karolinska Institute. M.A. with focus on biology from Uppsala University. Degree from Sundsvall Vocational College with focus on clinical chemistry. Karin has more than 20 years of experience working with academic research and product development in the medical technology industry. She has held a variety of technology-related and leading positions at companies and she has extensive experience in the development and production of in vitro diagnostics. Her most recent employment was at Olerup SSP AB.

**Current assignments:** -

**Holding in the company:** 1,000 Class B shares, 20,000 warrants (TO2), 20,000 warrants (TO3)

## MATTIAS BERGQVIST (1970) Clinical Development Director since 2011

**Education/background:** B.Sc. in Business & Marketing. Mattias has more than 20 years of experience in the pharmaceutical and biotech industry working with oncology. His previous experience includes working as Nordic Marketing Director for specialist care and oncology at AstraZeneca. He has published several scientific articles on DiviTum®.

**Current assignments:** Board member of Life Science Solution Consulting Scandinavia AB.

**Holding in the company:** Indirectly 106,560 Class A shares, 20,000 warrants (TO2)

## WING CHENG, PH.D. (1974) Market Access and Quality Assurance Director since 2018

**Education/background:** Ph.D. in clinical immunology, M.Sc. in molecular biotechnology from Uppsala University. Wing has held leading positions in regulatory and reimbursement at government authorities, including TLV, Swedish Medical Products Agency, EMA and the European Commission. He most recently held the position of Manager Clinical Utility at Thermo Fisher Scientific.

**Current assignments:** -

**Holding in the company:** 3,700 Class B shares, 20,000 warrants (TO3)

## ADAM GERMUNDER (1984), Operations Director since 2017

**Education/background:** Adam has a B.Sc. in mechanical engineering from Uppsala University. He has extensive experience working with product management and process development. For example, he was involved in developing and implementing the new production methods in ISO 13485 Medical devices--Quality management systems. He previously worked as Head of Production at Fiom Diagnostics, where he was responsible for ongoing production. He also worked as Team Leader at Fresenius Kabi.

**Current assignments:** -

**Holding in the company:** 4,600 Class B shares, 20,000 warrants (TO3)

## PONTUS NOBRÉUS (1964) Business Development Director since 2018

**Education/background:** M.Sc. in mechanical engineering from Lund University (LTH). MBA from Henley Business School. Pontus has more than 20 years of experience in various positions in industry, primarily diagnostics and in the laboratory sector. He has extensive international experience and has worked abroad in both USA and South Africa. For example, he was Regional Sales Manager at HemoCue and he most recently worked as Global Export Manager at Euro Diagnostica.

**Current assignments:** -

**Holding in the company:** 6,000 Class B shares, 20,000 warrants (TO3)

## REMUNERATION TO SENIOR EXECUTIVES

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.

### The Board of Directors' proposal for guidelines for remuneration to senior executives

The Board of Directors proposes that remuneration to senior executives shall consist of fixed salary, variable remuneration (possibly), other ordinary benefits and pension. The total annual remuneration shall be market-based and competitive having considered the labor market and position that the individual holds. It should also take into account the individual's qualifications, experience, and any outstanding achievements. Fixed salary shall be reviewed annually. Senior executives include the President/CEO and other members of the executive management team.

Fixed salary and variable remuneration shall be related to the senior executives responsibilities and authority. Variable salary shall not exceed 40% of fixed salary. Conditions for variable remuneration should be designed so that the Board is able to limit or exclude it if the variable remuneration is deemed to be unreasonable or incompatible with the company's responsibilities towards its shareholders. For annual bonus, it should be possible to limit or exclude variable remuneration if the Board feels that it is motivated for other reasons.

Pension benefits shall be defined contributions. Notice of termination for the CEO and other senior executives shall be 12 months, at most. Fixed salary during the notice period and severance pay shall not, in aggregate, exceed an amount corresponding to the fixed salary for one year and shall also be deductible.

These principles shall be applied by all subsidiaries in the Group. The Board of Directors shall have the right to deviate from the above guidelines if it considers that, in a particular case, there are special reasons for doing so. Matters having to do with salary and other remuneration to the CEO and other senior executives are pre-

pared by the CEO and resolved in consultation with the Chairman of the Board.

### Internal audit

The Group has a simple legal and operational structure, along with a detailed governance and internal control system. Based on that, the Board has decided not to set up a special internal audit function.

### The Board's report on internal control over the financial statements

The Board's responsibility for internal control and governance is regulated in the Swedish Companies Act and the Annual Accounts Act. The Swedish Corporate Governance Code is also applied. Biovica strives to run the business as efficiently as possible. The financial reporting must be reliable and reflect the Company's operations in a correct manner and be prepared in accordance with applicable laws and regulations. The Board determines which reports must be prepared in order for it to monitor the Company's progress. The quality of financial reporting to the Board is evaluated primarily by the audit committee.

### Internal control and control environment

The Board's responsibility for internal control is regulated in the Swedish Companies Act and the Annual Accounts Act, which requires that information on the most important elements of the Company's systems for internal control and risk management in connection with the financial reporting is included in the corporate governance report. The Swedish Corporate Governance Code is also applied. The Board of Directors must, for example, make sure that the Company has good internal control and formalized procedures that ensure that established principles for financial reporting and internal control are complied with, and that there are appropriate systems for monitoring and controlling the Company's operations along with the risks associated with the Company and its operations. An important component of the control environment is clearly-defined decision paths, powers and responsibilities that must also be communicated between different levels in the organization. Furthermore, governing documents must exist

in the form of policies and guidelines covering all essential areas. Such documents must provide guidance to the senior executives of the Group.

One of the important tasks of the Board is to formulate and approve various fundamental policies, guidelines and frameworks. These include: the Board's rules of procedure, instructions to the CEO and policies on information, insiders, the treasury function and investments. The aim of such policies is to, among other things, create the foundation for good internal control. All policies are reviewed annually and adopted by the executive management team or the Board. Furthermore, the Board is responsible for ensuring that the organizational structure has clearly-defined roles, responsibilities and process which facilitate efficient management of the company's risks and fulfillment of its goals.

The overall purpose of internal control is, to the extent possible, ensure that the Company's operational strategies and goals are monitored and that the owners' investments are protected. Furthermore, internal controls must ensure that external financial reporting is, with reasonable assurance, reliable and that it has been prepared in accordance with generally accepted accounting principles, applicable laws and regulations and the requirements for listed companies.

### Financial reporting

The Board of Directors has overall responsibility for internal control over financial reporting. In order to both create and maintain a functioning control environment, the Board has adopted several policies and governance documents that regulate the financial reporting. These consist of, primarily, the Board's rules of procedure, instructions to the CEO and instructions for financial reporting. The Board has also adopted a specific attestation and approvals instruction along a treasury policy and investment policy. The Board has overall responsibility for ensuring that there are established principles for financial reporting, that the internal controls are being followed and that ongoing contact with the Company's auditor is maintained. Responsibility for maintaining an effective control environment and

the ongoing work with internal controls pertaining to financial reporting has been delegated to the Company's CEO. The CEO regularly reports to the Board in accordance with the adopted instruction to the CEO and the instructions for financial reporting. The Board also receives reports from the Company's auditor. Based on its assessment that the control environment is good and on external review by the auditors, the Board has concluded that there are no particular circumstances or other conditions that would motivate setting up an internal audit function.

#### **Risk assessment**

Risk assessment includes identifying the risks that could arise if the fundamental requirements on financial reporting for the Company are not met. The Company's executive management team has identified and evaluated the risks associated with Biovica's operations, along with how to manage such risks. The Board is responsible for continuously evaluating Biovica's risk situation, after which the Board carries out its own annual review of the same. Control activities limit the identified risks and ensure that financial reporting is accurate and reliable. The Board is responsible for internal control and follow-up of the company management. This occurs via both internal and external control activities and via review and monitoring of the Company's governance documents associated with risk management.

#### **Control activities**

Control activities limit the identified risks and ensure that financial reporting is accurate and reliable. The Board is responsible for internal control and follow-up of the company management. This occurs via both internal and external control activities and via review and monitoring of the Company's governance documents associated with risk management.

#### **Information and communication**

The company has information and communication paths aimed at promoting accuracy in its financial reporting. It also facilitates reporting and feedback from its operations to the Board and management. For example, governance documents in the

form of policies, guidelines and instructions for financial reporting have been issued and understood by all of the employees concerned. The Board has also adopted an information policy which regulates how the Company reports various types of information, such as financial information, in the form of interim reports, year-end reports, annual reports and press releases on significant events that could impact the share price.

Biovica's issuance of information complies with Nasdaq Stockholm's rules and regulations for issuers. The Board of Directors reviews the external financial reports before they are published. The information policy also stipulates how communication shall occur and the individuals with authority to represent the Company. Information that is made public via press releases is also published on the Company's website, along with other information deemed relevant and important.

#### **Follow-up**

Compliance with, and effectiveness of, internal controls are monitored on an ongoing basis. The CEO ensures that the Board regularly receives reports on the Company's progress and included in that is information on its earnings and financial position, along with significant events such as research results and important agreements that are being considered. The CEO reports on such matters at each Board meeting.



# KEY PERFORMANCE INDICATORS FOR THE GROUP

SEK thousands	2018/2019	2017/2018	2016/2017	2015/2016
Net sales	3,005	2,723	632	2,432
Operating profit (loss)	-21,718	-17,956	-14,690	-4,617
Profit (loss) for the year	-21,556	-18,010	-14,715	-5,049
Capitalized R&D expenditure	6,464	6,596	5,075	4,700
Capitalized R&D expenditure as a percentage of operating expenses	-22	-26	-27	-37
Earnings per share, basic	-1.23	-1.02	-0.84	-0.54
Earnings per share, after dilution	-1.18	-1.00	-0.82	-0.53
Cash and cash equivalents at the end of the period	16,831	42,127	65,469	928
Cash flow from operating activities	-17,966	-14,882	-10,746	-9,385
Cash flow for the period	-25,295	-23,342	64,541	-179
Equity	52,097	73,713	91,664	24,943
Equity per share	2.96	4.19	5.22	44.51
Equity ratio (%)	86	91	94	88
Average number of employees	16	14	8	5

The Group was established in 2009 by setting up the subsidiary company, Biovica Services AB. Biovica's subsidiary is a dormant company, which explains why the Parent Company's and Group's KPIs are essentially the same. Small-scale operations got underway towards the end of the financial year in Biovica's US subsidiary, Biovica Inc. The impact of that on the figures stated in the Parent Company are, on the whole, marginal.

## 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.

Key performance indicators	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 2018/2019	May-April 2017/2018
Income	5, 6	3,005	2,723
Other income	8	932	494
Work performed by the company and capitalized		6,464	6,596
Change in WIP inventory		43	132
		<b>10,444</b>	<b>9,945</b>
Materials cost		-875	-1,148
Other external costs	9, 11	-11,962	-9,503
Employee benefit expenses	10	-16,245	-14,495
Depreciation/amortization		-3,020	-2,738
Other expenses		-60	-17
<b>Operating profit (loss)</b>		<b>-21,718</b>	<b>-17,956</b>
Other interest income and similar profit or loss items		229	0
Interest expenses and similar items		-35	-54
<b>Profit (loss) after financial items</b>		<b>-21,524</b>	<b>-18,010</b>
Tax expense	12	-32	-
<b>Profit (loss) for the year</b>		<b>-21,556</b>	<b>-18,010</b>
<b>Earnings per share</b>			
Earnings per share, before dilution (SEK)		-1.23	-1.02
Average number of shares, before dilution		17,573,372	17,573,372
Earnings per share, after dilution (SEK)		-1.18	-1.00
Average number of shares, after dilution		18,343,372	17,968,372
<b>Consolidated statement of comprehensive income</b>			
Profit (loss) for the year		-21,556	-18,010
<i>Items that may be subsequently reclassified to profit and loss</i>			
Exchange rate differences, foreign net investments		0	0
Other comprehensive income for the year		0	0
<b>Comprehensive income for the year (loss)</b>		<b>-21,556</b>	<b>-18,010</b>





# Consolidated statement of financial position

SEK thousands	Note	2019-04-30	2018-04-30
<b>ASSETS</b>			
<i>Intangible assets</i>			
Capitalized expenditure for R&D	13	31,560	26,395
Patents	14	6,347	7,383
<b>Total intangible assets</b>		<b>37,907</b>	<b>33,778</b>
<i>Property, plant and equipment</i>			
Machinery, equipment, tools, fixtures and fittings	15	2,917	2,616
<b>Total fixed assets</b>		<b>40,825</b>	<b>36,394</b>
Inventories		446	403
<i>Current receivables</i>			
Accounts receivable		1,732	1,068
Current tax assets		0	73
Other receivables		582	405
Prepaid expenses and accrued income		443	301
Cash & cash equivalents including short-term investments	23	16,831	42,127
<b>Total current assets</b>		<b>20,035</b>	<b>44,377</b>
<b>TOTAL ASSETS</b>		<b>60,859</b>	<b>80,771</b>
<b>EQUITY</b>			
Share capital		1,172	1,172
Other contributed capital		133,776	133,776
Retained earnings (losses), including loss for the year		-82,850	-61,235
<b>Total equity</b>		<b>52,097</b>	<b>73,713</b>
<b>LIABILITIES</b>			
Other liabilities		940	387
<b>Total non-current liabilities</b>		<b>940</b>	<b>387</b>
Advance payments from customers		3,571	3,047
Accounts payable		860	1,009
Current tax liabilities		557	255
Other liabilities		545	482
Accrued expenses and deferred income		2,289	1,878
<b>Total current liabilities</b>		<b>7,822</b>	<b>6,672</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>60,859</b>	<b>80,771</b>

## Consolidated statement of changes in equity

SEK thousands	Share capital	Other contributed capital	Retained earnings	Profit (loss) for the year	Total equity
<b>Opening balance, 1 May 2017</b>	<b>1,172</b>	<b>133,776</b>	<b>-28,569</b>	<b>-14,715</b>	<b>91,664</b>
Appropriation in accordance AGM decision			-14,715	14,715	–
Adjustment due to change in accounting policy		59		59	
Profit (loss) for the year				-18,010	-18,010
<b>Closing balance, 30 April 2018</b>	<b>1,172</b>	<b>133,776</b>	<b>-43,225</b>	<b>-18,010</b>	<b>73,713</b>
Appropriation in accordance AGM decision			-18,010	18,010	–
Adjustment due to change in accounting policy		-59		-59	
Profit (loss) for the year				-21,556	-21,556
<b>Closing balance, 30 April 2019</b>	<b>1,172</b>	<b>133,776</b>	<b>-61,294</b>	<b>-21,556</b>	<b>52,097</b>



# Consolidated statement of cash flows

SEK thousands	Note	May-April 2018/2019	May-April 2017/2018
Profit (loss) after financial items		-21,524	-18,010
Depreciation/amortization		3,020	2,738
Other non-cash items	18	373	292
Paid income tax		343	-29
Change in current receivables		-983	-911
Change in current liabilities		848	1,133
Change in inventories		-43	-96
<b>Cash flow from operating activities</b>		<b>-17,966</b>	<b>-14,882</b>
Investments in intangible assets		-6,464	-6,596
Investments in PPE		-865	-1,989
Investments in financial assets		0	125
<b>Cash flow from investing activities</b>		<b>-7,329</b>	<b>-8,459</b>
New share issue		0	0
Loan amortization		0	0
<b>Cash flow from financing activities</b>		<b>0</b>	<b>0</b>
<b>Cash flow for the period</b>		<b>-25,295</b>	<b>-23,342</b>
Cash and cash equivalents at the beginning of the period		42,127	65,469
Cash and cash equivalents at the end of the period		16,832	42,127



# Parent Company income statement

SEK thousands	Note	May-April 2018/2019	May-April 2017/2018
Net sales	5, 6	3,005	2,723
Change in WIP inventory		43	132
Work performed by the company and capitalized		6,464	6,596
Other operating income	8	751	494
		<b>10,263</b>	<b>9,945</b>
Goods for resale		-875	-1,148
Other external costs	9, 10	-12,638	-9,595
Employee benefit expenses	11	-15,736	-14,495
Depreciation/amortization		-2,840	-2,584
Other operating expenses		-60	-17
<b>Operating profit (loss)</b>		<b>-21,886</b>	<b>-17,894</b>
Other interest income and similar profit or loss items		307	0
Interest expenses and similar items		-26	-42
<b>Profit (loss) after financial items</b>		<b>-21,606</b>	<b>-17,935</b>
Income tax	12	-	-
<b>Profit (loss) for the period</b>		<b>-21,606</b>	<b>-17,935</b>

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



# Parent Company balance sheet

SEK thousands	Note	2019-04-30	2018-04-30
<b>ASSETS</b>			
<i>Intangible assets</i>			
Capitalized expenditure for R&D	13	31,560	26,395
Patents	14	6,347	7,324
<i>Property, plant and equipment</i>			
Machinery, equipment, tools, fixtures and fittings	15	1,801	2,191
<i>Financial assets</i>			
Participations in Group companies	16	108	108
Prepaid leasing fees	24	176	39
<b>Total fixed assets</b>		<b>39,993</b>	<b>36,057</b>
Inventories		446	403
<i>Current receivables</i>			
Accounts receivable		1,732	1,068
Changes in Group companies		1,045	
Current tax assets		-	73
Other receivables		559	405
Prepaid expenses and accrued income		418	301
Cash & cash equivalents and short-term investments	23	15,779	42,069
<b>Total current assets</b>		<b>19,979</b>	<b>44,319</b>
<b>TOTAL ASSETS</b>		<b>59,972</b>	<b>80,376</b>
<b>EQUITY</b>			
<i>Restricted equity</i>			
Share capital	17	1,172	1,172
Fund for development expenditure		18,135	11,671
<b>Total restricted equity</b>		<b>19,307</b>	<b>12,842</b>
<i>Non-restricted equity</i>			
Share premium reserve		120,380	126,844
Capitalized gain or loss		-66,075	-48,140
Profit (loss) for the year		-21,606	-17,935
<b>Total non-restricted equity</b>		<b>32,699</b>	<b>60,769</b>
<b>Total equity</b>		<b>52,005</b>	<b>73,611</b>
<b>LIABILITIES</b>			
Liabilities to Group companies		-	109
<b>Total non-current liabilities</b>		<b>0</b>	<b>109</b>
Prepayments from customers and prepaid grants		3,571	3,047
Accounts payable		845	1,009
Intra-Group accounts payable		242	-
Current tax liabilities		525	-
Other liabilities		545	482
Accrued expenses and deferred income		2,239	2,117
<b>Total current liabilities</b>		<b>7,966</b>	<b>6,655</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>59,972</b>	<b>80,376</b>

# Parent Company statement of changes in equity

SEK thousands	Share capital	Fund for development expenditure	Share premium reserve	Retained earnings	Profit (loss) for the year	Total equity
<b>Opening balance, 1 May 2017</b>	<b>1,172</b>	<b>5,075</b>	<b>133,440</b>	<b>-33,292</b>	<b>-14,848</b>	<b>91,546</b>
Appropriation in accordance AGM decision				-14,848	14,848	–
Capitalized development expenditure for the year		6,596		-6,596		-6,596
Profit (loss) for the year					-17,935	-17,935
<b>Closing balance, 30 April 2018</b>	<b>1,172</b>	<b>11,671</b>	<b>133,440</b>	<b>-54,736</b>	<b>-17,935</b>	<b>67,015</b>
Appropriation in accordance AGM decision				-17,935	17,935	–
Capitalized development expenditure for the year		6,464		-6,464		-6,464
Profit (loss) for the year					-21,606	-21,606
<b>Closing balance, 30 April 2019</b>	<b>1,172</b>	<b>18,135</b>	<b>133,440</b>	<b>-79,135</b>	<b>-21,606</b>	<b>38,945</b>





# Parent Company statement of cash flows

SEK thousands	May-April 2018/2019	May-April 2018/2019
Profit (loss) after financial items	-21,606	-17,935
Depreciation/amortization	2,840	2,584
Other non-cash items	—	59
Paid income tax	112	37
Change in current receivables	-935	-890
Change in current liabilities	157	1,117
Change in inventories	-43	-96
<b>Cash flow from operating activities</b>	<b>-19,476</b>	<b>-15,124</b>
Investments in intangible assets	-6,464	-6,655
Investments in PPE	-174	-1,563
Investments in financial assets	-176	0
Investments in subsidiaries	0	-8
<b>Cash flow from investing activities</b>	<b>-6,814</b>	<b>-8,226</b>
New share issue	0	0
Loan amortization	0	9
<b>Cash flow from financing activities</b>	<b>0</b>	<b>9</b>
<b>Cash flow for the period</b>	<b>-26,290</b>	<b>-23,341</b>
Cash and cash equivalents at the beginning of the period	42,069	65,410
Cash and cash equivalents at the end of the period	15,779	42,069

# Supplementary disclosures

## NOTE 1 - 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 primary place of establishment is: Dag Hammarskjölds väg 54B, 752 37 Uppsala, Sweden. Biovica's shares are traded on Nasdaq First North Premier in Stockholm.

## NOTE 2 - Accounting policies

The consolidated financial statements have been prepared in accordance with the Swedish Annual Accounts Act and RFR 1 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 2019 (including comparison figures) were approved by the Board on 28 June 2019.

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.

### 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 contains a summary of the important accounting policies applied in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated. The consolidated financial statements cover Biovica International AB and its subsidiaries.

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

IFRS 9 Financial Instruments covers classification, measurement and recognition of financial assets and liabilities based on new rules that will apply for hedge accounting. IFRS 9 replaces the parts of IAS 39 that have to do with the classification and measurement of financial instruments. It also introduces a new impairment model. The new model for calculating credit losses is based on expected credit losses, which could result in earlier recognition of them. The Group has not identified any impact on the classification and measurement of its financial assets and liabilities. IFRS 9 entered into force on 1 May 2018.

IFRS 15 Revenue from Contracts with Customers covers how such revenue shall be recognized and reported. In accordance with IFRS 15, revenue is recognized when control over the sold goods or services passes to the customer (i.e. the customer is able to use and derive benefits from the goods or services). With this standard, more detailed disclosures are required. IFRS 15 entered into force on 1 May 2018. It will not have any impact on the financial statements.

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

IFRS 16 Leasing will replace IAS 17 Leasing and the associated interpretations. The standard requires that assets and liabilities obtained through a lease agreement, with some exceptions, are reported in the balance sheet. This way of reporting is based on the view that the lessee is entitled to use an asset for a specific period of time, along with the obligation to pay for that right. The standard applies to annual reporting periods beginning on or after 1 January 2019. The Group has concluded its efforts associated with adapting to the new reporting standard.

IFRS 16 and its impact on the Group's financial statements. A thorough review has been conducted of all of the Group's lease agreements, which has involved collecting and compiling information that will be used in order to report in accordance with the new standard. Most of the Group's significant lease agreements are already reported as finance leases. With the transition to IFRS 16, leases on premises will be reported in the consolidated balance sheet as a right-of-use asset and financial liability. Note 24 contains details on the Group's non-cancellable operating leases. The Group will apply the modified retrospective approach, which means that comparison figures will not be restated. The amount of the Group's total assets will increase by SEK 3,618 thousand with implementation of IFRS 16.

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 that are controlled by the Group. 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 fully consolidated as of the date when the Group obtains a controlling influence. They are no longer consolidated as of the date when the Group no longer has a controlling influence.

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 and losses on transactions between Group companies are eliminated. The accounting policies of subsidiaries have been adjusted, where necessary, to ensure consistency with the policies applied by the Group.

## 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.

### (ii) Transactions eliminated upon consolidation

All intra-Group receivables and liabilities, 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 as-

sets 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*.



## LEASING COSTS WHERE THE GROUP IS LESSEE

### (i) Operating leases

Expenses relating to operating leases are recognized in profit or loss for the year on a straight-line basis over the lease term. Benefits received in connection with the signing of an agreement are recognized in profit or loss via a reduction to the leasing fees on a straight-line basis over the lease term. Variable fees are expensed in the periods that they arise.

### (ii) Finance leases

The minimum lease payments are divided between interest expense and amortization of the outstanding debt, which is reported in profit or loss for the year. The amount of the expense in each reporting period corresponds to a constant periodic rate of interest on the remaining balance of the liability. Variable fees are expensed in the periods that they arise.

## 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.

## TAX

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 prob-

able that they will be utilized. The value of deferred tax assets is reduced when it is no longer deemed likely that they can 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:

## OTHER FINANCIAL ASSETS

All other financial assets are reported at amortized cost. 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 classified as measured at amortized cost or at fair value through profit or loss. Financial assets at fair value through profit or loss consist of contingent consideration for busi-

ness combinations along with Biovica's negative fair value derivatives that do not meet the criteria for hedge accounting. All other financial liabilities are measured at amortized cost using the effective interest method.

## CLASSIFICATION AND MEASUREMENT OF FINANCIAL INSTRUMENTS BEFORE 1 MAY 2018

Prior to its application IFRS 9 on 1 May 2018, the Group classified its holdings of financial assets in the following measurement categories, in accordance with IAS 39: "Financial assets at fair value through profit or loss; "Available-for-sale financial assets" (measured at fair value via other comprehensive income) and "Loans and receivables" (measured at amortized cost).

According to IAS 39, financial liabilities were classified as "Financial liabilities at fair value through profit or loss" and "Other financial liabilities" (measured at amortized cost).

## PROPERTY, PLANT AND EQUIPMENT

### (i) Owned assets

Property, plant and equipment is 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) Leased assets

Leases are classified as either operating leases or finance leases. A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee. Otherwise, a lease is classified as an operating lease.

Assets that are leased through a finance lease are reported as fixed assets in the statement of financial position and they are initially measured at the fair value of the leased asset, or the present value of the minimum leasing fees as the start of the lease (whichever is lower).

The obligation to make future lease payments is reported as non-current and current liabilities. The leased assets are depreciated over each asset's useful life. The lease payments, however, are reported as interest and amortization of the liabilities.

### (iii) 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.

### (iv) Depreciation

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 year
- equipment, tools, fixtures and fittings: 5 year

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

## 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 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.

The carrying amount includes all directly attributable expenses; e.g. for materials and services, compensation for employees, registration of a legal right, amortization of patents & licenses and borrowing costs.

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.

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.

### 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 life of the patent.

### Borrowing costs

Borrowing costs attributable to qualifying assets are capitalized as part of the qualifying asset's cost of acquisition. A qualifying asset is an asset that necessarily takes a substantial period of time to get ready for its intended use or sale. Development projects, where

expenditure for development is capitalized, fall into this category. First and foremost, the borrowing costs associated with loans specific to the qualifying asset are capitalized. Otherwise, the borrowing costs associated with general loans that are not specific to any qualifying asset are capitalized.

#### Amortization

Amortization, which is reported as part of cost of goods sold in the income statement, 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. Amortization of intangible assets with a finite useful life starts on 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. According, 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.

IAS 36 is applied for impairment of assets other than: financial assets that are reported in accordance with IAS 39, 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

At the end of each reporting period, the company evaluates whether there is objective evidence that a financial asset or group of financial assets has become impaired. Objective evidence consists of observable conditions that have occurred and which have a negative impact on the possibility of recovering the cost amount.

The company classifies accounts receivable as doubtful if the customer has become insolvent or is having payment difficulties.

Impairment of receivables is determined on the basis of historical experience of customer losses on similar claims.

Impaired accounts receivable are reported at the present value of expected future cash flows. However, receivables with a short duration are not discounted.

#### (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.

##### 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) Share-based remuneration

The Group has a warrants scheme for employees. See Note 18 for more information.

### (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 Swedish Act (1967:531) respecting retirement pensions, 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 and equity. Furthermore, 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) Financial instruments and hedge accounting**

Given the relationship between accounting and taxation, the rules on financial instruments and hedge accounting stipulated in IFRS 9 Financial Instruments are not applied to the Parent Company as legal entity.

In the Parent Company, non-current financial assets are measured at cost less any impairment losses. Current financial assets, however, are measured in accordance with the "lowest value" principle. Short-term investments are reported at fair value.

The cost amount of interest-bearing instruments is adjusted for the accrued difference between what was originally paid, after deduction of transaction costs, and the amount paid on the due date (premium or discount).

**(ii) Leased assets**

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

**(vii) 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.

**(viii) 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.

**NOTE 3 - Financial risk management and capital risks****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 2019 would have been SEK 8 (17) 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 8 (17) thousand. Recalculation effects from operations in the US subsidiary, Biovica Inc. are still at such a low level that they have no impact on Biovica's reporting in SEK.

**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, 2019, a change in the market interest rate of one percentage point would affect the Group's and the Parent Company's earnings by SEK 119 (400) 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 0 (0) thousand on April 30, 2019. The corresponding figure for the Parent Company was SEK 0 (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 twelve months.

The maturity structure for the Group's financial liabilities is presented below.

	Within 3 months	Between 3 months and 1 year	Between 1 and 2 years	Between 2 and 5 years	More than 5 years
Accounts payable	860				
Accrued liabilities	1,961	328			
	<b>2,821</b>	<b>328</b>	<b>0</b>	<b>0</b>	<b>0</b>

### 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	2018/2019	2017/2018
Accounts payable	0	0
Accrued liabilities	16,831	42,069

#### Net debt/equity ratio

Net debt divided by equity.

### 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.

### 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:

SEK thousands	2018/2019	2017/2018
Goods	2,942	2,006
Services	-	168
Other	63	549
	<b>3,005</b>	<b>2,723</b>

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

SEK thousands	2018/2019	2017/2018
Sweden	63	527
EU, excl. Sweden	1,016	45
USA	1,909	2,134
Asia	17	17
	<b>3,005</b>	<b>2,723</b>

### 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. 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 37,907 (33,778) thousand, of which SEK 31,560 (26,395) thousand is capitalized development expenditure and SEK 6,347 (7,383) is patents. Changes in the assumptions made by the company's senior executives when testing for impairment could have a significant impact on the company's reported earnings and financial position.

### 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 2019/2020. Gross margin is calculated based on the product calculation.

**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 has three customers that individually 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 907 thousand.

**NOTE 8 - Other operating income**

	The Group		Parent Company	
	2018/2019	2017/2018	2018/2019	2017/2018
Grants	666	481	666	481
Sales of securities	181			
Gain on disposal of fixed assets	44		44	
Foreign exchange gains/losses	41	13	41	13
	<b>932</b>	<b>494</b>	<b>751</b>	<b>494</b>

The grants have been received from BIOVALID, which is a Horizon 2020 project (Phase II) and from SUBLYME, which is a Eurostar project. The income from grants is recognized at the rate that the associated projects are completed.

**NOTE 9 - Audit expenses**

	The Group		Parent Company	
	2018/2019	2017/2018	2018/2019	2017/2018
Audit assignment	-275	-271	-260	-256
Tax advice	-4	-23	-4	-23
	<b>-279</b>	<b>-294</b>	<b>-264</b>	<b>-279</b>

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 distribution, employee benefit expenses and remuneration to senior executives**

Average number of employees	The Group		Parent Company	
	2018/2019	2018/2019	2017/2018	
Women	7	7	7	
Men	9	9	7	
	<b>16</b>	<b>16</b>	<b>14</b>	

Gender distribution, senior executives	The Group		Parent Company	
	2018/2019	2018/2019	2017/2018	
Women	2	2	3	
Men	5	5	3	
	<b>7</b>	<b>7</b>	<b>6</b>	

Gender distribution, Board of Directors	The Group		Parent Company	
	2018/2019	2018/2019	2017/2018	
Women	3	1	1	
Men	7	4	5	
	<b>10</b>	<b>5</b>	<b>6</b>	

Employee benefit expenses	The Group	Parent Company	
	2018/2019	2018/2019	2017/2018
Salaries and other benefits to the Board of Directors	629	629	628
Salaries and other benefits to the CEO	1,093	1,093	1,089
Salaries and other benefits to other senior executives (6 people)	5,089	4,581	4,413
Salaries and other benefits to other employees	4,282	4,282	2,907
Social security contributions	3,272	3,272	2,639
Pension expenses for the Board and CEO	227	227	210
Pension expenses for other senior executives	722	722	693
Pension expenses for other employees	437	437	320
<b>Total salaries, other benefits, social security contributions and pension contributions</b>	<b>15,751</b>	<b>15,242</b>	<b>12,900</b>

Remuneration to the Board of the Parent Company	2018/2019	2017/2018
Lars Holmqvist, Chairman of the Board*	40	-
Göran Brorsson, Chairman of the Board*	117	175
Mats Danielsson	-	100
Maria Holmlund	117	100
Ulf Jungnelius	117	100
Jesper Söderqvist	117	100
Anders Rylander**	-	-
	<b>508</b>	<b>575</b>

\* At the extraordinary general meeting on 20 March 2019, Lars Holmqvist took over the position of Chairman of the Board from Göran Brorsson.

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

As of 1 January 2019, the Group has had one employee from the Parent Company working in Boston, Massachusetts. Employee benefit expenses for Biovica's US subsidiary amount to SEK 509 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. Invoiced board fees are also included.

## NOTE 11 - 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 194 thousand. Transactions were in accordance with market-based terms and conditions.

## NOTE 12 - Tax expense

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 11.5 million as of 30 April 2019. 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 2019, the Group's tax loss carryforwards amounted to SEK 52,349 (31,894) thousand.

The Group	2018/2019	2017/2018
Profit (loss) before tax	-21,524	-18,010
Tax according to the applicable tax rate	4,735	3,962
Tax effect of non-capitalized loss carryforwards	-4,542	-3,799
Tax effect of non-deductible expenses	-177	-163
Tax effect of non-taxable income	-	-
Effect of loss carryforwards not previously assessed	16	-
<b>Reported tax</b>	<b>32</b>	<b>-</b>

Parent Company	2018/2019	2017/2018
Profit (loss) before tax	-21,606	-17,935
Tax according to the applicable tax rate	4,753	3,946
Tax effect of non-capitalized loss carryforwards	-4,576	-3,782
Tax effect of non-deductible expenses	-177	-163
Tax effect of non-taxable income	-	-
Effect of loss carryforwards not previously assessed	-	-
<b>Reported tax</b>	<b>-</b>	<b>-</b>

New rules enter 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 R&D and similar work

Group and Parent Company	2019-04-30	2018-04-30
Opening cost	32,234	25,638
Capitalized expenditure	6,464	6,596
<b>Closing accumulated cost</b>	<b>38,698</b>	<b>32,234</b>
Opening amortization	-5,839	-4,540
Amortization for the year	-1,299	-1,299
<b>Closing accumulated amortization</b>	<b>-7,138</b>	<b>-5,839</b>
<b>Closing carrying amount</b>	<b>31,560</b>	<b>26,395</b>

In addition, SEK 153 (743) thousand was expensed for R&D during the year.

### NOTE 14 - Patents

Group and Parent Company	2019-04-30	2018-04-30
Opening cost	9,896	9,896
<b>Closing accumulated cost</b>	<b>9,896</b>	<b>9,896</b>
Opening amortization	-2,513	-1,653
Amortization for the year	-1,036	-860
<b>Closing accumulated amortization</b>	<b>-3,549</b>	<b>-2,513</b>
<b>Closing carrying amount</b>	<b>6,347</b>	<b>7,383</b>

### NOTE 15 - Machinery, equipment, tools, fixtures and fittings

	The Group		Parent Company	
	2019-04-30	2018-04-30	2019-04-30	2018-04-30
Opening cost	3,414	1,425	2,989	1,425
Purchases	865	1,989	174	1,563
<b>Closing accumulated cost</b>	<b>4,279</b>	<b>3,414</b>	<b>3,162</b>	<b>2,989</b>
Opening depreciation	-798	-431	-798	-431
Depreciation for the year	-564	-367	-564	-367
<b>Closing accumulated depreciation</b>	<b>-1,361</b>	<b>-798</b>	<b>-1,361</b>	<b>-798</b>
<b>Closing carrying amount</b>	<b>2,917</b>	<b>2,616</b>	<b>1,801</b>	<b>2,191</b>

The Group has leased assets amounting to SEK 1,220 (425) thousand. Depreciation of those assets amounts to SEK 180 (94) thousand.

### NOTE 16 - Participations in Group Companies

	2019-04-30	2018-04-30
Opening cost	108	108
Purchases	0	0
<b>Closing accumulated cost</b>	<b>108</b>	<b>108</b>
<b>Closing carrying amount</b>	<b>108</b>	<b>108</b>

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

Name/Registered office	Equity	Profit (loss)
Biovica Services AB	273,355	130,554
Biovica Inc.	-71,777	-81,285

**NOTE 17 - Shares**

The company has both Class A shares (each worth 3 votes) and Class B shares (each worth 1 vote). As of 30 April 2019, there were 7,297,438 Class A shares (these are unlisted) and 10,275,934 Class B shares that are traded on Nasdaq First North Premier. The total number of shares was thus 17,573,372. Share capital amounted to SEK 1,171,558.13 and the quotient value per share is SEK 0.07. The total number of votes amounted to 32,168,248.

**NOTE 18 - Warrants**

Biovica has four outstanding warrant schemes. The warrants were transferred following market valuation in accordance with the Black & Scholes pricing model. During the year, warrants were issued for the TO3 and TO4 warrant schemes. The TO3 warrant scheme for employees of the company was approved at the AGM on 30 August 2018. At the extraordinary general meeting on 20 March 2019, it was decided to set up a warrant scheme for members of the Board of Directors (TO4).

Program	To	Class B shares	Subscription price	Option price	Subscription period	Share capital increase	Number of class B shares
TO1	Board of Directors	195,000*	16.67*	0.68*	7 July 2014 – 30 June 2019	13,650.00	195,000
TO2	Employees	200,000	25	0.54	29 March 2017 - 30 March 2020	13,333.33	200,000
TO3	Employees	200,000	21.9	0.44	30 March 2020 - 25 August 2021	13,333.33	200,000
TO4	Board of Directors	175,000	19.5	0.94	25 March 2022 - 25 August 2023	11,666.67	175,000
						<b>51,983.33</b>	<b>770,000</b>

\*Warrants were issued prior to the 1:15 split that occurred in 2016.

**NOTE 19 - Non-cash items**

	The Group		Parent Company	
	2018/2019	2017/2018	2018/2019	2017/2018
Leasing	583	292		
Depreciation/amortization	3,020	2,738	2,840	2,584
	<b>3,603</b>	<b>3,030</b>	<b>2,840</b>	<b>2,584</b>

**NOTE 20 - Pledged assets**

	2019-04-30	2018-04-30
Pledged assets	None	None

**NOTE 21 - Contingent liabilities**

	2019-04-30	2018-04-30
Contingent liabilities	None	None

**NOTE 22 Categories of financial instruments**

Amortized cost, SEK thousand	The Group	Parent Company
	2018/2019	2018/2019
<b>Financial assets</b>		
Accounts receivable	1,732	1,732
Other current receivables	582	559
Other current receivables Group companies		1,045
Prepaid expenses and accrued income	443	418
Cash and cash equivalents	4,898	3,846
Short-term investments	11,933	11,933
<b>Total financial assets</b>	<b>17,274</b>	<b>16,197</b>
<b>Other financial liabilities</b>		
Other non-current liabilities	940	
Accounts payable	860	845
Intra-Group accounts payable		242
Accrued expenses and deferred income	2,289	2,239
Other current liabilities	545	525
<b>Total financial assets</b>	<b>4,634</b>	<b>3,851</b>

	The Group	Parent Company
	2017/2018	2017/2018
<b>Loan receivables and accounts receivable measured at amortized cost</b>		
Accounts receivable	1,068	1,068
Financial assets	0	39
Other receivables	405	405
Accrued income	301	301
Cash and cash equivalents	2,168	2,110
Short-term investments	39,959	39,959
	<b>43,901</b>	<b>43,882</b>
<b>Borrowings and accounts payable measured at amortized cost</b>		
Accounts payable	1,009	1,109
Accrued expenses	2,117	2,117
	<b>3,126</b>	<b>3,226</b>

#### 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 23 Financial instruments at fair value

Information on financial instruments at fair value:

	2018/2019		2017/2018	
Group and Parent Company	Carrying amount	Value change reported	Carrying amount	Value change reported
Available-for-sale financial assets	11,933	-26	39,959	-42

### NOTE 24 Operating leases

Leases where the company is lessee  
Expensed lease payments for the year:

Group and Parent Company, SEK thousand	2018/2019	2017/2018
Total leasing costs	1,148	1,079
	<b>1,148</b>	<b>1,079</b>

Non-cancellable lease payments amount to:

Group and Parent Company, SEK thousand	2018/2019	2017/2018
Within one year	1,148	1,079
Between 1 and 5 years	2,470	3,618
More than 5 years		
	<b>3,618</b>	<b>4,697</b>

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 25 IFRS 16 Leases

IFRS 16 Leases replaces IAS 17 Leases as of 1 January 2019. For Biovica, as lessee, the application of IFRS 16 means that essentially all leases will be reported in the balance sheet as assets (its right to use the underlying leased asset) and liabilities (the obligation to make future lease payments). Biovica must also recognize depreciation of the right-of-use asset and interest on the lease liability in the income statement. The impact on earnings before tax is assessed as being insignificant. Leases that are affected are primarily for rental of office space and leased vehicles. For transition to the new standard, Biovica has decided to apply the modified retrospective approach and option two, where the right-of-use asset equals the liability upon transition, subject to certain adjustments (any prepaid or accrued lease payments). Election of this method also means that comparison periods are not restated. Leases that are shorter than 12 months or which terminate within 12 months from the date of acquisition are classified as short-term contracts and are therefore not included in the reported liabilities or among right-of-use assets. Furthermore, Biovica has elected to apply the recognition exemptions to leases for which the underlying asset is of low value. Existing lease agreements previously reported in accordance with "IAS 17 Leases" have been reclassified in accordance with "IFRS 16 Leases" at the amount at which they were reported the day before application of the new standard occurred. A marginal lending rate has been established per country, useful life and asset class as of May 1, 2019.

The effects of the transition to IFRS 16 are detailed below.

	Reported balance sheet	Adjustment to IFRS 16	Adjusted balance sheet
SEK thousands	2019-04-30	2019-05-01	2019-05-01
<b>ASSETS</b>			
Capitalized expenditure for R&D	31,560		31,560
Patents	6,347		6,347
Machinery, equipment, tools, fixtures and fittings	2,917	3,618	6,535
<b>Total fixed assets</b>	<b>40,825</b>	<b>3,618</b>	<b>44,676</b>
Inventories	446		446
Current receivables	2,758		2,758
Cash & cash equivalents including short-term investments	16,831		16,831
<b>Total current assets</b>	<b>20,035</b>	<b>0</b>	<b>20,035</b>
<b>TOTAL ASSETS</b>	<b>60,859</b>	<b>3,851</b>	<b>64,711</b>
<b>EQUITY</b>			
Total equity	52,098		52,098
Total non-current liabilities	940	2,543	3,716
Total current liabilities	7,822	1,075	8,897
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>60,859</b>	<b>3,618</b>	<b>64,711</b>

## NOTE 26 Significant events after the financial year-end

In early May 2019, the company implemented a targeted new share issue that generated SEK 60 million. The price of Biovica's Class B share amounted to SEK 10 and it was established via a book building process. The new share issue resulted in dilution of approximately 25.5 percent on the number of shares and 15.7 percent on the number of votes in Biovica (calculated on the number of outstanding shares after the new issue). The new issue increases the number of outstanding shares by 6,000,000 from

17,573,372 to 23,573,372 and the number of votes increases from 32,168,248 to 38,168,248 (allocated between 7,297,438 Class A shares and 16,275,934 Class B shares). Share capital increased by SEK 400,000.00 (from SEK 1,171,558.13 to SEK 1,571,558.13).

The reason for deviating from shareholders' preemptive rights was the desire to broaden our ownership base, adding more Swedish and international institutional investors. The Board and main owners were also in agreement that this was the best opportunity for acquiring capital on favorable terms.

Before the new share issue, Biovica's largest shareholder, Anders Rylander, CEO and member of Biovica's Board of Directors owned 22% (via company) of Biovica's shares, which corresponds to 34 % of the votes in the Company. After the targeted new share issue, Anders Rylander's holding was 17% of the shares and 29% of the votes in the Company.



# The Board of Directors' and CEO's assurance

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The consolidated income statement and balance sheet will be brought forth at the Annual General Meeting on 29 August 2019 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 have been prepared in accordance with generally accepted accounting principles 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, 28 June 2019

Lars Holmqvist  
*Chairman of the Board*

Maria Holmlund  
*Board member*

Jarl Ulf Jungnelius  
*Board member*

Jesper Söderqvist  
*Board member*

Anders Rylander  
*President/CEO, Board member*

Our audit report was issued on 28 June 2019

Grant Thornton Sweden AB

Stéphanie Ljungberg  
*Authorised Public Accountant*

# Audit report

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

## REPORT ON THE ANNUAL REPORT AND CONSOLIDATED FINANCIAL STATEMENTS

### Opinions

We have conducted an audit of the annual report and consolidated financial statements of Biovica International AB (publ) for the financial year 2018-05-01 -- 2019-04-30, except for the corporate governance report on pages uu-vv. The company's annual report and consolidated financial statements are provided on pages xx-yy of this document.

In our opinion, the annual report has been prepared in accordance with the Annual Accounts Act and in all material respects, it gives a true and fair view of the Parent Company's financial position as at 30 December 2019 and of its financial performance and cash flow for the year in accordance with the Annual Accounts Act. The consolidated financial statements have been prepared in accordance with the Annual Accounts Act and in all material respects, they give a true and fair view of the Group's financial position as at 30 December 2019 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. Our opinions do not cover the corporate governance report on pages uu-vv. The Board of Directors' report is consistent with the other parts of the annual report and the consolidated financial statements.

We therefore recommend that the general meeting of shareholders should adopt the income statements and balance sheets 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 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 as a basis for our opinions.

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

The Board and the CEO are responsible for this other information. The other information comprises pages aa-bb and pages ää-öö of this document (but does not include the annual report, consolidated financial statements and our audit report on those).

Our opinion on the financial statements and consolidated financial statements does not include this other information, and we make no statement of assurance regarding this other information.

In connection with our audit of the financial statements, it is our responsibility to read the information identified above and consider whether the information is substantially incompatible with the financial statements and consolidated financial statements. During this review, we also take into account knowledge we obtained during the audit and we assess whether the information in general seems to contain material misstatements.

If, based on the work that has been conducted on this information, we conclude that the other information contains a material misstatement, we are obliged to report it. We have nothing to report in that regard.

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

The Board and the CEO are responsible for preparing an annual report and consolidated financial statements that provide a true and fair view in accordance with the Annual Accounts Act and with regard to the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU. The Board of Directors and CEO are also responsible for any internal control they deem necessary for preparing an annual report and consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements the Board and CEO are responsible for assessing the ability of the Company and Group to continue operations. They must disclose, when applicable, any circumstances that may affect the ability to continue operations and apply the assumption of continued operations. However, the assumption of continued operations is not applied if the Board and CEO intend to liquidate the company, cease operations, or if they have no realistic alternatives than either of these two options.

### Auditor's responsibility

Our goal is to achieve a reasonable degree of assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to submit an audit report containing our opinions. Reasonable assurance is a high degree of assurance. However, it does not guarantee that an audit performed in accordance with ISA and generally accepted auditing standards in Sweden will always detect a material misstatement if one exists. Errors may occur due to fraud or error, and they are deemed material if, individually or together they can reasonably be expected to influence the economic decisions that users make based on the financial statements and consolidated financial statements.

As part of an audit in accordance with ISA, we use professional judgment apply professional skepticism throughout the entire audit. We also:

- identify and assess the risks of material misstatement of the annual report and consolidated financial statements, 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 report and consolidated financial statements. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists relate to events or conditions that may cast significant doubt on the company's and group's ability to continue as a going concern. If we conclude that there is a substantial element of uncertainty, we must in the auditor's report draw attention to the information in the annual report and consolidated financial statements on the essential element of uncertainty, or, if such information is insufficient, modify our opinion on the annual report and consolidated financial statements. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or circumstances could arise such that the company or Group is no longer able to continue operations.
- we evaluate the overall presentation, structure and content of the annual report and consolidated financial statements, including the disclosures, and whether the annual report and consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- we collect adequate and sufficient audit evidence on the financial information for the units or business activities within the Group for stating an opinion on the consolidated financial statements. We are responsible for the control,

monitoring and execution of the Group audit. We are 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 have identified.

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

##### **Opinions**

In addition to our audit of the financial statements 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 2018-05-01 -- 2019-04-30 and the proposed appropriation of the profit or loss.

We recommend to the general meeting of shareholders that the appropriation of profit should be in accordance with the proposal in the Board of Directors' report and that the members of the Board of Directors and the CEO should be discharged from liability for the fiscal year.

##### **Basis for opinions**

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Our responsibility in accordance with this is described in the section, Auditor's responsibility. We are independent of the 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 as a basis for our opinions.

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

The Board of Directors is responsible for the proposed appropriation of the company's profit or loss. With proposal of a dividend,

this includes an assessment of whether the dividend is justifiable considering the demands that the nature of operations, scope and risks place on the size of the company's and Group's equity, consolidation requirements, liquidity and position in general.

The Board is responsible for the company's organization and management of its affairs. This includes, for example, assessment of the company's and Group's financial situation on an ongoing basis and ensuring that the company is organized such that there are adequate controls on its bookkeeping, fund management and other financial matters. The CEO is responsible for ongoing management that is in accordance with the Board's guidelines and instructions, including taking the actions necessary to ensure that the company's accounting complies with law and that assets are managed in a satisfactory manner.

##### **Auditor's responsibility**

Our goal regarding the audit of the administration, and therefore our opinion, is to obtain audit evidence that with a reasonable degree of certainty enables us to determine whether any Board member 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
- or in any other way acted in contravention of the Swedish Companies Act, Annual Accounts 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 proposal for dispositions of the company's profit or loss is based primarily 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.

#### **Auditor's review of the corporate governance report**

The Board of Directors is responsible for the 2018 Corporate Governance Report on pages uu-vv and for ensuring that it has been prepared in accordance with the Annual Accounts Act. Our review has been conducted in accordance with RevU 16, Auditor's Review of the Corporate Governance Report. This means that our review of the Corporate Governance Report has a different focus and significantly smaller scope than the focus and scope required for performing an audit in accordance with International Standards on Auditing and generally accepted auditing practices in

Sweden. We believe that this review provides a reasonable basis for our opinion set out below.

A corporate governance report has been prepared. Disclosures in accordance with Chapter 6, Section 6, second paragraph, items 2-6 of the Annual Accounts Act, along with Chapter 7, Section 31, second paragraph of the Annual Accounts Act are consistent with the other parts of the annual report and consolidated financial statements, as well as in accordance with the Annual Accounts Act.

Uppsala, 28 June 2019  
Grant Thornton

**Stéphanie Ljungberg**  
AUTHORISED PUBLIC ACCOUNTANT



# Glossary

**510(k)** 510(k) premarket notification. This is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to Premarket Approval (PMA).

**AACR** American Association for Cancer Research

**Adjuvant** Adjuvant therapy is given to prevent recurrence of a disease. It is known as adjunct therapy, add-on therapy, and adjuvant care. It is common following, for example, an operation for breast cancer or colon cancer; particularly in cases where the cancer tumor is growing aggressively.

**Hormone therapy** See Endocrine therapy

**ASCO** American Society of Clinical Oncology

**BIG** Breast International Group

**Diagnostic imaging** This is a collective term for the technique and process of creating visual representations of the interior of the human body for medical purposes. It includes radiology, endoscopy and microscopy, as well as medical applications of imaging and visualization.

**Biopsy** or tissue sampling is when samples are taken from living body tissue for further examination, which is often performed using a microscope and for the purpose of diagnosis.

**CDK inhibitor** *Cyclin-Dependent Kinase inhibitor*. CDK inhibitors belong to a new group of drugs that inhibit the function of CDK proteins, which regulate the cell cycle. CDK inhibitors are used to treat cancer by inhibiting the proliferation of cancer cells. The US FDA approved the first CDK inhibitor drug, palbociclib (IBRANCE®) in February 2015, and the European EMA approved the drug in November 2016. IBRANCE® is a CDK4/6 inhibitor that has been approved for treating women with metastatic, hormone-receptor-positive, breast cancer. More drugs in this same class are being developed.

**Chemotherapy** also called cytostatics is a drug treatment that uses powerful chemicals to kill cells in the human body. These drugs primarily target fast-growing (proliferating) cells.

**Cell proliferation** see Proliferation

**CT** *Computed Tomography* is an imaging procedure that uses special x-ray equipment to create detailed pictures, or scans, of areas inside the body. It is also called computerized tomography and computerized axial tomography (CAT). It allows you to view and inspect the external and internal structures of an object in 3D space. Ordinary X-rays only produce 2D images.

**ELISA** *Enzyme-Linked Immunosorbent Assay*. This is a method for quantifying and detecting an antibody or antigen in a sample.

**Endocrine therapy** or Hormone therapy. With endocrine therapy, tumor cells that depend on certain hormones (such as estrogen) for their growth are inhibited by either lowering the estrogen levels in the body or by blocking the estrogen receptors. It thus slows or stops the growth of hormone-sensitive tumors. Women with hormone receptor-positive breast cancer are typically prescribed endocrine drugs.

**Hematologic malignancies** Hematologic malignancies are types of blood cancer. Examples are acute and chronic leukemias, various forms of lymphoma, myeloma, myeloproliferative neoplasias and myelodysplastic syndrome.

**Hormone-receptor-positive, breast cancer** A hormone-receptor-positive tumor consists of cells that have receptors for various types of hormones. A cancer is called estrogen-receptor-positive (or ER+) if it has receptors for estrogen. There are also progesterone-receptor-positive tumors (PR+). For continued cell proliferation, ER+ tumors require the presence of estrogen.

**IBCSG** The International Breast Cancer Study Group

**In vitro** In vitro is a term that describes a biological process that has occurred outside of a living cell or organism, such as in a test tube or petri/culture dish.

**Invasive** Invasive medical examinations include methods of penetrating the body with instruments through an orifice or via a surgical procedure.

**IVD** An IVD Medical Device is intended by the manufacturer for the in-vitro examination of samples (including donated blood and donated tissue) from the human body for the purpose of obtaining, solely or principally, information on a physiological condition or disease state, or a congenital malformation or which makes it possible to determine safety and compatibility with possible recipients, to monitor therapeutic procedures.

**MRI** Magnetic resonance imaging is a medical imaging technique. It is used to detect, determine and classify certain diseases and injuries that are difficult to detect with traditional X-ray or computer tomography.

**Targeted therapy** Targeted therapy is one of the most important types of cancer treatments. Targeted therapy works by targeting the cancer's specific genes, proteins, or the tissue environment that contributes to cancer growth and survival.

**PET** A positron emission tomography scan is a type of 3D imaging test. It uses a radioactive substance called a tracer to look for disease in the body or observe metabolic processes.

**PMA** *Pre-Market Approval (PMA)* is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. This class includes those products that support or maintain human life, are of vital importance for preventing deterioration of human health, or which are considered to pose a high risk of complications. Devices for which there is no legally marketed predicate device in USA have automatic Class III designation via the De Novo Classification Process.

**Poster presentation** Results from studies are presented on a large poster at a scientific conference. Visitors and attendees are then able to discuss the results with the researchers.

**Proliferation** This is the word used when speaking of the growth of cells. A tissue with a high rate of proliferation contains many cells that are growing.

**Prospective** A prospective study is a cohort study, where the focus is future-oriented (retrospective, on the other hand, looks to the past). A prospective study is used to study the relationship between various risk factors and a particular disease. This type of study follows individuals both with risk factors and without (the control group), for a period of time into the future.

**Retrospective** A retrospective study is a scientific study where a period of time in the past is studied to understand what has happened.

**SABCS** San Antonio Breast Cancer Symposium

**Metastatic breast cancer** This is the term used for describing breast cancer that is in the advanced stage or has spread to other parts of the body. It means that the cancer cells have spread from the place where they first formed (primary tumor) to another part of the body (metastatic tumors). Breast cancer that has spread to other parts of the breast and surrounding tissues (but not to primary organs) is often called locally advanced breast cancer.

**TK activity** TK (thymidine kinase) is an enzyme present in cells during cell division. The level of TK activity is thus closely correlated with tumor cell proliferation rate and aggressiveness.

**Toxic treatment** This is treatment with drugs in doses that cause damage to the body's normal tissues and cells.

**Thymidine kinase (TK)** Thymidine kinase is an enzyme present in cells during cell division. The enzyme plays an important role in cell proliferation, since TK is one of four nucleotides required for DNA synthesis.



# Shareholder information

## AGM

The AGM for the 2018/2019 financial year will be held on 29 August 2019 at 4 p.m. The location is Hubben, Dag Hammarskjölds väg 38 in Uppsala, Sweden. Notice of the AGM will be published on Biovica's website, in Post- och Inrikes Tidningar (gazette) and in SvD (newspaper). The Board of Directors proposes that no dividends shall be distributed to shareholders.

Shareholders who would like to participate in the AGM must be registered in the shareholders' register maintained by Euroclear Sweden AB by Friday 23 August 2019. That is also the deadline for registering intent to participate in the AGM. Notification is by letter to: Biovica International AB, att. Cecilia Driving, Dag Hammarskjölds väg 54B, 752 37 Uppsala, by telephone: +46 (0)18 444 48 30 or by email: [info@biovica.com](mailto:info@biovica.com).

## NOMINATION COMMITTEE

The Nomination Committee has been appointed in accordance with the AGM guidelines and its members are: Gunnar Rylander, Leif Glantz and Biovica's Chairman of the Board, Lars Holmqvist. If you would like to contact the Nomination Committee, please send an email to: [ir@biovica.com](mailto:ir@biovica.com)

## FUTURE REPORTING DATES:

Q1 Interim Report: May-July 2019/2020	29 August 2019
AGM	29 August 2019
Q2 Interim Report: August-October 2019/2020	5 December 2019
Q3 Interim Report: November-January 2019/2020	12 March 2020
Year-end Report for 2019/2020:	12 June 2020

## MORE INFORMATION

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