

# ANNUAL REPORT 2019

CALMARK SWEDEN AB (PUBL) 556696-0141  
ACCOUNTING YEAR 01/01/2019 - 31/12/2019



# Caring for a calm start

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## THIS IS CALMARK

Calmark is a medical technology company developing a point-of-care (POC) analysis method with easier and faster sampling of medical conditions in newborns. The unique test platform consists of a reader and single-use products. The first three tests are being launched in 2020. WHO predicts 1.5 billion children to be born worldwide prior to 2030. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter care chains.

In less developed healthcare systems, the product will offer a decision support which is currently lacking, since the access to hospital laboratories often is limited. Calmark aims to become the global leader in POC diagnostics for newborns and, in the long term, to offer all relevant tests for the first period of life. The B share is listed on the Spotlight Stock Market and is traded under the CALMA B ticker. Read more at [www.calmark.se/eng/home](http://www.calmark.se/eng/home).

## COMPANY INFORMATION

Calmark Sweden AB (publ)

**Corporate Identity Number:** 556696-0141

**Legal form:** Public limited company

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**Telephone:** +46 70 213 25 35

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**Definition**

"The Company" refers to Calmark Sweden AB (publ) with corporate identity number 556696-0141.

All figures are stated in SEK unless otherwise indicated.

Calmark's B-share is listed on Spotlight Stock Market with the short name "CALMA B".





# YEAR IN BRIEF

## Q1

- On January 11, Calmark received approval from Chinese authorities of their application for design protection in China for the reader. The design already has protection in Europe and the USA.
- On January 18, an agreement was signed with Frohe AB regarding manufacturing Calmark's single-use product.
- On January 21, the board at Calmark Sweden AB indicated that the decision was made to prioritize the CE-marking of the bilirubin test separately, before the other tests, in order to get the test to market faster and generate revenue earlier.
- On January 22, it was announced that Emma Lif was recruited as Clinical Director. Her position began on March 1.
- On February 8, the first reader, that was manufactured in the production environment of Note AB, was delivered.
- On February 14, the first single-use products, that were manufactured in the Frohe AB production environment, were delivered.
- On February 22, the board of directors of Calmark Sweden AB decided on a preliminary launch strategy for the company's products. In the first phase, the launch will take place in the Nordic region, the UK and Vietnam, followed by gradually expanding to multiple countries in Europe as well as Singapore, Malaysia and India.
- On February 25, the Ministry of Science and Technology in Vietnam approved Calmark's patent application regarding the "Testing system for determining hypoxia induced cellular damage." The patent is part of in Calmark's patent family regarding the methodology for the biomarker LDH and is valid until 2030.

## Q2

- On April 15, Calmark announced that they had been nominated as the best IPO company in 2018 by the IPO guide that was organized by SvD Borsplus. On May 22, Calmark was awarded an honorary mention as the runner-up micro-company in the Quality category.
- On May 9, the annual general meeting was held for Calmark Sweden AB (publ). At the annual meeting, the decision was made to empower the board, until the next annual meeting, to be able to make decisions about issuing a maximum number of B-shares and/or warrants that carry the right to subscribe to newly issued shares, or involve issuing a maximum number of B-shares to a maximum amount of SEK 25 000 000 (total issue payment), with or without deviating from the shareholders' preferential rights. The entire board was re-elected.
- On May 16, negotiations started with Triolab regarding a distributor agreement in the Nordic region and Baltic countries.
- On June 4, approval of the application for design protection for the reader was also granted in India.
- The outcome of warrant exercise in the TO 1 B series was published on June 17. The overall exercise rate amounted to approximately 83%, and the company received approximately SEK 13.4 million before issue expenses.
- On June 26, the scientific journal Scientific Reports published an article with the results of Calmark's early clinical study from 2015/2016 that was conducted in Stockholm and Hanoi. The article concludes that the POC analysis method provided reliable results within four minutes.

## Q3

- On July 5, Calmark Sweden AB received approval for its application for design protection for the reader in Vietnam as well.
- On August 15, Calmark announced the addition of an experienced international sales director to the team, Marianne Alksnis, who started the position on October 15.
- On September 2, SvD Borsplus updated their analysis of Calmark's shares saying, "Calmark is more interesting as an investment now than the last time we analyzed the company. The company is slightly ahead of schedule and a successful issue of warrants has strengthened their cash reserves. We see an upside if everything goes as planned. We are raising our recommendation for Calmark slightly."
- On September 13, equipment was delivered for the first phase in the automated production line for the single-use product. The assembly equipment was manufactured by AutomationsPartner in Ramlösa and was installed at Calmark's production partner Frohe AB in Tyresö.

## Q4

- On October 7, a 100% secured rights issue of SEK 24.3 million was announced.
- On October 8, it was announced that the project for the bilirubin biomarker entered into the verification and validation phases.
- On October 18, Calmark announced that the company's products for the LDH and Glucose biomarkers will be CE-marked during the first quarter of 2020, the market launch is not expected to be impacted.
- On November 6, Calmark held an extraordinary general meeting due to the scheduled rights issue.
- On November 7, the Swedish Ethical Review Authority announced that Calmark's application regarding the study on newborns at Sachsska pediatric clinic at Södersjukhuset hospital had been approved.
- On November 14, a statement was published on account of the rights issue of units that was adopted at the extraordinary general meeting.
- On November 27, it was announced that the legal department at Södersjukhuset hospital approved the clinical trial.
- The results of the rights issue were published on December 4. The issue was subscribed to approximately SEK 34.6 million, corresponding to a subscription rate of approximately 142.4% and brought the company approximately SEK 24.3 million before issue expenses.
- On December 4, it was also announced that Creades AB became the third largest owner in Calmark after having signed and acquired B-shares corresponding to 9.44% of share capital.
- On December 23, the final remaining milestone for 2019 was achieved, as previously communicated, when the first patient was included in the clinical study at Södersjukhuset hospital.
- On December 23, it was also announced that Calmark's first product Neo-Bilirubin was scheduled to be CE-marked in January 2020.
- Calmark's rights issue was registered on December 23, 2019.



At the award ceremony on May 22, 2019 for the "IPO of the Year 2018", Calmark was given an honorary mention since the company had zero warning flags and was the second place micro-company in the Quality category and the fifth place winner in the Price Trend category.



## CEO COMMENTS

### A STABLE PLATFORM PRIOR TO MARKET LAUNCH

Calmark attracted a lot of attention in 2019, both from investors as well as distributors from all corners of the globe. This has strengthened my conviction that we have a unique concept that really can make a difference!

In 2019, Calmark refilled their cash reserves twice by redeeming warrants in June and through a rights issue at the end of the year. Many new owners invested in the company, including Creades, which further proves that we have an interesting case. Our share issues mean that we have good liquidity going into 2020, which is a nice feeling to have in these unstable times. The money we took in will firstly be used to invest in production in order to ensure that we have low production costs and the capacity for a global launch. Having production facilities near-by provides security, and I have been impressed with their competency and problem-solving skills over the past year. In 2020, work will continue automating production even further.

The organization has grown over the past year, both on the development side and on the sales/clinical side. As the development project ended, we started a pre-launch of our platform. We displayed the product at international trade exhibits and met a large number of potential distributors. There has been strong interest in our products from many parts of the world, which bodes well for the future.

My team has made it a point to meet all of the established goals for the company by the prescribed time. By December 2019, we were able to achieve all of our previously announced milestones without any delays, which is very unusual for a medtech company in the development phase. However, the last milestone of completing the clinical trial has been forced to be delayed, which means that the CE mark is not yet in place. At the time of writing, there are a small number of children remaining to be included before we can complete the CE-marking of our first product Neo-Bilirubin. In these times of the COVID-19 pandemic and a healthcare system under great strain, it is difficult to predict what the coming



months will look like. However, appreciation of the importance of quick, point-of-care diagnostics has probably increased.

In a turbulent time, where the world around us and the conditions in it change on a daily basis, I am happy that we have already built a stable platform for the future; a competent, dedicated team; production lines that are already prepared and not least a strong owner group that has chosen to put their trust in us. At the same time, I am humbled by the challenges and consequences that the pandemic poses for us.

Despite the global instability at the start of the year, I remain positive about Calmark's opportunities to enter the market with our product in 2020 and to start fulfilling our mission to provide all children with a calm start in life.

  
Anna Söderlund  
CEO, Calmark Sweden AB



# AN INNOVATIVE PRODUCT

## DEVELOPMENT OF PRODUCTS

Calmark is developing a point-of-care (POC) diagnostic analysis method, which makes it easier and faster to measure biomarkers for medical conditions in newborns. In developed healthcare systems, the product will lead to faster responses for healthcare professionals, shorter waiting times for the newborn and its family, and smarter healthcare chains that save time and money. In less-developed healthcare systems, Calmark will be able to offer an instrument for diagnostics that currently does not exist, because access to hospital laboratories is often limited. Even though the survival rate for children up to five years has almost doubled in the world since 1990, survival within the first 28 days has not increased at the same rate. Being able to diagnose common medical conditions that can be easily treated can make a big difference.

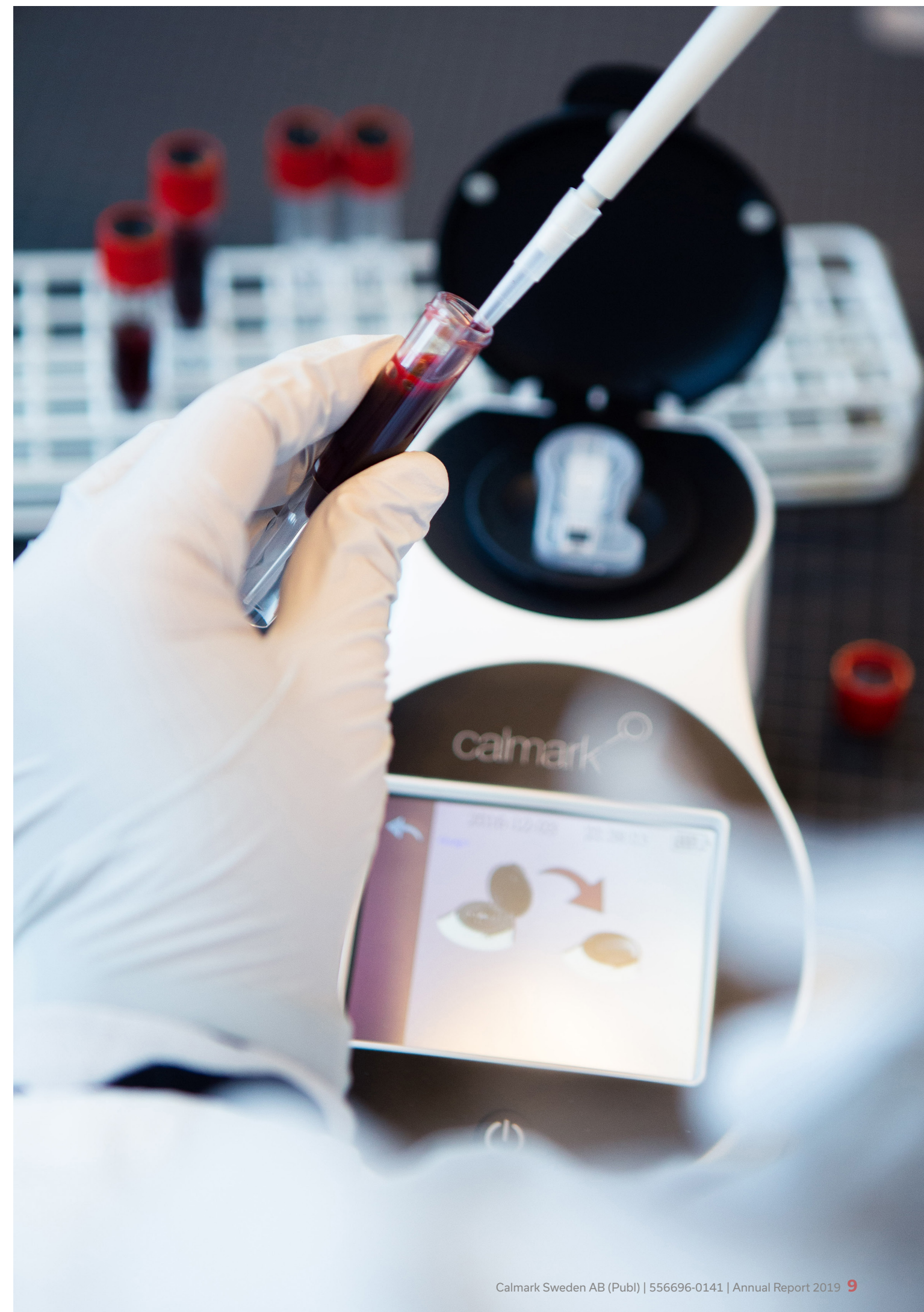
Calmark Neo consists of a reader and single-use tests. Testing can take place where the patient is, for example, during a return visit to the maternity unit or at the delivery ward right after the baby's birth.

Two of the most common tests that are taken during a child's first week of life include bilirubin and glucose. As a first step, Calmark will launch point-of-care tests for measuring these markers and for the LDH biomarker, see below. Each test is CE-marked separately with the reader and launched as a separate product.

The reader is design-protected and contains electronics, software and a camera. The single-use product consists of plastic parts and a filter construction impregnated with chemicals. When the reader's lid is closed, the single-use product is activated, and blood hits a filter that changes color based on its chemistry. The changing color is then converted to a numerical value using the reader's software. This process occurs within a few minutes and is a process patented by Calmark.

By changing the chemicals in the filter, different tests can be developed using the same platform. Calmark plans to continue developing more tests once these three biomarkers are completed. Calmark wants to reconcile the qualitative demands placed on point-of-care diagnostics here in Sweden with the criteria required for point-of-care diagnostics to function on a global level. The objective is to become the global leader in point-of-care products for newborns and eventually offer all of the relevant tests for the first period in life.

*The Calmark Neo platform consists of a reader, Neo-Reader, and different single-use tests that quickly detect medical conditions in newborns.*







## CE MARKING

Medical technology products to be sold to the healthcare industry must meet high safety and regulatory requirements. The products are tested in several stages: in a laboratory environment, by an independent testing institute, and finally on patients. All tests are performed on products manufactured on the production lines that will be used, and by suppliers certified in accordance with ISO 13485.

These verification- and validation phases for the first test Calmark Neo-Bilirubin began in the autumn of 2019, which involves ensuring that the product meets technical requirements, accuracy requirements and all applicable standards. Most of the tests in the verification phase were carried out at Calmark's laboratory by analyzing the same blood at Calmark Neo and sending it to the reference laboratory at Karolinska Hospital as well, and comparing the results. In addition, transport studies and sustainability studies were carried out.

Prior to CE-marking, the product also needs to be tested on patients, which takes place in a clinical trial. The trial is being run by the research department at Sachsska pediatric clinic in the Södersjukhuset hospital, which includes children on a voluntary basis during daytime. Work on validating Neo-Bilirubin started in the fall of 2019 in parallel with verification. When this report was written, a few children still needed to be included.

The reader is CE-marked together with each individual biomarker, which means that the development project for the first product, Neo-Bilirubin, is the most extensive. The CE-marking and launch of the tests for the biomarkers glucose and LDH is also scheduled to take place in 2020.

Calmark's products will follow the regulations for in vitro devices (IVDD/IVDR), which means that no notified body (i.e. an external auditor) is needed to perform the CE-marking.

## Neo-LDH - asphyxia

LDH (lactate dehydrogenase) is a substance found naturally in all of the body's cells and helps convert sugar to lactic acid. If the body is injured, the cell releases LDH freely into the bloodstream. For example, LDH rises when a baby experiences oxygen deficiency (asphyxia) during delivery. An elevated value along with other symptoms after childbirth is a sign that action needs to be taken. In Sweden, about 10% of childbirths are complicated, and a pediatrician needs to be involved.

By measuring LDH in the baby's blood after childbirth, an important test response is obtained, which facilitates the decision to quickly begin treatment and thus reduce the risk of permanent brain damage or, in the worst case, death, which could otherwise be the outcome. The development of the LDH test is central for Calmark, as there is no other globally established player that offers POC diagnostics for LDH in newborns.

## Neo-Glucose - blood sugar

Around 15 to 20% of newborn babies suffer from low blood sugar during the first few days of life. This is because, after birth, the baby should be able to keep its blood sugar at normal levels on its own, after having received sugar directly from the mother via the umbilical cord during pregnancy.

If the baby shows signs of low blood sugar, or if it is part of a risk group, the baby's blood sugar level should be monitored. In the event of low blood sugar levels, the baby should be treated with extra milk or glucose. Untreated low levels of blood sugar can otherwise lead to permanent brain damage in the newborn. There are many POC blood glucose meters on the market, but they are not optimized for the low levels in newborns.

## Neo-Bilirubin - jaundice

Bilirubin is a waste product released when blood cells break down, which is a natural process in the body. The degradation occurs mostly in the liver, but since the newborn's liver function is immature, it takes some time before the degradation takes place in an effective way, which leads to the levels of bilirubin rising.

Bilirubin is yellow in color, and in 60 to 80% of all newborns, the skin becomes slightly yellow during the first week of life, known as neonatal jaundice. The yellow color usually disappears spontaneously, but some children need phototherapy for the skin, which helps the bilirubin disappear faster from the body. In the Nordic countries, about 5% of all newborns receive this treatment, and in the rest of the world, the proportion is often higher.

Excessively high levels of bilirubin can be harmful and lead to persistent neurological disease or, at worst, death, if not detected and treated. It is therefore important to be able to measure the amount of bilirubin in the blood, and it is the most common blood test taken in newborns. In the US, for example, about 40% of all newborns need at least one test. The bilirubin test is the product that Calmark estimates has the greatest market potential, so this is the test that will be launched first.





# BUILDING THE PRODUCTION LINES AND ORGANIZATION

## START OF PRODUCTION

The process of building production intensified in 2019 with investments and quality control of production lines for both the reader and the single-use product. Calmark has chosen to use high-quality suppliers in Sweden to gain proximity, speed and flexibility in the sensitive fine-tuning period. Both suppliers have very high capacity and can handle the expected future increase in production demand.

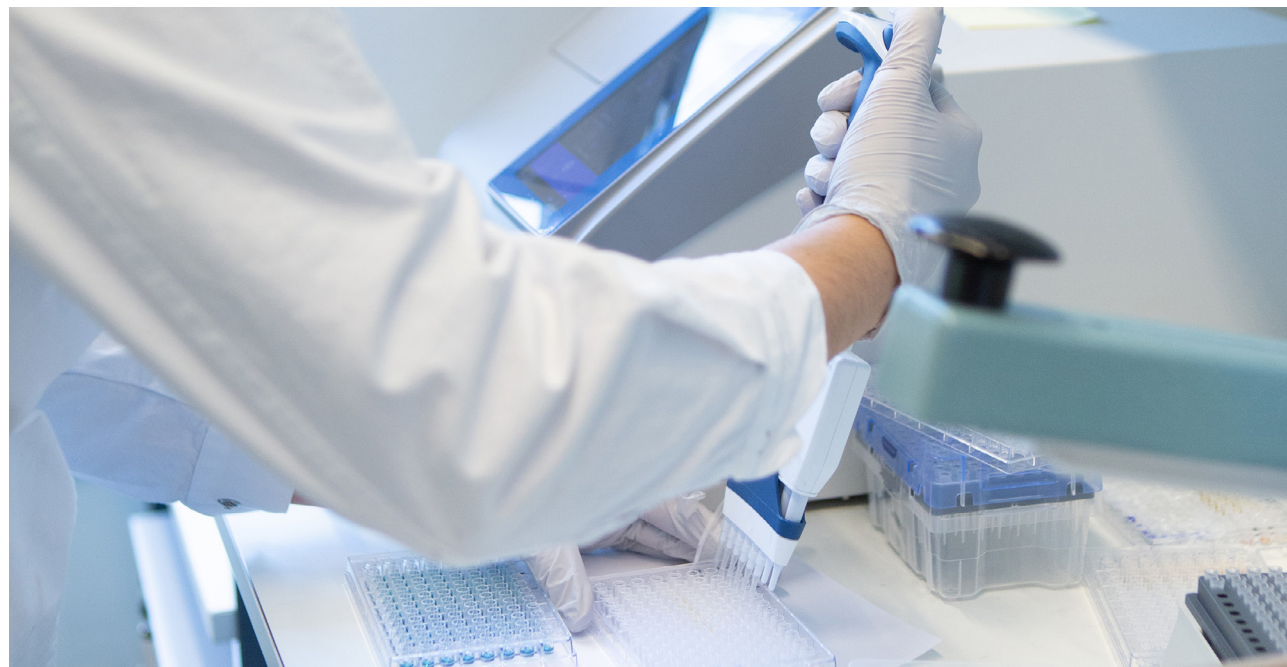
The single-use product is manufactured by Frohe AB in Tyresö, which specializes in the manufacture of complex and advanced plastic parts with very high precision requirements. The company holds ISO 13485 certification, which is required to manufacture Calmark's products. Frohe also has extensive experience in manufacturing similar products for customers in the medical technology field. The production line will be developed in several steps to cope with increased volumes of the product. The first two stages of production development were completed in 2019 and approved according to the applicable standards.

The reader is manufactured by Note AB in Norrtälje, a leading northern European manufacturing partner with an international platform for manufacturing electronic-based products. Note specializes in manufacturing that requires a high level of technical expertise and flexibility during the product lifecycle. Note also holds ISO 13485 certification, which is required to manufacture Calmark's products.

In February 2019, the first series-manufactured products were delivered from both of these production lines. The products are used in the continued CE-marking process but will later be available in hospitals for testing newborns.

Calmark is planning for a global launch of their products, starting in 2020. In order to be successful globally, a well-developed production with a large amount of capacity is required.

In the coming years, Calmark will continue to work on expanding the production lines in multiple steps in order to be able to increase capacity as launches are made in more countries. The work reducing production costs and streamlining production is taking place in parallel and in close collaboration with both suppliers Frohe and Note.



## STRENGTHENING THE TEAM

During the year, Calmark strengthened the organization with the relevant skills and resources in several areas in order to complete the development project, perform clinical trials and start selling internationally. First up was the role as Clinical Director, which is held by Emma Lif. This was announced on January 22.

On August 15, the team was strengthened with an experienced international sales director. Marianne Alksnis took on the role on October 15 and is responsible for establishing a broad distributor network which will make up the core of Calmark's sales strategy.

A new CFO on a consulting basis, Sara Wili-Blomé was hired as of April 1, 2019 on a part-time basis via the Inhouse AB staffing agency.

The software resources were secured through agreements with Evidente and an extended agreement with Code is King AB. The agreement with Stravus AB was extended, which provides services in terms of project management and quality assurance through the consultant Michael Lundh. The agreement with Marknadsmotivation Sverige AB was also extended, which provides marketing and communication services through the consultant Camilla Arneving.

Calmark expects to continue expanding the organization ahead of and during the product launches.

## SECURING FINANCING

Calmark performed two share issues during 2019. The redemption period for the warrants that were subscribed during the IPO took place in June. The results of redeeming the warrants was a subscription rate of approximately 83%, which brought in SEK 13.4 million to the company before issue expenses.

In October, an extraordinary general meeting was held where it was decided that a rights issue would be held in November. During the rights issue, units were offered consisting of twelve (12) new B-shares and four (4) free subscription warrants for the 2019/2020 series for every twenty-one (21) existing shares that were held on the date of record, November 13. The issue was performed in cooperation with Stockholm Corporate Finance and had a subscription rate of 142%, which brought in SEK 24.2 million to the company before issue expenses.

The warrants are traded under the name CALMA TO2 on the Spotlight Stock Market. Subscribing to B-shares using warrants can take place as of December 4, 2020 until December 16, 2020. The subscription price per B-share shall correspond to 75 percent of the volume-weighted average price as of October 12, 2020 until October 23, 2020, however with a minimum of SEK 4.20 and a maximum of SEK 6.60. Full subscription of the warrants will bring Calmark between approximately SEK 10.3 million and 16.2 million before issue expenses.





# LAUNCH IN AN EXPANSIVE MARKET

## MARKET POTENTIAL

Calmark's product is the first POC analysis platform that is completely optimized for newborns. The platform meets a need on the market that has previously not been filled.

In the countries where there is a well-developed healthcare and medical system, Calmark's product will facilitate the care processes for the smallest patients and their families. The POC tests make things easier for those who work in healthcare and provide valuable information for doctors, nurses and midwives to make decisions. In less developed countries, Calmark's product will offer an opportunity to diagnose common medical conditions where access to hospital laboratories is limited, and thereby it may be possible to reduce the prevalence of disease and save lives.

Calmark intends to generate revenue through the sale of readers and single-use products. According to the assessment by the board of directors, the market for Calmark's POC instrument is extensive. Until 2030, WHO estimates that 1.5 billion children will be born worldwide. The three tests that Calmark is developing in the first launch phase are all designed to diagnose common conditions that are easy to treat. Of all newborns, approximately 20% are estimated to have a clinical need for one or more of these tests.

The general trend also shows a strong increase in POC analyses that constitute a growing part of the laboratory medical examinations in modern healthcare. Demand is growing as a result of value changes in the healthcare sector and increased technological advances.

The global POC market for 2019 amounted to approximately USD 28.5 billion and is estimated to reach approximately USD 46.7 billion by 2024<sup>1</sup>.

## LAUNCH

In 2019, the planning work for the global launch of the products continued. Calmark Neo was demonstrated at two international trade exhibitions at the end of 2019 and the start of 2020. The product aroused a lot of attention. Conversations were held with a large number of distributors from around the globe. In the first phase, the products are planned to be launched in the domestic market of the Nordic countries and the UK. Registration in Vietnam will start as soon as the CE-mark is ready for Europe.

The first exclusive distributor agreement was signed on February 14, 2020 with Triolab AB and covers the Swedish market. Triolab is active within the customer segments that are important for Calmark, and they sell blood gas equipment for maternity departments and intensive care departments.

The launch plan is expanded in phase two by adding countries in Europe and Southeast Asia. Registrations and distributor networks will be primarily sought in Vietnam, Singapore and Malaysia, but also in markets where the CE-mark is valid, and there is a lot of interest, for example in the Middle East. In terms of size, India is considered to be an interesting market for Calmark's launch after this. Based on WHO's estimates, approx. 300 million children will be born until 2030 in India.

For the important markets of China and the USA, registration, equivalent to the CE-mark which is now taking place and which applies to Europe is planned to be started within a two-year period.

1) <https://www.marketsandmarkets.com/PressReleases/point-of-care-diagnostic.asp>



# BOARD OF DIRECTORS



## **Mathias Karlsson – Chairman of the board since 2016 and co-founder**

Mathias Karlsson, born in 1972, is Calmark's founder and also the company's medical advisor. Dr. Karlsson is a physician and completed his doctoral thesis at Karolinska Institute in Sweden in the field of perinatal asphyxia. He has also worked as chief manager in the county council sector and is the founder and co-owner of HemCheck Sweden AB, and thus has experience with the market as well as with the listed company. On May 1, 2019, Mathias Karlsson took over as Chief Medical Officer for the Nordic region at IBM.



## **Anna-Karin Edstedt Bonamy – Board member since 2018**

Anna-Karin Edstedt Bonamy, born in 1974, received a PhD in pediatrics from Karolinska Institutet in 2008 and has been a specialist in pediatric and youth medicine since 2009. She worked as a medical doctor in neonatal care between 2006 and 2017. In her research, she has led the Swedish section of a large European research project (EPICE) on the care of premature babies. Since 2014, Edstedt Bonamy has been associate professor of pediatrics at Karolinska Institutet. In 2017, Edstedt Bonamy started working on the e-health company Doctrin AB, where she is now Medical Director and Head of Medical Product Development.



## **Kjersti Berg Marthinsen - Board member since 2018**

Kjersti Berg Marthinsen, born in 1972, holds an MSc in strategy from BI Norwegian Business School in Oslo. She has worked for several years as a consultant both nationally and internationally with assignments in the areas of strategy, organizational development and management and governance. In recent years, she has held various senior positions at Värmland County Council, with responsibility for among other things, planning and monitoring, development support, innovation support and the Council's investment in service design and user involvement. In 2018, Berg Marthinsen started working as a management consultant at Effect Management Development AB.



## **Stefan Blomsterberg - Board member since 2018**

Stefan Blomsterberg, born in 1964, was trained in the Swedish Armed Forces and has worked in education development and pedagogy, as well as with international armament control. Blomsterberg started working within medtech in 2002 and has held senior positions at Vitrolife AB, Mölnlycke Healthcare AB and Bioeffect AB and is now acting as CEO of Medfield Diagnostics AB.

# DIRECTORS' REPORT

The board of directors and CEO for Calmark Sweden AB presents the following annual report for financial year 2019. The annual report has been prepared in Swedish kronor (SEK) and all amounts are shown in SEK unless otherwise specified.

## **The business in general**

Calmark Sweden AB is a medical technology company that develops a point-of-care analysis method (POC) with easier and faster sampling of medical conditions in newborns. This unique test platform consists of a reader and single-use products. The market launch of the first three tests is scheduled to start in 2020. Until 2030, WHO estimates that 1.5 billion children will be born worldwide. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter healthcare chains. In less developed healthcare systems, the product helps save lives. Calmark aims to become the global leader and to ultimately offer all relevant tests for the first period of life, regardless of where in the world the baby is born. The B-share is listed on the Spotlight Stock Market and is traded under the name CALMA B.

The purpose of the company's operations is to conduct research and development in medical diagnostics and to market and sell products and services in the same area, as well as to conduct associated activities.

The company name is Calmark Sweden AB. The company is public and has its registered headquarters in Karlstad.

## **Significant events during the financial year**

In 2019, the phase started where Calmark will transition from a product development company to a commercial medical technology company with a focus on building up distributor networks, organization and production. Several important steps were taken in this direction over the year.

On February 22, the board of directors of Calmark Sweden AB decided to adopt a preliminary launch strategy for the company's products. In the first phase, the launch will take place in the Nordic region, the UK and Vietnam, followed by gradually expanding to multiple countries in Europe as well as Singapore, Malaysia and India.

Calmark's listing on the Spotlight Stock Market, which occurred in July 2018, received positive attention when the company was nominated on April 15, 2019 as best IPO company for 2018 by the IPO guide that was organized by SvD Börsplus. On May 22, Calmark was awarded an honorary mention as the runner-up micro-company in the Quality category. In the Price Trend category, Calmark came in fifth place (of a total of 29 companies) as one of the micro-companies that

had a positive price trend after being listed on the stock exchange.

On May 9, 2019, the Annual General Meeting was held in Karlstad. At the annual meeting, the decision was made to empower the board, until the next annual meeting, to make decisions about issuing a maximum number of B-shares and/or warrants that carry the right to subscribe to a maximum number of new B-shares corresponding to a maximum amount of SEK 25,000,000 (total issue payment), with or without deviating from the shareholders' preferential rights. The entire board was re-elected.

On May 16, it was announced that negotiations had started with Triolab AB regarding a distributor agreement for sales rights in the Nordic countries and the Baltic countries. The parties have previously signed a Letter of Intent (LOI).

When the subscription period for Calmark's warrant TO 1 B ended in June, the subscription rate amounted to approximately 83 percent, and the company took in roughly SEK 13.4 million before issue expenses.

On June 26, the scientific journal Scientific Reports, which is a part of Nature Research, published an article with the results of Calmark's early clinical study from 2015/2016. The study was completed in collaboration with Södersjukhuset hospital in Stockholm and Vietnam National Children's Hospital (VNCH) in Hanoi, which are two of Calmark's priority markets. The article concludes that the POC analysis method provided reliable results within four minutes.

On October 7, 2019, Calmark announced a 100% secured rights issue of SEK 24.3 million. On November 6, Calmark held an extraordinary general meeting due to the rights issue.

On November 14, 2019, a statement was published on account of the rights issue of units that was adopted at Calmark's extraordinary general meeting on November 6, 2019. The rights issue was secured up to 100 percent through subscription and guarantee commitments.

The results of the rights issue were published on December 4, 2019. The issue was subscribed to approximately SEK 34.6 million, corresponding to a subscription rate of approximately 142.4% and provided the company with approximately SEK 24.3 million before issue expenses, which amounted to approx. SEK 2.7 million. The share issue issued 7,366,680 new B-shares and 2,455,560 warrants in the TO 2 B series. The rights issue was registered on December 23, 2019.

On December 4, it was also announced that Creades AB became the third largest owner in Calmark after having signed and acquired B-shares and warrants in the TO 2 B series, corresponding to SEK 6.3 million. The transactions corresponded to 9.44 percent of the share capital. Creades is an investment company that is listed on the stock exchange.



**The development project**

On January 21, the board of Calmark Sweden AB decided to prioritize the CE-marking of the bilirubin test separately, before the other tests, in order to get the test to market faster and generate revenue earlier. On October 8, it was announced that the development project for this biomarker entered into the verification and validation stage, which is one of the last parts of the CE-marking process.

As a result of the prioritization, Calmark announced on October 18 that the company's products for the biomarkers LDH and glucose were estimated to be CE-marked during the first quarter of 2020, instead of prior to the start of the year as previously announced. The market launch was not expected to be affected by this.

On November 7, 2019, the Swedish Ethical Review Authority announced that Calmark's application regarding the study on newborns at Sachsska pediatric clinic at Södersjukhuset hospital in Stockholm had been approved. Formal start of the study was possible on November 27, when the hospital's legal department provided their approval, and on December 23, the first patient was included in the study. With that, Calmark achieved one of the last remaining milestones for 2019 that had been previously announced.

On December 23, it was announced that Calmark's first product, Neo-Bilirubin, was scheduled to be CE-marked in January 2020 instead of prior to the start of the year as previously communicated. After the accounting date, the schedule was modified, see Note 12.

**Production Development**

On January 18, Calmark Sweden AB signed an agreement with Frohe AB in Tyresö regarding manufacturing Calmark's single-use product. Delivery of the first single-use products that were manufactured in the serial production environment took place on February 14. The readers are manufactured in Note AB in Norrtälje, and on February 8, Calmark received delivery of the first reader that was manufactured in the serial production environment.

On September 13, equipment was delivered for the first step in the automated production line for the single-use product. The assembly equipment was manufactured by AutomationsPartner in Ramlösa and installed at Frohe.

**Organization**

During the year, the organization was strengthened with the resources that were needed to complete the development project, perform clinical trials and start selling internationally. First up was the role as Clinical Director, which is held by Emma Lif. This was announced on January 22.

On August 15, the team was strengthened with an experienced international sales director. Marianne Alksnis took on the role on October 15 and is

responsible for establishing a broad distributor network, which will make up the core of Calmark's sales strategy.

A new CFO on a consulting basis, Sara Wili-Blomé was hired on April 1, 2019 on a part-time basis via the Inhouse AB staffing agency.

The software resources were secured through agreements with Evidente and an extended agreement with Code is King AB. The agreement with Stravus AB was extended, which provides services in terms of project management and quality assurance through the consultant Michael Lundh. The agreement with Marknadsmotivation Sverige AB was also extended, which provides marketing and communication services through the consultant Camilla Arneving.

**Patent and intellectual property rights**

On January 11, Calmark received approval from Chinese authorities of their application for design protection for the Neo-Reader in China. The design already has protection in Europe and the USA. Approval of design protection was granted in India as well on June 4 and in Vietnam on July 11. Hence, the reader has protection in the most important markets.

On February 25, the Ministry of Science and Technology in Vietnam approved Calmark's patent application regarding the "Testing system for determining hypoxia induced cellular damage." The patent is part of in Calmark's patent family regarding the methodology for the biomarker LDH and is valid until 2030.

**Expected future development**

Calmark is focusing on completing the development of tests for bilirubin, glucose and LDH in 2020. The company also plans on investing in production in order to reduce production costs for the single-use product and increase production capacity. Expansion of distributor networks to sell in priority markets is planned to continue, and the market launch of the first tests are scheduled to occur in 2020.

Calmark plans to continue developing more tests on the same platform after these three biomarker tests are completed.

In connection with the new share issue in 2019, warrants were also issued that have a redemption date between December 4 and December 16, 2020. The subscription price per B-share shall correspond to 75 percent of the volume-weighted average price as of October 12, 2020 until October 23, 2020, however with a minimum of SEK 4.20 and a maximum of SEK 6.60.

**Significant risks and uncertainty factors**

All business activities are associated with risks. Risks managed well can result in opportunities and create

value, while risks that are not managed well can lead to damage and losses. Calmark is exposed to various external and internal risks. Risk management is therefore an important part of the management and control of the company.

**Financing needs and currency risks**

The company does not yet have any income. Consequently, depending on when a positive cash flow is reached, Calmark may need to seek new external capital in the future. The size as well as the timing of the company's future capital requirements depends on a number of factors, including the successful commercialization of products, research and development projects and the conclusion of cooperation agreements. There is a risk that new capital cannot be acquired when the company needs it, or that capital cannot be acquired on terms acceptable to the company. This can have negative consequences for Calmark's business, financial positions and results.

The value of the company's capitalized development work expenses depends on financing being received for the completion of the development project. The board of directors has a plan for the pace and scope of future development work and investments. The company's liquidity as of the balance sheet date of December 31, 2019 is sufficient for development and planned investments in accordance with the board's plans until December 2020. The planned redemption of warrants in December 2020 corresponds to between SEK 10.3 million and 16.2 million before issue costs. In the event that the new share issue, for reasons that the board cannot predict today, will not be possible to implement, the board and management are currently preparing alternative means of financing. As a further alternative, the company can slow the pace of the development project and the investments and seek bridge financing until other financing can be obtained.

Calmark Sweden AB is exposed to currency risks through its international collaboration in the development of technology. Exchange rate fluctuations affect the company's income statement and balance sheet.

**Calmark is a development company**

The company has so far been devoted exclusively to product development and has not yet launched any product on the market. Developing a new product from invention to finished product takes a very long time. Consequently, when product development is in progress, it is uncertain whether there will be any market for the product when it is fully developed, or how large that market might be in which competing products will be on the market in the future. There is also a risk that the company will not be able to encourage potential customers to replace existing methods and procedures with Calmark's. Another risk

is that competitors, who in many cases have larger resources than the company, will develop alternative products that are more efficient, safer and cheaper than Calmark. This can lead to the company being unable to sell its products, which can adversely affect the company's market value, operations, financial position and results.

**Administrative authorization and registration**

In order to be able to market and sell medical technology equipment, permits must be obtained from and the products must be registered with the relevant authorities in each market. The current rules and interpretations may change, which may adversely affect Calmark's conditions for meeting current regulatory requirements. There is a risk that the company, directly or through its partners, will not receive, or cannot maintain, the required permits and registrations with the authorities. If so, there is a risk that Calmark's earnings capacity and financial position will be affected negatively.

**Dependence on key people and qualified employees**

Calmark's operations are largely dependent on a number of key employees, as well as the company CEO and board of directors. If one or more key persons choose to leave Calmark, and Calmark fails to replace them, it could adversely affect the company's operations, financial position and results. Calmark is also dependent on being able to attract and retain existing qualified personnel. If Calmark were not to succeed in recruiting and retaining qualified personnel to a sufficient extent and on the terms required, it could adversely affect the company's operations, financial position and results.

**Intellectual property issues**

Calmark is largely dependent on its ability to obtain and defend patents, as well as the ability to protect specific knowledge. There is a risk that Calmark will not be granted a patent for patent-pending inventions, that granted patents will not provide sufficient patent protection, or that granted patents will be circumvented or repealed.

**Economic situation and restrictions**

The COVID-19 pandemic and its impact on the economy and society currently constitutes a risk and uncertainty factor that affects all companies, more or less. The board of directors and the management are monitoring the situation continuously and adjusting operations based on current conditions. How the company's operations are being affected is published in press releases on the company's website [www.calmark.se](http://www.calmark.se).



OWNERSHIP

Owner's name	Number of A-shares	Number of B-shares	Total number of shares	% of capital	% of votes
Wingefors Invest AB	129,300	4,422,852	4,552,152	22.47	22.75
Försäkringsaktiebolaget, Avanza Pension*	0	2,882,908	2,882,908	14.23	11.48
Olcon Engineering AB	51,000	1,908,296	1,959,296	9.67	9.63
Karlsson, Mathias**	95,400	1,058,560	1,153,960	5.69	8.01
Flodberg, Måns Ola	0	1,000,000	1,000,000	4.94	3.98
Nordnet Pensionsförsäkring AB	0	591,095	591,095	2.92	2.35
Almi Invest Norra Mellansverige	55,050	400,350	455,400	2.25	3.78
Hiort Af Ornäs, Sofia***	41,250	356,250	397,500	1.96	3.06
Ålandsbanken****	63,300	304,310	367,610	1.81	3.73
Bengt Braun Förvaltnings AB	18,600	327,336	345,936	1.71	2.05
Other owners (1580)	86,550	6,465,975	6,552,525	32.35	29.18
<b>TOTAL</b>	<b>540,450</b>	<b>19,717,932</b>	<b>20,258,382</b>	<b>100.00</b>	<b>100.00</b>

\*Creades AB ownership is included  
\*\* Private and via company  
\*\*\* Private and via company  
\*\*\*\* Hans Risberg Förvaltning AB ownership is included

The ownership list above refers to January 27, 2020 when all effects of the rights issue were registered. Trading in the share until January 27 may have affected the listing.

MULTI-YEAR OVERVIEW (SEK thousand)

	2019	2018	2017	2016	2015
Profit/loss after financial items	-7,792	-5,363	-2,935	-1,731	-1,202
Balance sheet total	61,977	36,089	18,837	17,567	13,272
Equity/assets ratio (%)	89.54	81.29	72.45	81.31	90.41
Cash flow (%)	500.21	312.56	87.43	353.70	79.30
Adjusted cash flow after investments (SEK thousand/month)	-1,715	-876	-438	-348	-159
Number of outstanding shares at the balance sheet date*	20,258,382	10,404,500	5,404,500	4,686,000	3,903,000
Earnings per share (SEK)	-0.38	-0.52	-0.54	-0.37	-0.31

\*adjusted for split (1:1500) 2015-2017

For definitions of key figures, see 'Accounting and valuation principles'.

CHANGES IN SHAREHOLDER'S EQUITY

	Share capital	Fund for development expenditures	Share premium reserve	Profit/loss brought forward	Net profit/loss for the year	Total
Amount at start of year	1,040,450	9,633,640	59,172,610	-35,146,357	-5,362,841	<b>29,337,502</b>
New share issue	985,388		32,963,536			<b>33,948,924</b>
Allocation of profit/loss based on decision at the AGM:				-5,362,841	5,362,841	<b>0</b>
Fund for development expenditures		11,226,147		-11,226,147		<b>0</b>
Net profit/loss for the year					-7,792,013	<b>-7,792,013</b>
<b>Amount at end of year</b>	<b>2,025,838</b>	<b>20,859,787</b>	<b>92,136,146</b>	<b>-51,735,345</b>	<b>-7,792,013</b>	<b>55,494,412</b>

PROPOSED ALLOCATION OF PROFITS

The board of directors proposes that the existing profit of (SEK):

Accumulated loss	-51,735,345
Share premium reserve	92,136,146
Loss for the year	-7,792,013
	<b>32,608,787</b>
be allocated such that carried forward:	32,608,787

The company's results and financial position are otherwise shown in the following income statement and balance sheet as well as the cash flow with notes.



# INCOME STATEMENT

	Note	01/01/2019 - 12/31/2019	01/01/2018 - 12/31/2018
Net sales		0	0
Work performed by company for own use	2	11,226,147	4,798 249
		<b>11,226,147</b>	<b>4,798 249</b>
<b>Operating expenses</b>			
Other external expenses		-14,197,288	-7,252 460
Personnel costs	3	-4,653,421	-2,675,213
Depreciation and write-downs		0	-20,784
Other operating expenses		-3,325	0
		<b>-18,854,034</b>	<b>-9,948,457</b>
<b>Operating profit/loss</b>	4	<b>-7,627,888</b>	<b>-5,150,208</b>
<b>Profit/loss from financial items</b>			
Other Interest income and similar profit items		0	623
Interest expenses and similar profit/loss items		-164,126	-213,256
		<b>-164,126</b>	<b>-212,633</b>
<b>Profit/loss after financial items</b>		<b>-7,792,013</b>	<b>-5,362,841</b>
<b>Profit/loss before tax</b>		<b>-7,792,013</b>	<b>-5,362,841</b>
<b>NET PROFIT/LOSS FOR THE YEAR</b>		<b>-7,792,013</b>	<b>-5,362,841</b>

# BALANCE SHEET

	Note	12/31/2019	12/31/2018
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Capitalized expenditures for development work and similar work.	2	33,306,033	22,079,886
		<b>33,306,033</b>	<b>22,079,886</b>
<b>Property, plant and equipment</b>			
Equipment, tools, fixtures and fittings	5	0	368,334
Ongoing new construction and advances regarding tangible fixed assets	6	1,933,890	
		<b>1,933,890</b>	<b>368,334</b>
<b>Total non-current assets</b>		<b>35,239,923</b>	<b>22,448,220</b>
<b>Current assets</b>			
<b>Current receivables</b>			
Other receivables		1,342,470	602,498
Prepaid expenses and accrued income		242,261	136,995
		<b>1,584,731</b>	<b>739,493</b>
<b>Cash and bank balances</b>		25,152,461	12,901,497
<b>Total current assets</b>		<b>26,737,192</b>	<b>13,640,990</b>
<b>TOTAL ASSETS</b>		<b>61,977,115</b>	<b>36,089,210</b>



# BALANCE SHEET

	Note	12/31/2019	12/31/2018
<b>EQUITY AND LIABILITIES</b>	7		
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital		2,025,838	1,040,450
Fund for development expenditures		20,859,787	9,633,640
<b>Total restricted equity</b>		<b>22,885,625</b>	<b>10,674,090</b>
<b>Non-restricted equity</b>			
Share premium reserve		92,136,146	59,172,610
Profit/loss carried forward		-51,735,345	-35,146,357
Net profit/loss for the year		-7,792,013	-5,362,841
<b>Total non-restricted equity</b>		<b>32,608,787</b>	<b>18,663,412</b>
<b>Total equity</b>		<b>55,494,412</b>	<b>29,337,502</b>
<b>Long-term liabilities</b>			
Liabilities to credit institutions	8	1,137,492	2,387,492
<b>Total long-term liabilities</b>		<b>1,137,492</b>	<b>2,387,492</b>
<b>Current liabilities</b>			
Liabilities to credit institutions	8	1,250,008	1,250,008
Accounts payable		2,787,847	1,985,374
Other liabilities		166,452	108,082
Accrued expenses and deferred income		1,140,904	1,020,752
<b>Total current liabilities</b>		<b>5,345,211</b>	<b>4,364,216</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>61,977,115</b>	<b>36,089,210</b>

# CASH FLOW STATEMENT

	Note	01/01/2019 - 12/31/2019	01/01/2018 - 12/31/2018
<b>Operating activities</b>			
Operating profit/loss		-7,627,888	-5,150,208
Interest received		0	623
Interest paid		-164,126	-213,256
Adjustments for non-cash items		0	20,784
<b>Cash flow from operating activities before changes in working capital</b>		<b>-7,792,013</b>	<b>-5,342,057</b>
<b>Cash flow from changes in working capital</b>			
Changes in operating receivables		-845,238	-508,397
Changes in operating liabilities		980,995	2,354,253
<b>Cash flow from operating activities</b>		<b>-7,656,257</b>	<b>-3,496,201</b>
<b>Investing activities</b>			
Investments in intangible assets		-11,226,147	-4,798,249
Investments in tangible fixed assets		-1,565,556	-372,052
<b>Cash flow from investing activities</b>		<b>-12,791,702</b>	<b>-5,170,301</b>
<b>Financing activities</b>			
New share issue		33,948,923	21,051,990
Borrowings		0	0
Repayment of debt		-1,250,000	-791,667
<b>Cash flow from financing activities</b>		<b>32,698,923</b>	<b>20,260,323</b>
<b>Cash flow for the period</b>		<b>12,250,964</b>	<b>11,593,821</b>
Cash and cash equivalents at start of the year		12,901,497	1,307,676
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>		<b>25,152,461</b>	<b>12,901,497</b>

The liquid assets consist solely of bank balances.



# ACCOUNTING PRINCIPLES AND NOTES

## Note 1 - General information

### ACCOUNTING AND VALUATION PRINCIPLES

#### General information

This annual report has been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 Annual Report and Consolidated Financial Statements (K3).

The accounting principles are unchanged compared with previous years.

Assets, provisions and liabilities have been valued at the acquisition value unless otherwise stated below.

#### Revenue recognition

Revenue has been recognized at the fair value of what has been received or will be received and reported to the extent that it is probable that the economic benefits will be utilized by the company and the revenues will be calculated reliably. Deductions have been made for trading discounts, volume discounts and similar price reductions.

#### Foreign currency

Monetary items in a foreign currency are recalculated at the rate on the closing date. Non-monetary items are not recalculated but are reported at the price at the time of acquisition.

Exchange rate differences arising from the recognition or recalculation of monetary items are recognized in the income statement in the financial year in which they arise.

#### Intangible assets

*Expenditures on research and development*  
Research expenditure (i.e. planned and systematic applications for the purpose of obtaining new scientific or technical knowledge and insight) are reported as costs when they arise.

When reporting expenses for development, the activation model is applied. This means that expenses incurred during the development phase are reported as assets when all of the following conditions are met:

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

Internally generated intangible fixed assets are reported at the acquisition value less the accumulated depreciation, amortization and any write-downs.

The acquisition value of an internally generated intangible fixed asset consists of all directly attributable expenses. Indirect manufacturing costs that make up more than an insignificant part of the total cost of production and amount to more than an insignificant amount are included in the acquisition value.

#### Other intangible fixed assets

Other acquired intangible fixed assets are recognized at the acquisition value, less the accumulated depreciation, amortization and any write-downs. Expenses for internally generated goodwill and trademarks are recognized in the income statement as costs when they arise.

#### Depreciation

Depreciation is made on a linear basis across the estimated useful life of the asset. Depreciation is a reported as an expense in the income statement. Due to the fact that the company's development work is not yet completed, and the assets are therefore not ready to use, depreciation of capitalized development work has not yet begun. The company will assess the useful life at the time the assets are ready to use.

#### Property, plant and equipment

Property, plant and equipment are reported at the acquisition value, less the accumulated depreciation and any write-downs. In addition to the acquisition value, the acquisition cost also includes expenses that are directly attributable to the acquisition.

Additional expenses that meet the asset criterion are included in the asset's reported value. Expenses for ongoing maintenance and repairs are reported as costs when they arise.

Depreciation takes place linearly over the estimated useful life of the asset as it reflects the expected consumption of the asset's future economic benefits. The depreciation is reported as an expense in the income statement.

Type	Useful life	Percent
Equipment, tools, fixtures and fittings	5 years	20%

#### Depreciation of property, plant and equipment and amortization of intangible fixed assets.

At each balance sheet date, an assessment is made whether there is any indication of an asset's value is lower than its reported value. If such an indication exists, the asset's recoverable amount is calculated.

The recoverable amount is the highest of fair value, less selling costs and useful value. When calculating the useful value, the present value is calculated of the future cash flows that the asset is expected to generate within the current operations and when it is sold or disposed of. The discount rate that is used is before tax and reflects market-based assessments of the time value of money and the risks related to the asset. An earlier write-down is only reversed if the reasons that form the basis for the calculation of the recoverable amount at the latest write down have changed.

#### Financial assets and liabilities

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

#### Recognition in and de-recognition from the balance sheet

A financial asset or liability is recognized in the balance sheet when the company becomes a party to the instrument's contractual terms. A financial asset is removed from the balance sheet when the contractual right to the cash flow from the asset has ceased or been settled. The same applies when the risks and benefits associated with the holding have in all material respects been transferred to another party, and the company no longer has control over the financial asset.

A financial liability is de-recognized from the balance sheet when the contractual obligation is fulfilled or terminated.

#### Valuation of financial assets

On initial recognition, financial assets are valued at acquisition cost, including any transaction expenses that are directly attributable to the acquisition of the asset.

Financial current assets are valued at the lower of the acquisition value and net realizable value on the balance sheet date after the first reporting date.

Accounts receivable and other receivables that constitute current assets are valued indirectly at the amount that is expected to be received.

Financial fixed assets are valued at their acquisition value at initial costs, less any write-downs and with the addition of any appreciation.

Interest-bearing financial fixed assets are reported at the accrued acquisition value using the effective interest rate method.

#### Valuation of financial liabilities

Long-term financial liabilities are reported at the accrued cost. Expenses that are directly attributable to borrowing have corrected the loan's acquisition value and been accrued according to the effective interest method. Current liabilities are reported at cost.

#### Hedge accounting

The company does not apply hedge accounting.

#### Leases

All leases are reported as operating leases.

Leasing fees according to operational lease agreements, including increased initial rent but excluding expenses for services, such as insurance and maintenance, are reported as expenses on a linear basis over the lease term.

#### Income tax

Total tax consists of current tax and deferred tax.

Taxes are recognized in the income statement, except when the underlying transaction is reported directly against equity, whereby the associated tax effects are reported in equity.

#### Deferred tax

Deferred tax is income tax that relates to future financial years as a result of past events. On the balance sheet date, the company has unutilized loss carry-forwards that have not been capitalized for precautionary reasons.

At the beginning of the year, the loss carry-forwards amounted to SEK 26,136,271 and at the end of the year to SEK 31,454,883.

#### Provisions

A provision is recognized in the balance sheet when the company has a legal or informal obligation as a result of an event that has occurred, and it is probable that an outflow of resources will be required to settle the obligation, and a reliable estimate of the amount can be made.

At initial recognition, provisions are valued at the best estimate of the amount that will be required to settle the obligation on the balance sheet date. Provisions are reviewed at each balance sheet date.

The provision is reported at the present value of the future payments required to settle the obligation.

#### Contingent liabilities

A contingent liability is:

- A possible obligation which, as a result of events occurring and whose occurrence will only be confirmed by one or more uncertain future events that are not entirely within the control of the company, occurs or fails; or
- an existing obligation arising from events occurring, but not reported as a liability or provision, since it is unlikely that an outflow of resources will be required to settle the obligation, or the amount of the liability cannot be calculated with sufficient reliability.

Contingent liabilities is a collective term for such guarantees, financial commitment and any liabilities that are not included in the balance sheet.

#### Remuneration to employees

*Remuneration to employees after termination of employment*  
Plans for post-employment remuneration is classified as either a defined-contribution or defined-benefit plan.

For defined-contribution plans, fixed fees are paid to another company, normally an insurance company, and the company no longer has an obligation to the employee when the fee is paid. The size of the employee's remuneration after termination of their employment depends on the fees that have been paid and the return on capital provided by the fees.

In defined-benefit plans, the company has an obligation to provide the agreed remuneration to current and former employees. Essentially, the company carries the risk that the remuneration will be higher than expected (actuarial risk), and the risk that the return on the assets will deviate from expectations (investment risk). Investment risk exists even if the assets are transferred to another company.

#### Defined-contribution plans

The fees for defined-contribution plans are reported as expenses. Unpaid fees are reported as liabilities.

#### Defined-benefit plans

The company has chosen to apply the simplification rules in BFNAR 2012:1. Plans for which pension premiums are paid are reported as defined-contribution plans, which means that the fees are expensed in the income statement.

#### Public grants

A public grant that is not associated with requirements for future performance is reported as revenue when the conditions for obtaining the grant are met. A public grant that is associated with requirements for future performance is reported as revenue when the performance is completed. If the contribution is received before the conditions for reporting it as revenue are met, the contribution is reported as a liability.

#### Reporting of grants related to non-current assets

Public grants related to assets are recognized in the balance sheet by reducing the asset's reported amount.

#### Key definitions

##### Equity/assets ratio (%)

Adjusted equity (equity on tax reserves, less deductions for deferred tax) as a percentage of the total assets.

##### Cash flow (%)

Current assets, excluding inventories and work in progress, as a percentage of current liabilities.

##### Adjusted cash flow after investments (SEK thousand/month)

(Cash flow from operating activities before changes in working capital + Cash flow from investing activities)/number of months.



Note 2 - Capitalized expenditures for development work in similar work.

	12/31/2019	12/31/2018
Opening acquisition values	22,079,886	17,281,637
Purchases and capitalizations	11,226,146	4,798,249
Reclassifications	0	0
Closing accumulated acquisition values	33,306,032	22,079,886
Closing reported value	33,306,032	22,079,886

Note 3 - Personnel

	2019	2018
Wages, salaries and other remuneration		
Board and CEO	1,340,816	878,778
Other employees	1,913,001	1,009,531
Total wages, salaries and other remuneration	3,253,817	1,888,309
Social security contributions and pension costs		
Social security contributions	1,137,303	577,348
(of which are pension costs for the board and CEO and equivalent)	129,600	97,200
(of which are pension costs for other employees)	81,555	80,911
Total salaries, other remuneration, Social security contributions and pension costs	4,391,120	2,465,657
Average number of employees		
Men	1	0
Women	5	3
Average number of employees	6	3
Number of board members		
Men	2	2
Women	2	2
Number employees in senior roles		
Men	0	0
Women	1	1

The company CEO has a notice period of six months and is entitled to a further three months of salary in addition to the notice period for termination by the company.

Note 4 - Purchase of goods and services from related parties.

Legal person	Owner	Role	2019
Nublis AB	Torbjörn Enström	CFO until March 31	282,250

All transactions with related parties have been made according to market terms.

Note 5 - Equipment, tools, fixtures and fittings

	12/31/2019	12/31/2018
Acquisition values		
Opening acquisition values	516,644	144,592
Purchases during year	0	372,052
Reclassifications	-372,052	0
Closing acquisition values	144,592	516,644
Accumulated depreciation		
Opening depreciation	-148,310	-127,526
Depreciation for the year	0	-20,784
Reclassifications	3,718	0
Opening depreciation	-144,592	-148,310
Total reported value	0	368,334

Note 6 - Fixed assets under construction and advances related to tangible fixed assets

	12/31/2019	12/31/2018
Opening balance	0	0
Investments for the year	1,565,556	0
Reclassifications for the year	368,334	0
Closing balance	1,933,890	0

Note 7 - Equity

The share capital consists of a total of 20,258,382 shares consisting of 540,450 A-shares and 19,717,932 B-shares. The quotient value of the shares amounts to 10 öre.

Warrants which were acquired by the company's employees and board members have been valued at market value at the time of acquisition. The market value has been calculated using the Black-Scholes formula.

In conjunction with the IPO and the new share issue in June 2018, units were offered, where the purchase of five shares provided three warrants at no extra cost. On July 20, 2018, the company issued 3,000,000 warrants with a subscription price of SEK 5.40 per share to exercise the warrants. The warrants can be exercised to subscribe to shares during the period from May 23, 2019 until June 13, 2019. Each option entitles the holder to subscribe for one (1) newly issued B-share in the company. When the subscription period ended in June, the subscription rate amounted to approximately 83 percent, and the company took in roughly SEK 13.4 million before issue expenses.

On October 7, 2019, Calmark announced a 100% secured rights issue of SEK 24.3 million. The announcement of the issue of units was published on November 14. The results of the share issue were published on December 4. The issue was subscribed to approximately SEK 34.6 million, corresponding to a subscription rate of approximately 142.4% and brought the company approximately SEK 24.3 million before issue expenses, which amounted to approx. SEK 2.7 million. The share issue offered 7,366,680 new B-shares and 2,455,560 warrants in the TO 2B series. Each warrant provides the right to subscribe to a B-share at a subscription rate corresponding to 75% of the weighted average price during the period from October 12, 2020 to October 23, 2020, however at a minimum of SEK 4.20 and a maximum of SEK 6.60. Application to subscribe to B-shares can take place from December 4, 2020 until December 16, 2020. The rights issue was registered on December 23, 2019.

Other warrants programs

In July 2010, the company issued 138 warrants with a subscription price for exercising a warrant of SEK 41.00 per share (after adjustment for split 1:1500) to owners, employees and the board. The warrants can be exercised to subscribe to shares between December 31, 2010 until December 31, 2020. Each option is entitled to a subscription of 1500 newly issued shares in the company (after adjustment of the split 1:1500). If all warrants are exercised, the dilution effect will be approximately 2% of the share capital against outstanding shares as of the closing date.

In July 2012, the company issued 70 warrants with the subscription price to exercise a warrant of SEK 41.00 per share (after adjustment for split 1:1500) to owners, employees and the board. The warrants can be exercised to subscribe to shares during the period from December 31, 2012 until December 31, 2020. Each option is entitled to a subscription of 1500 newly issued shares in the company (after adjustment of the split 1:1500). If all warrants are exercised, the dilution effect will be approximately 1% of the share capital against outstanding shares as per the closing date.

In October 2014, the company issued 415 warrants with a subscription price for exercising a warrant of SEK 41.00 per share (after adjustment for split 1:1500) to owners, employees and the board. The warrants can be exercised to subscribe to shares between October 23, 2014 until December 31, 2020. Each option is entitled to a subscription of 1500 newly issued shares in the company (after adjustment of the split 1:1500). If all warrants are exercised, the dilution effect will be approximately 6% of the share capital against outstanding shares as of the closing date.

Note 8 - Liabilities to credit institutions

	12/31/2019	12/31/2018
Long-term liabilities		
Liabilities that fall due within 12 months	1,250,008	1,250,008
Liabilities that fall due within 1-5 years	1,137,492	2,387,492

Note 9 - Estimates and assessments

The company makes estimates and assessments about the future. The estimates for accounting purposes that result from these will, by definition, seldom correspond to the actual results. The estimates and assumptions that entail a significant risk of significant adjustments to the reported value of assets and liabilities in the coming year are outlined below.

Valuation of intangible fixed assets

The company conducts research and development of products in the area of point-of-care (POC) analyses. The value of intangible assets depends on future profits from the sale of the finished product/service. Determining the present value of the future cash flow generated by the finished product is a significant and difficult assessment issue.

Note 10 - Financial arrangements that are not reported in the balance sheet

On November 22, 2016, the company entered into a cross license agreement with HemCheck. Under the agreement, the companies grant reciprocal, eternal, transferable, non-exclusive licenses to intellectual property rights regarding the company's product concepts (Separation Technology and Reader Technology). The licenses are limited to each company's business area (point-of-care detection of hemolysis in body fluids) for HemCheck and point-of-care diagnostics based on biomarkers for Calmark.

Since the agreement can be transferred without Calmark's approval, Calmark cannot control to which company HemCheck can transfer its rights (within its business area). If Calmark were to broaden its current business to include methods within HemCheck's specified business area, the company must adhere to the limitations made applicable by the cross license.

Note 11 - Pledged assets

	12/31/2019	12/31/2018
Corporate mortgage	4,000,000	4,000,000
Total pledged assets	4,000,000	4,000,000

Note 12 - Important events after the end of the financial year

On January 14, 2020, the World Intellectual Property Organization (WIPO) announced that Calmark Sweden AB had been granted design protection within the EU and USA for the company's unique single-use product.

On January 28, 2020, Calmark announced that the schedule for the clinical study taking place at Södersjukhuset hospital had been updated. Consequently, CE-marking of the company's first product, Neo-Bilirubin, was estimated to occur in the first quarter.

On February 13, it was announced that the schedule for the development project regarding the Neo-Glucose and Neo-LDH products had been updated. CE-marking for these products would not occur until the second quarter at the earliest.

An exclusive distribution agreement was signed on February 14 between Calmark and Triolab. The agreement covers marketing and sales of the Calmark Neo platform on the Swedish market.

The verification phase of Calmark's first product Neo-Bilirubin was completed on March 13 after approved results from all parts of the product's function and performance.

On March 26, it was announced that the schedule for the clinical study at Södersjukhuset hospital was updated as a result of COVID-19. Not all of the children had been included yet, and under the extraordinary circumstances, it was judged to be difficult to predict when the study could be completed. CE-marking of the company's first product Neo-Bilirubin could therefore not occur during the first quarter



The annual report was approved for publication by the board of directors and CEO on April 2, 2020 and will be subject to approval at the annual general meeting on May 14, 2020.

Karlstad, April 2, 2020

**Mathias Karlsson**  
Chairman

**Stefan Blomsterberg**

**Kjersti Berg Marthinsen**

**Anna-Karin Edstedt Bonamy**

**Anna Söderlund**  
Chief Executive Officer

Our auditor's report was submitted on April 15, 2020.  
KPMG AB

**Mattias Eriksson**  
Certified public accountant

# Caring for a calm start



# AUDITORS' REPORT

To the general meeting of the shareholders of Calmark Sweden AB (publ), corp. id 556696-0141

## Report on the annual accounts

### Opinions

We have audited the annual accounts of Calmark Sweden AB (publ) for the year 2019.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of Calmark Sweden AB (publ) as of 31 December 2019 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

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

### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Calmark Sweden AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Other Information than the annual accounts

The Board of Directors and the Managing Director are responsible for the other information. Calmark Sweden AB (publ) produces a freestanding printed document "Annual report 2019" which contains other information and a copy of the content in the formal annual report. Our opinion on the annual accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

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

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error. In preparing the annual accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of ac-

counting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

### Auditor's responsibility

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

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

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

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

# AUDITORS' REPORT

## Report on other legal and regulatory requirements

### Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Calmark Sweden AB (publ) for the year 2019 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Calmark Sweden AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

### Responsibilities of the Board of Directors and the Managing Director

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

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### Auditor's responsibility

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

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Karlstad den 15 april 2020  
KPMG AB

**Mattias Eriksson**  
Authorized Public Accountant



## Vision

Calmark will become the global leader in POC diagnostics for newborns, and in the long term will offer all relevant tests during the child's first time in life.

## INFORMATION TO SHAREHOLDERS

### Notice of 2020 Annual General Meeting for Calmark Sweden AB (publ)

The shareholders of Calmark Sweden AB (publ), Corp. ID No. 556696-0141, (Company) are hereby invited to attend the annual general meeting on Thursday, May 14, 2020 at 1:00 p.m. at Karlstad Innovation Park, conference room Manegen, Sommargatan 101A, 656 37 Karlstad.

### Right to participate in the annual meeting

Shareholders who wish to attend the annual meeting must:

- be included in the share register kept by Euroclear Sweden AB on Friday, May 8, 2020 and
- register with the company no later than Friday, May 8, 2020 in writing to Calmark Sweden AB, Teknikringen 38A, 114 28 Stockholm.

Registration can also be made by phone: +46 70 213 25 35 or by email: [anna.soderlund@calmark.se](mailto:anna.soderlund@calmark.se)

The application must state the full name, personal or corporate identity number, shareholding, address, daytime telephone number and, if applicable, information about the deputy or representative (maximum of two) must be provided. The application should, where appropriate, be accompanied by proxies, registration certificates and other authorization documents.

Proxies are available at [www.calmark.se](http://www.calmark.se).

### Nominee-registered shares

Shareholders whose shares are nominee-registered, either with the bank or other nominee, must register the shares in their own name with Euroclear Sweden AB in order to be entitled to attend the annual general meeting. Such re-

registration must be completed no later than Friday, May 8, 2020, which means that shareholders who wish such re-registration must notify the nominee in good time before that date. Registration may be temporary.

### Representatives, etc.

If shareholders are to be represented by a proxy, the proxy must have authorization to attend the meeting, in writing, dated and signed by the shareholder. The proxy authorization may not be older than one year, unless a longer term of validity (but no longer than five years) has been stated in the authorization. If the proxy authorization is issued by a legal person, the representative must also include the current registration certificate or equivalent authorization document for the legal person. To facilitate entry, a copy of the proxy authorization and other authorization documents should be enclosed with the notification to the meeting. Proxy forms are available at the company's website, [www.calmark.se](http://www.calmark.se), and sent by mail to shareholders who contact the company and provide their address.

### Number of shares and votes

The number of shares in the company at the time of this notice amounted to 20,258,382, of which 540,450 are shares and 19,717,932 are B-shares, corresponding to a total of 25,122,432 votes.

### Future Financial Statements

May 20, 2020 - Interim financial statement, first quarter  
August 27, 2020 - Interim financial statement, first half year  
November 25, 2020 - Interim financial statement, third quarter





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