

Calmark

Sector: Medtech

Calmark: Diagnosing the New Generation

Redeye initiates coverage on Calmark, a Swedish diagnostics company offering point of care testing for biomarkers in newborns. Commercialization is now starting, and we believe further regulatory approvals are underway. Calmark is rather uniquely positioned, in our view, and our supportive valuation reflects a base case of significant sales ramp-up in 2022-23. While not in our numbers yet, the possibility of Covid-19 relevance adds spice.

Several regulatory approvals expected in 2021

During Q2'20 Calmark acquired CE-marking for its Neo-Bilirubin test. We estimate further regulatory approvals during H1'21 for its additional three tests which should have a positive impact on the shares. In September, Calmark reported its first sales in the Nordic market, marking an important milestone. We expect a broader geographical reach in the coming years, in line with its focus on the EMEA and Asian markets.

Targeting a global niche-market with a scalable product

Currently, there are sub-optimal to non-existing POC-tests for newborns, allowing Calmark to operate in a relatively competition-free market, potentially enabling an attractive long-term market position. The company's razor-and-blade business model allows for a quick and scalable expansion, and we anticipate sales to grow rather aggressively in the coming years, reaching SEK 24m in 2023.

50% upside in a base scenario

Redeye's fundamental analysis of Calmark presents a Base Case value of SEK 8.4 per share. The case is dependent on Calmark gaining regulatory approvals on its tests for Neo-Glucose and Neo-LDH, and a subsequent successful global commercialization.

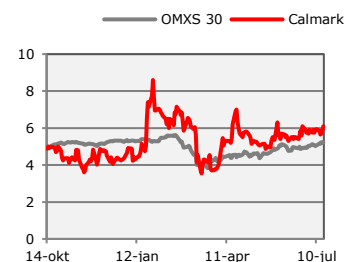
We caution, however, that further equity infusions are most likely.

| KEY FINANCIALS (SEKm) | 2018 | 2019 | 2020E | 2021E | 2022E | 2023E |
|-----------------------|------|------|-------|-------|-------|-------|
| Net sales | 0 | 0 | 0 | 3 | 14 | 24 |
| EBIT | -5.2 | -7.6 | -20 | -22 | -17 | -16 |
| EPS (adj) | N/A | N/A | -1.0 | -1.5 | -1.4 | -1.0 |
| EV/Sales | N/A | N/A | 569.0 | 149.5 | 13.5 | 8.9 |
| EV/EBIT | N/A | N/A | -7.4 | -22.1 | -10.7 | -13.1 |
| P/E | N/A | N/A | -6.0 | -3.9 | -4.4 | -6.3 |

FAIR VALUE RANGE

| BEAR | BASE | BULL |
|------|------|------|
| 2.6 | 8.4 | 12 |

VERSUS OMXS30



REDEYE RATING



KEY STATS

| | |
|--------------------------|-----------|
| Ticker | CALMA B |
| Market | Spotlight |
| Share Price (SEK) | 5.6 |
| Market Cap (MSEK) | 122 |
| Net Debt 20E (MSEK) | -7.3 |
| Free Float | 78% |
| Avg. daily volume ('000) | 99.51 |

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Investment Thesis

Calmark's point of care (POC) testing supports the strained healthcare system by freeing resources from time-consuming laboratory procedures. With its initial sales recently recorded and additional regulatory approvals on the way, we see a positive outlook for the company that is founded on:

- Highly supportive macro trends
- Limited competition in targeted markets
- A global expansion strategy, initially targeting Europe and the Middle East with an already established distribution system in place

Macro trends point in the right direction

With the world making a push towards lower neonatal mortality, Calmark offers a solution that facilitates accurate and time-efficient point of care (POC) diagnostics. Backed by political and financial incentives, the company is well positioned to capitalize on this opportunity with its value proposition through its established global distributors.

Limited competition

Calmark's POC tests for biomarkers target a group with none to sub-optimal testing, providing Calmark with a substantial competitive advantage against current methods. Moreover, features such as user friendliness, cheapness, and mobility allow it to be used in areas where such tests would fill a great unmet medical need.

Strategic Partnerships Already in Place

With production partnerships in place and a distribution partnership ready, management is well on the way to accelerate its launch of Calmark's POC test. With sales recently initiated, the coming years sales progression should bring greater confidence to the company's long-term prospects. We emphasize its scalability and lack of current clear competition.

Key metric for success

Given that Calmark is a small company with limited resources it is a bold strategy to expand globally within only a few years. However, if well executed it could pave way for a substantial sales ramp up in short time.

We identify new market entries, sales growth and no further delays of regulatory approval as main drivers for closing the valuation gap to our Base Case.

As Calmark is a small company with limited resources, its strategy of expanding globally in just a few years is bold. However, if well executed it will allow a substantial and rapid sales ramp-up. We forecast sales of SEK 14m in 2022, growing to SEK 64m by 2025.

This sales growth, along with new market entries and no further delays in regulatory approval, are the main catalysts we identify that should close the share's valuation gap to our Base Case.

Catalysts

Regulatory approvals

Additional regulatory approvals (CE marking of Neo-LDH and Neo-Glucose) should benefit the share significantly as these would allow the company to shift its focus towards commercialization

Strength: Major

Time Horizon: 6-12 months

Further sales in new markets and sales ramp-up

We expect further sales ramp-up to act as a catalyst for the share as it confirms the demand for Calmark's products. While initial sales are likely to be limited, they should open the way for recurring orders and help build traction for the company.

Strength: Major

Time Horizon: 3-9 months

Additional partnerships for global launch

To fulfill its global aspirations, we expect Calmark to put additional partnerships in place.

Strength: Moderate

Time Horizon: 3-12 months

Covid-19 triage, a further possible boost

In view of the pandemic's urgency and increased use of medical triage, CE marking of the LDH test for COVID-19 could be a significant catalyst for the share. However, as the diagnostics market for COVID-19, is highly competitive and the pandemic's duration and impact are uncertain, we do not include this in our sales forecast at this stage.

Strength: Moderate to Major

Time Horizon: 6-9 months

Counter Thesis

Neo-LDH and Neo-Glucose not yet CE-marked

To scale up fully, Calmark has to offer its complete product portfolio, which requires CE marking of its Neo-LDH and Neo-Glucose tests. Delay in achieving these marks would cost valuable patent time and make obtaining regulatory approval in other markets more difficult.

Industry conservatism and competition

Altering the behavior of practitioners in the conservative healthcare industry is time-consuming and difficult. In addition, the industry's central role for committees, regulatory approvals and clinical validation stretches out the time involved in adopting a new technology even further.

Experienced leadership is needed to navigate new products through to commercial launch. Accordingly, we see a considerable risk that ramping up sales could take longer than expected - particularly in view of Calmark's global ambitions.

Distribution scale up-risk

Calmark plans to launch its products globally within just a few years. We expect the first sales in Europe, India, and the Middle East in 2021, and in China in 2022. This ambitious plan will challenge both the company and its partners and distributors, upon which Calmark relies heavily. Any setbacks for the partners could harm Calmark and delay its sales ramp-up.

Company Description

Founded in 2007, Calmark focuses on newborn care, primarily researching the established bilirubin, LDH, and glucose biomarkers, which indicate an array of severe conditions. The company has developed an accurate, easy-to-use, and cost-effective point-of-care (POC) diagnostics platform for these biomarkers.

Calmark intends to operate with a razor-and-blades business model and outsource production, sales, and distribution to specialized partners. Recently (April 2020), Calmark received CE approval for Neo-Bilirubin with the POC analyzer. Three more products are awaiting regulatory approval. Ahead of this, the company is steadily expanding its geographical reach by signing new partnerships.

The company has an established distributor for Sweden, Finland, Latvia, Estonia, and Lithuania. Recently, it also signed a distribution agreement with Alpha Tech for the Jordanian market. Calmark currently has 12 employees based at its office in Stockholm.

Calmark has been listed on the Spotlight Stock Market since July 2018. Its IPO raised SEK 23m at a price of SEK 4.60 per share. Since then, the share has increased by approximately 20% and currently trades at SEK 5.6.

Historical milestones

| | |
|------------------|---|
| 2007 | Calmark AB is founded by Mathias Karlsson and Sofia Hiort af Ornäs |
| 2007-2010 | The company researches LDH and builds a patent portfolio |
| 2012 | Calmark starts clinical studies on LDH as a biomarker for critical conditions in newborns |
| 2012 | The hildaNeo System is developed |
| 2013 | Calmark attracts Almi as an investor |
| 2015 | Mathias Karlsson is recruited as chairman of the board |
| 2015 | Version two of the platform is developed, named Helga |
| 2016 | External recruitment of Anna Söderlund As CEO |
| 2016 | The company pivots into developing the Calmark POC |
| 2017 | Development of tests for bilirubin and glucose are started alongside development of LDH |
| 2018 | The company is listed on Spotlight Stock Market Development of the cassette design are finalized |
| 2019 | Negotiations with Triolab are initiated Neo-Bilirubin is given a CE marking |
| 2020 | Negotiations with Triolab are finalized Calmark receives first order on the Calmark POC from its distributor |

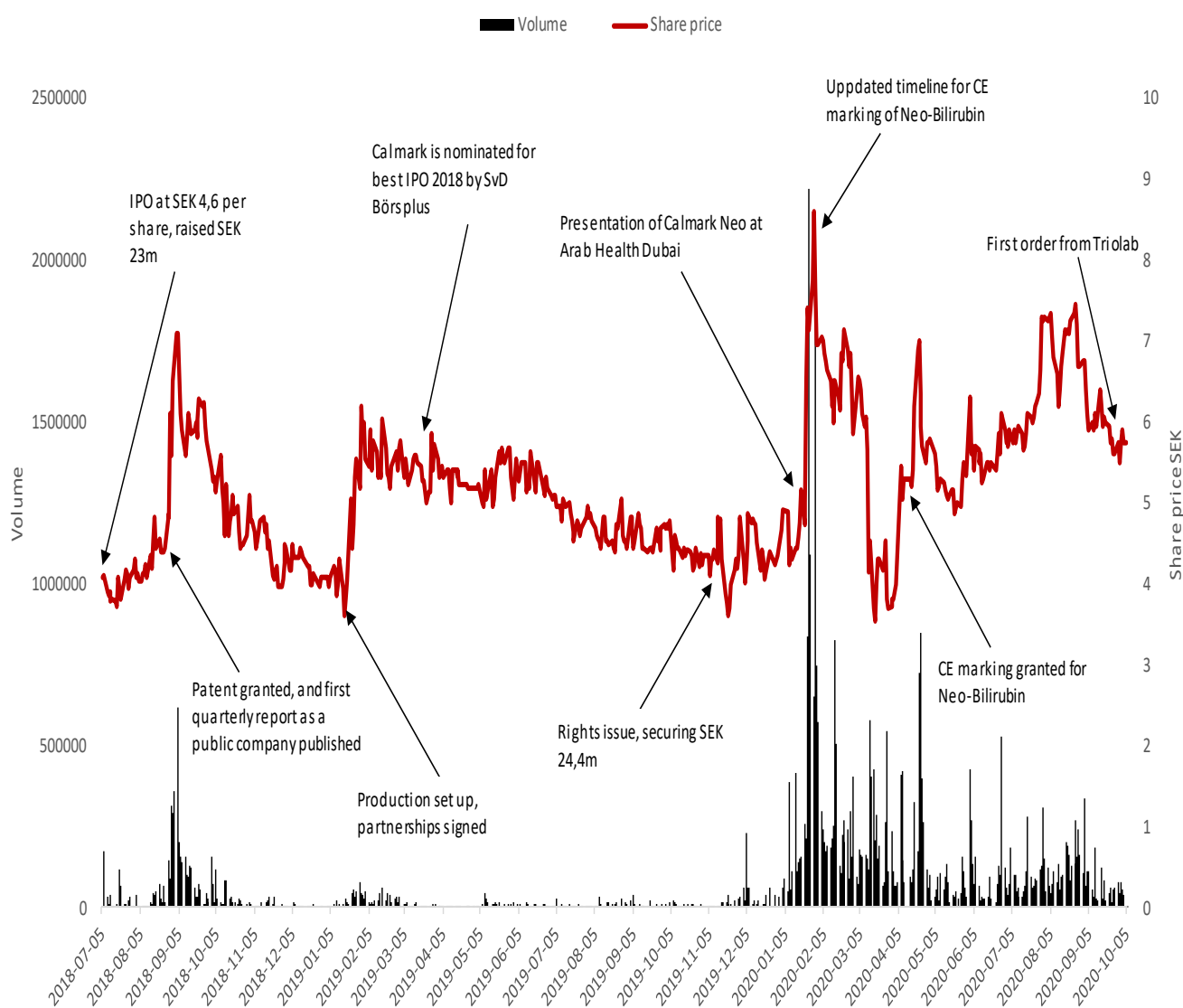
Source: Calmark

Stock performance

Since its IPO in July 2018, the share has had a volatile journey, currently trading some 20% above its IPO-price. During this time the company has achieved several milestones illustrated below. The share started 2020 strong, but the outbreak of Covid-19 resulting in delayed regulatory approvals took the share to an all-time low in early March. Since then the share has gained some momentum, until just recently.

Going forward, fueled by fundamental progress, particularly further sales and entrance in new markets. Further bolstered by regulatory approvals we expect the share to gain positive momentum, eventually closing the valuation gap to our Base Case.

Calmark: Share price performance since IPO



Source: Redeye Research, Bloomberg terminal

Governance and Ownership

Insider ownership

We are encouraged by that Mathias Karlsson, founder, and chairman of the board, is a large shareholder in Calmark. However, Mr. Karlsson aside, insider ownership is relatively scarce in the company. Additional share purchases by insiders would be encouraging from an investor's point of view.

| Owner | % Capital | % Votes |
|----------------------|-------------|-------------|
| Mathias Karlsson | 5,69 | 8,19 |
| Anna Söderlund | 0,79 | 0,89 |
| Magdalena Tharaldsen | 0,12 | 0,10 |
| Camilla Arneving | 0,06 | 0,05 |
| Stefan Blomsterberg | 0,03 | 0,02 |
| Total | 6,69 | 9,25 |

Source: Holdings

The largest owner is Lars Wingefors, CEO and founder of Embracer Group. Despite Mr. Wingefors not having historically had a MedTech background, we have a favorable view of his ownership in Calmark. As a skilled entrepreneur, Mr. Wingefors provides a seal of approval with his 22,47% holding of the capital in Calmark.

The current institutional holding of Calmark is somewhat limited, aside from Creades holding some 9,44% of the shares. Moreover, start-up investor ALMI holds 2,25%. Apart from the co-founders, private investors make up the majority of the shareholders.

Top 10 owners

| Owner | % Capital | % Votes |
|-----------------------------|--------------|--------------|
| Lars Wingefors | 22,47 | 22,75 |
| Johnny Olsson | 9,67 | 9,63 |
| Creades AB | 9,44 | 7,61 |
| Mathias Karlsson | 5,70 | 8,01 |
| Avanza Pension | 5,18 | 4,17 |
| ALMI | 2,25 | 3,78 |
| Sofia Hiort af Ornäs | 1,91 | 3,02 |
| Bengt Braun Förvaltnings AB | 1,71 | 2,04 |
| Lars Hansson | 1,68 | 2,50 |
| Grete Aronsson | 1,12 | 0,9 |
| Total | 61,13 | 64,41 |

Source: Holdings, Redeye Research

The management and board of Calmark provide a diverse range of skills relevant to the company's operations, particularly in medical technology and finance. For a more detailed description of management and the board, we refer to the appendices.

Medical Need

Diagnostics tools are of great importance during childbirth, as early care can significantly reduce long-term complications for newborns. Most newborns in the EU and the US, as well as in other developed countries, are tested for bilirubin and glucose.

In less developed countries, these tests are still taken frequently and are of great importance, as they provide physicians with information about a newborn's health in the vital first hours of life. Testing for LDH is carried out in cases of more problematic childbirth where there have been complications; this accounts for roughly 10% of childbirths. However, it is crucial to observe any health deviations in a newborn early to provide adequate treatment and avoid long term disease.

Bilirubin

Bilirubin is a yellow compound that forms when heme is broken down. Heme is the molecule in red blood cells to which oxygen binds for transportation to the organs. Elevated levels of bilirubin are usually the reason for newborn jaundice. Elevated levels are natural as the newborn's body breaks down old heme and replaces it; usually, newborn jaundice subsides after a couple of days. Still, it is crucial to observe bilirubin-levels continuously. Abnormally high values are critical for a baby, as they can lead to brain damage. Too high levels of bilirubin can indicate that the liver is underdeveloped and, cannot efficiently clear the bilirubin. On the bright side, if the baby is treated in time, the prognosis is good. High bilirubin levels are easily treatable by exposing the newborn to photo therapy treatment

Lactate Dehydrogenase

Lactate dehydrogenase (LDH) is an enzyme found in almost every cell of the body. Its role is vital in the Krebs cycle, which regulates the release of stored energy. Levels of LDH rise when the body has undergone tissue damage or is suffering from hypoxia.

In newborn care, LDH is tested to determine whether a baby is at risk for, or suffering from respiratory conditions, brain damage, or tissue damage (examples being asphyxia, respiratory distress, necrotizing enterocolitis, ischemic encephalopathy, among others). This makes LDH an excellent predictor in determining whether intensive care procedures are required.

If critical levels are detected, the newborn is often treated by cooling; if this is done early enough (preferable within 4-6 hours), it greatly reduces the risk of long-term complications.

Glucose

The third test provided by Calmark is of glucose levels. Currently, approximately 15-20% of all newborns experience low glucose levels (hypoglycemia) during their first days of life. Persistent hypoglycemia is harmful, however, and can lead to brain damage and even death in severe cases.

Hypoglycemia in newborns is generally caused by low nutrition levels during birth. It has also been shown to be connected to the mother's health, with a higher prevalence among mothers diagnosed with diabetes or other metabolic diseases.

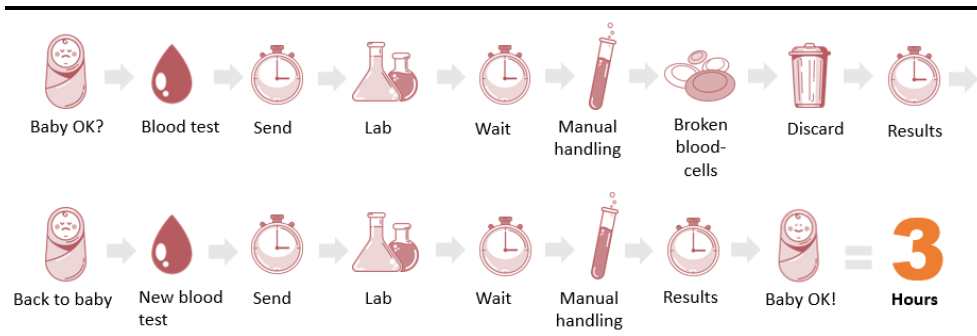
Hypoglycemia is usually treated by giving the newborn a sugar cube dissolved in water.

Streamlining the current chain of care

Testing a newborn for LDH, bilirubin, and glucose is time-consuming and expensive in high-income countries. In low- to middle-income countries, testing is infrequent, costly, and complicated.

The illustration below shows the current chain of care (from symptoms to diagnosis).

Chain of Care – Today’s Process



Source: Calmark

Not only is the current chain of care time-consuming, but it also requires valuable resources – specialized lab-technicians and manual handling – resulting in bottlenecks owing to time lags. Typically, the entire chain would take around 1.5 hours; however, in 10-15% of cases, time lags lead to a condition called hemolysis, which means that the blood cells break. This effectively results in two invasive procedures (blood tests), doubling the chain of care to three hours.

To prevent hemolysis and resolve the higher blood sample requirements, Calmark has developed an efficient POC test. Calmark’s test requires only 50-60 microliters of blood, compared with the 400 microliters of blood needed for the lab-analyzed test.

Chain of care – Calmark’s POC System



Source: Calmark

Eliminating the need for manual handling by specialized technicians results in fewer time lags and bottlenecks, reducing healthcare costs and providing a more efficient process. We argue that the platform would meet an unmet medical need in low- to middle-income countries in particular.

Incentives

In a study by Linköping University (Schilling, 2015), the researcher estimated that POC testing could reduce healthcare costs by 8-25%. This indicates significant potential cost savings within newborn care through implementing more POC testing. However, most of the cost-savings effect is hard to measure and somewhat intangible, as it mainly relates to reductions in neurological problems and disabilities.

According to the National Institutes of Health in the US, the cost-efficiency aspect is one of the main reasons why so many children die in the first 28 days of life in low- to middle-income countries¹. Research suggests that 98% of reported neonatal deaths are in less developed countries and that up to 70% of neonatal deaths occur because effective yet simple interventions do not reach those in need².

Research suggests that the first step to reduce newborn mortality is to align policy decisions with newborn health. There is strong political will, given the ratification of the United Nations Sustainable Development Goals. We thus believe there are adequate financial, humanitarian, and political incentives in favor of Calmark's products.

Product Portfolio

Calmark POC

The basis of the company's platform is the Calmark POC. The system works by dropping a blood sample from a newborn baby onto a test cassette that is inserted into the POC analyzer. Within minutes, the instrument provides on-screen analytical data gained from the newborn's blood sample.

The instrument is easy to carry and operate. The reader calibrates itself when started and provides clear graphical guidance for the user. Installation of the device is simple, and the reader is easy-to-use. The user just needs to plug the charger into the instrument; the battery life is eight hours, and the reader can store 25 test results locally.

The Calmark POC Analyzer (left) and Neo-Bilirubin Test-Kit (right)



Source: Calmark

Test cassettes

The instrument uses colorimetric measurement analysis to read the test cassette. When blood in the test cassette hits a chemical-laced filter, a chemical reaction creates a change in color that is analyzed by a camera and the software in the instrument. Calmark estimates that the process takes only a few minutes. The underlying design and functionality of all Calmark's tests are the same. The Calmark POC is designed to be used as subsequent tests are developed, facilitating future economies of scale.

¹ Institute of Medicine (US) Committee on Improving Birth Outcomes; Bale JR, Stoll BJ, Lucas AO, editors. Improving Birth Outcomes: Meeting the Challenge in the Developing World. Washington (DC): National Academies Press (US); 2003. 3. Reducing Neonatal Mortality and Morbidity.

² Neonatal Care Public Policy and Care for the Neonate. Fossari Sippel Marcio A, 2014

Neo-Bilirubin

To discover abnormal bilirubin levels, newborns are measured non-invasively using a skin screening method as the first line of testing. Calmark is targeting second-line testing of newborns who have shown high bilirubin values during first testing, or when non-invasive testing is not available.

The JH20-1C (a transcutaneous bilirubinometer) is an example of non-invasive testing. It is deemed a reliable method for determining hyperbilirubinemia (jaundice caused by elevated levels of bilirubin) when levels are below 222 $\mu\text{mol/L}$. Levels above this show discrepancies between the total bilirubin measured in blood serum versus transcutaneous bilirubin (Ercan Ş & Özgün G, 2018). Furthermore, discrepancies and inaccuracies vary between test brands. Discrepancies also increase significantly when testing darker skin colors (Taylor et al., 2015), suggesting a further need for invasive testing methods.

The Neo-Bilirubin test is more accurate and can be considered a second-line diagnostics tool. Approximately 20% of all newborns undergoing first-line testing require second-line continuous testing that allows the care provider to diagnose the severity of the higher bilirubin levels accurately. The care provider takes a blood sample, roughly 60 μL venous blood, and places this into the test cassette.

Invasive blood tests should be more accurate in detecting higher levels. However, as discussed in *Current Chain of Care* above, issues arise when another blood test is needed due to hemolysis or other factors. Calmark says its bilirubin test is still accurate after the effect of hemolysis up to 2g/L. In other words, even with a time lag, the test is still accurate, further reducing the need for a second invasive procedure. A bilirubin test is usually taken within the first week after birth. If levels are high, the newborn's bilirubin levels will be measured several times.

Neo-bilirubin is currently commercially viable having been granted a CE mark in April 2020.

Neo-LDH

Roughly 10% of childbirths are complicated and require assistance from a pediatrician. In these cases, LDH tests are conducted on the newborn. These tests currently require lab analysis, as shown in the *Chain of Care – Today's Process* illustration.

Neo-LDH is therefore a time-efficient decision-making tool that allows the caregiver to be able to provide adequate treatment, reducing the risk of long-term damage to the newborn. LDH tests are taken just after birth and are only taken once.

We estimate that the Neo-LDH test will be the second of Calmark's tests to receive a CE mark. We expect this during H1'21.

Neo-Glucose

A glucose meter is currently used to test newborns, typically the same type that is used by people with diabetes. However, these meters are not optimized for use on newborns; values below 3mmol/L are often classified as low on these meters. If this happens, another blood sample has to be gathered for analysis in a lab, taking valuable time in severe cases. Moreover, this also runs the risk of hemolysis (the breaking of red blood cells) in the blood sample, which occurs due to the fragility of a newborn's blood ex vivo. This ultimately renders the sample unusable for testing, and the whole process needs to start again.

According to Calmark, Neo-Glucose has been developed to measure the glucose levels in newborns and can show a higher precision of values than existing products. The company believes it is accurate to 1-4mmol/L. A glucose test is usually taken more than once on a newborn to verify the effect of the treatment.

We estimate Neo-Glucose will be the last of Calmark's tests to receive a CE mark. We expect this during Q4'21.

Redeyes estimated timeline for CE marking

The tests require CE marks before Calmark can initiate sales and marketing activities in the EU. Moreover, regulatory processes in most of the additional targeted markets rely on CE marks as guidelines, allowing for full geographical reach once acquired. CE approval also directly opens up the markets with which the EU has mutual recognition agreements, such as Australia, Switzerland, and New Zealand.

Obtaining CE marks for the LDH and glucose tests requires Calmark to demonstrate the tests safety, accuracy, and minimal deviation. Calmark needs to collaborate with a hospital to acquire such data. It has chosen Södersjukhuset in Stockholm. Owing to the recent coronavirus pandemic, however, the entire healthcare system experienced abrupt changes and hospitals have had to relocate their resources. There are currently no staff available for these studies. We expect the studies to be initiated when hospitals have the possibility to relocate their teams.

The CE approval process for Neo-Bilirubin took roughly four months, and we anticipate that it will take 3-6 months for Neo-LDH and Neo-Glucose once testing is initiated. Below we estimate the timeline of CE approval, based on Södersjukhuset being able to initiate testing during Q4'20.

Estimated CE approvals

| | Q1 20' | Q2 20' | Q3 20' | Q4 20' | Q1 21' | Q2 21' | Q3 21' | Q4 21' |
|------------------|-----------------|--------|--------|--------|-----------------|-----------------|--------|-----------------|
| Neo-Bilirubin | Approved | | | | | | | |
| LDH | | | | | | Expected | | |
| Glucose | | | | | | | | Expected |
| LDH For Covid-19 | | | | | Expected | | | |

Source: Redeye Research

Publications and studies based on Calmark's technology

Currently, Calmark's products have been technically validated through the study at Södersjukhuset used for its CE approval. The study was based on 40 newborns and aimed to compare the results from the Calmark POC with results from the hospital's laboratory. Due to the COVID-19 pandemic, the study had to be stopped. Still, the requirements to effectively verify and validate the bilirubin test were met, allowing CE approval for the Neo-Bilirubin.

There is another clinical study that we have identified based on Calmark's products from 2015, using an earlier prototype of the platform, which essentially works differently to the current version. Instead of the POC analyzer, the user would use a smartphone. However, the essential technology, filtering, and colorimetric analysis are identical.

Halvorsen et al. 2019

This study was conducted on two cohorts of newborn children (n=88) at Södersjukhuset in Stockholm (n=62) and Vietnam National Children's Hospital in Hanoi (n=26).

The study was intended to describe a possible method for a diagnostic tool fulfilling the ASSURED (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, and deliverable to end-users) criteria. Furthermore, while LDH is a known biomarker of cell damage, its role as a biomarker of critical illness in newborns is relatively unexplored, and so this was the study's objective.

The study concluded its results, showing that LDH values are statistically significantly higher in ill patients, thus rendering it a credible predictor of severe illness in newborns.

Furthermore, the study concluded that a POC device that fulfills the ASSURED criteria would be attractive in resource-limited settings. As 85% of newborns with infection die due to lack of screening and treatment, the study suggests that methods such as these could contribute to reducing this significant medical issue.

Patent Portfolio

The protection of intellectual property is of absolute importance for any innovative company. In Calmark's case, its extensive patent portfolio protects it from possible product infringement, with expiration dates ranging from 2026 to 2037. In our view, this portfolio provides adequate time for the company to gain and hold market share and to further develop new tests to bolster its competitive position.

Patent Portfolio

| Patent No. | Country | Description |
|------------------|---------|---|
| 0602158-8 | Sweden | Method of determining hypoxia in scalp blood during childbirth |
| 5655307 | Japan | Method of determining hypoxia in scalp blood during childbirth |
| 8945824 | USA | Method of determining hypoxia |
| 0950717-9 | Sweden | Test system for determining hypoxia-induced cellular damage |
| 1050958-6 | Sweden | Test system for determining hypoxia-induced cellular damage |
| 21005 | Vietnam | Method of determining hypoxia |
| 1151115-1 | Sweden | System and method for analyzing the risk or presence of organ failure In vitro method for analyzing a comparison of an indicative numerical value to a predetermined threshold |
| 1151116-9 | Sweden | so as to assess a likelihood of risk or presence of organ failure |
| ZL201080054087.0 | China | Testing system setup and method for testing |
| 21008 | Vietnam | Testing system setup and method for testing |
| 9045792 | USA | Testing system setup and method for testing |
| 9228953 | USA | In vitro method for analyzing a comparison of an indicative numeric value to a predetermined threshold so as to assess a likelihood of risk or presence of organ failure |
| 1750028-1 | Sweden | POC testing system for biomarkers |
| 540437 | Sweden | Detection of a biomarker in a sample of a flowable substance Detection of the presence of a biomarker in a sample of a flowable substance. A method of detecting the presence of a biomarker in a sample of a flowable substance, a detector assembly for use in the detection of a biomarker in a sample of flowable substance and a detector unit |
| 543001 | Sweden | Detection of the presence of bilirubin in a sample of a flowable substance. A method of detecting the presence of bilirubin in a sample of a flowable substance, a detector assembly for use in the detection of bilirubin in a sample of flowable substance and a detector unit |
| 543002 | Sverige | |

Source: Calmark

POC-Analyzer and Test Cassette Protection Status

| Protection No. | Country | Description |
|----------------|-----------------------|---|
| DM/103451 | Europe and USA (WIPO) | Design protection regarding the POC Analyzer |
| | China | Design protection regarding the POC Analyzer |
| | India | Design protection regarding the POC Analyzer |
| | Vietnam | Design protection regarding the POC Analyzer |
| | Europe and USA (WIPO) | Design protection regarding the POC test cassette |

Source: Calmark

Business Model

Calmark has a razor-and-blades business model, selling its instruments at a low margin and its single-use tests at a high margin. Having its POC analyzer at hospitals will provide recurring revenue from sales of its test cassettes. We do not expect the readers to generate any particular sales, we forecast that the absolute majority of sales will stem from its test cassettes.

The company owns its production equipment but outsources production to specialized manufacturers. Calmark is currently developing a further production line that is expected to be completed during H1'21. It should raise annual production capacity to 6,000,000 units from the current 500,000 units.

Given the coming global expansion, targeting many less developed countries, Calmark intends to sell its products at lower margins but at high volumes. We emphasize the importance of Calmark having an agile production line, allowing it to expand production capabilities quickly if needed. This enables economies of scale, although at the loss of some operational control and increased dependency on manufacturers and distributors.

Business strategy

We have identified Calmark's strategy as built upon four pillars: *automated production, distribution and production partnerships, global launch, and product innovation*. Calmark has developed a unique strategy to execute its business model within each. We detail the current progress in each pillar below.

Automated production

In collaboration with Frohe, Calmark aims to enable production capacity of 6,000,000 test cassettes per year. Currently, the company's semi-autonomous production line has capacity for 500,000 tests per year. This is not enough to meet long-term demand. We view the steps that Calmark is taking to meet long-term demand as positive. Furthermore, having the production based in Sweden at least initially will enable agile production, we argue.

We identify some risks associated with outsourcing production to partners. Firstly, not having production in-house brings the risk of dependence vulnerability. Effectively, if something happens to Calmark's manufacturing partner Frohe, it could mean that Calmark is unable to deliver the test cassettes, ultimately resulting in lost sales.

Distribution and production partnerships

As previously mentioned, rather than establishing a sales and production infrastructure itself, Calmark is aiming to partner with reputable companies with established relationships and representation in their local markets. Current partnerships are detailed below.

Note AB

Calmark has outsourced production of the instruments to Note, a Swedish manufacturer that specializes in niche products and holds broad medtech experience.

Frohe AB

Frohe is a Swedish manufacturing company that specializes in medical technology, focusing on production of niche plastic products. Calmark has outsourced production of its test cassettes to Frohe's plant in Tyresö.

Triolab

Triolab is a distributor that specializes in medtech products. It has extensive experience in dealing with these. Triolab is primarily established in the diagnostics market with wide-ranging relationships. Currently, it is Calmark's distributor for Sweden, Finland, Estonia, Lithuania, Latvia, and Estonia.

Alpha-Tech

In August 2020, Calmark signed a distribution partnership with Alpha Tech Est. covering the market in Jordan. Aside from marketing, the partnership also includes Alpha Tech assisting with the regulatory approval process. Alpha Tech has a network of hospitals in Jordan, and so we consider this partnership an important step towards Calmark launching in the Middle East.

Nordic Match

To further facilitate a launch in the important Chinese market, Calmark has partnered with Nordic Match, a consultancy firm with offices in both Stockholm and China, a broad network of Chinese investors, and a profound knowledge of its local markets.

In October, Calmark registered a subsidiary company in Hong Kong with Nordic Match's help. We expect a registered subsidiary company on mainland China, located in the Greater Bay Area, to be announced soon.

Global Launch

Calmark is consistently looking for opportunities to expand into new markets, a process that it undertakes in stages. Initially, it hires a limited number of personnel to train and educate the distributors and end-customers. This results in a less costly process and offers flexibility for further geographical expansion.

Currently, we expect Calmark to launch an expansion plan in two phases.

So far

Calmark has launched and generated sales in Sweden. We expect it also to launch Neo-Bilirubin in Jordan after signing a distribution partnership with Alpha Tech in August. We anticipate a launch in Jordan in late Q4'20 or early Q1'21.

Phase one

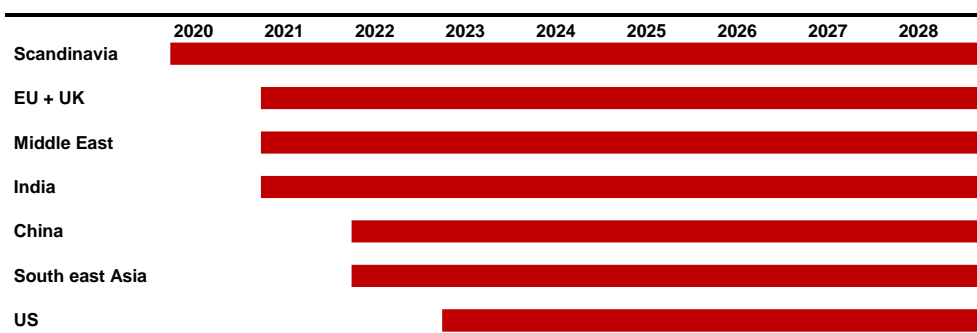
The first phase of Calmark's global expansion will be into the rest of the EU, the UK, the Middle East, and India. Calmark is currently working on establishing the required distribution partners and the necessary regulatory approvals for launch.

Phase two

In the second phase of the launch, Calmark plans to enter the large markets of China and the US. Entering the US market will require a 510(k) approval from the FDA. If Calmark makes any changes to the Calmark POC, it will have to file for complimentary 510(k) approval from the FDA, consuming both money and time. We thus expect Calmark to launch in the US market last. As during the first years of use, feedback from customers is expected to lead to improvements in the current instrument, which could be implemented before the 510(k) filing and US launch.

Below is Redeye’s estimated timeline for when we expect Calmark to start generating sales in each market.

Calmark: Our anticipated expansion timeline



Source: Redeye Research, Calmark

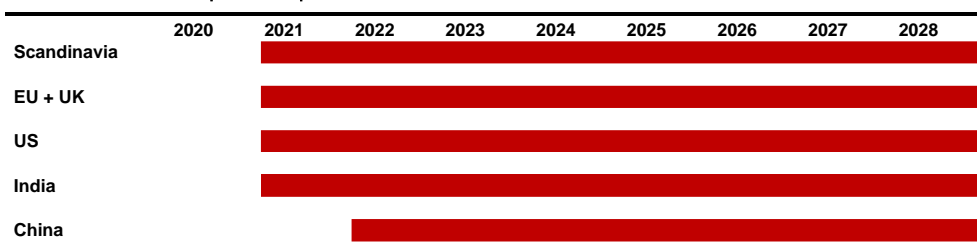
Product innovation

Later, Calmark aims to develop more tests that are compatible with the Calmark POC. The company has announced that it wants to offer all tests taken on a newborn during the first month of its life. According to the company, development of further tests of biomarkers for infectious disease is a possibility that would complement its current product portfolio.

LDH for COVID-19 triage

Calmark has recently proven its product innovation capacity. With minor modification, it re-modelled the LDH test to assist with COVID-19 triage. We estimate that the test will achieve regulatory approvals during Q1'21.

Calmark: Our anticipated expansion timeline for COVID-19 LDH-test



Source: Redeye Research, Calmark

Multiple studies have verified that LDH plays a large role in estimating the likelihood of death from and the severity of COVID-19. Research shows that elevated LDH levels are associated with a six-fold increase in the odds of developing severe disease and a sixteen-fold increase in mortality. These results are compiled from nine different published studies (Henry et al., 2020). However, this meta-study does not specify the causal relationship between LDH, death and severity, and other diseases. In other words, the study does not specify if the elevated LDH levels were exclusively due to COVID-19, or whether they were also affected by other risk factors that in turn led to the increased severity of COVID-19.

The regulatory pathway for devices targeting COVID-19 is more simplified than normal CE approval. As the purpose is to facilitate the diagnostics and triage of the pandemic, LDH COVID-19 can bypass some of the processes needed for normal CE approval. We thus expect the process to be completed within three to six months.

Competition

The POC testing markets for LDH, glucose, and bilirubin are highly fragmented, with several companies selling different versions of bilirubinometers, glucose meters, and blood gas analyzers. However, the lack of POC testing methods specifically for newborns gives Calmark a strong competitive advantage. We consider this the strongest underlying driver for Calmark acquiring market share.

We believe competition comes from two angles: other products for these tests, such as glucose meters or blood-gas tests; and industry conservatism.

We argue that the latter will be the largest hurdle for Calmark. Healthcare is sluggish when it comes to adopting new technologies, even if they provide economic and clinical value. This puts substantial pressure on the sales strategy and further clinical validation of the Calmark POC. That said, we believe Calmark is in an attractive position and the conditions are in place for it to execute this launch successfully.

Below, we compare the Calmark POC with the current methods for taking these tests on newborns.

Calmark POC and peer test methods

| | Calmark POC | Glucose | Bilirubin | LDH |
|--|-------------|----------|-----------|-----------|
| Type of test | POC | POC | Labratory | Labratory |
| Accurate within given intervall | Yes | Mediocre | Yes | Yes |
| Procedure speed | Fast | Fast | Slow | Slow |
| Is cost efficient | Yes | Yes | No | No |
| Ease of use | Easy | Easy | Hard | Hard |

Source: Redeye Research

By specifically targeting newborns, for whom there are today sub-optimal tools for conducting these tests, we view Calmark's product portfolio as a strong competitor. Currently, bilirubin and glucose can be tested using the typical blood-gas analyzers, such as ABL90 and RAPIDPoint 500. These are usually stationed at neonatal intensive care units (NICU). However, the LDH test cannot be taken using such blood-gas analyzers and the test requires a more manual process performed in a lab. The Calmark POC is intended to be located where there is no access to blood-gas analyzers. Consequently, we do not consider these as close peers to Calmark's product.

Moreover, the price difference between the two is immense. Typically, they cost around SEK 300,000 compared with our estimated price to the customer of SEK 10,000-20,000 for the Calmark POC. This makes it a far less expensive option, without compromising its clinical utility. In general, cost-efficiency and mobility are not blood-gas analyzers' strong suit.

The current testing for bilirubin can be divided into screening and more accurate testing, as described earlier. When the non-invasive bilirubinometer has screened the newborn as requiring more testing, usually the test is sent to a laboratory for analysis. As illustrated in the illustration *Chain of Care – Today's Process*, this is not time, resource or cost-efficient compared with Neo-Bilirubin.

Wong et al. (2017) states that POC blood glucose monitors for newborns must be accurate, rapid, inexpensive, and accept small blood volumes. Currently, glucose meters developed for adult diabetics are used for newborns. These fulfill the above criteria except for their reduced accuracy when blood glucose levels are beneath 3 mmol/L. The blood required is also more than is preferred for a newborn. When suspecting an inaccurate test, another blood sample is

taken and sent to a lab for further and more accurate analysis. Requiring a large sample of blood nullifies the cost-efficiency criteria and is also time-inefficient. Like bilirubin meters, glucose meters are manufactured by many different companies, including Bayer, Abbot Laboratories, and Thermo Fisher.

Market Analysis

The market for Calmark

One aspect of the market Calmark is addressing must be considered: the number of children born. This, the essence of Calmark's market, is shrinking globally. As a result, we choose a conservative approach when calculating the addressable market and potential market share for Calmark.

In this large and global market, there is vast growth potential for Calmark, given the right expansion, pricing, and distribution strategy. We use calculations on the number of newborns expected in the targeted markets (Scandinavia, rest of the EU, China, the US, the UK, South-East Asia, India, and the Middle East) multiplied by the percentage of newborns that we expect to need each test as the basis for our estimates. We then multiply the number of tests each child will need by its price. We base our expectations for incidence on the factors below. When approaching global expansion with a product that has clinical and economic relevance, we still argue that a successful commercialization plan is hard to execute. Therefore, we choose a conservative approach when considering the anticipated market share for Calmark.

LDH – 10%

As LDH is a biomarker for several leading causes of death among newborns – such as, but not limited to, perinatal asphyxia, transient tachypnea, necrotizing enterocolitis, and hypoxia-ischemia – we are confident in the company's estimate that 10% of newborns will need LDH tests in the future. This test is only taken once on a newborn.

Bilirubin – 15%

Around 60-80% of neonates experience jaundice within the first 28 days of life. Research shows that 18% of cases are so severe that treatment is needed. We estimate that 15% will need ongoing bilirubin testing; on tested newborns, we assume an average of two Neo-Bilirubin tests.

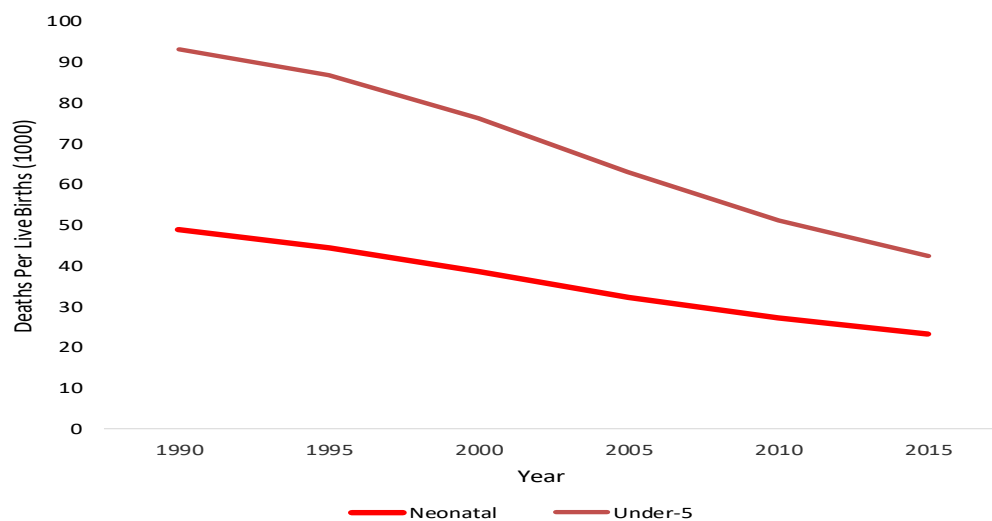
Glucose – 15%

Taking a conservative approach, we estimate that 15% of newborns need ongoing glucose testing. Usually, newborns suffering from hypoglycemia during birth will require several glucose tests to ensure that the treatment is sufficient. We estimate an average of two Neo-Glucose tests taken on each newborn tested.

Child mortality

Global child mortality among the under 5s has been declining for decades. While this is a positive trend, the mortality rate for children between 0 and 28 days of life has not seen the same level of improvement. However, the statistic is skewed, as newborn mortality is implicit as a proportion of under 5s mortality. According to the World Health Organization, newborn mortality represents roughly 46% of all deaths among the under 5s. Today, around 2 million newborns die within their first month of life each year, with most of these deaths occurring in low- to middle-income countries.

Neonatal vs. Under-5 years mortality



Source: Redeye Research, World Bank, UNICEF

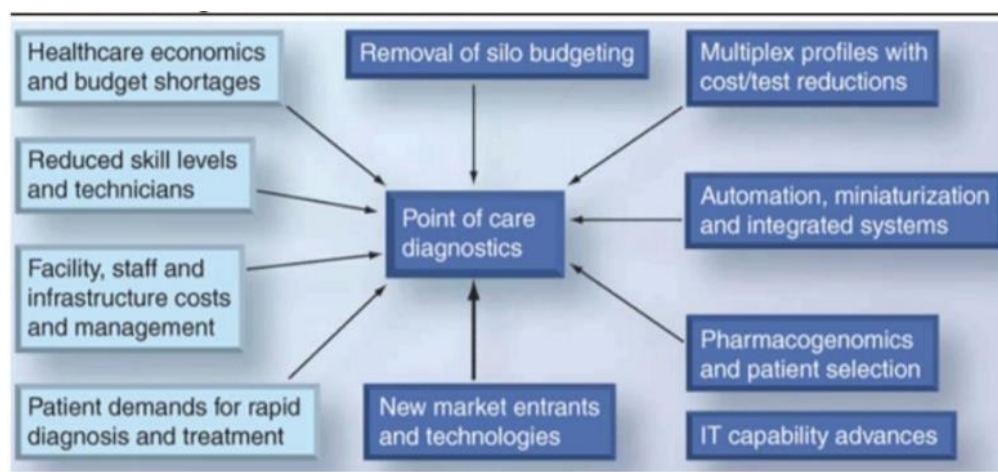
Point of Care – Fighting child mortality

Research from the National Institutes of Health, the WHO, and others states that low-cost and accurate POC diagnostics will play a large part in reducing this dreadful statistic. An increasing population will result in more laboratory testing at hospitals becoming unsustainable, pushing for POC testing. This further strengthens our confidence in Calmark’s case as a provider of POC tests for newborns.

Furthermore, contributing factors such as a higher standard of living, incentives from governments, and political ambitions will drive the market. A rise in the standard of living leads to the prioritization of healthcare spending, resulting in innovation and development. Moreover, when standards of living rise, fertility rates decline, increasing healthcare spending per child. This effectively protects the market size against the estimated decline in fertility.

We judge that the market for POC diagnostics has many drivers, and we foresee it growing further in the decade to come. Although we see the above-mentioned drivers as the most important, we also highlight additional factors in the illustration below.

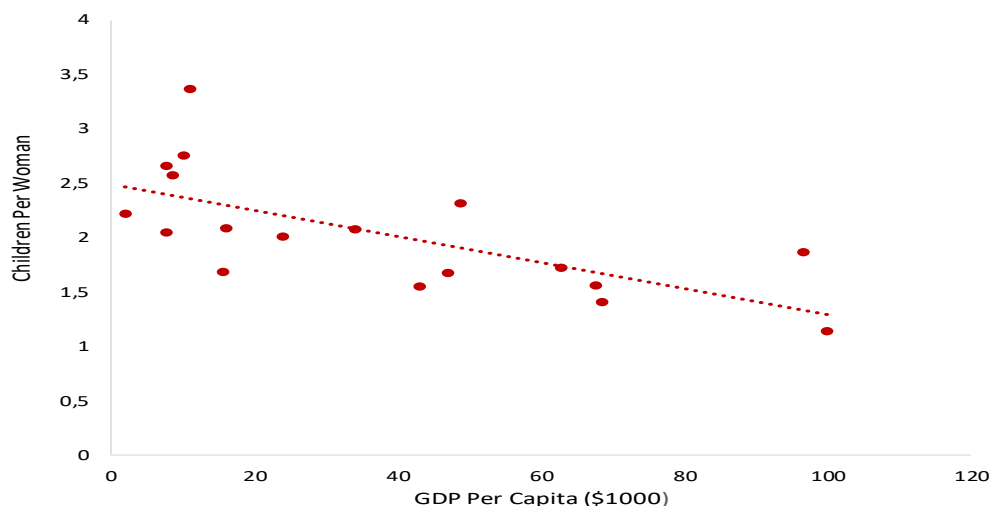
Point of Care Market Drivers



Source: MedScape

We are confident in the long-term market need for POC diagnostics and in accelerating market growth. This is further strengthened by market research carried out by *Markets and Markets*, which estimates that the global POC diagnostics/testing market will reach USD 46.7bn by 2025 from USD 28.5bn today, representing a CAGR of 10.4%. It expects that a rise in innovation and the growing use of novel POC tests and devices (such as Calmark's) will fuel industrial progression.

Total fertility rate vs GDP (PPP) per capita (\$1000)



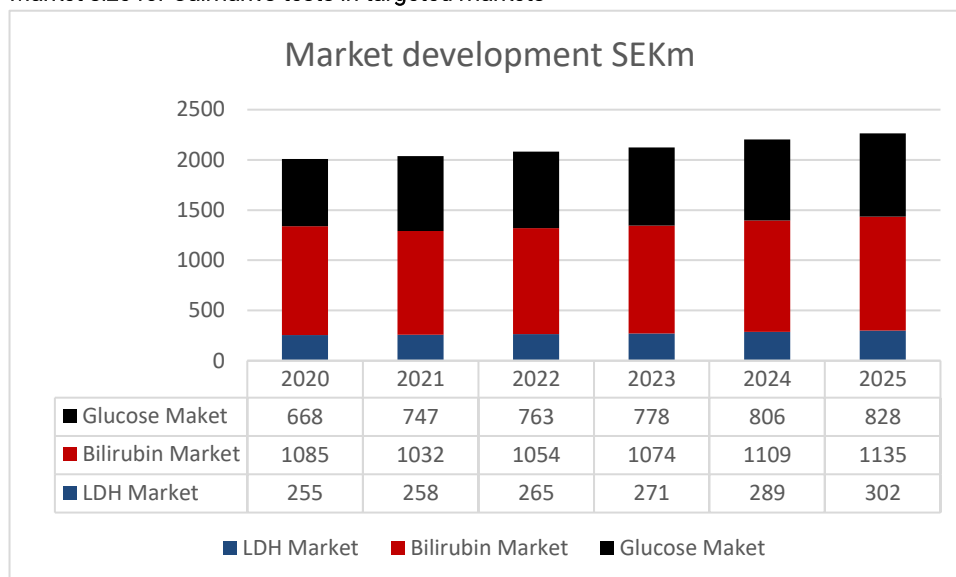
Source: World Bank Group, Redeye Research

Addressable market

We calculate that the addressable market for Calmark's products (Neo-Bilirubin, Neo-Glucose, and Neo-LDH) in the countries it targets entering will grow from SEK 2bn in 2020 to SEK 2.21bn in 2025. The LDH test is taken once per newborn, for glucose and bilirubin we assume an average of two tests taken per tested newborn.

In many cases these tests are taken more than twice, which would imply a larger TAM for Calmark. Given our conservative approach, we have calculated the market size without regard for eventual price changes and inflation.

Market size for Calmark's tests in targeted markets



Source: Redeye Research, World Bank Group

Bilirubin market

We expect the Bilirubin to be the biggest of these three markets for the company. We expect it to grow from SEK 1bn in 2020 to SEK 1,1bn in 2025, and that Calmark will be able to capture a market share of 10-15 percent in the long term.

LDH market

There are currently no POC LDH tests on the market. This gives us confidence that Neo-LDH will be able to capture 15-20 percent of this market in the long term, given that it achieves CE approval. We see a higher market uptake in low- to middle-income countries.

We expect the addressable market for LDH testing to grow from SEK 255m in 2020 to SEK 302m in 2025.

Glucose market

We foresee Calmark having a more challenging time capturing market share in the glucose testing market, as there are already POC tests on the market. However, we suggest that care providers will, over time, become aware of the benefits of using the Neo-Glucose test thanks to its superior accuracy for newborns. This should result in an accelerating ramp-up in market penetration.

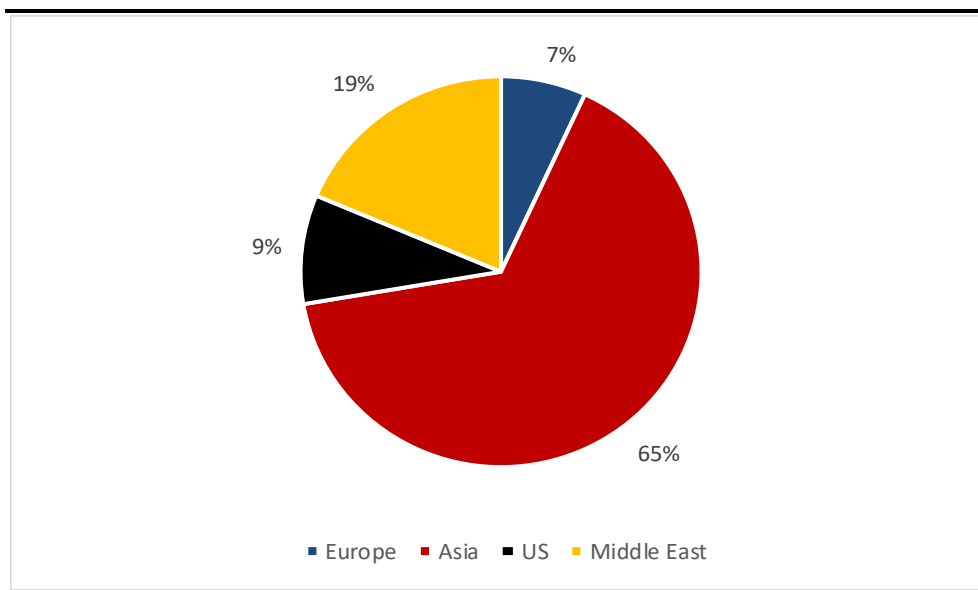
We expect the market for glucose testing in the scheduled markets to grow from SEK 668m in 2020 to SEK 828m in 2025.

LDH COVID-19 market

This particular market is volatile and extremely hard to estimate accurately, owing especially to uncertainty as to how long the pandemic will last and the extent to which a vaccine will affect its prevalence. For now, we choose a conservative approach and do not include this in our current DCF valuation, as it is hard to assign it a realistic value at present. Instead, we see this as a value-adding option that complements Calmark's product portfolio.

Geographical Market Analysis

Targeted markets for Calmark divided by region



Source: Redeye Research

Scandinavia, the EU, and the UK

Due to its low population and fertility rates, we do not expect the Scandinavian market (including Finland) to be the significant income drivers for Calmark. However, we argue that it is essential for the company to have a presence in its home markets. We expect the use of the platform in Scandinavia to act as a marketing tool, spreading awareness and increasing interest, and leading to other markets both in and beyond the EU to use its platform. As discussed, phase one involves launching in the Scandinavian market, with the rest of the EU following in phase two. We characterize the EU, the UK, and the Scandinavian markets as particularly difficult due to their mature landscape and industry conservatism.

Currently, the EU and the UK have respective fertility rates of 1.5 and 1.7 children per woman. Scandinavia has a fertility rate of 1.6 children per woman. These markets already exhibit some of the lowest newborn mortality rates. Consequently, we believe Calmark's competitive edge stems from the cost-efficiency aspect of its product portfolio.

South-east Asia

Due to the willingness to invest resources to combat child and maternal mortality in South East Asia, we are confident in Calmark's plans to enter this region.

Singapore is characterized as a high-income country with a small population, and so we do not foresee any significant revenues from this market initially for Calmark. However, we consider it an excellent reference market that can facilitate future geographical expansion in the region.

Vietnam's relatively high fertility rate of 2.04 children per woman works in Calmark's favor; the initial addressable market is massive. We expect Calmark to begin registration for its products in Vietnam as soon as its CE mark has been granted. We thus see Neo-Bilirubin being filed for registration soon. The country has seen a drop in its child mortality rate of 64% between 1990 and 2015. Over this period, maternal mortality has also come down by 69%. We compare this to the global average drops of 52% and 44%, respectively, signaling strong incentives.

Another interesting country in this region is Malaysia. It provides an attractive market for Calmark thanks to its substantial GDP growth rate of 4.7% and increasing investments in healthcare, which offer a lucrative opportunity for Calmark's products.

China

We argue that entering China is vital for Calmark's long-term prospects. China has seen an accelerating drop in its fertility rate in the decades following the 1979 implementation of its one-child policy. This has recently been reformed as a two-child policy, which experts argue could lead to rising fertility rates in the future. Given the estimated size of the Chinese market, this also presents a lucrative opportunity for Calmark.

Given the significant economic growth generated in China in recent decades, increased healthcare investments have led to the child mortality rate falling from 37% in 2000 to 7.9% in 2019. This signals strong incentives to improve China's healthcare, further strengthening our optimistic view on the Chinese market for Calmark.

The US

The US is especially interesting regarding bilirubin testing. Depending on the hospital, all newborns are blood-tested for bilirubin. We thus calculate a higher addressable market for the bilirubin test in the US, with approximately 40% of newborns being tested. We also see a high demand for LDH testing due to the high risk of malpractice lawsuits in US healthcare.

Hospital access is practically universal. With this in mind, we see the market as mature. Even though the US has the third-largest population globally, we expect the market for these tests to shrink in the coming decades, given the country's declining fertility rate.

The Middle East

The Middle Eastern market is defined by Calmark as comprising the UAE, Jordan, Saudi Arabia, Kuwait, Bahrain, Egypt, and Qatar. As in South East Asia, these countries experience large-scale economic growth, resulting in more resources being spent on healthcare. The healthcare industry is expected to experience increased investment and a larger share of national budgets. For these reasons, we consider these markets attractive for Calmark.

Furthermore, the company has generated interest through its participation in the Arab Health Convention, resulting in an established partnership with Alpha Tech. The regulatory process of approval in Jordan is now underway. We view this positively as it could lead to a faster launch in the Middle East.

However, we believe the negative aspects of population decline are offset by the rise in income levels and healthcare spending in the region.

India

Like China, India represents a significant portion of the global population. With a fertility rate of 2.22 children per woman and a population of 1.35 billion, India promises to become an important market for Calmark. Potential market entry presents a vast opportunity in the country, as rural areas usually have underdeveloped healthcare and hospital care, with obstacles such as long wait times, overcrowding, and extended travel. We estimate market introduction in 2021, presenting a convincing opportunity for Calmark POC.

India has been experiencing substantial economic growth, hovering around 7% per year in the last 30 years. Owing to this growth, investments in healthcare have increased, resulting in a decline in the child mortality rate (deaths per 1,000 live births) to 34 in 2019 from 126 in 1990.

Geographical risks

Investors should be aware of the substantial risks of entering low- to middle-income countries. Difficulties might arise when trying to reach end-users, mainly owing to a lack of healthcare infrastructure. Also, in many cases, regulatory approval processes might be

unclear. However, we are confident that the POC market growth drivers and incentives can offset this risk.

Declining fertility

The market that Calmark is addressing is based on the birth of newborns. It is an established fact that when countries become more prosperous and more developed, their fertility rate declines. This suggests a coming decline in the markets that Calmark is addressing. However, this situation instead allows more resources to be spent on every newborn; in other words, more testing per capita. Adding this to the product innovation that allows for more indications available with the Calmark POC, we assume that the market will be profitable for Calmark in the future as well.

Fertility rate (Children per woman)

| Region | 2014 | 2015 | 2016 | 2017 | 2018 |
|-----------------|------|------|------|------|------|
| Europe | 1,7 | 1,7 | 1,7 | 1,7 | 1,6 |
| United States | 1,9 | 1,8 | 1,8 | 1,8 | 1,7 |
| China | 1,7 | 1,7 | 1,7 | 1,7 | 1,7 |
| South East Asia | 1,8 | 1,8 | 1,8 | 1,7 | 1,7 |
| India | 2,3 | 2,3 | 2,3 | 2,2 | 2,2 |
| Middle East | 2,4 | 2,4 | 2,3 | 2,3 | 2,3 |

Source: World Bank Group

Financial Situation

Sales Estimates

After the regulatory approvals, we anticipate further clinical validation in the following years, and that positive data will boost the long-term prospects for its sales potential. We also see further geographical expansion as paramount for the company to aggressively increase its sales in the coming years.

Income statement forecast

With Calmark's sales ramping up we expect a CAGR of 73% from 2021-2027, and forecast breakeven in 2025.

As Calmark initially is selling in more developed countries, where the company can take a higher price for each test, we expect a higher gross margin. However, we expect it to consolidate around roughly 70-75% from 2027 and beyond, as the company gains more sales from regions with a lower average price to distributor.

Income statement 2020-2027 (SEKm)

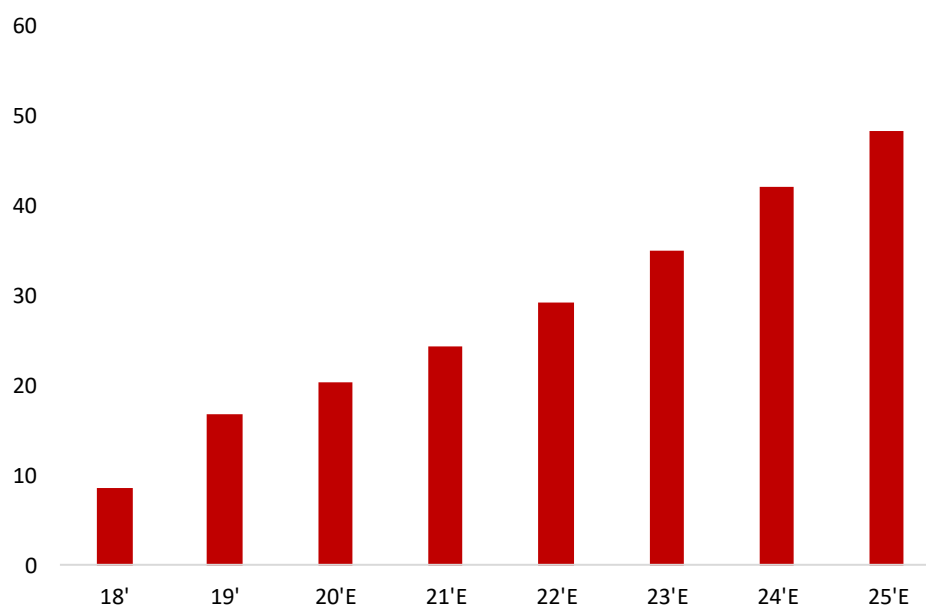
| | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 |
|---------------------|------------|------------|------------|------------|------------|-----------|-----------|------------|
| Net Sales | 0 | 3 | 14 | 24 | 37 | 65 | 93 | 138 |
| <i>Gross Margin</i> | 81% | 87% | 88% | 85% | 85% | 77% | 76% | 75% |
| <i>Sales Growth</i> | N/A | 1114% | 328% | 76% | 55% | 74% | 43% | 49% |
| EBIT | -20 | -22 | -17 | -15 | -11 | 1 | 15 | 40 |
| <i>EBIT Margin</i> | N/A | N/A | N/A | N/A | N/A | 2% | 16% | 29% |
| Taxes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Net Income | -20 | -22 | -17 | -15 | -11 | 1 | 15 | 40 |

Source: Redeye Research

EBIT and cost drivers

In pivoting from research to sales, we expect Calmark to increase its costs. Calmark will have to hire more personnel to handle relations with distributors, partners, and manufacturers. We also expect Calmark to conduct further studies related to development and regulatory approvals of subsequent tests compatible with the Calmark-POC. With these cost-increases in mind, we estimate the following OPEX in the future.

Calmark: OPEX between 2018 and 2025.



Source: Redeye Research, Calmark

We expect an aggressive ramp-up in costs to continue until – 2025, beyond then we expect a lower ramp-up as the YoY-growth is anticipated to cool off.

Additional Capital is Required

At the end of Q2 2020, the company had SEK 11,6m in cash and cash equivalents. Calmark currently has outstanding warrants expected to raise between SEK 10,3m and SEK 16,2m, depending on the subscription price decided as 75% of the share price during the period 12-23 October 2020.

Valuation

Our valuation of Calmark is based on a discounted cash flow (DCF) model. Our fundamental long-term analysis suggests upside of some 53 percent from current levels to our Base Case of SEK 8,4 per share.

Fair Value Range – scenario-based approach

At Redeye, we approach valuation through a set of three scenarios to provide a more dynamic view of the case.

Of the three, the Base Case is the one we judge most likely. Our Bull and Bear Cases reflect more optimistic and pessimistic scenarios (valued at +114 percent and -46 percent versus the share's current levels, respectively)

Base Case – SEK 8,4 per share, 50 percent upside

Our Base Case is based on the following;

- Strong sales growth for Calmark POC and test cassettes in the coming years, bolstered by a broad geographic expansion
- Sales to reach SEK 13m in 2022, SEK 24m in 2023, and SEK 64m in 2025. Reaching a positive cash flow in 2025
- Bilirubin market share 15 percent (10 percent in Europe), LDH market share 20 percent (15% in Europe), Glucose market share 10 percent

Bear Case – SEK 2,6 per share, 54 percent downside

Our pessimistic scenario factors in, a lower market share and slower sales ramp-up for all of Calmarks tests, as well as including a delayed process for acquiring CE marking of the LDH and glucose tests.

- Sales expected to reach SEK 9m in 2022, SEK 18m in 2023, and SEK 55 in 2025. Reaching a positive cash flow in 2027
- Bilirubin market share 10%, LDH market share 15%, Glucose market share 8%

Bull Case – SEK 12 per share, 114 percent upside

Our optimistic scenario factors in, a higher market share and faster sales ramp-up for all of Calmark's tests, as well as the assumption that all of Calmark's tests are granted during H1'21.

- Sales expected to reach SEK 16m in 2022, SEK 30m in 2023, and SEK 72 in 2025. Reaching a positive cash flow in 2025
- Bilirubin market share 15%, LDH market share 25%, Glucose market share 12,5%

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

Business: 2

Financials: 1

| INCOME STATEMENT | 2018 | 2019 | 2020E | 2021E | 2022E |
|-----------------------|------|------|-------|-------|-------|
| Net sales | 0 | 0 | 0 | 3 | 14 |
| Total operating costs | 0 | -34 | -20 | -24 | -26 |
| EBITDA | 0 | -34 | -20 | -21 | -13 |
| Depreciation | 0 | 0 | 0 | -1 | -1 |
| Amortization | 0 | 0 | 0 | 0 | -4 |
| Impairment charges | 0 | 0 | 0 | 0 | 0 |
| EBIT | -5.2 | -7.6 | -20 | -22 | -17 |
| Share in profits | 0 | 0 | 0 | 0 | 0 |
| Net financial items | 0 | 0 | 0 | -10 | -10 |
| Exchange rate dif. | 0 | 0 | 0 | 0 | 0 |
| Pre-tax profit | -5.2 | -7.6 | -20 | -22 | -17 |
| Tax | 0 | 0 | 0 | 0 | 0 |
| Net earnings | -5.2 | -7.6 | -20 | -22 | -17 |

| BALANCE SHEET | 2018 | 2019 | 2020E | 2021E | 2022E |
|----------------------------|------|------|-------|-------|-------|
| Assets | | | | | |
| <i>Current assets</i> | | | | | |
| Cash in banks | 13 | 25 | 0 | 0 | 1 |
| Receivables | 1 | 2 | 315 | 3,824 | 1 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 0 | 0 | 0 | 0 | 0 |
| Current assets | 14 | 27 | 315 | 3,824 | 2 |
| <i>Fixed assets</i> | | | | | |
| Tangible assets | 0 | 2 | 3 | 4 | 4 |
| Associated comp. | 0 | 0 | 0 | 0 | 0 |
| Investments | 0 | 0 | 0 | 0 | 0 |
| Goodwill | 0 | 0 | 0 | 0 | 0 |
| Cap. exp. for dev. | 0 | 0 | 0 | 0 | 0 |
| 0 intangible rights | 24 | 33 | 35 | 37 | 36 |
| 0 non-current assets | 0 | 0 | 0 | 0 | 0 |
| Total fixed assets | 24 | 35 | 38 | 42 | 40 |
| Deferred tax assets | 0 | 0 | 0 | 0 | 0 |
| Total (assets) | 38 | 62 | 353 | 3,866 | 42 |
| Liabilities | | | | | |
| <i>Current liabilities</i> | | | | | |
| Short-term debt | 1 | 1 | 15 | 186 | 33 |
| Accounts payable | 2 | 3 | 289 | 3,505 | 1 |
| 0 current liabilities | 1 | 1 | 1 | 1 | 1 |
| Current liabilities | 4 | 5 | 305 | 3,692 | 35 |
| Long-term debt | 2 | 1 | 13 | 169 | 30 |
| 0 long-term liabilities | 0 | 0 | 0 | 0 | 0 |
| Convertibles | 0 | 0 | 0 | 0 | 0 |
| Total Liabilities | 7 | 6 | 318 | 3,862 | 66 |
| Deferred tax liab | 0 | 0 | 0 | 0 | 0 |
| Provisions | 0 | 0 | 0 | 0 | 0 |
| Shareholders' equity | 29 | 55 | 35 | 4 | -23 |
| Minority interest (BS) | 0 | 0 | 0 | 0 | 0 |
| Minority & equity | 29 | 55 | 35 | 4 | -23 |
| Total liab & SE | 36 | 62 | 353 | 3,866 | 42 |

| FREE CASH FLOW | 2018 | 2019 | 2020E | 2021E | 2022E |
|-----------------------|------|------|-------|-------|-------|
| Net sales | 0 | 0 | 0 | 3 | 14 |
| Total operating costs | 0 | -34 | -20 | -24 | -26 |
| Depreciations total | 0 | 0 | 0 | -1 | -5 |
| EBIT | 0 | -34 | -20 | -22 | -17 |
| Taxes on EBIT | 0 | 0 | 0 | 0 | 0 |
| NOPLAT | 0 | -34 | -20 | -22 | -17 |
| Depreciation | 0 | 0 | 0 | 1 | 5 |
| Gross cash flow | 0 | -34 | -20 | -21 | -13 |
| Change in WC | 2 | 0 | -27 | -292 | 319 |
| Gross CAPEX | -24 | -11 | -3 | -4 | -3 |
| Free cash flow | -22 | -45 | -51 | -317 | 303 |

| CAPITAL STRUCTURE | 2018 | 2019 | 2020E | 2021E | 2022E |
|-----------------------|------|------|-------|-------|-------|
| Equity ratio | 81% | 90% | 92% | 89% | 83% |
| Net debt | -9 | -23 | -7.9 | -25 | -31 |
| Capital employed | 20 | 33 | 63 | 35 | 39 |
| Capital turnover rate | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 |

| GROWTH | 2018 | 2019 | 2020E | 2021E | 2022E |
|------------------|------|------|--------|--------|-------|
| Sales growth | 0% | 0% | 6,461% | 1,114% | 328% |
| EPS growth (adj) | 0% | 0% | 0% | 55% | -11% |

| DCF VALUATION | | CASH FLOW, MSEK | |
|---------------------------|---------|------------------------------|-----|
| WACC (%) | 15.0 % | NPV FCF (2020-2021) | -94 |
| | | NPV FCF (2022-2028) | 39 |
| | | NPV FCF (2029-) | 155 |
| | | Non-operating assets | 25 |
| | | Interest-bearing debt | -2 |
| | | Fair value estimate MSEK | |
| Assumptions 2020-2026 (%) | | | |
| Average sales growth | 167.3 % | Fair value e. per share, SEK | 8.4 |
| EBIT margin | N/A | Share price, SEK | 5.6 |

| PROFITABILITY | 2018 | 2019 | 2020E | 2021E | 2022E |
|---------------|------|-------|--------|-------|-------|
| RDE | 0% | -80% | -44% | -157% | 0% |
| ROCE | 0% | -75% | -33% | -10% | -9% |
| ROIC | 0% | -169% | -61% | -34% | -5% |
| EBITDA margin | N/A | N/A | -7657% | -659% | -92% |
| EBIT margin | N/A | N/A | -7657% | -678% | -126% |
| Net margin | N/A | N/A | -7657% | -978% | -203% |

| DATA PER SHARE | 2018 | 2019 | 2020E | 2021E | 2022E |
|----------------|------|------|-------|-------|-------|
| EPS | 0.00 | 0.00 | -0.99 | -1.54 | -1.37 |
| EPS adj | 0.00 | 0.00 | -0.99 | -1.54 | -1.37 |
| Dividend | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Net debt | 0.00 | 0.00 | -7.3 | 17.51 | 3.07 |
| Total shares | 0.00 | 0.00 | 20.26 | 20.26 | 20.26 |

| VALUATION | 2018 | 2019 | 2020E | 2021E | 2022E |
|-------------|------|------|-------|-------|-------|
| EV | N/A | N/A | 149.3 | 476.3 | 183.7 |
| P/E | 0.0 | 0.0 | -6.0 | -3.9 | -4.4 |
| P/E diluted | 0.0 | 0.0 | -6.0 | -3.9 | -4.4 |
| P/Sales | 0.0 | 0.0 | 463.1 | 38.1 | 8.9 |
| EV/Sales | 0.0 | 0.0 | 569.0 | 149.5 | 13.5 |
| EV/EBITDA | 0.0 | 0.0 | -7.4 | -22.7 | -14.6 |
| EV/EBIT | 0.0 | 0.0 | -7.4 | -22.1 | -10.7 |
| P/BV | 0.0 | 0.0 | 3.4 | 28.8 | -5.2 |

| SHARE PERFORMANCE | | GROWTH/YEAR | 18/20E |
|-------------------------|--------|----------------------|--------|
| 1 month | - | Net sales | 0.0 % |
| 3 month | 1.7 % | Operating profit adj | 0.0 % |
| 12 month | 21.0 % | EPS, just | 0.0 % |
| Since start of the year | 39.4 % | Equity | 9.8 % |

| SHAREHOLDER STRUCTURE % | CAPITAL | VOTES |
|-------------------------|---------|-------|
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| SHARE INFORMATION | |
|-----------------------|------------------------|
| Reuters code | |
| List | Spotlight Stock Market |
| Share price | 5,6 |
| Total shares, million | 20.3 |
| Market Cap, MSEK | 121.6 |

| MANAGEMENT & BOARD | |
|--------------------|-------------------------|
| CEO | Anna Söderlund |
| CFO | Marielle Bos |
| IR | |
| Chairman | Kjersti Berg Marthinsen |

| FINANCIAL INFORMATION | |
|-----------------------|--|
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Appendix 1 - Management

| Calmark - Management | Position | Experience |
|----------------------|---|--|
| Anna Söderlund | CEO | Serving as CEO since 1st of April 2018. Before that, Anna served as a external CEO for Calmark since 2016. She has over 15 years of experience in the medical technology industry. Including start-ups and several leading positions involving global launches and international sales. Previous employers include Jolife, LMA and Vivoline. Anna has a certified nurse. |
| Marielle Bos | CFO | Serving as CFO since Febuary 2020. Marielle has previously woked within finance and medical technology in both small and large companies. Marielle has previously served as CFO, business controller and financial controller, both internationally and domestically. |
| Michael Lundh | QA/RA | Employed since spring 2016, Michael has worked with QA/RA. Michael has over 10 years of experience from the medical technology industri, primarily within QA and product development. Michael is a engineer and has been a private contractor for over 15 years. |
| Emma Lif | Clinical Director | Employed since March 2019, Emma is the head of clinical research. She is originally a certified nurse and a midwife. She has previous experience form both neonatal and maternal care as well as childbirth. |
| Camilla Arneving | Marketing Director | Employed since September 2018, Camilla has over 20 years of experience within marketing and communication. Primarily Camilla has worked in tourism and IT. Camilla has a graduate degree in Business & Economics. |
| Magdalena Tharaldsen | Director International Business Development | Employed since Augusti 2020, Magdalena has a long experience in leading positions within Life Science companies, mainly responsible for establishment of new sales channels and development of new markets. Magdalena has worked several years within Diagnostics and has a master's degree in Organic and Analytical chemistry. |

Appendix 2 – Board of Director

| Calmark - Board of Directors | Position | Experience |
|------------------------------|--------------------------|--|
| Kjersti Berg Marthinsen | Chairman of the Board | Kjersti took over the reins as chairman of the board in 2020, after serving as a member since 2018. She has a Msc from Handelshögskolen BI in Oslo. She has previous domestic and international experience within strategy, organisational development, management and controlling. She has in later years worked in several managerial positions within Region Värmland. She is a part-owner and head of consulting at Effect Management Development AB. |
| Mathias Karlsson | Founder and Board Member | Founder and medical advisor for Calmark. Member of the board since 2016 and chairman between 2016 and 2020. Mathias is originally a doctor has a PhD from the Karolinska Institute in Stockholm. Currently, Mathias is the head of clinical chemistry at the Central Hospital in Karlstad. Mathias is also the founder and part-owner of HemCheck Sweden. |
| Anna-Karin Edstedt | Board Member | Member of the board since 2018, Anna-Karin has a PhD in pediatrics from the Karolinska Institute. She is a specialist in child- and juvenile medicine since 2009. Anna-Karin has worked as a doctor within neonatal care between 2006 and 2017. In her research-career, Anna-Karin has led the EPICE-project with respect to care of premature births. Since 2017 she has also been working at Doctrin, where she is the head of medical development and head of medicine. |
| Stefan Blomsterberg | Board Member | Member of the board since 2018, Stefan has a background within the Swedish Armed Forces and has worked in areas of education and international arms control. Stefan has also worked within medical technology since 2002 in managerial positions at Vitrolife, Mölnlycke Healthcare, Bioeffect and is now the CEO of Medfield Diagnostics. |

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redev.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

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Redeye Rating (2020-10-14)

| Rating | People | Business | Financials |
|-----------|--------|----------|------------|
| 5p | 19 | 14 | 3 |
| 3p - 4p | 107 | 87 | 38 |
| 0p - 2p | 5 | 30 | 90 |
| Company N | 131 | 131 | 131 |

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CONFLICT OF INTERESTS

Filip Einarsson owns shares in the company : No

Oscar Bergman owns shares in the company : No

Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.