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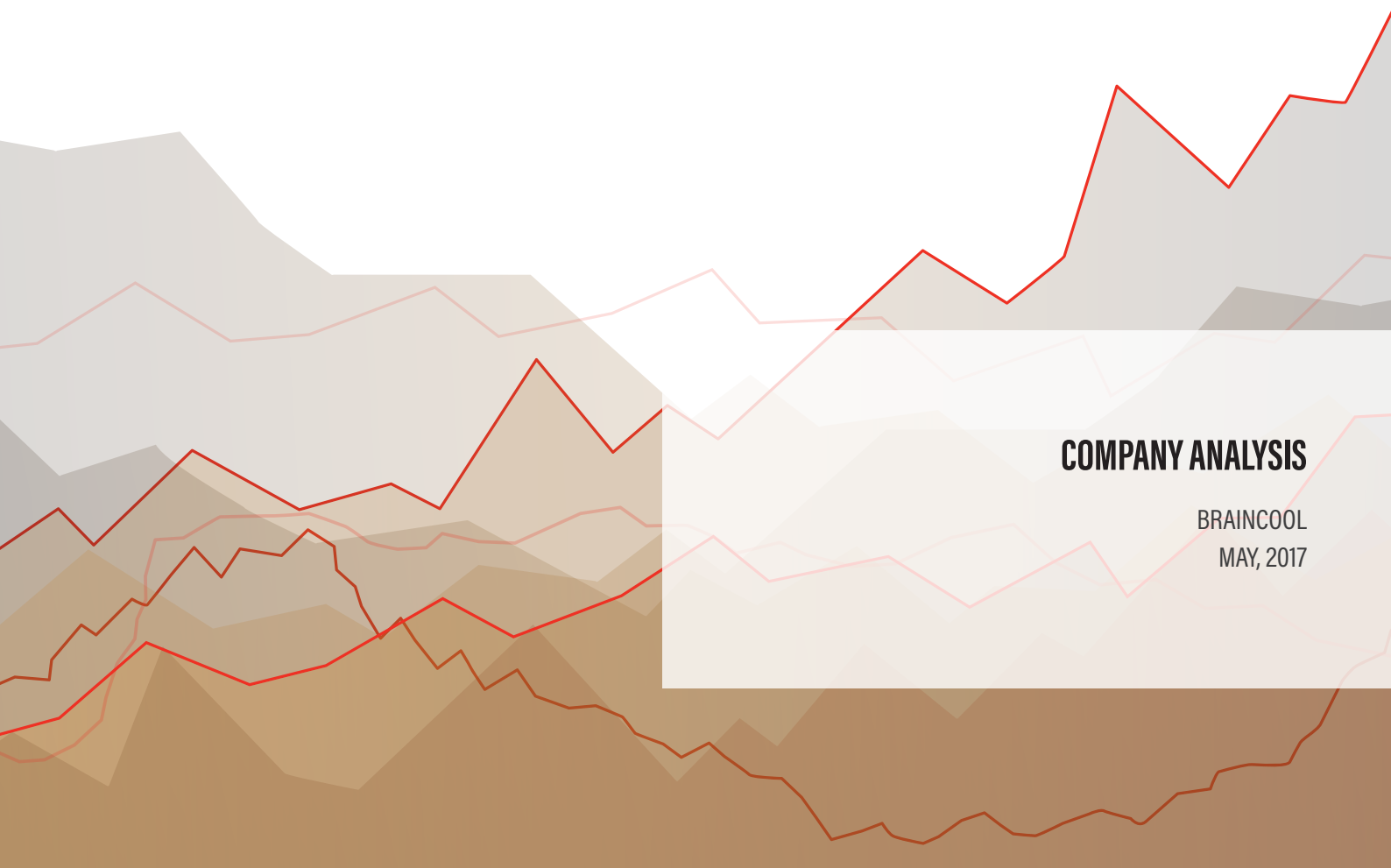

COMPANY ANALYSIS

BRAINCOOL

MAY, 2017

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BRAINCOOL

ANALYTICAL SUMMARY

Swedish medical device company BrainCool develops and markets hypothermia-based products based on a long history of research and development within medical cooling since the beginning of 2000. The lead product is a combination of two different cooling systems; The BrainCool System and RhinoChill, which facilitates rapid early treatment of cardiac arrest and stroke patients in for instance an ambulance and in the emergency department. A key part of BrainCool's technology platform is its patented shivering control systems that can circumvent one of the largest documented side effects of hypothermia treatment, recently highlighted by many US hospitals as an unmet clinical need. This leads to a more optimized and controlled cooling of patients, which is something that is very important to fully extract the benefits of hypothermia treatment.

BrainCool recently acquired Benechill and rights to the product RhinoChill IntraNasal Cooling System. BrainCool thereby acquired a strong patent platform for medical cooling from Benechill and RhinoChill can make a large impact with its selective brain cooling functions. The company had identified strong synergies with RhinoChill and the BrainCool System – BrainCool's main internal technology platform - and is now combining the two products to provide a unique product offer for early hypothermia treatment in an emergency setting. Furthermore, the company is now seeking additional external funding through a new share issue, 58.5 MSEK, to finance further development costs and especially to build up the commercial sales. Against this background, a BioStock analysis has been performed to estimate the market potential of the BrainCool System combined with RhinoChill as a hypothermia treatment product targeting early treatment of cardiac arrest and stroke patients. We have calculated a theoretical peak opportunity of annual sales, in the period 2017 to 2037, based on several assumptions, in this setting for the two combined systems, to almost USD 400 million (profit USD 290 million) for consumables with aggregated sales reaching above USD 4.8 billion (USD 3.7 billion in profit). While for cooling systems a theoretical peak opportunity of annual sales to above USD 23 million (approx. USD 12 million in profit), and the aggregated sales of cooling systems was estimated to about USD 150 million (around USD 77 million in profit). This significant market potential does not account for any of the company's other envisioned indications such as concussion, migraine or oral mucositis, which all have substantial market potential and will be analyzed more in depth in future analyses.

The BrainCool System and RhinoChill targets a market where there are various available treatments such as pharmacological options, surgery procedures, and competing hypothermia treatment solutions. The purpose of hypothermia treatment is to limit the damage that results in the brain due to oxygen depletions, in the events of sudden cardiac arrest or stroke. Directly competing products often achieve hypothermia by intravenous injection of cold saline solutions or by means of larger cooling blankets that cover the body. BrainCool's head cooling technologies utilize pads that are placed on the scalp/neck or inserted through the nose, and are convenient to use.

BrainCool is currently running studies in multiple indications and several key academic and industrial partnerships have been signed since the launch of the company. While the BrainCool System and RhinoChill have received CE certification, the systems are still awaiting final market approval in all targeted regions. Moreover, commercial success is dependent both on a positive outcome from the clinical program and on building up revenue from sales. BrainCool knows that this is challenging and has begun to implement a business model where the company intends to build up its own sales capacity as well as utilizing distribution partners. This is certainly positive and BioStock believes it is necessary for BrainCool - in order to achieve a strategic partnership or a future trade sale - to build up sales as a demonstration that its business can be profitable. Other remaining challenges for the company could be large scale production of especially consumables with an aim to enhance the profit margin since competition from the market could need adaptation of prices to be able to take market shares, among others.

The company is expecting an interesting newsfeed and given the company's rapid development, the future looks both exciting and promising for BrainCool. Read the Conclusion section in the end to learn about the catalysts to watch.

ABOUT THE COMPANY

Background

BrainCool AB started as a subsidiary to Dignitana AB and was listed on the stock market Aktietorget, after a Lex ASEA-dividend in May 2014. BrainCool's business idea is to develop and market products within medical cooling, so called hypothermia.

Initially the company focused on developing a selective brain-cooling product for the treatment of stroke. However, already during the first six months a decision was made to develop a complete surface cooling system for brain-cooling, with numerous unique and patented advantages compared to competing products. In conjunction with this the initial focus was broadened to include two business areas, namely stroke and cardiac arrest.

The company has since the beginning continuously worked towards a stated goal: to utilize clinical and technological synergies, which has resulted in two additional business areas; oncology with the focus on preventing oral mucositis and treatment of concussions with an initial focus on sport injuries. For the two later indications BrainCool has developed a portable cooling system for head/neck or mouth-cooling.

A subsidiary, IQool Technology (now named PolarCool AB), was launched in 2016 for the development and treatment of concussions due to sports injuries and for the general healthcare at emergency department units (The PolarCap System). The plan is to list the company on the stock exchange during second half of 2017 or early 2018.

Furthermore, in 2016, BrainCool acquired the rights to RhinoChill from Benechill, which was one of the competitors to BrainCool. This has led to a strategic competitive positioning on the market, as BrainCool has discovered interesting synergistic effects with its own product, the BrainCool System.

In 2017, the company recently announced that it is also targeting a new indication, namely migraine.

BrainCool

BrainCool is a medical device company located in the innovative life science cluster in Lund, Sweden, focused on developing products for hypothermia treatment of a range of diseases such as stroke, cardiac arrest, concussions, migraine and oral mucositis. The company is in an expansive growth phase and currently has six full-time employees, and three half-time employees, with several new recruitments of experienced industry professionals during the past year. 2016 was a busy year with numerous new established academic and industrial collaborations, launch of new clinical studies and an acquisition of a competitor.

Most of its peers on AktieTorget or Nasdaq First North employ a business model where the majority of investments are poured into a lucrative but distant license deal of its lead asset, which is not the case for BrainCool. Compared to drug developing companies, BrainCool has already reached the market with some of its products and initiated sales on a small scale. The cooling systems can be purchased or leased by hospital units (e.g. emergency departments) although the sizable revenue is expected to come from disposable consumable products such as cooling pads which on average can be used on 1-5 patients.

On the other hand, BrainCool has created a unique position as a medical device company and are in direct competition with certain pharmaceutical products. Examples of these areas are in oral mucositis, migraine and stroke. This could potentially create additional opportunities such as license agreements with pharma companies.

"We believe that the combination of the RhinoChill and BrainCool System provides a unique product offering as early treatment in an emergency setting . The two systems can have a large impact on the current treatment of cardiac arrest and stroke patients.

Martin Waleij, CEO BrainCool

Academic partnerships

Strategic partnerships have been essential to BrainCool's business strategy and currently the Karolinska University Hospital is involved in two leading international studies within oral mucositis and cardiac arrest.

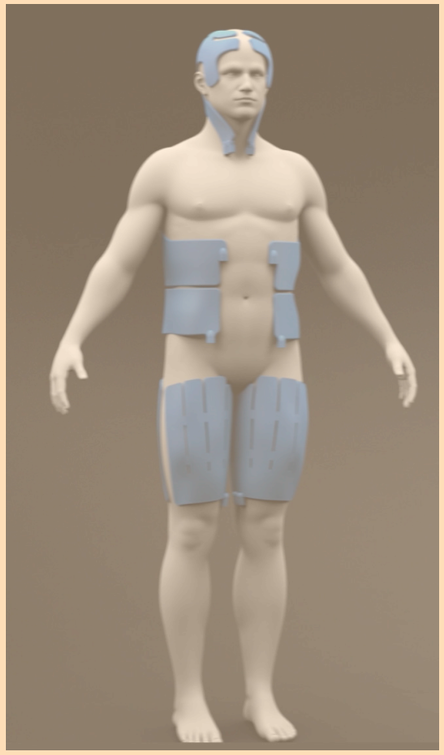
ORAL MUCOSITIS

In October 2016, BrainCool reported news related to new collaboration partners within oral mucositis. This time four University Hospitals in Sweden, including The Karolinska Institute, were included in a new extended clinical trial with the COORAL® System. The study had been delayed according to the original time plan, yet the company reasoned that it would be important to fully optimize the study through correspondence with the FDA and discussions with KOLs at Karolinska before commencing the trial. Meanwhile the company conducted studies on healthy volunteers and in in-vitro models. Finally, in December 2016, BrainCool announced that a smaller study will take place at the Imperial College of London, which will be funded by an organization within the British National Health Service (NHS). With key study sites engaged in Sweden and now in the UK, in addition to presentations held at key conferences, BrainCool has obtained interest on an international level for the COORAL product in the treatment of oral mucositis. Other academic collaborations within oral mucositis are for instance with researchers at the Sahlgrenska Academy and at the Academic University Hospital in Uppsala, which has tested the COORAL System for treatment of oral mucositis (OM) on healthy volunteers. Results from this study were presented during the MASCC/ISOO conference in June 2015.

CARDIAC ARREST

BrainCool recently acquired rights to RhinoChill IntraNasal Cooling System from Benechill. Benechil was founded in year 2004 with a focus on developing products for fast medical cooling. The company had an ongoing clinical trial entitled the PRINCESS study, a clinical multicenter study on patients with cardiac arrest, which is now conducted under BrainCool's management. Shortly after the acquisition a new collaboration was established with two important research clinics in Sweden, namely The Karolinska University Hospital and the new Södersjukhuset (SÖS), involving Per Nordberg as coordinating investigator for the study. The collaboration with the two new sites will, according to Martin Waleij, make it possible to stick to the original time plan and complete the study in 2017. At present time, 550 of a total of 700 patients have been included. The primary goal is to evaluate if more patients will survive with a good neurological function after prehospital treatment with RhinoChill. A previous European study in cardiac arrest patients was conducted with 200 patients (PRINCE study), which proved that a protecting temperature in the brain could be reached with RhinoChill several hours earlier than in patients cooled with more traditional methods. The primary goal of the PRINCE study was not to evaluate survival, but the results indicated that 44% of patients treated with RhinoChill left the hospital alive compared to 31% of patients that were treated with other hypothermia methods. The ongoing PRINCESS study will hopefully provide further evidence of the benefits of early cooling after cardiac arrest. Furthermore, further clinical studies with the BrainCool System in cardiac arrest are planned to be initiated at two-three well reputable universities in the US in 2017. If BrainCool succeeds to involve the right physicians and Key Opinion Leaders (KOLs) as investigators for the planned clinical trials, and if the study results are positive, it could potentially be a door opener to the US market. This will be of great support to establish strong partnerships in the US for the commercial sale of the product.

What is medical cooling?



Much of the medical cooling is so-called therapeutic hypothermia in patients with different diseases, and it is an accepted method of treatment and briefly the method implies that the body temperature is lowered by a few degrees, for example, between 32-38.5 ° Celsius. An example of hypothermia treatment is the protection of the brain and other organs from damage when they are not obtaining sufficient oxygen, e.g. after a stroke or cardiac arrest. In addition to hypothermia treatment, medical cooling is also divided into cooling with medical benefit, which includes cooling treatment such as of patients exposed to damage from for instance radiation / chemotherapy treatment, or to subdue and control fever or migraine. BrainCool has rapidly succeeded in producing several products in the area to be applied within the current five different business areas. In the long term, it is likely that the basic technology will be applied in new areas, which can create new opportunities and business areas.

BRAINCOOL ANALYSIS

ABOUT THE COMPANY

MIGRAINE

BrainCool recently signed two separate Clinical Trial Agreements, with the National Health Service (NHS) in the Northern England and with four Dutch institutes for clinical multicenter trials for the treatment of migraine patients with medical cooling. Each study aim to recruit up to 80-90 patients and are follow up trials to the first clinical study in migraine with RhinoChill (CoolHead 1, conducted by BeneChill) which took place in a hospital setting. The NHS trial will investigate migraine treatment in a home setting and the Dutch trial in a hospital setting for patients that have overdosed triptans based migraine drugs.

STROKE

The initial collaboration partner was Skåne's University Hospital (SUS), which has assisted with various testing and pilot tests with a focus on the development of new applications, as well as ensuring the quality of models for temperature measurements. BrainCool also signed a collaboration agreement with University of Edinburg in 2012, to conduct a proof of concept (POC) study.

Furthermore, during 2012 it was decided that a European multicenter study named EuroHYP-1 (NCT01833312) should be initiated after receiving 15 million Euros as funding. BrainCool and five other companies were selected to participate in the study, including market-leading firms such as ZOLL and BARD, to evaluate their technologies in the treatment of stroke. The phase III study was initiated in year 2013 and in the beginning the recruitment of patients was slow, which in part could be explained by the monitoring rules set by the German regulatory agency in which the clinical protocol was

ABOUT THE COMPANY

administered. The reason being that the study had to follow the same monitoring criteria's as for the development of a pharmaceutical drug. However, the protocol was amended after an interim analysis of the first recruited patients to enhance the recruitment rates. Another factor resulting in slow recruitment was that several study subjects in the trial experienced shivering, which is a common side effect during hypothermia treatments. The BrainCool System is one of only four different products that have been approved to be used on patients in the study and the only one with the application to counter shivering. In October 2016, it was announced that 62 patients had been recruited so far and that around 30 new sites in hospitals in 16 new countries would be added to the trial. So far, the safety and tolerability of medical cooling has been confirmed in the study. According to the company, if strong efficacy data can be generated from the hypothermia treatment it could potentially transform the emergency stroke treatment algorithm worldwide, which could be compared to the introduction of intravenous thrombolysis treatment in year 1995. The rehabilitation of stroke patients is much more expensive compared to cardiac arrest patient that to a less extent gets affected neurologically or obtains cognitive problems, which is often common for stroke patients. The implementation of hypothermia treatment of stroke will be based on enhanced survival, but also through evidence that fewer patients will suffer from physical disabilities. According to CEO Martin Waleij, the treatment can also be of added value for patients that despite the treatment will suffer from disabilities, yet to a lower extent compared to patients that do not receive the treatment.

In 2016, BrainCool published plans to conduct another clinical trial together with the trial unit at SUS, with the product the BrainCool System for cooling of patients with stroke. The goal was to evaluate the product's unique shivering-function during cooling of stroke patients and the company has performed tests and optimized the product.

CONCUSSIONS

In 2015, BrainCool initiated collaborations with two Swedish elite ice hockey clubs, Malmö Redhawks and IK Pantern, to evaluate The PolarCap® System for treatment of concussions obtained during athletic activities. In October 2016, the company announced that the study had been extended to include six additional elite hockey teams: HV71, Färjestads BK, Örebro Hockey and Skellefteå AIK (and two of Skellefteå's junior teams). Following strong interest from other ice hockey clubs, an additional four clubs joined the study as of February 2017. What's notable is that this indication (sports injuries) is now developed in a subsidiary to BrainCool, namely PolarCool AB. The plan is to perform a lex ASEA dividend, which is tax free for BrainCools shareholders. After the dividend, a separate listing on the stock market for PolarCool AB is planned in either 2017 or 2018.

Industrial partnerships

Industrial partnerships are becoming increasingly important when scaling up for commercial sales. BrainCool is not producing its own products, that function is outsourced to collaboration partners. The initial manufacturing agreement was signed with Partnertech AB which under 2015 was acquired by Scanfil, a company based in Finland. Scanfil is a large Contract Manufacturing Organization (CMO) with experience of taking products to the Japanese and US market.

BrainCool is actively working to establish collaboration agreements together with distributors in Europe and in Asia. In 2015, an agreement was signed with the Australian based company Aurora Biosciences, a company with previous experiences of working with cardiac arrest and stroke.

In addition, in 2016 the company managed to sign a distribution agreement with a subsidiary to Schiller AG in Austria. This agreement is expected to generate income in a near future. The collaboration with the Schiller-concern is interesting for various reasons. As a well-established actor within medical devices with a focus on cardiac arrest, the Schiller-concern has presence in over 100 countries. The organization also has previous experience with medical hypothermia products, indicating strong competence within medical cooling. However, Schiller decided to discontinue that previous collaboration as the product they distributed did not reach a high enough efficacy.

Furthermore, another distribution agreement was signed in August 2016, with FINGAL Link, a distributor with a strong sales network in the Japanese market. Japan is the key Asian market and hypothermia treatment is an established method in the market with reimbursements available for both cardiac arrest and stroke. Asia is also of interest due to its higher incidence of stroke compared to for instance Europe. Already in the beginning of September, an order for the first ten cooling systems was placed in Japan through the FINGAL collaboration.

TECHNOLOGY PLATFORM

BrainCool's platform of cooling systems

BrainCool's first product The BrainCool System is authorized to monitor and regulate the temperature of patients and initially focused on two main areas; stroke and cardiac arrest. Based on this technology platform, the company has developed a broad product portfolio, where the technical and clinical synergies were utilized in the development of two cooling systems with different configurations for the treatment of stroke, cardiac arrest, oral mucositis and concussions.

- The BrainCool System (named IQOOL in the US) is a powerful semi-portable system for use in different departments in the hospital, and is initially focusing on the treatment of stroke and cardiac arrest.
- The COORAL System is a slightly smaller, portable system for the treatment of oral mucositis in the hospital environment.
- The PolarCap System is a similar portable system configured for cooling the brain for prehospital treatment, that is, before the patient reaches the hospital. The specific focus is on the treatment of concussions (traumas) caused by sports injuries, and this development track was recently spun out to a new subsidiary, PolarCool AB.
- Additionally, BrainCool acquired rights to RhinoChill IntraNasal Cooling System, which has a similar technical description as the PolarCap® System (except that this product cools the head through the nose instead of the scalp), but can start the cooling treatment much earlier/faster than the larger BrainCool System. RhinoChill is indicated for the early treatment of cardiac arrest and stroke patients. Furthermore, a modified version of this product, COOLHEAD, will be developed to treat pain caused by migraine.

Martin Waleij mentioned in an interview that the acquisition of Benechill and rights to RhinoChill opened a very interesting opportunity to combine RhinoChill with the BrainCool System and the combination is now the primary focus of the company (lead product), which targets early hypothermia treatment in an emergency department setting.

The cooling systems are combined with various consumable items (such as; BrainCoolPads, PolarCap, PolarNeck and COORAL depending on the indication). The BrainCool System is sold along with supplies named BrainCoolPads. The consumables are used on approximately 1-5 patients per week, depending on the indication. The COORAL System and The PolarCap System is also sold along with supplies; COORAL for oral cooling to prevent the occurrence of oral mucositis in cancer patients and the cooling cap PolarCap in treating concussions. These consumables are an important cornerstone of the company's business model as they generate an ongoing revenue source where the implied leverage increases with a growing installed base of the various cooling systems.

The Figure below gives an overview of the various products and their development phase.

While this analysis focuses on the hypothermic treatment of the brain in an early emergency setting with the BrainCool System and RhinoChill (cardiac arrest and stroke combined), the additional projects in BrainCool's portfolio are presented in brief below:

Product	Design	Prototype	Proof of Concept	CE Mark	FDA
BrainCool (IQool) *- Stroke & Cardiac arrest*	√	√	√	2015 Awaiting 510 (k) approval	2017 *(recently approved in Australia)*
Cooral *- Oral Mucositis*	√	√	√	2015 De Novo 510 (k) (no need for PMA) and EAP	2018
PolarCap *-Concussions after sports injuries (trauma)*	√	√	√	2016*	**
RhinoChill *-Early cardiac arrest and stroke*	√	√	√	2010	2018
Coolhead *-migraine pain*	√	√	√	2016*** Q1 2017 De Novo 510	2018

Figure. BrainCool's pipeline for the cooling systems; The BrainCool System, the COORAL System, the PolarCap System, RhinoChill and Coolhead. FDA: US Food and Drug Administration; EAP – Expedited Access Program; PMA: Premarket approval (given by the FDA). The BrainCool System (named IQOOL in the US) is soon expecting a notification regarding its potential approvals in the US and Japan (was recently approved in Australia).

* CE Marking for home care 2017.

** BrainCool intends to list the company, goals and strategies will be established in parallel to the IPO.

*** The product will be CE-marked for the indication migraine in 2018, and it is currently CE-marked for hypothermia treatment in general.

TECHNOLOGY PLATFORM

THE COORAL SYSTEM – ORAL MUCOSITIS

Oral mucositis (OM) is a very common side effect after treatment with chemotherapy drugs, such as the commonly administered drug Fluorouracil. OM significantly affects the quality of life for cancer patients in terms of pain, ability to eat, swallow and talk. The symptoms are often of such severity resulting in requiring an interruption and curtailment of therapy. It can also lead to dose reduction of the cancer therapy or even treatment delays and in many cases these patients require hospitalization. Only in the US approximately 400 000 patients suffer from oral mucositis each year, making this a very interesting market, especially since there are few other treatment options available.

In 2015, BrainCool received a marketing approval in Europe for the COORAL® System. CE marking for the treatment of oral mucositis was received and the US FDA granted a DE NOVO 510(k) -application. Therefore, the company does not need a Premarket Approval (PMA). The product is currently being tested in clinical trials and last year the product was also included in a so-called Expedited Access Program (EAP) process by the FDA. The approval includes a so-called priority review, granted only to products with potential for treating difficult diseases with unmet clinical needs. Oral mucositis is thus considered by the US to be a prioritized medical condition to treat. The product was tested in a Phase I trial in healthy volunteers with good results and is currently being tested in cancer patients at Swedish and American clinics. Worth noting is that the Swedish study already received a clearance by the FDA in 2016, to act as the basis for an application for marketing approval in the United States.

Milestones - oral mucositis

- *BrainCool aims to recruit all patients in the Swedish OM study in 2017. The follow up period is approximately one month after treatment.*
- *The study will form the basis of a De Novo 510(k) application for market approval in the US.*

THE POLARCAP® SYSTEM – CONCUSSIONS

The PolarCap® System in combination with the consumable product PolarCap® is currently being evaluated in a clinical study among ice hockey players for the treatment of concussion. The study is conducted in collaboration with eleven Swedish elite hockey clubs, including Malmö Redhawks and Skellefteå AIK among others. The PolarCap® System cools the scalp and neck blood vessels by circulating cold liquid in a hat with an attached collar. Concussions in contact sports such as hockey has attracted increasing attention in recent years as players face interruption from training and competition, or in many cases forced to end their career prematurely. The problems are even greater in American football and boxing, as well as in e.g. soccer and horse riding. According to BrainCool, just in the US alone approximately 3.8 million concussions related to sport injuries occurs annually, illustrating a significant market potential. It has long been known that the brain's demand for oxygen and blood glucose is reduced when the brain temperature is decreased, and increases at elevated brain temperatures. Since the brain has such high perfusion rates of blood it is quickly affected by an increased body temperature- often between 38-40 degrees Celsius which is a natural state during athletic activity.

Milestones - concussions

- *Interim analysis of the concussion study conducted in collaboration with Swedish elite hockey clubs is expected after the first ice hockey season. In the second season, additional data and experience will be gathered in addtion to adding more teams.*
- *A new study in another sport is planned and approval from ethics commitee is expected in 2017.*
- *Aim for a public listing of PolarCool AB in H2 2017 based on decisions at a BrainCool general annual meeting in 2017.*

THE RHINOCHILL SYSTEM - MIGRAINE

As previously mentioned, BrainCool acquired the rights to the product RhinoChill IntraNasal Cooling System, a mobile, battery powered, non-invasive product that facilitates early and quick cooling with the aid of a catheter that sprays cooling liquid in the nostrils. The product is targeting the market for early hypothermia treatment prior to arriving at the hospital, for instance for emergency workers in ambulances and at emergency departments.

Benechill has previously conducted several clinical studies (Link) within different indications such a cardiac arrest, myocardial infarction, catheterization laboratory (cath lab) and hearth surgery, as well as a number of studies on healthy volunteers and preclinical animal models.

The planned business model for this product is primarily to combine it with the BrainCool System, but also as a stand-alone product for instance as treatment of migraine and pain (a modified version named Coolhead is developed for this purpose). It is possible that the two combined cooling systems could cool down patients more rapidly, paving the way for a subsequent switch towards solely using the BrainCool System with its superior shivering reducing technology.

Recently, the FDA granted BrainCool a 510 (k) De Novo application, which was very positive news.

Milestones - migraine

- *Completion of patient recruitment in ongoing studies. Expected within 18 months.*
- *CE marking of Coolhead in migraine. Expected in 2017.*

Additional opportunities

In addition to the clearly stated indications that BrainCool is targeting; cardiac arrest, stroke, oral mucositis, concussions and migraine, there are other opportunities to target.

Examples of other indications that may be suitable for treatment with medical cooling- which either have been evaluated or could be further examined by BrainCool- are neonatal care (neonatal hypoxic-ischemic encephalopathy), spinal cord injury, acute coronary artery disease, whiplash, liver failure, sepsis, burns, myocardial infarction, epilepsy and insomnia.

In June 2016 BrainCool announced that it had submitted a new patent application for the BrainCool System concerning a fever control function. The new application opens for the treatment of new patient groups in other areas than indications such stroke and cardiac arrest, where the need for fever control is large. The company has examined new indications that are particularly interesting, for example, sepsis and burns, as mentioned above. Currently the market is awaiting more information about the company's plans, which can be addressed in detail in future analysis updates.

Intellectual property

ASSET PORTFOLIO

BrainCool has an exclusive, worldwide license from Dignitana AB to further develop the scalp cooling system DigniCap® (which reduces hair loss in cancer treatment with chemotherapy) for stroke, cardiac arrest and neonatal care. The license carries no ending date and are not tied to any royalties on future sales. BrainCool has used the license to exploit certain common components and testing during the development of the semi-portable cooling system to the BrainCool System. BrainCool, however, has developed a completely novel head/neck application that is not based on Dignitana's product.

Dignitana's DigniCap® System is patented in the US, Europe and Japan, and a new patent application has been submitted which provides a better scope and extended protection to 2028. The new patent has already been granted in China and by the EPO within the EU, and Dignitana expects that this patent will also be approved in the US and Korea.

BrainCool filed for a patent application in the United States in 2011 to protect its method of treatment of stroke with the BrainCool System. Currently, the company has several granted patents for the various cooling systems and several patents were added to the portfolio when RhinoChill was acquired from Benechil. Furthermore, in 2014 BrainCool filed another patent application for the treatment of oral mucositis with the COORAL System, which provides protection until 2034 if the application is approved (granted in Sweden so far). The company also has two PCT patent applications for the BrainCool System concerning its functions to flexibly control the temperature of different parts of the body, e.g. head / neck, and to regulate and adjust the cooling when the side effects of shaking or chills, so-called shivering, occurs in patients. These unique features are the main competitive advantages for BrainCool. Patent protection for these functions is sufficient until 2034, provided that the patent application is approved.

In addition to patents and patent applications, the products are also trademarked.

Patent portfolio

Claims	Status (estimated expiry)	Reference No.	Product
Device and method for reducing the body core temperature through multiple zone cooling	Pending PCT (2034)	WO/2016/059167	BrainCool System
Product and method to counter shivering	Pending PCT (2034)	WO/2016/059173	BrainCool System
Methods and devices for non-invasive cerebral and systemic cooling	Granted USA (2030)	8,308,786	BrainCool System
Cooling of localized areas of the body for cerebral flow augmentation	Granted USA (2030)	8,167,923	BrainCool System
Devices for cooling the nasal cavity	Granted USA (2030, 2030)	8,157,767; 8,512,280	RhinoChill
Methods and devices for non-invasive cerebral and systemic cooling via the nasal cavity	Granted USA (2028, 2027, 2030, 2027, 2029)	7,824,436; 7,837,722; 8,480,723; 8,721,699; 9,358,150	RhinoChill
Methods and devices for treatment of migraines	Granted USA (2026, 2026)	8,075,605; 8,313,520	RhinoChill / Coolhead system for migraine
Mouth cooling product	Pending PCT, granted in Sweden (2034)	WO/2016/023920; 537 769	Cooral System

Lead product

The BrainCool System, is a surface cooling system for temperature management between 32 – 38 degrees Celsius. The BrainCool System offers selective brain cooling, three different temperature zones and unique shivering detection. Shivering could be a side effect of cooling, which can be prevented with the BrainCool System. When shivering is imminent the BrainCool System can either alarm and/or slow down the cooling capacity of the system. The BrainCool System thus can place the patient just above the shivering trigger point and alert medical staff for further actions. BrainCool received a CE-mark, EC-certification, and approval of the ISO 13485 standard for the BrainCool System for both stroke and cardiac arrest in 2015. Thereafter, sales have slowly been initiated in Europe and preparatory activities are underway for market launches in both the US and Asia, where a notice of approval from the regulatory authorities is assumed to come soon (recently approved in Australia).

Current sales relate primarily to systems for study purposes, although early marketing activities are underway for commercial sale. At the end of last year, the company submitted a 510 (k) application to the FDA for using the BrainCool System in the treatment of cardiac arrest. The US authorities have requested BrainCool to change the name of the system in the territory. The company quickly adopted a new name in response to the Agency and in US the system will be sold under the name; IQOOL. Furthermore, the BrainCool System has been approved under the Japanese standard JPAL / JGMP and the company is now progressing towards obtaining final marketing approval in Japan. The next steps are to await the results of clinical trials, for example the EuroHYP-1-stroke study, initiate more follow-up clinical studies in cardiac arrest, and start another trial in stroke together with the Trial Unit at Skåne University Hospital (SUS).

The other system, RhinoChill, has several advantages. It is portable, battery operated, non-invasive and provides early-stage and rapid cooling by means of a catheter that sprays coolant liquid into the nasal cavity. It addresses pre-hospital treatment such as in ambulances and by rescue services as well as in the emergency room. RhinoChill has an instant cooling effect that would enhance the effect of The BrainCool System's rapid lowering of the patients' temperature. A combination of the two systems gives a capacity to reach the target temperature much faster in the cooling process. This is deemed to be crucial and renders BrainCool an important competitive edge. Furthermore, the BrainCool System has other advantages in the following hours of treatment, e.g. the management of shivering (mentioned above), a patent-protected feature which is necessary for successful and practical cooling over time.

The acquisition of Benechill also broadens BrainCool's product and customer range. As standalone non-invasive products, both the BrainCool System and RhinoChill have the necessary prerequisites to be successful in the market.

The RhinoChill is a CE-marked product currently undergoing a clinical study in the Princess Hypothermia Clinical Trial for cardiac arrest patients (NCT01400373). This is a multicentre randomized trial in which the device is used for pre-hospital cooling in the ambulance and emergency room.

Competitive advantage

To treat stroke or cardiac arrest optimally, early treatment is a requirement. One of BrainCool's main advantages, compared with its main competitors, as described in the market section below, is the fact that the company also develops portable cooling systems that can start treating patients early, e.g. already in the ambulance or next to sports events. The patent-pending features for selective surface cooling and the ability to automatically control the cooling to prevent shivering are also important competitive advantages. In a US market survey performed by Boston MedTech Advisors the three main limitations of existing hypothermia products in the market are:

- Over 35% of the hospitals mentioned that shivering is a problem (The BrainCool System can prevent shivering).
- Around 30% of products have no interface with bedside monitors and/or EMR systems (The management at BrainCool mentioned in an interview that the company is working on a solution to this issue).
- Over 25% mentioned that pads do not cover body areas of obese patients (BrainCool is cooling the brain, and the head size does not differ a lot between obese and average weight patients, thus assumingly not a problem for BrainCool's products.

Milestones

- *Market approval of the BrainCool System in the US and Japan in 2017.*
- *Completion of patient recruitment in the Princess study. Expected in Q4 2017.*
- *FDA approval of the RhinoChill System: Expected in 2018*
- *The BrainCool System – Stroke: The next interim analysis time point in the Euro-HYP study. Expected in 2018.*
- *Implementing an evaluation of the combination of the BrainCool and RhinoChill Systems. Expected in 2018*
- *Initiation of full commercial sales, based on results from combination trials. Expected in 2018/2019.*

In addition, The BrainCool System utilize a sterile cooling agent which limits the risk for bacterial growth, compared to competing products using water as cooling liquid.

Target temperature and early treatment

Further advantages of non-invasive external cooling, as characterized by BrainCool's technologies, is that it does not require other sophisticated instruments or, above all expertise in catheter insertion. Equally important, non-invasive products do not carry the risks involved when inserting catheters in central veins. Cooling with external methods have traditionally been somewhat slower than intravenous methods. For temperatures below 35 degrees Celsius, it may be necessary to give patients - especially stroke patients who are conscious - sedation, to counter feelings of discomfort and shivering because of chills (Homes & Lyden, 2009).

Studies have been conducted which demonstrated the benefits of medical cooling during cardiac arrest. Nevertheless, in a large study that tested medical cooling at 33 and 36 degrees Celsius (Target Temperature Management After Cardiac Arrest trial TTM-1, NCT01020916), the result was slightly disappointing and there was moreover no major difference between cooling to 33 or 36 degrees Celsius (Nielsen et al., 2013). There are however some disagreements, and in articles from 2014 (Polderman & Varon, 2014) and 2015 (Polderman, 2015) researchers mentioned that one should not be deterred from using medical cooling after cardiac arrest, arguing that several non-optimal aspects of the large study- including patient selection and the fact that it took a long time to reach the target temperatures- were used as arguments. The researchers furthermore advocated that one should await further information from new clinical trials to find an optimal target temperature.

According to BrainCool, the company is equipped to handle cooling to 36 degrees and lower, and does not see a target temperature as a barrier for their product. The problems have been bypassed with BrainCool's new and proprietary technologies that can control the cooling system when the patients get chills and shivering. If consensus could be reached that a higher temperature such as 36 degrees Celsius (mild hypothermia) is sufficient, it may be beneficial to BrainCool's external cooling products that can reach the target temperature quickly. In addition, it becomes easier to outcompete intravenous cooling with cold saline (Homes & Lyden, 2009). Upon cooling to 36 degrees Celsius, fever control is particularly important, and the company's patent for this application in the BrainCool System clearly shows that the company is working strategically with its product development to meet this need.

However, the most important aspect of medical cooling is according to BrainCool primarily dependent on the time of onset of the treatment. According to Martin Waleij, the main reasons for the non-conclusive outcome from the TTM-1 study (see above), was possibly that the inclusion of patients to the study occurred 4-6 hours after a cardiac arrest event. The patients that made it so far were most likely healthy enough to survive either with or without hypothermia treatment. This is the main reason why BrainCool has decided to combine RhinoChill with the BrainCool System in follow up studies to prove that it is superior to first start the treatment early with RhinoChill (e.g. 90-120 minutes earlier than in the TTM-1 study) and later switch to the BrainCool System. A follow up study, TTM-2 (NCT02908308), was initiated in the second half of 2016 and according to BrainCool, a sub population of patients in this study will be treated with BrainCool's technologies to evaluate early treatment. Furthermore, the currently ongoing PRINCESS study is a key study to show the benefits of starting the treatment at an early stage.

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49.6 MSEK

target for current share issue (after costs)

2.6 MSEK

estimated burn-rate per month, in Q1 2017

19 months

estimated life time, until cash needed, at a constant burn rate if targeted amount is raised

Financial summary

BrainCool is financed by its shareholders. During the past year, the company had operating costs of approximately 18.1 MSEK, corresponding to an approximate burn-rate of 1.5 MSEK per month (2.6 MSEK per month in Q1 2017). After the 2016 Q3 report, a share issue was performed, which raised 1.5 MSEK for the company. Furthermore, on December 22, BrainCool announced that it had signed a loan of 10 MSEK from a few private investors at an interest rate of 8% and for a six months' term. The purpose of the loan was described to be utilized partly to finance the acquisition of BeneChill (recently completed), and to finance the upcoming market launch of the BrainCool System in the US market. In addition, BrainCool finalized a non-cash issue (Swedish Apportemission) on December 2, to a total value of 10.2 MSEK. With the assumption of a constant burn-rate, the 6.37 MSEK that was reported as cash in the bank in the company's latest quarterly report, together with the first installment of 4 MSEK (of the 10 MSEK loan) that according to the company was paid in Q1 2017, the new share issue is needed to support ongoing operations and to build up the commercial sales. The ongoing share issue is aiming to raise 58.5 MSEK (In total 49.55 MSEK after costs). The raised amount will - according to the company - provide enough capital to make substantial progress.
As a final note, the company estimates that it will break even in year 2018, which indicates that the need of external financing will potentially be significantly reduced in a near future.

Consolidated statement of comprehensive income (Q1, 2017 report)

[kSEK]	Q1, 2017	Q1-Q4, 2016	Q1-Q4, 2015
Net sales & operating income	620 532	4 760 376	2 512 753
Operating costs	-7 793 705	-18 127 054	-11 942 536
Operating income (before tax and financial items)	-7 173 173	-13 366 678	-9 429 783

Consolidated statement of financial position (Q1, 2017, report)

[kSEK]	2016-12-31	2015-12-31
ASSETS		
Intangible assets	*40 677 050*	*20 034 159*
Tangible assets	*2 732 803*	*182 706*
Total non-current assets	**43 409 853**	**20 216 865**
Inventory	*9 923 234*	*1 034 351*
Customer and other receivables	*3 095 885*	*1 083 135*
Cash and cash equivalents	*6 370 228*	*5 703 225*
Total current assets	**19 389 347**	**7 820 711**
TOTAL ASSETS	**62 799 200**	**28 037 576**
EQUITY AND LIABILITIES		
Restricted equity	*9 989 194*	*921 056*
Unrestricted equity	*36 309 715*	*23 243 769*
Long-term debt	*1 520 833*	*500 000*
Short-term debt	*14 979 458*	*3 372 751*
TOTAL EQUITY AND LIABILITIES	**62 799 200**	**28 037 576**

BOARD OF DIRECTORS

HANS ÅKE HENRIKSSON
CHAIRMAN

Åke has extensive experience in business development in the pharmaceutical and medical technology sector and has been a director at Pharmacia & Upjohn.

MATS FORSMAN
BOARD MEMBER

Background from senior positions at Astra Zeneca in production and marketing for more than 30 years.

BENGT FURBERG
BOARD MEMBER & ADVISOR

Bengt is a MD. with extensive experience in the industry including positions as medical director for the Swedish part of Glaxo Wellcome, among others. Also a medical advisor.

JENS KINANDER
BOARD MEMBER

Jens has previous experience as a lawyer at Mannheimer Swartling and as legal counsel of companies including AstraZeneca with advisory experience from the Life Science industry.

Shareholders

As of May 2014, the shares of Braincool AB (publ) are listed on Aktietorget. The company's current major shareholders are Avanza Pension (15.04%), Nordnet Pensionsförsäkringar (13.50%), Swedbank Försäkring (2.41%), Comac Invest AB (1.92%), and Mikael Rosberg (1.00%). The CEO Martin Waleij purchased shares for a value of 1 MSEK in 2015. Furthermore, board members and several individuals in the management team of BrainCool hold shares in the company, signifying a strong commitment towards the company.

BRAINCOOL ANALYSIS

OPERATIONAL TEAM

MARTIN WALEIJ
CEO & FOUNDER

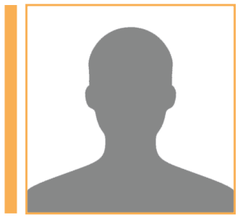
Long experience within hypothermia treatment and medical devices. Experience from two earlier IPOs.

CHRISTIAN STRAND
SALES DIRECTOR & FOUNDER

Has previous experience from working at Dignitana AB and DiLab AB (cma microdialysis), working towards the Asian market.

OLA STRÖMBERG
CTO

Ola has an extensive background from the technical field with several years at Anoto, among other assignments.



ANNE ANDERSSON
QUALITY ASSURANCE DIRECTOR

Anne has 17 years of experience from the Gambro concern. She has had various roles within quality development.

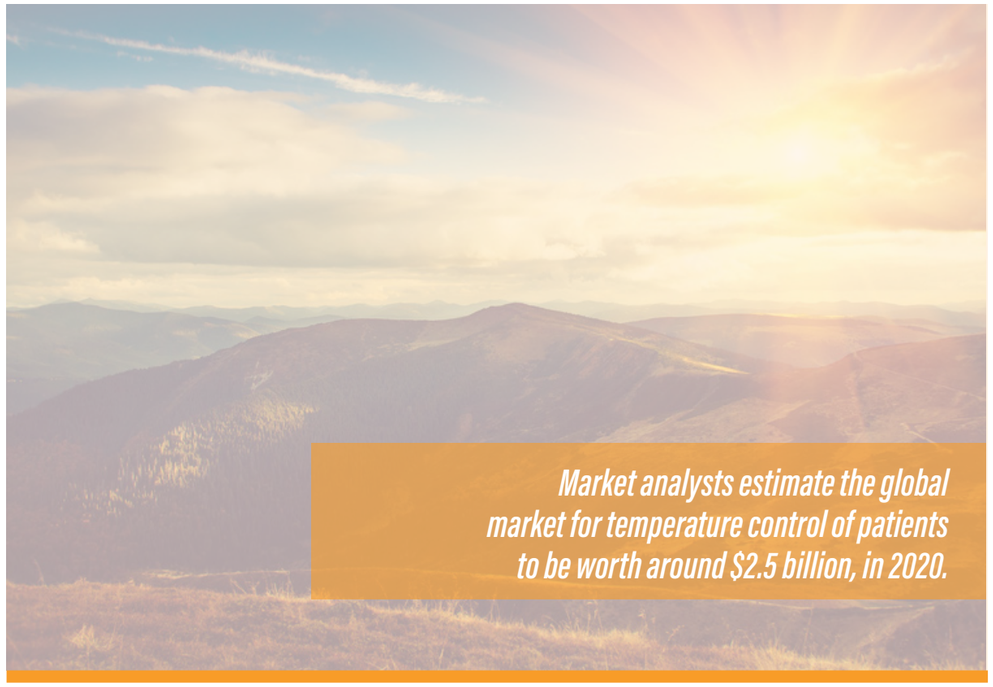
IMAN ZIAI
CONTROLLER/PRODUCT MANAGER

Iman has previously worked at the Goodyear concern as an controller and within supply chain management. He is a product manager for the PolarCap System.

Management team

Martin Waleij is the CEO and founder of BrainCool. He has led the company since its inception and has previous experience from hypothermia treatment and has hold positions as the CEO of Dignitana AB and DiLab i Lund AB. He also worked as an investment manager at Volito. Martin Waleij has extensive experience in developing and capitalizing growth and has participated in the IPO of two companies, one of which on the NASDAQ exchange in the US, as well as listings on the smaller lists AktieTorget and First North. BrainCool's medical director is Bengt Furberg, a physician with extensive experience in the industry. His experience includes positions as medical director during 10 years for the Swedish section of Glaxo Wellcome, and medical director of various companies in the medical technology industry. In addition to his senior management team position, Bengt Furberg is a member of Braincool's board of directors. He also serves as a director of the board in several other companies such as Hamlet Pharma, Redwood Pharma, and up to recently Immunicum AB. Other members of BrainCool's management team are Ola Strömberg, Chief Technology Officer, Christian Strand, Founder and Sales Director, Anne Andersson, Quality Assurance Director, as well as Iman Ziai, Controller and PolarCap Product Manager. Chairman of the board, Hans Henriksson, previously held a position as Senior Global Business Manager at Pharmacia & Upjohn and has extensive experience in business development in Japan in the pharmaceutical and medical technology sector with a focus on the Asian market. Board member Jens Kinnander is a lawyer and partner in the law firm Delphi. He has previous experience as a lawyer at Mannheimer Swartling and as legal counsel of companies including AstraZeneca, with advisory experience from the Life Science industry and in intellectual property rights. The board is also comprised of Mats Forsman who has a background from senior production and marketing positions at Astra Zeneca for more than 30 years.

MARKET OPPORTUNITY



Market analysts estimate the global market for temperature control of patients to be worth around $2.5 billion, in 2020.

Global market for temperature control

BrainCool has five major indications with significant market potential in sight. Analysts have estimated the global market for temperature control of patients to be worth around $2.5 billion in 2020. Most of the market relates to heat treatment, but the segment for cooling is also expected to have a high growth rate. To illustrate BrainCool's primary market, we have in this analysis chosen to look at the combined markets for ischemic stroke and cardiac arrest (referred to as brain cooling in an emergency setting) with a combination of the two products; the BrainCool System and RhinoChill. Cooling of patients can be initiated with RhinoChill after 5-15 min, and up to 3-4 hours thereafter, before switching to the more powerful product: the BrainCool System. The latter cools patients for a longer period and mitigates shivering problems experienced by patients.

In 2016, the US based Boston MedTech Advisors conducted a survey of the US market for medical cooling for BrainCool. The study concluded that approximately 70 percent of US hospitals had increased their use of medical cooling during the past five years. The US market alone was estimated to exceed $290 million annually, of which systems accounted for $68 million and cooling plates/catheters (e.g. consumables) accounted for $225 million. Roughly 100 000 patients are treated with medical cooling each year (approximately 80% were cardiac arrest patients). The market is expected to grow substantially over the coming years, both in terms of increased use and more indications. This is further illustrated by the reported CAGR of 5-7% in Europe according to INKWOOD Research.

The survey covered 40 hospitals in 37 cities and 26 states. Approximately 50 percent of the interviewed hospitals were large hospitals (400-1000 beds) and 50 percent of hospitals of small to medium size (100-400 beds). Almost all major hospitals used medical cooling during cardiac arrest, while a considerable number of medium-sized hospitals were also using the treatment method.

In Europe, the patient cooling systems market was valued at $221 million in 2015 and is expected to reach $327 million by 2022, growing at a CAGR of 5.7% during the forecast period 2015-2022 (INKwood research). Of these figures, the surface cooling market was estimated to be much larger than the intravascular cooling market ($166 million vs. $55 million in 2015; and $248 million vs. $80 million in 2022) in addition to a stronger growth rate (CAGR 5.9% vs: CAGR 5.3%).

Current approaches to general treatment of cardiac arrest and stroke patients are briefly described below.

MARKET OPPORTUNITY

This analysis focus only on the market potential of the combined RhinoChill and BrainCool Systems in the treatment of cardiac arrest and stroke.

BrainCool's other promising products and markets will be covered more in depth in future analyses.

Cardiac arrest

Approximately 15-20 percent of all deaths in the western world are caused by sudden cardiac arrest. The disease is a major burden on global healthcare systems and the number of new cases is expected to increase as the average life expectancy increases. The three main causes of sudden acute cardiac arrest are coronary heart disease (about 60-70 percent of cases), non-ischemic heart disease and other causes (e.g. trauma, bleeding, overdose, poisoning, drowning and pulmonary embolism). In Sweden, it is estimated that approximately 10 000 cases of cardiac arrest occur outside the hospital and 3 000 cases in hospitals, each year. In the US, the corresponding figures exceed 300 000 cases outside, and 200 000 cases in hospitals annually.

In general, advanced cardiac life support guidelines should be followed in all cases of sudden cardiac arrest and a brief overview of the US guidelines is:

BYSTANDER CARDIOPULMONARY RESUSCITATION (CPR)

- Immediate chest compression and defibrillation are reportedly the most important interventions to improve the outcome in SCA.

PHARMACOLOGICAL THERAPY

- Ventricular arrhythmia: Epinephrine or vasopressin; amiodarone and lidocaine can be used as antiarrhythmic drugs if defibrillation does not control the arrhythmia
- Pulseless electrical activity (PEA): Epinephrine; atropine used in case of bradycardia
- Asystole: One study suggested that vasopressin is more effective in acute therapy for asystole than epinephrine
- Medical stabilization: Empiric beta blockers are reasonable in many circumstances

THERAPEUTIC HYPOTHERMIA

- This intervention limits neurologic injury associated with brain ischemia during a cardiac arrest and reperfusion injury associated with resuscitation.

SURGERY

- Temporary cardiac pacing, radiofrequency ablation, cardioverter defibrillator therapy, coronary artery bypass grafting (CABG), excision of ventricular tachycardia foci, excision of left ventricular aneurysms, aortic valve replacement, and orthotopic heart transplantation.

As illustrated above, therapeutic hypothermia is a recommended treatment in the US guidelines. However, the treatment is not always used and up to 70% of the US hospitals, according to the Boston MedTech Advisors survey, utilized hypothermia treatments. The trend is rising and over 80% of the 100 000 hypothermia treated patients in the US, last year, were related to cardiac arrest.

Stroke

According to the WHO, about 15 million people across the world suffer from stroke each year. About five million of these patients die and another five million are permanently disabled. This makes stroke a very common disease with high societal burden that is expected to increase with longer life expectancy. Stroke can be classified into two main groups; ischemic stroke (85 percent of all cases), which is a result of reduced blood flow to the brain, for example, from thrombosis and embolism, and hemorrhagic stroke (15 percent of all cases), which result from broken capillaries (bleeding occurs). Cooling can theoretically always be used in patients with ischemic stroke but the hypothermia treatment is discontinued in cases where bleeding occurs. A brief overview of a simplified treatment algorithm for stroke is:

SURGERY

CONTROL BLOOD GLUCOSE LEVELS

- Treat hypoclycemia with D50 (glucose), or treat hyperclycemia with insulin if serum glucose >200 mg/dL

CONTROL/REGULATE BLOOD PRESSURE

- Various pharmacological alternatives are available such as candidates for fribrinolysis and noncandidates for fibrinolysis.

FLUID INTAKE REGULATION

- Avoid intravenous glucose (D5W) and excessive fluid administration.

OXYGEN

- Supplement use if needed.

TEMPERATURE

- Avoid hyperthermia, use oral or rectal acetaminophen and hypothermia treatment such as cooling blankets as needed.

As illustrated above, therapeutic hypothermia is a recommended treatment in the US guidelines. However,

MARKET OPPORTUNITY

the treatment is not always used and up to 70% of the US hospitals, according to the Boston MedTech Advisors survey, utilized hypothermia treatments. The trend is rising and over 80% of the 100 000 hypothermia treated patients in the US, last year, were related to cardiac arrest.

Hypothermia treatment

Today, there are cooling products on the market to cool either the whole body or parts of the body. These are often combined with invasive methods in which cooled saline solution is injected. BrainCool's method is based on a non-invasive procedure in which the brain is treated by an active cooling of the head. Other products that utilize non-invasive cooling of the head can be roughly grouped as follows:

- Cooling via the respiratory system: This is typically done via an exchange of gas or liquid flows (convection) to cool the upper airways. Often balloon-like products are applied in the nose or buccal cavity for contact directly with the tissue (like the COORAL System or RhinoChill).
- External cooling of the head: This is typically performed using caps cooled with cold air (fans) or active (like the BrainCool System) or passive (e.g. ice, gel hats) heat transfer fluid.

Competition

Hypothermic treatment of stroke and cardiac arrest currently involve a few key players. Bard (acquired Medicare Vance) and Asahi Kasei (acquired ZOLL/Philips Healthcare) reported joint annual sales of temperature controlling systems amounting to about $150 million, with an annual growth of between 30-40 percent, according to BrainCool.

US-based BARD Medical is a key player with its *Temperature Management Arctic Sun® 5000* product, which makes the company one of BrainCool's main competitors. This product was a part of the $250 million acquisition of Medicare Vance, in 2011, and is indicated for medical cooling between 32-38.5 degrees Celsius. It has similarities with the BrainCool System, including its pads for external cooling. The product has a 510 (k) FDA approval and is CE certified. However, the system is not combined with the same kind of disposable items for cooling the scalp/neck as BrainCool's product. Artic Sun System represented over 50% of the cooling systems used in the US hospitals, in the recent survey, making it the largest competitor in this geography.

Another important player is Japanese Asahi Kasei, which acquired ZOLL Medical Corporation in a $2.21 billion deal in 2012. ZOLL markets the cooling system *Thermo Gard XP*, with disposables in the form of intravenous catheters and the *STxTM Surface Pad System*, which competes directly with BrainCool's products. Following the acquisition, ZOLL acquired Phillips *Inner Cool RTX Endovascular System* in 2014, which regulates body temperature by inserting a catheter into a vein and infuse a cold or warm saline solution. *Thermo Gard XP* regulates body temperature via a controlled infusion of cold saline. ZOLL has performed studies which, according to ZOLL, show a better cooling effect compared to Bards external cooling system *Arctic Sun® 5000* (source: Thermo Gard XP Brochure).

A third large player on the hypothermia market is the US based CSZ (a Gentherm Company) that provides various devices for cooling of patients. All its products are used externally, often providing cooling through pads or blankets. Hence, not a direct competitor regarding cooling of the head.

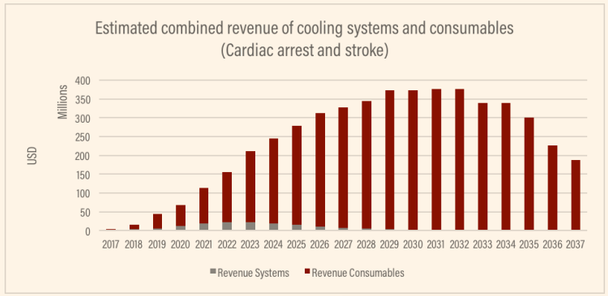
Another example of a competitor to BrainCool in the areas of stroke and cardiac arrest is the Swedish company QuickCool AB, which like BrainCool has its headquarter in Lund, Sweden. As mentioned earlier, BrainCool has recently acquired Benechill and thereby strengthening its competitive position in the market.

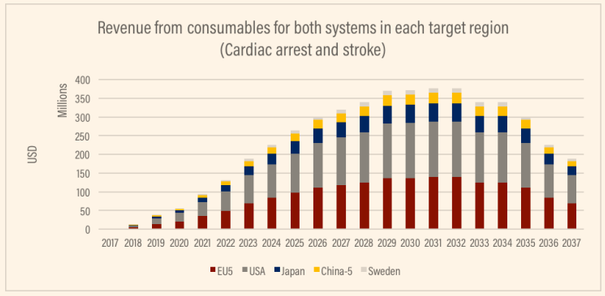
The fact that there are competing companies in the market are certainly not unequivocally negative. On the contrary, it enables a continued increase in marketing and clinical acceptance for medical cooling treatment, which also to some extent will help to build up a market need. BrainCool has also expressed the possibility that the company's products can be complementary to existing products, such as products that regulate body temperature by means of intravenous injections of chilled saline through a catheter, such as Philips *Inner Cool RTX Endovascular System* and Asahi Kasei / ZOLLs *Thermo Gard XP*.

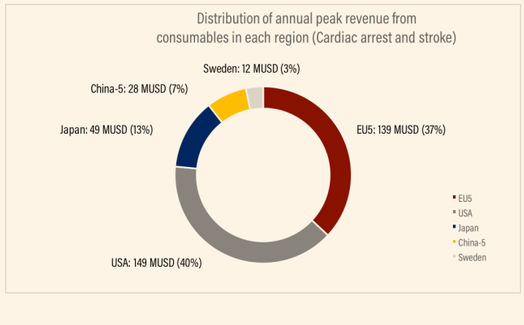
BioStock briefing about market potential of medical device products

To estimate the potential value of a medical device product in a company portfolio, BioStock determines a potential peak annual sales and aggregated total sale for the asset for a period between ten to 20 years. Assumptions about the market, pricing, timelines, costs, expected market share at peak, etc., are discussed with the analyzed company – these assumptions are then used to create a financial projection of future revenues. If nothing else is stated, peak sales are assumed to be reached after ten years from market approval and an aggressive sales erosion rate is assumed to begin on the expiry year of the main patent. Revenues are transformed into profits by assuming costs and tax for the sold goods. No likelihood of reaching a market approval and to account for this risk is included in the calculation.

MARKET POTENTIAL







Market potential

BrainCool's market potential has been estimated for early hypothermia treatment in an emergency department setting, by BioStock, based on the annual incidence of stroke and cardiac arrest patients and the number of emergency departments. A theoretical market potential and theoretical profit potential value have been calculated in addition to forecasted sales based on market launches in the regions: USA, the five largest countries in Europe (EU5), Sweden, Japan and the five largest cities in China ("China-5").

The market potential for the combined systems with consumables in this setting (see section Base Assumption) in the modelled regions is significant. In the period 2017 to 2037, we have calculated a theoretical peak opportunity of annual sales to almost USD 400 million (profit of around USD 290 million) for consumables with aggregated sales reaching above USD 4.8 billion (USD 3.7 billion in profit). While for cooling systems a theoretical peak opportunity of annual sales to above USD 23 million (approx. USD 12 million in profit), and the aggregated sales of cooling systems was estimated to about USD 150 million (around USD 77 million in profit). This clearly illustrates that the largest potential for BrainCool lies within repeated sales of consumables when a large enough installed base of cooling systems is available in the market.

During the modeled period above, BrainCool's combined systems and consumables would generate total aggregated revenues, exceeding USD 5 billion with a profit of almost USD 3.8 billion. The estimated peak year is in 2031 and an explanation of the estimated decline in sales, which is observed in 2033/2034 and after, is due to assumed patent expirations and competition faced by other competing products in the market.

The US and EU5 markets are by far the largest markets in terms of revenue, which can be explained by the larger populations, but also that consumables for the BrainCool System can be sold at a higher premium price in the US compared to in the other modelled regions.

Furthermore, the treatment of ischemic stroke patients has a larger theoretical market potential compared to cardiac arrest. This is due to the higher incidence of stroke, and that each consumable for the BrainCool System is assumed to be used for two cardiac arrest patients, but only for one stroke patients. Hence, more consumables can be sold within stroke to fulfill the estimated market demand.

As a note, it is worth mentioning that the presented market potential represents a theoretical project value based on the estimated sales, provided a set of base assumptions. It does not represent the share price of BrainCool neither does it account for potential extensions into other fields, company assets (physical, intangible or cash in the bank) or other external factors

MARKET POTENTIAL

Base assumptions

The calculations assume that the two systems will receive market approval for both indications and that results from ongoing trials illustrates a clear efficacy compared to other treatments to promote sales. Furthermore, an assumption was made that results from the EuroHyp-1 study in stroke will lead to a stronger adaptation of hypothermia treatment in the healthcare system. To estimate the combined theoretical market size for the BrainCool System and RhinoChill IntraNasal Cooling System, BioStock has modeled market launches in the US, the five largest countries in Europe (EU5), Sweden, Japan and the five largest cities in China ("China-5") with estimated peak market share penetrations described in Table 1-3. Further, we have assumed that 20 percent of all patients will not be treated due to death and other causes, which is calculated for in the "Annual patient number" column in Table 2 and 3 below.

We based the calculations on various prices for the cooling system and their consumables which were provided by the management at BrainCool:

- The BrainCool System: 28 000 USD for the cooling system through direct sales by BrainCool (20 300 USD through a distributor), with a profit margin of 50 percent (same profit margin if sold through distributor?). We have in the estimate assumed the same prices in all countries for the systems. However, various prices per consumable (US: 1 000 USD direct sales/700 USD by distributor & in the other regions: 700 USD through direct sales/500 USD by distributor) were adopted by the sale of either one article per patient (stroke) or one article per two patients (cardiac arrest), with a profit margin of 70 percent.

Table 1: Estimated aggregated market potential for cooling systems in both cardiac arrest and ischemic stroke

Region	Number of emergency departments	Peak market share penetration	Theoretical market potential.	Theoretical profit potential
EU5	5 659	20%	63 MUSD	31.5 MUSD
USA	5 025	15%	42 MUSD	21 MUSD
Japan	5 715	15%	48 MUSD	24 MUSD
China-5	180	15%	1.5 MUSD	0.75 MUSD
Sweden	74	20%	0.8 MUSD	0.4 MUSD
Total	**16 653**	**-**	**155 MUSD (BC:134; RC: 20)**	**77 MUSD (BC: 67; RC 10)**

We have assumed that each department purchase one BrainCool System adapted for stroke, one BrainCool System adapted for cardiac arrest and one RhinoChill System. The BrainCool System was assumed to cost 28 000 USD (direct sales) / 20 200 USD (through distributor), and the RhinoChill System 9 000 USD (direct sales) / 5 600 USD (through distributor).

Table 2: Estimated annual market potential for consumables in cardiac arrest (The BrainCool System & RhinoChill)

Region	Annual number of patients	Peak market share penetration	Price per consumables: Direct sales/partner (USD)	Theoretical profit potential	Theoretical profit potential
EU5	244 000	20%	BC: 700/500 RC: 1 100/800	61 MUSD	47 MUSD
USA	245 000	15%	BC: 1 000/700K RC: 1 100/800	51 MUSD	39 MUSD
Japan	97 000	15%	BC: 700/500 RC: 1 100/800	18 MUSD	14 MUSD
China-5	56 000	15%	BC: 700/500 RC: 1 100/800	11 MUSD	8 MUSD
Sweden	7 600	20%	BC: 700/500 RC: 1 100/800	1.9 MUSD	1.5 MUSD
Total	**649 600**	**-**		**142 MUSD (BC: 38; RC: 105)**	**110 MUSD (BC: 26; RC: 84)**

The epidemiological data for patients that suffers from cardiac arrest outside the hospital is more complete compared to data for patients that suffers from cardiac arrest in hospital. Hence, we have conservatively chosen to calculate the market potential with the incidence of cardiac arrest patients suffering from the medical condition outside the hospital in this example (Deo et al., 2012; Uray et al., 2015). Note, epidemiology data for Japan was extrapolated to China-5. BC: The BrainCool System, RC: RhinoChill IntraNasal Cooling System. Furthermore, the sales were assumed to be distributed as 50/50 between direct sales/through a partner based on input from the management of BrainCool. Note: 1 consumable per BC System and two patients and one consumable per RC System and patient.

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MARKET POTENTIAL

- RhinoChill IntraNasal Cooling System: 9 000 USD for the cooling system through direct sales by BrainCool (5 600 USD through a distributor), with a profit margin of 50 percent (same profit margin if sold through distributor?). We have in the estimate assumed the same prices in all countries as well as the same price per consumable (1 100 USD Direct sales/800 USD by distributor) adopted by the sale of one article per patient, with a profit margin of 80 percent.

Based on input from the management of BrainCool the assumption was made that a division of 50/50 in sales of systems and consumables between direct sales and through distributors will occur.

For the calculation of the number of sold cooling systems, we have estimated the number of emergency departments in each country (ambulances are not included). We have furthermore assumed that each hospital buys one of the cooling systems each (one BrainCool System for stroke, one BrainCool System for cardiac arrest and one RhinoChill System).

According to the management of BrainCool, the modelled market launches with commercial sale of the combined systems is year 2018/2019. However, the sales are estimated to start to ramp up slowly already in H2 2017 after receiving the first approval by the FDA for the BrainCool System. The market exclusivity was modelled based on the key patent for the BrainCool System expiring in 2034.

For simplicity and for conservative reasons, the annual growth rates (based on CAGR) was not used in the calculation of annual sales of BrainCool's products, but they were merely used to identify a reasonable future market penetration rate. This since the market peak penetration was based on the total annual patient number (incidence) of cardiac arrest and stroke in the target regions. As an example, by looking at the assumed market penetration for the treatment of cardiac arrest patients in the US in our model:

In 2016, approximately 245 000 patients were suffering from a cardiac arrest outside the hospital and eligible for treatment (20% was already deducted from this population to exclude too frail or already dead patients, etc). We assumed that BrainCool can target 15% of this population which equals 36 750 patients annually. This is approximately 50% of the number of hypothermia treated patients that was estimated in the survey by the Boston Medtech Advisors (approx. 100 000 patients annually and roughly 80 000 cardiac arrest patients) in year 2016. If this population grows with an annual growth rate like the CAGR estimated for Europe (5.9%), this population would be equal to roughly 220 000 patients in the year of BrainCool's modelled peak year (2031). Finally, if BrainCool's products are used to treat 36 750 cardiac arrest patients in 2031, it is equivalent to ~15% of the hypothermia treated cardiac arrest patients in the US).

As mentioned earlier, the number of sold cooling systems was assumed to be one of each type in each hospital that can be targeted, which is rather conservative since several departments in one hospital in theory could purchase a system.

Table 3: Estimated annual market potential for consumables in ischemic stroke (The BrainCool System & RhinoChill)

Region	Annual number of patients	Peak market share penetration	Price per consumables: Direct sales/partner (USD)	Theoretical profit potential	Theoretical profit potential
EU5	252 000	20%	BC: 700/500 RC: 1 100/800	78 MUSD	59 MUSD
USA	365 000	15%	BC: 1 000/700K RC: 1 100/800	96 MUSD	74 MUSD
Japan	131 000	15%	BC: 700/500 RC: 1 100/800	30 MUSD	23 MUSD
China-5	75 000	15%	BC: 700/500 RC: 1 100/800	17 MUSD	13 MUSD
Sweden	32 000	20%	BC: 700/500 RC: 1 100/800	10 MUSD	7.6MUSD
Total	**855 000**	**-**		**234 MUSD (BC: 99; RC: 135)**	**178 MUSD (BC: 70; RC: 108)**

Epidemiological data from Rosengren et al., 2013 and Datamonitor stroke rapport 2010. Note, epidemiology data for Japan was extrapolated to China-5. BC: The BrainCool System, RC: RhinoChill IntraNasal Cooling System. Furthermore, the sales were assumed to be distributed as 50/50 between direct sales/through a partner based on input from the management of BrainCool. Note: 1 consumable per system and one patient.

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CONCLUDING REMARKS

BrainCool and its management has succeeded in, during a short period of time, developing several products with a clear competitive advantage, and now the company stands before an exciting time frame. BrainCool has advanced a long way with the development of its products. The company has already reached the market, although with sales on a small scale, and evidence proves that the technology works. If the various ongoing studies – and more are planned - in different indications can show clear evidence of a good clinical effect of the company's products compared with existing medical cooling products, BrainCool has a very good potential to attract a strong interest from the market.

In the previous analysis of BrainCool (June 9th) it was mentioned that the company has chosen to work with several different indications or diseases, which can be seen both as a strength and a weakness. It is certainly important to maintain a clear focus while serving as a smaller development company such as BrainCool. Nevertheless, this risk factor is considered rather small since all BrainCool's products are based on the same basic principle, and has its base in a proven technology that has been developed over a long period, since the beginning of Dignitana AB in the early 2000s. One positive sign is that BrainCool has started to focus its development, evident with the recent incorporation of the subsidiary PolarCool AB, which will focus on concussions within sports injuries.

To achieve a strong market uptake of the company's products, it is important for BrainCool to either enter partnership agreements with several strong distributors, and/or to build an internal sales force. The strategy since 2015 have been towards the latter and BrainCool is negotiating with actors both in Europe and Asia. A couple of good example of such strong partnerships are the agreements with the global Schiller Group, a partnership which recently expanded to include a total of five European markets, and more recently with the Japanese company FINGAL. Thereby BrainCool has initiated the market launch together with strong partners and work is underway to attract and evaluate additional partners. To fully cover the analyzed countries in the market potential calculation, BrainCool should aim towards establishing strong partnerships with actors on the US market. In addition, according to the CEO, Martin Waleij, the company is now also planning to scale up the internal sales force, and aims towards a 50/50 split between direct sales by BrainCool and through partners. Furthermore, competing products for full body and scalp cooling, as well as for the treatment of oral mucositis, have been identified in various markets. Hence, BrainCool's initial choice of markets for launch and the sequence they should be approached could be an important strategic decision to minimize competition.

While the market size is identifiable, the market uptake of new medical cooling products is more difficult to determine. With large actors such as Bard Medical and Asah-Kasei possessing large market shares, truly strong efficacy data and a competitive pricing might be needed to take substantial market shares for new products. Therefore, the option of leasing cooling systems to hospital units is potentially a more viable option to spread the uptake and to focus on selling a larger number of consumables for each system. This is already something that the company is aware of and it is continuously being evaluated by the management at BrainCool. Since BrainCool is now entering an initial sales phase it is of great importance that the company is preparing for a future scaling up of production to meet the growing market needs of the company's products. At present time, the company is also investing in the development of automated production processes of some consumable parts to enhance the cost-efficiency of the production, an important step which shows that the management is very much in the planning phase in terms of the development of the sales area. This could for instance be witnessed by the higher profit margin for consumables sold for the RhinoChill product (80%) compared to the consumables for the BrainCool System (70%). Enhancing the profit margin is a key factor since competition from the market might result in the need of adapting prices to be able to take more market shares.

Sales revenue for both systems and supplies are expected in a near future and will increase when the clinical benefit of the company's products compared to other treatments is verified. However, we believe that the major market breakthrough is some year(s) away and prior to reaching profitability, the company is now releasing a share issue for additional external financing. One possible way for BrainCool to succeed is to aim at being acquired by, or to collaborate with, one of the major competitors in the market- or any large player who wants to reach into BrainCool's markets. It is very interesting that BrainCool managed to acquire the rights to RhinoChill from Benechill which was one of the competitors, showing that the company has determination and strength to target its goals. This illustrates that the management is very capable and driven with an aim to provide the market with unique hypothermia products. The main challenges ahead for the firm is to attract enough funding to gear up and truly show that it can be profitable to attract a potential acquirer.

The company is expecting an interesting news feed with many potential triggers in the short and long term. Given the company's rapid development so far and the position they created themselves by building up a broad product portfolio that addresses multiple markets with unmet medical needs, the future looks both exciting and promising for BrainCool. This year and in 2018, multiple milestones are expected (see below) and we will be following these closely.

Important catalysts for investors to watch:

- Market approval of the BrainCool System in the US and Japan in 2017.
- Completion of patient recruitment in the Princess study. Expected in Q4 2017.
- FDA approval of the RhinoChill System: Expected in 2018
- The BrainCool System – Stroke: The next interim analysis time point in the Euro-HYP study. Expected in 2018.
- Implementing an evaluation of the combination of the BrainCool and RhinoChill Systems. Expected in 2018
- Full commercial sales of The BrainCool and RhinoChill System. Expected in 2018/2019.
- BrainCool aims to recruit all patients in the Swedish OM study in 2017. The follow up period is approximately one month after treatment. The study will form the basis of a De Novo 510(k) application for market approval in the US.
- Interim analysis of the concussion study conducted in collaboration with Swedish elite hockey clubs is expected after the first ice hockey season. In the second season, additional data and experience will be gathered in addition to adding more teams.
- A new concussion study in another sport is planned and approval from ethics committee is expected in 2017.
- Aim for a public listing of PolarCool AB in H2 2017, based on decisions at a BrainCool general annual meeting in 2017.
- Completion of patient recruitment in ongoing migraine studies. Expected within 18 months.
- CE marking of Coolhead in migraine. Expected in 2017

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