ASARINA PHARMA

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ASARINA PHARMA AB (PUBL)

FOURTH QUARTER, YEAR-END REPORT

1 October – 31 December 2019

ASARINA PHARMA

YEAR-END REPORT

UNLOCKING NEW POTENTIAL IN WOMEN'S HEALTH

ABOUT ASARINA PHARMA

We are a Swedish biotech company developing Sepranolone, the world's first dedicated treatment for premenstrual dysphoric disorder (PMDD) and other menstrual-related conditions. Our product pipeline is built on over 40 years' research into menstrual-related disorders like PMDD and menstrual migraine (MM). With our new family of GAMSA compounds (GABA-A Modulating Steroid Antagonists), we aim to deliver a new generation of efficacious and safe drugs for still widely untreated conditions, thereby becoming a leading Women's Health company.

CONTACT

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FOURTH QUARTER 2019

OVERVIEW

FINANCIAL HIGHLIGHTS

Total operating expenses amounted to **20.8 million**, of which about 2/3 were clinical costs related to the Phase II studies in PMDD and menstrual migraine.

The Company conducted a directed share issue in October 2019, raising gross proceeds of **SEK 47.5 million.**

On 31 December 2019, the Company had a total cash position of **SEK 130 million**

PREMENSTRUAL DYSPHORIC DISORDER

We enrolled the last patient in our Phase IIb study in our lead indication, Premenstrual Dysphoric Disorder (PMDD), in September, and administered last injection on 26 January. We are on track to publish topline results by the end of April.

MENSTRUAL MIGRAINE TRIAL

We included the first patient in our Phase IIa proof-of-concept study in August and first patients started their treatment cycles in January. We expect last dose to be administered before the end of 2020, and topline results released Q1 2021.

TOURETTE SYNDROME

In October we raised SEK 48 million, mainly for conducting a Phase IIa proof-of-concept study in this large orphan indication. We aim to initiate the study at the National Danish Tourette Center at the University hospital in Herlev before the end of 2020.

AUTOINJECTOR – YPSOMATE FROM YPSOMED

In October, we signed an agreement with the Swiss company Ypsomed for a customized Ypsomate autoinjector for Sepranolone proprietary to Asarina Pharma. It will be used from our first phase III PMDD study onwards.

CEO STATEMENT

DEAR SHAREHOLDER

We were very busy during the last quarter of the year progressing Sepranolone in all our three indications; PMDD, menstrual migraine and Tourette syndrome, as well as signing a contract with Ypsomed for an autoinjector.

PREMENSTRUAL DYSPHORIC DISORDER

LAST PATIENT, LAST DOSE

In September, we enrolled the last patient in our Phase IIb study in our lead indication, Premenstrual Dysphoric Disorder (PMDD) and the last patient received her last injection on 26 January. A total of 206 patients have thus completed the study and we are on track to publish topline results by the end of April.

Our preparations for phase III continue. We expect to run two phase III studies in North America and the EU respectively, in total including almost one thousand patients. Asarina Pharma currently has the most extensive experience in the world in managing large clinical PMDD studies and we could thus offer strong support to a US partner and potentially, we could manage the study in the EU ourselves. In terms of manufacturing, we are on schedule to be able to start both of the two studies 15 months after publishing the topline phase IIb data. Both of these studies will be conducted with the Ypsomate autoinjector.

MENSTRUAL MIGRAINE TRIAL

FIRST PATIENTS HAVE RECEIVED TREATMENT

Menstrual migraine is a disabling condition that globally affects approximately 50 million women. Since standard prophylactic migraine treatments, as well as the recently introduced prophylactic antibody treatments, lack efficacy the condition remains a major unmet medical need and the demand for a new mode of action is huge.

We included the first patient in our Phase IIa proof-of-concept study in August. Some 80-90 patients aged 18-45 years will be included in the study that is ongoing in Finland and Sweden. By the end of the quarter more than 50 percent of the patients had been included and the first patients started the treatment cycles in January. Recruitment is thus well on track, and we expect last patient in and last dose administered before the end of 2020, and topline results released Q1 2021.

TOURETTE SYNDROME

PREPARING FOR PHASE IIA STUDY IN FALL OF 2020

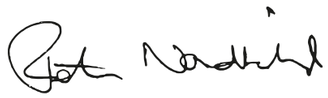
In May 2019 we published exciting data on Tourette syndrome that indicate that Sepranolone, without inducing any side effects, reduces tics on par with Haldol, which is a highly efficacious treatment but used as a last resort as side effects can be brutal. In October we managed to raise SEK 48 million, mainly for the conduction of a Phase IIa proof-of-concept study in this large orphan indication. We aim to initiate the study at the National Danish Tourette Center at the University hospital in Herlev before the end of 2020. This makes spring 2020 very eventful: We will conduct a toxicology study in juvenile male animals and also aim to come to an agreement with the Danish Medical Authorities regarding the clinical protocol. Furthermore, we are in the process of submitting an orphan drug designation application with both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

AUTOINJECTOR – YPSOMATE FROM YPSOMED

In October, we signed an agreement with the Swiss company Ypsomed for a customized Ypsomate autoinjector for Sepranolone proprietary to Asarina Pharma. Our intention is to employ the autoinjector in both female indications; PMDD and menstrual migraine and it will be used from the first phase III PMDD study and onwards.

THANK YOU

I would like to take this opportunity to thank previous and new owners for your support during this year. Not least for the support shown in the new share issue in October. We are on track in all our indications. We aim to publish topline results by the end of April in our PMDD trial, report topline results in menstrual migraine in Q1 2021 and initiate the Tourette's trial in the fourth quarter of 2020. I look forward to reporting back to you about our progress during the coming year.



Peter Nordkild,
CEO Asarina Pharma

EXPLORE OUR YEAR-END REPORT

MEET ERIN GAINER

WOMEN'S HEALTH PIONEER JOINS ASARINA PHARMA BOARD

Erin Gainer is a global pharma executive who led the development and launch of HRA Pharma's pioneering portfolio of groundbreaking women's health products. In January 2020 she joined the Board of Asarina Pharma. Here she talks women's health, developing new therapies and markets—and of course, PMDD.

Founded in 1996, HRA Pharma is a pioneer in women's healthcare who, in their own words, set out to "provide therapeutic solutions to medical needs that had not previously been addressed". Twenty year later they had more than met their goals—with an extensive women's healthcare franchise and a portfolio of eight new women's pharma products, including the company's two unique non-prescription emergency contraceptive treatments.

"I was thrilled to be contacted to join enormous talent and expertise on the Board of Asarina Pharma" says Gainer "I heard about early preclinical work in PMDD on a visit to Karolinska Institute way back, about 10 years ago—so the disease and the unmet need have been on my radar for a number of years."

PIONEERING PRODUCTS – AND PASSION

Gainer's is an extraordinary story. In her 15-plus years at HRA Pharma, of which 7 as CEO, she led the business from a few dozen people to its present staff of 200, clinically developing and launching an exceptionally innovative portfolio. "We developed the first products wholly dedicated to emergency contraception" she says "The medical need was there, millions of women were requesting these type of products, but there was no really effective treatment. Back in the 70's there were 'homegrown treatments'. They used rough combinations of oestrogen and progesterone oral contraceptives, which meant they had lots of side effects and weren't particularly effective. So we focused on developing emergency contraceptives that had no oestrogen in them, and had a better safety and tolerability profile."

The company's regulatory approach was highly innovative—and successful. "We said 'these are emergency brands, so we need to make them available as quickly as possible to women, ultimately that means accessing them without a doctor's prescription."

Neither of HRA Pharma's emergency contraceptives (the progesterone-only NorLevo and the selective progesterone receptor modulator ellaOne) contained oestrogen. "ellaOne proved significantly more effective at preventing pregnancies than previous generations of pills. But we didn't only do the R&D and clinical trials for approval, we also did subsequent safety studies in real-world use, and achieved non-subscription status. From a regulatory perspective there had been no previous product of this type that had actually done that."

PATIENT POWER AND PMDD

PMDD, like emergency contraception, intersects with sensitive issues that are often socially and medically ignored. Does Gainer see synergies between emergency contraception, and HRA Pharma's journey towards a dedicated treatment, and Asarina Pharma's journey developing a treatment for PMDD?

We developed the first products wholly dedicated to emergency contraception… and we achieved non-subscription status… there had been no previous product of this type that had actually done that.

"The unmet need with PMDD is striking. And the way patients learn about diseases has changed radically over the last 15 years. Their ability to educate themselves and self-advocate, via social media and the internet, creates a huge opportunity to help get the information to the end user. My gut tells me that with PMDD, women who demand a treatment, rather than a clinician comes up with a diagnosis in the classical manner, are going to be key. So the opportunity to reach out and provide robust medical information, within the right regulatory framework, will really help empower women to go to healthcare providers and find a treatment for what is often being neglected".

INCONTESTABLE CLINICAL EFFICACY

But as a scientists and seasoned veteran of clinical development, Gainer stresses that the data always have to come first. "As someone who really focuses on clinical development I know first-hand how essential it is to have very compelling results. The biggest challenge for Asarina Pharma now, as we move towards Phase IIb and hopefully achieve positive results there, is to design, execute and see Phase III present incredibly compelling, incontestable evidence of the efficacy and effectiveness of Sepranolone. This is an exciting but highly operational time in the company, setting the development goals for the Phase III trial, trying to execute on those and hopefully exceeding all expectations. I look forward to contributing."

PMDD PHASE IIB STUDY

DATA UPCOMING - WHAT IS A MEANINGFUL DIFFERENCE FOR PATIENTS?

Asarina Pharma's Phase IIb Study in PMDD will produce a substantial, high-quality database. But with a condition as complex as PMDD, which data best measure efficacy, for both regulators, payers and patients?

ASARINA PHARMA CHIEF OPERATING OFFICER KARIN EKBERG EXPLAINS.

"It's interesting to consider what results constitute a 'clinically meaningful effect' says COO Karin Ekberg, "not just for regulatory bodies and payers, but for patients as well. Following the request from the FDA, the primary variable for assessment of effect is the reduction in premenstrual Total symptom score—based on an average reduction in 11 key symptoms as an endpoint result, measured in the week directly before menstruation.

"This is a useful metric" says Ekberg "and of course a clinically meaningful measure. However, there are PMDD patients impacted by symptoms for up to 10 days before menstruation. For them, a clinically meaningful effect would also be the reduction of the number of days with symptoms. This is not part of the validated assessment in PMDD studies, but we will nevertheless analyse the data from women with a longer symptom duration, and assess if Sepranolone can also reduce symptom duration."

IMPAIRMENT: AN IMPORTANT VARIABLE

Impairment is another important variable. The impairment score consists of 3 questions about how the symptoms impact daily life, a woman's ability to interact with her daily routine at work/school or at home and if symptoms interfere with relationships and/or social activities.

"Prof Shaughn O'Brien, a leading PMDD KOL, advocates 'impairment', or the number of days where quality of life or work is impaired, as a key metric" says Ekberg. "I think he's right. Also, Professor Neill Epperson, another KOL and member of our Scientific Advisory Board, stresses 'distress' as an important clinical definition. The fact that many PMDD KOLs are discussing impairment shows how important it is."

Peter Nordkild, Asarina Pharma CEO agrees: "This is a complex highly cyclical disorder with devastating and often sustained symptoms during the menstrual cycle. The quality and volume of data we are generating will be impressive. We hope it will be valuable for scientists and for patients to better understand the complexity of this relatively little understood disease."

PMDD PHASE IIB STUDY

IMPORTANT LESSONS LEARNED FROM PREVIOUS EXPLORATIVE TRIAL

The data gathered from Asarina Pharma's Phase IIb Study, expected to be released in late April 2020, will be comprehensive, high-quality and give proof-of-concept for the patients' self-administration regimen. Asarina Pharma Chief Operating Officer KARIN EKBERG explains.

"Our 2015 Phase IIa trial was an exploratory study, and in our current Phase IIb study we have applied the lessons learned" says Karin Ekberg. "Three big steps in Phase IIb were taken from the lessons learned from the first study—we optimized the treatment regimen, applied stricter inclusion criteria and the treatment was put in the hands of the patients at home."

STEP #1: OPTIMIZED TREATMENT

PUTTING TREATMENT INTO THE PATIENT'S HANDS

"In our Phase IIa study, 32% of women did not have the drug present in their blood just prior to menstruation, when symptoms peaked and efficacy was assessed. This was because only five doses were administered per patient, and the method we chose to identify time of the start of treatment based on ovulation didn't work satisfactorily" says Ekberg.

The Phase IIa study results strongly indicated that Sepranolone needs to be present towards the end of the cycle, not just at the beginning of the luteal phase. "So in this Phase IIb Study we extended treatment from five injections to seven, extending treatment from 10 to 14 days" Ekberg says "that means a higher 'treated as intended population', and from what we see from the patient's reports so far the dose regimen has worked very well."

THE CALENDAR METHOD

Asarina have used the calendar method recommended by the FDA to time treatment initiation during its Phase IIb Study, rather than the earlier LH Urine testing method used in the Phase IIa study. "Treatment timing is crucial for a cyclical condition" Ekberg says "Patient experience of the LH Urine stick tests in the earlier Study was mixed, with some reporting they could feel they were ovulating, but the stick failed to show ovulation. "For this Study we, after consultation with the FDA, decided to opt for the Calendar Method" Ekberg says "and results have been positive. Initial review of data show that the average cycle in the Study lasted 28 days and 90% of cycles showed less than 2 days ± standard deviation. That will mean highly reliable, consistent data. It really confirms that the calendar method works."

> *This was a complete proof-of-concept Study. Women handled the injections themselves exactly as they will in a final treatment scenario. The volume of data we will generate will be higher, and so will the reliability and quality*
>
> **COO Karin Ekberg**

STEP #2: STRICTER INCLUSION CRITERIA

Entrance criteria for 2015's Study was based on the DSM-IV definition from 1994. In the Phase IIb UM203 study the DSM-5 criteria have been used. "Phase IIb benefitted from being based on DSM-5, which has a clearer PMDD definition and a stronger emphasis on PMDD not being mistaken for an exacerbation of an underlying psychiatric disease" says Ekberg. "Again from a clinical and statistical perspective this makes for a stronger more incontestable data base."

PHASE IIB PMDD STUDY
MORE TREATMENTS, MORE DATA

540 menstrual cycles treated

›3.000 separate doses of Sepranolone administered

28 days average cycle, 7 injections per cycle

90% of cycles varied in length less than 3 days

› 85% patients take 6 or 7 injections during cycle

15% drop out rate

(Numbers as of January 20, 2020)

STEP #3: THREE-CYCLE TREATMENT

2015's Phase IIa Study tested 120 randomized patients in Sweden, with one menstrual cycle studied – a total of five doses of Sepranolone per patient, administered in the 10 days from ovulation. The Phase IIb Study administered 6-7 injections per cycle, to 206 women, over three cycles, starting 14 days before menstruation.

"Additionally, we have a broader range of patients" says Ekberg, "with patients from Poland, Germany and the UK as well as Sweden. This was in fact the largest PMDD trial carried out in Europe in recent years. It was a complete, randomized proof-of-concept study, with women handling the injections themselves at home, exactly as they will in final treatment scenarios as well as when Sepranolone is marketed. The volume of data we will generate in this Study will be greater, and so will the reliability and quality."

STRONG SAFETY PROFILE

PMDD IIb data already demonstrate that Sepranolone has a strong safety profile. Fewer than 5% of all injections reported an Adverse Event, all were mild except for a few which showed moderate signs of irritability. "Our product is oil-based meaning that for some individuals there may be some skin irritation" Ekberg says "but the oil-based product is necessary to be able to achieve an extended release of the drug allowing patients to only have to take the product every second day. So out of approximately 3,000 injections we experienced fewer than 134 Adverse Events, almost all of them mild. In 80% of inspections of the stomach area there were no signs of irritation whatsoever."

2014–2017
PHASE IIA CLINICAL TRIAL

Double-blind, placebo controlled trial

120 randomized patients

Sweden

5 injections over

1 cycle

10 days from ovulation

2018 - 2020
PHASE IIB CLINICAL TRIAL

Double-blind, placebo controlled trial

206 randomized patients

Sweden, England, Germany, Poland

6-7 injections per cycle

3 cycles

14 days before menstruation

HIGH COMPLIANCE

"Compliance has been exceptional throughout the Study" Ekberg says "we have seen a 15% dropout, which is significantly less than we expected and much lower than seen in previous large clinical PMDD studies. With patients needing to spend around eight months including three menstrual treatment cycles in total in the Study this was a demanding trial, so just 15% dropping out is exceptional.

"It also bodes well for recruitment in our next Study. In Phase IIb women knew they would not be allowed to continue on the drug if they were lucky enough not to receive the placebo – but still the dropout rate was very low. Phase III will be a 12 months Study, during the first three months half the patients will be given the placebo, half the active substance. In the following nine months everyone will be given the active substance. High compliance in this Study not only means substantial data, it also suggests easier recruitment for Phase III:"

MENSTRUAL MIGRAINE PHASE IIA STUDY

RAPID RECRUITMENT REFLECTS MAJOR NEED

The first patient joined Asarina Pharma's Menstrual Migraine Study at the end of August 2019, the first dose was administered in December and by January 2020 over 50% of patients had already been recruited.

"It reflects how big the unmet need is, and how distinctive Sepranolone is as a treatment", says Asarina Pharma CMO and Menstrual Migraine Study Coordinator Märta Segerdahl.

> *Sepranolone is the first treatment to approach migraine as a condition that could be related to fluctuations in hormones. The specialists we're working with are highly interested in the potential*
>
> **CMO Märta Segerdahl**

"1-in-5 women with migraine suffer from menstrual migraine (MM)" says Märta Segerdahl, "That's 50 million women worldwide, yet it's often stubbornly resistant to standard treatments, both symptomatic ones like triptans and NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) – and old and newer prophylactic ones like CGRP antibodies. Sepranolone approaches MM from a different medical perspective to previous treatments, so it's of great interest both to clinicians and patients."

MENSTRUAL MIGRAINE, NEUROBIOLOGY AND ALLOPREGNANOLONE

Why have so few treatments proved to be fully effective against Menstrual Migraine? "We don't know for sure" says Segerdahl "but we do know that MM is probably triggered by different mechanisms to those which trigger 'regular' episodic migraine. Until now no treatments have treated migraine as a condition that could be related to fluctuations in hormones. Sepranolone is the first to do that. It targets Allopregnanolone, the potent neurosteroid we believe triggers menstrual migraine. Sepranolone inhibits allopregnanolone, and could so prevent attacks from occurring."

A 2019 paper in the Journal of Headache and Pain (Migraine and cluster headache show impaired neurosteroids pattern) found that migraine patients had significantly higher amounts of Allopregnanolone in their blood compared to people without migraine, both for mild and chronic migraine and that this was unrelated to whether or not the patients had a migraine attack. The paper concluded that neurosteroid levels are associated with chronic headache disorders and migraine, and that "fluctuations of neurosteroids… might shape the natural course of migraine and cluster headaches".

"Most migraine specialists are well aware of how distinctive and challenging Menstrual Migraine is" says Segerdahl "the ones we're working with are highly interested in Sepranolone's potential, and in referring Menstrual Migraine patients to the study. Both practitioners and patients in the Study are aware of how important this new direction could be in treating and maybe even finally preventing this disruptive, disabling condition".

8 FACTS AND FIGURES

ASARINA PHARMA PHASE IIA MENSTRUAL MIGRAINE STUDY

1. Randomized, double blind study
2. Two doses of Sepranolone compared to placebo
3. Women age 18-45
4. Estimated top line results: Q1 2021
5. Diagnostic baseline: three menstrual cycles, followed by three cycles of Sepranolone or placebo treatment
6. Women self-administer treatment every 48 hours of luteal phase of their cycle
7. Primary endpoint: reduction from baseline in number of migraine days
8. Recruitment on track, with more than 50% of patients enrolled

WHAT'S SO SPECIAL ABOUT MENSTRUAL MIGRAINE?

- ✔ Highly specific and disabling
- ✔ Predictable, prolonged, recurrent attacks
- ✔ Attacks start 2 days before to 3 days into menstruation
- ✔ Challenging to treat
- ✔ Frequently does not respond to standard migraine treatments
- ✔ More likely to go unreported and undiagnosed

"Because MM attacks are so closely tied to progesterone and allopregnanolone levels, we believe they occur in response to falling levels of the potent neurosteroid allopregnanolone" says Segerdahl.

"Women with MM are highly sensitive to allopregnanolone levels. It's sudden withdrawal of allopregnanolone that we believe triggers these disabling, painful migraine attacks. Sepranolone is the body's natural, endogenous regulator of allopregnanolone. It is a highly specific, targeted hormone metabolite that inhibits allopregnanolone, preventing the devastating effects of allopregnanolone withdrawal from occurring—and effectively preventing MM attacks."

THE STUDY WILL TAKE PLACE IN FINLAND AND SWEDEN WITH 80-90 PATIENTS AGED 18-45 YEARS. LAST PATIENT IN AND LAST DOSE ADMINISTERED BY END 2020, WITH TOPLINE RESULTS RELEASED Q1 2021.

TOURETTE SYNDROME PHASE IIA STUDY

SEPRANOLONE: A NEW APPROACH TO TS

Tourette syndrome (TS) is a cruel condition. Always striking first in childhood, 32% of children with TS consider suicide or self-harm, whilst current standard treatments like the anti-psychotic Haldol have serious side effects.

Asarina Pharma's endogenous neurosteroid compound Sepranolone could mean reduced side effects—it already has a strong safety profile and represents an entirely new approach to treating TS. Asarina Pharma CMO Märta Segerdahl and the University of Utah's Professor Marco Bortolato explain.

Compulsive, shaming and powerfully isolating, Tourette's typically impacts children at a particularly vulnerable age, with devastating social effects: 32% of children with TS have considered suicide and/or /self-harming, 63% feel discriminated against and 40% are forced to miss school.

SEPRANOLONE'S STRONG SAFETY PROFILE

Asarina Pharma's Sepranolone offers the prospect of a Tourette's therapy with few if any serious side effects. In its current Phase IIb PMDD Study 3000 injections of Sepranolone were administered, with fewer than 134 Adverse Events, almost all of them mild. In April 2019 the company announced that Sepranolone reduced tics on par with Haldol, without inducing any motor side effects, in an animal model of Tourette's. The company now plans to be starting a Phase IIa clinical study in TS, with 20 patients aged 14-45 years beginning treatment in Q4 2020 at the Herlev University Hospital's Department of Paediatrics in Copenhagen, one of Europe's largest Tourette's units.

Asarina Pharma CMO Märta Segerdahl is managing the Study: "It's so important to be able to help this population, who suffer from such a severe social handicap. For us, exploring Sepranolone in this new indication presents new opportunities to learn more about the treatment.

"Previously, Sepranolone has been tested on women in two-month or three-month cycles. For the first time now, it will be administered every two days, and to a totally different target group – male and female patients as young as 14. The fact that this affects the central nervous system means that this time round we are working with the compound as it directly effects the brain, so this is neuroendocrinology in its essence. It underlines how broad and fascinating the research opportunities for Sepranolone are."

A NEW DIRECTION IN TOURETTE'S TREATMENT

Professor Marco Bortolato, Faculty of Pharmacology and Toxicology at the University of Utah, and leader of Asarina Pharma's first animal Tourette's Study, agrees: "The Study represents a new direction in the treatment of TS. There are no neurosteroid-based medications currently being used to treat TS. This is a completely new approach; the logic of the treatment is completely different. As a highly targeted hormone metabolite it offers the possibility of a treatment that could be efficacious – without any of the side effects commonly caused by anti-psychotics like Haldol. A positive result would be extremely promising for patients."

If the clinical endpoint in this Study, the reduction in tics according to the YGTSS (the Yale Global Tic Severity Scale) is reached, says Professor Marco Bortolato "then I would certainly hope to see a new wave of research into the role of neurosteroids in a range of stress and compulsion disorders—even beyond Tourette's.

SEPRANOLONE AS AN ADJUNCT TREATMENT FOR CBIT?

"Sepranolone could, if successful, help patients get far better results from their CBIT, (comprehensive behavioural intervention for tics)", Bortolato says. "CBIT is a major therapy for TS primarily based on teaching patients how to recognize their urges to tic and suppress them. At this point CBIT is quite effective for many patients, but many don't get the results they need. Pharmacological aid could help people who do not experience improvement with CBIT to reduce stress, improve control and get better results. I definitely think that, if effective, Sepranolone could work as an adjunct therapy for CBIT. Any possibility we have to intervene pharmacologically on the key triggers that unleash tics would be extremely important for treatment".

> *If the clinical endpoint is reached in this Study I hope to see a new wave of research into the role of neurosteroids in a range of stress and compulsion disorders—even beyond Tourette's.*
>
> **Professor Marco Bortolato**

SAFE TREATMENT REMAINS A CHALLENGE

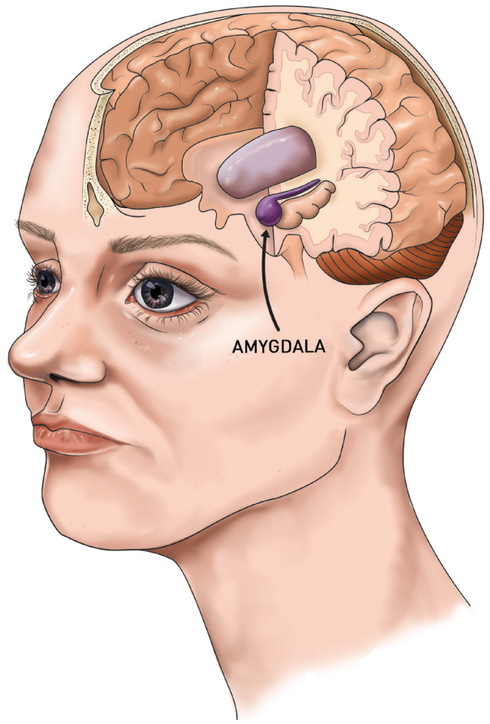
Yet developing a safe treatment with few side effects remains a challenge. TS is a complex condition. Patients often have a high rate of related disorder comorbidities such as OCD and ADHD. And the condition is highly refractory:

- 59% of children and adolescents take prescription medication to manage TS
- 44% of parents feel their child's symptoms are not adequately controlled by existing medication
- 29% of children and adolescents have tried five or more different medications

THE SCIENCE OF ALLOPREGNANOLONE

Progesterone is a female hormone playing a major role in the menstrual cycle and during pregnancy. Similar to all endogenous sex and stress hormones, progesterone produces $GABA_A$ receptor active metabolites and especially Allopregnanolone (ALLO) and isoallopregnanolone (ISOALLO) are of interest in the context of Premenstrual Dysphoric Disorder (PMDD) and MM.

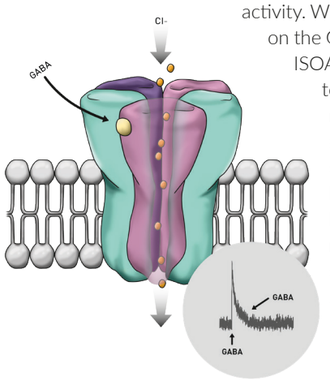
Both of these metabolites are active neurosteroids autonomously formed within the brain but also in peripheral endocrine tissues. Both ALLO and ISOALLO easily pass the blood brain barrier so changes in peripheral production are noted in the brain. The concentrations of Progesterone and thus the metabolites ALLO and ISOALLO are increased following ovulation and production from the corpus luteum but concentrations drop rapidly at the onset of menstrual bleeding if there is no pregnancy. The concentration of ALLO in the brain is also increased during stress. [1, 2]



AMYGDALA. *The amygdala plays a crucial role in processing emotional responses. Inside the amygdala, neurons use the neurotransmitter GABA (gamma-aminobutyric acid) to modulate feelings such as fear, anxiety and agreession. The GABA system is the brain's primary inhibitory neurotransmitter.*

LACK OF ADVERSE EFFECTS CONFIRMED IN PHASE II A AND B STUDIES

ISOALLO does not have an effect on the GABA receptor as such, but where ALLO opens the GABA receptor increasing the electrical activity of the receptor, ISOALLO reconfigures the GABA receptor to normal without influencing the electrical activity. Without a direct effect on the GABA receptor activity ISOALLO was not expected to produce adverse reactions. This lack of adverse events has been confirmed in the Phase II A and B studies in PMDD, except for some mild injection site signs observed in fewer than 5 % of all injection sites.

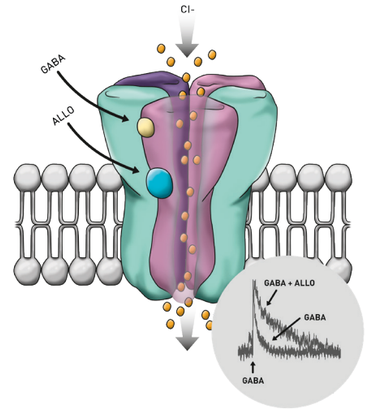


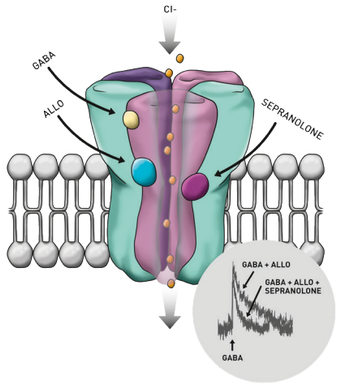
ALLOPREGNANOLONE, IMPORTANT IN MOOD AND ANXIETY DISORDERS

As many of the endogenous steroids Allopregnanolone possesses both positive and negative effects depending on the situation and individual. A wide variety of effects exists including sedative, anesthetic, analgesic, pro-sleep etc. Fluctuations of ALLO and other neurosteroids seem to play an important role in the pathophysiology of mood and anxiety disorders as well as menstrually related conditions like PMDD, MM, epilepsy and various other neuropsychiatric conditions. However, increased levels of ALLO can produce negative paradoxical effects, including negative mood, anxiety, irritability and aggression. In addition, prolonged increasing levels of ALLO e.g. following ovulation can induce tolerance development resulting in withdrawal symptoms setting off e.g. migraine attacks, when the ALLO concentration rapidly drops prior to the next menstruation, when there is no pregnancy. [3]

ALLOPREGNANOLONE IN POSTPARTUM DEPRESSION

Boston-based Sage Pharmaceuticals are focusing on developing products based on the positive effects of ALLO. Sage product Brexanolone (ALLO) has just been approved by the FDA for postpartum depression. Sage are also developing analogs of ALLO e.g. Sage 217, which is in Phase II clinical development for e.g. insomnia. Asarina Pharma on the contrary is focusing on developing products alleviating the negative effects of ALLO. [4]



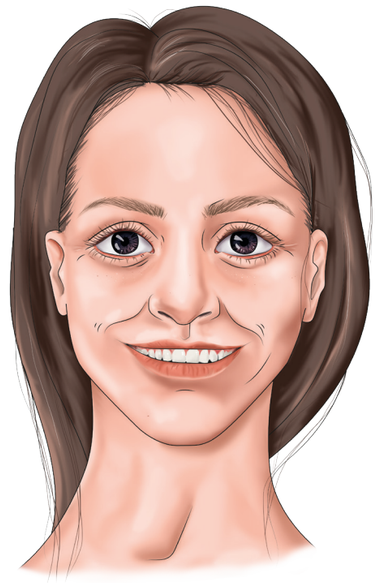


ALLOPREGNANOLONE IN PMDD

Women suffering from PMDD are particularly sensitive to the increasing concentrations of ALLO during the luteal phase and PMDD symptoms disappear as soon as the concentration of ALLO drops at menstruation or during menopause, when the woman is no longer ovulating. Administration of Sepranolone (ISOALLO) seems to alleviate the brain related PMDD symptoms of depression, anxiety and aggression, through action as a GAMSA (a $GABA_A$ modulating steroid antagonist). [5, 6]

ALLOPREGNANOLONE IN MM

Migraine can occur at any time, but for women at fertile age the intensity and frequency of attacks seem to be concentrated just prior to and during menstruation, when there is no pregnancy and the concentration of ALLO is dropping rapidly. MM is thus believed to be an ALLO substance withdrawal syndrome based on the rapid withdrawal of ALLO following ALLO tolerance development during the luteal phase. The medical rationale is that prophylactic treatment with Sepranolone from ovulation during the luteal phase will prevent tolerance development to ALLO and thus prevent ALLO withdrawal symptoms e.g. induction of migraine. [7]



ALLOPREGNANOLONE IN STRESS-RELATED DISORDERS

Tourette´s Syndrome, Obsessive Compulsive Disorder and Pathological Gambling are all stress-related syndromes characterized by unnatural behaviours that an individual involuntarily performs particularly in response to stress. Stress induces increased production of a number of neurosteroids including ALLO in the brain and adrenal glands. Studies from the University of Utah suggest that stress increases the severity of the tics experienced by Tourette syndrome patients, by promoting the production of Allopregnanolone in the brain. Data published in June 2019 in the Journal of Neuroendocrinology showed that ISOALLO reduced tics in an animal model of Tourette syndrome without inducing any motor side effects, validating its role in reducing the negative effects of ALLO whether produced peripherally in the corpus luteum of the ovaries, or centrally in the brain.

4TH QUARTER AND YEAR-END 2019

FINANCIAL OVERVIEW AND OTHER INFORMATION

KEY FINANCIALS

SEK '000	2019 OCT. – DEC.	2018 OCT. – DEC.	2019 FULL YEAR	2018 FULL YEAR
Net sales, KSEK	0	0	0	0
Operating profit, KSEK	-20 817	-20 481	-81 484	-51 596
Result after taxes, KSEK	-16 297	-14 047	-71 520	-44 025
Earnings per share, after dilution, SEK	-0.88	-0.84	-4.13	-4.26
Total assets, KSEK (end-of-period)	139 894	149 580	139 894	149 580
Equity ratio, % (end-of-period)	85.1	93.5	85.1	93.5
Return on equity, % (end-of-period)	-15.7	-9.9	-55.2	-31.2
Return on total assets, % (end-of-period)	-19.7	-24.6	-54.6	-61.3

REVENUE

Net sales amounted to 0 MSEK (0).

OPERATING EXPENSES

Total operating expenses for the 4th quarter 2019 amounted to 20.8 MSEK compared with 20.5 MSEK in the same period in 2018. Reflecting that Asarina was operating at a relatively stable activity level during much of 2019. Research and development costs amounted to 15.9 (16.5) MSEK, primarily driven by the clinical trial costs for PMDD and menstrual migraine. Staff costs increased to 3.3 (2.6) MSEK due to a small increase in headcount in preparation for the Company's third clinical study (in Tourette Syndrome). General and administration costs remained stable at 1.6 (1.4) MSEK.

FINANCIAL ITEMS AND TAX

Financial items generated a loss of 3.3 (-1.1) MSEK. No tax was reported for the quarter. Asarina Pharma had accumulated tax losses of 149.9 MSEK as of 31 December 2018.

RESULT AND FINANCIAL POSITION

The operating result for the 4th quarter was -20.8 (-20.5) MSEK and the result after taxes amounted to -16.3 (-14.0) MSEK. Cash flow for the period was positive 34.6 (-1.0) MSEK as a result of the equity financing in October 2019 which generated net proceeds of 44.5 MSEK. The consolidated cash balance on 31 December 2019 amounted to 129.5 (141.5) MSEK. The shareholder's equity on 31 December 2019 amounted to 119.0 (139.9) MSEK representing an equity ratio of 85.1 % (93.5%).

STAFF

As of 31 December 2019, the Group had 8 employees/ permanent consultants (6), corresponding to 5½ FTEs.

NOTE* Amounts in parenthesis refer to the 4th quarter in 2018 unless otherwise stated.

THE ASARINA PHARMA SHARE

On 24 October 2019, the Company conducted a directed issue of 2,159,148 new shares to a group of existing and new institutional shareholders. The new shares were issued at SEK 22 per share which generated gross proceeds of SEK 47,5 million.

As of 20 February 2020, Asarina has issued a total of 18,442,800 shares, which are held by approx. more than 1,000 shareholders.

OWNERSHIP AS OF 15 JANUARY 2020 (INCL. SUBSEQUENT CHANGES AS AVAILABLE)

SHAREHOLDER	COUNTRY	NO. OF SHARES	%
Kurma Biofund	France	3,145,132	17.1
Östersjöstiftelsen (Baltic Foundation)	Sweden	2,667,092	14.5
AP4	Sweden	1,685,000	9.1
Idinvest Patrimonie	France	1,639,824	8.9
Swedbank Robur Fonder	Sweden	1,500,476	8.1
Rosetta Capital	UK	1,058,329	5.7
Sectoral Asset Management	Canada	1,001,496	5.4
Länsförsikringer	Sweden	909,000	4.9
Catella Fonder	Sweden	754,627	4.1
Handelsbanken Fonder	Sweden	655,952	3.6
Others		3,425,872	17.6
TOTAL		**18,442,800**	**100.0**

Asarina Pharma has an incentive warrant program for independent directors and management members. As of 31 December 2019, the program comprised warrants entitling the holders to subscribe for a total of 758,822 new shares at the end of 2021 at a fixed price of SEK 25.20 per share.

EVENTS AFTER THE END OF THE REPORT PERIOD

On 21 January 2020, an extraordinary general meeting in Asarina Pharma authorized the board of directors to issue up to 922,140 new shares at market price as part of the Company's agreement with Ergomed, plc. (CRO for the PMDD study). Furthermore, the EGM authorized the board to issue warrants to two board members and one management member entitling the recipients to subscribe for a total of 117,000 new shares.

FINANCIAL CALENDAR

2020

15 April:	Annual Report 2019
5 May:	Annual General Meeting
26 May:	Interim report for 1st quarter 2020
19 Aug.:	Interim report for 2nd quarter 2020
25 Nov.:	Interim report for 3rd quarter 2020

STATEMENT BY THE BOARD OF DIRECTORS

The board of Directors and the CEO hereby certify that this report gives a true and fair presentation of the Group´s and parent company´s operations, financial position and result of operations and describes material risks and uncertainties facing the Group.

Stockholm, 21 February 2020

Asarina Pharma AB

Board of directors

PUBLICATION

The report was submitted for publication by the CEO at 08.00 CET on 21 February 2020.

This report has not been subject to review by the company's auditors.

CONSOLIDATED INCOME STATEMENT

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Net sales	0	0	0	0
Other income	0	0	0	0
Total sales	**0**	**0**	**0**	**0**
Research and development costs	-15 891	-16 494	-63 897	-39 033
Other external costs	-1 598	-1 416	-5 696	-6 190
Personell costs	-3 333	-2 571	-11 896	-6 373
Total costs	**-20 817**	**-20 481**	**-81 484**	**-51 596**
Operating profit	**-19 541**	**-20 481**	**-81 484**	**-51 596**
Financial income	-3 167	689	2 502	1 826
Financial cost	-114	-1 824	-339	-1 824
Financial net	**-3 281**	**-1 135**	**2 163**	**2**
Result before taxes	**-24 098**	**-21 616**	**-79 321**	**-51 594**
Taxes	-	7 569	7 801	7 569
Result for the period	**-16 297**	**-14 047**	**-71 520**	**-44 025**

EARNINGS PER SHARE

	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Number of shares, average (non-diluted)	17 738 730	15 888 849	16 539 685	10 152 064
Number of shares, average (fully-diluted)	18 497 552	16 647 674	17 298 507	10 343 328
Earnings per share, non-diluted, (SEK)	-0.92	-0,88	-4.32	-4,34
Earnings per share, fully-diluted, (SEK)	-0.88	-0,84	-4.13	-4,26
Number of shares end of period (non-diluted)	18 442 800	16 037 218	18 442 800	16 037 218
Number of shares, end of period (fully-diluted)	19 201 622	16 796 040	19 201 622	16 796 040

CONSOLIDATED BALANCE SHEET

SEK '000	2019-12-31	2018-12-31
ASSETS		
Non-current assets		
Equipment, tools and installations	1 768	0
Other long-term financial assets	1	1
Total non-current assets	**1 769**	**1**
Current assets		
Current tax asset	7 698	7 732
Other receivables	547	246
Prepaid expenses and accrued income	375	58
Total current receivables	**8 620**	**8 036**
Cash and cash equivalents	129 505	141 543
Total current assets	**138 125**	**149 579**
TOTAL ASSETS	**139 894**	**149 580**
EQUITY AND LIABILITIES		
Restricted equity		
Share capital	4 611	4 009
Total restricted equty	**4 611**	**4 009**
Unrestricted equity		
Share premium reserve	264 500	213 890
Accumulated losses, incl loss for the period	-150 080	-77 989
Total unrestricted equity	**114 420**	**135 901**
Total equity	**119 031**	**139 910**
Current liabilties		
Accounts payable	16 532	5 601
Other current liabilities	586	782
Accrued expenses and prepaid income	3 745	3 287
Total current liabilities	**20 863**	**9 670**
TOTAL EQUITY AND LIABILITIES	**139 894**	**149 580**

STATEMENT OF CHANGES IN EQUITY FOR THE GROUP

SEK '000	SHARE CAPITAL	SHARE PREMIUM RESERVE	ACCUMULATED LOSSES INCL LOSS FOR THE PERIOD	TOTAL EQUITY
Opening balance 1 January 2018	1 782	46 263	-38 177	9 868
Share issue	2 227	179 106		181 333
Share issue costs		-11 479		-11 479
Warrants			2 225	2 225
Share based payment			2 692	2 692
Translation difference			-704	-704
Result for the period			-44 025	-44 025
Closing balance 31 December 2018	**4 009**	**213 890**	**-77 989**	**139 910**
Opening balance 1 January 2019	**4 009**	**213 890**	**-77 989**	**139 910**
Share issue	602	50 610		51 212
Translation difference			-571	-571
Result for the period			-71 520	-71 520
Closing balance 31 December 2019	**4 611**	**264 500**	**-150 080**	**119 031**

CONSOLIDATED STATEMENT OF CASH FLOWS

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Operating activities				
Operating profit/loss	-19 541	-20 481	-81 484	-51 596
Adjustment for non-cash flow affecting items				
Share based payments	-2 647	2 692	0	2 692
Interest received	2 139	22	1 920	22
Interest paid	-35	-796	-339	-816
Paid taxes	7 835	3 898	7 835	3 898
Cash flow for operating activities before changes in working capital	**-13 525**	**-14 665**	**-72 068**	**-45 800**
Cash flow from changes in working capital				
Decrease(+)/Increase(-) in receivables	-357	577	-624	-38
Decrease(-)/Increase(+) in liabilities	5824	4 175	11 193	6 713
Cash flow from operating activities	**-8 058**	**-9 913**	**-61 499**	**-39 125**
Financing activities				
Share issue	44 434	7 350	51 212	181 333
Share issue costs	-	-624	-	-11 479
Warrants	-	2 225	-	2 225
Acquisition of fixes assets	-1 768	-	-1 768	-
Cash flow from financing activities	**42 666**	**8 951**	**49 444**	**172 079**
Cash flow for the period	**34 608**	**-962**	**-12 055**	**132 954**
Cash and cash equivalents in the beginning of the period	94 929	142 523	141 543	8 384
Translation difference	-32	-18	17	205
Cash and cash equivalents at the end of the period	**129 505**	**141 543**	**129 505**	**141 543**

PARENT COMPANY INCOME STATEMENT

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Net sales	0	0	0	0
Other income	608	637	2 280	2 247
Total sales	**608**	**637**	**2 280**	**2 247**
Research and development costs	-2 150	-462	-1 684	-1 521
Other external costs	-1 236	-953	-3 753	-5 005
Staff costs	-952	-1 284	-4 624	-2 990
Total costs	**-4 338**	**-2 699**	**-10 061**	**-9 516**
Operating profit	**-3 730**	**-2 062**	**-7 781**	**-7 269**
Financial income	222	561	5 623	1 618
Financial cost	-51	-784	-252	-795
Financial net	**171**	**-223**	**5 371**	**823**
Result before taxes	**-3 559**	**-2 285**	**-2 410**	**-6 446**
Taxes	0	0	0	0
Net result	**-3 559**	**-2 285**	**-2 410**	**-6 446**

PARENT COMPANY BALANCE SHEET

SEK '000	2019-12-31	2018-12-31
ASSETS		
Non-current assets		
Financial non-current assets		
Shares in subsidiaries	128 460	51
Other long-term financial assets	1	1
Total non-current assets	**128 461**	**52**
Current assets		
Receivables on group companies	2 421	59 978
Current tax asset	16	164
Other receivables	89	131
Prepaid expenses and accrued income	375	58
Total current receivables	**2 901**	**60 331**
Cash and cash equivalents	116 319	137 564
Total current assets	**117 417**	**197 895**
TOTAL ASSETS	**247 681**	**197 947**
EQUITY AND LIABILITIES		
Restricted equity		
Share capital	4 611	4 009
Total restricted equty	**4 611**	**4 009**
Unrestricted equity		
Share premium reserve	264 500	213 890
Accumulated losses	-22 108	-15 662
Result for the period	-2 410	-6 446
Total unrestricted equity	**239 982**	**191 782**
Total equity	**242 790**	**195 791**
Current liabilties		
Accounts payable	280	233
Other current liabilities	586	601
Accrued expenses and prepaid income	2 222	1 322
Total current liabilities	**3 088**	**2 156**
TOTAL EQUITY AND LIABILITIES	**247 681**	**197 947**

NOTES

1. GENERAL INFORMATION

This interim report covers the parent company Asarina Pharma AB (publ), Corp. Reg. No 556698-0750 and the subsidiaries Asarina Pharma ApS (Denmark) and Asarina Pharma Finans AB.

2. ACCOUNTING PRINCIPLES

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 (K3).

The accounting principles adopted in this interim report are consistent with those of the 2018 Annual Report and should be read in conjunction with that annual report.

3. RISKS AND UNCERTAINTIES

RISK MANAGEMENT

The Board of Directors of the company continuously and systematically assess risks in order to identify risks and to take action on them. The internal control environment is primarily comprised of the following five components: control environment, risk assessment, control activities, information and communication and review. Mitigating actions are developed for each identified material risk.

OPERATIONAL RISKS

At the current stage of development, Asarina's main operations consist of pre-clinical and clinical studies in order to demonstrate safety and clinical efficacy in its pharmaceutical candidates. There is no guarantee that a certain (pre-) clinical trial will generate the required data to enable Asarina to progress to the subsequent development phase of the pharmaceutical candidate. Consequently, Asarina's goal is to gradually generate a portfolio of different pharmaceutical candidates for other indications, thereby reducing risk.

Also, clinical trials may be delayed and costs for the trial may exceed budget. Prior to initiating a clinical trial, Asarina conducts a detailed assessment of the trial period and budget to ensure sufficient funding to conclude the trial, including delays and increased costs for the trial.

Asarina develops medical products and is dependent on assessments and decisions by relevant authorities such as the EMA in Europe and the FDA in the USA. Asarina cannot guarantee that it will obtain the regulatory approvals required to continue clinical studies and to obtain market approval. In order to mitigate this risk regarding regulatory risks, the Company retains leading experts concerning regulatory issues and preparation of protocol of clinical studies.

Asarina focuses on therapeutic areas in which few other companies are active. The company conducts extensive monitoring of potential competitive activity within the IP-area, in relevant publications and through participation in biotech conferences.

FINANCIAL RISKS

Asarina does not at present generate any income from product sales or licensing of the Company's IP-assets and is therefore dependent upon raising new capital from investors. Asarina aims to have sufficient liquidity for its planned activities for the next 1-2 years. Therefore, Asarina may at any point have in discussions with current and potential new investors, which may be interested in injecting new finance into theCcompany.

Asarina incurs costs mainly in three currencies: Swedish kronor, Euro, and Danish kronor (which is closely linked to EUR). The company mitigates its exchange rate risk by allocating its financial reserves between EUR and SEK mirroring Asarina's future costs in the three currencies.

DEFINITION ALTERNATIVE KPIS

KPI	DEFINITION	OBJECTIVE
Solidity	Calculated on adjusted equity divided by total assets. Adjusted equity comprises of equity including untaxed reserves deducted with deferred tax liabilities.	The company believes the KPI gives investors information regarding the relation between equity and external financing of the company. The company also believes that the KPS gives investors information about the financial stability and long-term ability.
Return on equity	Result for the period divided by average adjusted equity.	The KPI is included to show the return on the owners invested capital.
Return on total assets	Result before tax with reversal of interest cost in relation to average total assets.	The KPI is included to show the return on the total assets in the company.

RECONCILIATION ALTERNATIVE KPIS

EQUITY RATIO

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Equity	119 031	139 910	119 031	139 910
+ Untaxed reserves	0	0	0	0
- Deferred tax liability	0	0	0	0
Adjusted equity	**119 031**	**139 910**	**119 031**	**139 910**
Adjusted eqity	119 031	139 910	119 031	139 910
Total assets	139 894	149 580	139 894	149 580
Equity ratio, %	**85,1**	**93,5**	**85,1**	**93,5**

RETURN ON EQUITY

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Result for the period	-16 297	-14 047	-71 520	-44 025
Average adjusted equity	103 059	142 171	129 471	141 063
Return on equity, %	**-15,7**	**-9,9**	**-55,2**	**-31,2**

RETURN ON TOTAL ASSETS, %

SEK '000	2019 OCT-DEC	2018 OCT-DEC	2019 FULL YEAR	2018 FULL YEAR
Result before tax	-24 098	-21 616	-79 321	-51 594
+ Interest costs	114	1 824	339	1 824
Average total assets	121 716	80 321	144 375	81 228
Return on total assets, %	**-19,7**	**-24,6**	**-54,6**	**-61,3**

CERTIFIED ADVISER

The company´s certified adviser is Erik Penser Bank, tel. +46 (08) 463 80 00

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