

**REMAIN IN
CONTROL
OF YOUR LIFE**

ASARINA PHARMA AB (PUBL)

INTERIM REPORT

1 January – 31 March 2019

ASARINA PHARMA

INTERIM 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.

CONTACTS

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FIRST QUARTER 2019: OVERVIEW

FINANCIAL HIGHLIGHTS

The company maintained a strict management of its costs

*At the end of the quarter, the total cash position was **SEK 128.9 million***

THE QUARTER IN BRIEF

PMDD

Our Phase IIb study in our lead indication, Premenstrual Dysphoric Disorder (PMDD) made good progress, with a drop-out rate of less than 15% compared to more than 30% average in other late stage clinical PMDD studies. We expect topline results in early 2020.

MENSTRUAL MIGRAINE

Our Phase IIa proof-of-concept study in Menstrual Migraine (MM) is on schedule to start enrollment of patients in July. A CTA has been submitted in Sweden and CTAs will be submitted in Denmark and Finland shortly.

AUTOINJECTORS

We are focusing on identifying the best possible autoinjector to administer Sepranolone in future studies and expect to select the final autoinjector for Phase III studies and commercialization in June.

TOURETTE SYNDROME

We published exciting data on Tourette syndrome in March. The data indicate that Sepranolone reduces tics in an animal model of Tourette syndrome on a par with Haldol, the current first-line treatment, without inducing any motor side effects.

CEO STATEMENT

Dear Asarina Pharma shareholder,

I am pleased to report that Asarina Pharma has made a strong start to 2019. This Quarter we have strengthened our team and capabilities, yet still maintained strict financial management - leading to a solid cash position at the end of the First Quarter.



Peter Nordkild,
CEO, Asarina Pharma

- **The Phase IIb study with 225 patients in our lead indication**, Premenstrual Dysphoric Disorder (PMDD) made good progress and we expect topline results in early 2020. The drop-out rate (women enrolled but not completing the study) continues to be less than 15% compared to more than 30% as the average in other late stage clinical PMDD studies.
- **The Phase IIa proof-of-concept study in Menstrual Migraine (MM)** is on schedule to start enrollment of patients in July. A CTA has been submitted in Sweden and CTAs will be submitted in Denmark and Finland shortly.
- **We are focusing on identifying the best possible autoinjector to administer Sepranolone** in future studies, instead of the somewhat inconvenient syringe presently used by patients. We expect to select the final autoinjector for the Phase III studies and commercialization in June.



On behalf of the entire Asarina team, I thank you for your continued support.

- **We published exciting data in a mouse model of Tourette syndrome in March.** The data indicate that Sepranolone is capable of attenuating the negative effects of stress-induced Allopregnanolone production in the brain and thus reducing Tic frequency on par with today's first-line treatment with Haldol but without any of Haldol's serious, negative side effects. We are presently evaluating different alternatives for administering Sepranolone to human subjects in this orphan indication with a great unmet medical need.
- **We maintained strict financial management** leading to a solid cash position at the end of the First Quarter.

A handwritten signature in black ink, which appears to read "Peter Nordkild". The signature is fluid and cursive.

Peter Nordkild,
CEO Asarina Pharma

IT'S TIME TO TREAT PMDD

PHASE IIB CLINICAL STUDY, SEPRANOLONE FOR PMDD

4 COUNTRIES, 14 STUDY CENTERS, 225 PATIENTS

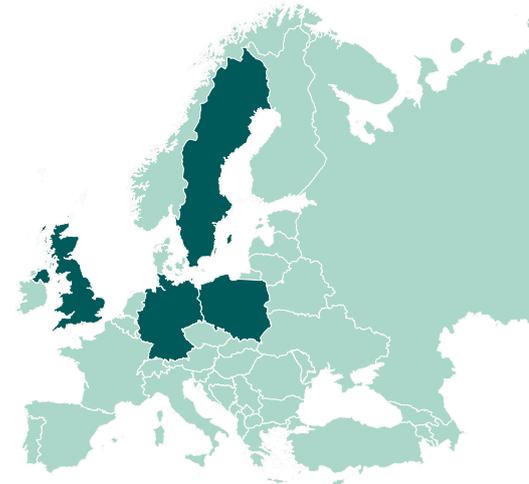
MORE THAN

3/4

of planned study participants now enrolled into trials in Sweden, Poland, UK & Germany

976,800

Almost a million women living near Study sites in Europe have shown interest in our digital PMDD survey



5 NEED-TO-KNOWS

SEPRANOLONE, THE WORLD'S FIRST DEDICATED TREATMENT FOR PMDD

1 TARGETED

Sepranolone is the world's first dedicated treatment specifically for PMDD.

2 NATURAL

Sepranolone is not an anti-depressant, nor a hormone.

3 EFFECTIVE

Sepranolone reduced key PMDD symptoms by over 80% in Phase IIa clinical tests.

4 ENDOGENOUS

Sepranolone is endogenous (or naturally-occurring) in the brain. It inhibits the effects of allopregnanolone, the neurosteroid that triggers PMDD

5 LOW-RISK

Sepranolone is highly specific, meaning low risk of side-effects: More than 200 patients have been exposed to Sepranolone in PMDD clinical trials, with no major side effects reported

DEFINING PMDD

PMDD (Premenstrual Dysphoric Disorder), the severest form of PMS, affects 1-in-20 women of fertile age worldwide

PMDD is a devastating, hereditary condition that robs millions of women of their full potential. Sufferers are four times more likely to attempt suicide, often have difficulty holding down a full-time job and are significantly more likely to experience family or relationship breakdowns.

YET THERE HAS NEVER BEEN A DEDICATED TREATMENT FOR PMDD. UNTIL NOW

THE PASSION OF PATIENTS

Asarina Pharma's COO Karin Ekberg has managed Clinical Trials at every level imaginable—as trial director, trial leader, project and data manager and site coordinator. But Asarina Pharma's Phase IIb Trial for PMDD has been different. How? Karin Ekberg explains.

Asarina Pharma's Phase IIb Clinical Study for PMDD is tough: Volunteers have to complete a detailed 27-question survey every single day—as well as taking a dose of Sepranolone 6-7 times per month. Yet drop-out has been exceptionally low, at just 15%. What sets this Study apart?

“The obvious difference is that this Trial is for a completely new indication. In some of the Study countries we're working in, few clinics or professionals had even heard of PMDD, so there's an extremely large unknown patient population. Fewer than 10% of patients were referred to the Study by clinics, which is unusually low in comparison to most other indications. Only two of the Study countries—Sweden and the UK—had substantial experience treating and diagnosing PMDD. We have a fantastically committed team who is genuinely resourceful in reaching out below the line and beyond the clinic—using social media, local press, outreach near research sites, a whole range of initiatives. It's been really exciting!

“By the nature of the illness many patients have not been treated well in clinical settings and can be suspicious. For some Study sites it's been a steep learning curve working with patients who need extra support, and understanding that this study is different. Moreover, all planning needs to be according to the individual cycles of women taking part, so the logistics can be challenging. But that's part of what makes the Study so special.

“And for the patients the logistics are easy. They administer injections at home so there are few demanding clinical visits or logistics around MR scans or other complicated tests.

Plus there is no real safety issues with the treatment. The overriding commitment to helping develop a therapy not just for them but future generations—few studies engage with a community as self-aware, articulate, self-advocating and determined as this one.

“When thinking of lessons it's useful to look at where the Study worked well and figure out which factors helped. In Sweden, for example, generally high PMDD awareness really supported the study. Clinically, Prof Torbjörn Bäckström has spent many years teaching about PMDD for the country's gynaecologists. Women's health is a traditionally fragmented field, with treatment divided amongst gynaecologists, split into obstetrics, infertility, gyn-surgery and oncology and endocrinologists, then neurologists and psychiatrists. Where you have a unifying research presence like Torbjörn, or, for example, like Prof Shaughn O'Brien in the UK, it makes a huge difference. Plus, Sweden has a strong tradition of talking about women's health issues openly—which contributes positively to the support women can count on from family and friends. Last but by no means least, there is a strong tradition of trusting medical and clinical research here too.

“So some lessons are clear: Take a long-run up to PMDD studies, prepare your ground, build bridges and knowledge throughout the gynaecological community, reach out to patient groups throughout the country, assess carefully how far along the country is in terms of recognizing and discussing women's health openly—and most of all, always, give it time and patience.



- **PhD** in Clinical Physiology
- **+70** scientific publications
- **20 + years'** experience of clinical research at Karolinska Institute at every level of drug development—CMC, pre-clinical, regulatory and clinical, IP and business
- **Clinical Trial roles** include trial director, trial leader, project and data manager and site coordinator

Karin Ekberg: COO Asarina Pharma

MENSTRUAL MIGRAINE PHASE IIA CLINICAL STUDY

Menstrual Migraine is a disabling, aggressive form of migraine where attacks are more predictable, but often more severe and prolonged than those in episodic Migraine.

Our Phase IIA proof-of-concept Study into Sepranolone for Menstrual Migraine is now underway. We expect to start enrolling volunteers and have First Patient In in July 2019. A CTA has been submitted in Sweden and CTAs will be submitted in Denmark and Finland shortly.

PHASE IIA TRIAL: KEY FACTS

TARGET SITES

Finland, Denmark, Sweden

NUMBER OF PATIENTS

80-90

AGE OF PATIENTS

18-45 yrs

CRO

SCRO (Scandinavian CRO)
based in Uppsala, Sweden

TREATMENT

Prophylactic neurosteroid
Sepranolone

ADMINISTRATION

Pre-filled syringes for
self-administration

TIMELINE

Study start in late June 2019
- completed end 2020

SEPRANOLONE AND MENSTRUAL MIGRAINE

MEETING AN UNMET NEED MM has a markedly different symptomatology to Migraine, and the implications in terms of prevalence and treatment are huge. MM reveals a large number of unidentified patients with major unmet needs currently receiving no dedicated prophylactic treatment. Sepranolone is part of a new generation of migraine treatments, yet it is unique: none of the clinical studies for new antibodies have specifically analysed the effect in women suffering from MM. It remains a major unmet medical need.

MEET THE EXPERTS:

STUDY COORDINATORS APPOINTED

We have now appointed Study Leaders in our three target countries Finland, Denmark and Sweden for our Phase IIa Study into Menstrual Migraine.



**DR MARKKU NISSLÄ:
INTERNATIONAL STUDY COORDINATOR**

Dr Nissilä is a senior neurologist specialising in headaches, and a highly experienced Director of Clinical Research programs.

A graduate of the University of Turku Medical Faculty, in 1992 he co-founded Northern Europe's largest medical centre devoted to headache in Turku. He has managed a wide range of clinical studies and is experienced in genomics, software development, big data and modelling of diagnostic processes.



**PROF MESSOUD ASHINA:
STUDY COORDINATOR DENMARK**

Prof Dr Messoud Ashina is one of Denmark's leading neurologists. He is a Professor of Neurology and Chief Physician at the Department of Neurology, Rigshospitalet, Faculty of Medical and Health Sciences, University of Copenhagen.

He is the Director of the Human Migraine Research Unit at the Danish Headache Center and has been involved in research about headache and migraine pathophysiology since 1995.



**DR YNGVE HALLSTRÖM:
STUDY COORDINATOR SWEDEN**

Senior neurologist Dr Yngve Hallström, with a medical degree from the Karolinska Institute, has decades of clinical experience in the field of headache and migraine. He is the Head and senior practitioner at a privately run neurology clinic in central Stockholm and has extensive experience in clinical studies in the field of headache and migraine.

**1-IN-10
PEOPLE WORLDWIDE**

suffer from migraine – making it more prevalent than diabetes and asthma combined

**2/3
OF THESE**

approximately 500 million, are women, half being of a fertile age

**1-IN-5
OF THESE WOMEN**

or approximately 50 million women worldwide, suffer from Menstrual Migraine

The WHO
RECOGNIZES MIGRAINE AS THE LEADING CAUSE
of YLD (Years Lived with a Disability) for women of a reproductive age

TOURETTE SYNDROME FOCUS FEATURE

REMAIN IN CONTROL OF YOUR LIFE

“ I remember my first tic as if it were yesterday. It was a crowded classroom, everyone was working quietly and suddenly I had to throw my head back and shriek. I couldn't stop it. I had to do it. The teacher asked me to stop, other kids started laughing. They ended up taking me to the Emergency Room where the Doctor told me it was Tourette's. I was so mad. I was 8. I had absolutely no idea what was going on. 'JOSH', 12, Oregon



PMDD, MM AND NOW TOURETTE'S:

ALLOPREGNANOLONE: WOMEN AND CHILDREN FIRST

Asarina Pharma's release of its pre-clinical data on Tourette Syndrome (TS) demonstrates how the neuro-steroid Allopregnanolone plays a crucial role not only in PMDD and MM, impacting the lives of millions of women worldwide, but also in Tourette syndrome, the neurological condition that strikes in childhood. Could Sepranolone, the body's natural, endogenous compound that dampens the effects of Allopregnanolone, offer a no-side effect solution?

Tourette syndrome overwhelmingly impacts children and teenagers most severely. Sufferers experience their first tics on average between 3 and 9 years old. At such a vulnerable age onset is disturbing and powerfully socially disruptive.

TS tics are involuntary, startling, repetitive movements and vocalisations.

For up to 60% of TS sufferers, tics can also include mild self-injuring behaviour (SIB) such as compulsive skin picking, self-hitting, lip- and hand-biting and self-poking.

Yet the more a sufferer tries to suppress a symptom, the more severe and compulsive it becomes.

SIMPLE TICS

include eye blinking, facial twitching and grimacing, shoulder shrugging, head or shoulder jerking, sniffing, grunting, repetitive throat-clearing and more.

COMPLEX TICS

involve coordinated patterns of movements involving several muscle groups. They include facial grimacing combined with head twists and shoulder shrugs

Bewilderingly to those suffering and seeing them for the first time, complex tics often appear purposeful. They include sniffing or touching objects, jumping, bending, twisting or bursting out with expletives and longer words and phrases.

COMPULSION IS KEY

In fact recent phenomenological studies confirm sufferers' own accounts: They reveal that tics are often the secondary symptoms of complex behavioral sequences, typically beginning with powerful, intrusive premonitory urges, and fixations on physical cues that sufferers are then compelled to act on. Evidence suggests that these urges are initiated or exacerbated by stressful environmental triggers, with a marked sense of discomfort that can only be alleviated by acting on the tic. Tics can be temporarily suppressed, but this deferment results in an escalation of psychological pressure—making it almost impossible for the sufferer not to act on the urge.

TEEN TOURETTE'S

TS can be chronic, with symptoms lasting a lifetime, but for most sufferers, symptoms are worst in their early teens, improving in their late teens and on into adulthood. Many sufferers find themselves symptom-free by their early 20's with no need for Tic-suppression medication. 10 - 15 % of TS sufferers have TS that does last into adulthood, but TS is not degenerative, does not impair intelligence and people with it have a normal life expectancy. 200.000 Americans suffer from the most severe form of TS, making it an orphan indication.

TS: NO STRESS—NO SYMPTOMS?

Stress, anxiety or excitement all exacerbate TS tics. Calm reduces and improves them. Ongoing Asarina Pharma research being carried out by Assoc Prof of Pharmacology and Toxicology Marco Bortolato of the University of Utah, highlights stress as a powerful correlative factor in TS. The DSM-V (Diagnostic and Statistical Manual of Mental Disorders Fifth Edition) diagnoses TS by the presence of multiple motor, and one or more phonic, tics—lasting at least 1 year, with onset prior to age 18.



COMPULSION IS KEY: TOURETTE CO-MORBIDITIES

The compulsivity of TS is underlined by its most common co-morbidities:

→ **ADHD**

attention-deficit hyperactivity disorder

→ **OCD**

obsessive compulsive disorder

→ **OBSESSIVE COMPULSIVE DISORDER**

autism spectrum disorder

HYPERACTIVITY AND IMPULSIVITY

NEUROLOGIC COMPLICATIONS SUCH AS MIGRAINE

SEPRANOLONE FOR TOURETTE SYNDROME: A SAFER SOLUTION

In April 2019 Asarina Pharma released new preclinical data showing that its flagship product Sepranolone reduced tics in Tourette as effectively as today's first-line treatments—but with no side effects.

The specificity of Sepranolone is key to the absence of side-effects. Unlike current first-line anti-psychotic treatments, Sepranolone is not a sedative. It is the natural, endogenous compound in the body that inhibits the effects of Allopregnanolone, the neurosteroid which powerfully triggers the stress-exacerbation of TS tics in the frontal pre-cortex of the brain and which also triggers PMDD (Premenstrual Dysphoric Disorder) and Menstrual Migraine (MM).

"Haldol is used to treat a number of psychiatric disorders like bipolar disorder and it is very efficacious in reducing tic frequency," says Asarina Pharma CEO Peter Nordkild. "However it does not target any of the specific neurosteroids like Allopregnanolone that correlate closely to TS, and is unfortunately associated with many serious side effects. Tardive dyskinesia for example can be permanent. We've exposed more than 200 patients to Sepranolone in our clinical programs for PMDD—and we've have seen no major side effects."

As with all severe neurosteroid and hormone conditions, complex co-morbidities are the rule not the exception. TS sufferers commonly live with other compulsive and neurobehavioral disorders such as ADHD, OCD/B, inattention, hyperactivity and impulsivity—all of which could also be heavily impacted by Allopregnanolone. Common coexistent problems with TS include anxiety, depression and childhood conduct disorder.

CEO Peter Nordkild: "Thanks to our years of work with women with PMDD we're deeply familiar with helping people manage complex, often misunderstood disorders. For TS sufferers we believe Sepranolone could mean safe, secure prevention of symptoms with no complicating side effects.

"Just as with our key treatment areas, PMDD and Menstrual Migraine, our ultimate aim is to help children and teenagers with TS receive efficacious treatment that will empower them to remain in control of their lives."



We've exposed more than 200 patients to Sepranolone in our clinical programs for PMDD—with no major side effects

Peter Nordkild, Asarina Pharma CEO.

THE SERIOUS SIDE EFFECTS OF TODAY'S TREATMENTS

As Tic symptoms often do not cause impairment, and recede in later life, the majority of people with TS require no medication. But for those who do, current treatments involve challenges.

Today's most commonly prescribed effective treatments (anti-psychotic neuroleptics like haloperidol (Haldol) and pimozide) are associated with frequent and serious side effects. Paradoxically, the neurological side effects (like tremor, Parkinson-like symptoms and involuntary dyskinetic movements) can be so severe that they themselves are mistaken for symptoms—meaning higher doses of anti-psychotics being prescribed and so a worsening of side effects. Consequently there is a large unmet medical need for an effective treatment for TS not associated with serious side effects.



Having a tic is like having a really powerful itch that you just have to scratch. If you try to suppress it you just end up having to do it even more. No matter how weird it seems or ashamed you feel—you have to satisfy it. Like other people need to breathe – that's how you need to act on your Tic.

'AARON', 15, EDINBURGH

THE AGE OF ALLO

New preclinical data from Assoc. Prof of Pharmacology and Toxicology Marco Bortolato, and his team at the University of Utah, highlights the powerful role Allopregnanolone (ALLO) may play in Tourette Syndrome (TS), stress and compulsion

TS PRECLINICAL TESTS: THE RESULTS

→ ANIMAL MODEL

The D1CT-7 mouse model was used to test the efficacy of Sepranolone in suppressing tic-like responses. "This model shows a consolidated validity in terms of both a close resemblance to tics in humans and responsiveness to drugs."

→ EARLY EXPERIMENT

showed a dramatic, dose-dependent effect of Sepranolone ($p < 0.0001$).

→ FOLLOW-UP STUDY

STUDY revealed that Sepranolone also counters the enhancement in tics induced by ALLO ($p = 0.001$).

→ LATEST EXPERIMENTS

demonstrated that the tic-reducing effects of Sepranolone are on par with Haldol (Haloperidol), as well as Finasteride, a drug that suppresses ALLO synthesis ($p < 0.00001$).

From initial work on tics using Finasteride, a drug that blocks the synthesis of Allopregnanolone (ALLO), Assoc Prof Marco Bortolato and his team soon realized that ALLO itself was playing a primary role in how stress exacerbates tics.

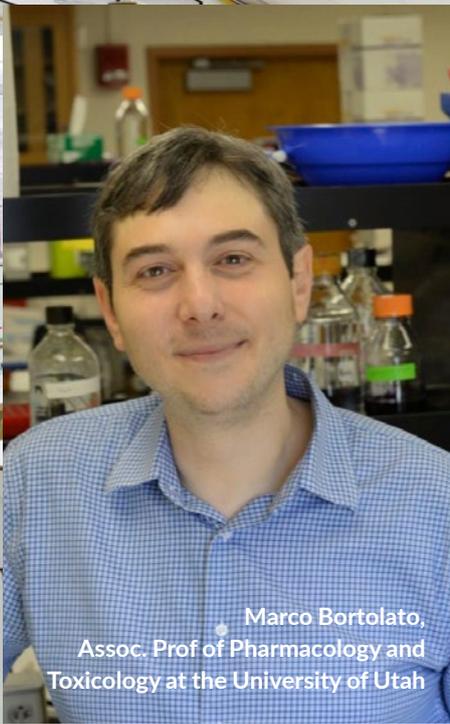
But it didn't end there... ALLO may also be crucial in the brain's central mechanism for balancing obsession with compulsion—and our need to act on compulsion.

"The implications are potentially huge", Bortolato says.

"Our research has been 12 years in the making", says Marco Bortolato, Assoc. Prof of Pharmacology and Toxicology at the University of Utah. "Because TS occurs predominantly in males, with a prevalence of roughly 4-to-1 male to

female, we began working on Finasteride, a therapy that reduces the levels of some male hormones, and the effects were profound. However, as research progressed in animal models, we started realizing that a good part of the efficacy was accounted for by the reduction of Allopregnanolone. Plus, there was an issue of stress reactivity that we had not originally hypothesized, with some patients reporting an improvement with Finasteride because it seemed to control their tics particularly in stressful contexts.

"We knew from animal literature that Finasteride reduced the synthesis of steroids implicated in stress response, like Allopregnanolone, so based on this we started looking at stress sensitivity, finding that one of our TS animal models too was exquisitely sensitive to stress."



Marco Bortolato,
Assoc. Prof of Pharmacology and
Toxicology at the University of Utah

COMPULSION IS KEY

The role of Allopregnanolone and stress may be crucial in the mechanisms by which individuals feel the urge to carry out a tic. This sequence is roughly similar to the link between obsessions and compulsions. “TS patients can temporarily suppress their tics,” Bortolato says, “but this does increase the stress itself—and ultimately the severity of the tics. Many adult patients report that they compulsively enact their tics in order to relieve themselves of a premonitory urge. It is likely that, when TS people suppress their tics, their Allopregnanolone levels in the brain go higher and higher—to the point where they may just not be able to stop from acting on them. We believe ALLO is crucial to that irresistible drive, that compulsion to Tic and keep Ticing.”

Paradoxically, Bortolato points out, for most people Allopregnanolone has the positive function of helping people find positive ways of relieving stress. “In the case of TS, however, this way of relieving stress is maladaptive and pathological, and results in an exacerbation of tics. In fact, several TS patients do experience a certain level of relief from their urges when they tic.”

STRESS AND TOURETTE

“Sensitivity to stress is one of the worst aspects of TS we see in patients, and it can really lead to a rapid increase in tics,” Bortolato says. “We identified which stressors might be most relevant to the animal’s tic-like behaviours, then started looking at paradigms that would let us identify, measure and record these phenomena. Sure enough, we found that Allopregnanolone was a key actor in the mechanism of stress exacerbation of tics. Our paper on ALLO was published in 2017, and when we were contacted by Asarina we immediately started thinking of a collaboration.”

Bortolato emphasizes that ALLO does not cause tics, but is key to the mechanism by which tics break out in stressful situations. “Stress may facilitate the outburst of tics by

interfering with the balance of neuronal activation and inhibition,” says Bortolato. “We found that in the presence of stress our animals synthesize more Allopregnanolone in the prefrontal cortex, which is crucial in behavioural control. These raised levels of Allopregnanolone correlate to other TS-related responses too, including deficits in information filtering—the crucial ability of individuals to extract relevant information from the environment around them, and filter out irrelevant stimuli. In animals and humans with TS-like symptoms the ability to do this is lost, and we identified that Allopregnanolone is critical in facilitating this type of deficit. When we administered Allopregnanolone to our animals the deficit was dramatically exacerbated.”

“Our preliminary data lead us to believe that these processes are not limited just to TS, but point to a much broader biological mechanism that speaks directly to the relationship between obsession and compulsion. If we can prove that mechanism then this therapy would be relevant to a far, far wider set of problems.

Marco Bortolato, Assoc. Prof of Pharmacology and Toxicology at the University of Utah

SEPRANOLONE FOR TOURETTE SYNDROME:

A SAFER SOLUTION

“After discussions with Asarina we tested Sepranolone in our animal models and the results showed extremely good promise. Plus, the specificity of Sepranolone and the fact that it does not interfere with male hormones, means that we may get efficacy but fewer side effects.”

After one year of experiments Bortolato’s team has now substantiated that Sepranolone does indeed reduce the effects of Allopregnanolone on tic-like responses in animal

models, both when ALLO is administered directly to the animals, and when it is synthesized by the brain due to stress. “Plus”, Bortolato points out, “we’ve identified an improvement in information filtering.”

“Our data strongly suggest that Sepranolone should not have any of the major side-effects associated with Finasteride, such as sexual maturation issues, so it could potentially become a good therapy for children – our target population.”

TOURETTE & SEPRANOLONE:

COMMERCIAL POTENTIAL

TREATABLE CHILDREN IN US

150,000–200,000

A number of peer-reviewed articles (1) have confirmed that the prevalence of Tourette in the Western world is about 0.2 – 0.6%. This means that the treatable population in the US will be some 150.000-200.000 children between the ages of 6-17.

PROFOUND CO-MORBIDITIES

+ 75%

Tourette co-occurs with other mental health or neurodevelopment conditions in 75% of cases, typically including ASD (Autism Spectrum Disease); ADHD (Attention-Deficit Hyperactivity Disorder) and ADD (Attention Deficit Disorder). Mild SIB (self-injuring behavior) is also thought to affect up to 60% of Tourette patients. In reality therefore market penetration could be relatively low as TS patients may already be treated with both CBIT and pharmacological treatment.

MILLION USD

300 – 1500

Tourette is an orphan disease, and with Sepranolone treatment being efficacious and with none of the serious side effects of competitors, the US market potential is calculated to be approximately 150.000-200.000 patients, at 40.000 - 80.000 USD per year. Factoring in that many patients may already be treated with CBIT and pharmacological treatment, the market penetration could realistically reach 5-10% of patients. Resultant peak sales would therefore be approximately 300 – 1.500 MUSD.

1. Population Prevalence of Tourette Syndrome: A Systematic Review and Meta-Analysis Jeremiah M. Scharf, MD, PhD,1,2* Laura L. Miller, MSc,3 Caitlin A. Gauvin, BS,1 Janelle Alabiso, MA,1 Carol A. Mathews, MD,4 and Yoav Ben-Shlomo, MBBS, PhD3

THE AGE OF ALLO

“I believe we are on the crest of a new wave of understanding of just how broad the implications of Allopregnanolone really are,” says Bortolato. “Compulsivity impacts on so many different conditions, from ADHD and OCD/B through to eating disorders and addiction. Our preliminary data lead us to believe that these processes are not limited just to TS, but point to a much broader biological mechanism that speaks directly to the relationship between obsession and compulsion. If we can prove that mechanism, then this therapy would be relevant to a far, far wider set of problems.”



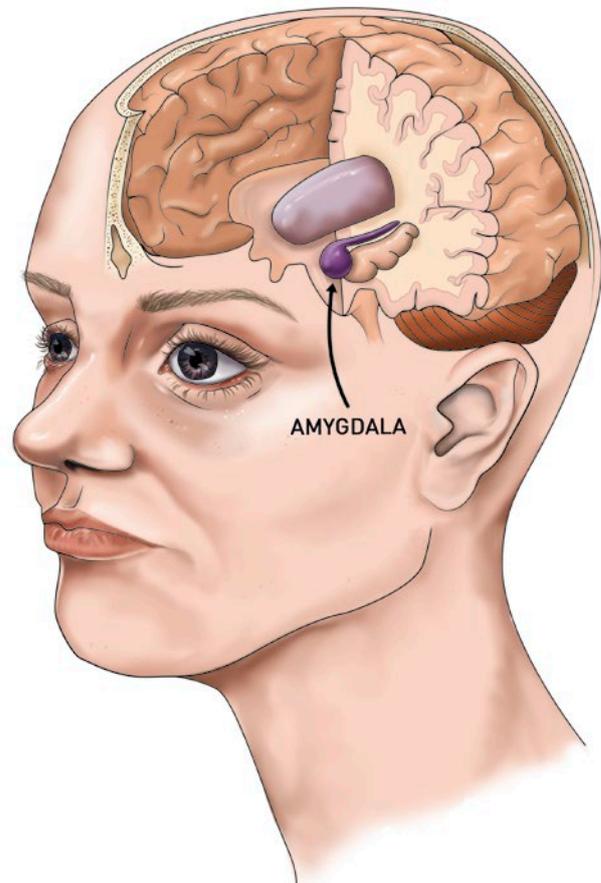
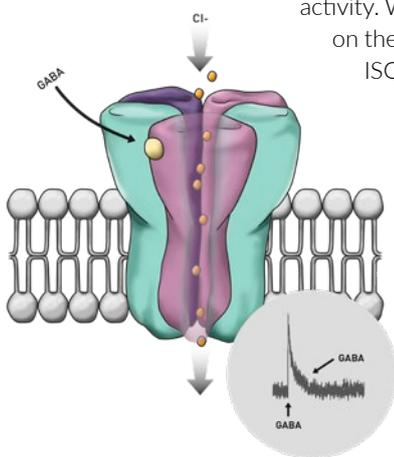
THE SCIENCE OF ALLOPREGNANOLONE

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 isallopregnanolone (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)

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.



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 aggression. The GABA system is the brain's primary inhibitory neurotransmitter.

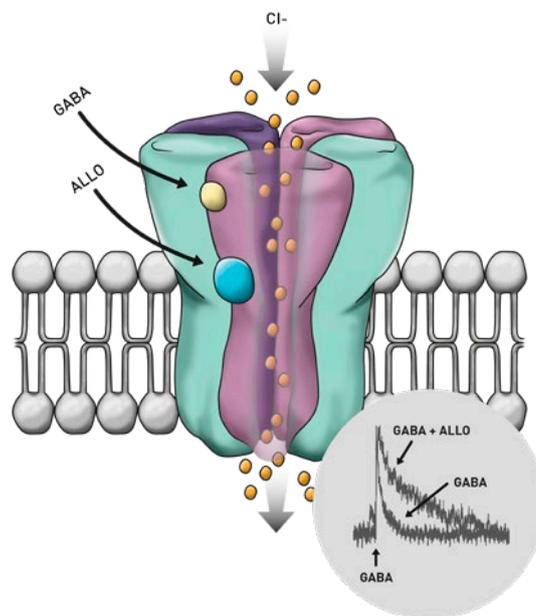
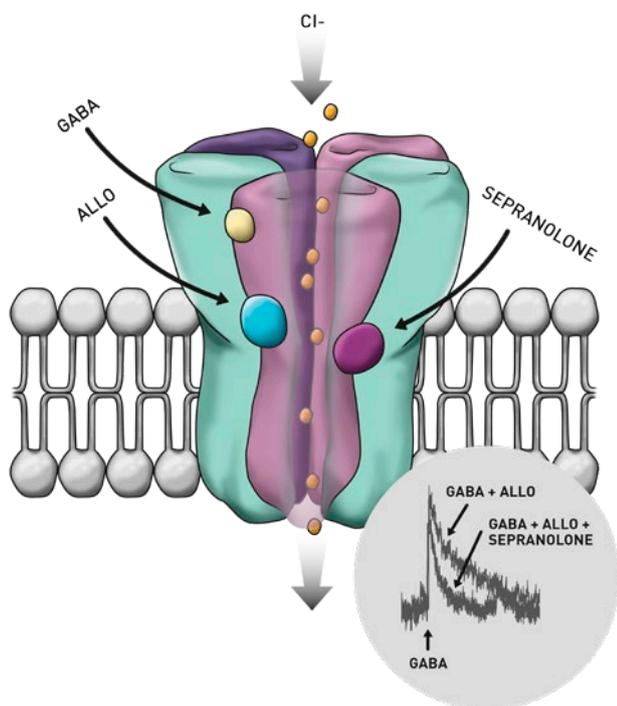
ALLOPREGNANOLONE, IMPORTANT IN MOOD AND ANXIETY DISORDERS

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 neuro-

psychiatric 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

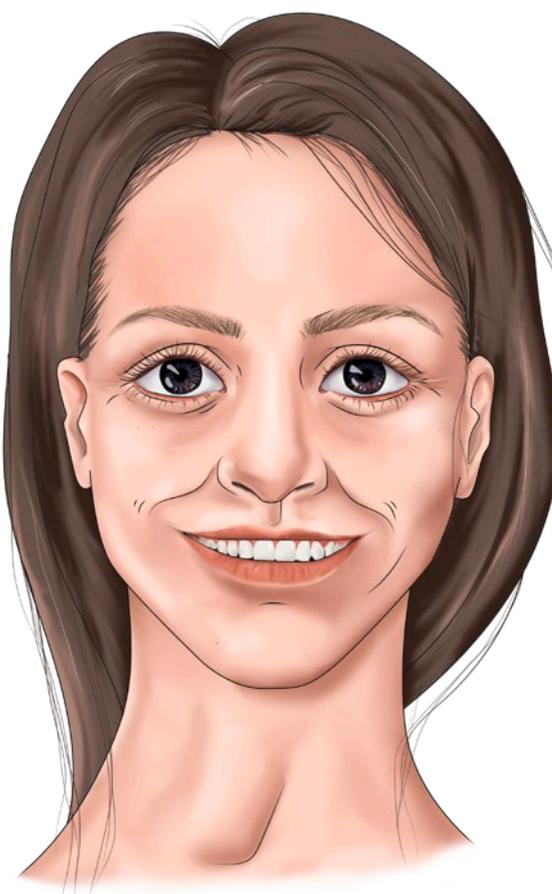
Women suffering from PMDD are particularly sensitive to the increasing concentrations of ALLO during the luteal phase and PMDD symptoms disappear as soon as the concentration of ALLO drops at menstruation or during menopause, when the woman is no longer ovulating. Administration of Sepranolone (ISOALLO)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

Stress induces increased production of a number of neurosteroids e.g. ALLO in the brain and adrenal. Tourette's Syndrome, Obsessive Compulsive Disorder and Pathological Gambling are all syndromes characterized by unnatural behaviours, that an individual involuntarily performs in particular in response to stress.



FINANCIAL OVERVIEW

KEY FINANCIALS

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Net sales	0	0	0
Operating profit	-10,753	-5,003	-51,596
Result for the period	-9,430	-5,093	-51,594
Earnings per share, non-diluted, SEK	-0.59	-0.71	-4.34
Total assets (end-of period)	137,235	16,458	149,580
Equity ratio, %	94.5	66.7	93.5
Return on equity, %	-7.0	-48.9	-60.4
Return on total assets, %	-6.5	-34.1	-61.3

REVENUE

Net sales amounted to 0 MSEK (0).*

OPERATING EXPENSES

Operating expenses for the first quarter amounted to 10.8 (5.0) MSEK.

Research and development costs increased to 6.8 (3.6) MSEK as the Phase IIb study in PMDD progressed at full capacity. Staff costs increased to 2.7 (1.1) MSEK reflecting the recruitment of senior staff in the second half of 2018.

During the first quarter, general and administration costs amounted to 1.1 (0.3) MSEK, comprising expenses related to i.a. patents, consultants, administration and IT.

TAX

No tax was reported for the quarter. Asarina Pharma AB had accumulated tax losses of 149.9 MSEK as of 31 December, 2018.

RESULT AND FINANCIAL POSITION

The operational result amounted to -10.8 (-5.0) MSEK and the result after taxes amounted to -9.4 (-5.1) MSEK.

Cash flow for the period amounted to -12.6 (3.4) MSEK. The Group's cash balance on March 31, 2019 amounted to 128.9 (11.9) MSEK.

The Group's shareholder's equity on March 31, 2019 amounted to 129.7 (11.0) MSEK.

The Group's equity ratio amounted to 94.5 % compared to 93.5 % on December 31, 2018.

STAFF

As of 31 March, 2019, the Group had 7 (3) employees, 5 of whom are on part-time contracts.

NOTE* Amounts in parenthesis refer to the same period or date in the previous year unless stated otherwise.

ASARINA PHARMA SHARES

As of 20 May 2019, Asarina has issued 16,037,218 shares, which are held by approx. 660 shareholders.

OWNERSHIP AS OF 2 MAY 2019 (AS AVAILABLE)

SHAREHOLDER	COUNTRY	NO. OF SHARES	OWNERSHIP (%)
Kurma Biofund	France	3,145,132	19.6
Ôstersjöstiftelsen	Sweden	2,352,092	14.7
Rosetta Capital	United Kingdom	2,058,329	12.8
Idinvest Patrimoine	France	1,639,824	10.2
Sectoral Asset Management	Canada	1,190,476	7.4
Swedbank Robur Fonder	Sweden	1,190,476	7.4
Catella Fonder	Sweden	906,122	5.7
Ergomed plc	United Kingdom	391,898	2.4
Handelsbanken Fonder	Sweden	380,952	2.4
PEG Capital	Sweden	350,000	2.2
Others		2,431,917	15.2
TOTAL		16,037,218	100.0

Asarina Pharma has established an incentive program for the board of directors and management. Under this program, the independent directors and members of management have been granted warrants which entitle them to subscribe for a total of 758,822 new Asarina shares at the end of 2021 at a fixed price of SEK 25.20 per share (the IPO price plus 20%).

EVENTS AFTER THE END OF THE REPORT PERIOD

No major events have occurred after 31 March, 2019.

STATEMENT BY THE BOARD OF DIRECTORS AND THE CEO

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, 19 MAY 2019

Asarina Pharma AB

Board of directors

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

CONSOLIDATED INCOME STATEMENT (GROUP)

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Net sales	0	0	0
Other income	0	0	0
Total revenue	0	0	0
Research and development costs	-6,840	-3,566	-39,033
Other external costs	-1,197	-324	-6,190
Personel costs	-2,716	-1,113	-6,373
Depreciation	0	0	0
Total costs	-10,753	-5,003	-51,596
Operating profit	-10,753	-5,003	-51,596
Financial income	1,420	-	1,826
Financial cost	-97	-90	-1,824
Financial net	1,323	-90	2
Result before taxes	-9,430	-5,093	-51,594
Taxes	-	-	7,569
Result for the period	-9,430	-5,093	-44,025

EARNINGS PER SHARE

	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Number of shares, average (non-diluted)	16,037,218	7,127,203	10,152,064
Number of shares, average (fully-diluted)	16,647,671	7,127,203	10,343,328
Earnings per share, non-diluted, (SEK)	-0.59	-0.71	-4.34
Earnings per share, fully-diluted, (SEK)	-0.57	-0.71	-4.26
Number of shares end of period (non-diluted)	16,796,040	7,127,203	16,037,218
Number of shares, end of period (fully-diluted)	16,647,671	7,127,203	16,796,040

¹Number of shares is adjusted for the reverse split (1:25) made in 2018.

CONSOLIDATED BALANCE SHEET (GROUP)

SEK '000	2019-03-31	2018-03-31	2018-12-31
ASSETS			
Non-current assets			
Financial non-current assets			
Other long-term financial assets	1	1	1
Total non-current assets	1	1	1
Current assets			
Current tax asset	7,901	4,476	7,732
Other receivables	207	104	246
Prepaid expenses and accrued income	205	19	58
Total current receivables	8,313	4,599	8,036
Cash and cash equivalents	128,921	11,858	141,543
Total current assets	137,234	16,457	149,579
TOTAL ASSETS	137,235	16,458	149,580
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,009	1,916	4,009
Total restricted equity	4,009	1,916	4,009
Unrestricted equity			
Share premium reserve	213,890	55,009	213,890
Accumulated losses, incl loss for the period	-88,245	-45,942	-77,989
Total unrestricted equity	125,645	9,067	135,901
Total equity	129,654	10,983	139,910
Current liabilities			
Accounts payable	5,289	1,712	5,601
Other current liabilities	592	170	782
Accrued expenses and prepaid income	1,700	3,593	3,287
Total current liabilities	7,581	5,475	9,670
TOTAL EQUITY AND LIABILITIES	137,235	16,458	149,580

STATEMENT OF CHANGES IN EQUITY (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
Translation difference			-826	-826
Result for the period			-9,430	-9,430
Closing balance 31 March 2019	4,009	213,890	-88,245	129,654

CONSOLIDATED STATEMENT OF CASH FLOWS (GROUP)

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Operating activities			
Operating profit/loss	-10,753	-5,003	-51,596
Adjustment for non-cash flow affecting items			
Share based payments	0	0	2,692
Interest received	638	0	22
Interest paid	-97	-90	-816
Paid taxes	-232	-265	3,898
Cash flow for operating activities before changes in working capital	-10,444	-5,358	-45,800
Cash flow from changes in working capital			
Decrease(+)/Increase(-) in receivables	-107	140	-38
Decrease(-)/Increase(+) in liabilities	-2,087	2,462	6,713
Cash flow from operating activities	-12,638	-2,756	-39,125
Financing activities			
Share issue	-	6,190	181,333
Share issue costs	-	-	-11,479
Warrants	-	-	2,225
Cash flow from financing activities	0	6,190	172,079
Cash flow for the period	-12,638	3,434	132,954
Cash and cash equivalents in the beginning of the period	141,543	8,384	8,384
Translation difference	16	40	205
Cash and cash equivalents at the end of the period	128,921	11,858	141,543

PARENT COMPANY INCOME STATEMENT

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Net sales	0	0	0
Other income	599	575	2,247
Total sales	599	575	2,247
Research and development costs	-298	-465	-1,521
Other external costs	-623	-169	-5,005
Personell costs	-1,240	-484	-2,990
Depreciation	0	0	0
Total costs	-2,161	-1,118	-9,516
Operating profit	-1,562	-543	-7,269
Financial income	1,294	0	1,618
Financial cost	-96	0	-795
Financial net	1,198	0	823
Result before taxes	-364	-543	-6,446
Taxes	0	0	0
Result for the period	-364	-543	-6,446

PARENT COMPANY BALANCE SHEET

SEK '000	2019-03-31	2018-03-31	2018-12-31
ASSETS			
Non-current assets			
Financial non-current assets			
Shares in subsidiaries	51	1	51
Other long-term financial assets	1	1	1
Total non-current assets	52	2	52
Current assets			
Receivables on group companies	71,512	27,350	59,978
Current tax asset	222	179	164
Other receivables	86	55	131
Prepaid expenses and accrued income	205	18	58
Total current receivables	72,025	27,602	60,331
Cash and cash equivalents	125,499	9,174	137,564
Total current assets	197,524	36,776	197,895
TOTAL ASSETS	197,576	36,778	197,947
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,009	1,916	4,009
Total restricted equity	4,009	1,916	4,009
Unrestricted equity			
Share premium reserve	213,890	55,009	213,890
Accumulated losses	-22,108	-20,581	-15,662
Result for the period	-364	-543	-6,446
Total unrestricted equity	191,418	33,885	191,782
Total equity	195,427	35,801	195,791
Current liabilities			
Accounts payable	245	303	233
Other current liabilities	592	60	601
Accrued expenses and prepaid income	1,312	614	1,322
Total current liabilities	2,149	977	2,156
TOTAL EQUITY AND LIABILITIES	197,576	36,778	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 Pharma 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 capital from investors. Asarina aims at any given time to have sufficient liquidity for the planned activities for the next 1-2 years. Therefore, Asarina is in continuous discussions with current and potential new investors, which may be interested in injecting new finance into the company.

Asarina incurs costs mainly in three currencies: Swedish kronor, EURO, and Danish kronor (the value of which is closely correlated to EURO). The company mitigates its exposure to exchange rate risk by placing excess liquidity in a combination of Swedish kronor and EURO, mirroring Asarina's costs in the three currencies.

KEY PERFORMANCE MEASURES (KPM)

	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 this KPM 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 KPM 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 KPM is included to show the return on the total assets in the company.

RECONCILIATION KEY PERFORMANCE MEASURES

EQUITY RATIO

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Equity	129,654	10,983	139,910
+ Untaxed reserves	0	0	0
- Deferred tax liability	0	0	0
Adjusted equity	129,654	10,983	139,910
Adjusted equity	129,654	10,983	139,910
Total assets	137,235	16,458	149,580
Equity ratio, %	94.5	66.7	93.5

RETURN ON EQUITY

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Result for the period	-9,430	-5,093	-44,025
Average adjusted equity ¹	134,782	10,426	72,885
Return on equity, %	-7.0	-48.9	-60.4

RETURN ON TOTAL ASSETS, %

SEK '000	2019 JAN-MAR	2018 JAN-MAR	2018 FULL YEAR
Result before tax	-9,430	-5,093	-51,594
+ Interest costs	97	90	1,824
Average total assets ¹	143,408	14,667	81,228
Return on total assets, %	-6.5	-34.1	-61.3

CERTIFIED ADVISER

The company's certified adviser is Erik Penser Bank,
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