

REMAIN IN CONTROL OF YOUR LIFE

ASARINA PHARMA AB (PUBL)

THIRD QUARTER 2020, INTERIM REPORT

1 July – 30 September 2020

ASARINA PHARMA AB

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INTERIM REPORT, THIRD QUARTER 2020

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ABOUT ASARINA PHARMA

We are a Swedish biotech company developing Sepranolone for allopregnanolone-related stress, menstrual and neurological disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. With our new family of GAMSAs compounds (GABA_A Modulating Steroid Antagonists) we aim to deliver a new generation of efficacious and safe drugs for still widely untreated neuroendocrinological conditions.

CONTACT

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THIRD QUARTER 2020 OVERVIEW



Jakob Dynnes Hansen
Chief Financial Officer

FINANCIAL HIGHLIGHTS

- R&D costs at same level as in Q2, 2020
- Reduction in G&A and staff costs after reorganisation
- Cash position on 30 September 2020: SEK 65 million

R&D UPDATE

- ✓ **COMPLETED ENROLMENT FOR PHASE IIA STUDY IN MENSTRUAL MIGRAINE** in Finland and Sweden. We are on schedule to publish topline results in June 2021.
- ✓ **CONTINUED COMPLETING NON-CLINICAL STUDIES IN PREPARATION FOR PHASE IIA STUDY IN TOURETTE SYNDROME.** On schedule to submit a CTA to the Danish Regulatory Authorities before the end of February for approval, initiating study in June 2021.
- ✓ **FULLY IMPLEMENTED INTERNAL REORGANIZATION.** We remain committed to completing the two Phase II studies in Menstrual Migraine and Tourette without raising additional funds.

CEO STATEMENT

DEAR SHAREHOLDER

Actions speak louder than words - during the third quarter 2020 we have focused firmly on execution, taking important steps forward towards realizing our vision of a new treatment modality for devastating, under-treated conditions that would help millions remain in control of their lives.

DURING THE QUARTER WE:

- ✓ **COMPLETED ENROLMENT FOR OUR PHASE IIA STUDY IN MENSTRUAL MIGRAINE** in Finland and Sweden. Achieving this in the middle of tough Covid-19 restrictions underlines the scale of the unmet need for a treatment. We are on schedule to publish topline results in June 2021.
- ✓ **CONTINUED COMPLETING NON-CLINICAL STUDIES IN PREPARATION FOR OUR PHASE IIA STUDY IN TOURETTE** – another condition characterized by an intense unmet need. We are still on schedule to submit a CTA to the Danish Regulatory Authorities before the end of February for approval, initiating the study in June 2021.
- ✓ **FULLY IMPLEMENTED OUR INTERNAL REORGANIZATION** and, hopefully temporarily, paused our Phase III production, significantly decreasing our burn rate. We remain committed to completing the two Phase II studies in Menstrual Migraine and Tourette without raising additional funds.

Peter Nordkild,
CEO Asarina Pharma



THE CASE FOR SEPRANOLONE IN NEUROLOGY

Behind both of our present indications, and many more, lies the potent neurosteroid Allopregnanolone (ALLO). ALLO modulates GABA, the brain's most powerful inhibitory neurotransmitter. Whilst for most of us ALLO helps reduce stress, fear and anxiety, for a significant minority it has the opposite effect. Elevated ALLO levels or a heightened sensitivity to ALLO are implicated in conditions from Tourette to Menstrual Migraine, OCD (Obsessive Compulsive Disorder), PTSD (Post Traumatic Stress Disorder), compulsive gambling, addiction—and more.

Sepranolone (isovalpregnanolone) is a safe, powerful, endogenous compound that significantly reduces the negative effects of ALLO. Just as few of us had heard of serotonin 40 years' ago, yet now understand its important role in depression, anxiety and more—so the role of GABA_A-active compounds like ALLO and Sepranolone in compulsion- and stress-related conditions is becoming increasingly understood.

As the first company in the world to develop and synthesize Sepranolone, we see it as the first GAMSAs (GABA_A Modulating Steroid Antagonist) - a new generation of GABA_A active therapies. We believe that our present trials in Menstrual Migraine and Tourette could be gateway studies to a larger therapeutic landscape, and that GAMSAs could bring new treatments and understanding to many under-treated, overlooked neurological conditions.

A NEW SALIVA ANALYSIS TEST FOR THE PRESENCE OF ALLO

Of course, being able to test for the presence of ALLO and Sepranolone using a trusted and simple diagnostic technique would be decisive in increasing understanding of Sepranolone and its role in key neurological conditions. This quarter we have taken an important step towards that.

In cooperation with the Swedish company Labyrinthica, we have successfully developed an analysis for ALLO in saliva. Saliva testing is a standard diagnostic laboratory technique commonly used to identify and measure hormones and metabolite levels. Our next step will be to ascertain if the concentrations measured in saliva correspond closely with plasma concentrations. If yes, it may be possible to develop a saliva-based analytical test for TS children. Such a test in the short term would mean significantly less use of needles for children in our study (with saliva instead of plasma being taken). In the long term it could ultimately mean adult saliva analysis tests for TS or other ALLO-induced conditions.





MENSTRUAL MIGRAINE TRIAL

164 WOMEN HAVE BEEN RECRUITED

Since August 2019, we have enrolled a total of 164 patients which should enable us to randomize 85-90 patients for treatment in our Phase IIa proof-of-concept study in Sweden and Finland. Despite recruitment having slowed somewhat due to Corona restrictions, all seven centers have been fully operational since the summer and the remaining 23 women in the Study are now going through the 3-months screening phase before randomization of the last woman in the second half of January 2021. This would mean the last woman taking her last injection during April, depending on the length of her menstrual cycle. We are confident that we will be able to report topline results from this first dedicated, prophylactic clinical study with intermittent treatment of Menstrual Migraine in June 2021.

” *Achieving full enrollment in a clinical study in the middle of tough Covid-19 restrictions underlines the scale of the unmet need for a treatment for this highly aggressive type of migraine*

Peter Nordkild, CEO Asarina Pharma

TOURETTE SYNDROME

Phase IIa proof of concept study to be initiated in the spring of 2021

In March, we received important input and encouraging support from the Danish Medical Agency regarding our plans for a clinical study in Tourette. The agency shared our opinion that the need for a treatment for Tourette with a strong safety profile is greater than ever. It has stated that even a modest reduction of tics by > 25% would be considered clinically relevant.

This echoes what we have heard from other experienced TS professionals who point out that a safe therapy with even partial tic reduction would also play a valuable role in strengthening and consolidating CBIT therapy – today’s first-line TS treatment. CBIT is a combination of relaxation training, habit-reversal training and behavioral training – all techniques that help reduce tics. With 85% of TS patients having complex co-morbidities, and current pharmaceutical therapies including side effects from blurred vision to severe involuntary movement disorder, a safe therapy with no severe side effects that could support and consolidate the first-line treatment, and be safely co-prescribed in a complex treatment landscape, could be a historic step forward for TS patients.

” *With the disturbing lack of safe pharmaceutical options currently available for Tourette we look forward to initiating a newer, safer treatment that could help children with Tourette finally remain in control of their lives.*

In this quarter we completed our 4-months' tox study in juvenile animals of both sexes with no clinical or behavioral observations. The histology analysis has now been initiated and we expect to receive the final report by early February 2021, submitting a CTA to the Danish Medical Agency later in February 2021.

Following the initial feedback we received from the FDA on our orphan drug designation application for Tourette, we are now compiling additional and revised data which we will be submitting during Q4. We remain optimistic that our application will be approved.

With all proceeding to plan we are confident that we will be able to initiate our Phase IIa study in the National Danish Tourette Clinic at the University hospital in Herlev in June 2021 with the first patient receiving his first injection in early August 2021, Covid-19 restrictions permitting.

With the disturbing lack of safe pharmaceutical options currently available for TS, its complex treatment landscape and the massive social, emotional and educational impact on children of this devastating condition, we look forward proudly to initiating a newer, safer treatment that could help children with Tourette finally remain in control of their lives.

FINANCIALS

- R&D costs at same level as in Q2, 2020
- Reduction in G&A and staff costs after reorganisation
- Cash position on 30 September 2020: SEK 65 million



We continue to believe that GAMSAs will ultimately constitute a new generation of safe, effective treatments for devastating conditions in urgent need of a new treatment modality, enabling existing and new generations to remain in control of their lives.

THANK YOU FOR YOUR CONTINUED SUPPORT.

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

Peter Nordkild,
CEO Asarina Pharma

MENSTRUAL MIGRAINE UPDATE

“THERE ARE MANY WAYS TO CLIMB A MOUNTAIN”

MIGRAINE, MENSTRUAL MIGRAINE AND THE SEARCH FOR AN EFFECTIVE TREATMENT

For over 25 years Dr Yngve Hallström, Senior Consultant Neurologist at Stockholm Neuro Center outpatient clinic, has treated thousands of migraine patients and played a key role in pioneering Clinical Studies for new migraine treatments from Triptans to CGRP antibodies. As Asarina Pharma completes the enrolment for its Phase IIa Menstrual Migraine Study, we ask him: Why is Menstrual Migraine so resistant to standard treatments, and how can we be sure hormones or neurohormones play a part in triggering it?

“When I first became a specialist at an outpatient clinic in 1993, I encountered a huge demand for migraine treatment” says Dr Yngve Hallström. “Migraine represented 50% of the disorders consulted for at the clinic. 20% of females and 10% of males have migraine. Patients travelled from all over for treatment.”



CONTINUED DEMAND.

The demand for a treatment for Menstrual Migraine (MM) remains undimmed—even though the condition is still widely un-recognized and under-diagnosed. “I didn’t receive any specific guidelines or directives on it when I started out” says Dr Hallström, “I was lucky to attend a lecture on MM by a female specialist at a congress. I was aware of course that menstruation was a triggering factor for migraine, but I didn’t know about the real extent of MM. I learnt that partly from her, but mostly from practice, and how difficult it was to treat.”

” Menstrual Migraine is more intense and the pain is more acute.

Dr Yngve Hallström

20% of women who suffer from migraine also suffer from MM (WHO)

“MM can be the most challenging kind to treat, and frequently does not respond to the same medicines that work the rest of the month”

(American Migraine foundation)

WHAT MAKES MENSTRUAL MIGRAINE SO SPECIAL?

So, if 20% of women with 'regular' episodic migraine also suffer from Menstrual Migraine—how do they distinguish their MM attacks? "It's more intense" says Dr Hallström, "the pain is more acute and difficult to treat. MM is highly disabling. Women have to take time off work, sometimes days every month. Leisure and social activities have to be cancelled - it's a major problem and it effects all family members. And even if the medication women take works for their episodic attacks, it won't work as well for MM. I had two patients recently who I met again after starting them on two different sorts of prophylaxis - one on Botox and the other on amitriptyline. Both had complete remission of all migraine attacks - except Menstrual Migraine."

THE MIGRAINE SPECTRUM AND MIGRAINE TRIGGERS

MM is on a broad spectrum of migraines, Dr Hallström points out, meaning a broad spectrum of treatments could work and be needed. "There are several ways to climb Mount Everest" he says, "and a lot of chemistry in the brain stem area where migraine originates from - therefore a broad range of triggering factors. It's extremely common for example that women with normal episodic migraine also experience their worst attacks during the first phase of their cycle. This menstrual-related migraine can respond to triptans and

even certain kinds of CGRP antibodies - but the effect is far less potent than the effect it has on episodic migraine, it's not comparable to its effect on other types of pain."

THE ROLE OF HORMONES

So if the triggers and treatments for MM are so complex and diverse, how can we be sure that hormones and neuro-hormones like ALLO or Sepranolone do actually play a role?

"One of the ways to treat MM today is to abolish the menstrual cycle altogether with Oral Contraceptives," says Dr Hallström. "A lot of patients today take OCs for 21 days, then continue for the next 21 days - going on for 3 or 4 cycles. That works and does stop the attacks. So that clearly shows the strong hormonal component to migraine. Plus, when we treat patients with other problems, like fibromyalgia for example, it's quite obvious that hormones play a role in pain in other parts of the body as well - which means that treatment connected directly to the hormone mechanism should - logically - be effective. Migraine is so complex and aggressive that as practitioners we need everything in our bag to combat it. For example 30 - 40% of patients don't respond to CGRP antibodies, so not all migraine has something to do with CGRP. We need beta blockers, we need amitriptyline we need CGRP inhibitors, we need anti-epileptic drugs and yes, we definitely need hormonal treatments. Migraine is so multi-faceted and triggered by so many different mechanisms -there is an important place for many different kinds of treatment."

” *Migraine is so complex and aggressive that as practitioners we need everything in our bag to combat it—there is an important place for many different kinds of treatment.*

Dr Yngve Hallström

TOURETTE SYNDROME UPDATE

HIGHLY VISIBLE... BUT SO OVERLOOKED

Few conditions are as visible yet overlooked as Tourette syndrome, the complex, compulsive condition that most commonly begins to strike between the ages of 5 and 7.



AMANDA TALTY IS THE CEO AND PRESIDENT OF THE TOURETTE ASSOCIATION OF AMERICA (TAA).

For almost 50 years the TAA has supported patients and families impacted by Tourette syndrome and tic disorders and funded and advanced new research. Here she talks to Asarina Pharma about the need for better diagnosis, recent milestones in treatment guidelines and the future role of a pharma therapy that could prove itself safe, free of side effects, and able to work effectively in a complex treatment landscape.

Imagine your own body betraying you. Instead of allowing you to hide your most inappropriate thoughts - conscious or unconscious - it forces you to vocalize them. Constantly and compulsively. No matter where, no matter when. And it forces you with an urge so powerful that resisting it makes you feel even more compelled. Now imagine all this beginning to happen to you just as you start school, anxious to make new friends, or as you become a teenager, eager to interact and impress...

Few conditions expose their sufferers to stigma and shame as much as the common neurological disorder Tourette syndrome (TS). Yet for a condition that is often so highly visible, Tourette is still often overlooked, despite tics starting and manifesting most commonly in childhood and adolescence.

EXPOSED BUT OVERLOOKED: UNDER-DIAGNOSIS

"In the US it takes up to two years on average to get a Tourette diagnosis" says Amanda Talty, "for a five to eight-year-old child that can feel like a lifetime, with so many things happening socially and developmentally."

The Tourette Association of America (TAA) and the CDC (US Centers for Disease Control and Prevention) estimate that 50% of the one million people in the US currently thought to be living with TS, based on prevalence, are going undiagnosed.

"Studies show that if you go undiagnosed - particularly in a school environment - your long-term outcomes are lower because you're not getting the educational accommodation you need. Children living with Tourette have a far harder time getting through their school age years - not only academically but also socially - the bullying is off the charts and that really impacts their self-esteem, you see higher rates of rage associated with these kids if they're being bullied, which impacts their home lives so there's a snowball effect."



32 %
OF CHILDREN

living with TS have considered
suicide and/or self-harm

63 %
OF CHILDREN

have felt discriminated
against (incl. bullying,
suspension, exclusion)

40 %
OF CHILDREN

are forced to
miss school

COMPLEX TREATMENT LANDSCAPE

A major factor in non-diagnosis is the complexity of Tourette itself. Recent genetic research suggests that TS is not a discrete, unitary condition, but rather covers a spectrum of subtypes across a broad range of compulsive disorders (1). 86% of Tourette patients have at least one co-occurring disorder, from ADHD, OCD/B, inattention, hyperactivity, impulsivity and childhood conduct disorder – all of which creates a complex treatment landscape, with multiple treatments sometimes running concurrently and no one medication able to treat all symptoms - often obscuring Tourette itself and leading it to go untreated.

Tourette tics too are complex and changeable. Defined as multiple motor and at least one vocal tic lasting for more than one year, TS tics wax and wane, changing in type, frequency, and severity over weeks or days. They range from transient mild tics that may be almost imperceptible and disappear quickly, to chronic tics that can cause serious physical injury. The result is an elusive, highly nuanced condition that is challenging to diagnose.

“Often co-occurring conditions will get diagnosed, but the tic itself will get written off as secondary or something that will go away” says Talty, “if it’s a sniffing tic a pediatrician

might send the child to an ENT (Ear Nose or Throat) specialist. If it’s a blinking tic it might be attributed to an allergy and the child sent to an allergist. Almost every family we speak to identifies getting a diagnosis as the number one challenge, and most have had the experience of being bounced between doctors before landing on a neurologist – and it usually is a neurologist – who finally diagnoses them. We hear that a hyper-focus on one thing, be it ADHD or OCD, is a big challenge that often leads to other important symptoms being ignored. Current medication too can sometimes exacerbate one condition over the other – whilst those of us working with TS understand that it’s a soup. You can tease out certain ingredients but ultimately there will always be a whole range of issues involved in Tourette.”

THE RISE OF CBIT AND THE NEED FOR A SAFE, STABLE PHARMA SOLUTION

A major milestone in Tourette treatment came in 2019 when the American Academy of Neurology issued its first ever treatment guidelines for Tourette. The guideline recommended Comprehensive Behavioral Intervention for Tics (CBIT) as the first-line treatment, and advised neurologists to routinely evaluate people with tics for ADHD, OCD and mood and anxiety disorders. “The new guideline elevated TS in the minds of all neurologists, pediatric or otherwise” Talty says. “Neurologists are typically medication prescribers, so recommending CBIT, a behavioral therapy, was a big step forward for patients, it reflects the effort that went into making sure the new guidelines serve patients as best as possible.”

Focused on identifying and managing the tic’s promontory urge, CBIT combines relaxation training, habit-reversal training and behavioral therapy. Since its inception TAA has advocated for and funded new research into Tourette, and has been long-time champions of CBIT as a safe treatment modality with no side effects. “We provided the original seed funding for the pioneering work of Dr Doug Woods in creating the CBIT curriculum and technique” Talty says “we’re proud to have him as a member of our Medical Advisory Board now. CBIT has been proven to be as effective, in some cases more effective, as medication in treating tics, and crucially it has no side effects. Our impact survey shows that almost a third of children and adolescents try five or more different medications, and all too often parents feel that those medications just aren’t getting the job done.”

“Imagine your own body betraying you. Constantly and compulsively. No matter where, no matter when. Now imagine it happening just as you first start school.

Amanda Talty,
CEO Tourette Association of America.



Parents want to give their kids something that will maximize their quality of life, but not take anything away. If pharma could develop an effective Tourette drug that had no negative side effects, I think it would have a winner.

Amanda Talty, CEO Tourette Association America

SAFETY: THE #1 PHARMA PRIORITY FOR PARENTS

“But what we hear most about when it comes to medication is complaints about side effects,” Talty says. “Parents are not going to prescribe their children pharmaceutical products if they think the solution is worse than the problem. Patients tell us ‘I want to take a drug that helps me stop my tics but isn’t going to make me gain 50 pounds’ or ‘I want to be able to offer my child a drug that will help them with their ADHD but won’t affect their physical growth because it suppresses appetite”.

Currently 59% of children and adolescents take prescription medication to reduce tics, 29% have tried five or more different medications, and 44% of parents feel current medications

do not adequately treat symptoms. Safety and side effects are major concerns. Today’s most commonly prescribed treatments (anti-psychotic neuroleptics like haloperidol (Haldol) can have side effects ranging from blurred vision, nausea and diarrhoea to irregular heartbeat and tremors and severe involuntary movement disorders that can themselves be mistaken for Tourette.

Does TAA still hear interest from parents in a safe, effective medication despite these concerns? “Absolutely!” Talty says. “Parents want to give their kids something that will maximize their quality of life, but not take anything away. If pharma could to that, if it could develop an effective Tourette drug that had no negative side effects, I think it would have a winner.”

59 %

of children and adolescents living with TS take prescription medication to manage it.

44 %

of parents feel their child’s symptoms are not adequately controlled by existing medication.

29 %

of children and adolescents living with TS have tried five or more different medications (1).

1. 2018 Impact Survey, Tourette Association of America

TOWARDS A PHARMA TREATMENT THAT CAN SUPPORT CBIT

With complex co-conditions in 85% of cases, and CBIT the first-line treatment, any new Tourette therapy would need to be able to fit into a complex treatment landscape too. “We hear from a lot of parents that if their child is on an ADHD medication, they might simultaneously be doing CBIT so they can better control the body. Most families who have lived with TS for some time understand that there is no magic bullet. There’s never going to be the one thing you take and suddenly everything is 100% perfect. If you are on medication, you’re likely going to need therapy as well because you’re always going to need coping mechanisms. But that’s the beauty of medication - for those that it works for

- it gives someone that space from their tic within so they can better focus and learn the lessons that they’re learning. You’re much better able to have different conversations and get different outcomes if your medication is giving you that extra space.”

Even a partial reduction in tics, Talty agrees, could give someone more space to start learning better coping strategies and better methods for managing their Tics. “For a child with a light whistling Tic that’s really disruptive say, even a 5% reduction would give them an improvement. I think anything that brings the tic profile down, even with small tic reductions, would be something of value - and if it were as safe and free of side effects, yes - I think you’d certainly find families who were interested in that.”

(1) Fernandez TV, State MW, Pittenger C (2018). “Tourette disorder and other tic disorders”. Handbook of Clinical Neurology (Review). 147: 343–54.



TAA was started around a kitchen table by a handful of families who needed support and knew there were others out there just like them

CEO Amanda Talty

31
chapters

83
support groups

18
centers of Excellence

REDUCING STRESS AND STIGMA

Social stigma triggers stress which in turn can trigger more tics. Whether teachers or school-mates, what advice would TAA CEO Amanda Talty give on reducing stress and stigma?

- ✓ **DON'T JUDGE** "Remember this is a person! A person who has dreams and families and loved ones. See the person not the tic"
- ✓ **CARE** "The important thing is compassion. Assume the best in people – don't always assume that the person is doing this to annoy you. If you're a teacher don't assume the child is intentionally not listening to you. Instead – assume that there is something else underneath. And that you really have to peel the onion to get to the heart of it. So ask genuine questions, if you see that your questions are making them uncomfortable express that that is not your intent but you do really want to understand.
- ✓ **TREAD LIGHTLY** "We all have 'a thing' right? This just happens to be theirs. And remember - Tickers don't have the luxury of being able to hide their tics"
- ✓ **ASK AUTHENTIC QUESTIONS** "If you're seeing a certain pattern of behavior repeatedly, over and over, that should be a cue to begin a conversation, ask 'hey, are you able to stop doing that or not? Because if not that's cool - and let's talk about it.'"



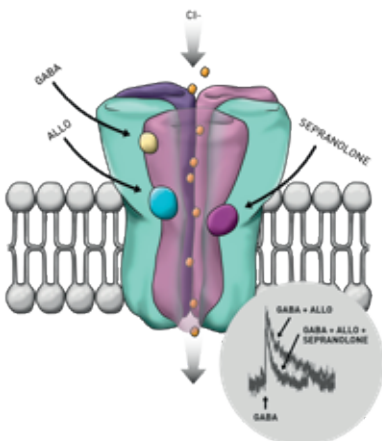
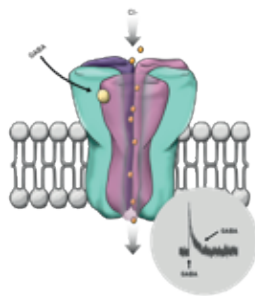
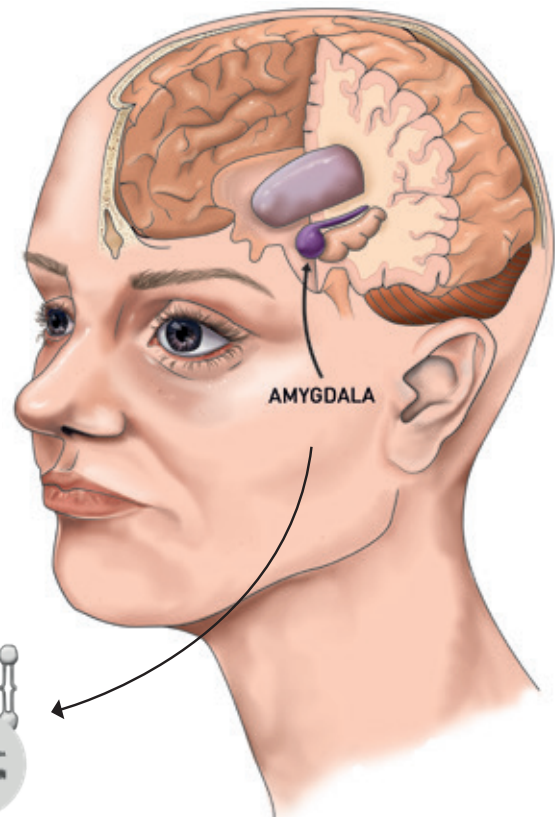
ALLO AND GABA THE BRAIN'S 'BRAKE' SYSTEM

So, what does it mean neurologically, to remain “in control”? Although our lives and feelings change constantly, sometimes even dramatically, when it happens most of us still feel that fundamentally we remain “in control” of our deepest emotions, impulses and compulsions. GABA, the brain’s most powerful inhibitory neurotransmitter, is a crucial part of that. For most of us GABA, and the neurosteroid Allopregnanolone that interacts with it, reduces stress, fear and anxiety levels—helping us remain firmly in control of our lives. But for others, there is an altogether different effect.

THE ALLO PARADOX

The neurosteroid Allopregnanolone (ALLO) modulates GABA, acting on the GABA_A receptor, the chloride channel in the brain that is the major channel for GABA. For most of us ALLO plays an important role in helping GABA reduce our stress, fear and anxiety levels. For a significant minority of us though, ALLO has the exact opposite effect.

Instead of calming or reducing stress and anxiety levels it increases them, producing severe, mood- and personality-altering symptoms or triggering powerful, irresistible compulsions. Increased ALLO levels or a heightened sensitivity to ALLO is implicated in conditions ranging from Tourette to OCD, PTSD, compulsive gambling, addiction—and more.



SEPRANOLONE AND THE GABA_A RECEPTOR

The body's modulator of these effects is Sepranolone, an endogenous neurosteroid that specifically regulates the negative effects of ALLO. Sepranolone does this by resetting the GABA_A receptors to normal. But ALLO is not the only neurosteroid that acts on our behavior through the GABA_A receptor.



This whole area of GABA_A-active steroids is really new. 20 years ago nobody even knew about Allopregnanolone and its effect on GABA_A receptor mediated actions in the brain, so a lot has happened. Today there are several different research groups working with these kinds of substances, I'm hopeful more research will keep being carried out.

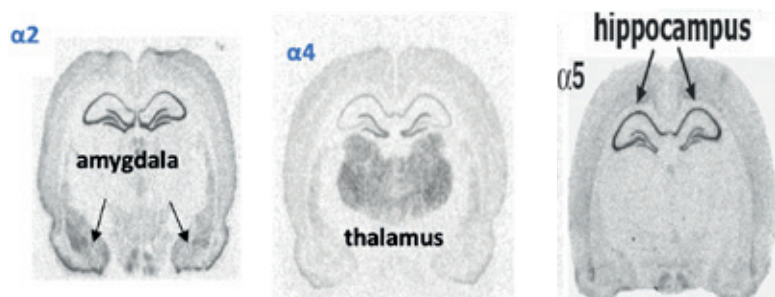
PROFESSOR MARIE BIXO University of Umeå.

THE GABA_A RECEPTOR A MAJOR THERAPEUTIC CHANNEL

Allopregnanolone, THDOC, Androstandiol and Pregnanolone—few have heard of them, yet these powerful neurosteroids are some of the body's most powerful, high-impact compounds, hugely influencing our lives and modulating our emotions, reward and pleasure centers. They are synthesized in both the brain and endocrine glands, primarily targeting the GABA_A receptor, the brain's major channel for GABA. So what keeps these powerful neurosteroids in check? Which compounds modulate them? A new generation of highly specific therapeutic compounds—GAMSA— can now potentially “modulate the modulators”, operating within the GABA_A receptors, the brain's major inhibitory signaling system, and a fast-emerging therapeutic channel.

GABA_A RECEPTORS: WHAT THEY ARE AND WHERE THEY ARE

GABA_A receptors are the chloride channels that are opened, closed and modulated by the chemical action of neurosteroids. They are the brain's major inhibitory signaling system and exist in several subtypes with specific location in the brain related to the function of the brain area. GABA_A receptors of different types exist within the amygdala, the thalamus and the hippocampus.



PROFESSOR MARIE BIXO ANATOMICAL DISTRIBUTION OF GABA_A RECEPTOR SUBCLASSES¹

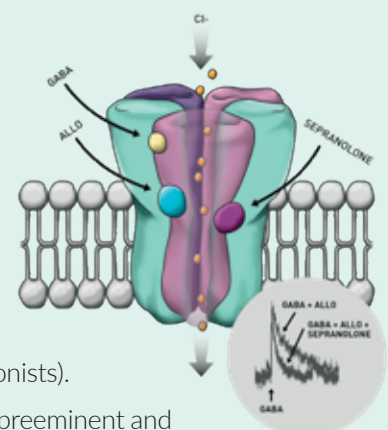
¹Bäckström et al, Springer NY 2008

GABA_A RECEPTORS: A MAJOR THERAPEUTIC PATHWAY

Over the last 20 years, the GABA_A receptor has been at the center of a fast-emerging research field of great pharmaceutical potential. Groundbreaking research has been carried out into the receptor, the potent neurosteroids that influence it, and a newly discovered group of highly targeted modulating compounds that in turn impact those neurosteroids.

These compounds have been named GAMSA_s (GABA_A Modulating Steroid Antagonists).

Asarina Pharma's Founder and CSO Prof Torbjörn Bäckström is one of the world's preeminent and pioneering researchers into the GABA_A receptor and GAMSA_s.



GAMSA_s

A NEW GENERATION OF THERAPIES

WHAT ARE GAMSA_s?

GABA-active neurosteroids like ALLO, THDOC, Androstenediol and Pregnanolone have been of great pharmaceutical interest for many years. Many have already been launched as standalone therapies. Such is their potency however, that development and safety have often been a concern. Amongst the body's most powerful compounds, GABA-active neurosteroids are quite capable of inducing seizures, anesthesia or worse.

Built on the work of Asarina Pharma's CSO and Founder Prof Torbjörn Bäckström, a new subgroup of neurosteroids – GAMSA_s (GABA_A Modulating Steroid Antagonists) – has now been developed that specifically modulate GABA-active neurosteroids with no CNS effect or impact on the GABA receptor itself. The result could be a new treatment modality for stress- and compulsion-related compounds—with no major side effects.



For us GAMSA_s represent a paradigm shift in the treatment of stress- and compulsion-related conditions. Selective, specific and safe, they can modulate the dramatic effects of GABA, one of the body's most powerful neurotransmitters— with no broader CNS or GABA impact, meaning no severe side effects.

PETER NORDKILD
CEO, Asarina Pharma





I believe we are on the crest of a new wave of understanding of just how broad the impact of Allopregnanolone really is. Compulsivity impacts on so many different conditions, from ADHD and OCD/B through to eating disorders and addiction.

PROF MARCO BORTOLATO University of Utah

GAMSA_s: SELECTIVITY AND SAFETY

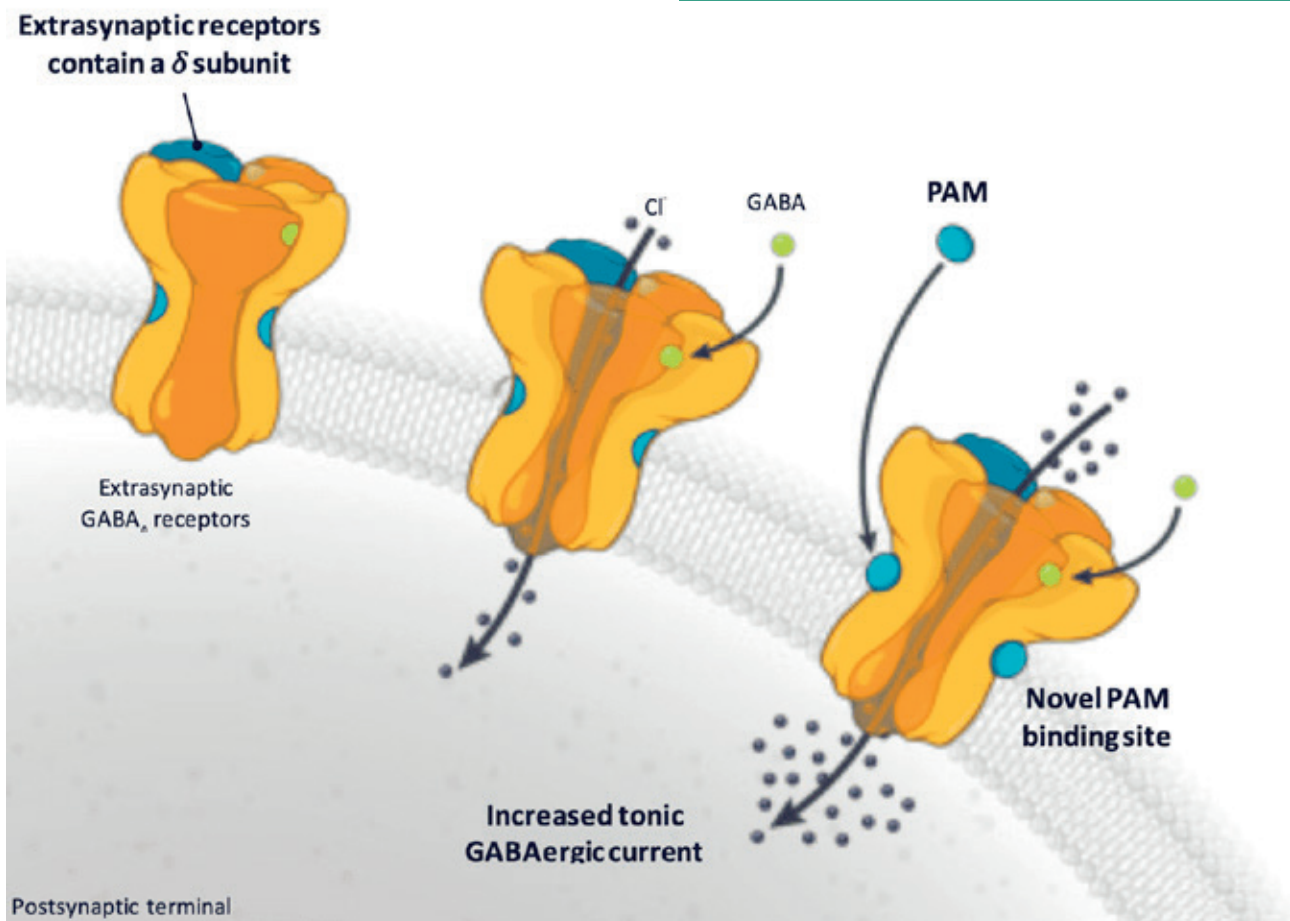
GAMSA_s directly target the effects of neurotransmitters at different GABA_A receptor subtypes with high specificity. Their effect is confined to a very specific subtype of the GABA_A receptor, meaning minimal effect on any other CNS mechanism.

AS A TREATMENT THIS ENSURES:

- » Fine-tuned receptor activity without overstimulation
- » High selectivity
- » Minimal off-target effect

Professor Torbjörn Bäckström's work has been instrumental in transforming understanding of how powerfully GABA_A modulating steroids impact our mood, behavior and neurological symptoms. Professor Bäckström has developed, synthesized and patented over 30 GAMSA_s. With potential GAMSA compounds available for development to treat:

- » Epilepsy
- » Tourettes
- » Stress-related fatigue
- » Cognitive impairments
- » Balance treatments



3RD QUARTER 2020

FINANCIAL OVERVIEW AND OTHER INFORMATION

KEY FINANCIALS

SEK '000	2020 JULY – SEP.	2019 JULY – SEP.	2020 JAN. – SEP	2019 JAN. – SEP	2019 JAN – DEC.
Net sales	0	0	0	0	0
Operating profit	-17,535	-21,786	-56,494	- 60,667	-81,034
Result after financial items	-17,561	-19,973	-56,609	-55,223	-78,877
Earnings per share, fully-diluted	-0.90	-1.17	-2.89	-3.27	-4.11
Total assets, end of period	77,084	103,537	77,084	103,537	139,894
Cash balance, end of period	65,111	94,929	65,111	94,929	129,505
Equity ratio, %	92.6	85.1	92.6	85.1	85.4
Return on equity %	-21.6	-20.2	-59.3	-48.4	-54.8
Return on assets %	-20.9	-18.0	-51.8	-43.5	-54.3

REVENUE

Net sales amounted to 0 MSEK (0).

OPERATING EXPENSES

Total operating expenses for the 3rd quarter 2020 amounted to 17.5 (21.8) MSEK. Research and development costs amounted to 14.6 (18.1) MSEK, comprising primarily costs related to the phase IIa study in menstrual migraine and the CMC activities. Staff costs decreased to 2.1 (3.2) MSEK reflecting the headcount reduction as of 1 September 2020. General and administration costs were only 0.8 (1.1) MSEK.

FINANCIAL ITEMS AND TAX

Financial items balanced at 0.0 (1.8) MSEK as the SEK/EUR exchange rate remained rather stable in Q3. No tax was reported for the quarter.

RESULT AND FINANCIAL POSITION

The operating result for the 3rd quarter was -17.5 (-21.8) MSEK and the result after taxes amounted to -17.6 (-20.0) MSEK.

Cash flow for the period was -18.4 (-14.6) MSEK. On 30 September 2020, the total cash balance amounted to 65.1 (94.9) MSEK. Shareholder's equity amounted to 71.4 (88.2) MSEK representing an equity ratio of 92.6% (85.1%).

The Covid-19 pandemic has had a relatively moderate impact on Asarina Pharma's financials. The phase IIa study in menstrual migraine has been delayed by 2–3 months which will increase the total study costs by an estimated SEK 2-3 million.

STAFF

As of 30 September 2020, Asarina's operational team comprised 7 members (employees and permanent consultants), corresponding to 4.3 full-time employees (FTEs) compared to 5.5 FTEs on 30 June 2020.

NOTE: Unless otherwise stated, amounts in brackets refer to the 3rd quarter in 2019.

THE ASARINA PHARMA SHARE

As of 30 September 2020, Asarina has issued a total of 18,744,524 shares, which are owned by approx. 4,375 shareholders.

OWNERSHIP AS OF 30 SEPTEMBER 2020*

SHAREHOLDER	COUNTRY	NO. OF SHARES	%
Kurma Biofund	France	3,145,132	16.8
Östersjöstiftelsen (Baltic Foundation)	Sweden	2,657,092	14.2
Idinvest Patrimoine	France	1,639,824	8.7
AP4	Sweden	1,585,000	8.5
Handelsbanken Fonder	Sweden	855,952	4.6
Torbjörn Persson	Sweden	465,553	2.5
Torbjörn Bäckström	Sweden	315,989	1.7
Peter Nordkild	Denmark	263,124	1.4
Others		7,807,858	41.7
TOTAL		18,744,524	100.0

*Sources: Euroclear, company estimates

Asarina Pharma has an incentive warrant program for independent directors and management members. As of 30 September 2020, the warrant holders are entitled to subscribe for a total of 860,822 new shares at fixed prices ranging from SEK 25.20 to SEK 28.73.

EVENTS AFTER THE END OF THE REPORT PERIOD

Not applicable.

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, 25 November 2020

Asarina Pharma AB
Board of directors

FINANCIAL CALENDAR

25 FEBRUARY 2021

Q4/2020 report and Annual Report for 2020

21 APRIL 2021

Annual General Meeting

12 MAY 2021

Q4/2021 report

PUBLICATION

The report was submitted for publication by the CEO at 08.00 CET on 25 November 2020.

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

CONSOLIDATED INCOME STATEMENT (GROUP)

SEK '000	2020 JULY – SEP.	2019 JULY – SEP.	2020 JAN. – SEP.	2019 JAN. – SEP.	2019 JAN. – DEC.
Net sales	0	0	0	0	0
Other income	0	0	0	0	0
Total sales	0	0	0	0	0
Research and development costs	-14,587	-18,056	-43,815	-48,006	-63,447
Other external costs	-807	-1,111	-4,877	-4,098	-5,696
Staff costs	-2,141	-2,619	-7,802	-8,563	-11,891
Total costs	-17,535	-21,786	-56,494	-60,667	-81,034
Operating profit	-17,535	-21,786	-56,494	-60,667	-81,034
Financial income	-481	1,840	260	5,669	2,496
Financial cost	455	-27	-375	-225	-339
Financial items (net)	-26	1,813	-115	5,444	2,157
Result before taxes	-17,561	-19,973	-56,609	-55,223	-78,877
Taxes	0	0	0	0	7,801
Result for the period	-17,561	-19,973	-56,609	-55,223	-71,076

EARNINGS PER SHARE

	2020 JULY – SEP.	2019 JULY – SEP.	2020 JAN. – SEP.	2019 JAN. – SEP.	2019 JAN. – DEC.
Number of shares, average (non-diluted)	18,744,524	16,283,652	18,689,465	16,135,611	16,539,685
Number of shares, average (fully-diluted)	19,620,346	17,042,474	19,556,747	16,894,433	17,298,507
Earnings per share, non-diluted, (SEK)	-0.94	-1.23	-3.03	-3.42	-4.30
Earnings per share, fully-diluted, (SEK)	-0.90	-1.17	-2.89	-3.27	-4.11
Number of shares end of period (non-diluted)	18,744,524	16,283,652	18,744,524	16,283,652	18,442,800
Number of shares, end of period (fully-diluted)	19,620,346	17,042,474	19,620,346	17,042,474	19,201,622

CONSOLIDATED BALANCE SHEET (GROUP)

SEK '000	30-09-2020	30-09-2019	31-12-2019
ASSETS			
Non-current assets			
Equipment, tools and installations	2,012	0	1,768
Other long-term financial assets	1	1	1
Total non-current assets	2,013	1	1,769
Current assets			
Current tax asset	7,893	8,036	7,698
Other receivables	1,858	329	547
Prepaid expenses and accrued income	209	242	375
Total current receivables	9,960	8,607	8,620
Cash and cash equivalents	65,111	94,929	129,505
Total current assets	75,071	103,536	138,125
TOTAL ASSETS	77,084	103,537	139,894
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,686	4,072	4,611
Total restricted equity	4,686	4,072	4,611
Unrestricted equity			
Share premium reserve	272,813	220,605	264,500
Accumulated losses, incl loss for the period	-206,135	-136,523	-149,641
Total unrestricted equity	66,678	84,082	114,859
Total equity	71,364	88,154	119,470
Current liabilities			
Accounts payable	1,715	12,030	16,608
Other current liabilities	81	522	147
Accrued expenses and prepaid income	3,924	2,831	3,669
Total current liabilities	5,720	15,383	20,424
TOTAL EQUITY AND LIABILITIES	77,084	103,537	139,894

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 2019	4,009	213,890	-77,989	139,910
Share issue	602	53 679		54,281
Share issue costs		-3 069		-3,069
Translation difference			-576	-576
Result for the period			-71,076	-71,076
Closing balance 31 December 2019	4,611	264,500	-149,641	119,470
Opening balance 1 January 2020	4,611	264,500	-149,641	119,470
Share issue	75	8 313		8,388
Translation difference			115	115
Result for the period			-56,609	-56,609
Closing balance 30 September 2020	4,686	272,813	-206,135	71,364

CONSOLIDATED STATEMENT OF CASH FLOWS (GROUP)

SEK '000	2020 JULY – SEP.	2019 JULY – SEP.	2020 JAN. – SEP.	2019 JAN. – SEP.	2019 JAN. – DEC.
Operating activities					
Operating profit/loss	-17,535	-21,786	-56,494	-60,667	-81,034
Interest received	750	703	1,122	2,647	1,914
Interest paid	-882	-27	-1,236	-219	-339
Paid taxes	-31	-153	-92	-304	7,835
Cash flow from operating activities before changes in working capital	-17,698	-21,263	-56,700	-58,543	-71,624
Cash flow from changes in working capital					
Decrease(+)/Increase(-) in receivables	-9,578	-49	-10,797	-267	-629
Decrease(-)/Increase(+) in liabilities	8,922	6,709	-4,780	5,369	10,754
Cash flow from operating activities	-18,354	-14,603	-72,277	-53,441	-61,499
Investing activities					
Acquisition of equipment, tools and installation	-1	0	-219	0	-1,768
Cash flow from investing activities	-1	0	-219	0	-1,768
Financing activities					
Share issue	0	0	8,388	6,778	54,281
Share issue costs	0	0	0	0	-3,069
Warrants	0	0	0	0	0
Cash flow from financing activities	0	0	8,388	6,778	51,212
Cash flow for the period	-18,355	-14,603	-64,108	-46,663	-12,055
Cash and cash equivalents at the beginning of the period	83,827	109,514	129,505	141,543	141,543
Translation difference	-361	18	-286	49	17
Cash and cash equivalents at the end of the period	65,111	94,929	65,111	94,929	129,505

INCOME STATEMENT (COMPANY)

SEK '000	2020 JULY – SEP.	2019 JULY – SEP.	2020 JAN. – SEP.	2019 JAN. – SEP.	2019 FULL YEAR
Net sales	0	0	0	0	0
Other income	209	513	1,273	1,672	2,280
Total income	209	513	1,273	1,672	2,280
Research and development costs	-329	-909	-1,330	-1,337	-1,684
Other external costs	-609	-731	-3,893	-2,517	-3,753
Staff costs	-993	-1,148	-3,320	-3,672	-4,624
Total costs	-1,931	-2,788	-8,543	-7,526	-10,061
Operating profit	-1,722	-2,275	-7,270	-5,854	-7,781
Financial income	60	1,927	492	5,401	5,623
Financial cost	-33	-51	-120	-201	-252
Financial items (net)	27	1,876	372	5,200	5,371
Result before taxes	-1,695	-399	-6,898	-654	-2,410
Taxes	0	0	0	0	0
Result for the period	-1,695	-399	-6,898	-654	-2,410

BALANCE SHEET (COMPANY)

SEK '000	30-09-2020	30-09-2019	31-12-2019
ASSETS			
Non-current assets			
Financial non-current assets			
Shares in subsidiaries	181,715	51	128,460
Other long-term financial assets	1	1	1
Total non-current assets	181,716	52	128,461
Current assets			
Receivables on group companies	12,396	129,359	2,231
Current tax asset	107	132	16
Other receivables	176	103	89
Prepaid expenses and accrued income	210	242	375
Total current receivables	12,889	129,836	2,711
Cash and cash equivalents	55,075	74,942	116,319
Total current assets	67,964	204,778	119,030
TOTAL ASSETS	249,680	204,830	247,491
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,686	4,072	4,611
Total restricted equity	4,686	4,072	4,611
Unrestricted equity			
Share premium reserve	272,813	220,605	264,500
Accumulated losses	-24,014	-22,108	-22,108
Result for the period	-6,898	-654	-2,410
Total unrestricted equity	241,901	197,843	239,982
Total equity	246,587	201,915	244,593
Current liabilities			
Accounts payable	260	512	280
Liabilities to group companies	0	0	248
Other current liabilities	81	522	147
Accrued expenses and prepaid income	2,752	1,881	2,223
Total current liabilities	3,093	2,915	2,898
TOTAL EQUITY AND LIABILITIES	249,680	204,830	247,491

NOTES

1. GENERAL INFORMATION

This interim report covers the parent company Asarina Pharma AB (publ), Corp. Reg. No 556698-0750 and its subsidiaries, Asarina Pharma ApS (Denmark) and Asarina Pharma Finans AB, Corp. Reg. No. 559169 – 2032

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 2019 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 four components: 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 with the aim 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 any

pharmaceutical candidate. Consequently, Asarina's goal is to gradually generate a portfolio of different pharmaceutical candidates for several 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 aims to have sufficient liquidity for its planned activities for the next 1-2 years. At present, Asarina does not generate any income from product sales or licensing of the Company's IP assets and is therefore dependent upon raising new capital from investors. Therefore, Asarina may at any point have 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 kroner (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 projected 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	2020 JULY - SEP.	2019 JULY - SEP.	2020 JAN. - SEP.	2019 JAN. - SEP.	2019 FULL YEAR
Equity	71.364	71.364	71.364	88.154	119.470
+ Untaxed reserves	0	0	0	0	
- Deferred tax liability	0	0	0	0	
Adjusted equity	71.364	88.154	71.364	88.154	119.470
Adjusted equity	71.364	71.364	71.364	88.154	119.470
Total assets	77.084	103.537	77.084	103.537	139.894
Equity ratio, %	92,6	85,1	92,6	85,1	85,4

RETURN ON EQUITY

SEK '000	2020 JULY - SEP.	2019 JULY - SEP.	2020 JAN. - SEP.	2019 JAN. - SEP.	2019 FULL YEAR
Result for the period	-17.561	-19.973	-56.609	-55.223	-71.076
Average adjusted equity	81.239	98.939	95.417	114.032	129.690
Return on equity, %	-21,6	-20,2	-59,3	-48,4	-54,8

RETURN ON TOTAL ASSETS, %

SEK '000	2020 JULY - SEP.	2019 JULY - SEP.	2020 JAN. - SEP.	2019 JAN. - SEP.	2019 FULL YEAR
Result before tax	-17.561	-19.973	-56.609	-55.223	-78.877
+ Interest costs	-455	27	375	225	339
Average total assets	86.407	110.795	108.489	126.559	144.737
Return on total assets, %	-20,9	-18,0	-51,8	-43,5	-54,3

CERTIFIED ADVISER

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