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ASARINA PHARMA AB (PUBL)

## **INTERIM REPORT**

1 April – 30 June 2020

## ASARINA PHARMA AB

(PUBL) 556698-0750

INTERIM REPORT, SECOND 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

ASARINA PHARMA AB

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Peter Nordkild, CEO | Phone +45 25 47 16 46

# SECOND QUARTER 2020: OVERVIEW

## FINANCIAL HIGHLIGHTS

- Decrease in R&D costs after completion of PMDD study
- All budgets revised after PMDD results
- Cash position on 30 June 2020 sufficient to fund phase II studies in menstrual migraine and Tourette Syndrome

## R&D UPDATE

### MENSTRUAL MIGRAINE

95% of patients have been recruited in our Phase IIa proof-of-concept study. In total since August 2019, we have enrolled 139 patients. Recruitment was slowed somewhat by Corona restrictions, but all seven of our test centers have now been recruiting at the pre-Covid rate since June 2020. We are confident in reporting topline results in Q2 2021.

### TOURETTE SYNDROME

We plan to initiate our Phase IIa proof-of-concept study in Tourette in the spring of 2021. In May we submitted an application for orphan drug designation in children below the age of 18 to the FDA, hoping to receive approval in the fall of 2020. Our 4 months' tox study is progressing on schedule and we aim to submit a Clinical Trial Application to the Danish Medical Agency during Q1 2021, initiating the study in Q2 2021.

### PMDD

In April 2020 we released negative topline results from our phase IIb study in PMDD. Our active Sepranolone substance performed on a par with previous study results, however, a statistically significant difference from placebo could not be demonstrated due to an unusually high placebo response. Sepranolone achieved an excellent safety profile during the study and results were extensively covered in our 2020 First Quarter Interim Report and on our website.

## CEO STATEMENT

# DEAR SHAREHOLDER

*The second Quarter 2020 has given us continued proof of the urgent need for new, safe and effective treatments for the devastating conditions that our flagship compound, Sepranolone, targets. Despite disappointing results in our Phase IIb PMDD study at the beginning of the Quarter, which we covered extensively in our Q1 Interim Report, this second Quarter powerfully underlined the unmet need for new, safe, effective treatments for menstrual migraine and Tourette.*

After a temporary Covid-19 slowdown in March, April and early May, all seven of our test centers in Finland and Sweden have continued to recruit patients for our Menstrual Migraine study. We are now, with only a few months' delay due to Covid-19, close to full patient enrolment, and we expect topline results in Q2 2021.

The urgent medical need for an effective Tourette treatment with a strong safety profile was underlined too this Spring with the failure of Teva's Austedo in late stage clinical development. Both the failure and the urgent need were confirmed by newly elected President of the US Tourette Society, Amanda Talty, in a recent meeting with the society. The positive feedback we received in March from the Danish Medical Agency on our upcoming clinical phase IIa study in Tourette has encouraged us to apply for Orphan Drug Designation in the US.

## THE CASE FOR SEPRANOLONE IN NEUROLOGY

Behind both of our present indications, and many more, lies the powerful neurosteroid Allopregnanolone (ALLO). ALLO modulates GABA, the brain's most powerful inhibitory neurotransmitter. For most people, ALLO plays a crucial role in reducing stress, fear and anxiety. For a significant minority though, it has the exact opposite effect. Elevated ALLO levels or a heightened sensitivity to ALLO are implicated in socially and psychologically disruptive conditions from Tourette to Menstrual Migraine to OCD (Obsessive Compulsive Disorder), PTSD (Post Traumatic Stress Disorder), compulsive gambling, addiction—and more.

Sepranolone is a safe, powerful, endogenous compound that reduces the negative effects of ALLO significantly. As the first company in the world to develop and synthesize Sepranolone, Asarina Pharma remains totally committed to producing it as the first of a new range of GABA<sub>A</sub> active therapies—GAMSAs (GABA<sub>A</sub> Modulating Steroid Antagonists). We believe GAMSAs could bring new treatments and understanding to a wide range of stress- and compulsion-related conditions, and that our present trials in Menstrual Migraine and Tourette could be gateway studies to a larger therapeutic landscape.

## MENSTRUAL MIGRAINE

### 95% OF PATIENTS HAVE BEEN RECRUITED

Since August 2019, we have enrolled 139 patients in our Phase IIa proof-of-concept study in Sweden and Finland. Recruitment has been slowed somewhat by Corona restrictions, but all seven centers have been recruiting at the pre-Covid rate since June, reducing delay of the study to a few months.

A large clinical study by Koverech et al "Migraine and cluster headache show impaired neurosteroid patterns" published in the spring of 2019 demonstrated that ALLO levels are elevated in both cluster and chronic migraineurs whether or not they are having a migraine attack. This study clearly demonstrates that ALLO and to a lesser extent other neurosteroids play a major role in migraine. With Sepranolone effectively negating the effects of ALLO in a number of animal models and human studies we remain optimistic about the effect of Sepranolone in women suffering from Menstrual Migraine.

Despite Covid-19, we are confident in reporting topline results from the first dedicated clinical study with intermittent treatment of Menstrual Migraine in Q2 2021.

## TOURETTE SYNDROME

**”** *This second Quarter has given us continued proof of the urgent need for new, safe and effective treatments for the devastating conditions that our flagship compound, Sepranolone, targets.*

### 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 was of the opinion that the need for a treatment for Tourette with a strong safety profile is bigger than ever and thus suggested that even a modest reduction of tics by > 25% would be considered clinically relevant.

The 4 months' tox study in juvenile animals of both genders is progressing on schedule and we should be able to submit a CTA to the Danish Medical Agency during the first Quarter of 2021.

In May, we submitted an application for orphan drug designation in children below the age of 18 to the FDA and hope it will be approved in the fall of 2020.

We remain optimistic that we will be able to initiate the phase IIa study in the National Danish Tourette Center at the University hospital in Herlev in the second quarter of 2021, Corona restrictions permitting.

## FINANCIALS

Asarina was well funded prior to the negative PMDD study outcome in April.

All budgets have been revised in May to ensure that the clinical study in both menstrual migraine and in Tourette syndrome can be completed without additional funding.

” *The urgent need for an effective, safer Tourette treatment was underlined this Spring with the failure of Teva's Austedo in late stage clinical development. We're confident in reporting topline results from the first dedicated clinical study with intermittent treatment of Menstrual Migraine in Q2 2021.*”

## NEW WEBSITE

Finally, we have launched a new website presenting the wide range of conditions (both neurological as well as neuroendocrinological) impacted by ALLO. Our new website examines Sepranolone's role as the first GAMSAs, and how GAMSAs represent a paradigm shift in the treatment of stress- and compulsion-related conditions—modulating the dramatic effects of GABA, one of the body's most powerful neurotransmitters— with no broader CNS or GABA impact, and so no severe side effects.

We continue to believe that GAMSAs ultimately will constitute a new generation of safe, effective treatments for devastating conditions in urgent need of new treatment modalities.

Thank you for your continued support.



*Peter Nordkild*

**Peter Nordkild,**  
CEO Asarina Pharma

## MENSTRUAL MIGRAINE UPDATE

# CLINICAL TRIAL IN THE TIME OF COVID-19

### 95% ENROLMENT ACHIEVED IN CENTER OF PANDEMIC

*“In the middle of the pandemic four of our test sites had to suddenly halt recruitment immediately, only picking up again after seven weeks. Yet today, despite so many test sites being based in hospitals, we have reached 95% enrolment with all seven test centers open and working. It’s a fantastic achievement, and a powerful testament to the professionalism and resilience of test center staff and the scale of the unmet need for an effective Menstrual Migraine treatment.”*

#### **DR MÄRTA SEGERDAHL**

Asarina Pharma CMO, Study Director for Menstrual Migraine.

When Asarina Pharma CMO Märta Segerdahl heard, in March 2020, that four of the company’s test sites, in Stockholm and all sites in Finland, were to halt recruitment immediately due to Coronavirus it was expected—but still troubling. “Many of our test centers are on the sites of hospitals,” Segerdahl says “so we knew it might happen. Decisions were taken to reduce the risk of contagion for study participants and study staff. At one site, staff were also required to support in-patient care. Measures were taken to reduce physical site visits for the patients already participating in the trial, exchanging many site visits to virtual meetings. After sites started to reopen enrollment, the investigators began making up for a lot of the time lost. It’s a powerful testament to the professionalism and resourcefulness of the staff working at the sites in such challenging times, and the commitment of migraine patients determined to take part.”

#### **WAS IT CHALLENGING ASKING WOMEN TO TRAVEL TO OFTEN CROWDED HOSPITAL SITES DURING A PANDEMIC IN ORDER TO TAKE PART IN THE STUDY?**

“Obviously on all the sites hospitals really want to separate clinical trials from daily health care” Segerdahl says “both to have dedicated resources for research and avoid competition for space and staff—it’s essential good management. So study patients weren’t going to the same part of the hospital as Covid-19 patients. Plus of course all distancing measures were followed scrupulously. But nevertheless—achieving 95% enrolment despite a major pandemic really



Sahlgrenska University Hospital Gothenburg: its MM test center, run by CTC Clinical Trial Consultants AB, stayed open throughout the Covid-19 pandemic.

does reflect the magnitude of the unmet need for an effective treatment for Menstrual Migraine. Migraine is a disproportionately female condition; the WHO recognizes it as the leading cause of life lived with a disability for women of a reproductive age—yet even the latest migraine treatments like CGRP antibodies are not effective against Menstrual Migraine. I think the high turnout in such an extraordinary situation reflects the scale of the need for an effective treatment for this disruptive, disabling condition.”

Many of Asarina Pharma’s larger study sites like those in Gothenburg and Lund carried on recruiting and testing throughout the pandemic. Since August 2019 139 patients have been enrolled in the Phase IIa proof-of-concept, with the company now close to full enrollment.

**TOPLINE RESULTS FOR THE MENSTRUAL MIGRAINE STUDY ARE EXPECTED IN Q2 2021.**

**DR MÄRTA SEGERDAHL**  
Asarina Pharma CMO, Study  
Director for Menstrual  
Migraine.



## TOURETTE SYNDROME UPDATE

# UNMET NEED OF PEDIATRIC PATIENTS HIGHLIGHTED IN Q2

*The unmet need for a safe, effective Tourette treatment was firmly back in the spotlight in Q2 following the failure of Teva's Austedo treatment to reduce Tourette tics in pediatric patients in late-stage clinical trials at the end of Q1. Interest in the potential of Sepranolone as a Tourette treatment, and its proven safety profile, was high at a recent meeting with the Tourette Association of America. CEO of Asarina Pharma Peter Nordkild was there.*

"Few conditions inflict such huge damage on a young, vulnerable patient group the way that Tourette does," says Asarina Pharma CEO Peter Nordkild. "Patients typically experience their first tics between 3 and 9 years old, 36% consider suicide or self-harm (1), yet the side effects of today's most efficacious treatments still include severe involuntary movement disorder (tardive dyskinesia), blurred vision, nausea, diarrhoea, irregular heartbeat, even renal failure. We're seeing growing interest in our endogenous compound Sepranolone, with its well-established safety profile, as a new approach to Tourette."

### AUSTEDO AND INGREZZA: THE NEED FOR A NEW APPROACH

Teva's Austedo (deutetrabenazine) is a treatment for chorea and tardive dyskinesia (both movement disorders). Austedo failed to reach its primary endpoint of reducing motor and phonic tics versus placebo in pediatric Tourette patients in two clinical studies reported in

Q1 2019—a Phase 2/3 study and a Phase 3 study. The side effects of Austedo as currently prescribed include increased suicidality, irregular heartbeat, Neuroleptic Malignant Syndrome, restlessness and Parkinsonism.

Another tardive dyskinesia treatment with a similar mechanism—Neurocrine's Ingrezza (valbenazine)—also reported disappointing results for Tourette clinical studies in 2018, prior to Austedo. Ingrezza's side effects too include irregular heartbeat, Parkinsonism and sleepiness (somnolence).

Peter Nordkild: "VMAT2 (vesicular monoamine transporter 2) inhibitors like Austedo and Ingrezza have their place, but it seems increasingly unlikely they'll ever constitute safe or effective Tourette treatments. We're seeing greater interest in a safer treatment, and indeed a new approach. At a recent meeting we had with the President and CEO of the Tourette Association of America, Amanda Talty, for example, we found the Association was well aware of Sepranolone, its safety profile and mechanism. This was through the important work on tic reduction carried out by Prof Marco





<sup>1</sup> 2018 Impact Survey, Tourette Association of America

<sup>2</sup> Isoallogpregnanolone reduces tic-like behaviours in the D1CT-7 mouse model of Tourette syndrome. (2019)

<sup>3</sup> US Center for Disease Control and Prevention <https://www.cdc.gov/ncbddd/tourette/data.html>

## UPCOMING CLINICAL STUDY: GOALS AND TIMELINE

In March 2020 Asarina Pharma received input and support from the Danish Medical Agency for its plans for a clinical study in Tourette. “The agency was of the opinion that the need for a treatment with a strong safety profile was bigger than ever” Nordkild says, “it even suggested that a modest reduction of tics by > 25% would be clinically relevant, when our original target had been 50%. This too underlines the urgency of the unmet need.”

Asarina Pharma plans to submit a Clinical Trial Application to the Danish Medical Authority during Q1 2021 following the successful completion of its current 4-month tox study in juvenile animals of both sexes. An application for orphan drug designation in children below the age of 18 was sent to the US Food and Drug Administration in May.

“We hope to get approval of our orphan drug designation from the FDA during the fall of 2020, and to begin our phase IIa study in the National Danish Tourette Center in the second quarter of 2021,” Nordkild says. “I believe a successful tic-reduction effect in this Study could open up new research avenues and therapeutic possibilities. After all, 86% of patients with TS have at least one additional behavioral or developmental disorder (3) ranging from ADHD, OCD/B, inattention, hyperactivity, impulsivity and childhood conduct disorder, many likely impacted by ALLO. We believe the therapeutic potential of GAMSAs compounds (GABA<sub>A</sub> Modulating Steroid Antagonists) like Sepranolone could ultimately represent a new direction in the treatment of an even wider range of neuroendocrinological conditions. Tourette is a vital and exciting first step.”

Bortolato, our Scientific Advisory Board member and Associate Professor of Pharmacology and Toxicology at the Department of Pharmacology and Toxicology at the University of Utah.”

## SEPRANOLONE: A SAFER MECHANISM

Teva’s Austedo (deutetrabenazine) is a treatment for chorea and tardive dyskinesia (both movement disorders). Austedo failed to reach its primary endpoint of reducing motor and phonic tics versus placebo in pediatric Tourette patients in two clinical studies reported in Q1 2019—a Phase 2/3 study and a Phase 3 study

Sepranolone’s mechanism, Nordkild points out, is innovative and distinct from VMAT2 inhibitors. “VMAT2

function is necessary for the vesicular release of GABA, the brain’s major inhibitory neurotransmitter and ‘brake’ system. Unlike VMAT2 inhibitors though, Sepranolone does not inhibit or suppress any CNS functions. We know that Tourette tics are severely aggravated by stress, and we found in our last study (2) that the neurosteroid Allopregnanolone (ALLO), that interacts with GABA, was a key actor in the mechanism of stress exacerbation of tics. As the body’s endogenous inhibitor of ALLO, Sepranolone, is highly selective—it can modulate the dramatic effects of GABA, but with no broader CNS or GABA impact, meaning no severe side effects. For Tourette patients, so many of whom are young boys, this is crucial. We’ve run Sepranolone in large-scale Studies and found it to have no major side effects after hundreds of patients have administered thousands of doses. This proven safety profile is potentially a major breakthrough.”

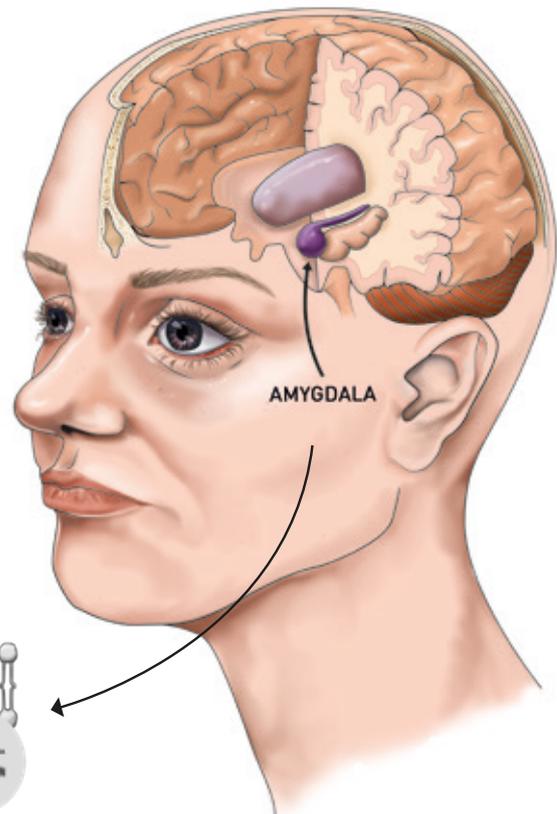
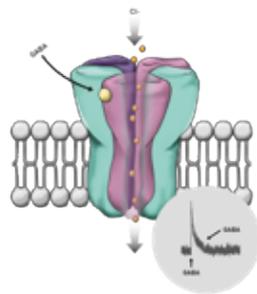
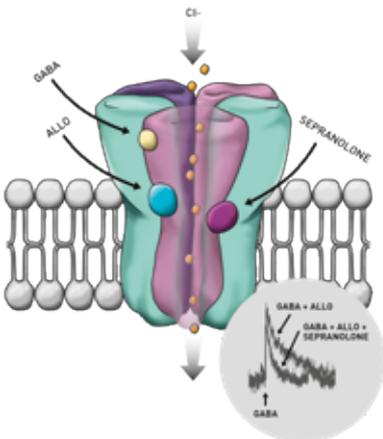
## ALLO AND GABA THE BRAIN'S 'BRAKE' SYSTEM

*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<sub>A</sub> 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<sub>A</sub> 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<sub>A</sub> receptors to normal. But ALLO is not the only neurosteroid that acts on our behavior through the GABA<sub>A</sub> receptor.



This whole area of GABA<sub>A</sub>-active steroids is really new. 20 years ago nobody even knew about Allopregnanolone and its effect on GABA<sub>A</sub> 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.

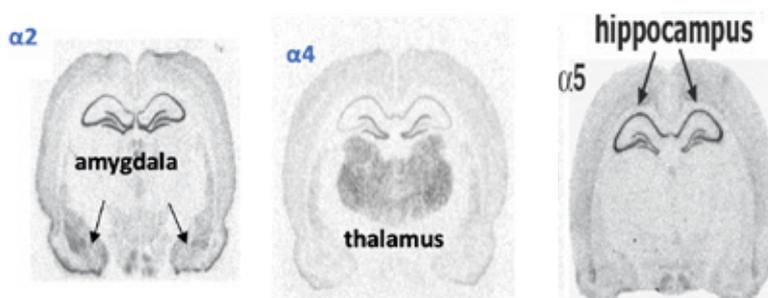
PROFESSOR MARIE BIXO University of Umeå.

## THE GABA<sub>A</sub> 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<sub>A</sub> 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—GAMsAs— can now potentially “modulate the modulators”, operating within the GABA<sub>A</sub> receptors, the brain's major inhibitory signaling system, and a fast-emerging therapeutic channel.*

### GABA<sub>A</sub> RECEPTORS: WHAT THEY ARE AND WHERE THEY ARE

GABA<sub>A</sub> 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<sub>A</sub> receptors of different types exist within the amygdala, the thalamus and the hippocampus.



PROFESSOR MARIE BIXO ANATOMICAL DISTRIBUTION OF GABAA RECEPTOR SUBCLASSES<sup>1</sup>

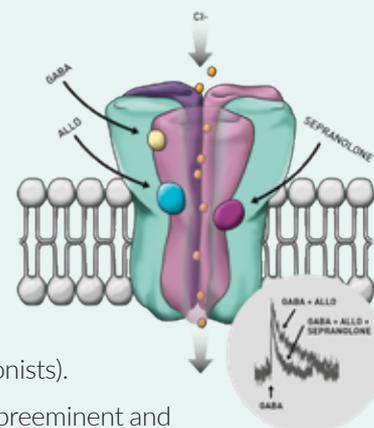
<sup>1</sup>Bäckström et al, Springer NY 2008

### GABA<sub>A</sub> RECEPTORS: A MAJOR THERAPEUTIC PATHWAY

Over the last 20 years, the GABA<sub>A</sub> 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 GAMsAs (GABA<sub>A</sub> 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<sub>A</sub> receptor and GAMsAs.



GAMSA<sub>s</sub>

## A NEW GENERATION OF THERAPIES

**WHAT ARE GAMSA<sub>s</sub>?**

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<sub>s</sub> (GABA<sub>A</sub> 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<sub>s</sub> 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<sub>s</sub>: SELECTIVITY AND SAFETY

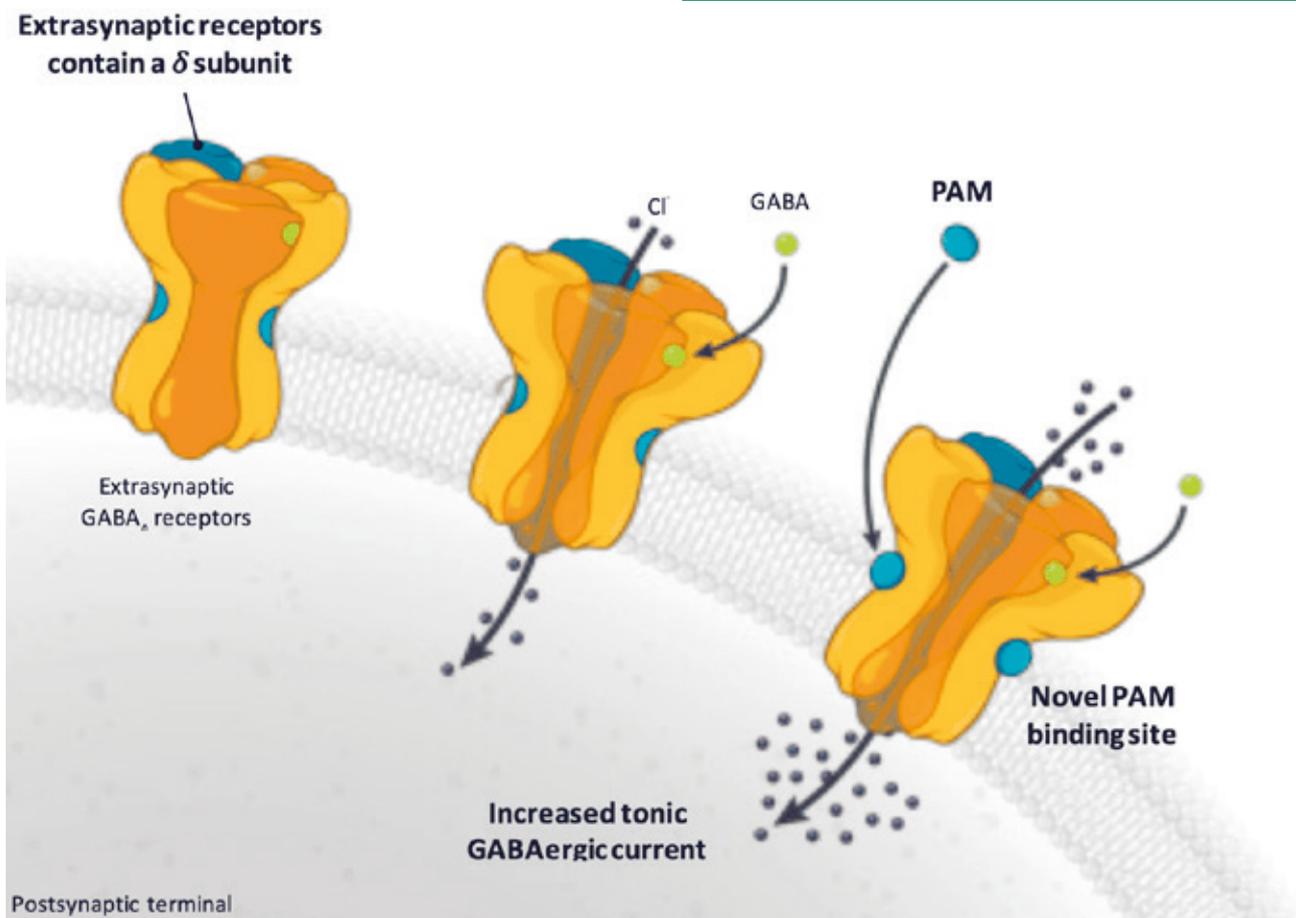
GAMSA<sub>s</sub> directly target the effects of neurotransmitters at different GABA<sub>A</sub> receptor subtypes with high specificity. Their effect is confined to a very specific subtype of the GABA<sub>A</sub> receptor, meaning minimal effect on any other CNS mechanism.

### 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<sub>A</sub> modulating steroids impact our mood, behavior and neurological symptoms. Professor Bäckström has developed, synthesized and patented over 30 GAMSA<sub>s</sub>. With potential GAMSA compounds available for development to treat:

- » Epilepsy
- » Tourette's
- » Stress-related fatigue
- » Cognitive impairments
- » Balance treatments



## 2<sup>ND</sup> QUARTER 2020

# FINANCIAL OVERVIEW

## KEY FINANCIALS

| SEK '000                               | 2020<br>APRIL - JUNE | 2019<br>APRIL - JUNE | 2020<br>JAN - JUNE | 2019<br>JAN - JUNE | 2019<br>JAN - DEC. |
|----------------------------------------|----------------------|----------------------|--------------------|--------------------|--------------------|
| Net sales, KSEK                        | 0                    | 0                    | 0                  | 0                  | 0                  |
| Operating profit, KSEK                 | -17 841              | -28 128              | -38 959            | -38 881            | -81 034            |
| Result after financial items, KSEK     | -20 679              | -25 820              | -39 048            | -35 250            | -78 877            |
| Earnings per share, fully-diluted, SEK | -1.05                | -1.53                | -2.00              | -2.10              | -4.11              |
| Total assets, end of period, KSEK      | 95 730               | 118 053              | 95 730             | 118 053            | 139 894            |
| Cash balance, end of period, KSEK      | 83 827               | 109 514              | 83 827             | 109 514            | 129 505            |
| Equity ratio, %                        | 95.4                 | 92.9                 | 95.4               | 92.9               | 85.4               |
| Return on equity, %                    | -20.4                | -21.6                | -37.1              | -28.2              | -54.8              |
| Return on total assets, %              | -18.3                | -20.1                | -32.4              | -26.2              | -54.3              |

## REVENUE

Net sales amounted to 0 MSEK (0).

## OPERATING EXPENSES

Total operating expenses for the 2nd quarter 2020 amounted to 17.8 (28.1) MSEK. Research and development costs decreased to 13.1 (23.1) MSEK, primarily because of a reduction in the clinical trial costs for PMDD. Staff costs decreased to 2.9 (3.2) MSEK. General and administration costs, i.e. legal and audit fees, investor relation costs, board fees and other administration expenses, increased slightly to 1.9 (1.8) MSEK.

## FINANCIAL ITEMS AND TAX

Financial items generated a net negative result of 2.8 (positive result of 2.3) MSEK which reflects exchange losses due to the increased value of the SEK against the EUR. No tax was reported for the quarter.

## RESULT AND FINANCIAL POSITION

The operating result for the 2nd quarter was -17.8 (-28.1) MSEK and the result after taxes amounted to -20.7 (-25.8) MSEK.

Cash flow for the period was -25.6 (-19.4) MSEK. On 30 June 2020, the total cash balance amounted to 83.8 (109.5) MSEK which the Company considers sufficient to finance the phase IIa studies in menstrual migraine and Tourette Syndrome (expected to complete in the second quarter of 2022). Shareholder's equity amounts to 91.3 (109.7) MSEK representing an equity ratio of 95.4% (92.9%).

## STAFF

As of 30 June 2020, Asarina's operational team comprised 8 members (employees and permanent consultants), corresponding to 5.5 full-time employees (FTEs). In view of the discontinuation of the PMDD project, the Company will reduce the headcount to approx. 3.7 FTE by the end of 2020.

**NOTE:** Unless otherwise stated, amounts in brackets refer to the 2nd quarter in 2019.

# THE ASARINA PHARMA SHARE

As of 30 June 2020, Asarina has issued a total of 18,744,524 shares, which are owned by approx. 4,800 shareholders.

## OWNERSHIP AS OF 30 JUNE 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  | 843,564           | 3.9          |
| Torbjörn Persson                       | Sweden  | 322,500           | 1.7          |
| Torbjörn Bäckström                     | Sweden  | 315,989           | 1.7          |
| Ergomed                                | UK      | 301,724           | 1.6          |
| Others                                 |         | 7,933,699         | 42.3         |
| <b>TOTAL</b>                           |         | <b>18,744,524</b> | <b>100.0</b> |

\*Sources: Euroclear, company estimates

Asarina Pharma has established an incentive warrant program for independent directors and management members. As of 30 June 2020, the program comprises warrants entitling the holders to subscribe for a total of 875,722 new shares at fixed prices per share (between SEK 25.20 and 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, 19 August 2020*

**Asarina Pharma AB**  
**Board of directors**

### FINANCIAL CALENDAR

**25 November:** Interim report for 3rd quarter 2020

### PUBLICATION

The report was submitted for publication by the CEO at 08.00 CET on 19 August 2020.

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

## CONSOLIDATED INCOME STATEMENT (GROUP)

| SEK '000                       | 2020<br>APRIL - JUNE | 2019<br>APRIL - JUNE | 2020<br>JAN. - JUNE | 2019<br>JAN. - JUNE | 2019<br>JAN. - DEC. |
|--------------------------------|----------------------|----------------------|---------------------|---------------------|---------------------|
| Net sales                      | 0                    | 0                    | 0                   | 0                   | 0                   |
| Other income                   | 0                    | 0                    | 0                   | 0                   | 0                   |
| <b>Total sales</b>             | <b>0</b>             | <b>0</b>             | <b>0</b>            | <b>0</b>            | <b>0</b>            |
| Research and development costs | -13 057              | -23 110              | -29 228             | -29 950             | -63 447             |
| Other external costs           | -1 926               | -1 790               | -4 070              | -2 987              | -5 696              |
| Staff costs                    | -2 858               | -3 228               | -5 661              | -5 944              | -11 891             |
| <b>Total costs</b>             | <b>-17 841</b>       | <b>-28 128</b>       | <b>-38 959</b>      | <b>-38 881</b>      | <b>-81 034</b>      |
| <b>Operating profit</b>        | <b>-17 841</b>       | <b>-28 128</b>       | <b>-38 959</b>      | <b>-38 881</b>      | <b>-81 034</b>      |
| Financial income               | -2 170               | 2 409                | 741                 | 3 829               | 2 496               |
| Financial cost                 | -668                 | -101                 | -830                | -198                | -339                |
| <b>Financial items (net)</b>   | <b>-2 838</b>        | <b>2 308</b>         | <b>-89</b>          | <b>3 631</b>        | <b>2 157</b>        |
| <b>Result before taxes</b>     | <b>-20 679</b>       | <b>-25 820</b>       | <b>-39 048</b>      | <b>-35 250</b>      | <b>-78 877</b>      |
| Taxes                          | 0                    | 0                    | 0                   | 0                   | 7 801               |
| <b>Result for the period</b>   | <b>-20 679</b>       | <b>-25 820</b>       | <b>-39 048</b>      | <b>-35 250</b>      | <b>-71 076</b>      |

## EARNINGS PER SHARE

|                                                 | 2020<br>APR-JUN | 2019<br>APR-JUN | 2020<br>JAN-JUN | 2019<br>JAN-JUN | 2019<br>FULL YEAR |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-------------------|
| Number of shares, average (non-diluted)         | 18 744 524      | 16 083 255      | 18 661 633      | 16 060 364      | 16 539 685        |
| Number of shares, average (fully-diluted)       | 19 620 346      | 16 842 077      | 19 524 598      | 16 819 186      | 17 298 507        |
| Earnings per share, non-diluted, (SEK)          | -1.10           | -1.61           | -2.09           | -2.19           | -4.30             |
| Earnings per share, fully-diluted, (SEK)        | -1.05           | -1.53           | -2.00           | -2.10           | -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                                     | 30-06-2020    | 30-06-2019     | 31-12-2019     |
|----------------------------------------------|---------------|----------------|----------------|
| <b>ASSETS</b>                                |               |                |                |
| <b>Non-current assets</b>                    |               |                |                |
| Equipment, tools and installations           | 1 999         | 0              | 1 768          |
| Other long-term financial assets             | 1             | 1              | 1              |
| <b>Total non-current assets</b>              | <b>2 000</b>  | <b>1</b>       | <b>1 769</b>   |
| <b>Current assets</b>                        |               |                |                |
| Current tax asset                            | 7 811         | 7 883          | 7 698          |
| Other receivables                            | 1 914         | 458            | 547            |
| Prepaid expenses and accrued income          | 178           | 197            | 375            |
| <b>Total current receivables</b>             | <b>9 903</b>  | <b>8 538</b>   | <b>8 620</b>   |
| Cash and cash equivalents                    | 83 827        | 109 514        | 129 505        |
| <b>Total current assets</b>                  | <b>93 730</b> | <b>118 052</b> | <b>138 125</b> |
| <b>TOTAL ASSETS</b>                          | <b>95 730</b> | <b>118 053</b> | <b>139 894</b> |
| <b>EQUITY AND LIABILITIES</b>                |               |                |                |
| <b>Restricted equity</b>                     |               |                |                |
| Share capital                                | 4 686         | 4 072          | 4 611          |
| <b>Total restricted equity</b>               | <b>4 686</b>  | <b>4 072</b>   | <b>4 611</b>   |
| <b>Unrestricted equity</b>                   |               |                |                |
| Share premium reserve                        | 272 813       | 220 605        | 264 500        |
| Accumulated losses, incl loss for the period | -186 205      | -114 954       | -149 641       |
| <b>Total unrestricted equity</b>             | <b>86 608</b> | <b>105 651</b> | <b>114 859</b> |
| <b>Total equity</b>                          | <b>91 294</b> | <b>109 723</b> | <b>119 470</b> |
| <b>Current liabilities</b>                   |               |                |                |
| Accounts payable                             | 2 884         | 6 074          | 16 608         |
| Other current liabilities                    | 83            | 519            | 147            |
| Accrued expenses and prepaid income          | 1 469         | 1 737          | 3 669          |
| <b>Total current liabilities</b>             | <b>4 436</b>  | <b>8 330</b>   | <b>20 424</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b>          | <b>95 730</b> | <b>118 053</b> | <b>139 894</b> |

## 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        |
| <b>Closing balance 31 December 2019</b> | <b>4 611</b>  | <b>264 500</b>        | <b>-149 641</b>                             | <b>119 470</b> |
| <b>Opening balance 1 January 2020</b>   | <b>4 611</b>  | <b>264 500</b>        | <b>-149 641</b>                             | <b>119 470</b> |
| Share issue                             | 75            | 8 313                 |                                             | 8 388          |
| Translation difference                  |               |                       | 2 484                                       | 2 484          |
| Result for the period                   |               |                       | -39 048                                     | -39 048        |
| <b>Closing balance 30 June 2020</b>     | <b>4 686</b>  | <b>272 813</b>        | <b>-186 205</b>                             | <b>91 294</b>  |

## CONSOLIDATED STATEMENT OF CASH FLOWS (GROUP)

| SEK '000                                                                    | 2020<br>APRIL-JUNE | 2019<br>APRIL-JUNE | 2020<br>JAN.-JUNE | 2019<br>JAN.- JUNE | 2019<br>FULL YEAR |
|-----------------------------------------------------------------------------|--------------------|--------------------|-------------------|--------------------|-------------------|
| <b>Operating activities</b>                                                 |                    |                    |                   |                    |                   |
| Operating profit/loss                                                       | -17 841            | -28 128            | -38 959           | -38 881            | -81 034           |
| Interest received                                                           | -2 529             | 1 306              | 372               | 1 944              | 1 914             |
| Interest paid                                                               | -192               | -95                | -354              | -192               | -339              |
| Paid taxes                                                                  | -31                | 81                 | -61               | -151               | 7 835             |
| <b>Cash flow for operating activities before changes in working capital</b> | <b>-20 593</b>     | <b>-26 836</b>     | <b>-39 002</b>    | <b>-37 280</b>     | <b>-71 624</b>    |
| <b>Cash flow from changes in working capital</b>                            |                    |                    |                   |                    |                   |
| Decrease(+)/Increase(-) in receivables                                      | -182               | -111               | -1 219            | -218               | -629              |
| Decrease(-)/Increase(+) in liabilities                                      | -4 572             | 747                | -13 702           | -1 340             | 10 754            |
| <b>Cash flow from operating activities</b>                                  | <b>-25 347</b>     | <b>-26 200</b>     | <b>-53 923</b>    | <b>-38 838</b>     | <b>-61 499</b>    |
| <b>Investing activities</b>                                                 |                    |                    |                   |                    |                   |
| Acquisition of equipment, tools and installation                            | -218               | 0                  | -218              | 0                  | -1 768            |
| <b>Cash flow from investing activities</b>                                  | <b>-218</b>        | <b>0</b>           | <b>-218</b>       | <b>0</b>           | <b>-1 768</b>     |
| <b>Financing activities</b>                                                 |                    |                    |                   |                    |                   |
| Share issue                                                                 | 0                  | 6 778              | 8 388             | 6 778              | 54 281            |
| Share issue costs                                                           | 0                  | 0                  |                   | 0                  | -3 069            |
| Warrants                                                                    | 0                  | 0                  |                   | 0                  | 0                 |
| <b>Cash flow from financing activities</b>                                  | <b>0</b>           | <b>6 778</b>       | <b>8 388</b>      | <b>6 778</b>       | <b>51 212</b>     |
| <b>Cash flow for the period</b>                                             | <b>-25 565</b>     | <b>-19 422</b>     | <b>-45 753</b>    | <b>-32 060</b>     | <b>-12 055</b>    |
| Cash and cash equivalents at the beginning of the period                    | 109 997            | 128 921            | 129 505           | 141 543            | 141 543           |
| Translation difference                                                      | -605               | 15                 | 75                | 31                 | 17                |
| <b>Cash and cash equivalents at the end of the period</b>                   | <b>83 827</b>      | <b>109 514</b>     | <b>83 827</b>     | <b>109 514</b>     | <b>129 505</b>    |

## INCOME STATEMENT (COMPANY)

| SEK '000                       | 2020<br>APRIL-JUNE | 2019<br>APRIL-JUNE | 2020<br>JAN.-JUNE | 2019<br>JAN.- JUNE | 2019<br>FULL YEAR |
|--------------------------------|--------------------|--------------------|-------------------|--------------------|-------------------|
| Net sales                      | 0                  | 0                  | 0                 | 0                  | 0                 |
| Other income                   | 465                | 560                | 1.064             | 1.159              | 2.280             |
| <b>Total income</b>            | <b>465</b>         | <b>560</b>         | <b>1.064</b>      | <b>1.159</b>       | <b>2.280</b>      |
| Research and development costs | -397               | -130               | -1.001            | -428               | -1.684            |
| Other external costs           | -1.752             | -1.163             | -3.284            | -1.786             | -3.753            |
| Staff costs                    | -1.123             | -1.284             | -2.327            | -2.524             | -4.624            |
| <b>Total costs</b>             | <b>-3.272</b>      | <b>-2.577</b>      | <b>-6.612</b>     | <b>-4.738</b>      | <b>-10.061</b>    |
| <b>Operating profit</b>        | <b>-2.807</b>      | <b>-2.017</b>      | <b>-5.548</b>     | <b>-3.579</b>      | <b>-7.781</b>     |
| Financial income               | -2.083             | 2.180              | 432               | 3.474              | 5.623             |
| Financial cost                 | -48                | -54                | -87               | -150               | -252              |
| <b>Financial items (net)</b>   | <b>-2.131</b>      | <b>2.126</b>       | <b>345</b>        | <b>3.324</b>       | <b>5.371</b>      |
| <b>Result before taxes</b>     | <b>-4.938</b>      | <b>109</b>         | <b>-5.203</b>     | <b>-255</b>        | <b>-2.410</b>     |
| Taxes                          | 0                  | 0                  | 0                 | 0                  | 0                 |
| <b>Result for the period</b>   | <b>-4.938</b>      | <b>109</b>         | <b>-5.203</b>     | <b>-255</b>        | <b>-2.410</b>     |

## BALANCE SHEET (COMPANY)

| SEK '000                            | 30-06-2020     | 30-06-2019     | 31-12-2019     |
|-------------------------------------|----------------|----------------|----------------|
| <b>ASSETS</b>                       |                |                |                |
| <b>Non-current assets</b>           |                |                |                |
| <b>Financial non-current assets</b> |                |                |                |
| Shares in subsidiaries              | 171.343        | 51             | 128.460        |
| Other long-term financial assets    | 1              | 1              | 1              |
| <b>Total non-current assets</b>     | <b>171.344</b> | <b>52</b>      | <b>128.461</b> |
| <b>Current assets</b>               |                |                |                |
| Receivables on group companies      | 11.628         | 106.169        | 2.231          |
| Current tax asset                   | 77             | 103            | 16             |
| Other receivables                   | 70             | 121            | 89             |
| Prepaid expenses and accrued income | 178            | 197            | 375            |
| <b>Total current receivables</b>    | <b>11.953</b>  | <b>106.590</b> | <b>2.711</b>   |
| Cash and cash equivalents           | 67.474         | 97.838         | 116.319        |
| <b>Total current assets</b>         | <b>79.427</b>  | <b>204.428</b> | <b>119.030</b> |
| <b>TOTAL ASSETS</b>                 | <b>250.771</b> | <b>204.480</b> | <b>247.491</b> |
| <b>EQUITY AND LIABILITIES</b>       |                |                |                |
| <b>Restricted equity</b>            |                |                |                |
| Share capital                       | 4.686          | 4.072          | 4.611          |
| <b>Total restricted equity</b>      | <b>4.686</b>   | <b>4.072</b>   | <b>4.611</b>   |
| <b>Unrestricted equity</b>          |                |                |                |
| Share premium reserve               | 272.813        | 220.605        | 264.500        |
| Accumulated losses                  | -24.518        | -22.108        | -22.108        |
| Result for the period               | -5.203         | -255           | -2.410         |
| <b>Total unrestricted equity</b>    | <b>243.092</b> | <b>198.242</b> | <b>239.982</b> |
| <b>Total equity</b>                 | <b>247.778</b> | <b>202.314</b> | <b>244.593</b> |
| <b>Current liabilities</b>          |                |                |                |
| Accounts payable                    | 401            | 316            | 280            |
| Liabilities to group companies      | 0              | 0              | 248            |
| Other current liabilities           | 83             | 519            | 147            |
| Accrued expenses and prepaid income | 2.509          | 1.331          | 2.223          |
| <b>Total current liabilities</b>    | <b>2.993</b>   | <b>2.166</b>   | <b>2.898</b>   |
| <b>TOTAL EQUITY AND LIABILITIES</b> | <b>250.771</b> | <b>204.480</b> | <b>247.491</b> |

# 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                                                                                                                                                                                                                                                     |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Solidity</b>               | 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. |
| <b>Return on equity</b>       | Result for the period divided by average adjusted equity.                                                                                                     | The KPI is included to show the return on the owners invested capital.                                                                                                                                                                                        |
| <b>Return on total assets</b> | 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<br>APRIL - JUNE | 2019<br>APRIL - JUNE | 2020<br>JAN. - JUNE | 2019<br>JAN. - JUNE |
|--------------------------|----------------------|----------------------|---------------------|---------------------|
| Equity                   | 91.294               | 109.723              | 91.294              | 109.723             |
| + Untaxed reserves       | 0                    | 0                    | 0                   | 0                   |
| - Deferred tax liability | 0                    | 0                    | 0                   | 0                   |
| <b>Adjusted equity</b>   | <b>91.294</b>        | <b>109.723</b>       | <b>91.294</b>       | <b>109.723</b>      |
| Adjusted equity          | 91.294               | 109.723              | 91.294              | 109.723             |
| Total assets             | 95.730               | 118.053              | 95.730              | 118.053             |
| <b>Equity ratio, %</b>   | <b>95,4</b>          | <b>92,9</b>          | <b>95,4</b>         | <b>92,9</b>         |

### RETURN ON EQUITY

| SEK '000                   | 2020<br>APRIL - JUNE | 2019<br>APRIL - JUNE | 2020<br>JAN. - JUNE | 2019<br>JAN. - JUNE |
|----------------------------|----------------------|----------------------|---------------------|---------------------|
| Result for the period      | -20.679              | -25.820              | -39.048             | -35.250             |
| Average adjusted equity    | 101.320              | 119.689              | 105.382             | 124.817             |
| <b>Return on equity, %</b> | <b>-20,4</b>         | <b>-21,6</b>         | <b>-37,1</b>        | <b>-28,2</b>        |

### RETURN ON TOTAL ASSETS, %

| SEK '000                         | 2020<br>APRIL - JUNE | 2019<br>APRIL - JUNE | 2020<br>JAN. - JUNE | 2019<br>JAN. - JUNE |
|----------------------------------|----------------------|----------------------|---------------------|---------------------|
| Result before tax                | -20.679              | -25.820              | -39.048             | -35.250             |
| + Interest costs                 | 668                  | 101                  | 830                 | 198                 |
| Average total assets             | 109.186              | 127.644              | 117.812             | 133.817             |
| <b>Return on total assets, %</b> | <b>-18,3</b>         | <b>-20,1</b>         | <b>-32,4</b>        | <b>-26,2</b>        |

## CERTIFIED ADVISER

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