

ASARINA PHARMA AB (PUBL)

INTERIM REPORT THIRD QUARTER 2021

1 July – 30 September 2021



**REMAIN IN
CONTROL
OF YOUR LIFE**



ASARINA PHARMA AB

(PUBL) 556698-0750

INTERIM REPORT, THIRD QUARTER 2021

ABOUT ASARINA PHARMA

We are a Swedish biotech company developing Sepranolone for allopregnanolone-induced stress and compulsivity-driven disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. With our new family of GAMSA compounds (GABA_A Modulating Steroid Antagonists) we aim to deliver a new generation of safe, efficacious drugs for neurological conditions from Tourette syndrome to Obsessive-compulsive disorder that still lack safe, efficacious pharmaceutical treatments.

ASARINA PHARMA AB

Karolinska Institutet Science Park | Fogdevreten 2, SE 171 65 Solna, Sweden

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



OVERVIEW



Jakob Dynnes Hansen
Chief Financial Officer

FINANCIAL HIGHLIGHTS

- Significant reduction in operating costs in Q3
- Cash position on 30 September (SEK 23.5 million) still expected to cover Tourette study

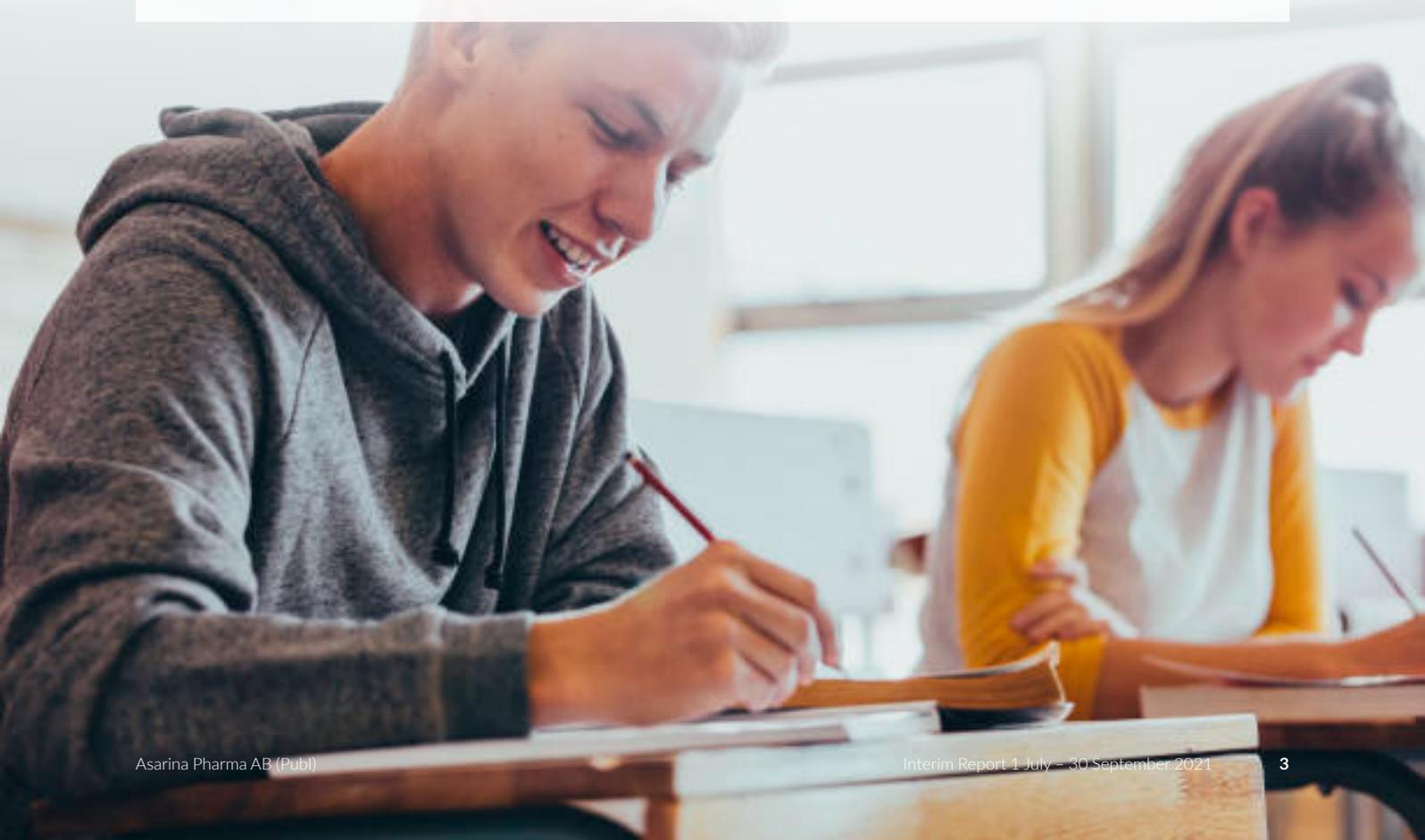
R&D HIGHLIGHTS

✓ TOURETTE SYNDROME

Following a delay from Region Hovedstaden (the Capital Region of Denmark) we expect final, complete legal approval for our phase II proof of concept study in Tourette to be signed in Q4 2021, with the first patient to receive first dose of Sepranolone in December.

✓ OCD

This Quarter we have continued internal discussions on how best to finance a clinical study in OCD. This follows the granting of a US patent for Sepranolone for the treatment of Tourette, Obsessive-compulsive Disorder (OCD) and pathological gambling in June (valid until 2038).



CEO STATEMENT

DEAR ASARINA SHAREHOLDER,

Q3 2021 was a frustrating quarter for us and our shareholders. The CTA for our Phase II proof of concept study in Tourette was approved by the Danish Medical Agency in May and the approval from the ethics committee was obtained in August. The two University Hospital centers in Copenhagen were ready to enroll patients in early September as previously announced. Despite these approvals, the study has been delayed by three months as Region Hovedstaden (the Capital Region of Denmark) will not be able to sign the site agreements until Q4 2021 on behalf of the two clinical centers. The first patients should thus be enrolled in December pushing topline results till Q4 2022.

THE QUARTER'S HIGHLIGHTS

TOURETTE SYNDROME

Our Clinical trial application (CTA) was approved by the Danish Medical authority (DKMA) in May and approval from the ethics committee was received in August. We expect the legal approval for the study sites to be signed in Q4 2021 and the first patient to receive their first dose of Sepranolone in December.

OCD

The US Patent and Trademark Office granted a patent for Sepranolone for the treatment of Tourette, Obsessive-compulsive Disorder (OCD) and pathological gambling in June. The new patent is valid until 2038. This Quarter we have continued internal discussions on how best to finance a clinical study in OCD and we remain strongly committed to Sepranolone's possibilities in this important indication.

”” *We remain strongly committed to Sepranolone's possibilities in the important indication of OCD.*

Peter Nordkild,
CEO Asarina Pharma



THE QUARTER IN-DEPTH

TOURETTE SYNDROME

Our Phase IIa study will include 30 patients with or without OCD from the age of 12 to 45 years. 20 patients will receive 10 mg Sepranolone twice weekly for 16 weeks in addition to their standard Tourette treatment and 10 patients will continue on their standard Tourette treatment.

The study will be conducted at the Danish National Center for Tourette at Herlev and Bispebjerg University hospitals. Bispebjerg will primarily treat adult patients with Tourette; whilst Herlev University Hospital, a leading research hospital with Scandinavia's largest Tourette department, is expected to focus on children and teenagers. We expect the first patient to receive the first injection in December and to be able to publish topline results in Q4 2022.

OBSESSIVE-COMPULSIVE DISORDER

This Quarter our confidence in the scientific case for Sepranolone was further strengthened by the release in September of our post hoc Phase IIb PMDD study, which further demonstrated Sepranolone's ability to suppress symptoms affected by elevated allopregnanolone levels.

Combined with the additional OCD data we released in March⁽¹⁾ and original research carried out by Marco Bortolato's team at the University of Utah⁽²⁾ these new data strengthen our thesis that there is a clear connection between increased allopregnanolone levels and worsening of compulsions – and that Sepranolone can safely suppress and mediate those symptoms.

1.5% of all women and 1% of all men suffer from OCD - yet there remains no safe, highly efficacious pharma medication (SSRIs have an overall efficacy of <50%). Additionally, this quarter we have seen increased public and policy awareness of Tourette, particularly in Sweden, with the media highlighting its terrible impact on children. This growing medical and public understanding, plus valuable new data on Sepranolone have all underlined our commitment. OCD remains a key middle-to long-term priority for Asarina Pharma moving ahead.



**1.5% OF ALL WOMEN
AND 1% OF ALL MEN
SUFFER FROM OCD**

1. Preliminary study of finasteride in Tourette syndrome, Moroni, Bortolato et al, 2011

2. Behavioral fragmentation in the D1CT-7 mouse model of Tourette's syndrome, Bortolato et al 2018



FINANCES

As a result of the disappointing results in menstrual migraine, almost all CMC and autoinjector activities have been put on hold and the work time of all staff has been further reduced. The team and thus the competencies are still intact which I personally find the best guarantee for the future of Asarina. With these changes we have managed to reduce our cash burn significantly and the present cash will cover the cost of the Tourette study and last at least till the beginning of 2023.

MOVING FORWARD

We remain committed to working together with renewed determination to achieve positive results in our ongoing vital projects, delivering a renewed, prosperous future for all of our stakeholders and patients.

Thanks again for your commitment, and we look forward to moving ahead – together.

WARM WISHES,



Peter Nordkild,
CEO Asarina Pharma

FINANCIAL INFORMATION AND OTHER DETAILS

KEY FINANCIALS

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Net income, KSEK	0	0	0	0	0
Operating profit/loss, KSEK	-8,064	-17,535	-30,851	-56,494	-81,406
Profit/loss for the period, KSEK	-8,122	-17,561	-30,590	-56,609	-82,994
Earnings per share, fully-diluted, SEK	-0.40	-0.90	-1.53	-2.89	-3.84
Total assets (end of period), KSEK	32,727	77,084	32,727	77,084	68,285
Cash and cash equivalents (end-of-period), KSEK	23,256	65,111	23,256	65,111	58,501
Equity ratio, %	67.9	92.6	67.9	92.6	77.0
Return on equity, %	-31.0	-21.6	-81.8	-59.3	-87.5
Return on total assets, %	-21.1	-20.9	-60.1	-51.8	-78.2

REVENUE

Net income in Q3/2021 amounted to 0.0 (0.0) MSEK.

OPERATING EXPENSES

Total operating expenses for the 3rd quarter 2021 declined to 8.1 (17.5) MSEK reflecting the completion of the migraine program in the 2nd quarter and the delayed start of the Tourette Study. In particular, research and development costs dropped to only 5.8 (14.6) MSEK. Staff costs declined to 1.4 (2.1) MSEK due to the reduction in 2020 of the working time for all staff members. General and administration costs amounted to 0.7 (0.8) MSEK.

FINANCIAL ITEMS AND TAX

Financial items which comprise interest expenses as well as currency gains and losses resulted in a loss of 0.1 (0.0) MSEK.

No tax income was booked in the 3rd quarter, but the Company is still benefiting from the Danish tax credit scheme for R&D costs. The payment of the tax credit for 2020 is expected in the 4th quarter 2021.

RESULT AND FINANCIAL POSITION

The net result for the 3rd quarter 2021 amounted to -8.1 (- 17.6) MSEK.

The operating cash flow declined to - 10.6 MSEK (-18.4 MSEK) which confirms that the 3rd quarter was an "interim period" between two clinical studies. On 30 September 2021, the cash balance at group level amounted to 23.3 (65.1) MSEK which the Company considers sufficient to finance the Phase IIa study in Tourette Syndrome. The shareholders' equity on 30 September 2021 amounted to 22.2 (71.4) MSEK equal to an equity ratio of 67.9 (92.6) %.

STAFF

As of 30 September 2021, Asarina's operating team comprised 8 members (employees and long-term consultants), corresponding to 3½ (5½) FTEs. The working time was reduced for all team members as of 1 October 2021.

NOTE | Amounts in brackets refer to the 3rd quarter in 2020 unless otherwise stated.

THE ASARINA PHARMA SHARE

As of 30 September 2021, Asarina has issued a total of 18,744,524 shares, which are held by an estimated 3,500 shareholders. During the 3rd quarter 2021, the holdings of the major shareholders changed only moderately.

OWNERSHIP AS OF 30 SEPTEMBER 2021*

SHAREHOLDER	COUNTRY	NO. OF SHARES	OWNERSHIP %
Kurma Biofund	France	3,145,132	16.8
Ôstersjöstiftelsen (Baltic Foundation)	Sweden	2,667,092	14.2
Idinvest Patrimoine	France	1,639,824	8.7
Fjärde AP-fonden (AP4)	Sweden	1,585,000	8.5
Handelsbanken Läkemedelsfond	Sweden	855,952	4.6
Avanza Pension	Sweden	458,366	2.4
Torbjörn Bäckström	Sweden	324,989	1.7
Torbjörn Persson	Sweden	280,868	1.5
Peter Nordkild (CEO)	Denmark	263,124	1.4
Nordnet Pension	Sweden	250,000	1.3
Others		7,274,177	38.8
TOTAL		18,744,524	100.0

*Source: Euroclear, company estimates

The Company has established three warrant programs for board and staff members comprising a total of 1,560,822 warrants. Each warrant entitles the holder to subscribe one new Asarina share at fixed prices between SEK 9.87 and 28.73. One warrant program dating from September 2018 will expire on 31 December 2021.

EVENTS AFTER THE END OF THE REPORT PERIOD

No event has happened after the end of the 3rd quarter which could significantly change Asarina's financial position.

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 the parent company's financial position and result of operations and describes material risks and uncertainties facing the Group.

Stockholm, 25 November 2021

Asarina Pharma AB

Board of directors

FINANCIAL CALENDAR FOR 2022

24 February 2022

Report for 4th quarter and year-end 2021

6 April 2022

Annual report 2021

PUBLICATION

The report was submitted for publication by the CEO at 08.00 CET on 25 November 2021.

This report has not been reviewed by the company's auditors.

CONSOLIDATED INCOME STATEMENT

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Net sales	0	0	0	0	0
Other income	0	0	0	0	0
Total operating income	0	0	0	0	0
Research and development costs	-5,828	-14,587	-22,740	-43,815	-63,749
Other external costs	-698	-807	-3,008	-4,877	-7,444
Staff costs	-1,441	-2,141	-4,812	-7,802	-10,124
Depreciation	-97	0	-291	0	-89
Total operating costs	-8,064	-17,535	-30,851	-56,494	-81,406
Operating profit/loss	-8,064	-17,535	-30,851	-56,494	-81,406
Financial income (interest income, currency gains)	30	-481	506	260	6
Financial cost (interest expenses, currency losses)	-88	455	-245	-375	-1,594
Net financial items	-58	-26	261	-115	-1,588
Profit/loss before tax	-8,122	-17,561	-30,590	-56,609	-82,994
Tax on profit/loss	0	0	0	0	7,738
Profit/loss for the period	-8,122	-17,561	-30,590	-56,609	-75,256

EARNINGS PER SHARE

	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Number of shares, average (non-diluted)	18,744,524	18,744,524	18,744,524	18,689,465	18,703,305
Number of shares, average (fully-diluted)	20,320,346	19,620,346	19,943,423	19,556,747	19,572,734
Earnings per share, non-diluted, (SEK)	-0.43	-0.94	-1.63	-3.03	-4.02
Earnings per share, fully-diluted, (SEK)	-0.40	-0.90	-1.53	-2.89	-3.84
Number of shares, end of period (non-diluted)	18,744,524	18,744,524	18,744,524	18,744,524	18,744,524
Number of shares, end of period (fully-diluted)	20,320,346	19,620,346	20,320,346	19,620,346	19,620,346

CONSOLIDATED BALANCE SHEET

SEK '000	2021-09-30	2020-09-30	2020-12-31
ASSETS			
Non-current assets			
Property, plant and equipment	1,570	2,012	1,832
Financial non-current assets	1	1	1
Total non-current assets	1,571	2,013	1,833
Current assets			
<i>Current receivables</i>			
Current tax asset	7,626	7,893	7,532
Other receivables	210	1,858	247
Prepaid expenses and accrued income	64	209	172
Total current receivables	7,900	9,960	7,951
Cash and cash equivalents	23,256	65,111	58,501
Total current assets	31,156	75,071	66,452
TOTAL ASSETS	32,727	77,084	68,285
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,686	4,686	4,686
Total restricted equity	4,686	4,686	4,686
Unrestricted equity			
Share premium reserve	272,813	272,813	272,813
Retained earnings	-224,696	-149,526	-149,731
Profit/loss for the period	-30,590	-56,609	-75,170
Total unrestricted equity	17,527	66,678	47,912
TOTAL EQUITY	22,213	71,364	52,598
Non-current liabilities			
Convertible loan	5,300	0	0
Total non-current liabilities	5,300	0	0
Current liabilities			
Accounts payable	953	1,715	11,308
Other current liabilities	32	81	107
Accrued expenses and prepaid income	4,229	3,924	4,272
Total current liabilities	5,214	5,720	15,687
Total liabilities	10,514	5,720	15,687
TOTAL EQUITY AND LIABILITIES	32,727	77,084	68,285

STATEMENT OF CHANGES IN EQUITY FOR THE GROUP

SEK '000	SHARE CAPITAL	SHARE PREMIUM RESERVE	ACCUMULATED LOSSES INCL LOSS FOR THE PERIOD	TOTAL EQUITY
Opening balance 1 January 2020	4,611	264,500	-149,641	119,470
Share issue	75	8,313		8,388
Issue of warrants			504	504
Translation difference			-508	-508
Loss for the period			-75,256	-75,256
Closing balance 31 December 2020	4,686	272,813	-224,901	52,598
Opening balance 1 January 2021	4,686	272,813	-224,901	52,598
Share issue				0
Issue of warrants		371		371
Translation difference			-166	-166
Loss for the period			-30,590	-30,590
Closing balance 30 September 2021	4,686	273,184	-255,657	22,213

CONSOLIDATED STATEMENT OF CASH FLOWS

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Operating activities					
Operating profit/loss	-8,064	-17,535	-30,851	-56,494	-81,406
Adjustment for non-cash flow affecting items					
Depreciation	98	0	291	0	89
Interest received	-179	750	297	1,122	6
Interest paid	-81	-882	-239	-1,236	-1,580
Paid taxes	-30	-31	31	-92	7,641
Cash flow for operating activities before changes in working capital	-8,256	-17,698	-30,471	-56,700	-75,250
Cash flow from changes in working capital					
Decrease(+)/Increase(-) in receivables	270	-9,578	151	-10,797	496
Decrease(-)/Increase(+) in liabilities	-2,582	8,922	-10,650	-4,780	-4,314
Cash flow from operating activities	-10,568	-18,354	-40,970	-72,277	-79,068
Investing activities					
Acquisition of equipment, tools and installation	0	-1	0	-219	-218
Cash flow from investment activities	0	-1	0	-219	-218
Financing activities					
Convertible loan received	0	0	5,300	0	0
Share issue	0	0	0	8,388	8,388
Share issue costs	0	0	0	0	0
Issue of warrants	0	0	371	0	0
Cash flow from financing activities	0	0	5,671	8,388	8,388
Cash flow for the period	-10,568	-18,355	-35,299	-64,108	-70,898
Cash and cash equivalents at the beginning of the period	33,552	83,827	58,501	129,505	129,505
Translation difference	272	-361	54	-286	-106
Cash and cash equivalents at the end of the period	23,256	65,111	23,256	65,111	58,501

PARENT COMPANY INCOME STATEMENT

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Net sales	0	0	0	0	0
Other income	0	209	0	1,273	1,454
Total operating income	0	209	0	1,273	1,454
Research and development costs	-143	-329	-852	-1,330	-1,822
Other external costs	-475	-609	-2,238	-3,893	-4,766
Staff costs	-617	-993	-1,898	-3,320	-2,712
Total operating costs	-1,235	-1,931	-4,988	-8,543	-9,300
Operating profit/loss	-1,235	-1,722	-4,988	-7,270	-7,846
Financial income (interest income, currency gains)	29	60	413	492	338
Financial cost (interest expenses, currency losses)	-64	-33	-85	-120	-821
Net financial items	-35	27	328	372	-483
Profit/loss before tax	-1,270	-1,695	-4,660	-6,898	-8,329
Tax on profit/loss	0	0	0	0	0
Profit/loss for the period	-1,270	-1,695	-4,660	-6,898	-8,329

PARENT COMPANY BALANCE SHEET

SEK '000	2021-09-30	2020-09-30	2020-12-31
ASSETS			
Non-current assets			
<i>Financial non-current assets</i>			
Shares in subsidiaries	232,365	181,715	191,715
Other non-current financial assets	1	1	1
Financial non-current assets	232,366	181,716	191,716
Current assets			
<i>Current receivables</i>			
Receivables from group companies	3,122	12,396	13,994
Current tax asset	81	107	112
Other receivables	87	176	107
Prepaid expenses and accrued income	64	210	172
Total current receivables	3,354	12,889	14,385
Cash and cash equivalents	14,299	55,075	42,303
Total current assets	17,653	67,964	56,688
TOTAL ASSETS	250,019	249,680	248,404
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	4,686	4,686	4,686
Total restricted equity	4,686	4,686	4,686
Unrestricted equity			
Share premium reserve	272,813	272,813	272,813
Retained earnings	-31,972	-24,014	-24,518
Profit/loss for the period	-4,660	-6,898	-7,825
Total unrestricted equity	236,181	241,901	240,470
TOTAL EQUITY	240,867	246,587	245,156
Non-current liabilities			
Convertible loan	5,300	0	0
Total current liabilities	5,300	0	0
Current liabilities			
Accounts payable	131	260	372
Liabilities to group companies	0	0	0
Other current liabilities	32	81	107
Accrued expenses and prepaid income	3,689	2,752	2,769
Total current liabilities	3,852	3,093	3,248
Total liabilities	9,152	3,093	3,248
TOTAL EQUITY AND LIABILITIES	250,019	249,680	248,404

NOTES

1. GENERAL INFORMATION

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

2. ACCOUNTING PRINCIPLES

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

The accounting principles adopted in this interim report are consistent with those of the 2020 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, Asarina's operations mainly consist of pre-clinical and clinical studies in order to demonstrate safety and clinical efficacy of its drug candidates. There is no guarantee that a certain (pre-) clinical trial will generate the required data to enable Asarina to progress to the subsequent development phase of the product candidate. Asarina's goal is to gradually build a portfolio of different pharmaceutical candidates for other indications, thereby reducing risk.

Clinical trials may be delayed and costs for the trial may exceed budget. Prior to initiating a clinical trial, Asarina conducts a thorough assessment of the duration and the costs of the trial to ensure that it has sufficient funding to complete the trial taking into account possible delays and cost increases.

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 the regulatory risks, the Company retains regulatory consultants as part of the preparation of new clinical studies.

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

FINANCIAL RISKS

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. Asarina aims to have sufficient liquidity for its planned activities for the next 1-2 years. Therefore, Asarina may at any point have discussions with current or potential new investors, which may be interested in injecting new finance into the Company.

Asarina incurs costs mainly in Swedish kronor and Euro. The Company mitigates its exchange rate risk by allocating its financial reserves according to the expected break-down of expenses between the two 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	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Equity	22,213	71,364	22,213	71,364	52,598
+ Untaxed reserves	0	0	0	0	0
- Deferred tax liability	0	0	0	0	0
Adjusted equity	22,213	71,364	22,213	71,364	52,598
Adjusted equity	22,213	71,364	22,213	71,364	52,598
Total assets	32,727	77,084	32,727	77,084	68,285
Equity ratio, %	67.9	92.6	67.9	92.6	77.0

RETURN ON EQUITY

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Result for the period	-8,122	-17,561	-30,590	-56,609	-75,256
Average adjusted equity ¹	26,222	81,329	37,406	95,417	86,034
Return on equity, %	-31.0	-21.6	-81.8	-59.3	-87.5

RETURN ON TOTAL ASSETS, %

SEK '000	2021 JUL-SEP	2020 JUL-SEP	2021 JAN-SEP	2020 JAN-SEP	2020 FULL YEAR
Result before tax	-8,122	-17,561	-30,590	-56,609	-82,994
+ Interest costs	88	-455	245	375	1,594
Average total assets ¹	38,009	86,407	50,506	108,489	104,090
Return on total assets, %	-21.1	-20.9	-60.1	-51.8	-78.2

CERTIFIED ADVISER

The company's certified adviser is Erik Penser Bank.
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