

Sareum Holdings PLC

("Sareum" or the "Company")

Half-Year Report for the Six Months Ended 31 December 2023

Cambridge, UK, 28 March 2024 – Sareum Holdings plc (AIM: SAR), a biotechnology company developing next generation kinase inhibitors for autoimmune disease and cancer, announces its unaudited results for the six months ended 31 December 2023.

Sareum also provides a broader update on its operational activities and pipeline progress.

OPERATIONAL HIGHLIGHTS – INCLUDING POST-PERIOD UPDATES

SDC-1801 (autoimmune disease)

SDC-1801 is a TYK2/JAK1 inhibitor being developed as a potential new therapeutic for a range of autoimmune diseases with an initial focus on psoriasis, an autoimmune condition affecting the skin.

- After the period end, Sareum announced the completion of the single ascending dose (SAD) element and the food effect study of a Phase 1a clinical trial for the lead programme SDC-1801.
- Preliminary blinded safety, tolerability and pharmacokinetics data from the trial indicate a favourable profile and support once daily oral dosing of patients.
- These preliminary results indicate that SDC-1801 has the potential to achieve therapeutically effective dose levels with no serious adverse events.
- The multiple ascending dose (MAD) study of SDC-1801 is ongoing and topline data from the Phase 1a clinical trial are expected to be available during Q2 2024.
- Sareum's intellectual property portfolio has been strengthened with patent grants in China in June 2023 and Japan in November 2023. Post-period, in March 2024, the European Patent Office has issued a Notice of Allowance for a patent relating to SDC-1801.

SDC-1802 (cancer immunotherapy)

SDC-1802 is a TYK2/JAK1 inhibitor being developed for cancer immunotherapy.

- Sareum continued to work on the translational studies needed to support development of SDC-1802 during the period, in order define the optimal cancer application before completing toxicology and manufacturing studies, but the Company will now focus its resources on the clinical development of SDC-1801.

SRA737 (cancer)

SRA737 is a clinical-stage oral, selective Checkpoint kinase 1 inhibitor that targets cancer cell replication and DNA damage repair mechanisms.

- After the period end, on 2 January 2024, Sareum announced the Company's co-development partner, the CRT Pioneer Fund ("CPF"), has entered into a development and commercialisation licence agreement for SRA737 with a private biopharma company based in the United States.

- Under the terms of Sareum’s co-development agreements with CPF and Cancer Research Technology Ltd, Sareum is entitled to receive 27.5% of any income arising from this licensing of the SRA737 programme.
- Post period end, Sareum earned US\$137,500 pursuant to the upfront fee payable under the Licensing Agreement. The Company is also entitled to receive 27.5% of any future payments payable by the Licensee Company (including any Consideration Shares received), under the terms of the Licensing Agreement.

FINANCIAL HIGHLIGHTS

- Cash at 31 December 2023 of £0.4m (£2.9m as of 31 December 2022 and £1.0m as of 30 June 2023).
- Loss on ordinary activities after taxation for the six months ended 31 December 2023 of £2.5m, reflecting increased investment in clinical studies and a finance charge resulting from the Riverfort facility (2022: loss of £1.4m).
- Post period end a UK R&D tax credit of £0.4m received in January 2024.
- Post period end, the Company is today announcing a conditional equity fundraise of up to £1.5m (before expenses), via the issue of a total of up to 15,000,000 new ordinary shares of 1.25 pence each in the capital of the Company (“Ordinary Shares”) at a price of 10 pence per new Ordinary Share (the “Placing Price”) (the “Fundraise”).
- Up to £0.3m of the total Fundraise will be offered to retail shareholders via the Winterflood Retail Access Platform through the issue of new Ordinary Shares at the Placing Price.

Dr Tim Mitchell, Chief Executive Officer of Sareum, commented:

“Sareum is making steady progress with the ongoing trial of SDC-1801 and the data we have seen so far support our confidence that it has the potential to deliver therapeutically effective dose levels with no serious adverse events.

“More broadly, we’re increasingly encouraged by the potential of the TYK2/JAK1 class, both from a scientific and commercial perspective.”

“With the additional funding that will be announced today, we are well placed to complete the Phase 1a clinical trial of SDC-1801.”

“We look forward to the topline data from the MAD part of our Phase 1a clinical trial in Q2 2024, and to continuing to progress this promising molecule through clinical development.”

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About Sareum

Sareum (AIM: SAR) is a biotechnology company developing next generation kinase inhibitors for autoimmune disease and cancer.

The Company is focused on developing next generation small molecules which modify the activity of the JAK kinase family and have best-in-class potential. Its lead candidate, SDC-1801, simultaneously inhibits TYK2 and JAK1. SDC-1801 is a potential treatment for a range of autoimmune diseases, and is planned to enter clinical development with an initial focus on psoriasis.

Sareum is also developing SDC-1802, a TYK2/JAK1 inhibitor with a potential application for cancer immunotherapy.

Sareum Holdings plc is based in Cambridge, UK, and is quoted on the AIM market of the London Stock Exchange, trading under the ticker SAR. For further information, please visit the Company's website at www.sareum.com

CHAIRMAN'S STATEMENT

Sareum has made good progress during and after this period progressing its lead clinical asset, SDC-1801, through a Phase 1a study. The single ascending dose (SAD) part and the food effect study of SDC-1801 have progressed well, giving the Company continued confidence over the clinical momentum in the trial and optimism as we move towards the completion the study.

The multiple ascending dose (MAD) portion of SDC-1801 is nearing completion. Sareum aims to conclude this part of the trial by the end of Q2 2024. Subject to data review, additional funding and/or potential licencing opportunities, we endeavour to be in a position to commence a Phase 2a study in psoriasis patients before the end of 2024.

It is becoming increasingly clear that the TYK2/JAK1 class offers great potential for the treatment of autoimmune disease, with potential for broad coverage and increased efficacy across key targets, lower toxicity and potentially stronger efficacy. We believe SDC-1801 has the potential to be a best-in-class TYK2/JAK1 inhibitor for autoimmune diseases and we're excited about its progress in this ongoing clinical study. While the MAD study is still in progress, interim data shows that levels of SDC-1801 in blood are already in the expected therapeutic range, and achieve concentrations greater than those predicted to reduce signalling of cytokines dependent on TYK2 and/or JAK1 activity by 50% for a sustained period following once daily oral dosing. Safety data remains blinded, but no serious adverse events have been reported to date.

We were also encouraged that, after the period end, Sareum's co-development partner, the CPF entered into a development and commercialisation license agreement for SRA737 with a private

biopharma company based in the US. We are delighted that a partner has been identified to take this molecule forward into further development.

We look forward to providing further updates in due course.

PROGRAMME UPDATES

SDC-1801

SDC-1801 is a TYK2/JAK1 inhibitor being developed as a potential new therapeutic for a range of autoimmune diseases with an initial focus on psoriasis, an autoimmune condition affecting the skin.

SDC-1801 is currently in a Phase 1a trial, designed to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of an oral formulation of SDC-1801 in healthy subjects (trial ID ACTRN12623000416695p). This is a randomised, placebo-controlled trial with single and multiple ascending oral dose studies. This trial includes a single ascending dose study (Part 1), a multiple ascending dose study (Part 2) and a food effects study (Part 3).

Dosing of the final subjects in the SAD part of the trial has now concluded and the safety review committee for the trial has reviewed available data. The SAD study randomised participants in a 3:1 ratio to a single dose of SDC-1801 or placebo in six dose cohorts. Preliminary blinded safety, tolerability and pharmacokinetics data from the trial indicate a favourable profile and support one daily oral dosing of patients. These preliminary results indicate that SDC-1801 has the potential to achieve therapeutically effective dose levels with no serious adverse events.

The food effect study part of the trial has also been completed. The results of this study demonstrated no significant food effect on SDC-1801 blood levels, which will allow full flexibility in dose timing in future clinical studies.

The MAD study is nearing completion and topline data from the Phase 1a clinical trial are expected to be available during Q2 of 2024. If the results are satisfactory, the Company plans to assess funding and licensing options to further the development of SDC-1801 through a Phase 2a trial.

The goal of the proposed Phase 2a trial would be to recruit up to 24 psoriasis patients, with the study expected to be started by the end of 2024.

SDC-1802

SDC-1802 is a TYK2/JAK1 inhibitor being developed for cancer and cancer immunotherapy applications.

The Company is now prioritising existing resources on the clinical development of its lead product, SDC-1801.

FINANCIAL REVIEW

At 31 December 2023 Sareum had cash of £0.4m (2022: £2.9m) and subsequently received a UK R&D tax credit of £0.4m in January 2024.

The loss on ordinary activities after taxation for the six months ended 31 December 2023 was £2.5m (2022: loss of £1.4m), reflecting ongoing clinical trial preparation costs and a finance charge resulting from the Riverfort facility.

As announced on 12 March 2024, due to downward pressure on the Company's share price, Sareum was unable to draw down the third prepayment of £0.3m under the Equity Prepayment Facility with RiverFort entered into on 3 August 2023 (the "**Facility**"). The Company is today announcing a conditional equity fundraise of up to £1.5m (before expenses), via the issue of a total of up to 15,000,000 new Ordinary Shares at the Placing Price of 10 pence per new Ordinary Share (the "**Fundraise**"). The net proceeds from the Fundraise are intended to be used by the Company to complete its SDC-1801 Phase 1a clinical studies and, together with the receipt of anticipated R&D tax credits in the amount of £0.7m which is expected in September 2024, for general working capital purposes.

Furthermore, as part of the Company's ongoing steps to minimise its cash utilisation, certain Directors and advisers have agreed to settle cash amounts owed in new Ordinary Shares and the Directors have agreed to defer a portion of their salaries going forward, so as to ensure the completion of the SDC-1801 Phase 1a clinical trial can be achieved. Further details will be included in the Company's announcement regarding the Fundraise.

The Company has drawn £2.3m to date pursuant to the Facility from two prepayment deposits. Any amounts drawn under the Facility are due for settlement by August 2025 (the "**Maturity Date**"), either by the issues of shares or repayment in cash. As at 31 December 2023 there was a balance of £1.6m remaining to be settled, and as of 26 March 2024 this balance was £1.1m. The Company expects to settle this by the issuance of shares or cash payment prior to the Maturity Date. No further drawdown are expected to be made under the Facility.

OUTLOOK

Sareum has successfully completed the SAD segment and the food effect study of its Phase 1a clinical trial for its leading program, SDC-1801. These initial findings suggest that SDC-1801 has the potential to reach therapeutically effective dosage levels without causing any serious adverse events.

The MAD portion of SDC-1801 is nearing completion. The Fundraise announced today along with certain cash cost savings being implemented, will provide the Company with sufficient capital to complete its Phase 1a clinical trial and topline data from the Phase 1a trial are expected to be available by the end of Q2 2024. If the results are satisfactory, the Company plans to assess funding and licensing options to further the development of SDC-1801 through a Phase 2a trial.

Our preclinical findings and the growing commercial and scientific momentum building around the TYK2/JAK1 class, support our continued excitement about the potential for SDC-1801 to be a superior option to approved oral therapies for the treatment of autoimmune diseases.

The Board of Sareum continues to apply a rigorous approach to capital allocation to the development of our assets, particularly in the current challenging economic environment, and maintains a clear focus on bringing these medicines to patients as efficiently as possible, while maximising value for shareholders.

Consolidated Statement of Comprehensive Income for the six months ended 31 December 2023

	Notes	Unaudited Six months ended 31 Dec 23 £'000	Unaudited Six months ended 31 Dec 22 £'000	Audited Year ended 30 Jun 23 £'000
Revenue		-	-	-
Other operating income		-	-	-
Operating expenses		(2,536)	(1,748)	(4,048)
Share of profit/(loss) of associate		4	-	(18)
Operating loss		(2,532)	(1,748)	(4,066)
Finance expense		(761)	-	-
Finance income		19	17	41
Loss before tax		(3,274)	(1,731)	(4,025)
Tax	3	765	285	833
Loss on ordinary activities after taxation		(2,509)	(1,446)	(3,192)
Total comprehensive income for the period		(2,509)	(1,446)	(3,192)
Total comprehensive income attributable to:				
Owners of the parent		(2,509)	(1,446)	(3,192)
Basic and diluted loss per share (pence)	5	(3.6)p	(2.1)p	(4.7)p

Consolidated Balance Sheet as at 31 December 2023

	Note	Unaudited As at 31 Dec 2023 £'000	Unaudited As at 31 Dec 2022 £'000	Audited As at 30 Jun 2023 £'000
Non-current assets				
Computers and equipment		-	1	1
Investment in associate		46	23	46
		46	24	47
Current assets				
Debtors		1,513	380	979
Cash and cash equivalents		408	2,941	994
		1,921	3,321	1,973
Creditors: amounts due within one year		(489)	(460)	(867)
Net current assets		1,432	2,861	1,106
Total assets less current liabilities		1,478	2,885	1,153
Creditors: amounts due after one year	2	(1,061)	-	-
Net assets		417	2,885	1,153
Equity				
Called-up share capital		878	851	851
Share premium		22,675	20,925	20,925
Share-based compensation reserve		311	325	325
Foreign exchange reserve		10	-	14
Retained earnings		(23,457)	(19,216)	(20,962)
Total equity		417	2,885	1,153

Consolidated Statement of Changes in Equity for the six months ended 31 December 2023

	Share capital £'000	Share premium £'000	Share-based compensation reserve £'000	Foreign exchange reserve £'000	Retained earnings £'000	Total £'000
As at 30 June 2022 (audited)	851	20,925	325	-	(17,770)	4,331
Loss for the period	-	-	-	-	(1,446)	(1,446)
As at 31 December 2022 (unaudited)	851	20,925	325	-	(19,216)	2,885
Arising on consolidation	-	-	-	14	-	14
Loss for the period	-	-	-	-	(1,746)	(1,746)
As at 30 June 2023 (audited)	851	20,925	325	14	(20,962)	1,153
Issue of share capital (net)	27	1,750	-	-	-	1,777
Transfer in respect of options exercised	-	-	(14)	-	14	-
Arising on consolidation	-	-	-	(4)	-	(4)
Loss for the period	-	-	-	-	(2,509)	(2,509)
As at 31 December 2023 (unaudited)	878	22,675	311	10	(23,457)	417

Consolidated Cash Flow Statement for the six months ended 31 December 2023

	Unaudited Six months ended 31 Dec 2023 £'000	Unaudited Six months ended 31 Dec 2022 £'000	Audited Year ended 30 Jun 2023 £'000
Net cash flow from operating activities			
Continuing operations:			
Loss before tax	(3,274)	(1,731)	(4,024)
Add back/ (deduct):			
Depreciation	1	1	1
Finance expense	761		
Finance income	(18)	(17)	(41)
Foreign exchange differences	(4)		24
Share of result of associate	(4)	-	18
Operating cash flows before movements in working capital	(2,538)	(1,747)	(4,022)
(Increase)/decrease in trade and other receivables	(149)	(3)	(65)
Increase/(decrease) in trade and other payables	(377)	5	411
Cash used in operations	(3,064)	(1,745)	(3,676)
Tax received	378	408	409
Net cash outflow from operating activities	(2,686)	(1,337)	(3,267)
Cash flows from investing activities			
Purchase of tangible fixed assets	-	-	-
Interest received	18	17	41
Licence fee received from associate	88		
Investment in associate	(83)	-	(41)
Net cash inflow/(outflow) from investing activities	23	17	-
Cash flows from financing activities			
Other financing received	300	-	-
Net proceeds from issue of share capital	1,777	-	-
Net cash inflow from financing activities	2,077	-	-
(Decrease)/increase in cash and equivalents	(586)	(1,320)	(3,267)
Cash and cash equivalents at start of period	994	4,261	4,261
Cash and cash equivalents at end of period	408	2,941	994

NOTES TO THE UNAUDITED RESULTS FOR THE SIX MONTHS ENDED 31 DECEMBER 2023

1. Basis of financial information and accounting policies

These interim financial statements are unaudited and do not constitute statutory financial statements within the meaning of Section 434 of the Companies Act 2006. The Annual Report and Accounts for the year ended 30 June 2023 has been delivered to the Registrar of Companies and is available from Sareum's web site, www.sareum.com. The report of the auditor on those accounts was not qualified and contained no statement under Section 498 of the Companies Act 2006.

The accounting policies adopted are consistent with those used for the financial statements for the year ended 30 June 2023, as described therein. As at the date of approving these interim financial statements, there are no new standards likely to materially affect the financial statements for the year ending 30 June 2024.

The Group made a loss after tax for the period of £2.5 million (2022: £1.4 million), as it continued to progress its research and development activities. These activities, and the related expenditure, are in line with the budgets previously set and are funded by regular cash investments.

The Directors consider that the cash held at the period end, together with that projected to be received, will be sufficient for the Group to meet its forecast expenditure for at least one year from the date of approving the interim financial statements. If there is a shortfall, the Directors will implement the required cost savings to ensure that the cash resources last for this period of time. For these reasons, the interim financial statements have been prepared on a going concern basis.

2. Financing

In August 2023 the Company entered into an Equity Prepayment Facility ("the Facility") with RiverFort Global Opportunities PCC Ltd ("Riverfort") whereby Riverfort would advance up to £5 million to the Company in exchange for the issuance of equity shares. An initial advance of £2 million (net of associated costs) was made in August 2023 and a further advance of £0.3 million was made in November 2023.

The settlement of this to date has been as follows:

	£m	£m	£m
	Converted into shares	Held as cash	Total
Balance advanced	2.0	0.3	2.3
Realised by the sale of shares	(0.7)	-	(0.7)
Balance due to Riverfort as at 31 December 2023	1.3	0.3	1.6
This has been accounted for as follows			
Market value of shares still held	0.5	-	0.5
Cash advanced	-	0.3	0.3
Financing charge (*)	0.8	-	0.8
Balance due by the Company	0.8	0.3	1.1
	1.3	0.3	1.6

*The difference of £0.8m between the amount due to Riverfort as at 31 December 2023 in respect of shares issued to them, and the market value of the shares they still held at that date, has been accounted for as a non-cash financing charge. To the extent that further shares are subsequently issued to settle this balance, or the Company share price increases sufficiently, this charge will then be reversed.

The Company expects that the balance due under the Facility, which can be repaid by the issue of shares or payment in cash, will be settled by the issue of shares, on or before the Facility expires in August 2025.

3. Taxation

No liability to corporation tax arises for the six-months ended 31 December 2023. Research and development tax credits, receivable as cash, are estimated to be £0.8 million (2022: £0.3 million) for the period.

4. Dividends

The Directors do not propose a dividend in respect of the six months ended 31 December 2023.

5. Loss per share

The basic loss per share is 3.6 pence (2022: 2.1 pence), calculated by dividing the Group's loss for the six months by 70,221,369 (2022: 68,069,416), the weighted average number of shares in issue during the period. There is no dilutive effect in respect of share options during the six months to 31 December 2023 because the Group generated a loss in that period.

6. Availability of Half-yearly Report

This Half-yearly Report, including the interim financial statements, is available on request from the Company by writing to Unit 2a, Langford Arch, London Road, Pampisford, Cambridge CB22 3FX or can be downloaded from the Company's website www.sareum.co.uk.