RNS Number: 9310B Sareum Holdings PLC 25 March 2025

## **Sareum Holdings PLC**

("Sareum" or the "Company")

#### Half-Year Report for the Six Months Ended 31 December 2024

Cambridge, UK,25 March 2025 - 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 2024.

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.

- Successfully completed Phase 1 clinical trial for SDC-1801 with single ascending dose ("SAD"), multiple ascending
  dose ("MAD") and food effect studies.
- SDC-1801 achieved blood plasma levels significantly exceeding predicted therapeutic exposure with a half-life of 17-20 hours, confirming the potential for once-daily dosing. Significant dose-responsive biomarker effects were observed.
- No deaths or serious adverse events due to SDC-1801 were reported, with frequency of adverse events (all mild or moderate) similar in active and placebo groups.
- The Clinical Study Report was received in December 2024.
- Strengthened intellectual property position with:
  - US Patent and Trademark Office granted a patent (US Patent No. 12,187,716) on SDC-1801's chemical structure, its use in treating inflammatory diseases, and certain methods of chemical synthesis.
  - Patent allowance in China protecting certain crystalline forms of SDC-1801 and methods of their preparation with a similar Decision to Grant that was recently received from the Japanese Patent Office.

# 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, Sareum successfully acquired the licence for SRA737 following the termination of a licensing agreement between CRT Pioneer Fund ("CPF") and a US-based licensee in December 2024.
- Sareum renegotiated significantly improved economic terms, securing 63.5% of all future revenues compared to 27.5% under the former agreement.
- SRA737 has completed two phase 1/2 studies in patients with advanced cancers, one as a single agent and the
  other in combination with low-dose gemcitabine. An Investigational New Drug ("IND") application has now been
  approved by the US Food & Drug Administration.

## SDC-1802 (cancer immunotherapy)

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

• The additional funding secured in October 2024 has enabled further translational and preclinical development studies on SDC-1802.

## FINANCIAL HIGHLIGHTS

- Cash at 31 December 2024 of £4.1m (£0.4m as of 31 December 2023 and £1.5m as of 30 June 2024).
- Loss on ordinary activities after taxation for the six months ended 31 December 2024 of £1.2m, in line with
  expectations given the clinical trial activity (2023: restated loss of £1.7m).
- After the period end, Sareum successfully raised £1.07m through a subscription of 8,560,000 new ordinary shares at 12.5 pence per share.

# Dr Stephen Parker, Executive Chairman of Sareum, commented:

"Sareum has made strong progress this period, marked by the successful completion of our Phase 1 clinical trial for SDC-1801. The trial confirmed a favourable safety profile and pharmacokinetics, reinforcing its potential as a once-daily treatment for

autoimmune diseases such as psoriasis. To support its progression to Phase 2 trials, we are preparing the necessary toxicology studies, supported by our strengthened financial position following a successful fundraising round.

"Beyond SDC-1801, we have also strengthened our patent portfolio and secured the licence for SRA737 on significantly improved economic terms - important strategic advances that enhance our pipeline. With a clear development path ahead, we remain confident in delivering value to shareholders as we advance these promising therapeutic candidates."

#### - ENDS-

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#### About Sareum

Sareum (AIM: SAR) is abiotechnology 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, with a planned initial focus on psoriasis.

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

The Company has recently acquired the license for SRA737, a clinical-stage Checkpoint kinase 1 inhibitor that targets cancer cell replication and DNA damage repair mechanisms.

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 <a href="https://www.sareum.com">www.sareum.com</a>

## **EXECUTIVE CHAIRMAN'S STATEMENT**

We continue to make good progress with SDC-1801, highlighted by the successful completion of our Phase 1 clinical trial, which, coupled with the additional funding secured during the period provides us with the resources to advance SDC-1801 towards Phase 2 clinical trials. In parallel, we continue to develop our promising cancer immunotherapy candidate, SDC-1802.

Since the period end, we have further strengthened our position by acquiring the licence for SRA737, which significantly increases our economic interest to 63.5% of all future revenues. We believe SRA737 remains a valuable asset, and gaining control of the licence puts us in a stronger position to explore potential partnerships or development opportunities. Given the existing clinical and preclinical data, we remain optimistic about identifying a path forward that maximises SRA737's value, particularly as it received IND approval from the US Food and Drug Administration (FDA) last year, which could enable the start of clinical trials in the USA.

Evidenced by the recent fundraise of £1.07m, we are delighted by the continued support from our shareholders as we look to build value within the Company. With our strengthened patent portfolio and clear development pathway for our lead programmes, we are well-positioned to build on this momentum in the second half of the year and beyond. We remain focused on advancing our pipeline of next-generation kinase inhibitors to address significant unmet needs in autoimmune disease and cancer.

## 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.

Sareum has the successfully completed the Phase 1 clinical trial of SDC-1801 (Trial IDACTRN12623000416695), including both SAD and MAD stages. The randomised, placebo-controlled trial investigating the safety, tolerability, pharmacokinetics and pharmacodynamics of an oral formulation of SDC-1801 in healthy subjects, was conducted at a clinical unit in Melbourne, Australia and demonstrated that SDC-1801 achieved blood plasma levels well above the predicted therapeutic exposure, and induced significant dose-dependent biomarker changes

No deaths or serious adverse events were reported due to SDC-1801, and based on the unblinded data, the frequency of adverse events (all mild or moderate) was similar in the active and placebo groups. As a consequence, we believe that the safety and PK profile gives us a potential best-in-class advantage over similar products in development.

The Company also made significant progress in expanding its intellectual property protection for SDC-1801 during the period. This included securing patent allowances in key markets, with the US Patent Office approving claims covering the compound's structure and therapeutic applications, while Chinese authorities granted protection for specific crystalline forms of the molecule. After the period end, the Company also received a Decision to Grant letter from the Japanese Patent Office for similar crystalline form protection. These patents substantially strengthen Sareum's competitive position and

commercial potential for this promising therapy.

#### SRA737

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, Sareum successfully acquired the licence for SRA737 following the termination of a licensing agreement between CPF and a US-based licensee in December 2024. The Company renegotiated significantly improved economic terms, securing 63.5% of all future revenues compared to 27.5% under the former agreement at no cost to the Company.

We remain encouraged by the potential to secure a promising development path for the compound, given the data from the Phase 1/2 studies, where SRA737 was well tolerated as a monotherapy. Additionally, in combination with low dose gemcitabine, SRA737 demonstrated promising activity in anogenital cancers, where there is significant unmet medical need.

Preclinical data in disease models also indicate that SRA737 may be effective in combinations with Wee1 or PARP targeted therapies in ovarian cancers, and with low-dose gemcitabine and immunotherapy in lung and colon cancers.

### SDC-1802

 ${\tt SDC-1802}\ is\ a\ {\tt TYK2/JAK1}\ inhibitor\ being\ developed\ for\ cancer\ and\ cancer\ immunotherapy\ applications.$ 

The additional funding secured in October 2024 enabled further translational and preclinical development studies on SDC-1802. The Company continues to advance this programme in parallel with its lead asset, leveraging the expertise gained through the development of SDC-1801.

### **FINANCIAL REVIEW**

Following the 2024 fundraises, on 31 December 2024 Sareum had cash of £4.1m (2023: £0.4m). The loss on ordinary activities after taxation for the six months ended 31 December 2024 was £1.2m (2023: restated loss of £1.7m), reflecting ongoing clinical trial costs.

Post-period end, Sareum received UK R&D tax credits of £0.2m and successfully raised £1.07 m through a subscription of 8,560,000 new ordinary shares at 12.5 pence per share, representing a discount of approximately 24% to the closing midmarket price on 12 March 2025.

#### OUTLOOK

The Company's focus for the remainder of the financial year and beyond is advancing its strong pipeline of next-generation kinase inhibitors. Our focus remains on completing the manufacture of new drug product to allow the additional toxicology studies for SDC-1801 to commence by mid-2025, enabling preparation for Phase 2 clinical trials in psoriasis and potentially other autoimmune indications.

Sareum is now well positioned to realise the potential of the pipeline while maintaining flexibility to respond to new opportunities that may arise in the constantly evolving therapeutic landscape for kinase inhibitors.

The board of Sareum continues to apply a rigorous approach to capital allocation for 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 2024

	Notes	Unaudited Six months ended 31 Dec 24 £'000	Restated Unaudited Six months ended 31 Dec 23 £'000	Audited Year ended 30 Jun 24 £'000
Revenue		-	-	-
Other operating income		-	-	22
Operating expenses		(1,346)	(2,536)	(4,596)
Share of profit/(loss) of associate		(2)	4	(60)
Operating loss	<del>-</del>	(1,348)	(2,532)	(4,634)
Finance income		20	19	32
Loss before tax	-	(1,328)	(2,513)	(4,602)
Tax	3 _	167	765	1,182
Loss on ordinary activities after taxation	-	(1,161)	(1,748)	(3,420)
Total comprehensive income for the period	_	(1,161)	(1,748)	(3,420)

Total	compre	hensive	income	attributable	to:

Owners of the parent		(1,161)	(1,748)	(3,420)
				_
Basic and diluted loss per share (pence)	5	(0.9)p	(2.5)p	(4.2)p

## Consolidated Balance Sheet as at 31 December 2024

	Note	Unaudited As at 31 Dec 2024 £'000	Restated Unaudited As at 31 Dec 2023 £'000	Audited As at 30 Jun 2024 £'000
Non-current assets				
Computers and equipment		-	-	-
Investment in associate		7	46	9
	_	7	46	9
Current assets				
Debtors		553	1,513	1,299
Cash and cash equivalents		4,145	408	1,459
ous in a custificial control c	_	4,698	1,921	2,758
Creditors: amounts due within one year		(375)	(789)	(653)
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Net current assets	_	4,323	1,132	2,105
Total assets less current liabilities		4,330	1,178	2,114
Creditors: amounts due after one year	_	-	-	-
Net assets	_	4,330	1,178	2,114
Equity				
Called-up share capital		1,561	878	1,349
Share premium		28,012	22,675	24,802
Share-based compensation reserve		291	312	312
Foreign exchange reserve		(25)	10	20
Retained earnings		(25,509)	(22,697)	(24,369)
Total equity	_	4,330	1,178	2,114

# Consolidated Statement of Changes in Equity for the six months ended 31 December 2024

	Share capital £'000	Share premium £'000	Share-based compensation reserve £'000	Foreign exchange reserve £'000	Restated Retained earnings £'000	Restated Total £'000
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	-	-	(13)		13	-
Arising on consolidation				(4)		(4)
Loss for the period	-	-	-		(1,748)	(1,748)
As at 31 December 2023 (unaudited)	878	22,675	312	10	(22,697)	1,178
Issue of share capital (net)	471	2,127	-	-	-	2,598
Arising on consolidation	-	-	-	10	-	10
Loss for the period	-	-	-	-	(1,672)	(1,672)
As at 30 June 2024 (audited)	1,349	24,802	312	20	(24,369)	2,114
Issue of share capital (net)	212	3,210	-	-	-	3,422
Transfer in respect of options expired	-	-	(21)	-	21	-
Arising on consolidation	-	-	-	(45)	-	(45)
Loss for the period				-	(1,161)	(1,161)
As at 31 December	1,561	28,012	291	(25)	(25,509)	4,330

#### Consolidated Cash Flow Statement for the six months ended 31 December 2024

	Unaudited	Restated Unaudited	
	Six months	Six months	Audited
	ended	ended	Year ended
	31 Dec 2024 £'000	31 Dec 2023 £'000	30 Jun 2024 £'000
	£ 000	£ 000	£ 000
Net cash flow from operating activities Continuing operations:			
Loss before tax	(1,328)	(2,513)	(4,602)
Add back/ (deduct):	(=/===/	(=/-=-/	( - / /
Depreciation	-	1	1
Finance income	(20)	(18)	(32)
Foreign exchange differences	(45)	(4)	5
Share of result of associate	2	(4)	60
Operating cash flows before movements in working capital	(1,391)	(2,538)	(4,568)
(Increase)/decrease in trade and other receivables	(116)	(149)	42
Increase/(decrease) in trade and other payables	(278)	(77)	(213)
mercuse, (accrease, in trade and other payables	(270)	(,,,	(213)
Cash used in operations	(1,785)	(2,764)	(4,739)
Tax received	1,029	378	820
Net cash outflow from operating activities	(756)	(2,386)	(3,919)
Cash flows from investing activities			
Purchase of tangible fixed assets	_	_	_
Interest received	20	18	32
Licence fee received from associate	-	88	-
Investment in associate	-	(83)	(23)
_			
Net cash inflow/(outflow) from investing activities	20	23	9
Cash flows from financing activities	2.422	4 777	4.075
Net proceeds from issue of share capital	3,422	1,777	4,375
Net cash inflow from financing activities	3,422	1,777	4,375
(Decrease)/increase in cash and equivalents	2,686	(586)	465
Cash and cash equivalents at start of period	1,459	994	994
Cash and cash equivalents at end of period	4,145	408	1,459

## NOTES TO THE UNAUDITED RESULTS FOR THE SIX MONTHS ENDED 31 DECEMBER 2024

## 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 2024 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 2024, 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 2025.

The Group made a loss after tax for the period of £1.2m (2023: restated £1.8m), 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. Prior period figures

The comparative figures for the six months ended 31 December 2023 have been adjusted to remove the notional impact of the Riverfort Facility financing charge that might have been payable since all amounts due under that facility were subsequently settled by the issue of shares.

## 3. Taxation

No liability to corporation tax arises for the six-months ended 31 December 2024. Research and development tax credits, receivable as cash, are estimated to be £0.2m (2023:£0.8m) for the period.

#### 4. Dividends

The Directors do not propose a dividend in respect of the six months ended 31 December 2024.

#### 5. Loss per share

The basic loss per share is 0.9 pence (2023: restated 2.5 pence), calculated by dividing the Group's loss for the six months by 124,825,601 (2023: 70,221,589), 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 2024 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.

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