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Sareum Holdings PLC
22 March 2023

Sareum Holdings PLC

("Sareum" or the "Company")

Half-Year Report for the Six Months Ended 31 December 2022

Cambridge, UK, 22 March 2023- 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 2022.

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

The Company will hold a virtual presentation for all existing and potential investors today, 22 March at 12:30 GMT, via the Investor Meet Company platform. Please click the following link to register to attend: https://www.investormeetcompany.com/sareum-holdings-plc/register-investor.

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 submitted an application to perform Phase 1 clinical studies on SDC-1801 in Australia under the Clinical Trial Notification (CTN) scheme.
- Approval by the Human Research Ethics Committee (HREC) and acceptance of the CTN by Australia's medicines regulator, the Therapeutic Goods Administration (TGA), is expected in Q2 2023. Subject to this approval, Sareum plans to start the trial as soon as possible.
- Preparatory work for the trial is complete, including synthesis of the SDC-1801 drug substance under GMP conditions and GMP-compliant manufacturing of the SDC-1801 capsules.

SDC-1802 (cancer immunotherapy)

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

- Sareum continues to work on the translational studies needed to support development of SDC-1802,defining the optimal cancer application prior to completing toxicology and manufacturing studies.

- Expertise and experience gained through SDC-1801 will support Sareum in optimising its planning and maintaining cost discipline.

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 6 March 2023, Sierra Oncology, Inc. ("Sierra") (a subsidiary of GSK plc ("GSK")completed the return of the Clinical Study Reports and other associated documents and data associated with SRA737 to Sareum's co-development partner, the CRT Pioneer Fund LP ("CPF").

- Sareum is evaluating the potential development opportunities for this asset with CPF and will provide further updates as appropriate.
- Sareum also notes the expansion of the patent estate relevant to SRA737, with US patent number 11596637, "CHK1 (SRA737)/PARPi combination methods of inhibiting tumor growth" being granted on 7 March 2023.

FINANCIAL HIGHLIGHTS

- Cash at 31 December 2022 of £2.9m (£5.6m as of 31 December 2021 and £4.3m as of 30 June 2022).

- Loss on ordinary activities after taxation for the six months ended 31 December 2022 of £1.4m, reflecting investment in preparatory work for a clinical trial application (2021: loss of £0.9m).

- R&D tax credit of £0.4m received in December 2022.

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

"We are pleased to have submitted an application to conduct Phase 1 clinical studies on our lead molecule, SDC-1801, for the treatment of autoimmune diseases in Australia.

"We have identified Australia as the ideal location for these studies for a number of reasons, including its thriving research and development ecosystem, diverse patient population, internationally recognised regulatory authorities and supportive R&D tax credits system. We are confident that Australia's regulatory process will enable us to move forward efficiently and effectively.

"The continued commercial momentum building around the TYK2/JAK1 space supports our confidence in progressing SDC-1801, and we look forward to beginning clinical development. We remain committed to maintaining a lean business model and

controlling costs. By doing so, we can ensure that our resources are directed towards developing high-quality therapeutics that can help address patient needs."

For further information, please contact:

Sareum Holdings plc
Tim Mitchell, CEO — 01223 497700
Alex Harrison, Investor Relations — ir@sareum.co.uk

Strand Hanson Limited (Nominated Adviser)
James Dance / James Bellman — 020 7409 3494

Peel Hunt LLP (Joint Corporate Broker)
James Steel / Oliver Duckworth — 020 7418 8900

Hybridan LLP (Joint Corporate Broker)
Claire Noyce — 020 3764 2341

Consilium Strategic Communications (Financial PR)
Jessica Hodgson / Davide Salvi / Stella Lempidaki — 020 3709 5700

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, and is planned to enter clinical development with an initial focus on psoriasis.

Sareum has an economic interest in SRA737, a clinical-stage Chk1 inhibitor which it originally developed in collaboration with several Cancer Research UK-related organisations. SRA737 has shown promising safety and efficacy in two Phase 1/2 clinical trials.

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 is focused on advancing its next generation kinase inhibitors for autoimmune disease and cancer into clinical development.

An application to initiate Phase 1 clinical studies on SDC-1801 in Australia under the Clinical Trial Notification (CTN) scheme was submitted to a Human Research Ethics Committee (HREC) in Australia. Approval by the HREC and acceptance of the CTN by Australia's medicines regulator, the Therapeutic Goods Administration (TGA) is expected in Q2 2023. Subject to this approval, Sareum plans to start the trial as soon as possible.

Australia offers state-of-the-art research facilities and an efficient approval process, making it an attractive location for research and development. Moreover, the country provides significant tax incentives for companies that conduct their research there, allowing them to claim up to 43.5% of their eligible R&D expenditure as a cash payment. As such, Sareum has established the required local presence by setting up a legal entity in Australia.

In July 2022, Sareum submitted an application for a Clinical Trial Authorisation (CTA) to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) based on a robust preclinical data package produced in collaboration with several world-leading, internationally recognised contract research organisations (CROs) to evaluate the safety and tolerability of SDC-1801. However, in November of the same year, the MHRA informed the Company that the application could not be approved until an additional review of certain preclinical data by the UK Good Laboratory Practice (GLP) Monitoring Authority was conducted. Despite stipulating this requirement, the MHRA has not, to date, requested this review by the UK GLP. In parallel with seeking a response from the MHRA on multiple occasions, the Company has assessed alternative locations to conduct its clinical trial and identified Australia as the optimal route to progress its lead asset.

Whilst the decision of the MHRA and lack of response to Sareum's requests were disappointing, we are pleased to have identified a clear and attractive alternative path for the clinical development of SDC-1801.

Sareum remains confident in the potential of dual inhibition of both TYK2 and JAK1 for treating autoimmune diseases. In recent months, mounting evidence has supported this, including the approval of Sotyktu™(deucravacitinib), the first selective TYK2 inhibitor approved by the US Food & Drug Administration (FDA), signalling a growing scientific and commercial confidence in this approach.

With its clear and differentiated offering in SDC-1801, Sareum is eager to explore the potential efficacy and safety benefits in clinical development.

While SDC-1801 is the Company's primary focus, translational studies are also progressing in SDC-1802, an immunomodulating molecule that has demonstrated good efficacy in preclinical models of cancer.

Following the return of the Clinical Study Reports and other associated documents and data on SRA737 to CRT Pioneer Fund LP (CPF), Sareum now has the opportunity to participate in planning its future development. The promising preclinical and early clinical data generated by SRA737 reinforces our confidence in its potential for cancer treatment. Sareum will work with CPF to evaluate further development options, including re-licensing the programme to a third party, and will provide updates when appropriate.

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.

The preclinical development activities necessary to apply to perform a Phase 1 clinical trial have been completed and, consistent with the Company's clinical development plan, an application to perform the trial in Australia under the Clinical Trial Notification scheme has been submitted.

TYK2/JAK1 inhibition has demonstrated benefits in maintaining a healthy immune system and has strong clinical validation in psoriasis and psoriatic arthritis. Psoriasis is an autoimmune dermatological condition affecting more than 60 million adults worldwide, with a market size for potential treatments worth more than US$30 billion. Sareum believes that TYK2/JAK1 inhibition offers the potential for increased efficacy in psoriasis, compared with existing approved oral therapies.

Sareum, working alongside specialist consultants, contract research organisations (CROs), and clinical units, has designed a Phase 1a/b clinical trial with SDC-1801 in healthy subjects and psoriasis patients. As soon as regulatory approval is granted, Sareum plans to commence a Phase 1a trial to investigate the safety and tolerability of an oral formulation of SDC-1801 in ascending doses administered to healthy subjects. If the safety data proves satisfactory, the Company intends to commence a Phase 1b clinical study in psoriasis patients in 2024.

The Phase 1a part of the trial is expected to provide safety and dosing information applicable for any future trials in patients with other autoimmune diseases, and potentially in patients with the acute respiratory symptoms of viral infections should the Company decide to progress such trials.

Provided satisfactory safety data is obtained from this initial safety and dosing study, and subject to additional funding, a Phase 1b clinical study will commence in psoriasis patients.

Synthesis of SDC-1801 drug substance under GMP conditions has been completed successfully, with a surplus of material for the planned Phase 1 clinical trials. GMP-compliant manufacture of capsules of SDC-1801, for use in the Phase 1 trial, is also complete.

SDC-1802

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

Sareum continues to work on the translational studies needed to define the optimal cancer application prior to completing toxicology and manufacturing studies.

SRA737

SRA737 is a clinical-stage oral, selective Chk1 inhibitor that targets cancer cell replication and DNA damage repair mechanisms.

The asset was originally developed by Sareum in collaboration with several Cancer Research UK-related organisations, including CPF, with whom the Company entered a co-development agreement in 2013. Under the terms of the agreement, Sareum is entitled to a 27.5% share of any commercialisation revenues.

SRA737 was licenced to Sierra Oncology in 2016. Following its acquisition by GSK in 2022, Sierra has returned the rights for SRA737 to CPF. The return of the Clinical Study Reports and other associated documents was completed in March 2023. CPF and Sareum will evaluate potential options for future development opportunities for SRA737 and evaluate its next steps accordingly.

Sierra had reported positive preliminary efficacy and safety data in two clinical trials evaluating it as a monotherapy and in combination with chemotherapy in 2019, and preclinical data has been reported to support the potential for SRA737 in combination with other anti-cancer agents against hard-to-treat cancers.

The patent estate covering SRA737 was recently expanded by the granting of a patent in the US (no. 11596637) that describes the combination of SRA737 with a PARP inhibitor and its effectiveness in inhibiting tumour growth.

We remain confident, based on preclinical and early clinical data, that SRA737 holds strong promise for the treatment of cancer, particularly in combination settings and are confident in the potential of this molecule.

FINANCIAL REVIEW

At 31 December 2022 Sareum had cash of £2.9m (2021: £5.6m).

The loss on ordinary activities after taxation for the six months ended 31 December 2022 was £1.4m (2021: loss of £0.9m), reflecting ongoing clinical trial preparation costs.

In December 2022 the Company received £0.4m (2021: £0.2m) in R&D tax credits.

OUTLOOK

Sareum has submitted an application to conduct a Phase 1 clinical trial of SDC-1801 in Australia, and pending regulatory approval, we hope to begin dosing as soon as possible in 2023.

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.

Following the return of SRA737 by CPF, we will evaluate the potential for future development opportunities. While it is too early to comment on future strategy, we continue to believe that there is strong potential for this molecule in 'hard-to-treat' cancers.

The Board of Sareum continues to apply a rigorous approach to capital allocation to the development of our assets

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 Income Statement for the six months ended 31 December 2022

	Notes	Unaudited Six months ended 31 Dec 22 £'000	Unaudited Six months ended 31 Dec 21 £'000	Audited Year ended 30 Jun 22 £'000
Revenue		**-**	**-**	**-**
Other operating income		-	-	-
Operating expenses		(1,748)	(1,017)	(2,577)
Share of loss of associate		-	-	(3)
Operating loss		**(1,748)**	**(1,017)**	**(2,580)**
Finance income		17	-	1
Loss before tax		**(1,731)**	**(1,017)**	**(2,579)**
Tax	3	285	160	407
Loss on ordinary activities after taxation		**(1,446)**	**(857)**	**(2,172)**
Basic and diluted loss per share (pence)	**5**	**(2.1)p**	**(1.3)p**	**(3.2)p**

Consolidated Statement of Comprehensive Income for the six months ended 31 December 2022

	Unaudited Six months ended 31 Dec 22 £'000	Unaudited Six months ended 31 Dec 21 £'000	Audited Year ended 30 Jun 22 £'000
Loss for the period	**(1,446)**	**(857)**	**(2,172)**
Other comprehensive income	**-**	**-**	**-**
Total comprehensive income for the period	**(1,446)**	**(857)**	**(2,172)**
Total comprehensive income attributable to:			
Owners of the parent	**(1,446)**	**(857)**	**(2,172)**

Consolidated Balance Sheet as at 31 December 2022

	Unaudited As at 31 Dec 2022 £'000	Unaudited As at 31 Dec 2021 £'000	Audited As at 30 Jun 2022 £'000
Non-current assets			
Computers and equipment	1	3	2
Investment in associate	23	25	23
	24	**28**	**25**

Current assets			
Debtors	380	236	500
Cash and cash equivalents	2,941	5,613	4,261
	3,321	**5,849**	**4,761**
Creditors: amounts due within one year	(460)	(231)	(455)
Net current assets	**2,861**	**5,618**	**4,306**
Net assets	**2,885**	**5,646**	**4,331**
Equity			
Called-up share capital	851	851	851
Share premium	20,925	20,925	20,925
Share-based compensation reserve	325	325	325
Retained earnings	(19,216)	(16,455)	(17,770)
Total equity	**2,885**	**5,646**	**4,331**

Consolidated Statement of Changes in Equity for the six months ended 31 December 2022

	Share capital £'000	Share premium £'000	Share-based compensation reserve £'000	Retained earnings £'000	Total £'000
As at 30 June 2021 (audited)	**833**	**17,235**	**362**	**(15,635)**	**2,795**
Issue of share capital (net)	18	3,690	-	-	**3,708**
Transfer in respect of options exercised	-	-	(37)	37	**-**
Loss for the period	-	-	-	(857)	**(857)**
As at 31 December 2021 (unaudited)	**851**	**20,925**	**325**	**(16,455)**	**5,646**
Issue of share capital (net)	-	-	-	-	**-**
Transfer in respect of options exercised	-	-	-	-	**-**
Loss for the period	-	-	-	(1,315)	**(1,315)**
As at 30 June 2022 (audited)	**851**	**20,925**	**325**	**(17,770)**	**4,331**
Issue of share capital (net)	-	-	-	-	**-**
Transfer in respect of options exercised	-	-	-	-	**-**
Loss for the period	-	-	-	(1,446)	**(1,446)**
As at 31 December 2022 (unaudited)	**851**	**20,925**	**325**	**(19,216)**	**2,885**

Consolidated Cash Flow Statement for the six months ended 31 December 2022

	Unaudited Six months ended 31 Dec 2022 £'000	Unaudited Six months ended 31 Dec 2021 £'000	Audited Year ended 30 Jun 2022 £'000
Net cash flow from operating activities			
Continuing operations:			
Loss before tax	**(1,731)**	**(1,017)**	**(2,580)**
Add back:			
Depreciation	1	-	2
Finance income	(17)	-	(1)
Share of loss of associate	-	-	3
	(1,747)	(1,017)	(2,576)
(Increase)/decrease in trade and other receivables	(3)	73	56
Increase/(decrease) in trade and other payables	5	(53)	171
Cash used in operations	**(1,745)**	**(997)**	**(2,349)**
Tax received	408	218	218
Net cash outflow from operating activities	**(1,337)**	**(779)**	**(2,131)**
Cash flows from investing activities			
Purchase of tangible fixed assets	-	(2)	(3)
Interest received	17	-	1
Investment in associate	-	-	-
Net cash inflow/(outflow) from investing activities	**17**	**(2)**	**(2)**
Cash flows from financing activities			
Net proceeds from issue of share capital		3,708	3,708

Net proceeds from issue of share capital	-	3,708	3,708
Net cash inflow from financing activities	**-**	**3,708**	**3,708**
(Decrease)/increase in cash and equivalents	**(1,320)**	**2,927**	**1,575**
Cash and cash equivalents at start of period	4,261	2,686	2,686
Cash and cash equivalents at end of period	**2,941**	**5,613**	**4,261**

NOTES TO THE UNAUDITED RESULTS FOR THE SIX MONTHS ENDED 31 DECEMBER 2022

1. Financial information

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 2022 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.

2. Basis of accounting

The accounting policies adopted are consistent with those of the financial statements for the year ended 30 June 2022, as described in those financial statements. As at the date of approving the interim financial statements, there are no new standards likely to materially affect the financial statements for the year ending 30 June 2023.

Going concern

The Group made a loss after tax for the period of £1.4 million (2021: £0.9 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.

3. Taxation

No liability to for corporation tax arises for the six-months ended 31 December 2022. Research and development tax credits, receivable as cash, are estimated to be £285,000 for the period.

4. Dividends

The directors do not propose the payment of a dividend in respect of the six months ended 31 December 2022.

5. Loss per share

Basic loss per share is 2.1 pence (2021: 1.3 pence). The basic loss per ordinary share is calculated by dividing the Group's loss for the six months of £1,446,000 (2021: £857,000) by 68,069,416 (2021: 67,282,760), 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 2022 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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