

Sareum Holdings plc

("Sareum" or "the Company")

Final Results

Sareum Holdings plc (AIM: SAR), the specialist cancer drug discovery and development business, is pleased to announce its final results for the year ended 30 June 2015.

Operational Highlights

- Final preparations to submit CHK1 candidate for two concurrent Phase 1 clinical trials to assess different administration strategies: one as a single agent and the other in combination with chemotherapy.
- CHK1 clinical trial applications expected to be submitted in Q1 2016 with trials to commence, subject to approval, shortly thereafter.
- Preclinical development of Aurora+FLT3 inhibitor progressing to plan, with toxicology and additional efficacy studies ongoing.
- TYK2 inhibitor lead molecule demonstrates striking decrease in psoriasis pathology in a disease model and encouraging results in a rheumatoid arthritis model.

Financial Highlights

- Net assets at period end were £1.86 million (2014: £1.72 million) of which £1.48 million comprised of cash at bank.
- Loss on ordinary activities (after tax credit) of £1,255,368 (2014: Loss of £763,000), an improvement on expectations, reflecting re-phasing of commitments to CHK1 programme.
- Successful placing in June 2015 to raise £1.44 million (before expenses) to satisfy ongoing commitments to CHK1 co-development payments and to provide additional working capital.

Dr Tim Mitchell, Chief Executive Officer of the Company, said:

"Good progress has been made in the last year, with two cancer programmes advancing through preclinical validation and potential new indications for our autoimmune disease programme. With the two planned in-human clinical trials for CHK1 commencing in early 2016, as well as the progress in our other programmes adding further commercial value, we look forward to next year with real anticipation and optimism."

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Chairman and CEO's Statement

This year, in line with our stated strategy, we have concentrated on advancing our three lead drug discovery programmes in order to maximise their value and make them attractive to potential licensors and commercial partners.

The CHK1 programme, in collaboration with CRT Pioneer Fund, is in its final preparations before submitting the Clinical Trial Applications for Phase 1 clinical trials. With positive preclinical results for the candidate both as a single agent and in combination with chemotherapy, two clinical trials applications are now expected to be made in Q1 2016 and, if successful, trials should commence shortly thereafter.

We continue to make good progress with our TYK2 programme targeting autoimmune diseases, including psoriasis and rheumatoid arthritis. Further investigations, funded in part by the Innovate UK Biomedical Catalyst, will also be conducted on the efficacy of our lead molecules against certain cancers that require TYK2 signalling for survival.

Meanwhile, preclinical development of the Aurora+FLT3 candidate, with our Chinese partner HMUBEC (Hebei Medical University Biomedical Engineering Center), is progressing as planned.

In addition to progressing these programmes towards in-human clinical trials, we have continued our work in securing the intellectual property that protects them. Our SKIL platform is the foundation of our Aurora+FLT3 and TYK2 discoveries, and has the potential to produce inhibitors against many additional kinase targets. Patents for inventions associated with the platform have now been granted in the US, China and Japan, and we are currently awaiting confirmation for a European patent grant. European and US patents have also been secured for our most advanced programme, CHK1, and more recently European and US patent grants for Aurora+FLT3, and a European grant for TYK2.

Further work is being undertaken to bring our programmes to the attention of the scientific community, including potential licence partners and investors, through publication in peer-reviewed journals and presentations at conferences and investor meetings. In October 2014 the effect of SAR-20347, one of our TYK2 inhibitor molecules, on significantly reducing psoriasis pathology was described in the Journal of Immunology. In July this year, the first description of an orally active clinical development candidate CHK1 inhibitor was made with the publication in the journal, Oncotarget, of how CCT245737 boosts the effectiveness of chemotherapies used to treat lung and pancreatic cancers.

Financial review

The Company ended the year with net assets of £1.86 million (2014: £1.72 million) of which £1.48 million (2014: £701,000) comprised of cash at bank.

The loss after taxation for the year was £1.26 million (2014: loss of £763,000) reflecting the financial commitment of £497,000 made to the CHK1 programme during the course of the year as well as additional research funding invested in our TYK2 programme.

In June 2015, the Company raised £1.44 million (before expenses) via a share placing primarily to satisfy its ongoing commitment towards the co-development partnership for the CHK1 programme as we plan for its first in-human trials. A portion of the funds will also be used to provide additional working capital and research funding, particularly to progress our TYK2 autoimmune and inflammatory diseases programme.

Research Update

Checkpoint Kinase 1 (CHK1)

This is the most advanced programme in our pipeline. It is being developed in collaboration with CRT Pioneer Fund, and is now being prepared for clinical trials applications.

In preclinical studies, CCT245737, the clinical development candidate, has shown potent efficacy against various cancers when dosed, via the oral route, as a single agent as well as in combination with chemotherapies. These cancers include lung, colon and pancreatic, as well as certain types of Acute Myeloid Leukaemia (AML), neuroblastoma and B-cell lymphoma. We believe this molecule has the potential to be a best-in-class compound. In order to assess a fuller range of potential applications and therefore maximise the commercial value of the programme, two clinical trials are planned. The primary objectives of these trials are to assess the safety of CCT245737 and to determine dose levels for future studies. One trial plans to examine CCT245737 in combination with other chemotherapies, ultimately targeting lung and pancreatic cancers, and the second clinical trial plans to assess CCT245737 as a single agent in various cancer types.

Analysis of clinical trial data is greatly facilitated by the ability to monitor the extent of enzyme target inhibition that results from the administration of the candidate drug to patients. To this end, working with colleagues at the Institute of Cancer Research, the collaboration has developed a novel “biomarker” assay that quantitatively measures the degree of CHK1 inhibition by CCT245737. This biomarker assay is expected to translate into the clinical setting to confirm that CHK1 inhibition has occurred upon administering CCT245737.

These preclinical studies are on-track to complete in Q4 2015, as stated in our February 2015 Research Update. In our February 2015 Half-Yearly Results Statement, it was noted that application for clinical trials would be submitted within the same period. The additional data and administration required to support the plan for two Clinical Trials Applications means we now intend to submit these applications as early as possible in Q1 2016.

A financial commitment from Sareum of £797,500 will be triggered one month before the Clinical Trials Applications and this payment is expected to be made around the end of this calendar year.

Aurora+FLT3

In collaboration with our Chinese partner, HMUBEC, we are now able to manufacture the larger scale batches of our preclinical development candidate that would be required for Phase 1 clinical trials. We are now embarking on additional efficacy and toxicology studies which we expect to

complete before our financial year end and, if successful, to file clinical trials applications in multiple territories shortly thereafter.

In an *in vivo* disease model of AML, the candidate molecule demonstrates greater than 98% tumour inhibition. Patients with AML are susceptible to the development of resistance to current drugs used to treat their disease and, whilst our clinical strategy is still evolving, it is likely that such resistant patients will be a focus of any Phase 1 trial. The molecule also has potent cell-killing activity against other cancers, particularly Acute Lymphoblastic Leukaemia (ALL), neuroblastoma and Anaplastic Large-Cell Lymphoma.

Alongside this preclinical development of the compound intended for intravenous dosing, good progress has been made in developing a new formulation that can be used to administer the candidate molecule via the oral route. One formulation has been developed which we believe can deliver therapeutically useful amounts of the candidate when dosed orally. We have now begun assessment of efficacy and safety in a suitable disease model.

TYK2

TYK2 – Autoimmune and inflammatory disorders

Our autoimmune and inflammatory disorders programme, with co-development partner SRI International, is developing a series of orally bioavailable inhibitors of TYK2, a member of the Janus kinase (“JAK”) family of kinases. JAK family kinases are the targets of several marketed and clinical-stage drugs for cancer and autoimmune diseases, although none of these specifically target TYK2, giving us a potentially unique position in this area.

We have previously reported the discovery of our initial lead candidate SAR-20347, which has shown that, when dosed via the oral route, it can significantly decrease psoriasis pathology in a disease model. Furthermore, we are pleased to report here that we have subsequently demonstrated an equally striking effect in a standard model of rheumatoid arthritis. In this model, SAR-20347 reduces joint inflammation in a dose-dependent manner, and is more effective than a commonly-used steroid treatment.

Recently synthesised analogues of SAR-20347 show improved potency against TYK2 and selectivity profiles against other JAK family kinases. We are currently assessing their pharmacokinetic properties before progressing into additional disease models such as ulcerative colitis.

TYK2 – Cancer

Reports in the scientific literature have identified TYK2 inhibition as a potential strategy to directly target the growth of certain cancers, or to overcome resistance to targeted drugs in the treatment of certain cancers. Cancers potentially requiring TYK2 signalling to spread or to develop resistance include small cell lung cancer, bone cancers and T-ALL, a type of leukaemia that predominantly affects children and adolescents.

In order to determine the feasibility of this novel approach we successfully secured a grant of £140K from the Innovate UK Biomedical Catalyst Fund to investigate the potential of our lead molecules to treat T-ALL. This grant-supported project began in August 2015 and is expected to run for one year.

Given the wide potential for our TYK2 programme we continue to seek a commercial research partner to sponsor the ongoing research with a view to licensing the programme at a later stage of development.

Outlook

We are extremely pleased that the CHK1 programme will have, subject to receiving clinical trials approval, two opportunities to demonstrate its potential.

With our CHK1 programme reaching a pivotal point early next year, and our other two advanced programmes progressing we continue to seek licence partners for these programmes as well as opportunities for further programme development.

Dr Paul Harper
Chairman

Dr Tim Mitchell
Chief Executive Officer

Consolidated Income Statement for the year ended 30 June 2015

	Notes	2015 £	2014 £
CONTINUING OPERATIONS			
Revenue		—	—
Other operating income		—	149,960
Administrative expenses		(811,878)	(928,396)
Share of loss of associates	3	(496,989)	(63,204)
OPERATING LOSS		<u>(1,308,867)</u>	<u>(841,640)</u>
Finance expense	4	(135,348)	—
Finance income		2,997	4,515
LOSS BEFORE INCOME TAX	5	(1,441,218)	(837,125)
Income tax	6	185,850	74,252
LOSS FOR THE YEAR		<u>(1,255,368)</u>	<u>(762,873)</u>
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR			
		<u>(1,255,368)</u>	<u>(762,873)</u>
Loss attributable to:			
Owners of the parent		<u>(1,255,368)</u>	<u>(762,873)</u>
Total comprehensive income attributable to:			
Owners of the parent		<u>(1,255,368)</u>	<u>(762,873)</u>
Loss per share expressed in pence per share:	7		
Basic and diluted loss from continuing operations		<u>(0.06)p</u>	<u>(0.05)p</u>

Consolidated Balance Sheet as at 30 June 2015

	Notes	2015 £	2014 £
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		—	—
Property, plant and equipment		3,087	4,852
Investments	3	209,808	706,796
		212,895	711,648
CURRENT ASSETS			
Trade and other receivables		51,366	99,783
Tax receivable		186,297	76,234
Investments	8	—	200,000
Cash and cash equivalents	9	1,480,044	700,618
		1,717,707	1,076,635
LIABILITIES			
CURRENT LIABILITIES			
Trade and other payables		67,443	65,810
NET CURRENT ASSETS			
		1,650,264	1,010,825
NET ASSETS			
		1,863,159	1,722,473
SHAREHOLDERS' EQUITY			
Called up share capital		621,859	477,509
Share premium		10,761,261	9,549,595
Share-based compensation reserve		105,014	64,976
Merger reserve		27	27
Retained earnings		(9,625,002)	(8,369,634)
TOTAL EQUITY			
		1,863,159	1,722,473

Consolidated Statement of Changes in Equity for the year ended 30 June 2015

	Called up share capital £	Retained earnings £	Share premium £
Balance at 1 July 2013	380,384	(7,606,761)	7,611,588
Changes in equity			
Issue of share capital	97,125	—	1,938,007
Total comprehensive expense	—	(762,873)	—
Share-based compensation	—	—	—
Balance at 30 June 2014	<u>477,509</u>	<u>(8,369,634)</u>	<u>9,549,595</u>
Changes in equity			
Issue of share capital	144,350	—	1,211,666
Total comprehensive expense	—	(1,255,368)	—
Share-based compensation	—	—	—
Balance at 30 June 2015	<u>621,859</u>	<u>(9,625,002)</u>	<u>10,761,261</u>
	Share-based compensation reserve £	Merger reserve £	Total equity £
Balance at 1 July 2013	53,864	27	439,102
Changes in equity			
Issue of share capital	—	—	2,035,132
Total comprehensive expense	—	—	(762,873)
Share-based compensation	11,112	—	11,112
Balance at 30 June 2014	<u>64,976</u>	<u>27</u>	<u>1,722,473</u>
Changes in equity			
Issue of share capital	—	—	1,356,016
Total comprehensive expense	—	—	(1,255,368)
Share-based compensation	40,038	—	40,038
Balance at 30 June 2015	<u>105,014</u>	<u>27</u>	<u>1,863,159</u>

Consolidated Cash Flow Statement for the year ended 30 June 2015

	Notes	2015 £	2014 £
Cash flows from operating activities			
Cash used in operations	10	(720,026)	(838,947)
Tax paid		75,787	53,603
		<hr/>	<hr/>
Net cash outflow from operating activities		(644,239)	(785,344)
Cash flows from investing activities			
Purchase of tangible fixed assets		—	(5,296)
Purchase of fixed asset investments		—	(770,000)
Equity Swap arrangement		64,652	(200,000)
Interest received		2,997	4,515
		<hr/>	<hr/>
Net cash (outflow)/inflow from investing activities		67,649	(970,781)
Cash flows from financing activities			
Share issue		144,350	97,125
Share premium on share issue		1,211,666	1,938,007
		<hr/>	<hr/>
Net cash inflow from financing activities		1,356,016	2,035,132
Increase in cash and cash equivalents		779,426	279,007
Cash and cash equivalents at beginning of year		700,618	421,611
		<hr/>	<hr/>
Cash and cash equivalents at end of year	9	1,480,044	700,618
		<hr/>	<hr/>

Notes to the Consolidated Financial Statements for the year ended 30 June 2015

1. Basis of preparation

The consolidated financial statements of Sareum Holdings plc and its subsidiaries (the Group) have been prepared in accordance with International Financial Reporting Standards (IFRS), as adopted for use in the European Union, with IFRIC interpretations and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. The financial statements have been prepared under the historical cost convention.

IFRS comprise standards and interpretations approved by the IASB. IFRS as adopted by the European Union differ in certain respects from IFRS as issued by the IASB. However, consolidated financial statements for the financial years presented would be no different had IFRS as issued by the IASB been applied. References to IFRS hereafter should be construed as references to IFRS as adopted by the European Union.

Going concern

The Directors estimate that the cash held by the Group will be sufficient to support the current level of activities into the third quarter of 2016. The Directors also expect that the Group will secure equity-based financing sufficient for the future needs of the business beyond the third quarter of next year. The directors' confidence in the Group's ability to raise equity-based financing is underwritten by the funds of £1.44m (before expenses) raised by way of the placing of new ordinary shares on AIM in June 2015. Therefore the financial statements have been prepared on a going concern basis.

Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries) made up to 30 June each year. Control is achieved where the Company has the power to govern the financial and operating policies of another entity or business, so as to obtain benefits from its activities. The consolidated financial statements present the results of the Company and its subsidiaries ("the Group") as if they formed a single entity. Inter-company transactions and balances between group companies are eliminated on consolidation.

2. Accounting policies

The principal accounting policies applied are set out below.

Amortisation of intangibles

Amortisation is calculated so as to write off the cost of an asset over the useful economic life of that asset as follows:

Intellectual property – straight-line over five years

Property, plant and equipment

Depreciation is provided at the following annual rates in order to write off each asset over its estimated useful life.

Fixtures and computers – straight-line over three or four years

Financial instruments

Financial instruments are classified and accounted for, according to the substance of the contractual arrangement, as either financial assets, financial liabilities or equity instruments. An equity instrument is any contract that evidences a residual interest in the assets of the Company after deducting all of its liabilities.

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits and other short-term, highly liquid investments that are readily convertible to a known amount of cash and are subject to insignificant risk of change in value.

Taxation

Current taxes are based on the results shown in the financial statements and are calculated according to local tax rules, using tax rates enacted or substantially enacted by the balance sheet date.

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date where transactions or events have occurred at that date that will result in an obligation to pay more, or a right to pay less or to receive more tax, with the following exception:

Deferred tax assets are recognised only to the extent that the Directors consider that it is more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

Deferred tax is measured on an undiscounted basis at the tax rates that are expected to apply in the periods in which timing differences reverse, based on the tax rates and laws enacted or substantively enacted at the balance sheet date.

Research and development

Expenditure on research and development is written off in the year in which it is incurred.

Operating lease agreements

Rentals applicable to operating leases where substantially all the benefits and risks of ownership remain with the lessor are charged against profits on a straight-line basis over the period of the lease.

Pension contributions

The Group does not operate a pension scheme for the benefit of its employees but instead makes contributions to their personal pension policies. The contributions due for the period are charged to the profit and loss account.

Employee share scheme

The Group has in place a share option scheme for employees, which allows them to acquire shares in the Company. Equity settled share-based payments are measured at fair value at the date of grant. The fair value of options granted is recognised as an expense spread over the estimated vesting period of the options granted. Fair value is measured using the Black-Scholes model, taking into account the terms and conditions upon which the options were granted.

Revenue recognition

Revenue is measured as the fair value of the consideration received or receivable in the normal course of business, net of discounts, VAT and other sales related taxes and is recognised to the extent that it is probable that the economic benefits associated with the transaction will flow to the Company. Grant income is recognised as earned based on contractual conditions, generally as expenses are incurred.

Investment in associates

An associate is an entity over which the company has significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the Investee but is not control or joint control over those policies.

The amendment to IAS27, Separate financial statements (revised 2014), allowing investments in associates to be accounted for under the equity method in separate financial statements, has been adopted early.

Critical accounting estimates and areas of judgement

Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Actual results may differ from these estimates. The estimates and assumptions that have the most significant effects on the carrying amounts of the assets and liabilities in the financial information are considered to be research and development costs and equity settled share-based payments.

Accounting standards and interpretations not applied

At the date of authorisation of these financial statements, the following standards and interpretations relevant to the Group that have not been applied in these financial statements were in issue but not yet effective:

International Financial Reporting Standards	Effective for accounting periods starting on or after
IFRS 9 Financial Instruments	1 January 2018
IFRS 11 Accounting for Acquisitions of Interests in Joint Operations - Amendments to IFRS 11	1 January 2016
IFRS 15 Revenue from contracts with customers	1 January 2017
IAS 16 and 38 Clarification of Acceptable Methods of Depreciation and Amortisation - Amendments to IAS 16 and IAS 38	1 January 2016
IAS 27 Equity Method in Separate Financial Statements - Amendments to IAS 27	1 January 2016
Annual Improvements to IFRS - 2012-2014 Cycle	1 January 2016

The amendment to IAS27, Separate financial statements (revised 2014), allowing investments in associates to be accounted for under the equity method in separate financial statements, has been adopted early.

The Directors anticipate that the adoption of these standards and interpretations in future years will have no material impact on the financial statements of the Group.

No standards or interpretations adopted in the year had any material impact on the financial statements of the Group.

3. Investments in associates

	Interest in associates £
Cost	
At 1 July 2014 and 30 June 2015	<u>770,000</u>
Impairment	
At 1 July 2014	63,204
Impairment for year	496,988
At 30 June 2015	<u>560,192</u>
Net book value	
At 30 June 2015	<u><u>209,808</u></u>
At 30 June 2014	<u>706,796</u>

The Investment in associates represents the investment by the Group in the partnership with the Cancer Research Technology Pioneer Fund to advance the CHK1 programme. The associate has been accounted for using the equity method in the consolidated financial statements. Sareum's interest in the associate partnership is 27.5% and they have a seat on the joint research committee. As at 30 June 2015 the partnership had net assets of £762,937 (2014: £2,571,169) and had incurred cumulative losses of £2,137,063 (2014: £329,831).

4. Finance expense

	2015	2014
	£	£
Loss on settlement of swap	<u>(135,348)</u>	<u>—</u>

5. Loss before income tax

The loss before income tax is stated after charging:

	2015	2014
	£	£
Other operating leases	10,936	10,683
Depreciation – owned assets	1,765	444
Research and development	891,156	574,093
Auditor’s remuneration – see analysis below	12,300	13,800
	<hr/> 12,300	<hr/> 13,800

The analysis of auditor’s remuneration is as follows:

Fees payable to the Company's auditor for the audit of the annual accounts

Audit of the Company	4,200	4,200
Audit of subsidiaries	6,800	6,800
	<hr/> 11,000	<hr/> 11,000

Total audit fees

Fees payable to the Company's auditor for other services

Taxation services	1,300	1,300
Other assurance services	—	1,500
	<hr/> 12,300	<hr/> 13,800

Total fees payable to the Company's auditor

6. Income tax

	2015	2014
	£	£
Current tax:		
UK corporation tax credit on losses of the period	(185,850)	(74,252)
Adjustments recognised in the current year in relation to the current tax of prior years	—	—
	<hr/> (185,850)	<hr/> (74,252)
Tax credit to the income statement	(185,850)	(74,252)

The credit for the year can be reconciled to the accounting loss as follows:

	2015	2014
	£	£
Loss before tax	<u>(1,441,218)</u>	<u>(837,125)</u>
At standard rate of 20% (2014: 20%)	(288,243)	(167,425)
Effects of:		
Capital allowances in excess of depreciation	(63)	(1,478)
Unutilised tax losses	174,375	114,496
Losses surrendered for research and development tax credits (less uplift)	113,931	54,407
Research and development tax credits claimed	(185,850)	(74,252)
Prior year adjustments	<u>—</u>	<u>—</u>
Actual current tax credit in the year	<u>(185,850)</u>	<u>(74,252)</u>

The tax rate of 20% used above for the 2015 and 2014 reconciliations is the small company corporation tax rate applicable in the United Kingdom.

7. Loss per share

The calculation of loss per share is based on the following data:

	2015	2014
Loss on ordinary activities after tax	£(1,255,368)	£(762,873)
Weighted average number of shares for basic loss per share	1,941,676,629	1,693,479,365
Basic loss per share	(0.06)p	(0.05)p

As the Group has generated a loss for the period, there is no dilutive effect in respect of share options.

8. Investments

	2015	2014
	£	£
Other	<u>—</u>	<u>200,000</u>

The Investment arose from the Equity Swap Agreement entered into with YA Global Master SPV, Ltd (YAGM) in June 2014, whereby the Group paid £200,000 to YAGM which was due to repay the investment by making twelve equal monthly payments to the Group. The payments would be adjusted up or down depending upon the average of the lowest 10 day VWAP of the Group's shares during the relevant month. In May 2015 the Group announced the early conclusion of the Equity Swap Agreement.

9. Cash and cash equivalents

	2015	2014
	£	£
Bank deposit account	1,469,023	688,405
Bank accounts	11,021	12,213
	<u>1,480,044</u>	<u>700,618</u>

10. Reconciliation of loss before income tax to cash generated from operations

	2015	2014
	£	£
Loss before income tax	(1,441,218)	(837,125)
Depreciation charges	1,765	444
Share-based compensation	40,038	11,112
Share of loss of associate	496,988	63,204
Finance costs	135,348	—
Finance income	(2,997)	(4,515)
	<u>(770,076)</u>	<u>(766,880)</u>
Increase in trade and other receivables	48,417	(57,955)
Decrease in trade and other payables	1,633	(14,112)
	<u>(720,026)</u>	<u>(838,947)</u>

11. Dividend

The Directors are not able to recommend payment of a dividend.

12. Copies of the Report and Accounts

Copies of the Report and Accounts will be posted to those shareholders who have requested them. Copies will also be available from the Company's registered office at 2a Langford Arch, London Road, Pampisford, Cambridgeshire CB22 3FX and from the Company's website, www.sareum.co.uk.