Sareum Holdings

SDC-1801 CTA application hits a roadblock

Sareum has announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has turned down the clinical trial authorisation (CTA) for SDC-1801 based on the submitted data package. While Sareum awaits the formal letter of non-acceptance, initial insights suggest that the MHRA will seek a review by the UK Good Laboratory Practice Monitoring Authority or request additional information to support the submitted non-clinical data. As a reminder, Sareum filed the CTA for SDC-1801 in July 2022 with the intention of commencing the Phase Ia trial in Q4 CY22. While the company is seeking further clarification from the MHRA on the requirements for resubmission, we now anticipate a delay in launching clinical activity.

SDC-1801, a novel TYK2/JAK1 inhibitor, is Sareum's lead asset, targeting autoimmune indications such as psoriasis, lupus and inflammatory bowel disease. The drug has been engineered to selectively target the TYK2/JAK1 enzymes, with the aim of circumventing the safety and toxicity issues related to the JAK2 and JAK3 isoforms and thereby offering a safer alternative to the currently approved JAK inhibitors. SDC-1801 completed a preclinical toxicology studies in Q421 and the CTA was filed in July 2022. Sareum has developed a capsule formulation of the drug with the synthesis of the drug's active pharmaceutical ingredient, under good manufacturing practice conditions. We highlight that the company does not undertake any R&D activities internally and that all development work is outsourced to specialist contract research organisations (CROs).

The decision by the MHRA is unexpected as Sareum maintains that the preclinical data package it submitted was robust and collated in collaboration with highly specialised CROs. The magnitude of the issue and what exactly the MHRA observations relate to is unclear. Sareum is in talks with the MHRA to seek further information and will be updating the market on subsequent developments. The company had planned to initiate the Phase Ia trial (safety and dose-finding study in healthy volunteers) in Q422 which, in our opinion, is now likely to be delayed until 2023 at the earliest.

Historical estimates

Year end	Revenue (£m)	PBT (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/19	0.00	(1.7)	(2.6)	0.0	N/A	N/A
06/20	0.04	(1.1)	(1.6)	0.0	N/A	N/A
06/21	0.00	(1.7)	(2.3)	0.0	N/A	N/A
06/22	0.00	(2.6)	(3.2)	0.0	N/A	N/A

Source: Company data. Note: *EPS figures have been adjusted retrospectively for the 50:1 share consolidation in March 2022.

Pharma and biotech

9 November 2022

Price	153p
Market cap	£125m

Share price graph

Share details

Code	SAR
Listing	AIM
Shares in issue	68.07m
Net cash (£m) at 30 June 2022	4.3

Business description

Sareum Holdings is a UK-based drug development company, specialising in small molecule kinase inhibitors. Its lead programmes are its preclinical TYK2/JAK1 inhibitors, SDC-1801 for autoimmune diseases and SDC-1802 for cancer. Sareum filed a clinical trial authorisation application for SDC-1801 in July 2022. Other programmes include the CHK1 inhibitor SRA737, the rights of which have recently been returned to Sareum and its co development partner CRT Pioneer Fund LP from Sierra Oncology, and the de-prioritised FLT3+Aurora kinase inhibitor.

Bull

- SDC-1801's novel TYK2 selectivity may be attractive to partners, pending clinical validation.
- First-in-class opportunity for SDC-1802 in multiple cancer indications.
- Approval of Sotyktu provides regulatory feasibility of TYK2 inhibitors.

Bear

- Safety profile of combined TYK2/JAK1 inhibitor not certain or proved yet.
- Potential funding challenges delaying clinical progress of SDC-1801 and SDC-1802.
- Markets sought by SDC-1801 and SDC-1802 are highly competitive.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Jyoti Prakash, CFA +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

General disclaimer and copyright

This report has been commissioned by Sareum Holdings and prepared and issued by Edison, in consideration of a fee payable by Sareum Holdings. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia