Sareum Holdings

SDC-1801 poised for the clinic

Sareum's FY22 results (to end-June 2022) provided both a financial and operational update on the company's progress with its developmental pipeline. Encouraging progress has been made with SDC-1801 and the company has filed an exploratory clinical trial application (CTA) to initiate a UK-based Phase Ia/b study. Subject to regulatory approval, management intends for Phase Ia of the trial to commence in Q4 of CY22. Additionally, the company continues to progress its preclinical pipeline through the development of its immunoncology asset SDC-1802 as well as explore strategic options for its clinical oncology asset SRA737. With a gross cash balance of £4.3m at the end of FY22, Sareum expects to have sufficient funding to take SDC-1801 through the Phase Ia portion of the study. We see regulatory approval to initiate the SDC-1801 Phase Ia trial as the next major catalyst for Sareum.

SDC-1801 CTA submitted

The CTA filing of Sareum's lead TYK2/JAK1 inhibitor marks a significant milestone in the development plan for SDC-1801. The company is awaiting approval from the UK Medicines and Healthcare Products Regulatory Agency before initiating a Phase Ia assessing the safety and tolerability of SDC-1801 in healthy subjects. If successful, the results would provide support to initiate Phase Ib of the study in 2023; however, management has communicated further funding options will need to be explored to support this.

Clarity over SRA737 provides focus

Following GlaxoSmithKline's (GSK's) $1.9bn acquisition of Sierra Oncology in July 2022, Sierra has returned the rights to Sareum's out-licensed CHK1 asset SRA737 (held in partnership with the CRT Pioneer Fund, CPF), which is being investigated for the treatment of solid tumours. While this was a setback for Sareum, SRA737's development had been in limbo so, in our view, the decision provides clarity for Sareum to now explore other strategic options. The company and partner CPF now have an opportunity to assess future development or licensing plans for SRA737, leveraging the compound's existing positive clinical data.

Subscriptions bolster FY22 cash position

During FY22 Sareum raised c £3.6m, after expenses, through three equity issues to high-net-worth individuals in July, August and December 2021. The financing is intended to further support the clinical development of SDC-1801.

Historical financials

Year end	Revenue (£m)	PBT (£m)	EPS (£)	DPS (p)	P/E (x)	Yield (%)
06/19	0.00	(1.5)	(0.05)	0.0	N/A	N/A
06/20	0.04	(1.0)	(0.03)	0.0	N/A	N/A
06/21	0.00	(1.7)	(0.02)	0.0	N/A	N/A
06/22	0.00	(2.6)	(0.03)	0.0	N/A	N/A

Source: Company data

Pharma and biotech

25 October 2022

Price	£1.5
Market cap	£102m

Share price graph

Share details

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

Business description

Sareum is a UK-based drug development company, specialising in small molecule kinase inhibitors. Its lead programmes are its pre-clinical TYK2/JAK1 inhibitors, SDC-1801 for autoimmune diseases and SDC-1802 for cancer. Sareum plans to initiate clinical trials for SDC-1801 in Q422. Other programmes include the CHK1 inhibitor SRA737, the rights of which have recently been returned to Sareum 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.

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TKY2 approval provides encouragement

On 9 September 2022 the US FDA approved Bristol Myers Squibb's first-in-class tyrosine kinase 2 (TYK2) inhibitor Sotyktu (deucravacitinib) for the treatment of moderate-to-severe plaque psoriasis in adults, making it the first selective TYK2 inhibitor to be approved for any indication. Sotyktu's approval was based on the results from the Phase III POETYK PSO-1 and POETYK PSO-2 trials, with both studies reaching primary endpoints on efficacy and safety. Importantly, the drug showed no material toxicology issues, which have been a particular concern regarding the JAK class of drugs (which includes JAK1, JAK2, JAK3 and TYK2) recently, resulting in black box warnings. We see this development as positive for the progression of SDC-1801, with potential read-across that provides regulatory feasibility for the clinical utility, application and safety of TYK2 inhibitors. Additionally, SDC-1801's dual mechanism of action may offer differentiation over Sotyktu's single targeted therapy. The psoriasis market also represents a sizeable opportunity for Sareum, with global sales of psoriasis drugs estimated to reach c $30bn by 2028 (source: EvaluatePharma).

Financials

Sareum's FY22 operating loss was £2.6m, up from £1.7m in FY21, attributed to higher R&D expenses related to late-stage pre-clinical activities and preparatory activities for the initiation of clinical trials for SDC-1801. The company received an R&D tax credit of £0.2m in December 2021 and expects to receive a further £0.4m in December 2022. We believe R&D and operating expenses will likely continue to increase as the pipeline approaches the clinic.

The company's cash balance at the end of FY22 was £4.3m, supported by three equity issues in July, August and December 2021, which raised total gross proceeds of £3.9m (£3.6m after expenses). Sareum's annual cash burn for FY22 was £2.1m and we believe spending in FY23 is likely to be materially higher as assets approach clinical trials, reflected in management's communication that it has sufficient cash to complete the Phase Ia portion of SDC-1801's upcoming clinical trial and accelerate preclinical work on SDC-1802; however, further funding will be required to initiate the Phase Ib portion for SDC-1801. Additional funds may be secured either through partnerships and/or equity issues to advance the programmes further. We anticipate that Sareum may evaluate out-licensing opportunities for SDC-1801 following Phase Ia, leveraging the data from the study to potentially secure a partnership deal.

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