SynAct Pharma

ADVANCE data support continued development

Clinical data update

Pharma and biotech

15 June 2026

SynAct Pharma has announced top-line results from the Phase IIb ADVANCE study of resomelagon in rheumatoid arthritis (RA), delivering a mixed but clinically informative dataset. While the trial missed its primary DAS28-CRP endpoint, several secondary efficacy measures and inflammatory biomarkers were supportive of drug activity. Notably, the selected 40mg dose achieved a competitive ACR20 response rate of 76.4% versus 60.8% for placebo (p=0.06), with the treatment effect reaching statistical significance in the ACR/EULAR Class II–III subgroup (76.9% vs 56.5%; p=0.03), which comprised the majority of enrolled patients. Significant reductions were also observed in c-reactive protein (CRP) levels and improvements in the Simplified Disease Activity Index (SDAI), alongside a favourable safety profile with no evidence of immunosuppression. We view these findings as encouraging but believe that end-of-Phase II (EoP2) meetings with regulators will be critical in determining whether the data package is sufficient to support Phase III development. We will provide a more comprehensive update following further analysis.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/24	0.0	(90.8)	(2.08)	0.00	N/A	N/A
12/25e	0.0	(119.0)	(2.17)	0.00	N/A	N/A
12/26e	0.0	(91.9)	(1.49)	0.00	N/A	N/A
12/27e	0.0	(50.8)	(0.76)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The Phase IIb ADVANCE study evaluated resomelagon as a novel first-line treatment in combination with methotrexate in 246 newly diagnosed RA patients with elevated inflammatory burden and severe disease activity. The study identified 40mg as the optimal dose for future development (vs the other two tested doses of 70mg and 100mg), confirming the non-linear dose-response profile previously observed with resomelagon. While the improvement on the primary DAS28-CRP endpoint was not met (1.98 vs 1.79 for placebo), the secondary efficacy signal at 40mg was positive, with ACR20 responses of 76.4% versus 60.8% for placebo and a statistically significant benefit in the ACR/EULAR Class II–III subgroup (76.9% versus 56.5%). For context, Rinvoq, the last approved JAK inhibitor, delivered an ACR20 of 71% at 12 weeks in the Phase III SELECT-COMPARE trial.

Importantly, the study also demonstrated statistically significant reductions in CRP levels (13.5mg/L reduction in the treatment arm vs 5.7mg/L in the placebo + methotrexate arm) and improvements in the SDAI (35.9 vs 28.5 for placebo; p=0.03), a clinically relevant measure of RA disease activity. These are supportive of SynAct's pro-resolution approach, which aims to restore immune balance rather than suppress immune activity. We believe this remains a key strategic differentiator, particularly in an RA treatment landscape increasingly focused on balancing efficacy with long-term safety and tolerability.

Despite missing the primary endpoint, we believe the broader dataset supports continued development. We expect the company to focus on upcoming EoP2 meetings with the FDA and EMA, including discussions about Phase III design and dose selection, while advancing partnering discussions to support Phase III development. We will provide a more detailed update following further review.

Price	**SEK14.50**
Market cap	**SEK815m**
	SEK9.30/US$
Net cash/(debt) at 31 March 2026	SEK65.8m
Shares in issue	56.2m
Code	SYNACT
Primary exchange	OMX
Secondary exchange	N/A

Share price performance

Business description

SynAct Pharma is a clinical-stage biotechnology company focused on the development of treatments to resolve, rather than inhibit, ongoing inflammatory processes in acute and chronic diseases.

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