SynAct Pharma

Post-hoc analysis strengthens Phase III case

Clinical data update

Pharma and biotech

7 September 2026

SynAct Pharma has reported further analysis of the Phase IIb ADVANCE study (testing resomelagon in rheumatoid arthritis), providing a clearer explanation for the unexpectedly strong placebo response. Management estimates that around 20% of patients entered the study during a temporary inflammatory flare, with this subgroup accounting for much of the variability observed in the placebo arm. Excluding these patients, the 40mg resomelagon achieved an ACR20 response of 79% versus 55% for placebo ($p<0.05$), alongside greater separation in ACR50 and DAS28 improvements. We believe the analysis strengthens the overall interpretation of ADVANCE and should provide useful support for upcoming regulatory discussions. Importantly, we believe that these findings offer a practical framework for the Phase III design, where tighter selection of patients with stable baseline inflammatory activity should be as important as demonstrating deeper and more durable responses over the proposed 26-week treatment period.

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
12/25	0.0	(119.0)	(2.17)	0.00	N/A	N/A
12/26e	0.0	(101.4)	(1.68)	0.00	N/A	N/A
12/27e	0.0	(63.3)	(0.98)	0.00	N/A	N/A

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

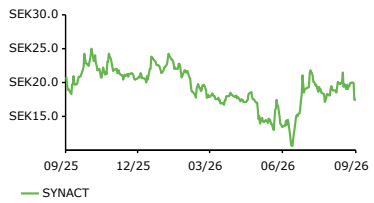
Management highlighted that one in five patients in ADVANCE had active inflammatory flare-ups, with this subgroup accounting for the majority of variance in placebo response. Excluding these, the ACR20 delta widened to 24pp versus 15.6pp in the original ADVANCE dataset. More importantly, on the primary DAS28-CRP endpoint, placebo-adjusted separation improved to 0.5 points from 0.19 points. This suggests that a single elevated inflammatory measurement such as hsCRP may not adequately identify stable inflammatory disease, with baseline stability potentially as important as the absolute CRP threshold. This aligns with prior rheumatoid arthritis (RA) research which noted that selecting patients during periods of temporarily high disease activity can result in material regression to the mean, supporting multiple assessments to establish a more representative baseline.

We believe this provides a strong framework for SynAct to design the Phase III study, which it expects to submit (alongside the supporting toxicology programme) to the FDA in Q426 ahead of a Type C meeting, with feedback expected by late 2026/early 2027. This could include repeated pre-randomisation assessments to confirm stable inflammatory activity. The proposed 26-week treatment period also appears informed by ADVANCE, where responses continued to deepen beyond week eight. The latest analysis showed ACR50 of 38% versus 30% in the new subset, which, while improved from the near-flat separation in the original analysis, was not statistically significant. Extending treatment beyond the 12-week Phase IIb window should therefore provide a more robust test of whether the strong ACR20 signal translates into greater differentiation on ACR50 and ACR70.

We view the Type C meeting as a key step in defining the next phase for resomelagon in RA, with regulatory endorsement of Phase III the most meaningful valuation catalyst. Other upcoming catalysts include the first Brazilian dengue commercial agreement and RESOVIR-2 Part 1 data, followed by full RESOVIR-2 and RESPIRE readouts.

Price	**SEK17.50**
Market cap	**SEK984m**
	SEK9.30/US$
Net cash/(debt) at 30 June 2026	SEK14.2m
Shares in issue	56.2m
Free float	56.5%
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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