Evaluate Vantage

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Mesoblast can’t catch a break

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Four years after Teva dumped Mesoblast’s then lead asset, Revascor, which later bombed in the clinic, the Australian group’s next hope, Ryoncil, has been hit with a US complete response letter. The slapdown, for childhood graft-versus-host disease, came in spite of an earlier positive advisory panel vote, and cited the need for at least one additional clinical trial plus further evidence that potency measurements support biological activity. Ryoncil, an allogeneic mesenchymal stem cell product, is marketed in Japan by JCR Pharmaceuticals, and Mesoblast had bought it from Osiris for $20m in 2013. At least long-suffering investors were not made to wait too long; when the Teva deal ended Mesoblast stock had been halted for 10 days pending an announcement, and this time Mesoblast had initially asked for a halt until Monday – with no indication as to whether a regulatory decision had been made. In the event the bad news was revealed yesterday, a day after the FDA’s action date, sending the Australian-listed stock down 37%. The GvHD market is becoming competitive, but as nothing is approved specifically for refractory, childhood use Mesoblast now wants to seek accelerated approval, and to conduct the additional study as a post-marketing requirement.

Mesoblast's late-stage mesenchymal cell therapy projects

Project	Status	Indication(s)	2026e sales ($m)	NPV ($m)
Ryoncil	US CRL (approved in Japan as Temcell HS)	Childhood GvHD	341	654
Revascor	Phase III (failed phase II)	Heart failure	576	913
MPC-06-ID	Phase III	Chronic low back pain	126	316

Source: EvaluatePharma.