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Biogen says goodbye to Vounatsos and remaining Aduhelm hopes

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The company's chief executive pays for the Aduhelm fiasco, but who will want to step up and take on the Biogen challenge?

It is pretty much universally agreed that Aduhelm ranks as one of the worst drug launches in the history of biopharma; Biogen's chief executive, Michel Vounatsos, has now paid the price for that failure. The company announced his departure today alongside news that the towel has been all but thrown in on the problematic Alzheimer's drug.

With Aduhelm pulling in just $2.8m in the first quarter, following CMS's refusal to reimburse it, Biogen will now "substantially eliminate" the drug's commercial infrastructure. It is almost ironic that on a call this morning the company listed the approval of Aduhelm as one of Mr Vounatsos's biggest achievements, when the controversy surrounding this and his heavy bets on the product's success were ultimately the source of his downfall.

Biogen will continue to fund patientaccess programmes and certain clinical trials, including the Embark re-dosing and the Envision post-marketing studies. This move, which just stops short of totally abandoning Aduhelm, could indicate some lingering hope that other phase 3 anti-amyloid approaches might show signs of efficacy, possibly leading to the resurrection of the doomed project.

Given Aduhelm's poisoned legacy this looks like wishful thinking of the highest order. But then Biogen's next biggest hope is another Alzheimer's asset.

Phase 3 data for the Eisai-partnered lecanemab are due in the third quarter. Given that the Centers for Medicare & Medicaid Services's strict rules extend to all anti-amyloid beta MAbs, any ambiguity in the data will see any potential reimbursement decision go the way of Aduhelm.

What next for Biogen: the big events		
Project	**Details**	**Next steps**
Lecanemab	Anti-amyloid beta Alzheimer's MAb jointly owned with Eisai	Rolling AA submission to complete Q2; ph3 data from Clarity AD trial due Q3
Zuranolone	Depression asset jointly owned with Sage	Rolling submission in MDD to complete H2 2022; ph3 PPD trial Skylark to read out mid-year
BIIB104	AMPA receptor potentiator	Ph2 Tally trial, in CIAS, to read out mid-year
BIIB800	Biosimilar referencing anti-IL-6 MAb Actemra	US and EU filings due H2 2022
Byooviz	Biosimilar referencing anti-VEGF MAb Lucentis	US launch due mid year
BIIB080	Anti-tau antisense oligonucleotide optioned from Ionis	Ph2 study to start this year
Note: AA=accelerated approval; MDD=major depressive disorder; PPD=post partum depression; CIAS=cognitive impairment associated with schizophrenia. Source: company communication.		

So what else does Biogen have in the locker? Depression data from zuranolone in major depressive disorder is a big event; the asset recently scored in the phase 3 Coral trial, but concerns have been voiced about lack of durability.

The rest of Biogen’s portfolio remains either relatively early or in the tough biosimilars area, where several big players have recently scaled back activities. Biogen itself has sold its stake in a joint venture with Samsung Bioepis.

As for future opportunities Priya Singhal, Biogen's interim head of R&D, said the company would keep its focus on neuroscience, but could be open to “adjacencies”, pointing to Biogen’s work in lupus.

Another outstanding question is who will be willing to take on what must be one of the biggest turnaround jobs in the sector. Issues include the continuing turmoil surrounding Aduhelm, a lacklustre pipeline, generic competition eating into former cash cows Rituxan and Tecfidera, and net debt of $2.5bn.

Whoever it is will have their work cut out.