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Aerie parties like it's 2015 with Roclatan win

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Pivotal trial success for Aerie Pharmaceuticals' combination glaucoma therapy has returned it to pre-biotech bust valuations. Roclatan outperformed both its constituents, generic latanoprost and Aerie's single agent Rhopressa, in the Mercury 1 trial, one of two pivotal studies the California-based group will need to achieve US approval.

The data will not do much to improve the profile of Rhopressa, a Rho kinase inhibitor now under US regulatory review, as that asset showed only non-inferiority to latanoprost. Nonetheless, the Roclatan results provided Aerie with an opportunity to top up its cash pile: the company did not permit even a single trading session to pass before announcing a $50m fund raising.

One down, one to go

From Mercury 1, Aerie reported intraocular pressure data from the first 90 days of treatment, the primary endpoint in a 12-month trial that will continue to measure safety and visual acuity. Roclatan showed significantly reduced intraocular pressure compared with either Rhopressa or latanaprost when measured after two weeks, six weeks and three months.

Roclatan and Rhopressa had higher discontinuation rates, driven by adverse events – none of the patients taking latanoprost withdrew because of adverse events. Half of Roclatan patients reported conjunctival hyperaemia, compared with 14% of latanoprost patients, and 10% reported conjunctival haemorrhage, while less than 1% of those taking latanoprost did.

The other trial from which Aerie will need positive data to submit Roclatan for FDA approval, Mercury 2, should yield 90-day results in the first half of 2017, around the same time a European registration trial is expected to begin. Aerie executives expect to submit Roclatan for US approval by the end of 2017.

As for the project already under US review, Aerie reported that Rhopressa showed non-inferiority to latanaprost in patients with a baseline intraocular pressure below 25mmHg. This was the population that turned failure into success, as the FDA allowed a change to restrict the analysis for the primary endpoint of the pivotal Rocket-2 trial to the 25mmHg and below population after a broader analysis failed (*Aerie goes airborne as trial revision breeds win, September 17, 2015*).

The group's announcement of its filing for Rhopressa does not specify whether it is for just this population, but presumably, because of negotiation with the FDA during clinical development, it will be.

In any case, Roclatan is seen as the more important of the two projects, with the *EvaluatePharma* consensus of sellside analysts forecasting 2022 sales of $402m, compared with $170m for Rhopressa.

Cash is king

After the post-market announcement of trial results on Wednesday shares jumped 60% to $33.81 in early trading today, flirting with their record high of $34.15 recorded last April, before Rhopressa's initial stumble.

It is not surprising that Aerie decided to raise money, but the speed was perhaps a bit of a shock – a filing for a $50m at-the-market raise emerged before trading began today.

Aerie had $58.5m of cash on June 30 and had spent $44.8m on R&D and general corporate costs in the first half of 2016, so it could not hurt to top up reserves. If it is assuming that a solo commercial launch is on the cards, it could need more cash – however, if it believes that a trade sale is likely then the current sum might be enough to strengthen its negotiating position.

Glaucoma being an area with few innovative projects, big ophthalmology players like Allergan and Novartis might be in the M&A frame – Allergan is certainly not afraid to spend, and Novartis needs to boost its lagging Alcon division. Prospective buyers will need to assess what value Roclatan offers to a crowded and payer-pressured space before preparing their term sheets.

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