Evaluate Vantage

December 19, 2017

Christmas comes early for Aerie

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With a weighty $2bn market valuation, the casual observer could be forgiven for assuming that Aerie Pharmaceuticals is already well on the way to forging a successful glaucoma franchise.

But yesterday's earlier than expected approval for Rhopressa is only the first firm step on that path. Next year the company must prove itself capable of selling the product in a highly competitive space, and then repeat the trick with a much more important follow-on asset.

These are not insignificant hurdles, but many investors remain optimistic – in the wake of a positive FDA advisory committee review in September shares in the company have surged to above $60. The sellside remains even more excitable, with many banks publishing price targets above $70, and unashamedly pushing the theory that the California firm is a takeout target.

This is a bold call ahead of evidence that Aerie can make a mark in this space. Many of the eyedrops used to treat glaucoma are off-patent, providing payers with a strong case to push physicians to try cheaper options first. And there is also an effective surgical option on the table, meaning that Aerie's competitors will be coming from many sides. Regulators were never going to be this product's harshest critic.

Competitive forces

Rhopressa works by increasing the throughput of fluid through the eye. It is an inhibitor of Rho kinase and norepinephrine transporter, and represents a novel mechanism of action in this condition. However its pivotal programme struggled to demonstrate convincing evidence of non-inferiority to timolol, a type of beta blocker also used in drop form to treat glaucoma.

Only one of three phase III trials managed to demonstrate non-inferiority to timolol across patients with high and low intraocular pressure (IOP); data in Rhopressa's label emphasises its efficacy in patients with lower IOP at baseline.

The company argues that Rhopressa's minimal systemic side effects compared with beta blockers are important, but the project is not devoid of unwanted impacts – 53% of patients experienced eye redness and around 20% developed corneal deposits. With undifferentiated efficacy and its own tolerability issues, Rhopressa looks destined to remain an add-on to the most widely used first-line treatment, prostaglandins, and expensive next to cheap beta blockers.

The hugely successful prostaglandin class is now almost completely off-patent, and is dominated by Pfizer's Xalatan. It is this active ingredient, latanoprost, that Aerie has combined with netarsudil to create Roclatan, its follow-on asset.

This has been pegged by the company and the sellside as a potential first-line therapy as two phase III trials found superiority for the combination over its components. A US filing is on the cards in the coming months, while in Europe the company is awaiting results of a trial that pits Roclatan against Ganfort, a combination of Allergan's prostaglandin Lumigan and timolol. That should report early-2019, and remains an important test.

Pitched perfectly? Sellside and market valuations for Aerie

	Global sales ($m)			
Product	**2018e**	**2020e**	**2022e**	**Today's NPV ($m)**
Roclatan	-	154	389	370
Rhopressa	27	126	208	471
			Total NPV	841
			Market cap	2,140

Source: EvaluatePharma.

In the meantime a slow start is expected for Rhopressa next year as reimbursement is ironed out. Aerie plans to

launch in May, and the sellside has pencilled in $27m in sales for 2018, according to *EvaluatePharma's* consensus.

Quicker uptake is forecast for Roclatan, but much will depend on how Aerie manages Rhopressa's launch. In a genericised market where payers have the upper hand, it is easy to see how this product could fare better in the hands of an owner with deeper pockets.

Thus finding the correct price is now critical for both the company and its investors. If Rhopressa is pitched too high, Aerie's market value will look similarly inflated.

This story has been corrected to show that Mercury 3 results are expected in 2019, not 2018.

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