

How deep does the rabbit hole go?

European Life Sciences

19 September 2018, 08:38

Pharming reported that the FDA issued a complete response letter (CRL) in relation to its sBLA for Ruconest as HAE prophylaxis treatment, requesting an additional trial be run to consider the application. Although we assumed approval in our base case valuation, as detailed in our recent report, we had concerns regarding the small size of the trial (n=32 vs. n=125 in lanadelumab phase III) and an unrepresentative sample with very high HAE attacks at baseline. As per our sensitivity analysis, we now expect flat sales in the coming years and lower our PT to €0.40 (from €0.60). We reiterate our SELL rating and add Pharming to our favorite ideas list. For the full details on the case, please find our initiation of coverage report from last week [here](#).

Ruconest was destined for niche market share

Due to US regulatory delays, Ruconest was launched in 2014 in a market dominated by Shire and CSL. Apart from a rather theoretically safer profile, Ruconest as acute HAE treatment had on par efficacy data and no administration advantage. Moreover, repeated change in ownership never allowed Ruconest to ramp-up meaningful sales. Ruconest recently caught a break due to competitor shortages and sales tripled in 2017. With such issue resolved, Ruconest sales in the last two quarters were flat, which we believe is a return to normal and forecast only modest growth in the shrinking acute market with peak sales of \$88m.

BioCryst is likely to launch the first oral treatment in 2020

BioCryst's prophylaxis oral treatment is on track to report phase III data in Q2'19. We believe the probability of success is high, with a launch in 2020. We think this will accelerate the shift of patients towards prophylaxis as the convenience of a daily pill simply outweighs treating attacks as they come.

Curbed prophylaxis sales growth reduces our PT to €0.40

We estimated Pharming's prophylaxis sales to grow to just above \$150m at peak, which reduces to ~€70m now with the approval rejection. As a result, we cut our PT to €0.40 (from €0.60). We reiterate our SELL rating and add Pharming to our favorite ideas list.

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Rating	SELL
Price Target	€0.40
Closing price (18 Sep 2018)	€0.97

Previous rating and Price target

Change	Revision	Old
PT		€0.60

Company data

Market capitalization	\$815.0m
52-week range	€0.54 - €1.62
Number of shares	616.7m
Free float	91.6%
Avg. daily volume (20d)	15,950,440
Avg. daily turnover (20d)	€18,301,899
Daily turnover	€85,130,810
Next announcement date	25 October 2018
Reporting Period	Q3'18 results



Source: Bloomberg

Pharming - Company Profile

<p>Company description</p> <p>Pharming is a Dutch biotech company commercializing a recombinant C1-INH, Ruconest, for the treatment of hereditary angioedema (HAE)</p>		<p>Rating SELL</p> <p>Price Target €0.40</p> <p>Closing price (18 Sep 2018) €0.97</p> <p>Date 19 September 2018, 08:38</p>																			
<p>SWOT analysis</p>		<p>Source: Bloomberg</p>																			
<p>Strength</p> <ul style="list-style-type: none"> Cash generating biotech company Ruconest is safe and has reliable supply Available internal funds to invest in pipeline 	<p>Weakness</p> <ul style="list-style-type: none"> Ruconest is a single source revenue stream New compounds pipeline pre-clinical Potential pricing pressure in the US HAE market 																				
<p>Opportunities</p> <ul style="list-style-type: none"> Recurring supply issues with plasma-derived C1-INH Phase III failure of oral BCX7353 in Q2'19 Ruconest investigator-initiated trials are positive 	<p>Threats</p> <ul style="list-style-type: none"> Shire launch of more convenient lanadelumab in HAE Phase III success of oral BCX7353 in Q2'19 Phase II success of oral KVD9000 in mid-19 																				
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Source: Kempen estimates

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Companies mentioned in this report
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Definitions	
Method	Company reports include a discussion of valuation methods used in order to determine Price Targets. The resulting conclusions lead to a Rating as below.
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Total	167 (100%)	100%

Rating distribution based on data of 19 September 2018.

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12 Months Rating and Price Target history

Company	Bloomberg	Price*	Date & Time	Change	New	Previous	Analyst
Pharming	PHARM NA	€ 0.969	19 Sep 2018 07:38AM	Price Target	€ 0.4	€ 0.6	Alex Cogut

Source: Kempen estimates
* Price: Previous day closing price

Pharming 12 Months Rating and Price Target history as of 18 Sep 2018



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