STIFEL

18 July 2016

Pharming Group N.V.
BUY
EU Pharmaceuticals

Positive results from Phase II prophylaxis trial

Pharming has announced positive Phase II trial results from its 32-patient trial using Ruconest for the prophylactic treatment of hereditary angioedema (HAE). The intent-to-treat analysis (ITT) demonstrated a statistically significant reduction in mean number of placebo attacks during the 28-day period, for both twice-weekly and once-weekly administration of Ruconest. Approval in prophylaxis is an important step for Pharming, allowing it to access the c.$600m HAE prophylaxis market in the US, where Shire's Cinryze is the only approved product. We believe Pharming remains undervalued in light of the potential to be approved in prophylaxis in 2018, and reiterate our Buy recommendation.

Statistically significant reduction in HAE attacks. 32 HAE patients with at least four attacks/month were enrolled, receiving Ruconest once and twice-weekly and placebo. In the intent-to-treat analysis (ITT), there was a statistically significant reduction in the mean number of HAE attacks during the 28-day treatment period, from 7.2 attacks with placebo to 2.7 attacks with twice-weekly and 4.4 attacks with once-weekly dosing of Ruconest. In addition, 74% of patients on twice-weekly Ruconest had at least a 50% reduction in attack frequency. Ruconest was reported to be generally well-tolerated, with no treatment-related serious adverse events.

FDA approval for Ruconest in prophylaxis of HAE possible in 2018. At present, Shire's Cinryze is the only product approved for prophylactic use for HAE by the FDA, and is self-administered intravenously every three to four days. Shire reported $618m sales for Cinryze in 2015, versus its acute HAE treatment Firazyr of $445m. We forecast Ruconest sales of $85m in prophylaxis by 2020, assuming the product launches in 2018.

The study is the first step of a 50/50 shared cost collaboration with US partner Valeant to develop Ruconest for prophylaxis of HAE. We have previously assumed the FDA will require a Phase III clinical trial for approval, and that Pharming is likely to initiate this in 2H16, with FDA submission therefore expected in 2H17. The pathway to regulatory approval in the US is likely to be confirmed by an end-of-Phase II meeting with the FDA. Under the terms of the agreement with Valeant, Pharming is entitled to use the data from the prophylaxis trials for regulatory submission elsewhere.

Target price methodology/risks

Target price is based on our risk-adjusted product-based NPV valuation.

Risks to the investment include Pharming's reliance on distribution partners to execute commercialisation strategy for Ruconest, along with the risk that market acceptance is lower than expected or unforeseen safety and efficacy issues affect the global growth. Competition may also increase from 2018 onwards, and the increasing tendency of health insurers to reduce costs and reimbursement may provide additional headwind to Ruconest commercialisation.

Price (15 July 2016)	€0.22
Rating	BUY
Target Price	€0.71
Stock code	PHARM NA
Market cap (€m)	89

Key financials

Year to Dec	2015A	2016E	2017E
Sales (€)	10.8	14.2	18.9
EBIT adj	(13.01)	(9.15)	(7.23)
EBIT margin (%)	(120.5)	(64.4)	(38.2)
EPS adj (c)	(2.4)	(2.5)	(2.0)
EV/EBITDA (x)	--	--	--
PE adj (x)	NA	NA	NA
DPS (c)	0	0	0
Div yield (%)	0	0	0
FCF yield (%)	0	0	0

Prices are as of close 15 July 2016

All sources unless otherwise stated: Company data, FactSet, Stifel estimates

Olivia Manser	olivia.manser@stifel.com	+44 (0) 20 7710 7495
Max Herrmann	max.herrmann@stifel.com	+44 (0) 20 7710 7606
Christian Glennie	christian.glennie@stifel.com	+44 (0) 20 7710 7454
UK Sales desk		+44 (0) 20 7710 7600

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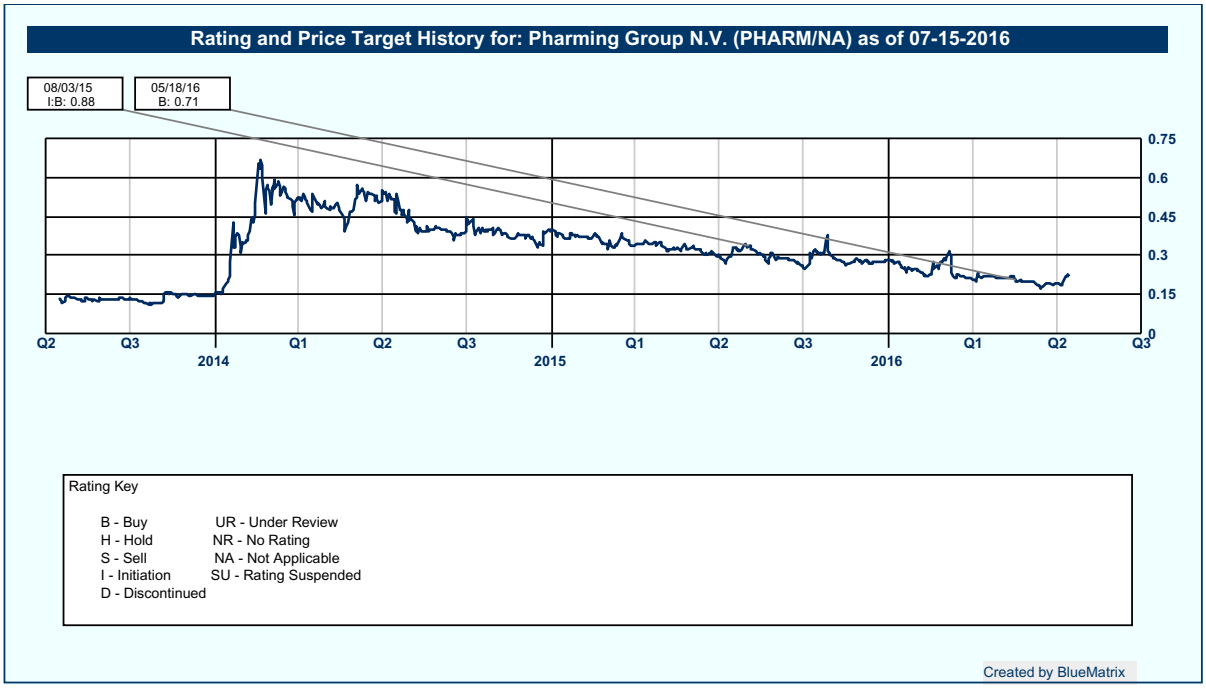

For a price chart with our ratings and any applicable target price changes for PHARM.NA go to
http://sf.bluematrix.com/bluematrix/Disclosure?ticker=PHARM.NA

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