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QuickView

Xbrane

Price-beating products for major markets

Xbrane's first product offering will be Spherotide: the first generic formulation of the prostate cancer GnRH agonist triptorelin (sales $446m) made by Xbrane's Italian subsidiary. First sales are likely to be in Iran from 2017. Bigger sales could be generated by a biosimilar of Lucentis, Xlucane, produced at a low cost using a proprietary process. Xlucane might be marketed in the US from 2021, a year after patent expiry, and from patent expiry in Europe in 2022. Lucentis sales worldwide are about $3.6bn.

Prostate cancer – a $500m generic opportunity

Triptorelin, branded as Decapeptyl (total sales 2015: $446m – Ipsen sales €334m plus Allergan and Ferring) is indicated for advanced, non-metastatic prostate cancer. It also treats Endometriosis. Triptorelin is one of a well-established class that down-regulate GnRH receptors; all brands are off patent. Most sales are of three-month depot formations; continuity of dosing is crucial. The leaders are goserelin (Zoladex, AstraZeneca sales 2015: $816m) and leuprolide (Lupron Abbive: $826m). Generic depot formulations been very difficult to make. Spherotide is produced in Xbrane's Italian subsidiary, acquired in September 2015. Initial sales are planned to Iran in 2017; Xbrane estimates this market as worth $30m. It is awaiting GMP approval to ship a SEK7m order. A recent Chinese SEK70m deal should yield SEK17m cash in Q117. Clinical trials will be required for approval elsewhere. EU and US applications are planned in 2018. There is no clinical data.

Lucentis – limited competition for a share of $3.6bn

Xlucane is a biosimilar product of Lucentis (rabinizumab, Roche/Novartis 2015 sales: $3.6bn) to treat wet acute macular degeneration (AMD). Sales fell in 2015 due to competition with Eylea (Regeneron/Bayer 2015 sales: $4bn). Xbrane has a patented production method that lowers its bulk material cost by 85%. The process is being scaled up and needs GMP validation. For the US and EU, Xbrane plans a 400-700 patient clinical trial that might start by late 2017. The US patent on Lucentis expires in 2020 and in 2022 in Europe. A Lucentis biosimilar was launched in India by Intas in 2015. Formycon and bioeq GmbH are in Phase III aiming for H1 2020 data. Pfenex has Phase II data on PF582 but no partner. Xbrane indicates that Iran sales are possible from H217 and in EU/US upon patent expiry.

Valuation: attractive generic markets

Xbrane's value progression will depend on revenues over 2017-18 and its ability to fund and run clinical development on Spherotide and Xlucane. These are attractive generic markets. Partnering for sales into bigger markets will be needed. Cash (30 June) was SEK57m making the EV about SEK130m at the current market value.

Consensus estimates

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/14	0.2	0.1	0.0	0.0	N/A	N/A
12/15	0.4	(11.6)	(5.2)	0.0	N/A	N/A
12/16e	N/A	N/A	N/A	N/A	N/A	N/A
12/17e	N/A	N/A	N/A	N/A	N/A	N/A

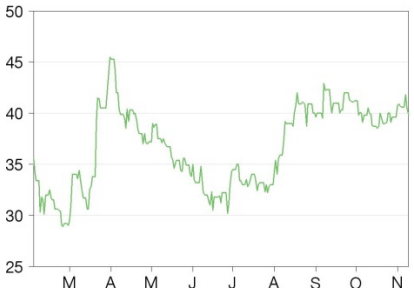
Source: Company data

Pharma & biotech

10 November 2016

Price	SEK39.9
Market cap	SEK188m

Share price graph



Share details

Code	XBRANE
Listing	NASDAQ First North
Shares in issue (current)	4.7m

Business description

Xbrane is a Swedish developer of biosimilars using a patented, more efficient bacterial culture technology. The lead product is Xlucane, a Lucentis biosimilar. Xbrane acquired an Italian slow-release generic pharmaceutical developer in 2015. The first product, Spherotide is planned for sale from 2017 in Iran.

Bull

- Spherotide sales in Iran possible from 2017 due to the less regulated market
- Limited generic competition in GnRH agonist class offering major generic substitution potential
- Only two or three Lucentis biosimilar projects

Bear

- Neither Spherotide or Xlucane has been GMP validated and there is no clinical data
- Depot formulations of GnRH agonists have been very hard to produce
- Xlucane's estimated bulk material cost advantage has to convert into competitive prices. Avastin remains as an off-label low-cost alternative

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Xbrane is a research client of Edison Investment Research limited

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