

Xbrane Biopharma

Biosimilar focus with Phase III trial about to start

Xbrane now focuses on developing high-margin biosimilar products with Xlucane, its Lucentis biosimilar, as the lead product. After the July 2018 SEK78m upfront deal with STADA, Xbrane is starting the global XPLORE Phase III trial. The primary endpoint reports in mid-2020 and XPLORE completes in February 2021. Xbrane is raising SEK59.3m at SEK30/ share to help fund its 50% share of the XPLORE study. Xbrane sold SEK20m of Spherotide (a triptorelin generic) to Iran in 2018. A partner is needed to progress development in Europe. Our valuation remains at SEK581m.

Year end	Revenue* (SEKm)	PBT** (SEKm)	EPS** (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	20.77	(44.16)	(8.14)	0.0	N/A	N/A
12/18	20.49	(12.59)	(2.04)	0.0	N/A	N/A
12/19e	20.00	(146.95)	(19.06)	0.0	N/A	N/A
12/20e	20.00	(240.41)	(28.96)	0.0	N/A	N/A

Note: *Revenue includes other income. **PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Xlucane now the core focus with STADA partnering

Xbrane is developing Xlucane, a monthly biosimilar of Lucentis (ranibizumab, Roche (US) Novartis (Eur); 2018 sales: \$3.6bn) to treat wet age-related macular degeneration. In July 2018, it was globally partnered with STADA, a private, €2.3bn sales company. Costs and profits are split 50:50. In Europe, the partners aim to launch in 2022 on Lucentis patent expiry; US patent expiry is in 2020. The global Phase III (NCT03805100, XPLORE) aims to recruit 580 patients starting in March 2019. The primary endpoint data are due in May 2020. The full 52-week trial ends in February 2021. Competitors include bioeq - Formycon with Phase III data and Samsung Bioepis with a Phase III reporting primary data soon. Roche has a bispecific antibody, Faricimab, entering Phase III after a good Phase II performance with one injection every 16 weeks. It is also trialling new Lucentis delivery systems.

Spherotide seeking a European partner

Spherotide is a generic triptorelin depot that treats prostate cancer, endometriosis and uterine fibroids. In 2018, Ipsen, the market leader, sold €372.6m of Decapeptyl (triptorelin), an 8% volume rise. Spherotide 2018 bulk sales to Iran were SEK20m at a 22% margin; payment is difficult due to sanctions. Xbrane reported a SEK13m upfront in H118 in a deal with Chinese CR Pharma. European development depends on signing a partner to fund trials; Xbrane does not plan to invest directly.

Valuation: Value at SEK581m, SEK59.3m rights issue

Our indicative valuation revised in November 2018 remains at SEK581m based on Xbrane expectations of up to a €100m Xlucane yearly profit share. This equates to SEK92/share before dilution. Xbrane is raising SEK59.3m at SEK30/share before expenses less a pro-rata of SEK6.4m set off against the SEK45m loan; further funds will be needed in 2020 to cover its 50% share of the company-estimated €30–40m XPLORE costs. Operating costs after sales in 2018 were SEK111m. Pre-payments for XPLORE are SEK34m, (SEK1m 2017). Xbrane gained SEK99.7m in deal fees and borrowed SEK45m in 2018. Year-end cash was SEK101m.

FY18 results and rights issue

Pharma & biotech

4 March 2019

Price SEK35.6

Market cap SEK294m

SEK9.14/US\$

Cash (SEKm) at 31 December 2018 101

Shares in issue (post rights) 8.27m

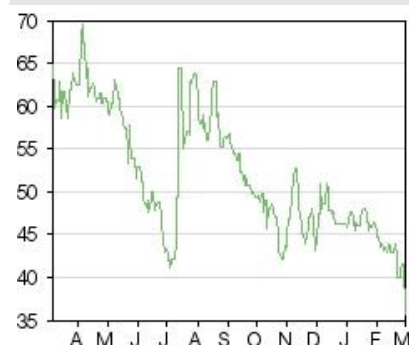
Free float 69%

Code XBRANE

Primary exchange NASDAQ First North

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (20.2) (25.1) (47.2)

Rel (local) (23.1) (28.4) (49.2)

52-week high/low SEK69.5 SEK35.6

Business description

Xbrane Biopharma is a Swedish developer of biosimilars using a patented, more efficient manufacturing system. The lead product is Xlucane, a Lucentis biosimilar, partnered with STADA for 2022 European launch. Xbrane sells a triptorelin generic, Spherotide, in Iran and aims to develop a Chinese product with CR Pharma.

Next events

Xlucane Phase III March 2019

Q119 results 14 May 2019

Analyst

Dr John Savin MBA +44 (0)20 3077 5735

healthcare@edisongroup.com

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Xbrane Biopharma is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

	SEK 000s	2017	2018	2019e	2020e
Year end 31 December		GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS					
Revenue		20,771	20,485	20,000	20,000
Cost of Sales		(15,829)	(15,907)	(15,800)	(15,800)
Gross Profit		4,942	4,578	4,200	4,200
Other income		2,515	99,742	0	0
EBITDA		(40,871)	(7,468)	(140,527)	(233,986)
Operating Profit (before amort. and except.)		(43,939)	(10,890)	(143,949)	(237,408)
Intangible Amortisation		(779)	(525)	(525)	(525)
Other		0	0	0	0
Operating Profit		(44,718)	(11,415)	(144,474)	(237,933)
Net Interest		(217)	(1,700)	(3,000)	(3,000)
Exceptionals		0	0	0	0
Profit Before Tax (norm)		(44,156)	(12,590)	(146,949)	(240,408)
Profit Before Tax (FRS 3)		(44,935)	(13,115)	(147,474)	(240,933)
Tax		0	(121)	0	0
Profit After Tax (norm)		(44,156)	(12,711)	(146,949)	(240,408)
Profit After Tax (FRS 3)		(44,935)	(13,236)	(147,474)	(240,933)
Average Number of Shares Outstanding (m)		5.4	6.2	7.7	8.3
EPS - normalised (öre)		(814)	(204)	(1,906)	(2,896)
EPS - normalised fully diluted (öre)		(814)	(204)	(1,906)	(2,896)
EPS - FRS 3 (öre)		(828)	(213)	(1,913)	(2,903)
Dividend per share (öre)		0	0	0	0
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		82,861	89,798	83,532	81,610
Intangible Assets		63,657	64,182	59,838	59,838
Tangible Assets		18,569	16,745	14,823	12,901
Investments		635	8,871	8,871	8,871
Current Assets		28,101	161,658	65,070	46,585
Stocks		3,065	5,525	5,525	5,525
Debtors		8,072	10,494	10,494	10,494
Cash		7,903	100,972	4,384	10,139
Other current assets		9,061	44,667	44,667	20,427
Current Liabilities		(17,029)	(160,439)	(154,039)	(154,039)
Creditors		(17,029)	(114,878)	(114,878)	(114,878)
Short term borrowings		0	(45,561)	(39,161)	(39,161)
Long Term Liabilities		(4,664)	(7,704)	(17,629)	(258,036)
Long term borrowings		(1,119)	(4,159)	(4,159)	(224,159)
Other long term liabilities		(3,545)	(3,545)	(3,545)	(3,545)
Net Assets		89,269	83,313	(23,065)	(283,881)
CASH FLOW					
Operating Cash Flow		(36,848)	46,707	(143,016)	(212,238)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(3,347)	(1,598)	(1,500)	(1,500)
Acquisitions/disposals		0	0	0	0
Financing		20,004	48,238	48,437	0
Dividends		0	0	0	0
Other		(2,637)	(278)	(508)	(508)
Net Cash Flow		(22,828)	93,069	(96,588)	(214,246)
Opening net debt/(cash)		(29,612)	(6,784)	(51,252)	38,936
HP finance leases initiated		0	0	0	0
Other		0	(48,601)	6,400	0
Closing net debt/(cash)		(6,784)	(51,252)	38,936	253,181

Source: Edison Investment Research, Xbrane Biopharma accounts

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