

Orexigen Therapeutics

Contrave outperforming

Financial update

Pharma & biotech

Orexigen's re-launch of Contrave continues to be successful, with an 18% increase in prescriptions in the United States in Q217 compared to Q117. Importantly, net revenue per unit sold increased 37%, indicating better coverage and less discounting. Outside of the US, progress continues as the product has launched in 17 countries, with another 10-15 expected by Q118, including Germany and Italy. The company has also announced that it has commenced an exploration of strategic transactions as a means to maximize the value creation for shareholders.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/15	24.5	(67.3)	(5.24)	0.0	N/A	N/A
12/16	33.7	(138.1)	(9.73)	0.0	N/A	N/A
12/17e	94.0	(141.4)	(7.96)	0.0	N/A	N/A
12/18e	160.3	(72.7)	(4.67)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Continued success in patient-centric campaign

A shift from previous partner Takeda's healthcare provider-focused marketing to a campaign focused on consumers (but with continued detailing of high prescribing physicians) has yielded a dramatic increase in prescriptions. Prescriptions increased 39% in Q117 compared to the prior quarter and a further 18% in Q217. They now have approximately 50% of the branded obesity market (~8.5% of the total) according to Symphony Health.

10-15 more international launches by Q118

Contrave (Mysimba outside the US) has now launched in 17 countries, including South Korea, the UK, Spain and Poland. Launches in Germany, Italy and the Nordic countries (Denmark, Finland, Norway and Sweden) are expected in Q417. Orexigen is partnered in a total of 48 countries outside of the US.

Strategic review commenced

Orexigen has announced that it has formally engaged with a financial advisor to help explore strategic transactions to unlock value for shareholders. Whether that means acquiring an on-market product that is being divested from somewhere else or selling the company is unclear, though both moves make sense due to the tremendous operating synergies from selling multiple products with one salesforce.

Valuation: \$214m or \$13.87 per share

We are adjusting our valuation to \$214m (\$13.87/share), from \$194m (\$12.76/share). This is mainly due to higher 2017 Contrave estimates and rolling forward our NPV, and was mitigated by a higher net debt level as well as a larger number of shares. Orexigen's financing requirement is \$90m through to 2020, although this does not include the \$238m in convertible debt due in that year.

17 August 2017

Price **US\$2.44**
Market cap **US\$38m**

Net debt (\$m) at 30 June 2017	85
Shares in issue	15.4m
Free float	66.1%
Code	OREX
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



Business description

Orexigen Therapeutics is a biopharmaceutical company focusing on obesity treatments. It recently reacquired the rights to sell its sole product, weight management treatment Contrave, in the US from its previous partner, Takeda. Contrave was launched in the US in October 2014 and approved in the EU in March 2015 under the trade name Mysimba.

Next events

Contrave patent litigation decision	September/October 2017
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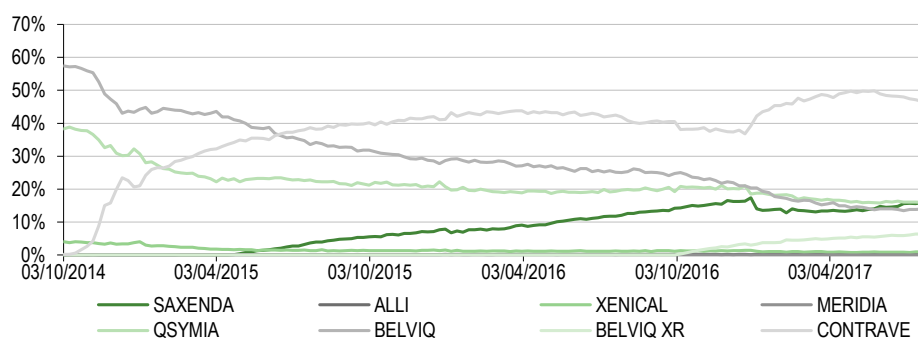
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Quarterly update

The re-launch of Contrave with a more patient-centric marketing campaign continues to pay dividends. Quarterly net sales increased 40% over the prior quarter and prescriptions increased 18% over the prior quarter. Importantly, the net revenue per unit sold increased to \$96, 37% higher than in Q216. This is also an 8% sequential improvement over the \$89 figure last quarter and surpasses the original 2017 guidance of \$85-90 in net revenue per unit sold. This indicates improving coverage as well as less discounting.

Based on prescription data from Symphony Health, this strategy has been particularly effective, increasing Contrave's market share by 10% to close to 50% of the branded obesity market (8.5% of the total market, which includes phentermine) since the consumer campaign started at the beginning of 2017 (see Exhibit 1). There has been a bit of a dip since the beginning of June, which is likely the result of less television advertising. It bears watching but given how much share it has gained, it is not surprising that it would give back a few points.

Exhibit 1: Market share in the branded obesity market



Source: Symphony Health

International momentum continues

Contrave, which is known as Mysimba in most international markets, has now launched in 17 countries (see Exhibit 2), including South Korea, the UK, Spain and Poland. Launches in Germany, Italy and the Nordic countries (Denmark, Finland, Norway and Sweden) are expected in Q417. Orexigen's goal is to launch in a total of 10-15 additional countries by Q118 as well as find partners in an additional 10-15 countries this year (focused on Latin America and Europe). For the first time, the company has recently included OUS net sales guidance of \$10-15m into its 2017 guidance (there have been \$7m in OUS net sales through Q217).

Exhibit 2: International Contrave launch timelines

Country	Partner	Launch date	Notes
South Korea	Kwangdong	Q216	
Czech Republic	Valeant	Q416	
Slovakia	Valeant	Q416	
Hungary	Valeant	Q416	
Poland	Valeant	Q416	
Romania	Valeant	Q416	
Spain	ROVI	Q117	
Bulgaria	Valeant	Q117	
Estonia	Valeant	Q117	
Lithuania	Valeant	Q117	
Latvia	Valeant	Q117	
Croatia	Valeant	Q117	
Slovenia	Valeant	Q117	
Greece	Valeant	Q217	
UK	Consilient Health	Q217	
Ireland	Consilient Health	Q217	
Cyprus	Valeant	Q317e	
Italy	Bruno	Q417e	
Denmark	Navamedic ASA	Q417e	
Finland	Navamedic ASA	Q417e	
Norway	Navamedic ASA	Q417e	
Sweden	Navamedic ASA	Q417e	
Malta	Valeant	Q417e	
Austria	Cheplapharm	Q417e	
Germany	Cheplapharm	Q417e	
Serbia	Valeant	Q118e	
Saudi Arabia	Biologix FZCO	Q118e	Regulatory submission Q317
Kuwait	Biologix FZCO	Q118e	Regulatory submission Q217
Lebanon	Biologix FZCO	Q118e	Regulatory submission Q217
UAE	Biologix FZCO	Q118e	Regulatory submission Q217
Canada	Valeant	2018e	Regulatory submission Q117
Australia	Valeant	2018e	Regulatory submission Q217
Turkey	Valeant	2018e	Regulatory submission expected Q317
South Africa	Valeant	2018e	Regulatory submission expected Q317

Source: Orexigen Therapeutics

Evaluating strategic options

The company has announced that it has formally engaged with a financial advisor to help explore strategic transactions to unlock value for shareholders. Whether that means acquiring an on-market product that is being divested from somewhere else or selling the company is unclear, though both moves make sense due to the tremendous operating synergies from selling multiple products with one salesforce. It will likely be easier for it to acquire a new product rather than sell itself to someone else, as just about every specialty pharma (for example Valeant) and large pharma (for example GSK) appears to be divesting a large numbers of assets.

The value of the Contrave asset will likely improve in the eyes of partners when the Paragraph IV litigation with Actavis over its filing for approval of a generic version of Contrave is successfully concluded. As a reminder, in April 2015, notice of a Paragraph IV certification regarding an abbreviated new drug application (ANDA), the type of application needed to get a generic approved, was received. In June 2016, following a May 2016 claim construction hearing, the court adopted Orexigen's proposed constructions with regard to the majority of the disputed claim terms in a Markman ruling. The trial was in June of this year and Orexigen believes it went as expected and that it has a strong case. There should be a ruling from the judge in the September/October timeframe.

Valuation

We are adjusting our valuation to \$214m (\$13.87/share) from \$194m (\$12.76/share). This is mainly a result of improved 2017 Contrave estimates due to a higher than expected run rate of sales and rolling forward our NPV, and was mitigated by a higher net debt level as well as a larger number of shares. Orexigen's financing requirement is \$90m through to 2020, although this does not include the \$238m in convertible debt due in that year.

Exhibit 3: Orexigen valuation table

Product	Launch	Peak sales (\$m)	Royalty rate	NPV (\$m)	rNPV/share (\$)
Contrave US	Oct-14	342	100%	1,708	110.71
Contrave W. Europe	2016	118	30%	133	8.63
Contrave C. and E. Europe	2016	27	37.5%	35	2.28
Contrave S. Korea	2016	15	37.5%	15	0.98
Contrave ROW	2017	15	37.5%	15	0.96
PV costs including taxes				(1,608)	(104.20)
Net cash/(debt) (30 June 2017)				(84.91)	(5.50)
Overall valuation (per share based on 15.4m shares outstanding)				214	13.87

Source: Edison Investment Research

Financials

Sales of Contrave in the US were \$20.7m in Q217, up 69% compared to Q216 and up 40% compared to Q117. Orexigen also booked \$2.7m in sales of Contrave to international partners. Operating expenses were \$58.5m in the quarter, down 12% compared to the previous quarter due mainly to lower SG&A. These expenses are expected to continue to decline over the course of the year. Following the recent results, we have increased our revenue estimates in 2017 by \$5m, increased our SG&A expense estimates for 2017 by \$10m due to a higher than expected run rate (although the expense itself is decreasing quarter to quarter), and also decreased our R&D expense estimates by around \$2m per year as the run rate has been lower than we expected. The company had \$86.6m in cash and marketable securities at the end of Q217 and continues to guide for a cash balance of \$40-50m at the end of 2017. Note that while Orexigen currently lists \$172m in long-term convertible debt on its balance sheet, it actually owes \$238m in principal value on these notes, which will need to be paid in 2020 (\$165m by 1 July 2020 and the rest on 1 December). The difference is due to rules related to the fair value accounting of convertible notes with liability and equity components.

Exhibit 4: Financial summary

	\$000s	2015	2016	2017e	2018e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue		24,459	33,709	94,025	160,251
Cost of Sales		0	(7,995)	(28,111)	(29,680)
Gross Profit		24,459	25,714	65,914	130,572
Research and development		(40,750)	(38,023)	(30,926)	(34,019)
Selling, general & administrative		(43,762)	(118,583)	(173,126)	(164,470)
EBITDA		(60,276)	(134,627)	(138,255)	(68,092)
Operating Profit (before amort. and except.)		(60,053)	(130,892)	(138,138)	(67,916)
Intangible Amortization		0	(3,307)	(7,936)	(5,769)
Exceptionals/Other		0	77,229	(2,100)	0
Operating Profit		(60,053)	(56,970)	(148,174)	(73,685)
Net Interest		(7,219)	(7,228)	(3,264)	(4,769)
Other (includes change in fair value of warrants)		(39)	39,807	(1,997)	0
Profit Before Tax (norm)		(67,272)	(138,120)	(141,402)	(72,685)
Profit Before Tax (FRS 3)		(67,311)	(24,391)	(153,435)	(78,454)
Tax		(1,376)	(133)	0	0
Deferred tax		0	0	0	0
Profit After Tax (norm)		(68,648)	(138,253)	(141,402)	(72,685)
Profit After Tax (FRS 3)		(68,687)	(24,524)	(153,435)	(78,454)
Average Number of Shares Outstanding (m)		13.1	14.6	15.2	15.5
EPS - normalized (\$)		(5.24)	(9.73)	(7.96)	(4.67)
EPS - FRS 3 (\$)		(5.24)	(9.73)	(7.96)	(4.67)
Dividend per share (c)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		2,694	79,940	71,283	65,339
Intangible Assets		0	76,061	68,125	62,356
Tangible Assets		1,284	1,044	584	409
Other		1,410	2,835	2,574	2,574
Current Assets		233,895	224,461	87,070	48,091
Stocks		10,802	23,193	15,753	15,753
Debtors		6,828	1,102	7,636	7,636
Cash		214,011	103,993	59,358	20,379
Other		2,254	96,173	4,323	4,323
Current Liabilities		(32,241)	(65,360)	(41,804)	(41,804)
Creditors		(32,241)	(65,360)	(41,804)	(41,804)
Short term borrowings		0	0	0	0
Long Term Liabilities		(170,970)	(178,842)	(206,563)	(225,950)
Long term borrowings		(88,129)	(166,179)	(191,529)	(211,529)
Other long term liabilities		(82,841)	(12,663)	(15,034)	(14,421)
Net Assets		33,378	60,199	(90,015)	(154,324)
CASH FLOW					
Operating Cash Flow		(54,473)	(109,713)	(137,316)	(59,137)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(538)	(330)	0	0
Acquisitions/disposals		0	(63,504)	(3,414)	0
Financing		64,259	188	0	0
Dividends		0	0	0	0
Other		(3,843)	(15,424)	76,073	188
Net Cash Flow		5,405	(188,783)	(64,657)	(58,949)
Opening net debt/(cash)		(121,629)	(125,882)	62,186	132,171
HP finance leases initiated		0	0	0	0
Exchange rate movements		29	715	0	0
Other		(1,181)	0	(5,328)	(30)
Closing net debt/(cash)		(125,882)	62,186	132,171	191,150

Source: Orexigen Therapeutics accounts, Edison Investment Research

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