

# Orexigen Therapeutics

Driven by DTC

Financial update

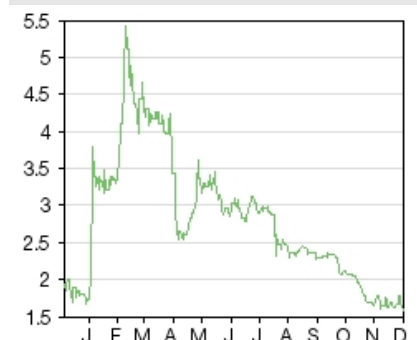
Pharma & biotech

4 December 2017

**Price** **US\$1.57**  
**Market cap** **US\$29m**

Net debt (\$m) at 30 September 2017 101  
 Shares in issue 18.7m  
 Free float 71%  
 Code OREX  
 Primary exchange NASDAQ  
 Secondary exchange N/A

## Share price performance



	1m	3m	12m
%			
Abs	(4.3)	(31.7)	(13.7)
Rel (local)	(6.5)	(36.0)	(28.5)
52-week high/low	US\$5.4	US\$1.6	

## 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

10-15 additional international launches Q417/Q118

## Analysts

Maxim Jacobs +1 646 653 7027  
 Nathaniel Calloway +1 646 653 7036

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

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Contrave sales took a bit of a breather during Q317, which is considered part of the off-season for obesity drugs, with net US Contrave sales falling 14% sequentially. A more unfavorable payer mix, which reduced average net revenue per unit, as well as some excess inventory in the retail channel, added to the weakness. On a year-over-year basis, however, Q317 prescription growth continues to be strong, up 26%. A key overhang that remains is the renegotiation/restructuring of the \$165m in 0% convertible senior secured notes, which may need to be repurchased in mid-2018.

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	84.7	(137.7)	(7.13)	0.0	N/A	N/A
12/18e	156.5	(68.9)	(3.54)	0.0	N/A	N/A

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

## Fall season DTC campaign commenced

On 10 September, Orexigen commenced its fall season direct-to-consumer (DTC) campaign (digital and print ads were the primary method of reaching consumers since mid-May). This has resulted in a spike in prescriptions, new physicians writing prescriptions and visits to Contrave.com.

## Signed deal with Merck KGaA for Latin America

Orexigen recently announced that it had signed a distribution deal with Merck KGaA to sell Contrave in almost all of Latin America, which represents around 25% of the global prescription weight loss opportunity and where 56% of adults are overweight or obese. Orexigen will receive undisclosed upfront and milestone payments.

## Debt covenant overhang continues

The 0% convertible senior secured notes that mature on 1 July 2020 contain an indenture, which stipulates that if net product sales for 2017 are less than \$100m (the company estimates they will fall short), the note holders can require Orexigen to repurchase the notes on 30 June 2018. As the principal on the notes is \$165m and the company does not have the cash to repay, Orexigen will need to renegotiate/restructure these notes with the note holders. The company has described its negotiations with the note holders as "productive and positive".

## Valuation: \$223m or \$11.92 per share

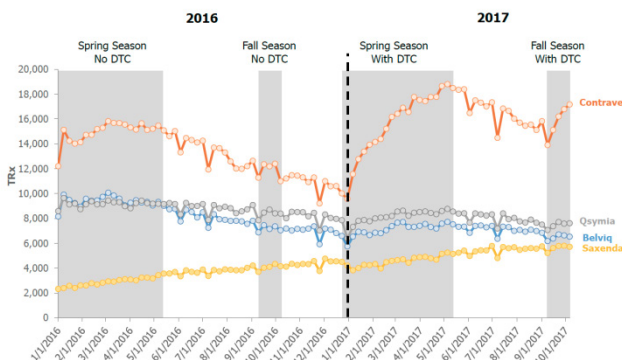
We are adjusting our valuation from \$214m (\$13.87/share) to \$223m (\$11.92/share). The higher absolute valuation is due mainly to rolling forward our NPV and slightly reducing expense estimates. This was mitigated by a reduction in Contrave estimates and a lower cash balance. The per-share value declined due to a higher number of shares outstanding. On our forecasts Orexigen's financing requirement is \$90m through to 2020, although this does not include the \$230m in convertible debt due in that year or any acceleration of payments on the 0% debt.

## Quarterly update

Orexigen reported Q317 revenues of \$18.9m, including \$17.8m in US net sales of Contrave, down 14% sequentially. Contrave sales had a setback in Q3 for a number of reasons. First, it is historically considered the off-season for obesity medication (people tend to be more interested in losing weight as part of New Year's resolutions and in preparation for beach season). Second, the company also moved significantly away from TV spots in favor of digital and print advertising (due to the fact that it was the off-season) and there was also excess inventory in the retail channel, although the company has little visibility on that or how big it is. Finally, there was also some variation with regard to the payer mix (the company will make different levels of revenue per unit depending on whether the patients pay cash, pay cash with a savings card or have Contrave covered by insurance), which reduced net revenue per unit sold to \$92 from \$96 last quarter. However, this is still an improvement over the \$89 in net revenue per unit sold seen in Q117 and is above original 2017 guidance for \$85-90 per unit.

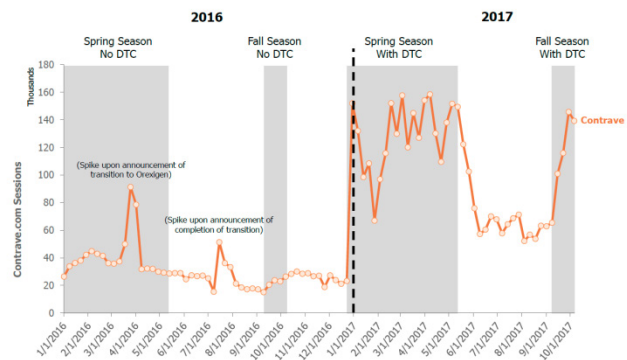
The company launched an fall season DTC marketing campaign on 10 September and, based on several metrics such as prescriptions, the number of new physicians writing prescriptions and visits to Contrave.com (which is often the first stop for people looking to find out more before approaching their physician), it appears to be going well (see Exhibits 1 and 2).

**Exhibit 1: Branded obesity market prescriptions**



Source: Orexigen Therapeutics

**Exhibit 2: Contrave.com visits (in thousands)**



Source: Orexigen Therapeutics

## A new major international partnership

Orexigen recently announced that it had signed a distribution deal with Merck KGaA to sell Contrave in almost all of Latin America, including Mexico, Brazil, Argentina, Colombia, Venezuela, Chile, Peru, Ecuador, Bolivia, Paraguay, Uruguay, Panama, Costa Rica, Nicaragua, Honduras, Guatemala, Belize and the Dominican Republic. According to prescription data these countries represent around 25% of the global prescription weight loss opportunity and are where 56% of adults are overweight or obese, according to the Overseas Development Institute. Orexigen will receive undisclosed upfront and potential sales and regulatory milestone payments from Merck KGaA.

Orexigen is now partnered in 67 countries outside the US, which represent around 96% of the global prescription weight loss opportunity. Contrave (branded as Mysimba in certain markets) is currently launched in 17 countries outside the US, with Cyprus being the most recent in Q3. Launches in Germany, Italy and the Nordic countries (Denmark, Finland, Norway and Sweden) are expected in Q417. Outside the United States (OUS) net sales guidance for 2017 is \$10-15m with \$8m in OUS net sales through Q317.

**Exhibit 3: International Contrave launch timelines**

Country	Partner	Launch date	Notes
South Korea	Kwang Dong	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	Q317	
Italy	Bruno	Q417e	
Denmark	Navamedic ASA	Q417e	
Finland	Navamedic ASA	Q417e	
Norway	Navamedic ASA	Q417e	
Sweden	Navamedic ASA	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 Q317
South Africa	Valeant	2018e	Regulatory submission Q317

Source: Orexigen Therapeutics

## Patent protection until 2030

In April 2015, notice of a Paragraph IV certification regarding an abbreviated new drug application (ANDA) filed by Actavis for approval of a generic version of Contrave 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 2017 and in October the judge ruled in favor of Orexigen upholding the validity of the patents in the case. Importantly, the favorable ruling included patent 8,916,195, which does not expire until February 2030, providing Contrave with more than 12 years of additional protection, a significant length of time. The validation of this patent in a court of law should improve the value of the Contrave asset in the eyes of other pharmaceutical companies.

**Exhibit 4: Contrave Orange Book patents**

Patent number	Title	Expiration
7,375,111	Compositions for affecting weight loss	26 March 2025
7,462,626	Compositions for affecting weight loss	20 July 2024
8,088,786	Layered pharmaceutical formulations	3 February 2029
8,318,788	Layered pharmaceutical formulations	8 November 2027
8,722,085	Layered pharmaceutical formulations	8 November 2027
8,815,889	Compositions and methods for increasing insulin sensitivity	20 July 2024
8,916,195	Sustained release formulation of naltrexone	2 February 2030
9,107,837	Sustained release formulation of naltrexone	4 June 2027
9,125,868	Methods for administering weight loss medications	8 November 2027
9,248,123	Methods of providing weight loss therapy in patients with major depression	13 January 2032

Source: FDA

## Valuation

We are adjusting our valuation from \$214m (\$13.87/share), to \$223m (\$13.45/share). The higher absolute valuation is due mainly to rolling forward our NPV and slightly reducing expense estimates. This was mitigated by a reduction in Contrave estimates and a lower cash balance. The per share value declined due to a higher number of shares outstanding. On our forecasts Orexigen's financing requirement is \$90m through to 2020, although this does not include the \$230m in convertible debt due in that year or any acceleration of payments on the 0% debt.

**Exhibit 5: Orexigen valuation table**

Product	Launch	Peak sales (\$m)	Royalty rate	NPV (\$m)	rNPV/share (\$)
Contrave US	Oct-14	334	100%	1,708	91.14
Contrave W. Europe	2016	118	30%	136	7.28
Contrave C. and E. Europe	2016	27	37.5%	35	1.88
Contrave S. Korea	2016	15	37.5%	16	0.83
Contrave ROW	2017	15	37.5%	15	0.81
PV costs inc taxes				(1,592)	(84.97)
Net cash (as of the end of Q3 but including November 30 debt exchange)				(94.57)	(5.05)
Overall valuation (per share based on 18.7m shares outstanding)				223	11.92

Source: Edison Investment Research

## Financials

Sales of Contrave in the US were \$17.8m in Q317, down 14% compared to Q217, although prescriptions are up 26% compared to Q316. Orexigen also booked \$1.1m in sales of Contrave to international partners (although part was amortized upfront revenue). Operating expenses were \$37.6m in the quarter, down 36% compared to the previous quarter due mainly to lower SG&A as the DTC campaign became less intense over the off-season. These expenses are expected to increase in the final quarter due to the fall season DTC campaign. Following the recent results, we have decreased our revenue estimates in 2017 by \$9.7m and in 2018 by \$3.7m. We have also reduced our SG&A expense estimates for 2017 and 2018 by \$2.8m and \$2.6m, respectively, due to far lower than expected spending in Q3. We also decreased our R&D expense estimates by around \$4m per year as the run rate has been lower than we expected. The company had \$70.6m in cash and marketable securities at the end of Q317 and is guiding for a cash balance of \$40-45m at the end of 2017 (previously \$40-50m).

Note that while Orexigen listed \$172m in long-term convertible debt on its balance sheet as of the end of Q317, it actually owed \$236m in principal value on these notes (currently around \$230m after the company exchanged 2.1m new shares for \$6.46m worth of principal on 30 November), with maturity dates in 2020 (the difference is due to rules relating to the fair value accounting of convertible notes with liability and equity components). Importantly, the 0% convertible senior secured notes that mature on 1 July 2020 contain an indenture, which stipulates that if net product sales for 2017 are less than \$100m (the company estimates that they will fall short), the note holders can require Orexigen to repurchase the notes on 30 June 2018. As the principal on the notes is \$165m, less than the company's current cash on hand, Orexigen will need to renegotiate/restructure these notes with the note holders. One possibility would be for an exchange, similar to the one recently in which the company exchanged around \$3.5m worth of stock for \$6.46m worth of debt principal in the 2.75% convertible senior notes that mature on 1 December 2020. The company has described its negotiations with the note holders as "productive and positive" and will update investors at a later time.

We believe Orexigen has a decent chance in achieving a successful renegotiation/restructure of the debt. The original debt was issued when Contrave was in limbo as Takeda had stopped detailing



the product, market share was sinking and it was as yet unclear what Orexigen would be able to do with the product. Since then the company has successfully turned around Contrave prescriptions and shown that it can execute a national sales and marketing campaign.

Orexigen's financing requirement, not including debt repayments, is an additional \$90m through to 2020. The company is exploring various options to provide additional working capital. It currently has a \$20m at-the-market (ATM) equity offering agreement in place with Cantor, with approximately \$19.6m remaining. It is also looking into an asset-backed line of credit, monetization of its preclinical programs (OREX-1038 for chronic pain and OREX-1019 for opioid addiction), additional upfronts or milestones from international partners, as well as a capital infusion as part of a debt restructuring/refinancing.

**Exhibit 6: Financial summary**

	\$'000s	2015	2016	2017e	2018e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP
<b>PROFIT &amp; LOSS</b>					
Revenue		24,459	33,709	84,740	156,541
Cost of Sales		0	(7,995)	(21,830)	(28,938)
Gross Profit		24,459	25,714	62,910	127,604
Research and development		(40,750)	(38,023)	(27,292)	(30,021)
Selling, general & administrative		(43,762)	(118,583)	(170,365)	(161,847)
EBITDA		(60,276)	(134,627)	(134,864)	(64,441)
Operating Profit (before amort. and except.)		(60,053)	(130,892)	(134,747)	(64,264)
Intangible Amortisation		0	(3,307)	(7,938)	(5,769)
Exceptionals/Other		0	77,229	(1,600)	0
Operating Profit		(60,053)	(56,970)	(144,285)	(70,033)
Net Interest		(7,219)	(7,228)	(3,000)	(4,645)
Other (includes change in fair value of warrants)		(39)	39,807	550	0
Profit Before Tax (norm)		(67,272)	(138,120)	(137,747)	(68,910)
Profit Before Tax (FRS 3)		(67,311)	(24,391)	(146,735)	(74,679)
Tax		(1,376)	(133)	0	0
Deferred tax		0	0	0	0
Profit After Tax (norm)		(68,648)	(138,253)	(137,747)	(68,910)
Profit After Tax (FRS 3)		(68,687)	(24,524)	(146,735)	(74,679)
Average Number of Shares Outstanding (m)		13.1	14.6	16.1	19.5
EPS - normalised (\$)		(5.24)	(9.73)	(7.13)	(3.54)
EPS - FRS 3 (\$)		(5.24)	(9.73)	(7.13)	(3.54)
Dividend per share (c)		0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>					
Fixed Assets		2,694	79,940	69,177	63,231
Intangible Assets		0	76,061	68,123	62,354
Tangible Assets		1,284	1,044	590	413
Other		1,410	2,835	464	464
Current Assets		233,895	224,461	109,122	73,512
Stocks		10,802	23,193	16,105	16,105
Debtors		6,828	1,102	19,103	19,103
Cash		214,011	103,993	67,404	31,794
Other		2,254	96,173	6,510	6,510
Current Liabilities		(32,241)	(65,360)	(56,232)	(56,232)
Creditors		(32,241)	(65,360)	(56,232)	(56,232)
Short term borrowings		0	0	0	0
Long Term Liabilities		(170,970)	(178,842)	(206,382)	(225,745)
Long term borrowings		(88,129)	(166,179)	(191,607)	(211,607)
Other long term liabilities		(82,841)	(12,663)	(14,775)	(14,137)
Net Assets		33,378	60,199	(84,315)	(145,234)
<b>CASH FLOW</b>					
Operating Cash Flow		(54,473)	(109,713)	(129,500)	(55,663)
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	438	0
Dividends		0	0	0	0
Other		(3,843)	(15,424)	75,725	188
Net Cash Flow		5,405	(188,783)	(56,751)	(55,475)
Opening net debt/(cash)		(121,629)	(125,882)	62,186	124,204
HP finance leases initiated		0	0	0	0
Exchange rate movements		29	715	0	0
Other		(1,181)	0	(5,267)	(135)
Closing net debt/(cash)		(125,882)	62,186	124,204	179,814

Source: Company accounts, Edison Investment Research

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