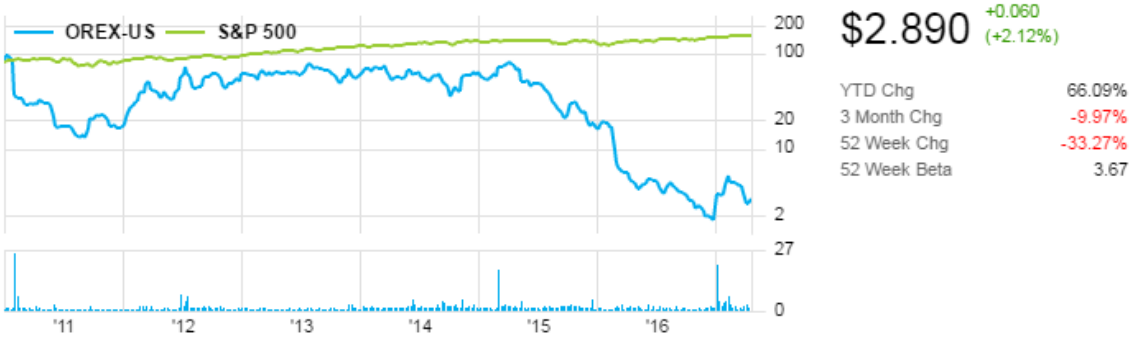
Company Report (4/20/17)

Recommendation: SELL
Price Target: $0
Downside Potential: 100%

Executive Summary

- Despite the recent success of Orexigen's Contrave, the company has no path to a positive valuation
- Orexigen is exposed to regulatory risk in the form of a compelled Cardiovascular Outcome Trial by the FDA, costing as much as $200MM
- Telemedicine pilot for Contrave in California and Texas has proven successful, Orexigen is taking the model nationwide in the US, however the model is also exposed to regulatory risk and is yet unproven on a national scale
- Orexigen would have trouble finding a path to positive equity value under even the most wildly optimistic conditions
- Pre-clinical product pipeline is too far away from approval to be a significant value-add for Orexigen
- Our model projects Orexigen to be in default of its debt covenants in 2017, potentially leading to a large cash payout requirement



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Investment Thesis Overview

Shares of Orexigen have taken a pummeling over the past two years. We believe this trend is likely to continue in 2017.

The value of Orexigen is tied to the success or failure of it sole marketed drug, Contrave. Contrave is marketed in the US and abroad for chronic weight management in roughly 50% of obese adults.

Sales of Contrave had proven lackluster under the stewardship of Orexigen's marketing partner, Takeda Pharmaceuticals. Under this partnership, Takeda was responsible for the development and commercialization of Contrave in the US, where 80% of net sales are generated.

This partnership with Takeda was terminated in May of 2016 with Orexigen paying Takeda $60 million in Mar 2016 and a further payment of $15 million in Jan 2017. Orexigen has since embarked on an ambitious new program for marketing Contrave. The company initiated a new direct-to-consumer (DTC) marketing campaign focused on repositioning Contrave as a modifier to the brain's reward system. This campaign was paired with a new strategy for physician engagement and marketing.

Finally, Orexigen initiated a pilot program for telemedicine in California and Texas. Through a web portal, potential patients can assess their fit for treatment, connect with a physician for diagnosis and prescription, and have their medication delivered straight to their door. The success of this initial pilot has lead Orexigen to expand the program nationwide in the US.

Despite the recent success of the DTC marketing campaign, we see no path to a positive equity value for Orexigen. The window between profitability and generic entry into its Contrave space is too short, and it may very well be on the hook for a $200MM cardiovascular outcomes clinical trial. For this reason we have a sell rating on the stock.

Orexigen Background

Orexigen is a biopharmaceutical company focused primarily on the treatment of obesity. It was founded in 2002. It is primarily engaged in the commercialization of Contrave/Mysimba its weight loss product that was approved in 2014. Orexigen does not undertake large-scale R&D but rather seeks to acquire, in-license and develop products from large pharma. In addition, Orexigen uses contract manufacturers to produce Contrave. Contrave is the first and only product marketed by Orexigen. They were previously in partnership with Takeda for the commercialization in the US but have bought-out the agreement and now are solely responsible for marketing Contrave in the US while using partners in rest of the world (ROW).

Orexigen has no history of being profitable since being founded. As at Dec 31st 2016, it had accumulated losses of $645.2 million and recently issued an equity offering of $20 million dollars. Orexigen's pipeline products are preclinical.

Financials and Returns

Orexigen's performance over the last 3 years has been horrendous with a crash in market capitalization from almost a billion dollars to less than $50 million today. While the numbers paint a dire picture of Orexigen, it is important to note that YTD the stock is up 61%.

Contrave

Contrave is currently Orexigen's sole marketed product. In line with the company's focus on obesity, the US FDA has approved Contrave for chronic weight management. The FDA approved Orexigen's New Drug Application for Contrave in October of 2014. As part of the FDA's approval, Orexigen is required to conduct studies to assess the efficacy of the drug in weight management. Orexigen is also required to conduct a randomized double-blind study to evaluate the effect of Contrave on the incidence of major cardiovascular events in overweight patients.

Contrave is approved as an adjunct therapy for weight management, along with reduced caloric intake and increased physical activity to combat obesity. Contrave is a formulation of two generic drug components that have been previously approved for other indications. We will have more to say on this formulation later on in our report.

Partnerships

Orexigen had been in partnership with Takeda pharmaceuticals for the development and commercialization of Contrave within the US. That agreement was terminated in May of 2016, and Orexigen now maintains responsibility over these activities. The partnership with Takeda had initially been in dispute after Orexigen released early data from a study showing a reduction in heart-related deaths for patients taking Contrave. The FDA criticized this early release of data and mandated a second trial after the integrity of the first trial had been breached. Takeda initiated legal action against Orexigen calling for Orexigen to fully fund a second study. A further update from the first clinical trial appeared to show no benefit in cardiovascular outcomes associated with Contrave.[1]

Contrave is also approved for sale in Europe under the name Mysimba. Orexigen works through partnerships to market Contrave in other parts of the world, and is actively seeking partnerships in areas where Contrave is not currently commercialized. Orexigen works with its partner, Valeant Pharmaceuticals, to market Contrave in Western Europe. Orexigen is expanding this partnership to include parts of Eastern Europe and Turkey.

Market Exclusivity

Orexigen holds two types of patents on Contrave. The FDA issued the first patent under the Hatch Waxman Act on approval of Orexigen's NDA. This patent grants market exclusivity for three years, beginning in October of 2014. This patent will likely expire in 2017, potentially increasing competition in the chronic weight management space.

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[1] https://www.bloomberg.com/news/articles/2015-05-13/takeda-threatens-to-end-orexigen-partnership-after-study-halted

The second type of patent held by Orexigen is patent on the composition of Contrave, specifically the combination of the two generic drugs bupropion and naltrexone. These patents are held in both the US and Europe, and expire in 2025 and 2024.

Formulation

Contrave is an extended release formulation of two generic drugs, bupropion and naltrexone. These drugs have been prescribed separately for a number of years. Bupropion has been prescribed for depression and to stop smoking, and naltrexone has been prescribed to counter dependence on alcohol and opioids.

Addressable Market

The FDA approved Contrave for treatment of chronic weight management in patients with a body mass index (BMI) of 30 or greater, as well as a BMI of greater than 27 in patients with at least one comorbid condition.

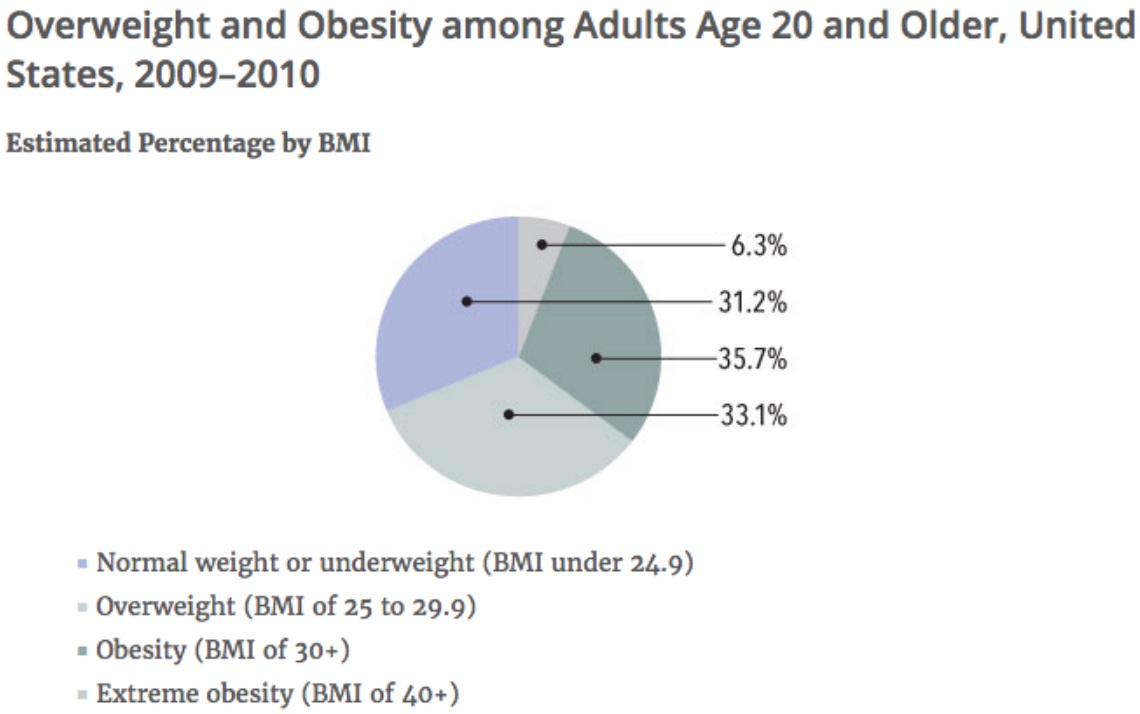
BMI of Adults Age 20 and Older	
BMI	**Classification**
18.5 to 24.9	Normal weight
25 to 29.9	Overweight
30 +	Obesity
40 +	Extreme obesity

[2]

According to the information above from the NIH, Contrave is approved in overweight patients with at least one comorbid condition, and in all obese and extremely obese patients.

We use these indications in combination with further epidemiological information from the NIH to get a sense of the total addressable market for Contrave.

[2] Source: NIH

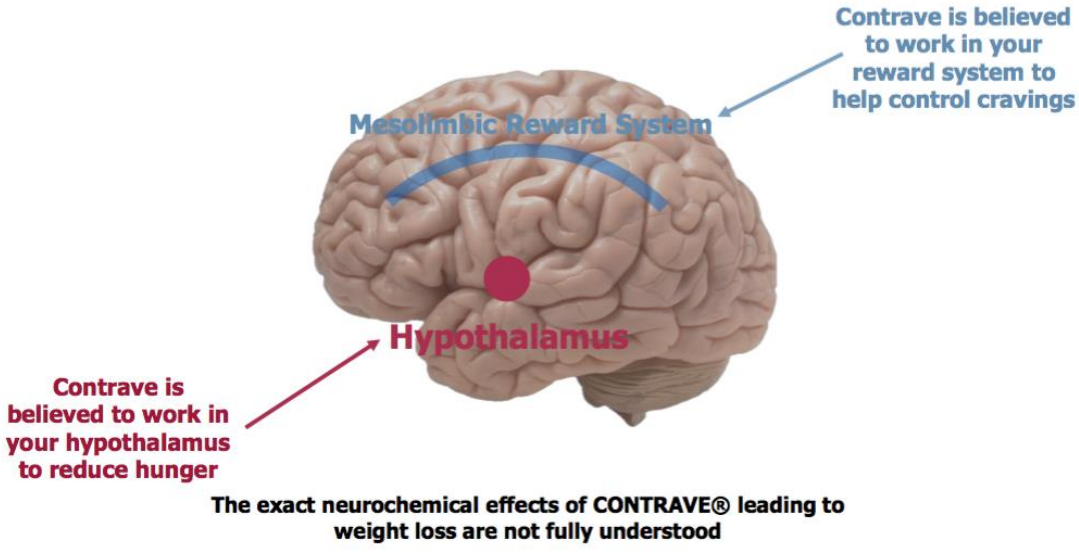


[3]

Given Contrave's specific BMI approval range, we estimate the addressable market for this treatment to be roughly 50% of overweight and obese adults in the US.

Marketing

As noted above, commercialization and development of Contrave had been the responsibility of Takeda prior to May of 2016. Orexigen viewed the termination of this agreement as an opportunity for a re-launch of Contrave within the US. The re-launch involves a different messaging strategy for Contrave.



[3] Source: NIH

Specifically, the campaign plays on the dual mechanisms of Contrave and the impact of the drug on the hypothalamus and the brain's reward system. Contrave is the only weight loss drug with this type of labeling.

Contrave Re-Launch

The re-launch of Contrave has two components:

1) A new physician activation campaign and a newly built-out commercial sales force of 160 contract sales team members
2) A patient-centered campaign with DTC advertising

January 2017 marked the launch of management's new ambitious marketing program. The following chart shows new-to-brand prescription volume from January 2016 through March 2017.

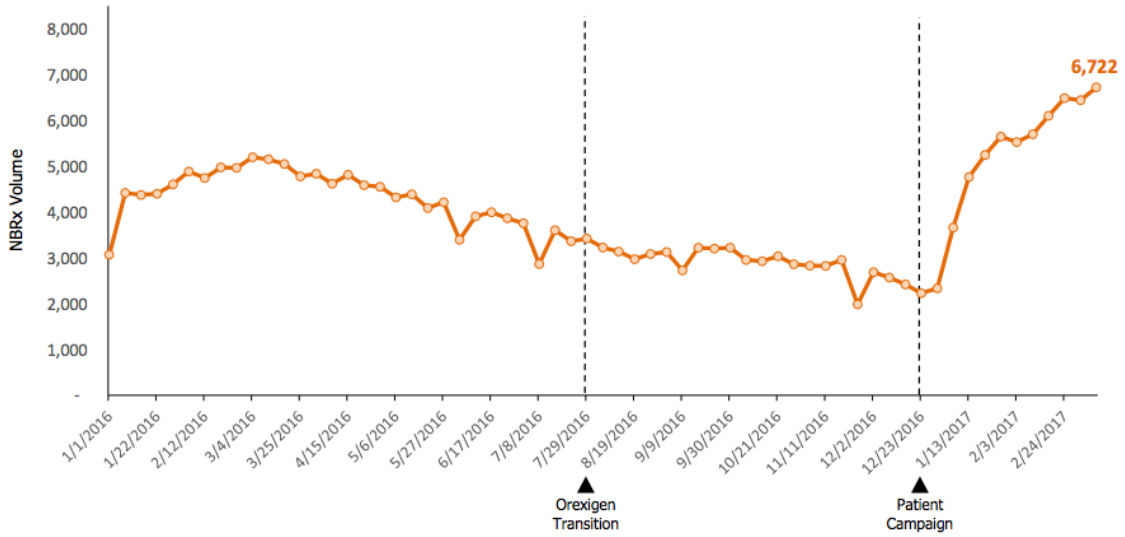


Figure 1:Orexigen 2017 1st Quarter Presentation

The impact of the new patient-centered campaign was immediate, and new-to-brand prescription volume increased through the first quarter of 2017. The obvious questions that arise are:

1) How much has this campaign cost Orexigen?
2) Is this model sustainable?

Orexigen provided the following information on the cost of the new campaign in the Q4 2016 earnings deck:

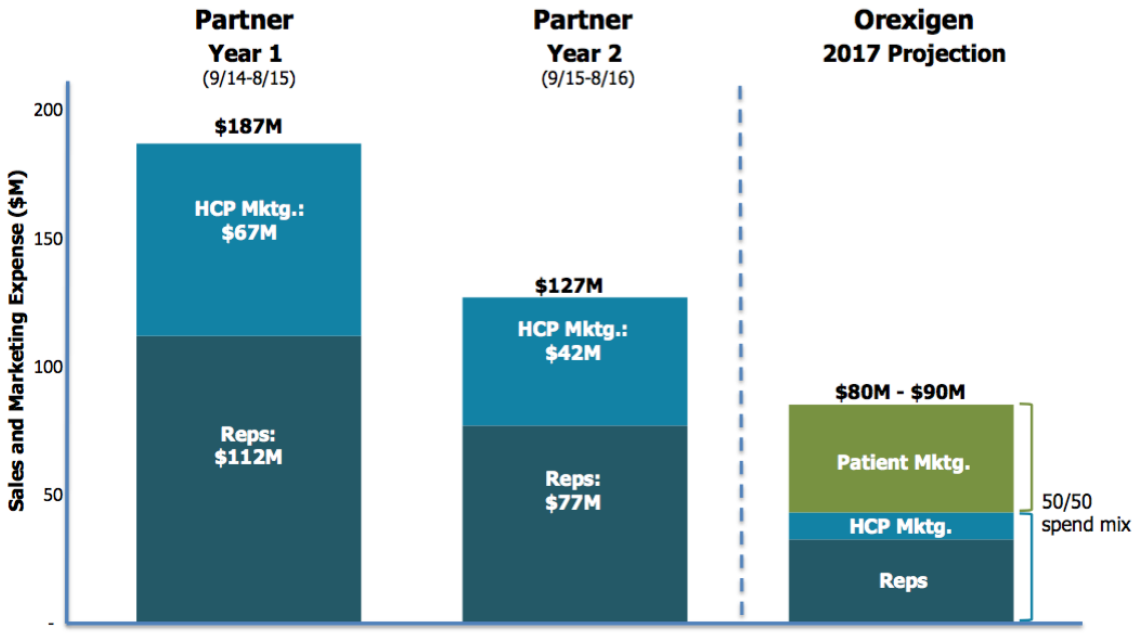


Figure 2: Orexigen Investor Presentation slides

The chart shows how Takeda's spend on marketing to physicians and maintaining a sales force in 2015 and 2016 were much higher than Orexigen's projected spend in 2017. However, in Orexigen's Q4 2016 earnings deck, management guided 2017 commercial expenses in the range of $115-$125MM. This guidance indicates the new marketing campaign will be expensive.

The second concern is harder to answer with certainty and is where most of the variation in valuation will play out. In clinical trials, discontinuation rates of Contrave were in the high 40% range. *High discontinuation rates do not bode well for the longevity of the bump currently experienced by Contrave.*

Telemedicine

We believe there is value to be unlocked through Contrave's unique telemedicine platform. As the exhibit below shows, the traditional market for treatment of chronic weight loss is crowded, and includes many drugs that are classified as controlled substances by the DEA.

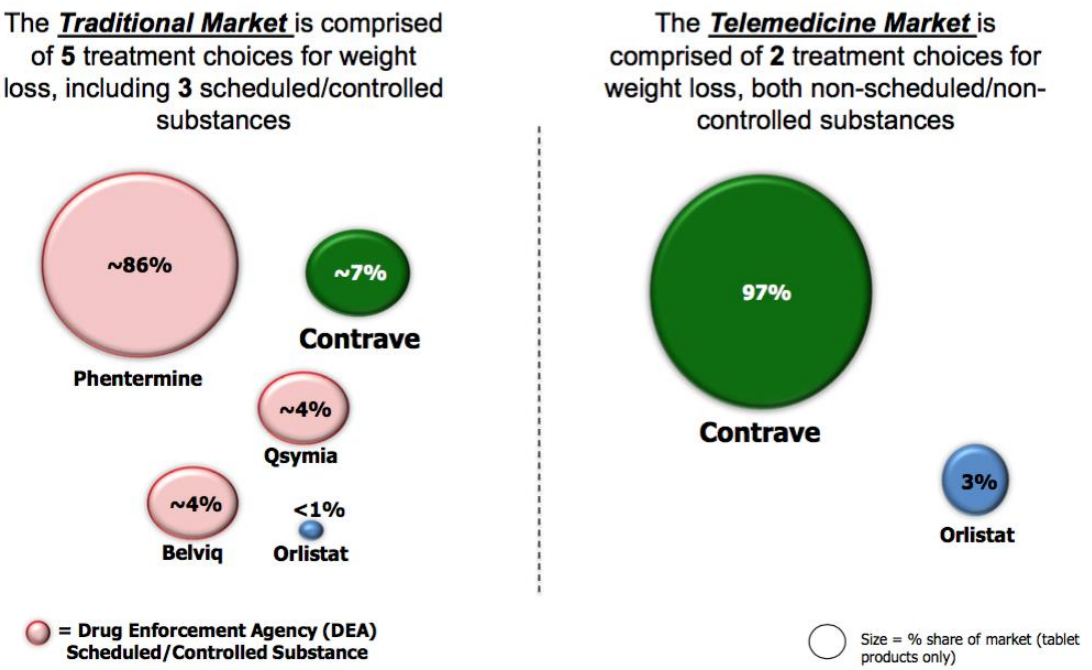


Figure 3: Orexigen Company reports

The exhibit also shows that Contrave dominates the telemedicine market. However, information is not provided on the size of each market, only the relative market share.

Regulatory Risk

We also recognize that enthusiasm for this new model must be tempered somewhat by regulatory concern. Adverse effects or abuse of the platform may lead the FDA to impose tighter controls on remote consultations and prescriptions of Contrave.

Orexigen was approved with a requirement for a large-scale post-marketing cardiovascular outcomes trial (CVOT) to prove the cardiovascular safety of Contrave. This requirement is a result of potential increased blood pressure in the phase 3 clinical trials that led to the approval of the Contrave and the FDA's overall low risk-tolerance for anti-obesity medication. The FDA has been known to order the withdrawal of anti-obesity medications in the past. Examples include the withdrawal of Fen-phen in 1997 and Meridia in 2010 for increased cardiovascular risks.

Orexigen conducted a CVOT prior to the approval of Contrave, however it was deemed unacceptable by the FDA. This necessitated Takeda's initiation of the CONVENE study prior to termination of its agreement with Orexigen. Upon termination, the study was transferred to Orexigen, which subsequently terminated the study. Orexigen has not provided any guidance on when a new study will be conducted but our estimation is that such a study will include over 8000 patients

and will conservatively cost at least $200 million. Technically, Orexigen is in violation of its approval requirements timeline from the FDA. See below

2778-5 A randomized, double-blind, placebo-controlled trial to evaluate the effect of long-term treatment with Contrave (naltrexone hydrochloride/bupropion hydrochloride) extended-release tablets on the incidence of major adverse cardiovascular events (MACE) in obese and overweight subjects with cardiovascular disease or multiple cardiovascular risk factors. The primary objective of this trial should be to demonstrate that the upper bound of the 2-sided confidence interval for the estimated risk ratio comparing the incidence of MACE (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) observed with Contrave to that observed in the placebo group is less than 1.4. The trial should be designed to provide sufficient data to reflect the "on-treatment" cardiovascular risk associated with Contrave. Sample size calculation should take into account that "on-study" events would be censored 365 days after treatment discontinuation. The ongoing LIGHT trial will not be sufficient to meet this requirement; a new trial is required.

The timetable you submitted on September 2, 2014, states that you will conduct this trial according to the following schedule:

Final Protocol Submission:	April 2015
Trial Completion:	July 2021
Final Report Submission:	January 2022

Figure 4: Contrave approval document. Source FDA.gov

Financing Risk

Of special note are the following convertible loans:

- $165MM Convertible Senior Secured Notes due 2020 convertible to 21,999,999 shares
- $115MM 2.75% Convertible Senior Note due 2020 of which $80 million is outstanding convertible to 917,000 shares if share price greater than $81

The holders have the right to require repurchase for cash if certain changes occur. Perhaps the most concerning finding from the debt covenants, is that this right could be triggered if worldwide net sales were below $100MM in 2017. Orexigen had net sales of $34MM in 2016.

Our current model projects 2017 revenue to come in about $10MM shy of this requirement, putting Orexigen at risk of default and a potential large cash payout.

In addition, Orexigen just announced an equity offering for $20MM with a buy as needed from the market approach. This could potentially lead to dilution of current shareholders.

As part of the financing agreement of 2016, Orexigen is required to hold restricted cash investments of $90 million until March 2017 and $40 million until June 21, 2017 respectively.

Orexigen debt obligations are listed below:

	Payments Due by Periods			
	Total	Less Than 1 Year	1-3 Years	4-5 Years
Debt obligations	$ 245,000	$ —	$ —	$ 245,000
Interest on debt obligations (1)	8,617	2,200	4,400	2,017
Purchase obligations	2,937	2,937	—	—
Operating lease obligations	1,762	1,508	254	—
Total	$ 258,316	$ 6,645	$ 4,654	$ 247,017

Figure 5: Orexigen 2016 Annual Report

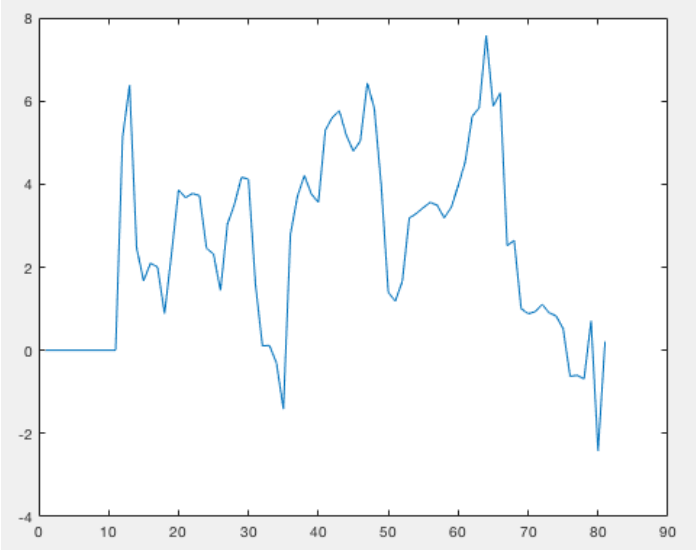
Model

Beta Estimate

We ran a rolling beta estimate using the following assumptions:

- Series Length: 7 years
- Rolling Window Size: 12 months
- Risk Free Rate: One-Month US Treasury
- Market Proxy: Wilshire 5000

Our rolling beta estimate is illustrated graphically below:



As we can see from the graph above, Orexigen's covariance with the market proxy is highly volatile, but has been trending down recently. A time-series estimate over the

past seven years yields a beta estimate of 2.63, and the Yahoo Finance estimated beta is 2.9. Given these various estimates, we use an estimated beta of 1.4 in our model based on the Beta by Sector report by NYU for biotech stocks.[4]

Further Assumptions

- Market Risk Premium: 7.91% as estimated by NYU Stern
- Risk Free Rate: 1.35% from the 3-Year US Treasury Note
- Cost of Debt: 5.2% from average biotech cost of debt[5]
- WACC: 4.33%
- Perpetual Growth Rate: 3%
- Tax Rate: 22.3% from average effective rate for profitable biotech firms[6]

Revenue Projections

We project revenue based on historic performance and guidance from management. We take market share and total Rx projections from Orexigen to back-out the total market size in 2017. From there we estimate Contrave market share and grow the total market by 4%, the mid range of Orexigen guidance, based on obesity demographics. We project a 3% growth in Rx net revenue for Contrave.

Rx Net Revenue	90
Rx Net Revenue Growth	3%
2017 Scripts	0.955
2017 Market Share	8.5%
2017 Implied Market	11.23529412
Market growth rate	4.0%
Generic Entry	2025
Generic Loss	80%
Implied Peak Sales	409.1296101

Our full revenue model can be found in the Valuation section.

Generic Entry

Based on the current patent portfolio, we expect a generic formulation to come to market in 2025. At this point, we believe Contrave will lose 80% of its market share to a generic entrant, as is common in the industry.

Cost Projections

Orexigen management breaks down SG&A into Commercial and G&A expenses in their guidance for 2017. The cost of re-launching Contrave will be the most important driver on the cost side. For Commercial expenses, we took the middle of

[4] http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/Betas.html
[5] http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/wacc.htm
[6] http://www.biotech-now.org/business-and-investments/inside-bio-ia/2011/01/effective-tax-rates-for-biotech

management's guidance, $120MM for 2017. We project this line to decrease steadily to $90MM in 2021 based on Orexigen's marketing cost projections and likely lower costs as the sales force is stood up and stabilized. Further cost reductions are likely to come from shifting away from more expensive traditional broadcast media towards targeted social media advertising.

We take a midpoint in Orexigen's 2017 guidance for G&A and R&D and grow them by inflation throughout the projection period.

When a generic hits the market it 2025, we model a complete cut to Orexigen's Commercial and no increase in R&D spending, yea the company does not reach positive equity value.

Taxes:

Orexigen as net operating loss carryforwards of approximately $445.4 million, $417.4 million and $39.0. The federal loss carryforwards begin to expire in 2027, unless previously utilized while the state loss carryforwards begin to expire in 2017.

Time to Bankruptcy

Cash burn analysis: Using the following formula of (current cash/annual operating loss)*12 we estimated that Orexigen has cash on hand to finance its operations for the next 11 months. Assuming it issues the $20 million dollar in equity it has announced already the total cash on hand will still be insufficient to finance the company beyond this year.

If Orexigen is able to raise funds and survive past the next 12 months it faces another day of reckoning in 2020 when it has $245 million in debt repayment due. That will be more than the total revenue we are projecting for Orexigen in 2020. As a comparison the overall obesity prescription market is around $500 million in 2017.

Assuming the 2016 Convertible debt is converted into stocks (fully diluted) the outstanding share count will go from 14.6 million to 36.5 million which will effectively lead to the stock price being cut by 60%. However, it is unlikely that the Convertible notes will be converted into equity since it will mean the debt holders will be taking a cut on their notes. We believe the note holders will ask for their cash back further driving Orexigen closer to bankruptcy.

Valuation

Our model implies a share price of $0 for Orexigen.

Revenue projection:

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Contrave Share	8.50%	11.00%	15.00%	17.00%	20.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%
Total Market Rx	11.23529412	11.68470588	12.15209412	12.63817788	13.143705	13.6694532	14.21623133	14.78488058	15.3762758	15.99132683	16.63097991	17.2962191	17.98806787	18.70759058
Rx Net Revenue	90	92.7	95.481	98.34543	101.2957929	104.3346667	107.4647067	110.6886479	114.0093073	117.4295865	120.9524741	124.5810484	128.3184798	132.1680342
Contrave Revenue	85.95	119.1489459	174.0441148	211.2941965	266.2804039	356.5494608	381.9357824	409.1296101	87.65192767	93.89274492	100.5779084	107.7390554	115.4100762	123.6272736

DCF Model:

	Actual	Projected														
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Terminal
Revenue	33.709	85.95	119.1489459	174.0441148	211.2941965	266.2804039	356.5494608	381.9357824	409.1296101	87.65192767	93.89274492	100.5779084	107.7390554	115.4100762	123.6272736	
COGS	7.99	17.19	23.82978918	34.80882295	42.2588393	53.25608078	71.30989216	76.38715648	81.82592202	17.53038553	18.77854898	20.11558167	21.54781109	23.08201524	24.72545472	
Gross Profit	25.719	68.76	95.31915671	139.2352918	169.0353572	213.0243231	285.2395686	305.5486259	327.3036881	70.12154214	75.11419594	80.46232669	86.19124435	92.32806094	98.90181888	
Commercial	77	120	115	110	105	90	92.7	95.481	98.34543	0	0	0	0	0	0	
G&A	33.3	33	33.99	35.0097	36.059991	37.14179073	38.25604445	39.40372579	40.58583756	41.80341269	43.05751507	44.34924052	45.67971773	47.05010927	48.46161254	
R&D	36	40	41.2	42.436	43.70908	45.0203524	46.37096297	47.76209186	49.19495462	50.67080326	52.19092735	53.75665517	55.36935483	57.03043547	58.74134854	
D&A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Opex	146.3	193	190.19	187.4457	184.769071	172.1621431	177.3270074	182.6468176	188.1262222	92.47421594	95.24844242	98.10589569	101.0490726	104.0805447	107.2029611	
EBIT	-120.581	-124.24	-94.87084329	-48.21040819	-15.7337138	40.86217997	107.9125612	122.9018083	139.1774659	-22.35267381	-20.13424648	-17.64356901	-14.85782822	-11.7524838	-8.3011422	
Less Taxes		0	0	0	0	9.112266134	24.06450115	27.40710324	31.0365749	0	0	0	0	0	0	
EBIAT		-124.24	-94.87084329	-48.21040819	-15.7337138	31.74991384	83.84806006	95.49470503	108.140891	-22.35267381	-20.13424648	-17.64356901	-14.85782822	-11.7524838	-8.3011422	
Add D&A		0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Less Capex	0.174	1.719	2.382978918	3.480882295	4.22588393	5.325608078	7.130989216	7.638715648	8.182592202	1.753038553	1.877854898	2.011558167	2.154781109	2.308201524	2.472545472	
Less Increase in WC	-42.553	23.1125	23.805875	24.52005125	25.25565279	26.01332237	26.79372204	27.5975337	28.42545971	29.27822351	30.15657021	31.06126732	31.99310534	32.9528985	33.94148545	
Unlevered FCF		-149.0715	-121.0596972	-76.21134173	-45.21525051	0.410983389	49.9233488	60.25845568	71.53283909	-53.38393587	-52.16867159	-50.71639449	-49.00571466	-47.01358382	-44.71517312	-1048.74
Period	0	0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	13.5
Factor	1	0.979339181	0.939289333	0.900877314	0.864036146	0.828701589	0.79481203	0.762308376	0.731133953	0.7012344	0.672557582	0.645053496	0.618674183	0.593373646	0.569107769	0.569107769
PV of FCF	0	-145.9915608	-113.7100823	-68.65706886	-39.06761079	0.340582587	39.67967819	45.93552552	52.30008739	-37.43465221	-35.08643561	-32.71478756	-30.31857048	-27.89662164	-25.4477524	-596.8433649

Valuation:

Enterprise Value	-1014.912634
Less Net Debt	62.186
Less Preferred Stock	3.343
Less Noncontrolling Interest	0
Equity Value	0
Shares Outstanding	14.616751
Share Price	0

Sensitivity:

		Steady State Market Penetration							
	-73.91804334	21%	22%	23%	24%	25%	26%	27%	28%
Generic Loss	10%	156.9542477	173.5434995	190.1327514	206.7220032	223.311255	239.9005068	256.4897586	273.0790105
	20%	121.6021467	136.5079651	151.4137835	166.319602	181.2254204	196.1312388	211.0370573	225.9428757
	30%	86.25004558	99.47243063	112.6948157	125.9172007	139.1395858	152.3619708	165.5843559	178.8067409
	40%	50.89794451	62.43689617	73.97584784	85.5147995	97.05375117	108.5927028	120.1316545	131.6706062
	50%	15.54584344	25.40136172	35.25688	45.11239828	54.96791656	64.82343484	74.67895312	84.5344714
	60%	-19.80625764	-11.63417274	-3.462087846	4.70999705	12.88208195	21.05416684	29.22625174	37.39833663
	70%	-55.20865069	-48.6697072	-42.18105569	-35.69240418	-29.20375266	-22.71510115	-16.22644964	-9.73779813
	80%	-97.13259292	-91.32895552	-85.52531813	-79.72168073	-73.91804334	-68.11440594	-62.31076855	-57.26447509

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