BARRACK, RODOS & BACINE
STEPHEN R. BASSER (121590)
SAMUEL M. WARD (216562)
600 West Broadway, Suite 900
San Diego, CA 92101
Telephone: (619) 230-0800
Facsimile: (619) 230-1874

CARLSON LAW FIRM, APC
DANIEL CARLSON (169314)
600 West Broadway, Suite 1550
San Diego, CA 92101
Phone: (619) 544-9300
Fax: (619) 234-0043

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KURT R. YANTZ, individually and on behalf of all others similarly situated, Plaintiff, v. OREXIGEN THERAPEUTICS, INC., MICHAEL A. NARACHI and JOSEPH P. HAGAN, Defendants.	Case No.: CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff Kurt R. Yantz ("Plaintiff"), individually and on behalf of all others similarly situated, by his undersigned attorneys, makes the following allegations based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters based on the investigation conducted by and through his attorneys, which included, among other things, a review of Securities and Exchange Commission ("SEC") filings by Orexigen Therapeutics, Inc. ("Orexigen" or the "Company"), and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the federal securities laws on behalf purchasers of Orexigen common stock between March 3, 2015 and March 5, 2015, inclusive (the "Class Period").

2. Orexigen, headquartered in La Jolla, California and incorporated in Delaware, is a biopharmaceutical company developing pharmaceutical product candidates for the treatment of obesity. Its top drug development candidate is Contrave, which the Company claims, is designed to "regulate[] appetite and energy expenditure through [central nervous system] activity." Contrave was approved for commercial use by the U.S. Food and Drug Administration ("FDA") in September 2014.

3. As part of the FDA approval process for Contrave, Orexigen and its development partner, Takeda Pharmaceutical Company Limited ("Takeda"), were required to conduct a "LIGHT study," a "new randomized, double-blind, placebo-controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of [major adverse cardiac events, or 'MACE'] in overweight and obese subjects with [cardiovascular] disease or multiple [cardiovascular] risk factors."

4. On March 3, 2015, the Company filed a Form 8-K with the SEC disclosing the status of several patent applications for Contrave. Orexigen included in that Form 8-K the interim results of the LIGHT study, presenting the data in such a manner as to indicate that study participants taking Contrave were less subject to cardiovascular risks than were study participants who were given a placebo.

5. Following the Company's March 3, 2015 disclosures, the price of Orexigen stock rose from $5.79 at the close of trading on March 2, 2015 to $9.37 per share in intraday trading on March 3, 2015, closing that day at $7.64 per share on high volume of more than 95.7 million shares.

6. Shortly before the close of trading on March 3, 2015, the FDA issued a statement regarding the Company's disclosures, noting "serious concerns" about Orexigen's disclosure of the interim data, noting that it had "strongly urged Orexigen to protect the interim data from public disclosure" and indicating that the FDA was "very disappointed by Orexigen's actions."

7. Instead of acknowledging its wrongful disclosure of interim data, the Company issued a statement on March 3, 2015 asserting that it had filed the patent applications "based on the [interim] results in order to preserve the potential for additional intellectual property," and that the Company "believed it was appropriate and necessary to make sure this information was equally available to all investors."

8. The Company's assertion that its disclosures were "appropriate and necessary" caused the price of Orexigen stock to increase further on March 4, 2015, closing at $8.49 per share, on high trading volume of more than 40.5 million shares.

9. On March 5, 2015, *Forbes* published a report quoting stock analysts and drug development experts as speculating that the Company's improper

disclosure of interim trial data could threaten its ability to obtain further FDA drug approvals. On this speculation, the price of Orexigen stock began declining shortly before the market closed on March 5, 2015, closing at $8 per share.

10. After the close of trading on March 5, 2015, *Forbes* published a second article entitled "Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading.'" The *Forbes* article included detailed statements by an FDA official responsible for oversight of the Contrave clinical program who stated that the interim data from the study disclosed by Defendants was probably "'unreliable,'" "'misleading,'" and "'likely false.'"

11. The FDA's March 5, 2015 statements, which challenged the legitimacy of the interim results and called the future of Orexigen's Contrave development program into question, caused a sharp decline in the trading price of Orexigen stock, which closed at $7.10 per share on March 6, 2015.

II. JURISDICTION AND VENUE

12. The claims herein are asserted under §§10(b) and 20(a) of the Securities Exchange Act of 1934("1934 Act") and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act.

13. Venue is proper pursuant to §27 of the 1934 Act. Orexigen is headquartered and maintains its principal place of business is in La Jolla, California and the false and misleading statements were issued in large part from this District.

III. THE PARTIES

14. Plaintiff Kurt R. Yantz, purchased Orexigen common stock during the Class Period as set forth in the attached certification and was damaged thereby.

15. Defendant Orexigen is incorporated in Delaware, headquartered at 3344 N. Torrey Pines Court, Ste 700, La Jolla, California. Orexigen's common stock is traded under the ticker "OREX" on the NASDAQ.

16. Defendant Michael A. Narachi ("Narachi") is and at all relevant times was Chief Executive Officer, President and a director of Orexigen.

17. Defendant Joseph P. Hagan ("Hagan") is and at all relevant times was Chief Business Officer and acting Chief Financial Officer of Orexigen.

18. The defendants referenced in ¶¶16-17 above are referred to herein collectively as the "Individual Defendants."

19. The Individual Defendants, because of their positions with the Company, maintained the power and authority to control the contents of Orexigen's public statements, presentations, and filings with the SEC. The Individual Defendants were provided with copies of the Company's statements alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts set forth herein were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

20. During the Class Period, the defendants had the motive and opportunity to commit the alleged fraud. Defendants also had actual knowledge of the misleading statements they made and/or acted in reckless disregard of the true information known to them at the time. In doing so, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of

business that operated as a fraud or deceit on purchasers of Orexigen common stock during the Class Period.

IV. BACKGROUND TO THE CLASS PERIOD

21. Orexigen, headquartered in La Jolla, California and incorporated in Delaware, is a biopharmaceutical company developing pharmaceutical product candidates for the treatment of obesity. Orexigen common stock trades on the NASDAQ under the ticker symbol "OREX." The Company's top drug development candidate is Contrave, which the Company claims is designed to "regulate[] appetite and energy expenditure through [central nervous system] activity." The FDA approved Contrave for commercial use in September 2014.

22. Pursuant to its approval of Contrave, the FDA required Orexigen to conduct the "LIGHT study," a new randomized, double-blind, placebo controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of [MACE] in overweight and obese subjects with [cardiovascular] disease or multiple [cardiovascular] risk factors."

V. MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

23. On March 3, 2015, Orexigen filed a Form 8-K with the SEC, signed by defendant Hagan, which disclosed the issuance by the United States Patent and Trademark Office (the "USPTO") of U.S. Patent No. 8,969,371 (the "371 Patent") and the publication of provisional patent applications (U.S. Application No. 611913216, U.S. Application 611914938 and U.S. Application No. 611984580) (the "Provisional Patent Applications"). In addition to disclosing this patent information, the Company also disclosed details and interim results of ongoing clinical trials for Contrave.

> The 371 Patent and the Provisional Patent Applications incorporate data from a pre-planned interim analysis of the large, randomized, placebo controlled, cardiovascular ("CV") outcomes trial of Contrave® (naltrexone HCl / bupropion HCl Extended Release Tablets), (also known in Europe as Mysimba™), or the Light Study.

The 371 Patent, which expires in 2034, is the first in the Light Study family of patent applications Orexigen has prosecuted and covers two subgroups of the larger Light Study patient population. The Provisional Patent Applications are part of the same family of patent applications that were first filed in December 2013.

The 371 Patent and the Provisional Patent Applications contain claims related to a positive effect of Contrave on CV outcomes. The observed effects on CV outcomes were unexpected and appear to be unrelated to weight change.

Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index ("BMI") of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). ***Importantly, the U.S. package insert for Contrave states that the effect of Contrave on CV morbidity and mortality has not been established.***

The Light Study randomized 8,910 obese patients with a primary endpoint of evaluating the impact of treatment on the combined incidence of myocardial infarction (heart attack), stroke and CV death in patients taking Contrave versus placebo. For regulatory approval purposes, the Light Study included a pre-planned interim analysis designed to exclude a doubling of CV risk compared to placebo (i.e., to rule out a hazard ratio of 2.0 using the upper bound of the 95% confidence interval). This analysis was conducted based on 94 observed and adjudicated major adverse cardiovascular events ("***MACE***"), which was approximately 25% of the planned MACE for the Light Study (the "***25% Interim Analysis***"). The 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.

24. The Form 8-K also included detailed information on the "demographics and characteristics" of the study participants, identified as the

Table 1. Baseline Demographic and Clinical Characteristics (ITT Population)

Average age (years)		61
Sex (M/F) (%)		45.5 / 54.5%
Race	White (n)	7436
	Other races/not reported (n)	1469
BMI (kg/m2)		37.3
Current Tobacco Smoker (n)		819
History of Depression (n)		2048
Use of Selective Serotonin Reuptake Inhibitor (SSRI) (n)		1391
Use of Other Antidepressants (n)		781
Type 2 Diabetes Mellitus (Diabetes) (n)		7586
All CV Disease (n)		2861
Diabetes and CV Disease (n)		1544
Diabetes without CV Disease (n)		6042
CV Disease without Diabetes (n)		1317
Using Blood Pressure Lowering Medicines (n)		8321
Using Lipid Modifying Medicines (n)		7876

The values for MACE and its individual components, myocardial infarction (heart attack), stroke and CV death, in the ITT Population based on the 25% Interim Analysis are summarized in Table 2.

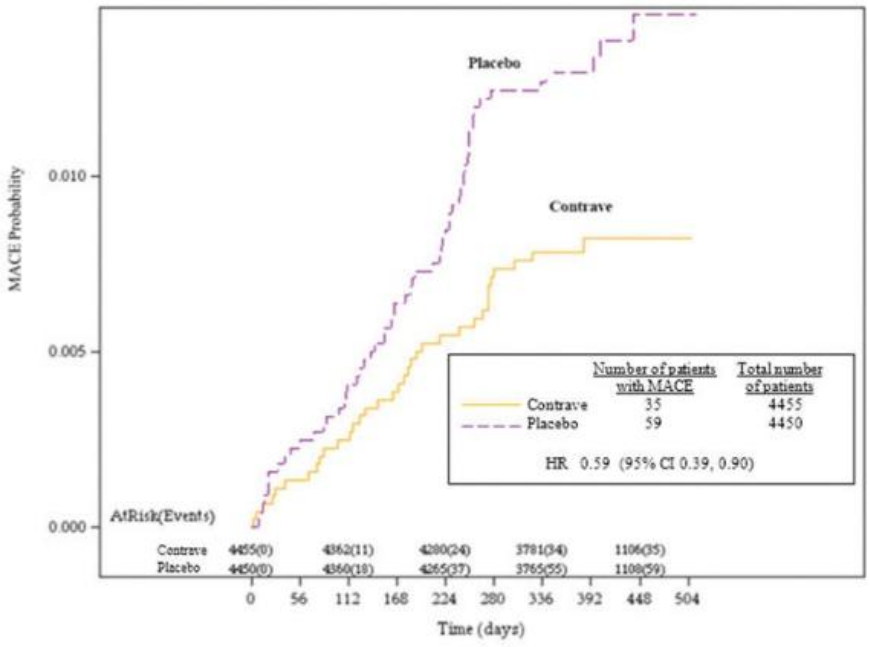
"ITT Population":

25. To highlight the significance of the results for the ITT population, the 8-K included a graph demonstrating the much lower incidence of MACE among patients receiving Contrave in the study as opposed to those receiving the placebo:

26. The impact of these disclosures on the price of Orexigen common stock was immediate and significant. After closing at $5.79 per share on March 2, 2015, Orexigen common stock skyrocketed on March 3, 2015, trading as high as $9.37 per share before closing at $7.64 on massive volume of 95.7 million shares.

27. Later in the day on March 3, 2015, as reported by *Forbes*, an FDA official stated that the agency was not aware that the patent applications contained specific interim study data and expressed "serious concerns" about Orexigen's disclosure of the interim data and noting that the interim analysis was performed

Figure 1. Time to First MACE at 25% Interim Analysis (ITT Population)



Abbreviations: MACE, Major Adverse Cardiovascular Events; ITT, Intent to Treat.

after the 9,000-patient trial had achieved ***only 25%*** of its primary endpoint events, and further noting that the analysis contained only 94 events: 59 in the placebo group and 35 in the Contrave group. However, endpoints with less than 100 total events are statistically unreliable and must be viewed with extreme caution. The

FDA official also stated that day that the agency had already "strongly urged Orexigen to protect the interim data from public disclosure and [that the agency was] very disappointed by Orexigen's actions."

28. After the close of the market on March 3, 2015, Orexigen responded to the statement issued by the FDA through a statement given to Matthew Herper of *Forbes*:

> Orexigen conducted a large cardiovascular outcomes trial in order to file for approval, with the study planned to continue after approval to serve a postmarketing regulatory requirement for additional risk exclusion. We observed an ***unexpected result in the interim analysis***. We filed patent applications based on the results in order to preserve the potential for additional intellectual property. During the course of the study, the FDA informed us it had determined that the Light Study would not serve as the postmarketing requirement for Contrave; a new trial would be required. At this point, the company decided to continue with the patent prosecution. The second cardiovascular outcomes trial is expected to start later this year, and we look forward to the results of that study which are anticipated by 2022.
>
> This morning the USPTO published the patent and supporting documentation, and we believed it was appropriate and necessary to make sure this information was equally available to all investors.
>
> ***Orexigen has been working closely with, and is committed to continuing to work with FDA and others to support its regulatory obligations to thoroughly explore Contrave's therapeutic profile. Just as important, Orexigen is committed to its obligation to patients to fully explore the drug's profile***.
>
> Orexigen is also committed to simultaneously meeting its obligations to other regulatory authorities in the U.S., such as the SEC, and abroad, such as the EMA, which are relevant to, and have authority over, its business. The Company is similarly committed to meeting its ***fiduciary duties*** to shareholders.

(Emphasis added throughout.)

29. Investors, responding to Orexigen's assertion that it had "discovered an unexpected result in the interim analysis" and chose to disclose the favorable interim data, pushed the price of company stock still higher and it closed at $8.49 per share on March 4, 2015, on high volume of 40.5 million shares.

30. Defendants' statements set forth above in ¶¶23-25 and 28 were false and misleading when made because defendants mischaracterized the interim results of the LIGHT study of Contrave as demonstrating its meaningful benefits and their statements to *Forbes* later on March 3, 2015 emphasized that this information was material to investors.

VI. THE TRUTH IS REVEALED

31. Approximately two hours before the market closed on March 5, 2015, *Forbes* published a report entitled "Orexigen 'Crying All The Way To The Bank' After 'Egregiously Unethical' Actions":

> On Tuesday morning the members of the Data Monitoring Committee of Orexigen's Light study began a planned meeting in a hotel in Chicago. They had no way of knowing that in a few hours their routine duties would be completely interrupted by the news that data from the trial – which they thought was known only to them and a very few other people within the company and the FDA – had been revealed to the world by Orexigen. When the news sank in the meeting broke into a scene of high drama and emotion. "I've never seen anything like this in 20 years," said one participant. At one point, I've been told, the DMC members were reading my initial story about the data release on a monitor in the meeting room.
>
> The disclosure of the data unleashed a firestorm of criticism directed at Orexigen but also a dramatic 40% increase in the company's stock, adding about $400 million to Orexigen's market capitalization. But some believe that despite the short term gain ultimately there may be important negative consequences for the company and its leaders. Certainly the company hasn't made any friends this week at the FDA or among the doctors and statisticians who perform clinical trials.
>
> The Tuesday meeting was extraordinarily eventful, but in truth the DMC's activities throughout the trial had never been a day at the beach. The DMC was breaking new ground with the trial. Contrave was one of the first drugs to gain FDA approval with the help of data obtained from the interim analysis of an ongoing trial. This is a novel and "highly innovative process that many had hoped would help give new drugs a more speedy approval without a substantial increase in risk. Indeed, many have thought until now that all future obesity, diabetes, and perhaps even lipid drugs would likely go through this process.
>
> The first interim analysis, which took place in November 2013 after 25% of the trial's endpoint events had occurred, played an important role in helping the FDA decide to approve the drug in 2014. But sometime after the meeting the FDA, and subsequently the DMC and members of the executive committee, became aware that the

results of the interim analysis had been disclosed to a lot of people. In the words of the FDA, "unblinded interim results are expected to be shared only with the DMC and a select set of personnel, essential for a regulatory submission." Instead, the FDA found that Orexigen had given the results to more than 100 people, including "members of Orexigen's Board of Directors, who have financial interest in the outcome of the trial. ... the Orexigen CEO, investment bankers, and several representatives from Takeda Pharmaceuticals (including Corporate Communications, Chief Commercial Officer, and Head of Global Marketing)" and others whose names have been redacted from the FDA document.

As a result of this disclosure the FDA decided that it could no longer rely solely on Light to provide a reliable assessment of the cardiovascular effect of Contrave. It said that Orexigen would have to also perform an entirely new trial to satisfy the requirement that it study the cardiovascular effects of Contrave.

But all the parties also agreed that the Light trial should continue. Although the trial's integrity had been damaged it was not clear if the damage would be fatal. ***The biggest concern – that knowledge of the results would have a harmful effect as patients in the trial crossed over to open label Contrave or simply stopped trial participation altogether – might not be an issue as long as the early results didn't become more widely known.***

In order to continue, however, the FDA, the trial executive committee, and the DMC insisted that Orexigen clam up and not repeat the breach of confidentiality. The company agreed, and everyone settled down to continue with the trial, satisfactorily or not.

Insidious Impact

But the data disclosure had another, even more insidious and long-lasting impact. Armed with the positive findings of the interim analysis Orexigen's leaders decided that the preliminary finding of cardiovascular benefit was something for which the company could and should seek a patent. Because the two compounds that comprise Orexigen have been previously approved and are no longer on patent; Orexigen's intellectual property is based on the novel application of the drug combination to reduce weight. The new data adds the CV outcomes as a new indication, independent of weight loss.

There is widespread speculation that Orexigen used the excuse of the patent filing to publicly reveal the interim results of the trial. According to this view, Orexigen benefits from the highly positive findings, despite the fact that all the experts agree that these preliminary results, based on only 94 events, are extremely unreliable and the positive effect will either disappear or diminish substantially as more events accrue. If confirmed, the 41% reduction in major adverse cardiovascular events would place Contrave among the most effective cardiovascular drugs of all time. No one except company officials and deluded investors believes this kind of effect is likely.

Disclosing the result, through the medium of a patent filing and an SEC disclosure, is a deeply cynical and manipulative action, they believe. "This is the most egregious ethical violation I've ever seen" in clinical trial conduct, said one source. In response to all the severe criticism they are "crying all the way to the bank."

The company signed an agreement that it wouldn't disclose the data to any persons outside of the small circle who were required to know for regulatory purposes. But this agreement turned out to be worthless when Orexigen leaders cynically ignored their commitment in favor of a quick buck, say critics.

In its statement to the press Orexigen suggested that it had acted the way it did in order to meet "its fiduciary duties to shareholders." But it is precisely for this reason that company officials, including board members and other employees responsible for the business side of the company, should not have seen this data. By contrast, employees involved with the data handling have duties that are completely independent of these sort of business decisions. "Here's the problem," said one source. "Most of these people should never have known. Everyone understood that if business people were given access to the data they might misuse it. They just signed the agreement and promptly ignored it."

Why The Trial Should Be Continued

Nevertheless, the Executive Committee and the DMC continue to believe that the trial should proceed as planned. It is not "ethically acceptable" to stop a trial for business or other reasons, said one trial investigator. To discontinue the trial now, they say, would represent a serious violation of the company's ethical obligation to the patient's [sic] who have volunteered to participate in the trial.

The ***viability of the trial is a complicated issue***. The number of endpoint events has now more than doubled since the previous analysis. Tuesday's DMC meeting was in all likelihood the planned meeting for the analysis at the 50% mark of the trial. ***But, I'm told, the trial will not reach the 400 or so endpoint events originally planned. Because of a lower than expected event rate the investigators now anticipate only reaching about 270 events. That lowers the statistical power of the trial, but that also means it may provide the best estimate that we will ever have of the CV effect of Contrave. Many believe that the second outcomes trial will not be able to provide an adequate answer since patients who fail to lose weight on the trial will now have, or believe they will have, a strong reason to switch to open label Contrave.*** Of course the same is true for the patients who are currently participating in LIGHT, but the trial leaders and DMC believe that with the current 200 events they have the best chance yet for the clearest assessment we are ever likely to get of the CV safety of Contrave. In any case, they say, whether the integrity of the trial has been irreversibly broken can't be known until after the trial is finished. At that point the investigators can look back at the drop-outs and crossovers and determine if the results are valid.

Implications For Future Drug Approvals

> The Orexigen action now puts a big question mark on the fate of the highly promising plan to use data from interim analyses to bring drugs to market earlier. What will prevent other companies from following the Orexigen playbook? Given a look at promising early data is there any way for the company to resist the temptation to make hay- while the sun seems to be shining? How can the FDA prevent this sort of action from occurring?
>
> ***"Orexigen threw the entire industry under the bus," said one source. "They may lose the ability to get early approval of drugs."***
>
> ***Most observers believe there is little the FDA or others can do to address the situation. One possibility is for the FDA to withdraw approval of the drug after concluding that the company is now unable to fulfill the post-approval requirement that it study the CV safety of Contrave.*** But that would be a drastic measure that would be uncharacteristic of the FDA. (One theory is that the requirement to perform a second trial was actually a punitive measure by the FDA in response to the first data disclosure, since the FDA is keenly aware that the trial will probably not be able to answer the question of cardiovascular safety.)

(Emphasis added).

32. These partial disclosures caused a drop in the trading price of Orexigen during the afternoon of March 5, 2015, causing the stock to fall from an opening price of $8.50 per share to close at $8 per share.

33. After the market closed on March 5, 2015, *Forbes* published a lengthy and damning report reflecting the FDA's strong reaction to Orexigen's disclosures. Titled "Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading,'" the *Forbes* report directly quoted an FDA official describing the Company's disclosed results as, *inter alia*, "likely false."

> ***The study results showing that Orexigen's obesity drug Contrave reduced the risk of heart attacks and cardiovascular death and sent shares of the tiny La Jolla, Calif., biotechnology company soaring 30% were probably "unreliable," "misleading," and "likely false," according to a top Food and Drug Administration official.*** If Orexigen cannot find a way to set things right, it could face fines, civil penalties, or even the withdrawal of Contrave from the market.
>
> John Jenkins is the director of the Office of New Drugs. He had a key role in negotiating the specifics of a big heart safety study of Contrave, as well as the safety of the guidance used to design big heart trials that are required of diabetes and obesity drugs. I interviewed him earlier today about the release of the Contrave data,

which Orexigen released on Tuesday via a patent and a filing with the Securities and Exchange Commission over the protests of the FDA, the researchers leading the clinical trial, and its marketing partner, Takeda, and about Orexigen's earlier failure to keep the data confidential to even its own executives.

The idea behind these heart trials, which the FDA began requiring of obesity and diabetes drugs in 2008, is that a small, firewalled group of employees of the drug company is given early access to the data in order to show it to the FDA to show that the drug doesn't cause a big increase in cardiovascular events. Takeda followed this protocol with its diabetes drug, alogliptin. Jenkins says Sanofi actually withdrew a marketing application because it was afraid to compromise a trial of one of its diabetes drugs by letting interim data slip out.

Says Jenkins:

> The paradigm has always been that the interim analysis data must be kept very confidential so that it doesn't become available for business purposes within the company.
> And that's intended to:
>
> (1) Make sure we don't do anything to compromise the integrity of completing the trial so we get the definitive answer on cardiovascular risk and
>
> (2) It's based on the knowledge that when you're looking at a sample of only 25% of the data any estimates you get of the treatment effect of the drug are highly unreliable and can lead to false conclusions about either the safety or the efficacy of the drug.
>
> So our two concerns right now are:
>
> (1) Making sure that we can get the definitive answer about cardiovascular risk for Contrave, meaning that the required studies can be enrolled and completed in a timely manner, and
>
> (2) We're concerned that physicians and patients not make healthcare decisions based on data that are highly unreliable. I characterized this earlier as trying to understand who is going to win a football game at the end of the first quarter. We have lots of examples where interim analyses can give very misleading results compared to what the eventual outcome of the trial may be.

Yes, he spoke in numerated bullet points, saying "number one" and "number two." When I asked him for examples, he referred me to a presentation that University of Washington statistician Thomas Fleming, the head of the Data Monitoring Committee that conducts interim analyses of the Contrave study made at an FDA meeting last August.

"Step back and think for a second," Jenkins says. "We required this study because we're concerned that Contrave may cause adverse cardiovascular events because of its effect on blood pressure and heart rate. So the likelihood that that drug is going to have an early benefit is highly unlikely. So people need to be very cautious about making medical decisions based on these data, and we're very concerned that investigators and patients may be unwilling to be in a trial based on these data when they are likely false readings of the actual effect of the drug."

But the p values (a measure of statistical significance) released by Orexigen were very low. That usually means the result shouldn't have happened by chance. Doesn't that at least mean that it's unlikely that Contrave causes cardiovascular harm, and mean that the trial will probably be positive? "I think those are highly unreliable findings,"

Jenkins responded. "I am not a statistician, but I can tell you that Dr. Fleming, who is a statistician, and the statisticians at the agency, and other people who are expert in this area will tell you the only thing you can really conclude with confidence from this trial is that excess cardiovascular risk is not two or greater. You have a 95% confidence that the excess risk is not two or greater. You also have 95% confidence that the actual point estimate of the effect of this drug [on cardiovascular events] is somewhere below two. So the finding of .59 at the interim is highly unreliable independent of the p value."

So what can the FDA do about this? It told Orexigen when Contrave was approved that it would need to do a second big study, because Orexigen had not kept the data fire walled, instead letting over 100 people, including people outside the company and Orexigen's CEO, learn about the results, according to FDA documents. Now, because of the release of data via a press release, some experts question whether doctors or patients will be willing to participate in that second trial. What if it can't be completed?

Jenkins said he wouldn't engage in "a hypothetical" and referred me to the FDA's guidance. I asked him to explain what the guidance means in a generic case, not specifically related to Orexigen.

"Congress passed a law in 2007, FDAAA," Jenkins said. "They gave us the authority to require these trials. If companies are not meeting their obligations there are fines, there are civil money penalties, there's a possibility for seizure, and there's even a possibility for initiating withdrawal procedures."

Documents released when the FDA approved Contrave say that the FDA had two problems with the Contrave heart trial. One was that Orexigen had allowed its data to leak out to far too many people to trust that it wouldn't change the final result of the trial. The second was that too many patients (more than two thirds) had dropped off study drug. Both were concerns, Jenkins said. But the drop-outs were the result of something FDA had built into the study: because it wasn't clear that Contrave was safe, patients were not to stay on treatment (or placebo) unless they were losing weight. "The main

> reason we no longer have confidence in this trial to be the definitive answer to this question is the unblinding," he says.
>
> ***He used this issue to come back to his main point to doctors, patients, and (though he never mentions them) investors: Don't trust the data that Orexigen released***. "It points out the paradox of people rushing to believe the interim point estimate, because going into this trial all the priors were about cardiovascular harm. That shows the paradox of believing the interim analysis suggesting benefit."

(Emphasis added).

34. The FDA's March 5, 2015 statements, as reported by *Forbes*, raised serious concerns regarding the future of Contrave development, triggering an immediate decline in the trading price of Orexigen stock. In response, Orexigen stock dropped below $7 per share in intraday trading on March 6, 2015 on hearing volume, the stock closed at $7.10 per share on March 6, 2015, down $2.27 per share from its intraday Class Period high on March 3, 2015.

VII. LOSS CAUSATION/ECONOMIC LOSS

35. During the Class Period, Defendants' false and misleading class period statements misrepresented the materiality of the interim clinical data and thereby deceived investors. Defendants' statements caused artificial inflation of Orexigen's stock price. When defendants' misrepresentations were disclosed to the market, Orexigen's stock price fell sharply. As a result of their purchases of Orexigen common stock during the Class Period, Plaintiff and members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

VIII. PRESUMPTION OF RELIANCE IS APPLICABLE

36. Plaintiff and the Class are entitled to a presumption of reliance. During the Class Period, defendants made material misstatements and omissions causing that artificial inflation of the price of Orexigen common stock. Plaintiff and other members of the Class purchased Orexigen common stock between the

time defendants issued their initial misstatements on March 3, 2015 and the time the true facts were disclosed on March 5, 2015, without knowledge of the misrepresented and omitted facts. At all relevant times, the market for Orexigen common stock was efficient and the price of Orexigen common stock was impacted by defendants' misstatements and omissions.

IX. CLASS ACTION ALLEGATIONS

37. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Orexigen common stock during the Class Period (the "Class"). Excluded from the Class are defendants and their immediate families, directors and officers of Orexigen and their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

38. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Orexigen had approximately 123.73 million shares of stock outstanding, owned by hundreds or thousands of persons.

39. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

(a) Whether the 1934 Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the price of Orexigen common stock was artificially inflated; and

(f) Appropriate measure of damages.

40. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

41. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

42. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5

Against All Defendants

43. Plaintiff incorporates ¶¶ 1-40 by reference.

44. During the Class Period, defendants disseminated or approved the false statements identified above, while knowing or recklessly disregarding that they were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

45. Defendants violated §10(b) of the 1934 Act and Rule 10b-5in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Orexigen common stock during the Class Period.

46. Plaintiff and the Class, in reliance on the integrity of the market, paid artificially inflated prices for Orexigen common stock and were damaged thereby. Plaintiff and the Class would not have purchased Orexigen common stock at the prices they paid, or at all, if were aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

47. As a direct and proximate result of the wrongful conduct described herein, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Orexigen common stock during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act

Against the Individual Defendants

48. Plaintiff incorporates ¶¶1-47 by reference.

49. During the Class Period, defendants acted as controlling persons of Orexigen within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Orexigen, the Individual Defendants had the power and ability to control the actions of Orexigen and its employees. Orexigen controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under

Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding Plaintiff and the members of the Class damages and prejudgment and post-judgment interest;

C. Awarding Plaintiffs reasonable costs, including attorneys' fees; and

D. Awarding such other relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury.

DATED: March 11, 2015

Respectfully submitted,

BARRACK, RODOS & BACINE
STEPHEN R. BASSER (121590)
SAMUEL M. WARD (216562)

/s/ STEPHEN R. BASSER
STEPHEN R. BASSER

600 West Broadway, Suite 900
San Diego, CA 92101
Telephone: (619) 230-0800
Facsimile: (619) 230-1874
Attorneys for Plaintiff Kurt R. Yantz

CARLSON LAW FIRM, APC
DANIEL CARLSON (169314)
600 West Broadway, Suite 1550
San Diego, CA 92101
Phone: (619) 544-9300
Fax: (619) 234-0043

Attorney for Plaintiff
Kurt R. Yantz

SWORN CERTIFICATION OF KURT R. YANTZ

I, Kurt R. Yantz, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

1. I have reviewed the complaint alleging violations of the United States federal securities laws against Orexigen Therapeutics, Inc. and certain of its officers, and I authorize the filing of the complaint on my behalf.

2. I did not purchase the securities that are the subject of this action at the direction of my counsel, or to participate in any private action under the Securities Act or Exchange Act.

3. I am willing to serve as a lead plaintiff and representative party on behalf of the class in this action, including providing testimony at deposition and trial, if necessary.

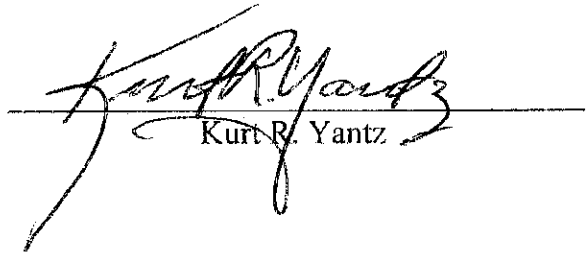
4. My transactions in Orexigen Therapeutics, Inc. securities that are the subject of this action are set forth in the attached schedule.

5. During the three years prior to the date of this certification, I have not sought to serve or served as a representative party on behalf of a class under the Securities Act or Exchange Act.

6. I will not accept any payment for serving as a representative party on behalf of a class beyond its pro rata share of any recovery, except such reasonable costs and expenses relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 11th day of March, 2015.



Kurt R. Yantz

Kurt R. Yantz
Orexigen Therapeutics, Inc.
Class Period: 03/03/2015 to 03/05/2015

PURCHASES/ACQUISITIONS				SALES			
DATE	SHARES	PRICE/SH	AMOUNT	DATE	SHARES	PRICE/SH	AMOUNT
3/4/2015	2,000	8.5800	17,160 *	3/5/2015	2,000	8.0016	16,003
3/4/2015	1,000	8.6300	8,630 *	3/5/2015	4,500	7.0500	31,725 *
3/5/2015	2,000	8.6768	17,354	3/5/2015	4,500	6.6600	29,970 *
3/5/2015	1,000	8.3784	8,378				
3/5/2015	1,000	8.4597	8,460				
3/5/2015	1,000	8.3084	8,308				
3/5/2015	1,000	8.4684	8,468				
3/5/2015	2,000	8.0684	16,137				

* Trades made after hours