UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WAHID TADROS, individually and on behalf of all others similarly situated, Plaintiff, v. CELLADON CORPORATION, KRISZTINA M. ZSEBO, and REBECQUE J. LABA, Defendants.	Case No.: 15cv1458 AJB (DHB) **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS**

Presently before the Court is Defendants Celladon Corporation, Krisztina Zsebo, and Rebecque Laba's (referred to collectively as "Defendants") motion to dismiss lead Plaintiff Wahid Tadros's ("Plaintiff") consolidated amended class action complaint. (Doc. No. 62.) Concurrently with the motion to dismiss, Defendants filed a request for judicial notice. (Doc. No. 63.) Plaintiff opposes the motion to dismiss and the request for judicial notice. (Doc. Nos. 65, 67.) For the following reasons, Defendants' motion to dismiss and request for judicial notice is GRANTED with leave to amend.[1]

[1] This motion is suitable for determination on the papers and without oral argument in accordance with Civil Local Rule 7.1.d.1. (Doc. No. 75.)

I. RELEVANT BACKGROUND[2]

The instant action is a securities class action brought by Court appointed lead Plaintiff individually, and on behalf of similarly situated persons and entities. The Class Period at issue is from January 30, 2014 through June 25, 2015. (Doc. No. 58 ¶ 1.) Plaintiff alleges that Defendants misled Celladon investors by creating materially false impressions as to the success of the CUPID 1 clinical trial of Mydicar and the likelihood that the CUPID 2 clinical trial would succeed.

A. Parties to the Litigation

Plaintiff brings the instant action on behalf of himself and all others similarly situated that purchased or otherwise acquired the publicly traded common stock or call options of Celladon, or sold Celladon options, and that were damaged. (*Id*.)

Defendant Celladon Corporation ("Celladon") was founded in December 2000 as a "clinical-stage biotechnology company with industry-leading expertise in the development of cardiovascular gene therapy." (*Id.* ¶ 19.)

Defendant Krisztina Zsebo ("Zsebo") was the chief executive officer of Celladon and a member of its Board of Directors from 2004 through June 1, 2015. (*Id*. ¶ 20.) Zsebo also served as President of Celladon from 2004 through June 2014. (*Id*.) Zsebo has a Ph.D. in comparative biochemistry and is described as having "30 years of experience in the pharmaceutical industry as well as experience with drug development." (*Id*. ¶ 21.) (internal quotation marks omitted).

Defendant Rebecque Laba ("Laba") was Celladon's vice president for finance and administration from 2007 through the end of the class period. (*Id*. ¶ 22.) In this capacity, Laba served as a consultant on finance and administration matters for the company from 2005 through 2007. (*Id*.)

///

---

[2] The following allegations are taken from the Plaintiff's consolidated amended complaint and are construed as true for the limited purpose of ruling on this motion. *Brown v. Elec. Arts, Inc.*, 724 F.3d 1235, 1247 (9th Cir. 2013).

B. General Background: Heart Failure and Gene Therapy

Heart failure is a chronic and devastating medical condition where the heart is unable to pump blood throughout the body properly. (Doc. No. 58 ¶ 29.) As a biotech company, Celladon worked on developing gene-based therapies for cardiovascular diseases. Celladon's primary product candidate, called Mydicar, was intended to be a one-time gene therapy treatment to replace portions of genetic material that regulates production of SERCA2a (sarco/endoplasmic reticulum CA2+- ATPase), an enzyme that becomes deficient in patients with heart failure. (*Id*. ¶¶ 32, 33.)

For a gene therapy to work, the corrective genetic material needs a delivery mechanism or "vector" to carry it to the patient's cells (*Id*. ¶ 34.) Mydicar used a "viral vector" (specifically, adeno-associated virus 1, or "AAV1") to deliver its gene therapy into targeted cells, encapsulating the corrective genetic material in a shell made of harmless viral protein that heart cells are known to absorb. (*Id*.)

C. Overview of FDA Regulations and Clinical Trials

There are three phases of clinical trials. (*Id*. ¶ 36.) A Phase I clinical trial will generally test the product candidate on a small sample of patients to determine if there are any safety issues, ascertain dose tolerance, and any possible adverse side effects of the treatment. (*Id*.) A Phase II clinical trial investigates safety and efficacy on a slightly larger scale, generally comparing patients receiving treatment with patients receiving a placebo. (*Id*. ¶ 36.) Phase III clinical trials generally involve a larger test population with broader geographic scope in an effort to further ascertain the drug's efficacy and determine whether the drug yields statistically significant results compared to a placebo or standard of care. (*Id*.)

Each Phase of a clinical trial is tested against clinical endpoints which are pre-specified scientific hypotheses that would establish success. (*Id*. ¶ 39.) Meeting the clinical endpoints is critical to showing a positive outcome from treatment and ultimately in obtaining FDA approval. (*Id*.)

///

D. Factual Allegations Underlying the Class Action Complaint ("CAC")

1. CUPID 1, Stage 1

In December 2006, Celladon filed an investigational new drug ("IND") application in support of clinical development of Mydicar. (Doc. No. 58 ¶ 40.) An IND permits a company developing medical treatments to undergo clinical trials to obtain regulatory approval from the FDA. (*Id.* ¶ 35.)

In an article that was co-authored by Zsebo and published by the *Journal of Cardiac Failure* in June of 2008, the underlying study was called "CUPID 1" (Calcium Up-regulation by Percutaneous Administration of Gene Therapy in Cardiac Disease) (*Id.* at 41.)

CUPID 1 was comprised of Stage 1 (safety) and Stage 2 (preliminary indication of clinical treatment effect), corresponding to the Phase I and Phase II testing described above. (*Id*. ¶ 42.) In Stage 1, researchers tested the safety of Mydicar at various dosing levels by administering four sequentially escalating doses of the product to 12 patients. (*Id*.) The test subjects were monitored for any "clinically meaningful" immune response to AAVI protein. (*Id*.) The primary endpoint for Stage 1-safety-was measured by the quantity and severity of "adverse events," which include death from any cause of progression of heart failure leading to hospitalization. (*Id*. ¶ 43.)

On November 9, 2008, Celladon issued a press release announcing the initial safety findings for the first nine patients that received Mydicar in Stage 1 of CUPID 1. (*Id*. ¶ 44.) Data from the final three patients in Stage 1 testing, which included those patients recovering from the highest dose of Mydicar were not included in the analyses that formed the basis for this announcement. (*Id*. ¶ 44.)

The press release stated that the study had "show[n] the product was safe and demonstrate[d] improvement across a number of key parameters." (*Id*. ¶ 45.) The release also quoted Zsebo as stating that the "data demonstrate[d] the safety of Mydicar, and the improvements in cardiac function and overall condition observed in some patients further validate our target and approach." (*Id*.)

2. CUPID 1, Stage 2

Stage 2 of CUPID 1 was a Phase II efficacy trial that compared the use of Mydicar at 3 dose levels with placebo. (Doc. No. 58 ¶ 47.) Celladon announced that enrollment in Stage 2 was complete on August 31, 2009. (*Id*.) The trial design included 24 subjects that would be randomized to 1 of 3 doses of Mydicar. (*Id*.) Of those 24 subjects, 9 subjects would be randomized to placebo. (*Id*.)

Stage 2 used a set of clinical endpoints designed to measure efficacy. (*Id*. ¶ 48.) The study would be deemed demonstrative of clinical effect if at the group level, the group mean improved in certain "domains." (*See* Doc. No. 58 ¶ 48.)

On April 28, 2010, Celladon issued a press release announcing that the primary endpoint for stage 2 of CUPID 1 had been met. (Doc. No. 58 ¶ 54.) On November 15, 2010, Celladon issued another press release announcing the CUPID 1, Stage 2 long-term results, presenting the full 12 months of trial data. (*Id*. ¶ 56.) Celladon stated that Stage 2, which studied 39 patients, met primary safety and efficacy endpoints after 6 months of high-dose Mydicar compared with placebo. (*Id*.)

3. Fast Track Status and Breakthrough Therapy Designation

On December 12, 2011, Celladon announced that the FDA's Center for Biologics Evaluation and Research ("CBER") had granted Mydicar "Fast Track" status based upon the results of CUPID 1. (*Id*. ¶ 88.) Fast Track status allows drugs that "treat a serious disease" and fill an "unmet medical need" to have an accelerated review. (*Id*.) When applying for Fast Track status, the FDA's May 2014 *Guidance for Industry: Expedited Programs for Serious Conditions- Drugs and Biologics ("FDA Guidance")* states that a submission for Fast Track designation is to contain basic information that "in most cases…could be captured in approximately 10 to 20 pages." (*Id*. ¶ 89.)

In a press release dated March 4, 2014, Celladon stated that it had received a Special Protocol Assessment ("SPA") in May 2012. (*Id*. ¶ 90.) Using the SPA, the FDA had agreed that "time-to-recurrent events in the presence of terminal events was an acceptable primary endpoint for any future Phase 3 trials." (*Id*.)

On April 10, 2014, Celladon issued a press release that announced the CBER had granted "Breakthrough Therapy" designation to Mydicar based on the results of CUPID 1. (Doc. No. 58 ¶ 94.) Like Fast Track Status, Breakthrough Therapy designation is a process "designed to expedite the development and review of drugs that are intended to treat a serious condition and demonstrate substantial improvement over available therapies." (*Id*.)

4. CUPID 2

Due to the completion of CUPID 1, Celladon advanced to Phase IIb testing of Mydicar, which it called CUPID 2. Celladon described CUPID 2 as a "phase 2b, double-blind, placebo controlled, multinational, multicenter, randomized event-driven study in up to 250 patients with moderate-to-severe heart failure…" (*Id*. ¶ 97.) CUPID 2 used only the "high dose" of Mydicar as used in CUPID 1, and specifically sought out patients with a "high risk for recurrent cardiovascular events requiring hospitalizations." (*Id*. ¶ 97.) Unlike CUPID 1, CUPID 2 had two defined investigatory endpoints. CUPID 2's "primary efficacy endpoint [was] time-to-recurrent events in the presence of terminal events at the primary analysis data cutoff." (*Id*. ¶ 98.) CUPID 2's secondary efficacy endpoint was "time-to-first terminal event." (*Id*. ¶ 99.) These endpoints differed significantly from any of the predefined efficacy endpoints identified in CUPID 1. (*Id*. ¶ 98.) In order to meet the study's primary endpoint, "CUPID 2 needed to show at least a 45% reduction in the risk of recurrent events." (*Id*. ¶ 100.) The clinical investigators made clear that the CUPID 2 study design was "based on the results of the earlier CUPID 1 phase 2 study." (*Id*.)

5. CUPID 2 Fails to Meet its Specified End Points

On April 26, 2015, Celladon issued a press release titled "Celladon Reports Negative Results for CUPID 2 Trial of Mydicar in Advanced Heart Failure- Investigational gene therapy fails to meet primary and secondary endpoints." (*Id*. ¶ 168.) As a result of the news, the price of Celladon stock plummeted 80%. (*Id*. ¶ 170.) On June 1, 2015, Celladon issued a press release that announced that it would begin seeking an acquisition or partnership. (*Id*. ¶ 174.) The press release also stated that Defendant Zsebo had resigned her positions

as CEO and a member of the Board of Directors. (*Id*.) In total, Celladon common stock lost 95% of its value. (Doc. No. 58 ¶ 177.)

Plaintiff's main contention is that CUPID 1 had fundamental shortcomings. For example, the patients in the high-dose treatment group, "by nearly every measure and to a statistically significant degree, were objectively healthier at baseline than the patients in the placebo group." (*Id*. ¶ 3.) Thus, the fact that patients receiving high-dose Mydicar were healthier at the outset influenced the results showing Mydicar to be effective compared to placebo. (*Id*.) In addition, Plaintiff argues that the post-hoc "sensitivity analyses" conducted by Defendants to reassure the public of Mydicar's effectiveness, was arbitrary and biased. (*Id*.) Moreover, Plaintiff believes that CUPID 1's unconventional domains and endpoints would allow Mydicar to yield false positives. (*Id*. ¶ 4.) As a result, Plaintiff argues that Defendants knew or should have known that CUPID 1 was so flawed in design and execution that it could not be used as a basis to find that Mydicar had a positive effect on heart disease patients or to proceed to phase IIb. (*Id*. ¶ 119.)

II. PROCEDURAL BACKGROUND

Plaintiff filed a complaint against the Defendants on July 2, 2015. (Doc. No. 1.) On July 29, 2015, Defendants' attorneys filed a Notice of Related Cases with this Court. (Doc. No. 7.) On August 5, 2016, both parties filed a Joint Motion for Extension of Time to file a response to the Complaint. (Doc. No. 8.) On August 7, 2015, the Court granted the Joint Motion to Extend Defendants' time to respond. (Doc. No. 11.) On August 31, 2015, Plaintiff filed a motion to be appointed Lead Plaintiff. (Doc. No. 16.) On December 3, 2015, both parties agreed to appoint Plaintiff as the Lead Plaintiff and to consolidate the cases. (Doc. No. 47.) On April 29, 2016, Defendants filed a motion to Dismiss Plaintiff's CAC. (Doc. No. 62.) On the same date, Defendants filed a request for judicial notice. (Doc. No. 63.) On June 28, 2016, Plaintiff responded to Defendants' motion to dismiss. (Doc. No. 65.) Plaintiff filed an objection to Defendants' request for judicial notice on June 28, 2016. (Doc. No. 67.) On July 21, 2016, this Court granted the parties' joint motion to continue the hearing on Defendants' Motion to Dismiss from August 11, 2016 to

September 22, 2016. (Doc. No. 70.) This case was fully briefed by both parties on July 28, 2016. (Doc. No. 73.)

III. THE ALLEGED MISLEADING STATEMENTS

The alleged misrepresentations and omissions are set forth in detail in the "Defendants' Materially False and Misleading Statements and Omissions of Material Fact" section of the CAC. The crux of Plaintiff's argument revolves around the contention that Defendants knew or were reckless in not knowing that CUPID 1 was fundamentally flawed in design and execution and that it could not be used as the basis to find that Mydicar had demonstrated any positive effects on the test subjects or to proceed to Phase IIb of the clinical trials. (Doc. No. 58 ¶ 127.) The following statements are the alleged misleading statements cited by Plaintiff in the CAC.

A. IPO Registration

On October 11, 2013, Celladon filed an initial public version of a Form S-1 Registration Statement and Prospectus with the SEC, and later filed several amendments to the Form S-1. (*Id*. ¶ 110.) The Registration Statement was signed by Defendants Zsebo and Laba, and stated:

> In Phase 2a of our Cupid 1 trial, 29 patients with systolic heart failure, . . . were enrolled in a randomized, double-blind, placebo controlled trial, where Mydicar was ***found*** to be safe and well-tolerated, ***reduced heart failure-related hospitalizations, improved patients' symptoms, quality of life and serum biomarkers, and improved key markers of cardiac function predictive of survival, such as end systolic volume. Based on these results, as well as our previous preclinical studies and clinical trials, we advanced Mydicar to an approximately 250-patient*** randomized, double-blind, placebo-controlled international ***Phase 2b trial*** in patients with systolic heart failure, which we refer to as CUPID 2.

(*Id*. ¶ 111.) The Registration Statement further stated:

> [T]he relative risk reductions or hazard ratios, at 12 months for the high-dose Mydicar group versus placebo for recurrent

> adjudicated clinical events was 0.12, p=0.003 (where the p-value is the statistical probability of a result due to chance alone), representing a risk reduction of 88% for these important events with the high-dose Mydicar. At 36 months, the high-dose Mydicar group versus placebo for recurrent adjudicated clinical events was 0.18, p=0.048, representing a risk reduction of 82% for these important events with high dose Mydicar.

(Doc. No. 58 ¶ 112.)

B. 2013 Form 10-K & March 31, 2014 Conference Call

On March 31, 2014, Celladon filed its Form 10-K Annual Report with the SEC for the year ending December 31, 2013 (2013 Form-K"). (*Id*. ¶ 120.) The 2013 Form-K was signed by Defendant Zsebo and Laba, and stated:

> In Phase 2a of our CUPID 1 trial, 39 patients with heart failure,… were enrolled in a randomized, double-blind, placebo controlled trial, Mydicar was safe and well-tolerated, ***reduced heart failure-related hospitalizations, improved patients' symptoms, quality of life and serum biomarkers, and improved key markers of cardiac function predictive of survival, such as end systolic volume. Based on these results, as well as our previous previous preclinical studies and clinical trials, we advanced Mydicar to a 250-patient randomized, double-blind, placebo-controlled international Phase 2b trial in patients with [heart failure] which we refer to as CUPID 2.***

(*Id*.)

Also on March 31, 2014, Defendants held a conference call with analysts to discuss Celladon's 2013 financial results. (Doc. No. 58 ¶ 124.) During the call, Defendant Zsebo stated:

> In our previous clinical studies of MYDICAR, we had demonstrated initial safety and evidence of improvement in a number of parameters important in heart failure therapeutic assessments as well as improved clinical outcome. Specifically, our Phase 2a trial, which we referred to as CUPID 1, demonstrated that high dose MYDICAR provided substantial improvement when added to an optimized heart failure regimen.

> MYDICAR high dose subjects had a decreased frequency of cardiovascular events, primary hospitalizations at 12 months versus placebo subject on optimized background therapy. Statistically measuring this treatment effect, we observed a hazard ratio of 0.12 or an 88% risk reduction of these cardiovascular events with a p-value of 0.003.

(Doc. No. 58 ¶ 124.) Defendant Zsebo also stated during the conference call that Celladon had advanced Mydicar to a Phase IIb trial "based on these very encouraging results." (*Id.* ¶ 125.) Additionally, in response to a question from an analyst, Defendant Zsebo responded, "in CUPID 1, all Mydicar dose groups demonstrated a reduced hospitalization rate as well as reduced mortality." (*Id.*)

C. April 10, 2014, Breakthrough Therapy Announcement

On April 10, 2014, Celladon issued a press release announcing that it had received a Breakthrough Therapy Designation from the FDA. (*Id.* ¶ 128.) The press release described Mydicar as "novel" and "first-in-class" with Defendant Zsebo also stating that the designation "validate[d] Mydicar's unique characteristics and clinical data to date …" (*Id.*)

D. May 13, 2014, Conference Call

On May 13, 2014, Defendants held a conference call with analysts to discuss Celladon's results for the first quarter of 2014. (*Id.* ¶ 130.) During the call, Defendant Zsebo reiterated the position that the FDA's Breakthrough Therapy designation "validated Mydicar's unique characteristics" and was "a testament to the strength of the clinical data to date, wherein the CUPID 1 trial Mydicar high dose subjects had an 88% reduction of cardiovascular events with a p-value of 0.003." (*Id.* ¶ 131.)

E. Jefferies 2014 Global Healthcare Conference

From June 2 through June 5, 2014, Jefferies LLC held its 2014 Global Healthcare Conference in New York City, a meeting that was attended by a broad range of public and private healthcare companies and potential investors. (*Id.* ¶ 133.) Defendant Zsebo

presented at the conference on June 5, 2014. (Doc. No. 58 ¶ 133.) Plaintiff asserts that Defendant Zsebo's presentation falsely highlighted Mydicar's "Promising Phase 2a Results" as demonstrating an 88% reduction in hospitalizations. (*Id*. ¶ 134.) Defendant Zsebo's presentation included a PowerPoint presentation, excerpts of which are included in the CAC. (Doc. No. 58 at 45–47.)[3] The slides cited by Plaintiff stated, "Mydicar reduced adjudicated heart failure clinical events through 12 months" for patients receiving high doses. (*Id*. at 45.)[4]

IV. LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a plaintiff's complaint. *See Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). "A court may dismiss a complaint as a matter of law for (1) lack of cognizable legal theory or (2) insufficient facts under a cognizable legal claim." *SmileCare Dental Grp. v. Delta Dental Plan of Cal*., 88 F.3d 780, 783 (9th Cir. 1996) (internal citation omitted). However, a complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In making this determination, a court reviews the contents of the complaint, accepting all factual allegations as true, and drawing all reasonable inferences in favor of the nonmoving party. *Cedars-Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S.*, 497 F.3d 972, 975 (9th Cir. 2007).

Notwithstanding this deference, the reviewing court need not accept legal conclusions as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). It is also improper for a court to assume "the [plaintiff] can prove facts that [he or she] has not alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526

---

[3] All pincite page references refer to the automatically generated CMECF page number, not the page number in the original documents.

[4] The Court notes that Plaintiff also lists statements from an August 7, 2014 press release, Celladon's secondary stock offering, presentations from the Best of *Circulation* Research Symposium, and Celladon's 2014 Form 10-K. The Court finds these statements to mimic the ones listed above and thus finds it unnecessary to repeat each statement again.

(1983). However, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679.

V. REQUEST FOR JUDICIAL NOTICE

"Although generally the scope of review on a motion to dismiss for failure to state a claim is limited to the complaint, a court may consider evidence on which the complaint necessarily relies if: (1) the complaint refers to the document; (2) the document is central to the plaintiff ['s] claim; and (3) no party questions the authenticity of the copy attached to the 12(b)(6) motion." *Daniels–Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) (internal quotation marks and citations omitted). Federal Rule of Evidence 201(b) permits judicial notice of a fact when it's "not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Welk v. Beam Suntory Imp. Co.*, 124 F. Supp. 3d 1039, 1041–42 (S.D. Cal. 2015).

Defendants request judicial notice of several exhibits filed in support of their motion to dismiss. (*See* Doc. No. 63.) Defendants contend all of the documents are appropriate subjects for consideration under Rule 201 or the doctrine of incorporation by reference. (*Id.*) Plaintiff filed an objection to Defendants' request for judicial notice, urging the Court not to consider Exhibits 15, 25, and 27. (Doc. No. 67.) As Plaintiff does not oppose Exhibits 1-14, 16-24, and 26, Defendants' request for judicial notice is **GRANTED** as to these exhibits. The Court will now turn to Plaintiff's objections.

Plaintiff objects to the Court taking judicial notice of Exhibit 15, *The Motley Fool* Article published on October 13, 2014, titled "Why Shares in Celladon Corp. Burst Today" (Doc. No. 67 at 3) and the March 25, 2015, *The Street* article, entitled "Celladon Heart-Failure Study Looms Large as Next Big Test for Gene Therapy." (*Id*. at 4.) Plaintiff argues that Defendants do not incorporate the article by reference or otherwise rely upon it in the CAC, and therefore the Court may not consider it in ruling on Defendants' motion to dismiss. (*Id.*)

Defendants request the Court take judicial notice of all Exhibits, 1–25, on the grounds that the information was "publicly available to reasonable investors at the time the defendant made statements plaintiffs alleged were fraudulent." (Doc. No. 63 at 8) (quoting *In re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 883 (W.D.N.C. 2001).

Courts may take judicial notice of publications introduced to "indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2009) citing *Premier Growth Fund v. Alliance Capital Mgmt.*, 435 F.3d 396, 401 n. 15 (3d Cir. 2006). *See also Brodsky v. Yahoo! Inc.*, 630 F. Supp. 2d 1104, 1111 (N.D. Cal. 2009) ("The Court also grants Defendants' request [for judicial notice] as to Exhibits 31 through 47, Yahoo! Press releases, news articles, analyst reports, and third party press releases to which the SAC refers, *but not for the truth of their contents"*) (emphasis added)). Accordingly the Court **GRANTS** Defendants' request for judicial notice as to these two exhibits to demonstrate what was in the public realm at that time but not to indicate that the contents of the articles are true.

Lastly, Plaintiff objects to the Court's consideration of Exhibit 27, a chart prepared by defense counsel "as it is cumulative of and mischaracterizes the allegations of the complaint." (Doc. No. 67 at 2.) In response, Defendants argue that the statements presented in the chart are "quoted directly from the CAC" and are not altered. (Doc. No. 73 at 5.)

Courts can take judicial notice of charts that compile information. *See Garden City Empl. Ret. Syst. v. Anixter Int'l. Inc.*, 2011 WL 1303387, at *9 (N.D. Ill. Mar. 31. 2011) (Deciding that though a District of Columbia ruling was not controlling, the court agreed that the chart at issue did not "present any information or argument that is not contained in [defendant's filing]; it is simply the same argument from the reply presented in a different manner")). The Court finds the same situation present here. Defendants' chart compiles the allegedly misleading statements together with a reference to where it appears in Plaintiff's and Defendants' motions. The statements are unaltered but are simply presented in an

organized, easy to use format. Thus, Defendants' request for judicial notice of this exhibit is **GRANTED**.[5]

VI. DISCUSSION

A. Section 10(b) of Securities and Exchange Act and the PSLRA

Plaintiff asserts claims under § 10(b) of the Securities Exchange Act of 1934 and Rule 10b–5 against Celladon (Count I), and individual Defendants Zsebo and Laba (Count II).

Section 10(b) forbids (1) the use or employment of any deceptive device, (2) in connection with the purchase or sale of any security, and (3) in contravention of Securities and Exchange Commission ("SEC") rules and regulations. 15 U.S.C. § 78j(b); *see Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341 (2005). Rule 10b–5, promulgated by the SEC under § 10(b), forbids the making of any "untrue statement of a material fact" or the omission of any material fact "necessary in order to make the statements made not misleading." 17 C.F.R. § 240.10b–5; *see Dura Pharmaceuticals, Inc.*, 544 U.S. at 341.

To succeed in a private civil action under § 10(b) and Rule 10b–5, a plaintiff must establish "(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance ...; (5) economic loss; and (6) loss causation, i.e., a causal connection between the material misrepresentation and the loss." *Dura Pharmaceuticals*, 544 U.S. at 341–42.

In support of dismissal, Defendants argue that Plaintiff has not adequately pled each element of §10(b) and Rule 10(b)-5. For the reasons mentioned below, the Court GRANTS Defendants' motion to dismiss.

///

///

[5] The Court notes that Plaintiff objects to Defendants' use of three argumentative titles for the chart at issue. (Doc. No. 67 at 5.) The Court clarifies that it is only taking judicial notice of the chart and its organization of the allegedly misleading statements and not of the three topic headers used by Defendants.

1. Materially False and Misleading

"Before the passage of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), the pleading requirements in private securities fraud litigation were governed by Fed. R. Civ. P. 9(b), which required only that 'falsity' be pled with particularity; scienter could be averred generally." *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1034 n. 12 (9th Cir. 2002). The PSLRA, however, imposed a heightened pleading standard in securities litigation and required that a complaint plead with particularity both falsity and scienter. *Id.* To meet the heightened pleading requirement, the complaint "must contain allegations of specific contemporaneous statements or conditions that demonstrate the intentional or deliberately reckless false or misleading nature of the statements when made." *In re Read-Rite Corp. Sec. Litig. v. Read-Rite Corp.*, 335 F.3d 843, 846 (9th Cir. 2003).

"Falsity" is any "untrue statement of a material fact." 15 U.S.C. § 78u–4(b)(1). It also occurs when a defendant "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading." *Id.* "Often a statement will not mislead even if it is incomplete or does not include all relevant facts." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Instead "a statement is misleading if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (internal citation and quotation marks omitted)).

To plead falsity with particularity, a complaint must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *In re Vantive*, 283 F.3d 1079, 1085 (9th Cir. 2002); 15 U.S.C. § 78u–4(b)(1). If allegations are made on information and belief, "a plaintiff must provide, in great detail, all the relevant facts forming the basis for her belief." *In re Silicon Graphics Inc. Sec. Litig*, 183 F.3d 970, 985 (9th Cir. 1999); *see also* 15 U.S.C. § 78u–4(b)(1) ("[I]f an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed"). "If the challenged statement is not

false or misleading, it does not become actionable merely because it is incomplete." *In re Vantive*, 283 F.3d at 1085.

Here, Plaintiff provides this Court with a great deal of facts but fails to sufficiently plead with particularity how each statement is allegedly misleading. Instead, after each allegedly misleading statement, Plaintiff directs the Court to look at parts IV F-H in the CAC to explain why Defendants knew or were reckless in not knowing that CUPID 1 was allegedly flawed. (Doc. No. 58 ¶ 119.) Plaintiff then repeatedly states the same conclusory argument; that Defendants "knew or were reckless in not knowing" that CUPID 1 was "fundamentally flawed in design and execution that it could not be used as the basis to either find that Mydicar had, in fact demonstrated those effects [reduction in heart disease], or, therefore, to proceed to Phase IIb." (*Id*. ¶ 119, 127, 132, 135, 143, 150, 159).

One of Plaintiff's main arguments is that Defendants are liable as participants in a "fraudulent scheme" that operated as a fraud or deceit on purchasers of Celladon securities by disseminating materially false and misleading statements and concealing adverse facts. (*Id*. ¶ 28.) However, this statement whether made on information or belief or sufficient facts, fails to provide specific information to successfully argue that Defendants allegedly schemed to create faulty tests that would help Mydicar pass FDA clinical trials, knew the clinical data was flawed, or that Defendants ignored the allegedly defective test results. Plaintiff's only supporting evidence is that the placebo group in CUPID 1 was supposedly less healthy than the high-dose Mydicar groups at the onset of the clinical trial. Plaintiff also tries to bolster his argument by stating that the post-hoc sensitivity analyses done by Defendants to ensure the public of Mydicar's effectiveness was also flawed. (*Id*. ¶ 67.) Under the heightened standard of the PSLRA, the broad arguments presented by Plaintiff do not provide sufficient facts or information to successfully plead that Defendants Zseba and Laba intentionally manipulated the CUPID 1 clinical trial, recklessly ignored clinical data or schemed to alter the sensitivity analyses all to defraud investors and drive up stock prices. *See Ronconi v. Larkin*, 253 F.3d 423, 429-30 (9th Cir. 2001) ("holding that complaint did not sufficiently plead falsity where it alleged that defendant made false

statements about earnings and sales expectations and that defendant stated that plan to cut jobs and costs was "on track," but complaint did not allege facts showing that defendant knew at the time that predictions were inaccurate")).

In *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1019-20 (S.D. Cal. 2005), plaintiffs argue that defendants in that case committed fraud by publicly reporting results that "they knew or should have known were either so incomplete or so statistically flawed as to lack clinical significance." Similarly, in the present matter, Plaintiff is alleging that Defendants knew or should have known that the clinical trials showing Mydicar as effective were flawed and could not provide a sound basis to proceed to CUPID 2. However, in direct contrast, plaintiffs in *In re Immune Response Sec. Litig.*, provided that court with "corroborating details of the internal reports, cite to specific reports, mention the dates or contents of reports and allege their sources of information about the reports." *Id*. In addition, plaintiffs in that case also demonstrated contemporaneous facts which suggest the falsity of defendant's statements. *Id*. *See In re Maxim Integrated Products, Inc.*, 574 F. Supp. 2d 1046, 1063-64 (2008) (finding that plaintiffs complaint adequately pleads that defendants made material misrepresentations because defendants representations were later shown to be false when the company announced that it would restate its financials)).[6] Here, we are not presented with any contemporaneous statements or specific facts to show falsity. In fact, Plaintiff's CAC provides more support against Plaintiff's arguments by providing positive evidence of Mydicar's fast track and breakthrough status, Celladon's success in raising over $100 million from venture capital funds and capital markets and press releases from other sources touting Mydicar's optimistic results. (Doc. No. 58 ¶¶ 105-

[6] The Court notes that Plaintiff also argues that the absence of effect at the low- and mid-dose levels of Mydicar in heart disease patients also proves that there were "flaws" in the "study design." (Doc. No. 58 ¶ 74.) However, Celladon's form 10k filing highlights this issue and as a result Celladon did a study to better determine the results and found that "in the low- and mid-dose groups, we [Celladon] believe the dose was not sufficient to insert the SERCA2a gene in enough cells. Our hypothesis for why the low- and mid-dose groups demonstrate a delay of the onset of clinical events which is not durable relates to the short term increase in blood flow into the heart after MYDICAR therapy; higher doses are required to insert the gene deep into the cardiac muscles." (Doc. No. 62-2, Ex. A at 19).

109, 117-118.) Plaintiff reliance on the baseline indifferences between the placebo and high dose Mydicar group to propel his argument is not adequate to satisfy the heightened pleading standard under the PSRLA. As a result, Plaintiff's main contention that Defendants' positive statements regarding Mydicar's efficacy in the IPO Registration, SEC filings, conference call transcripts and press releases were all misleading when made fails.

Lastly, the Court notes that Plaintiff's catalogue of press releases and conference call transcripts, also contain a number of comments made by Defendant Zsebo regarding Mydicar's success in the clinical trials. The Court finds these statements to be non-actionable. "Vague, generalized, and unspecific assertions" of "corporate optimism or statements of mere puffing" cannot state actionable material misstatements of fact under federal securities law." *See Glen Holly Entm't. Inc. v. Tektronix. Inc*., 352 F.3d 367, 379 (9th Cir. 2003). The non-actionable statements, or otherwise termed puffery rule, does have an outer boundary. The Ninth Circuit has defined the point at which a projection of optimism becomes an "actionable, factual misstatement under section 10(b), namely, when '(1) the statement is not actually believed, (2) there is no reasonable basis for the belief, or (3) the speaker is aware of undisclosed facts tending seriously to undermine the statement's accuracy.'" *In re Cornerstone Propane Partners, L.P*., 355 F. Supp. 2d 1069, 1087) *citing Grossman*, 120 F.3d at 1119.

The Court finds that Defendants' statements regarding the "encouraging results" of Mydicar and "Mydicar's unique characteristics" are all projections of general optimism. (Doc. No. 58 at 42-43.) The March 31, 2014, May 13, 2014, and August 7, 2014 conference calls and Celladon's April 10, 2014 press release that state phrases such as "encouraging results" and "unique characteristics" are all generalized statements of corporate optimism. Here, Defendants are speaking about Mydicar's success in CUPID 1 and its continual movement with Fast Track and Breakthrough Therapy status. Plaintiff has not provided this Court with any facts to prove that Defendants didn't believe Mydicar's positive clinical data or that they did not believe that Mydicar was not performing as they stated. Accordingly, as the complaint fails to provide information or facts that would undermine

Defendants' belief in the optimistic projections of Mydicar, Defendants' statements do not give rise to liability under the PSLRA.

Whether pled on information or belief or through factual allegations, Plaintiff's generalized allegations fail to sufficiently plead a cause of action under the first prong of his 10(b) claim. As a result, Defendants' motion to dismiss is **GRANTED.** However, as this Court will be granting Plaintiff leave to amend its complaint, the Court will continue and analyze Plaintiff's scienter claims to see if they satisfy the heightened pleading standards specified under the PSLRA.[7]

2. Scienter

"Scienter is [the] essential element of a § 10(b) claim." *In re Read–Rite Corp.*, 335 F.3d 843, 846 (9th Cir. 2003); *see also Lipton*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) ("Scienter is an essential element of a § 10(b) or Rule 10b–5 claim")). The Supreme Court has explained that scienter for purposes of § 10(b) and Rule 10b–5 is "the defendant's intention to deceive, manipulate or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). To satisfy this standard, a plaintiff must show that a defendant acted intentionally or with "deliberate recklessness." *In re Silicon Graphics*, 183 F.3d at 974. The Ninth Circuit has held that "recklessness only satisfies scienter under § 10(b) to the extent that it reflects some degree of intentional or conscious misconduct." *Id.* at 977. Deliberate recklessness is "conduct [that] may be defined as a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990).

---

[7] The Court cautions Plaintiff from using the word "design" or creating an argument around the design of Celladon's clinical testing if it decides to amend its complaint as "mere disagreements over statistical methodology and study design are insufficient to allege a materially false statement." *In re Rigel Pharm., Inc. Sec. Litig.* v. *Andre Deleage*, 697 F.3d 869, 877-78 (9th Cir. 2012).

"In assessing whether Plaintiffs have sufficiently pled scienter [the Court] must consider whether the total of plaintiffs' allegations, even though individually lacking, are sufficient to create a strong inference that defendants acted with deliberate or conscious recklessness." *Nursing Home Pension Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004). "In determining whether a strong inference of scienter exists, [the Court] must consider all reasonable inferences, whether or not favorable to the plaintiff." *Id.; see Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002) (noting the "inevitable tension... between the customary latitude granted the plaintiff on a [12(b)(6)] motion to dismiss...and the heightened pleading standard set forth under the PSLRA").

"Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a strong inference of scienter, a Rule 12(b)(6) dismissal is proper." *Lipton*, 284 F.3d at 1035; *see also No. 84 Empl'r–Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 931–32 (9th Cir. 2003) ("If a plaintiff fails to plead either the alleged misleading statements or scienter with particularity, his or her complaint must be dismissed.").

Parts IV of the CAC fails to establish a strong inference of scienter. Plaintiff does not provide any specific factual allegations that point to Defendants intent to manipulate the clinical trials, or intent to deceive the public. *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d at 1023 (holding that plaintiffs adequately pled scienter by providing the court with "specific factual allegations including the names of persons involved in the alleged fraud, the reports which evidence the alleged fraud, and the actions of Defendants in perpetuating the fraud").

Plaintiff also lists a variety of additional arguments to support its inference of scienter. As scienter must be analyzed based on the totality of allegations provided in the complaint, disposition of the issue will be reserved until this section's conclusion. *See Gompper*, 298 F.3d at 897.

///

///

a. Scienter Alleged by the Nature of the Flawed CUPID 1 Trial and that Mydicar was Celladon's Only Viable Product Candidate

Plaintiff's first two arguments allege that Scienter can be alleged by: (1) the nature of the flawed CUPID 1 trial and that (2) Mydicar was Celladon's only viable product candidate. (Doc. No. 58 ¶¶ 182-187.) Specifically, Plaintiff argues that Defendants hid the flawed data of CUPID 1 so as to save Defendants the cost and delay of having to re-conduct a Phase IIa clinical trial. (*Id*. ¶ 182.)

The Court believes that Plaintiff pleads these facts to argue both motive and opportunity. In *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 53-54 (2d Cir. 1995), the court held that allegations that corporate insiders were motivated to defraud the public to achieve an inflated stock price or to increase executive compensation were insufficient to prevent dismissal under Rule 9(b) and Rule 12(b)(6). Here, the CAC clearly states that "CUPID 1 results were published only a few months prior to the Company's efforts to attract private investors through rounds of venture capital funding" and Celladon's public decision to proceed with Phase IIb testing were central to venture capital investors' decision to invest providing a "strong motive" for Defendants' misrepresentations. (Doc. No. 58 ¶ 183.) As such, these two factors alone do not provide a strong indicia of scienter.

b. Scienter Alleged Through Celladon being a Small Company

Plaintiff alleges that Defendants Zsebo and Laba worked "side-by-side and were hands-on executives, closely familiar with all of the Company's research and development and the Mydicar project in particular." (*Id*. ¶ 61.) In other words, Plaintiff is arguing an inference of scienter through the core operations concept. The core-operations theory is applied in securities cases and permits courts to infer that corporate executives are aware of "facts critical to a business's core operations or an important transaction [which] are so apparent that their knowledge may be attributed to the company and its key officers." *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782-83 (9th Cir. 2008). However, "a plaintiff must allege more than that directors should have known or must have known about matters relating to the corporation's 'core business'". *In re Accuracy, Inc. S'holder Deriv. Litig.*, 757 F. Supp. 2d 919, 928 (N.D. Cal. 2010). In addition, a strong inference of scienter when

arguing core operations must be made in conjunction with management's exposure to factual information. *See In re Daou Sys., Inc.*, 411 F.3d 1006, 1022-23 (9th Cir. 2005) (plaintiffs relied on "specific admissions from top executives that they are involved in every detail of the company and that they monitored portions of the company's database" to support a strong inference of scienter"). Plaintiff provides no specific allegations or admissions from Defendants regarding their responsibilities within the corporation. Instead, Plaintiff states that Defendants were "deeply involved in all aspects of both clinical trials." (Doc. No. 58 ¶ 189.) Without more, these conclusory allegations do not provide a strong indicia of scienter.

c. Scienter Alleged from the Termination of Defendant Zsebo

Plaintiff claims that the timing of Defendant Zsebo's termination as CEO of Celladon and removal from the Board of Directors creates a strong inference of scienter. (*Id*. ¶ 191.) Defendants argue that Plaintiff does not include any specific allegations that the resignation was due to any accusations of fraud. (Doc. No. 62-1 at 19.) The Court finds that whether Defendant Zsebo was terminated or resigned after Mydicar failed to pass CUPID 2 testing is not evidence of scienter on its own. As was concluded in *In re Cornerstone Propane Partners*, 355 F. Supp. 2d at 1093, "most major stock losses are often accompanied by management departures, and it would be unwise for courts to penalize directors for these decisions."

d. Scienter Alleged from Insider Stock Sales

Plaintiff alleges that stock sales by Defendants Zsebo and Laba during the specified class period creates a strong inference of scienter. Courts have repeatedly held that the mere existence of stock sales does not raise a strong inference of fraudulent intent. *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1251 (N.D. Cal. March 31, 1998). Plaintiffs have the burden at the pleading stage of explaining why the stock sales were unusual or suspicious. *See In re Health Mgmt. Sys. Inc. Sec. Litig.*, 1998 WL 283286, *3 (S.D.N.Y. June 1, 1998). This requires a showing that the trading was "in amounts dramatically out of time with prior trading practices, at times calculated to maximize personal benefit from undisclosed inside information." *Alfus v. Pyramid Technology Corp.*, 764 F. Supp. 598, 605 & n.1

(N.D. Cal. April 11, 1991). Where a corporate insider sells only a small fraction of his or her shares in the corporation, the inference of scienter is weakened. *Acito*, 47 F.3d at 54 (finding sale of 11% of holdings insufficient).

The Court finds that both Defendants Zsebo and Laba sold over 20% of their shares during the Class Period. However, despite Plaintiff providing the Court with Defendants Zsebo and Laba's trading history during the Class Period, the Court is unable to analyze whether or not Defendants' stock sales during the Class Period were an unusual departure from past trading practices without Defendants' previous stock sale history. Without more the Court is unable to find a strong inference of scienter.

e. Scienter Alleged through Corporate Scienter

In evaluating allegations of corporate scienter, the Ninth Circuit has been wary of complaints that allege "facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its key officers." *In re Read-Rite Corp. Sec. Litig.*, 335 F.3d at 848. However, the Ninth Circuit has recently recognized two exceptions to the general rule and held that "bare allegations of falsely reported information [could be] probative under certain narrow conditions." *Zucco Partners LLC v. Digimore Corp.*, 552 F.3d 981, 1000 (9th Cir. 2009.) To satisfy this exception, plaintiffs might include in their complaint specific details about the defendants' access to and review of information within the company. *South Ferry LP*, No. 2, 542 F.3d at 785. *See also In re Daou Sys. Inc.*, 411 F.3d at 1022 ("Specific admissions from top executives that they are involved in every detail of the company and that they monitored portions of the company's database are factors in favor of inferring scienter in light of improper accounting reports"); *see also Nursing Home Pension Fund, Local 144*, 380 F.3d at 1231 (plaintiffs pled facts giving a strong inference of scienter because the CEO of the defendant company was quoted as saying: "All of our information is on one database. We know exactly how much we have sold in the last hour around the world"). The second exception "permits an inference of scienter to arise where the information that has allegedly been misrepresented is readily apparent to the defendant corporation's senior management." *Zucco Partners LLC*, 552 F. 3d at 1000.

Plaintiff alleges that corporate officials who were "sufficiently knowledgeable" about the company should have known that CUPID 2 would not have a positive outcome. In addition, Plaintiff highlights that "at least one authorized agent of the company authorized, requested, commanded, furnished information for, prepared, reviewed or approved the statements in which the misrepresentations were made before their utterance or issuance." (Doc. No. 58 ¶ 201.) These allegations are conclusory and do not provide specific details about each Defendants' access to information, what Defendants knew, nor how they knew it. In addition, Plaintiff's broad statements do not allege which "authorized agent" reviewed and ratified statements. These generalized conclusions do not add strength to Plaintiff's arguments for scienter.

f. Scienter Alleged through Sarbanes Oxley

Plaintiff alleges that Defendants Zsebo and Laba's certifications on the Company's Form 10-K filed with the SEC present an inference of scienter. "Boilerplate language in a corporation's 10-K form, or required certifications under Sarbanes Oxley section 302(a), however, add nothing substantial to the scienter calculus." *Zucco Partners LLC*, at 1004. Other circuits unanimously agree that "allowing Sarbanes-Oxley certifications to create an inference of scienter in 'every case where there was an accounting error or auditing mistake made by a publicly traded company' would 'eviscerate the pleading requirements for scienter set forth in the PSLRA.'" *Id*.; *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1266 (11th Cir. 2006); *accord In re Ceridian Corp. Sec. Litig.*, 542 F. 3d 240, 248 (8th Cir. 2008). As a result, we reject Plaintiff's argument that Defendants' Sarbanes-Oxley certifications create an inference of scienter.

g. Holistic Review

In *Matrixx Initiatives v. Siracusano*, 131 S. Ct. 1309, 1324 (2011), the Supreme court emphasized that courts must "review all allegations holistically" when determining whether scienter has been sufficiently pled. (quoting *Tellabs*, 551 U.S. at 326). The Court finds that when read together, Plaintiff's arguments for scienter are not sufficient to meet the heightened standard of the PSLRA.

At this time, the Court will not analyze the last factors of Plaintiff's section 10(b) claim. As Plaintiff has not pled his material misrepresentation and scienter claims to the heightened standard as set by the PSLRA, Defendants' motion to dismiss is **GRANTED**.

VII. CONCLUSION

The Court concludes that Plaintiff's CAC does not reach the heightened standard set by the PSLRA securities fraud complaints. Plaintiff's repetitive and conclusory analysis in stating an action for misrepresentation and scienter, though voluminous, do not plead with the particularity required to survive a Federal Rule of Civil Procedure 12(b)(6) dismissal of a Rule 10(b) and 10(b)-5 claim. Plaintiff's Consolidated Amended Complaint is dismissed in its entirety. We dismiss without prejudice and with leave to amend within 60 days from the date of the order. For the reasons set forth above, Defendants' Motion to Dismiss and request for judicial notice is **GRANTED**.

IT IS SO ORDERED.

Dated: October 7, 2016

Hon. Anthony J. Battaglia
United States District Judge