2017 YEAR IN REVIEW

SECURITIES LITIGATION AGAINST LIFE SCIENCES AND HEALTH CARE COMPANIES

GOODWIN

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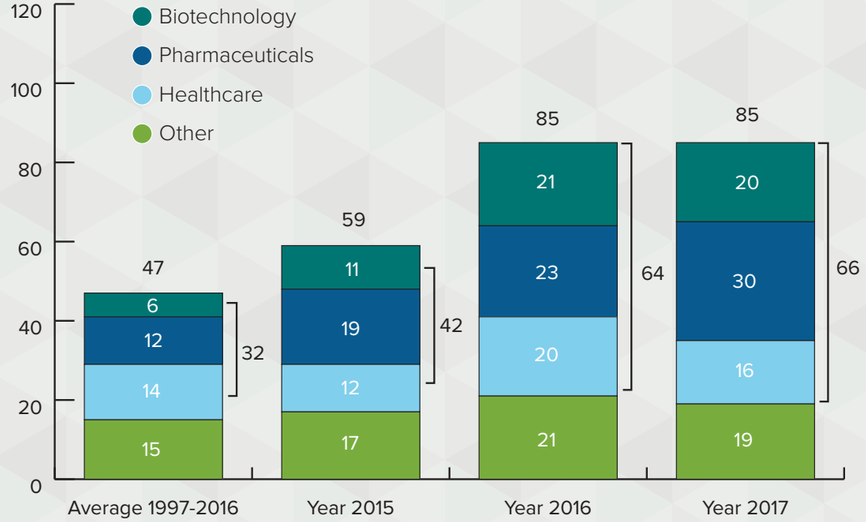
INTRODUCTION

As we reported in our 2016 Year in Review, the number of securities class actions filed nationally against publicly traded pharmaceutical, biotechnology, medical device and health care product and services companies (collectively referred to herein as "life sciences and health care companies") has steadily grown over the last several years. This trend continued in 2017. As compared to other sectors, the Consumer Non-Cyclical sector, which includes life sciences and health care companies, has had the most securities class actions filings for the last eight years.[1] In 2016, the number of non-M&A related securities class actions against life sciences and health care companies skyrocketed, and that number slightly increased in 2017.[2] Specifically, as depicted in Figure 1 below, in 2017, 66 securities class actions against life sciences and health care companies were filed in federal courts nationwide, as compared to 64 such actions in 2016 and only 42 such actions in 2015.

(Figure 1) Consumer Non-Cyclical Sector Filings Excluding M&A Filings 2015-2017



Note:
1. Sectors and subsectors are based on the Bloomberg Industry Classification System.
2. The Other category is a grouping primarily encompassing the Agriculture, Beverage, Commercial Services, and Food subsectors.
3. The Clearinghouse began separately tracking M&A filings in 2009.

[1] Source: Cornerstone Research Securities Class Action Filings 2017 Year in Review, at 30 and Appendix 6. Sectors and subsectors are based on the Bloomberg Industry Classification System.

[2] *Id.*

These cases are typically filed by shareholders seeking to recover investment losses after a company's stock price drops following the disclosure of a setback or problem experienced by the company with respect to its drugs or products, such as concerns or negative feedback from FDA, clinical trial delays or negative results, suspensions or terminations, adverse events experienced by patients, or manufacturing problems. Plaintiffs typically assert claims under Sections 10(b), 20(a) and Rule 10b-5 of the Securities Exchange Act of 1934 (the "1934 Act") based upon allegedly false and misleading statements made by the company and its officers, and, if the alleged misstatements or omissions are made in connection with a securities offering, under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "1933 Act").

(Figure 2) Pharmaceutical, Biotechnology, and Healthcare Subsectors Excluding M&A Filings

Year	Filings	Circuit					Case Status		
		1st	2nd	3rd	9th	Other	Percent Dismissed	Percent Settled	Percent Ongoing
1997	28	2	4	3	9	10	32.1%	67.9%	0.0%
1998	40	3	7	6	11	13	32.5%	67.5%	0.0%
1999	28	1	3	2	10	12	28.6%	71.4%	0.0%
2000	22	2	4	5	3	9	45.5%	54.5%	0.0%
2001	18	0	3	2	6	7	27.8%	72.2%	0.0%
2002	33	3	6	6	6	13	48.5%	51.5%	0.0%
2003	37	5	4	2	9	17	43.2%	56.8%	0.0%
2004	40	4	8	4	11	13	47.5%	52.5%	0.0%
2005	32	5	4	4	3	17	56.3%	43.8%	0.0%
2006	25	0	5	3	3	13	44.0%	52.0%	0.0%
2007	29	0	11	2	7	9	58.6%	41.4%	0.0%
2008	25	5	5	2	2	11	40.0%	60.0%	0.0%
2009	22	1	1	2	11	7	36.4%	63.6%	0.0%
2010	32	3	6	2	15	6	46.9%	53.1%	0.0%
2011	21	0	5	0	6	10	66.7%	33.3%	0.0%
2012	28	2	5	5	5	11	60.7%	35.7%	3.6%
2013	34	2	10	5	11	6	41.2%	47.1%	11.8%
2014	38	3	8	11	11	5	52.6%	39.5%	7.9%
2015	42	6	4	5	18	9	61.9%	21.4%	16.7%
2016	64	5	22	7	20	10	25.0%	6.3%	68.8%
2017	66	7	17	16	13	13	24.2%	0.0%	75.8%
Average (1997–2016)	32	3	6	4	9	10	44.8%	49.6%	5.6%

Note:
[1] Sectors and subsectors are based on the Bloomberg Industry Classification System.
[2] The Clearinghouse began separately tracking M&A filings in 2009.

The plaintiffs' bar, and a few select plaintiffs' law firms in particular,[3] has focused on life sciences and health care companies in recent years likely due to the inherently volatile nature of their stock prices. The good news, however, is that while a record number of securities class actions have been filed in 2017, a record number of these cases have been dismissed by federal courts. As detailed in Figure 2 above, approximately 24% of securities class actions filed against life sciences and health care companies in 2017 have already been dismissed, a higher rate than in years past[4]. Given that the typical life cycle of securities class actions is approximately 18 months from the filing of the initial complaint through the disposition of defendants' motion to dismiss, we expect that the percentage of dismissals will increase substantially by the end of 2018.

This year, we have focused our Year in Review on jurisdictions that are epicenters for life sciences and health care companies and, thus, have been among the most active jurisdictions in the country for securities class actions filed against such companies: First Circuit, District of Massachusetts, Ninth Circuit and California Federal Courts. In 2017, federal courts in these jurisdictions have issued several significant, detailed decisions dismissing virtually all claims against life sciences and health care companies in various growth stages, as well as their directors and/or officers. These cases involve disclosures concerning issues that life sciences and health care companies most often face, including the timing and length of clinical trials, adverse events arising during clinical trials or post-approval, negative clinical trial results, discussions with and requirements imposed by the FDA, the likelihood of obtaining FDA approval, and future growth prospects and revenue projections relating to approved drugs or other healthcare-related products. The First Circuit and District of Massachusetts courts dismissed such actions on the basis that plaintiffs failed to adequately allege that the defendants' statements were false or misleading and/or that plaintiffs failed to allege particularized facts as required under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA") that the defendants made false and misleading statements or omissions with scienter (i.e., intentionally or recklessly). Similarly, California Federal District Courts often dismissed securities class action complaints against life sciences and health care companies on the basis that the complaints failed to adequately plead falsity and/or materiality, or failed to allege the requisite scienter. As explained below however, the Ninth Circuit recently reversed in part a dismissal of a securities class action complaint, holding that plaintiffs sufficiently alleged the falsity and materiality of a public statement of opinion made by a biotechnology company and by certain of its officers and directors.

These decisions and pending cases in which we expect significant decisions to be issued in 2018 in these jurisdictions are summarized below, with the goal of providing you with an overview of the legal landscape to assist you in making informed disclosure decisions.

[3] Source: Cornerstone Research Securities Class Action Filings 2017 Year in Review, at 35.

[4] Securities class action filings overall in 2017 are on pace to have the highest rate of dismissals within the first year of filing on record. See Cornerstone Research Securities Class Action Filings 2017 Year in Review, at 2, 15-16.

FIRST CIRCUIT DECISIONS

Ganem v. InVivo Therapeutics Holdings Corporation, 845 F.3d 447 (1st Cir. 2017)

InVivo Therapeutics Holdings Corporation ("InVivo") is a clinical-stage biotechnology company that develops and commercializes technologies for the treatment of spinal cord injuries. In the company's 2012 annual report, it identified "biopolymer scaffolding" as its "Lead Product Under Development." On March 29, 2013, the Food and Drug Administration ("FDA") conditionally accepted InVivo's Investigational Device Exception ("IDE") application, allowing the company to conduct its first human clinical trial. In its conditional acceptance, the FDA presented the company with 13 issues to address before the initial study could begin. The FDA also required that the initial study be staged such that the company would follow single subjects for three months at a time before requesting approval to enroll the next subject, noting that this would result "in a total of 5 subject[s] enrolled over a minimum 15 month period." On April 5, 2013, InVivo issued a press release stating that the FDA approved its IDE and that it intended to commence a 15-month clinical study "in the next few months." On May 9, 2013, the company issued a second press release noting that it expected to "commence the study in mid-2013 and submit data to the FDA by the end of 2014." After a turnover in management, the company issued an August 27, 2013, press release disclosing the FDA's conditions and revising the schedule for the clinical trial, pushing the expected start date to the beginning of 2014 and increasing the anticipated length of the trial to 21 months. InVivo's stock dropped nearly 50%.

Investors filed a class action lawsuit against InVivo and its former CEO, alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. Plaintiffs alleged that the FDA's conditions and requirement of a staged study made it impossible for InVivo to follow through on its timeline, and the company's failure to disclose the FDA's conditions rendered its temporal predictions materially misleading. The defendants moved to dismiss, and the district court granted their motion, finding that plaintiffs had failed to adequately plead any material misrepresentations or scienter. The First Circuit affirmed the district court's dismissal, concluding that none of the challenged statements was false or misleading. The court noted that the FDA's own conditional acceptance letter explicitly permitted InVivo to enroll one patient immediately and stated that the minimum duration of the study would be 15 months. The court rejected plaintiffs' theory—that because the company's actual timeline lagged behind its proposed one, it must have always been impossible to achieve—as an attempt to plead "fraud by hindsight." As explained by the court, "the securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block to realizing those plans."

Brennan v. Zafgen, Inc., 853 F.3d 606 (1st Cir. 2017)

Zafgen, Inc. ("Zafgen") is a clinical-stage biopharmaceutical company dedicated to developing novel therapies for patients affected by metabolic diseases. In 2015, Zafgen began a Phase 3 clinical trial for its drug product candidate beloranib, an angiogenesis inhibitor developed for the treatment of a rare genetic disorder. On October 14, 2015, Zafgen announced that it had learned of a patient death in its ongoing Phase 3 trial, and two days later, the company disclosed that the FDA had placed beloranib on partial clinical hold. Following these announcements, Zafgen's stock price fell by more than 50%.

Investors filed suit against Zafgen and its CEO, alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. The complaint alleged that defendants knew beloranib could lead to an increase in the risk of thrombotic adverse events ("AEs"), and that defendants materially misled investors by failing to disclose two superficial AEs that occurred in one of the company's prior clinical trials more than one year before the 2015 patient death. The district court granted defendants' motion to dismiss on the basis that plaintiffs failed to allege a strong inference of scienter. The First Circuit affirmed the district court's dismissal, holding that the complaint lacked specific facts that, at the time of the allegedly deceptive disclosures, defendants knew that (or recklessly risked that) they were misleading investors by not disclosing the two superficial adverse thrombotic events. The court held that the complaint's allegations did not give rise to a strong inference of scienter because the superficial AEs became significant in hindsight "only after the patient death" in 2015, and Zafgen's robust risk disclosures—including the disclosure of two serious thrombotic AEs in the earlier trial—"at the very least support a strong competing inference that the defendants disclosed what they considered to be, at the time, the most relevant information about Beloranib's clinical trials."

In re Biogen Inc. Securities Litigation, 857 F.3d 34 (1st Cir. 2017)

Biogen Inc. ("Biogen") is a global biopharmaceutical company that develops, manufactures, and markets treatments for multiple sclerosis ("MS"), among other diseases. Its highest grossing product in 2015 was Tecfidera, an MS treatment approved for use in both the United States and Europe. During an October 2014 earnings call, Biogen disclosed that an MS patient who had taken Tecfidera as part of a clinical study had recently died of an infection related to her treatment. Biogen's CEO assured investors that despite this news, the drug's "overall positive benefit risk profile … remain[ed] unchanged." During the call, Biogen also announced its third-quarter financial results, including a 3.7% increase in total revenues from the previous quarter. While Tecfidera's growth rate for the quarter had decreased significantly from its growth rates in the previous four quarters, Biogen remained confident in Tecfidera's sales, and the company continued to project double-digit overall revenue growth in its 2015 guidance. Beginning in the first quarter of 2015, however, Biogen experienced a decline in both its overall revenues and Tecfidera revenues, due in part to its announcement of the patient death in 2014. Biogen ultimately revised its revenue guidance for 2015, indicating that its expected reacceleration of Tecfidera had not happened to an appreciable extent. Biogen's stock price dropped by 22%.

Investors filed a class action alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, claiming that Biogen and three of its executives made false or misleading statements regarding Tecfidera during various earnings calls and conferences, artificially inflating the company's stock price. Relying on statements by ten former Biogen employees acting as confidential witnesses, the complaint alleged that Biogen withheld material information about declining Tecfidera sales and the impact of the patient death, and made misleading positive statements about future revenue. The district court granted defendants' motion to dismiss, and denied a subsequent motion to vacate the judgment and for leave to file a second amended complaint. The First Circuit affirmed the dismissal. The court held that the complaint's confidential witness statements—which alleged that Tecfidera sales had dropped steeply following the announcement of the patient death and that Biogen executives knew of the decline—failed to precisely describe the size of the sales decline or its cause. Furthermore, the court found that the confidential witness statements did not establish that Biogen and its executives knew that their disclosures regarding Tecfidera were misleading when made. The court concluded that the confidential witness statements, which "[did] not speak with specificity as to why the defendants' alleged misstatements were untrue or misleading" and were "very often made about events occurring after the defendants' statements at

issue," were "so lacking in connecting detail that they cannot give rise to a strong inference of scienter." In reaching this conclusion, the First Circuit noted that the company's then-CEO and other executives named in the suit had increased their Biogen stock holdings during the relevant period, undermining plaintiffs' claim that they acted with scienter.

Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31 (1st Cir. 2017)

Sarepta Therapeutics, Inc. ("Sarepta") is a biopharmaceutical company focused on developing therapeutics for the treatment of rare and infectious diseases, including eteplirsen, its lead drug product candidate for the treatment of Duchenne Muscular Dystrophy ("DMD"). In March 2013, based in part on results of two Phase 2 clinical trials, Sarepta informed investors that it was moving toward filing an New Drug Application ("NDA") with the FDA for accelerated approval of eteplirsen. In April 2013, Sarepta informed investors about a meeting with the FDA, stating that the FDA had "not made a final decision" and that it was "too early to draw conclusions" about the FDA's position. Following a late July 2013 meeting with the FDA, the company issued a press release stating that Sarepta planned to submit an NDA "in the first half of 2014," that the FDA "requested additional information related to the methodology and verification of dystrophin quantification" from its previous trials, and that the company was "very encouraged by the FDA feedback" and hopeful that the FDA would accept its NDA for filing. In the months following, the company made several additional favorable statements about its progress towards FDA approval and its clinical data. On November 12, 2013, Sarepta announced that the FDA, citing a competing drug candidate for the treatment of DMD (drisapersen) in late September 2013, deemed premature Sarepta's application for approval of eteplirsen. Following this announcement, the company's stock price fell by more than 64%.

Investors filed suit against Sarepta and three of its current and former executives, alleging that Sarepta had misled investors by continually representing that its existing data would be sufficient to support an NDA, in violation of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. Plaintiffs alleged, based in part on alleged statements by three former Sarepta employees, that Sarepta overstated the significance of its clinical trial data and exaggerated in public statements the likelihood that eteplirsen would receive accelerated approval from the FDA. The district court granted defendants' motion to dismiss, finding that plaintiffs failed to allege facts creating a strong inference that defendants intentionally or recklessly deceived investors. The First Circuit affirmed the district court's dismissal, holding that the challenged statements provided "poor material for building a fraud claim" because they "convey[ed] opinion more than fact," and "came with caveats." For example, Sarepta offered a "mix of optimism and caution" when it made clear that the FDA had requested additional information related to the methodology and verification of the drug, and declined to offer any guarantee that the eteplirsen NDA would be accepted. The court found that "[e]ven if these and other caveats could have been more fulsome, they cut against the inference of scienter," so that, at worst, "there was a positive spin that put more emphasis in tone and presentation on the real signs of forward movement with the NDA than it did on causes for wondering if the journey would prove successful." The court found that "defendants had no legal obligation to loop the public into each detail and every communication with the FDA" and plaintiffs' "simply pointing us to omitted details and failing to explain how the omitted details rendered the particular disclosures misleading, misses the mark." Finally, the court rejected plaintiffs' argument that defendants had a motive because Sarepta needed to raise "essential funding" in a July 2013 offering, holding that the First Circuit "require[s] more than the ever present desire to improve results" to support an inference of scienter, such as "allegations that the very survival of the company w[as] on the line," which were absent in plaintiffs' complaint.

DISTRICT OF MASSACHUSETTS DECISIONS

Hensley v. Imprivata, Inc. et al., Case No. 16-cv-10160, 260 F. Supp. 3d 101 (D. Mass. May 16, 2017)

Imprivata, Inc. ("Imprivata") is an information technology company that provides authentication technology solutions for the healthcare and other industries. The company's flagship product is OneSign, an authentication system that helps companies manage who can access computer servers and files. Sales to large hospitals comprise 75% percent of Imprivata's total sales of OneSign, and the small hospital market and the non-healthcare market make up the remaining 25%. In April 2015, Imprivata expanded its product line with the acquisition of HT Systems, which makes a "palm-vein based identification technology" called PatientSecure. Following four quarters of exceeding its maximum revenue projections, Imprivata announced on November 2, 2015, that it underperformed its initial minimum revenue projection of $31 million for the third quarter of 2015 by about $1.7 million. On this news, Imprivata's share price fell 9.3%.

Investors filed a class action alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, claiming that Imprivata, its former CEO and CFO, three of its outside directors, and three funds with ownership interests in Imprivata issued a false and misleading revenue forecast for the third quarter of 2015. Relying on statements by five former Imprivata employees acting as confidential witnesses, the complaint alleged that defendants knew, and should have disclosed earlier, that (i) demand for Imprivata's IT solutions had fallen off; (ii) the integration of HT Systems was not going well; and (iii) due to regulatory changes driving a consolidation of the hospital industry, the third quarter of 2015 was an unlikely time for Imprivata's customers to purchase the company's solutions. In addition, plaintiff alleged that the individual and fund defendants engaged in unusual insider trading when they allegedly profited from sales of Imprivata stock during the class period. The district court dismissed the case in full and with prejudice, holding that the alleged misrepresentations were not actionable because, among other reasons, Imprivata's revenue forecasts fell squarely into the PSLRA's safe harbor provision, which immunizes forward-looking statements from liability when they are accompanied by meaningful cautionary language. In addition, the court held that there was no strong inference of scienter because after issuing its third quarter guidance, the company continued to warn investors of risks, and the fact that the company pre-released its third quarter 2015 results undermined any inference that defendants acted with intent to defraud. As to the allegations attributed to former employees, the court held these were "unduly threadbare and/or subjective" and could not survive the "hard look" necessary for scrutinizing confidential witness allegations in the First Circuit. In particular, the court noted that none of the former employees were alleged to have been involved in the revenue guidance process. Finally, the court rejected the insider trading allegations, holding that (i) nowhere did plaintiff plead that the CEO's or CFO's class period trading was in any way unusual when compared to their trades outside the class period; and (ii) alleged trading by the fund defendants could not on its own support a strong inference of scienter given the "dearth of other compelling evidence of scienter."

Harrington v. Tetraphase Pharmaceuticals Inc. et al., Case No. 1:16-cv-10133, 2017 WL 1946305 (D. Mass. May 9, 2017)

Tetraphase Pharmaceuticals is a clinical-stage biopharmaceutical company focused on making antibiotics for drug-resistant bacteria. Tetraphase's lead product candidate is eravacycline, which the company is developing as an intravenous and oral antibiotic for the treatment of multidrug-resistant infections. On September 8, 2015, the company announced that its Phase 3 clinical trial of eravacycline for the treatment of complicated urinary tract infections ("cUTIs") did not achieve its primary endpoint. Following the announcement, the company's stock price dropped by more than 80%.

Investors filed a federal securities class action against Tetraphase and three members of its senior management, alleging that Tetraphase made false and misleading statements regarding the prospects for bringing eravacycline to market, in violation of Sections 10(b), 20(a), and Rule 10b-5 of the 1934 Act. Specifically, the complaint alleged that Tetraphase's press releases, periodic reports, and other public statements were misleading because they failed to disclose that the Phase 3 trial would be a failure and that an NDA never would be filed. Plaintiffs alleged defendants' knowledge of these facts from (1) plaintiffs' inference that, because Tetraphase had previously stated a desire to report top-line results of its Phase 3 trial by "mid-year," the company must have received the trial results by early May 2015 in order to have the time to analyze the data before reporting the results "mid-year," and (2) prior, publicly available third-party studies and from Tetraphase's own prior studies, which allegedly confirm that eravacycline would not be an effective treatment for cUTIs. Plaintiffs also alleged that company executives delayed disclosure of their knowledge so they could sell off their personal holdings before Tetraphase's stock price diminished.

The district court granted defendants' motion to dismiss. Noting the "logical failings" of plaintiffs' theory that Tetraphase continued to invest in the development of a drug it knew would prove to be ineffective, the court held that the complaint failed to plead facts giving rise to a strong inference of scienter. The court also disagreed with plaintiffs' assumption that the company expected to release trial results in June because of its use of the term "mid-year," and, in any event, the complaint failed to allege any particular facts indicating that Tetraphase actually received the adverse Phase 3 results earlier than disclosed. The court also dismissed plaintiffs' argument that Tetraphase knew or should have known that eravacycline would not be effective based on the data from publicly available third-party studies, noting that publicly stated interpretations of the results of various clinical studies are nonactionable "opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions."

The court also dismissed plaintiffs' argument that Tetraphase knew or should have known that eravacycline would not be effective based on the data from publicly available third-party studies, noting that publicly stated interpretations of the results of various clinical studies are nonactionable "opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions."

Finally, the court found that the individual defendants' sales of company stock did not support an inference of scienter because the trades were made pursuant to 10b5-1 plans, and plaintiffs failed to demonstrate that the allegedly fraudulent scheme began prior to the implementation of the plans.

In re Psychemedics Corp. Securities Litigation, Case No. 1:17-cv-10186, 2017 WL 5159212 (D. Mass. Nov. 7, 2017)

Psychemedics Corp. ("Psychemedics") provides drug testing services through a proprietary process of hair sample analysis. For the last 15 years, Psychemedics has operated in Brazil through a Brazilian-owned, independent and exclusive distributor named Psychemedics Brasil. In December 2013, the Brazilian government announced plans to enact a law requiring all professional drivers to pass a hair drug test when applying for license renewals. In response to this new mandate, Psychemedics announced its intention to expand its testing capacity in anticipation of increased testing volume resulting from the forthcoming Brazilian drug testing requirement. The mandatory testing commenced in the first quarter of 2016. On April 26, 2016, Psychemedics told investors that it was "already seeing a meaningful pickup of testing volume in the second quarter" from the rapidly expanding Brazilian market. On January 31, 2017, Bloomberg pushed a report disclosing the existence of a scheme between Psychemedics Brasil and its competitor, Omega Brasil, pursuant to which Omega Brasil was bribed to steer exclusive drug collection points to Psychemedics Brasil. The Bloomberg report also disclosed a ruling by a Brazilian court in a lawsuit that had been filed by Omega USA, in which the court found that Psychemedics Brasil and Omega Brasil had conspired against Omega USA, effectively shutting it out of the Brazilian hair-testing market and ordered Psychemedics Brasil and Omega Brasil to indemnify Omega USA for a then-undetermined amount of loss profits. Bloomberg also reported that Psychemedics Brasil was under further investigation by Brazil's Administrative Council for Economic Defense for engaging in "cartel practices." In response to this news, Psychemedics' stock price dropped by more than 25%.

Investors filed a class action complaint alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, claiming that Psychemedics and the company's CEO misled investors by touting the company's growth in the Brazilian market while failing to disclose that its independent distributor had become secretly entwined in a cartel scheme with a competitor in violation of Brazilian law. The court granted defendants' motion to dismiss, finding that "the Complaint [was] devoid of any factual allegations that would tend to support an inference (much less direct evidence) that Psychemedics knew of the anti-competitive cabal between Psychemedics Brasil and Omega Brasil prior to it coming to light in the Brazilian lawsuit." Further, the court held that the plaintiff could not impute the scienter of Psychemedics Brasil absent an alter-ego relationship. In addition to finding that the complaint lacked any direct evidence of scienter, the court also rejected plaintiff's "core operations" and financial motive arguments, holding that the plaintiff's "'core operations' theory stands naked, unadorned by . . . the essential 'plus' factor – guilty knowledge," and "the mere fact that defendants stood to gain from the success of the company's planned expansion into Brazil, and that they therefore may have had an incentive to hide fraud . . . does not support an inference of scienter."

In addition to finding that the complaint lacked any direct evidence of scienter, the court also rejected plaintiff's "core operations" and financial motive arguments, holding that the plaintiff's "'core operations' theory stands naked, unadorned by . . . the essential 'plus' factor – guilty knowledge," and "the mere fact that defendants stood to gain from the success of the company's planned expansion into Brazil, and that they therefore may have had an incentive to hide fraud . . . does not support an inference of scienter."

NINTH CIRCUIT DECISIONS

In re Atossa Genetics, Inc. Sec. Litig., 868 F.3d 784 (9th Cir. 2017)

Atossa Genetics, Inc. ("Atossa") develops and markets products used to detect precancerous conditions that may indicate the development of breast cancer. The FDA had approved the device for other uses, but had not approved the diagnostic tool or the combination of the device and the tool. The company marketed the device and the tool together. After Atossa modified the device, the FDA informed the company it would have to reapprove the device and seek clearance for the tool. The FDA also said that in its view, Atossa's marketing was false and misleading to the extent that it characterized the device as "FDA-approved" and the tool as "FDA cleared." The company filed an 8-K disclosing the need for new approval of the device. But, the 8-K failed to mention the FDA's comments although it said that the FDA raised certain issues that, unless resolved, could disrupt the company's business and operations. Atossa's CEO later gave an interview and shared predictions about the company's prospects for 2013 and 2014. The FDA subsequently told Atossa that it must recall both the device and the tool. When Atossa disclosed the recall shortly thereafter, its stock price fell by 46 percent.

Shareholders filed a class action lawsuit against Atossa and certain of its officers, alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. The defendants moved to dismiss and the district court granted the motion, finding that the plaintiffs' allegations were inadequate because Atossa never explicitly stated that the ForeCYTE Breast Health Test was approved by the FDA, but instead that Atossa "uses the FDA-cleared MASCT System."

The Ninth Circuit partially reversed the district court's dismissal of the claims against Atossa. The court found that plaintiffs failed to plead the falsity of statements that the device used for collecting samples for the test had been cleared because it had, in fact, received 510(k) clearance as a sample-collecting device. However, the court also held that the plaintiffs sufficiently alleged the falsity and materiality of certain public statements about Atossa's breast cancer screening device and a related test. The court determined that certain statements in a Form 8-K filing and by the company's CEO that one of Atossa's cancer diagnostic tests had been cleared by the FDA met the pleading standards for falsity because clearance had not actually been obtained at the time of the statements. It also held that plaintiffs had adequately pled materiality given that the test was touted as a major source of revenue for Atossa and analysts had rated the company based on the claimed FDA clearance. The court deemed sufficient the plaintiffs' claims concerning Atossa's public description of an FDA warning letter, holding that the statements were misleading because they referred only to the FDA's concerns about the device and omitted any reference to the concerns the FDA raised about the related test. Notably, the court also permitted the plaintiffs to proceed with their claims regarding statements by the CEO explaining that, though arguably opinions, they were misleading under the Omnicare standard because they omitted material facts about knowledge at the time of Atossa's true prospects for FDA approval.

CALIFORNIA DISTRICT COURT DECISIONS

Markette, et al. v. XOMA Corporation, et al., Case No. 4:15-cv-03425, 2017 WL 4310759 (N.D. Cal. Sept. 28, 2017)

XOMA Corporation ("XOMA") is a clinical stage biotechnology company that develops and commercializes gevokizumab, an antibody for the treatment of inflammatory eye diseases. In 2012, XOMA began a randomized, double-blind, multi-part Phase 3 clinical trial, named EYEGUARD-B, to "provide the critical documentation of effectiveness and important additional safety data required for licensing." The primary endpoint of the study was set to a target number of clinical patients who exhibited a recurrence of episodes of worsening, exacerbating symptoms. In mid- and late-2014, XOMA made statements regarding the timeline of unblinding for EYEGUARD-B, including statements explaining that the unblinding of the EYEGUARD-B study would occur later than expected due to the study not having yet met its primary endpoint. In a March 2015 earnings call, and prior to the unblinding of the EYEGUARD-B data, XOMA also made statements responding to a question regarding an "apparent bifurcation" of the Phase 3 clinical patient group. On July 22, 2015, XOMA announced that the unblinded trial data had shown that there was "no statistical difference between" the gevokizumab and placebo groups.

Investors filed a class action lawsuit pursuant to Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that statements XOMA made during the 2014 and 2015 conference calls to investors were false or misleading. As a threshold matter, the court considered whether the alleged false or misleading statements were statements of fact or statements of opinion. If the latter, they were subject to the Ninth Circuit's recent holding in *City of Dearborn Heights Act 345 Police & Retirement Sys. v. Align Tech., Inc.*, 856 F.3d 605 (9th Cir. 2017), which clarified the standards for pleading falsity in statements of opinion under Section 10(b) and Rule 10b-5. Notably, *Dearborn* confirmed that a plaintiff may no longer plead falsity "by alleging that 'there is no reasonable basis for the belief' under a material misrepresentation theory of liability." Rather, "the plaintiff must allege *both* that 'the speaker did not hold the belief she professed' *and* that the belief is objectively untrue" (Emphasis added). Finding here that five of the shareholders' seven alleged false or misleading statements of opinion failed to plead that the speaker believed the statements to be "objectively untrue," under the clarified *Dearborn* standard, the court granted dismissal without prejudice as to those claims. As to the remaining two statements of fact not subject to the *Dearborn* standard, the court found neither misleading, in part because XOMA remained blinded to the EYEGUARD-B results at the time the statements were made. Reasonably taken, those statements would not have significantly altered the total mix of information available.

In re KaloBios Pharm., Inc. Sec. Litig., Case No. 5:15–cv–05841, 258 F. Supp. 3d 999 (N.D. Cal. June 23, 2017)

KaloBios Pharmaceuticals, Inc. ("KaloBios") is a biopharmaceutical company located in South San Francisco. By all accounts in early 2015, KaloBios was in "severe financial distress," and "was struggling, both operationally and financially." A number of KaloBios' clinical trials for key drug candidates had failed, and the company's leading commercial partner withdrew several hundred million dollars in previously promised funding. By late 2015, KaloBios announced it was halting enrollment

in its remaining clinical studies, and that limited cash resources precluded the company from further investigating strategic alternatives. KaloBios was beginning to wind down operations and liquidate its assets. Its stock declined to a low of $0.90 per share.

In November 2015, entrepreneur and investor Martin Shkreli purchased over two million shares of KaloBios common stock. Shkreli's purchase made him the largest shareholder of KaloBios, and prompted discussions with the company's existing management "regarding possible direction for the company to continue in operation." During the same time, reports of criminal investigations into Shkreli's other investments and companies surfaced in public news sources. These reports widely disseminated information about Shkreli, including that Shkreli was under investigation for allegations of "insider trading, disguising the purpose of corporate payments for his benefit, defrauding shareholders by snatching business opportunities for himself, destruction of evidence, failure to disclose material facts to shareholders and other potential crimes." Nevertheless, in spite of these public reports, the KaloBios Board of Directors accepted Shkreli's financing proposal, appointed him as CEO, and elected Shkreli as Chairman of the Board.

Thereafter, Shkreli made several public statements regarding KaloBios, about the financial strength of the company, about its strong potential and positive progress, and about his own qualifications to be the company's CEO. Shareholders allege that these statements led to a rise in the share price of KaloBios. In December 2015, however, Shkreli was arrested on charges related to misconduct with one of his previous companies. A federal indictment and SEC complaint were made public the same day. In response to the news, the share price of KaloBios fell by 53% in pre-open trading before NASDAQ halted trading. Several days later, NASDAQ delisted KaloBios, and the company filed for Chapter 11 bankruptcy.

Shareholders filed a lawsuit against the company and several of its officers and directors, including Shkreli. They allege that because of Shkreli's "prior improprieties, frauds, and illegal and criminal misconduct," the public statements he made about the financial strength of KaloBios, its progress, and his own qualifications were materially false and misleading. Moreover, shareholders alleged that those statements caused the company's shares to trade at artificially inflated prices during the class period.

Although a high burden, in the Ninth Circuit, the truth-on-the-market defense is available for a defendant to show "that the information withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by the insider's one-sided representations.'"

In moving to dismiss, Shkreli argued that the complaint's allegations of statements he made regarding his reputation or qualifications at KaloBios was subject to a "truth-on-the-market" defense. The court agreed. Although a high burden, in the Ninth Circuit, the truth-on-the-market defense is available for a defendant to show "that the information withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by the insider's one-sided representations.'" While Shkreli may have concealed or misrepresented material statements at the time of his arrest in December 2015, public information that "identify a multitude of personal and professional accusations of misconduct" of Shkreli was already widely available. Given the content of widely-disseminated news reports and the credibility of those reports, "the market was aware of the information plaintiffs accuse Shkreli of misrepresenting or failing to disclose." Moreover, the court also rejected shareholders' claims that Shkreli's statements about KaloBios' financial recovery and business potential were misleading. Shareholders failed to adequately allege the falsity of those statements, or sufficiently plead facts that would suggest "why an optimistic view of the company was patently misleading or disingenuous."

Hsingching Hsu v. Puma Biotech., Inc., Case No. 8:15-cv-00865, 2017 WL 3205774 (C.D. Cal. July 25, 2017).

Puma Biotechnology, Inc. ("Puma") is a pharmaceutical company focused on acquiring and developing cancer treatment drugs. One of Puma's drugs, neratinib, is used in connection with breast cancer treatments. In the consolidated amended complaint, plaintiffs alleged that Puma misled investors by overstating top-line efficacy results and understating safety results from a Phase 3 trial of neratinib, which compared extended treatment of neratinib to a placebo in HER2-positive breast cancer patients. In September 2016, the court denied defendants' first motion to dismiss.

Thereafter, the plaintiffs amended their complaint to add new allegations of related misstatements. The court denied for the second time a motion to dismiss securities claims against Puma related to neratinib, finding that the statements as pled were actionable and not subject to the PSLRA's safe-harbor provisions because plaintiffs sufficiently alleged that Puma possessed data at the time that contradicted the company's statements. Specifically, the court noted that the defendants could not "benefit from [the] safe harbor by simply saying they 'anticipated' success when, in fact, they had a reasonable belief that defeat was just around the corner." The court also determined that plaintiffs' new scienter allegations "buttress—rather than detract from—the already adequate allegations of scienter."

In re Dynavax Sec. Litig., Case No. 4:16-cv-06690, 2017 WL 4005584 (N.D. Cal. Sept. 12, 2017)

Dynavax Technologies Corporation ("Dynavax") is a clinical stage biopharmaceutical company focused on developing various products for the prevention of infectious diseases and the treatment of cancer. Dynavax's HEPLISAV-B vaccine was in the Phase 3 clinical development stage of the FDA approval process. In November 2016, Dynavax received a complete response letter ("CRL") related to the HEPLISAV-B Phase 3 clinical trial indicating that the FDA was continuing to review responses from Dynavax regarding various issues, including a numerical imbalance in cardiac events. Dynavax issued a press release in which it stated that "[t]he CRL is consistent with our opinion that HEPLISAV-B is approvable and [it] was seeking to meet with the FDA as soon as possible." During an earnings call the same day, Dynavax's CEO noted that it was not the company's practice to provide more information in response to analyst questions despite being pressed about "not having more transparency." The stock price dropped from $11.60 to $4.10 the next trading day.

Investors filed a class action lawsuit pursuant to Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that Dynavax made false and misleading statements regarding the cardiac events. Plaintiffs argued that these events were actually "Adverse Events of Special Interest" (or "AESIs"). Dynavax argued that plaintiffs' reliance on a purported failure to disclose "cardiac AESIs" was the fatal flaw in plaintiffs' complaint given that the clinical trial specifically analyzed a pre-specified list of disorders—which did not include cardiac events or diseases. Plaintiffs ultimately conceded that the cardiac issues did not actually qualify as AESIs, and the court dismissed the complaint, holding that plaintiffs' "repeated incorporation of this same mistaken allegation undermines the viability of the entire complaint."

In re Intrexon Corp. Sec. Litig., Case No. 3:16-cv-02398, 2017 WL 732952 (N.D. Cal. Feb. 24, 2017)

Intrexon Corp. ("Intrexon") is a biotechnology company that owns various technologies that design, build, and regulate DNA sequences. Its primary business model is based on licensing its technologies to partner companies, who then collaborate with Intrexon to develop products using those technologies. In April 2016, an anonymous short-seller released a report about the company and its technology. The report claimed that Intrexon's "core technology suite" was an "overhyped, undifferentiated collection of commodity and failed products." The report also claimed that Intrexon "created an intricate web of microcap, zero revenue, free cash flow negative companies that seem to exist solely for the purpose of inflating Intrexon's revenue and profitability."

Shortly thereafter, shareholders filed a securities class action against Intrexon and certain of its officers and directors, relying primarily on the claims in the anonymous report. The lawsuit alleged that Intrexon's generally positive statements about its technology suite were false or misleading because the individual technologies in the suite were either commodity products, or did not

work. Shareholders also alleged that Intrexon's financial statements were false and inflated certain of the company's revenues.

On a motion to dismiss, the company argued that the allegations, cast nearly wholesale from statements made in the anonymous report, failed to set forth any claim for relief. The court agreed. With respect to the shareholders' Rule 10b-5 claims, they lacked both the requisite specificity and allegations that the statements Intrexon or its officers or directors made were false. The complaint referenced a "core technology suite" and described it worthless, but nowhere defined what components of Intrexon's technology was within the scope of the alleged "suite." Moreover, the court rejected allegations by shareholders as to statements Intrexon made that were best characterized "as 'puffery' or other non-specific assertions that cannot give rise to a fraud claim." Even had the complaint cast allegations with the requisite specificity under Rule 10b-5, the claim still failed. Shareholders' allegations pertaining to the company's statements did not sufficiently allege falsity. Claiming that "the proof [was] in the market outcomes," shareholders raised a fraud-by-hindsight argument to sustain their allegations. As the court recognized, "[a] plaintiff cannot show that a prior statement was false or misleading merely by pointing to the market reaction upon a subsequent disclosure of information." Having failed to set forth adequate pleading of material misstatements or omissions, shareholders "necessarily" failed to plead scienter under Rule 10b-5. In view of shareholders' deficient pleading for its fraud claim, the court also summarily rejected the shareholders' second claim pursuant to Section 20(a) of the Exchange Act.

Norfolk County Retirement System, et al. v. Solazyme, Inc., et al., Case No. 4:15-cv-02938, 2016 WL 7475555 (N.D. Cal. Dec. 29, 2016)

Solazyme Inc. ("Solazyme") is an early-stage biotechnology company that uses genetically modified algae strains to convert plant-based sugars into high-value oils and other bioproducts. These products can be tailored for specific customer uses and are used in various food products. During the class period, Solazyme operated three production facilities. As to one of them, which was under construction, Solazyme provided regular updates about the progress of its commissioning, including statements that construction was progressing closer to completion. In late 2014, Solazyme reported that it would shift strategy regarding the production at this facility; rather than focus on larger-volume production, it would produce small volumes of product that could yield higher margins. As a result of the shift, Solazyme retired its previous strategy for the production facility in favor of small-volume productions.

The court dismissed the claims, noting that shareholders failed to assert standing to bring the claim as they failed to adequately allege their shares were traceable to either of Solazyme's two registered public offerings.

Shareholders brought a class action securities lawsuit against Solazyme, its directors and officers, and underwriters based on two registered public offerings executed in March 2014. The complaint primarily alleged that the defendants made false statements about the construction and commissioning of the production facility. In dismissing those claims, the court noted that the shareholders failed to assert standing, as they failed to adequately allege that their shares were traceable to either of Solazyme's two registered public offerings. Moreover, the complaint failed to plead with particularity the requisite false or misleading statement, as required under the Securities Act. Specifically, shareholders failed to allege that the facts contained in the statements existed and were known to defendants at the time the statements were made. The court dismissed the complaint, with leave to amend.

Crihfield v. CytRx Corp., Case No. 2:16-cv-05519, 2017 WL 2819834 (C.D. Cal. June 14, 2017)

CytRx Corp. ("CytRx") is a clinical stage biopharmaceutical research and development company specializing in the development of drugs used to treat certain cancers. One of its drug candidates is aldoxorubicin, which CytRx was developing as a second-line treatment for soft tissue sarcoma. In April 2013, CytRx announced that it had reached an agreement with the FDA pursuant to a Special Protocol Assessment ("SPA") for Phase 3 clinical trial testing of aldoxorubicin. The trial protocol set forth in the SPA was amended in January 2014 to allow dosing patients with aldoxorubicin until disease progression. As specified in the SPA, the trial was designed with the assumption that clinical data would be analyzed after reaching a target number of progression free survival events. In November 2014, CytRx announced that the FDA had placed a partial clinical hold on the trial because a patient with soft tissue sarcoma, although not part of the trial, had died after receiving aldoxorubicin. That hold was later lifted in early 2015, and CytRx announced that it would proceed with revised trial protocols in response to the partial hold. After reaching the specified endpoints, CytRx analyzed the clinical data and announced initial results. It noted, however, that insufficient time had passed to examine the efficacy of the drug on a large number of patients who enrolled after the partial hold was lifted, and therefore many patients were excluded from the initial clinical data analysis. Upon news of this limitation, the price of CytRx's stock fell over 59% to close at $1.01 per share on unusually heavy trading volume.

Shareholders filed a securities class action against CytRx and its directors and officers alleging that statements made regarding the Phase 3 clinical trial violated Section 10(b) and Rule 10b-5, and Section 20(a) of the Exchange Act. The court granted defendants' motion to dismiss, finding that shareholders failed to plead adequate scienter as to statements defendants made regarding patients who could continue receiving aldoxorubicin during the FDA partial hold.

The court could not infer from the allegations that defendants more likely than not knew that testing currently enrolled patients for acidosis would delay aldoxorubicin administration to such a degree that the trial's projected timeline and results would be negatively impacted.

The court could not infer from the allegations that defendants more likely than not knew that testing currently enrolled patients for acidosis would delay aldoxorubicin administration to such a degree that the trial's projected timeline and results would be negatively impacted. Moreover, the court rejected the shareholders' argument that defendants' statements regarding CytRx's compliance with the SPA were misleading: shareholders "point[] to no authority that a company's failure to comply with all assumptions underlying an SPA or a similar agreement with a regulatory body renders the company not in compliance with the agreement."

IMPORTANT CASES TO WATCH IN 2018[5]

Wang Yan et al. v. Rewalk Robotics Ltd. et al., Case No. 1:17-cv-10169 (D. Mass.)

ReWalk Robotics Ltd. ("ReWalk") is an early-stage medical device company that is designing, developing, and commercializing wearable robotic exoskeletons that enable wheelchair-bound individuals to stand and walk. In June 2014, the FDA granted ReWalk's petition for "de novo" classification, allowing ReWalk to market its products as Class II devices, which are subject to additional FDA controls. In ReWalk's case, the FDA ordered several additional controls, including a postmarket surveillance study ("PS study"), which, by statute, must be completed within 15 months of de novo classification. ReWalk disclosed the FDA-mandated additional controls in its offering documents as part of its September 2014 IPO. Shortly after the IPO, the FDA informed ReWalk that ReWalk's proposal for the PS study was deficient, lacking the required information to complete the agency's review, and ordered a complete response. From September 2014 to September 2015, ReWalk submitted two response letters aimed at addressing the FDA's concerns with the design of the PS study. Both responses were filed after the FDA's 30-day deadline, and both were eventually rejected on their substance. While ReWalk and the FDA's dialogue concerning the design of the PS study continued through the summer of 2015, on September 30, 2015, the FDA sent ReWalk a Warning Letter noting "a substantial lack of progress towards commencement of the . . . PS study," and informing ReWalk that its devices were considered misbranded as Class II because the PS study had not been approved and commenced within 15 months. Critically, the Warning Letter also noted that the PS study was ordered "because the device's failure to prevent a fall would be reasonably likely to cause serious user injury and/or death through fall related sequelae, such as traumatic brain injury (TBI), spinal cord injury (SCI), and fractures to the user." On March 1, 2016, the text of the Warning Letter was published on the FDA's website and ReWalk's stock price fell by more than 18% over the following two days.

Investors filed a federal securities class action against ReWalk, several of its current and former executives and directors, and its underwriters, asserting claims under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act and Sections 11 and 15 of the 1933 Act. Plaintiff's 1933 Act claims allege that ReWalk's disclosure of the PS study in its offering documents was misleading because ReWalk failed to disclose the basis for the FDA's requirement of a PS study—namely, the FDA's alleged observation that the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall. Plaintiff's 1934 Act claims, which are based in part upon alleged statements by three former ReWalk employees acting as confidential witnesses, allege that a number of ReWalk's public statements following its IPO were misleading for the same reason, and because ReWalk failed to disclose, among other things, that the company failed to submit a revised PS study plan that addressed deficiencies noted by the FDA;

[5] In addition to the cases summarized in this section, pending motions to dismiss in certain of the cases identified and summarized as important cases to watch in our 2016 Year in Review have yet to be decided, including in *Electrical Workers Pension Fund, Local 103, IBEW v. Kingsley et al.*, Case No. 1:16-cv-12101 and *Mazurek v. Seres Therapeutics, Inc. et al.*, Case No. 1:16-cv-11943. Moreover, the lead plaintiff process is still ongoing in *Garbowski et al v. Tokai Pharmaceuticals, Inc. et al.*, Case No. 1:16-cv-11963 and, thus, defendants have not yet filed a motion to dismiss.

ReWalk failed to commence the PS study within the 15-month window, causing the device to be considered misbranded by the FDA; and ReWalk failed to disclose the risks of approval from their dilatory responses and failure to comply with the FDA's order of a PS study. Defendants moved to dismiss the action on November 10, 2017, briefing was completed on January 10, 2018, and argument on the motion took place on January 19, 2018.

Whitehead v. Inotek Pharmaceuticals Corp. et al., Case No. 1:17-cv-10025 (D. Mass.)

Inotek Pharmaceuticals Corp. ("Inotek") is a clinical-stage biopharmaceutical company that was developing a drug, trabodenoson, to treat glaucoma. Inotek was attempting to develop trabodenoson both as a monotherapy and as a fixed-dose combination ("FDC") with latanoprost, a leading glaucoma treatment, with the hope of producing a drug that was effective through once-daily administration. The company performed separate Phase 2 trials in support of the monotherapy and FDC formulations. In the Phase 2 monotherapy trial, patients were dosed twice a day with trabodenoson monotherapy. In the FDC trial, trabodenoson was co-administered with latanoprost twice daily in the first part of the study and then co-administered with latanoprost once daily in the second part of the study. Following these trials, Inotek performed a Phase 3 trial in support of its monotherapy formulation of trabodenoson, which tested the effectiveness of the drug in a once-daily administration. In January 2017, Inotek announced that the Phase 3 trial did not achieve its primary endpoint. The price of Inotek common stock dropped approximately 70% on this news. Later, in July 2017, Inotek announced that a second Phase 2 trial in support of the FDC therapy, which tested the drug's effectiveness as a once-daily administration, also failed to meet its primary endpoint. The price of Inotek's stock again dropped approximately 48% on this news.

Investors filed suit, alleging that Inotek made false and misleading statements about the trials' prospects for success, in violation of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. Specifically, the complaint alleges that Inotek misled investors about the potential for trabodenoson to be marketed as a once-daily administration because neither the monotherapy Phase 2 study nor the first FDC Phase 2 trial tested a once-daily dose of trabodenoson alone. Thus, according to plaintiff, Inotek had no data from which to observe the effectiveness of trabodenoson as a once-daily dose. Defendants moved to dismiss the action on October 6, 2017 arguing that plaintiffs failed to allege scienter and that any of the statements at issue were materially false and misleading.

Dahhan v. OvaScience, Inc. et al., Case No. 1:17-cv-10511 (D. Mass.)

OvaScience, Inc. ("OvaScience") is a fertility company founded to develop and commercialize new fertility treatments utilizing egg precursor cells ("EggPC") to improve egg health and revolutionize in vitro fertilization ("IVF"). Since launching in 2011, OvaScience has developed one potential treatment, AUGMENT, to the point of commercialization. AUGMENT addresses certain developmental problems in newly formed embryos by supplementing the energy level in the egg. In 2012, OvaScience originally sought to commercialize AUGMENT in the United States. OvaScience, however, shifted its efforts to commercialize internationally after receiving criticism from the FDA for failing to file an investigative new drug application. Through a successful partnership with international IVF clinics, OvaScience quickly transitioned from performing free treatments to charging patients for the treatment. On December 17, 2014, OvaScience held its first Investor Day and announced that it had initiated 150 free cycles of AUGMENT and expected to have 1,000 commercial cycles in progress by the end of 2015. OvaScience's stock rose 62% on this announcement.

On January 13, 2015, OvaScience raised $132.25 million through a secondary public offering. On March 16, 2015 OvaScience filed its Form 10-K, which reaffirmed the 1,000-cycle target. On March 26 and 28, OvaScience reported at the Society for Reproductive Investigation's Annual Meeting that it had successfully achieved a 53% pregnancy rate at its Canadian clinic. The Society for Reproductive Investigation, however, released a report that indicated a much lower pregnancy rate, and noted that OvaScience had only performed a few treatments. While this caused OvaScience's stock to drop 23%, OvaScience still maintained that it was on track to meet the 1000-cycle target. On September 29, 2015, how-

ever, OvaScience announced that it would not achieve the 1,000-cycle target, and in fact, had only initiated a total of 35 commercial cycles of AUGMENT. Following this announcement, OvaScience's stock price dropped more than 40%.

Investors filed a federal securities class action against OvaScience and two of its executives, alleging violations of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. Specifically, the complaint alleges that OvaScience failed to disclose material facts related to AUGMENT, and knowingly or recklessly made false and misleading statements regarding both the number of AUGMENT treatment cycles performed, as well as AUGMENT's overall global success, such as its pregnancy rate. Plaintiffs allege defendants had knowledge of these facts from OvaScience's own routinely performed studies which tracked every AUGMENT cycle. Plaintiffs also infer defendants' knowledge based on OvaScience's desire to focus internationally, and the unexplained resignations of OvaScience's COO, President and Chief Scientific Officer, and CEO. On June 21, 2017, OvaScience announced that it was discontinuing all efforts related to AUGMENT outside of North America, and reduced its workforce by 50%. AUGMENT was eventually abandoned. On August 25, 2017, OvaScience's stock had dropped more than 97% from its Class Period high, and at that time, plaintiffs filed an amended complaint to include these additional facts. Defendants moved to dismiss the action on October 10, 2017.

On June 21, 2017, OvaScience announced that it was discontinuing all efforts related to AUGMENT outside of North America, and reduced its workforce by 50%. AUGMENT was eventually abandoned.

Westmoreland County Employee Retirement System v. OvaScience, Inc. et al., Case No. 1:17-cv-12312 (D. Mass.)

On November 22, 2017, investors filed a separate federal securities class action against OvaScience, the same defendant in *Dahhan v. OvaScience, Inc. et al.*, Case No. 1:17-cv-10511 (D. Mass.). The factual allegations are similar to *Dahhan* in that they relate to OvaScience's allegedly false and misleading statements regarding its IVF treatment, AUGMENT. However, unlike in *Dahhan*, plaintiffs here allege claims solely for violations under Sections 11, 12(a)(2) and 15 of the 1933 Act relating only to plaintiffs' purchase of OvaScience shares during the company's secondary offering on January 8, 2015. Plaintiffs have named OvaScience's underwriters for the secondary offering, J.P. Morgan Securities LLC, Credit Suisse Securities LLC, and Leerink Partners LLC.

The complaint alleges that defendants made material misstatements and omissions in its January 6, 2015 Preliminary Prospectus Supplement and its January 8, 2015 Prospectus Supplement for the secondary offering ("Offering Materials"). Specifically, the complaint alleges that the Offering Materials contained misleading statements and/or failed to disclose that the science behind AUGMENT was untested and in doubt and that the 2014 AUGMENT treatment pregnancy success rate was not much higher than standard IVF rates. Additionally, plaintiffs allege that the company misled investors when it failed to disclose that the company was forced to undertake its studies outside of the United States and that the company was far from being profitable.

King, Jr. v. Keryx Biopharmaceuticals, Inc. et al., Case No. 1:17-cv-10653 (D. Mass.)

Keryx Biopharmaceuticals, Inc. ("Keryx") is a biopharmaceutical company focused on marketing therapies for patients with renal disease. The company's lead product, Auryxia, is an oral, absorbable iron-based compound. Auryxia received marketing approval from the FDA in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease ("CKD") on dialysis. On April 28, 2016, Keryx issued a press release that stated it had received positive results during its Phase 3 clinical trials to treat iron deficient anemic adults suffering from renal disease with Auryxia. Based on these results, Keryx stated that it planned on submitting a supplemental new drug application for FDA approval in the third quarter of 2016. The press release also stated that Keryx was confident of the increased uptake of Auryxia in people with CKD, and thus, was preparing for its potential launch in 2017.

On August 1, 2016, however, Keryx announced that there was a supply interruption of Auryxia caused by a production-related issue. As a result, the company exhausted its reserve of finished drug product, but stated that it expected to both restore adequate supply of Auryxia and make it available to patients during the fourth quarter of 2016. Following this announcement, Keryx's stock price fell over 35%.

Investors filed a federal securities class action against Keryx and its CEO and CFO, asserting claims under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. The complaint alleges that defendants made materially false and/or misleading statements in the April 28, 2016 press release, and failed to disclose material adverse facts about the company's business. Specifically, plaintiffs allege that at the time of the April 28, 2016 press release, Keryx and the individual defendants knowingly or recklessly failed to disclose that the company was experiencing production-related difficulties in converting active pharmaceutical ingredients to finished drug product. Additionally, the complaint alleges that these difficulties caused decreased production yields of finished drug product and ultimately, exhausted the company's reserve of finished drug product. Finally, plaintiffs infer defendants' knowledge of the production-related issues by virtue of their positions at Keryx. Two other putative class actions based on substantially similar allegations were filed against Keryx in federal court (*Jackson v. Keryx Biopharmaceuticals, Inc. et al.*, Case No. 1:16-cv-061310-KMW (S.D.N.Y.) and *Erickson v. Keryx Biopharmaceuticals, Inc. et al.*, Case No. 1:16-cv-06218-KMW (S.D.N.Y.)). A motion to consolidate the cases and appoint a lead plaintiff is currently pending. On April 18, 2017, the case was transferred to the District of Massachusetts.

Emerson v. Genocea Biosciences, Inc. et al., Case No. 1:17-cv-12137 (D. Mass.)

Genocea Biosciences, Inc. ("Genocea") is a biopharmaceutical company that discovers and develops vaccines and immunotherapies. Genocea's lead product is GEN-003, which is a genital herpes immunotherapy product. On May 5, 2017, Genocea's 10-Q stated that GEN-003 had completed two successful Phase 2 clinical trials, and it was on track to initiate a Phase 3 trial in the fourth quarter of 2017. On September 25, 2017, however, Genocea disclosed that it was ceasing GEN-003 spending and activities because it wanted to "explore strategic alternatives to GEN-003," resulting in a workforce reduction of 40%. Following this announcement, the company's share price dropped by more than 75%.

Investors filed a federal securities class action under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that Genocea, its CEO, and its CFO made false and misleading statements regarding the prospects for bringing GEN-003 to market. The complaint alleges that Genocea's May 5, 2017 10-Q and August 9, 2017 10-Q included false and/or misleading statements and/or failed to disclose that the company's finances were insufficient to support Phase 3 trials of GEN-003 and that the company overstated the prospects for GEN-003. Specifically, plaintiffs rely on the May, 5 2017 10-Q, which stated that the company expected its existing cash, cash equivalents and investments to support all operating expenses and debt obligations into the first quarter of 2018. Plaintiffs also rely on the August 9, 2017 10-Q which stated that GEN-003 was still on track for Phase 3 clinical trials during the fourth quarter of 2017. The complaint alleges that defendants were aware that GEN-003 was not going to be market ready in the fourth quarter of 2017 when they filed the two 10-Qs. Plaintiffs infer defendants' knowledge of the false and/or misleading statements by virtue of their positions with Genocea.

Caraker v. Ocular Therapeutix, Inc. et al., Case No. 1:17-cv-12146 (D. Mass.)

Ocular Therapeutix, Inc. ("Ocular") is a biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. The company's lead product, DEXTENZA, is in Phase 3 clinical trial for the treatment of post-surgical pain and inflammation, and Phase 2 clinical trial for the treatment of inflammatory dry eye disease. On May 5, 2017, Ocular filed a Form 8-K with the SEC and disclosed that it had received a Form 483 from the FDA related to DEXTENZA. Ocular informed investors that the FDA found some potential issues related to the manufacturing of DEXTENZA, but that the issues were resolvable and would be fixed in a timely manner. On that same day, Ocular held an earnings call with investors during which it stated that the FDA Form 483 situation was under control and that they expected resolution of the issues in a timely manner. On July 6,

2017, analysts uncovered the FDA's Form 483 regarding DEXTENZA and published an article that reported its contents. In part, the analysts reported that Ocular's management had misled investors because there were ongoing and repeated manufacturing issues with DEXTENZA. According to the analysts, "even a layperson reading this [Form 483]" could tell that the company's approach to manufacturing and patient safety is "highly questionable." On the same day, another analyst reported that the Form 483 revealed that DEXTENZA could potentially be rejected by the FDA because some of the product was contaminated with aluminum. Ocular's share price fell over 30% over the two trading days following publication of the reports.

Investors filed a federal securities class action under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that Ocular and four of its directors and senior officers, made materially false and misleading statements regarding DEXTENZA and the FDA's Form 483. The complaint alleges that defendants made false and/or misleading statements regarding Ocular's significant manufacturing issues related to DEXTENZA and DEXTENZA's FDA approval chances. Specifically, plaintiffs allege that defendants, by virtue of their positions with Ocular, were aware at the time of the May 5, 2017 Form 8-K filing that the Form 483 situation was not under control, and in fact, 50% of the DEXTENZA lot was contaminated with aluminum and that this contamination greatly reduced DEXTENZA's chances for FDA approval.

There have been two other putative class actions based on substantially similar allegations filed against Ocular in federal court (*Gallagher v. Ocular Therapeutix, Inc. et al.*, Case No. 2:17-cv-05011-SDW-LDW (D.N.J.) and *Kim v. Ocular Therapeutix, Inc. et al.*, Case No. 2:17-cv-05704-SDW-LDW (D.N.J.)). A motion to consolidate the cases and appoint a lead plaintiff is currently pending. On November 2, 2017, the case was transferred to the District of Massachusetts.

Deora v. NantHealth, Inc., No. CV 17–01825 BRO (MRWx) (C.D. Cal.)

Nanthealth specializes in genetic diagnostics. It provides the product, GPS Cancer™, a Genomic Proteomic Spectrometry solution that enables the delivery of medical treatment tailored to a patient's genetic and molecular profile. In June 2016, Nanthealth conducted an initial public offering for 6,500,000 shares at $14.00 per share, and filed an IPO registration statement with the SEC. Among other things, the registration statement disclosed that Nanthealth had entered into an agreement with a university to provide researched-related sequencing services for projects related to understanding the genetic causes of certain hereditary diseases. The registration statement also disclosed that as part of the agreement, Nanthealth would receive $10 million in services earmarked as capital contributions. Following the IPO, in July 2016, Nanthealth announced additional details about its university partnership, and also announced that it would begin offering GPS Cancer commercially beginning in the third quarter of 2016. In a November 2016 earnings call, Nanthealth disclosed that it received a number of commercial orders for GPS Cancer, but cautioned investors that the company would not recognize revenue until insurance reimbursement for GPS Cancer was received. The next day, Nanthealth's stock price fell from $11.17 to $10.09 per share. In March 2017, an online newsletter published an article profiling Nanthealth, alleging that the company's relationship with the university was improper, and that its CEO had been laundering funds through that partnership. Following this publication, Nanthealth's stock price fell further from $7.17 to $5.50 per share.

Thereafter, three separate class action complaints were filed against Nanthealth and various officers and underwriters in connection with the June 2016 initial public offering. Each alleged claims that the defendants violated Sections 11 and 15 of the Securities Act, Section 10(b) of the Exchange Act and Rule 10b-5, and Section 20(a) of the Exchange Act. The Court consolidated the three cases, and defendants moved to dismiss the consolidated class action complaint. Defendants argued that the complaint failed to adequately plead allegations that either the registration statement or the company's post-IPO statements were false or misleading. Moreover, defendants argued that the complaint failed to plead loss causation, nor did any of the allegations give rise to a strong inference of scienter as required under the plaintiffs' securities fraud claims. The motion to dismiss has been fully briefed, and has been taken under submission by the court. An order on the motion is expected in early 2018.

HsingChing Hsu v. Puma Biotechnology, Inc., et al., No. SACV 15-00865 AG (JCGx) (C.D. Cal.)

As noted above, Puma Biotechnology, Inc. is a development-stage biopharmaceutical company developing its drug candidate, neratinib, for the treatment of HER2-positive breast cancers. In July 2014, Puma announced top-line results from the company's "ExteNET" trial, a Phase 3 clinical trial of neratinib. The company reported that it achieved its primary endpoint by demonstrating a marked improvement in disease-free survival ("DFS") at two years among female patients taking neratinib versus the placebo. However several months later, Puma updated its ExteNET results with additional, detailed data regarding neratinib. Following these new disclosures, Puma's stock price declined substantially.

Shareholders filed a complaint against Puma and its officers alleging that statements made following the Phase 3 ExteNET trial, including statements regarding the drug's safety results and efficacy over time, were false and misleading. Specifically, they allege that Puma's statements about ExteNET's top-line DFS results failed to disclose necessary efficacy metrics following the two-year mark. The Court denied defendants' first motion to dismiss, finding that the complaint adequately pled both falsity and scienter. Pointing to various statements made by the company and its officers, the court explained that the complaint sufficiently allege facts as to how the disclosures regarding the DFS rate in Puma's ExteNET trial could have misled investors regarding the efficacy of its drug candidate.

Plaintiffs subsequently filed an amended consolidated complaint alleging additional statements made by the company, including allegations of false or misleading statements about neratinib's safety results and dropout rates in the ExteNET trial. As noted above, the court denied the second motion to dismiss and allowed the case to proceed to discovery. Recently, in December 2017, the court granted plaintiffs' motion to certify the class of shareholders who acquired Puma securities during the class period. Discovery is underway, and trial is set for November 2018.

In Dynavax Securities Litigation, Case No. 4:16-cv-6690 (N.D. Cal.)

Dynavax Technologies Corporation is a clinical-stage biopharmaceutical company focused on developing various products for the prevention of infectious diseases and the treatment of cancer. As discussed above, its lead vaccine product, HEPLISAV-B, is a Phase 3 investigational adult hepatitis B vaccine. In January 2016, Dynavax issued a press release announcing preliminary top-line results of HEPLISAV-B in Phase 3 testing. The company also announced certain information pertaining to an "adverse event of special interest" experienced during the HEPLISAV-B trial. In November 2016, in response to an FDA request, Dynavax disclosed additional information concerning the adverse event. The price of Dynavax stock dropped 65% following this announcement, from $11.60 per share to $4.10 per share the next trading day. Plaintiffs filed a consolidated amended complaint in March 2017. The Court granted defendants' motion to dismiss on the basis that plaintiffs' claims misconstrued the "adverse event of special interest" in the HEPLISAV-B trial. As discussed above, the court explained that Plaintiffs' "repeated incorporation of this same mistaken allegation [regarding the adverse event] undermines the viability of the entire complaint."

Plaintiffs filed a second amended consolidated complaint in October 2017, and defendants again moved to dismiss. In an order recently issued in January 2018, the court granted the motion for the consolidation of further actions against Dynavax and its officers and directors. The court's decision on the motion to dismiss the second amended consolidated complaint is expected in early 2018.

In re Intuitive Surgical Sec. Litig., Case No.5:13-CV-01920 (N.D. Cal.)

Intuitive Surgical, Inc. ("Intuitive") develops, manufactures, and markets the da Vinci Surgical System, a product that allows surgeons to perform laparoscopic surgeries through a few small incisions in a patient's abdomen. During 2010 to 2012, Intuitive received medical device reports ("MDRs") indicating that certain da Vinci

systems may have allowed electricity to escape into patients' bodies, damaging tissue and internal organs. In February 2013, *Bloomberg News* reported that the FDA had launched a safety probe into Intuitive, whereby the FDA sent confidential surveys to da Vinci customers to determine the accuracy of Intuitive's adverse event reporting to the FDA. Intuitive's stock price dropped 11% on this news. A month later, in March 2013, another *Bloomberg* article reported that MDR's sent to U.S. regulators linked da Vinci to at least 70 deaths since 2009. The company's share price fell further on this news.

Following these reports, investors filed a federal securities class action against Intuitive and nine of its executives and officers asserting claims under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act. The complaint alleges that defendants made materially false and misleading statements and omissions regarding the safety of the da Vinci system and Intuitive's compliance with FDA regulations. The court granted in part defendants' motion to dismiss, finding no falsity with respect to certain ancillary statements concerning financial data. However, the court denied the motion to dismiss as to the core allegations, finding that the allegations gave rise to a strong inference of scienter.

With leave from the court, plaintiffs subsequently filed a second amended complaint in January 2017 following extensive discovery. Defendants once again moved to dismiss the complaint, contending that Plaintiffs had failed to plead actionable misstatements or omissions and failed to allege scienter. This motion to dismiss was predicated primarily on *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S.Ct. 1318 (2015), which the Supreme Court had decided following briefing of defendants' first motion to dismiss. Defendants argued that the challenged statements were statements of opinion, which are not actionable simply because the speaker "knows, but fails to disclose, some fact cutting the other way." The Court rejected this argument, holding that the plaintiffs' allegations fall within the "second category of *Omnicare* statements of opinion, namely those that allegedly omit material facts that render the statements misleading to an ordinary investor." The deadline for dispositive motions in *In re Intuitive Surgical Securities Litigation* is set for early February 2018. Trial is scheduled for later this year, in October 2018.

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