

2019 YEAR IN REVIEW

Securities Litigation Against Life Sciences and
Healthcare Companies



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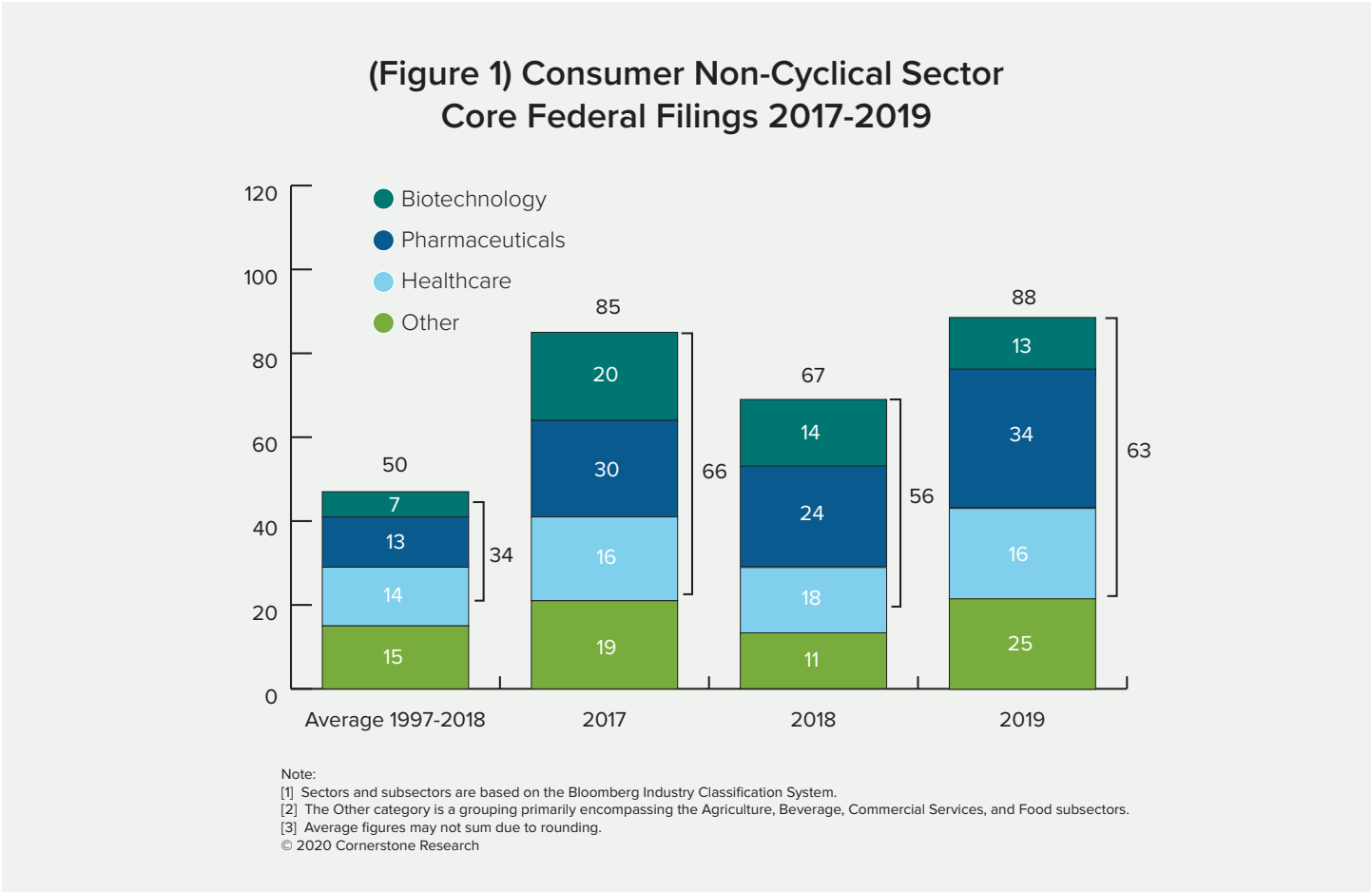
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INTRODUCTION

As we reported in our last three annual Year in Review publications, the number of securities class actions filed nationally against publicly traded pharmaceutical, biotechnology, medical device and health-care product and services companies (together, “life sciences and healthcare companies”) has steadily grown over the last several years. In 2019, that trend has continued and securities class actions reached an all-time record level, with a total of 428 federal and state class actions filed, 268 of which were “core filings”—the highest number on record and a 13% increase over 2018.¹ In 2019, 5.5% of U.S. exchange-listed companies were the subject of core filings, and core filings² against non-U.S. companies (primarily companies in China, Canada, the United Kingdom, and other European countries) rose to 57, which is the highest level on record.³

As in past years, the Consumer Non-Cyclical sector, primarily composed of life sciences and healthcare companies, once again had by far the greatest number of securities class action filings in 2019 as compared to other sectors.⁴ As depicted in **Figure 1** below, the number of filings against life sciences and healthcare companies increased from 56 securities class actions in 2018 to 63 securities class actions in 2019, with the greatest increase in class actions against pharmaceutical companies.



¹ Source: Cornerstone Research Securities Class Action Filings - 2019 Year in Review (“Cornerstone Report”), at 1, 5, Figure 4, Appendix 1. “Core filings” are defined by Cornerstone Research as class action filings excluding M&A filings.
² Cornerstone Report, at 11, Figure 10.
³ Cornerstone Report, at 30, Figure 29 and Figure 30.

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 negative feedback from or action by 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 or omissions 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”).

In 2019, we saw a significant uptick—40%—from 2018 in the filing of cases alleging 1933 Act claims in state courts⁵, as the effect of United States Supreme Court’s March 2018 decision in Cyan that class actions under the 1933 Act can be brought in state court and are not removable to federal court continues to reverberate

In 2019, we saw a significant uptick—40%— from 2018 in the filing of cases alleging 1933 Act claims in state courts⁵, as the effect of United States Supreme Court’s March 2018 decision in Cyan that

class actions under the 1933 Act can be brought in state court and are not removable to federal court continues to reverberate.⁶ The majority of the 1933 Act cases filed in 2019 were filed in state courts in New York and California, but the number such filings in other state courts almost tripled from 2018 to 2019.⁷ Almost half of these 1933 Act state court cases had a parallel action filed in federal court, often forcing defendants to defend such actions on two fronts simultaneously.⁸ While the majority (31 of 49) of 1933 Act state court class actions filed in 2019 related to initial public offerings (despite a drop in IPO activity during this period), there has been a significant increase in 2018 and 2019 in 1933 Act class actions relating to issuances of securities for mergers or spin-offs.⁹

In 2019, as in 2018, class action lawsuits generally and against life sciences and healthcare companies were driven primarily by a three plaintiffs’ law firms¹⁰ that have likely continued to focus on companies within this sector due to the inherently volatile nature of their stock prices. These three law firms filed the first complaint in 62% of all core filings for 2019, but were appointed lead counsel in a lower percentage of cases.¹¹

Unfortunately, the percentage of cases filed in 2019 that were dismissed by year-end dropped fairly substantially from 2018.

⁴ Cornerstone Report, at 36, Figure 35. Sectors and subsectors are based on the Bloomberg Industry Classification System.
⁵ Cornerstone Report, at 4; Figure 1.
⁶ See *Cyan, Inc. v. Beaver County Employees Retirement Fund*, 138 S. Ct. 1061, 583 U.S. ____ (2018).
⁷ Cornerstone Report, at 19, Figure 18. More specifically, 33 of the 49 1933 Act cases filed in 2019 were filed in New York and California. Id.
⁸ Cornerstone Report, at 4, 22.
⁹ Cornerstone Report, at 23, 27; Figure 22.
¹⁰ Cornerstone Report, at 39.
¹¹ Cornerstone Report, at 39, Figure 38.

(Figure 2) Pharmaceutical, Biotechnology, and Healthcare Subsectors
Core Federal Filings

Year	Filings	Circuit					Case Status			
		1st	2nd	3rd	9th	Other	Percent Dismissed	Percent Settled	Percent Remanded	Percent Ongoing
2009	22	1	1	2	11	7	36.4%	63.6%	0.0%	0.0%
2010	32	3	6	2	15	6	43.8%	53.1%	3.1%	0.0%
2011	21	0	5	0	6	10	57.1%	33.3%	4.8%	4.8%
2012	28	2	5	5	5	11	57.1%	42.9%	0.0%	0.0%
2013	34	2	10	5	11	6	41.2%	58.8%	0.0%	0.0%
2014	38	3	8	11	11	5	52.6%	39.5%	0.0%	7.9%
2015	42	6	4	5	18	9	54.8%	33.3%	7.1%	4.8%
2016	64	5	22	7	20	10	42.2%	20.3%	1.6%	35.9%
2017	66	7	17	16	13	13	43.9%	6.1%	4.5%	45.5%
2018	56	3	15	11	15	12	16.1%	0.0%	0.0%	83.9%
2019	63	3	23	13	11	0	9.5%	0.0%	0.0%	90.5%
Average (1997–2018)	35	3	7	5	9	0	44.3%	49.6%	0.9%	5.2%

Note: [1] Sectors and subsectors are based on the Bloomberg Industry Classification System. © 2020 Cornerstone Research.

Unfortunately, the percentage of cases filed in 2019 that were dismissed by year-end dropped fairly substantially from 2018. Specifically, as detailed in **Figure 2**, only approximately 9.5% of federal core filings against life sciences and healthcare companies were dismissed by December 31, 2019, as compared to a 16.1% year-end dismissal rate in 2018 and a 24% year-end dismissal rate in 2017. While it is more difficult to track 1933 Act cases pending in state court, the available data indicate that the year-end dismissal rate is even lower in 1933 Act state court cases.¹² However, 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 the case, we expect that the per-

centage of dismissals will increase substantially by the end of 2020, as it did for cases filed in 2018 by the end of 2019 (a year-end dismissal rate increase from 16% to approximately 29%).¹³ This year, we have expanded the focus of our Year in Review to include additional jurisdictions, all of which are epicenters for life sciences and healthcare companies and, thus, have been among the most active jurisdictions in the country for securities class actions filed against such companies: First Circuit and District of Massachusetts; the Second Circuit and New York District Courts; and the Ninth Circuit and California District Courts. The Second Circuit was particularly active this year, with the highest number of federal core securities class actions filed both across all industries and

¹² Cornerstone Report, at Appendix 5.
¹³ See Figure 2 above and Figure 2 in 2018 Year in Review. ¹⁴ Cornerstone Report, at 38, Figure 37; see also Figure 2 above.

against life sciences and healthcare companies, the latter increasing from 15 filings in 2018 to 23 filings in 2019.¹⁴

In 2019, federal courts in these jurisdictions have once again issued several significant, detailed decisions in securities class actions against life sciences and healthcare companies in various growth stages and their directors and officers. As in prior years, these cases involve disclosures concerning issues that life sciences and healthcare companies most often face, including negative clinical trial results, enrollment issues and clinical trial delays, discussions with and requirements imposed by FDA, supply and manufacturing issues, adverse events and other safety issues, and future growth prospects and revenue projections concerning approved drugs or other healthcare-related products. Several decisions issued out of the Ninth Circuit in 2019 also involved alleged anticompetitive conduct.

The First Circuit and District of Massachusetts federal courts remain defendant-friendly jurisdictions with deep understanding of the industry, as they dismissed all but one of the securities class actions in 2019, and the district court in the remaining federal class action dismissed the case in part and ultimately denied class certification.

The First Circuit and District of Massachusetts federal courts remain defendant-friendly jurisdictions with deep understanding of the industry, as they dismissed all but one of the securities class actions in 2019, and the district court in the remaining

federal class action dismissed the case in part and ultimately denied class certification. These federal class actions were largely dismissed on the basis that plaintiffs failed adequately to 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). In the lone decision from the First Circuit this year (*Biogen II*), the court affirmed dismissal of claims premised on six alleged misstatements relating to serious adverse events and their impact on commercial prospects that the district court had found to be “plausibly misleading.” Finding plaintiffs’ “imprecise” confidential witness allegations unpersuasive and rejecting plaintiffs’ “corporate scienter” theory, the First Circuit ultimately concluded that none of the alleged misstatements was made with an intent to defraud or a high degree of recklessness. In the one decision issued by a Massachusetts state court in a 1933 Act case in 2019, the court denied the defendants’ motion to dismiss, holding that the heightened pleading standards of Rule 9(b) did not apply and concluding that plaintiffs adequately alleged actionable misrepresentations and omissions in the defendant issuer’s IPO registration statement regarding enrollment prospects for its clinical trials. Parallel federal securities class actions were also filed (and later consolidated) against this same issuer, and defendants’ motion to dismiss in that action is pending.

The Second Circuit and New York federal courts issued relatively few decisions in 2019. As noted above, however, federal core class action filings in the Second Circuit jumped fairly substantially in

¹⁴ Cornerstone Report, at 38, Figure 37; see also Figure 2 above.

2019; we, thus, expect more significant decisions coming out of these federal courts in 2020 and have highlighted several such cases to watch in this Year in Review. In the Second Circuit’s sole decision this year, it affirmed the district court’s dismissal of claims premised on alleged misstatements and omissions relating to the defendant issuer’s contract renewal negotiations with a health insurer provider customer that accounted for 12 percent to 17 percent of the issuer’s revenues between 2012 to 2016. The Second Circuit held that positive statements about the issuer’s relationship with the customer were inactionable puffery. The Court also credited the issuer’s numerous disclosures throughout the class period warning that the negotiations with the customer could fail, emphasizing that courts must consider not only the “literal truth” of statements, but also the “context and manner of presentation” of such statements. Finally, the Second Circuit rejected plaintiffs’ omission theory, holding that defendants had no duty to disclose more about the uncertainty of the negotiations, given that they were ongoing.

Finally, while the Ninth Circuit did not issue any decisions in 2019, California district courts issued several decisions that reaffirmed that they continue to be a more plaintiff-friendly jurisdiction.

Finally, while the Ninth Circuit did not issue any decisions in 2019, California district courts issued several decisions that reaffirmed that they continue to be a more plaintiff-friendly jurisdiction. California district courts denied defendants’ motions to dismiss in part or in whole in several cases, and in the cases in which the courts dismissed complaints for plaintiffs’ failure to plead actionable misstatements and/or scienter, in all but one such case, they allowed plaintiffs leave to amend their complaints (in some cases, for a second or third time). Notably, in the fifteenth securities class action to reach a jury verdict since the passage of the PSLRA in 1995, a jury found that executives of Puma Biotechnology knowingly made false statements about clinical trial results for its breast cancer treatment drug; while the Company reported that the disease-free survival rate was 91%, as compared to 86% for those treated with a placebo (a 5% swing), when in fact the difference was 2.3%. Notably, however, the jury awarded damages of \$4.50 per share based on this false statement, which was only approximately 5% or less of the total damages sought. The jury found in favor of defendants on other claims premised on statements relating to adverse events experienced by patients in the trial.



FIRST CIRCUIT AND DISTRICT OF MASSACHUSETTS

Metzler Asset Management GMBH v. Kingsley (“Biogen II”), Case No. 18-1369, 928 F.3d 151 (1st Cir. 2019) – Post-approval SAEs and Impact on Commercial Prospects

Biogen Inc. (“Biogen”) is a global biopharmaceutical company that develops, manufactures, and markets treatments for multiple sclerosis (“MS”), among other diseases. Tecfidera—one of Biogen’s four principal MS drugs and which accounted for approximately one-third of its revenue—was first approved by FDA in March 2013. Since that time, Biogen had warned that “Tecfidera may cause lymphopenia,” a condition involving low counts of a certain type of white blood cells called lymphocytes. In August 2014, the Shepard Center, a leading MS clinic and Tecfidera prescriber, discontinued use of the drug for many of its patients and stopped prescribing it altogether after internal studies revealed that Tecfidera lowered lymphocyte counts in 30% of patients. The center’s medical director notified several Biogen employees of this development at that time. In October 2014, Biogen announced that an MS patient who had taken Tecfidera for several years died from progressive multifocal leukoencephalopathy (“PML”), an infection associated with low lymphocyte counts. Thereafter, Biogen added information related to the risk of PML to Tecfidera’s label. Although Biogen had stated that it had “always expected [that] Tecfidera’s growth rate would moderate over time,” in January 2015 it stated that it “believ[ed] Tecfidera [was] on track to become the most-prescribed therapy for MS worldwide.” During the months that followed, however, Tecfidera’s sales declined—down 10% by April 2015. In July 2015, Biogen revised its full-year projections, cutting expected revenue growth in half and attributing the change to dimin-

ished expectations for growth of Tecfidera. Biogen’s stock price fell 22% the same day.

Investors filed suit against Biogen and three of its executives, alleging that, through various public statements and omissions, they misled investors by fraudulently or recklessly misrepresenting and concealing the risk Tecfidera posed to lymphocyte counts and the subsequent impact of the PML death on sales, in violation of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder. Specifically, the complaint alleged 31 statements and omissions made by defendants between July 2014 and July 2015 either failed to account for the Shepard Center’s discontinuation of Tecfidera prescriptions in August 2014 and the drug’s known tendency to deplete lymphocyte levels, or understated the actual effect that the PML death was having on Tecfidera sales and usage rates following the October 2014 PML death. In support of these allegations, plaintiffs relied upon statements from 17 former Biogen employees acting as confidential witnesses, who alluded to declines in Tecfidera sales in the wake of the PML death and the measures taken by Biogen to mitigate the fallout. As to the drug’s effect on lymphocytes, plaintiffs cited statements from the director of the Shepard Center and a California-based neurologist who confirmed Tecfidera’s effect on lymphocytes through a study of his own in February 2015.

The district court granted defendants’ motion to dismiss in full, holding that plaintiffs’ allegations failed to support a strong inference of scienter (fraudulent intent). The court first determined, however, that plaintiffs had plausibly alleged that at least 6 of the 31 statements or omissions were materially false or misleading, some of which were also alleged in a previous suit dismissed

by the court, *In re Biogen Inc. Sec. Litig.* (“*Biogen I*”), 193 F. Supp. 3d 5 (D. Mass. 2016), *aff’d* 857 F.3d 34 (1st Cir. 2017), and some that were newly alleged. These alleged misrepresentations were positive statements concerning Tecfidera’s safety profile or expected growth issued by defendants after Biogen received notice of the Shepard Center’s change in prescription practice, and most were made following the October 2014 PML death. Nevertheless, the court concluded that plaintiffs had not sufficiently alleged that those statements were made with an intent to defraud or high degree of recklessness.

Upon plaintiffs’ appeal, the First Circuit affirmed. The court declined to decide the appeal based on a “claim preclusion” argument that defendants raised—that is, that the claims in the current lawsuit were precluded by the dismissal of *Biogen I*. In any event, the First Circuit concluded that plaintiffs’ allegations failed to support a strong inference of scienter. The court considered six statements that the district court had held to be “plausibly misleading,” and which fell into two categories: (i) statements as to Tecfidera’s safety profile; and, (ii) statements as to Tecfidera’s usage rate.

As to the safety profile statements, the court noted that the first was issued before the PML-related death was announced or known to any of defendants. Further, the First Circuit explained that a warning from a Shepard Center researcher to Biogen did not materially conflict with the company’s statement—that Tecfidera was associated with higher risk of developing low lymphocyte counts—that the drug was “effective” and that its safety profile was “supported by a growing body of data.” The court concluded that the second statement—that Tecfidera’s safety profile was “status quo”—was issued *after* Biogen had disclosed the PML-related death and updated Tecfidera’s label, and therefore could not support an inference of scienter.

The court likewise rejected plaintiffs’ reliance on statements allegedly misrepresenting Tecfidera’s declining usage rates—such as that Tecfidera was “on track to become the most prescribed therapy for MS worldwide,” and that there was no “meaningful change” to discontinuation rates. The court held that in the context of Biogen’s various disclosures—of the PML-related death, of the updated label, of expectations that the

drug’s growth rate would “slow,” and of higher-than-expected discontinuation rates—the statement was no more than “misguided optimism.” Further, the court held that the company’s disclosure of higher-than-expected discontinuation rates undercut an inference of fraudulent intent. In doing so, the court found the confidential witness statements unpersuasive for the same reason they were rejected in *Biogen I*: they “were imprecise, did not contain information that was directly communicated to the individual defendants, or concerned events that occurred after the individual defendants made the plausibly misleading statements at issue in that case.” The additional confidential witness allegations new to the *Biogen II* complaint—such as, “everyone in leadership had access to reporting metrics” and that executives monitored the metrics—did not influence the court’s scienter conclusion, as the statements did not specifically allege what defendants learned from those metrics and how they contradicted defendants’ statements.

The court also agreed with the district court’s rejection of plaintiffs’ “corporate scienter” theory—that the company could have acted with scienter without the requisite scienter by an individual defendant if *some other* high-level employee had knowledge that defendants’ statements were false. For example, the court explained that reports from one physician, “whose patients constituted less than 0.2% of all Tecfidera users,” that he would cease prescribing the drug was insufficient to raise a strong inference that the company knew that usage rates would fall short of overall expectations. Finally, the First Circuit rejected plaintiffs’ “additional scienter” arguments. Plaintiffs argued that because Tecfidera was part of the company’s “core operations” and because Biogen operated in a “highly regulated” industry, the company must have known about the declining usage and safety issues contradicting defendants’ public statements. In rejecting this must-have-known theory based on non-particularized allegations, the court explained that plaintiffs had not presented “any allegations in the complaint that show that anyone in the company had knowledge regarding the drug’s safety profile and sales that contradicted the company’s public representations.”

LSI Design & Integration Corp. v. Tesaro, Inc., Case No. 18-cv-12352 (LTS), 2019 WL 5967994 (D. Mass. Nov. 13, 2019) – Liquidity Concerns

Before its recent acquisition by GlaxoSmithKline plc, Tesaro, Inc. (“Tesaro”) was a public oncology-based biopharmaceutical company focused on cancer therapies and oncology supportive care products. As of November 2016, Tesaro had commercialized only one drug approved by FDA: Varubi, which was intended to prevent nausea and vomiting associated with chemotherapy. Varubi generated approximately \$5 million in sales in 2016.

In November 2016, the company and its officers made several public statements about the financial health of Tesaro. For example, in its Form 10-Q, the company stated: “Our balance of cash and cash equivalents as of September 30, 2016, and the cash we expect to generate from sales of Varubi, are expected to be sufficient to meet our existing cash flow requirements and fund our existing operations at their currently planned levels through at least the twelve months following the filing of this Quarterly Report on Form 10-Q.” Later that month, the company’s CEO stated that: “[O]ver the next 12 months or so, we anticipate four launches in the U.S. and in Europe and clinical data, obviously, around our immuno-oncology pipeline and additional trial strategies being implemented for niraparib [another drug]. And we finished up the third quarter with almost \$650 million in cash. So we’re well positioned to take this forward.” He also stated that “Varubi alone would not have been really an economically sensible thing to do in Europe. Varubi itself though can pretty much cover over time all of our expenses. So, from that point forward, anything else we put into the sales force is really economic leverage.”

Later that month, however, Tesaro announced that it would initiate a secondary stock offering to fund further operations and filed a prospectus with the SEC. After a columnist reported that there was only “light demand” for the offering, Tesaro announced that it was pricing its shares at \$135 per share, approximately 9% lower than the closing price the previous day, and Tesaro’s share price continued to fall on that news.

Investors then brought suit against Tesaro, its CEO, and its CFO in the District of Massachusetts on behalf of themselves and a purported class of Tesaro stockholders during a 10-day class period in November 2016, al-

leging violations of Sections 10(b) and 20(a) of the 1934 Act, as well as Rule 10b-5 promulgated thereunder. The amended complaint alleged that the statement in Tesaro’s November 2016 10-Q and the two statements by the company’s CEO were materially misleading because, among other allegations, the company “knew it was in trouble” after missing internal sales goals for Varubi, yet continued to falsely assure investors that it had adequate cash to fund its existing operations based on revenue generated by Varubi (without conducting a secondary public offering). The amended complaint alleged that, according to a confidential witness responsible for sales of Varubi in California, the drug had achieved only 53% and 67% of sales goals in the second and third quarters of 2016, respectively. Another confidential witness claimed that Tesaro’s senior leadership discussed these flagging results monthly, and that management did not expect Varubi to drive Tesaro’s revenue because sales were lagging behind internal goals.

The court granted defendants’ motion to dismiss, holding that (i) plaintiffs failed to adequately allege that the misstatements were false or misleading, and independently, (ii) plaintiffs failed to allege facts supporting a strong inference of scienter. The court first addressed the three allegedly material misstatements. As to the statement in the Form 10-Q, the court disagreed that the 10-Q’s assertion that Tesaro had adequate cash suggested that it would not conduct another public offering in the near term.

Tesaro did not promise investors that there would not be additional offerings in the next year, and in fact, the 10-Q explicitly cautioned that Tesaro would need additional capital.

As the court noted, Tesaro did not promise investors that there would not be additional offerings in the next year, and in fact, the 10-Q explicitly cautioned that Tesaro would need additional capital. The court further found that allegations from the confidential witnesses did not bolster plaintiffs’ claims because, while they provided information regarding missed sales goals, the amended complaint did “not explain the connection between these internal targets, Tesaro’s plans for procur-

ing additional capital through public offerings, and its overall financial health.” As to the CEO’s statement that Tesaro was “well positioned to take this forward,” the court explained that this was a classic non-actionable “statement of corporate optimism.” And the court held that the CEO’s statement that “Varubi itself can pretty much cover over time all of our expenses” fell squarely within at least two prongs of the PSLRA’s safe harbor immunizing forward-looking statements.

Independently, the court also concluded that plaintiffs had not alleged particularized facts supporting a strong inference that defendants issued the alleged misleading statements with intent to defraud or extreme recklessness. The complaint “at best” alleged, according to the court, that Tesaro and its leadership knew about missed internal sales goals for Varubi in North America, but it did not show how this knowledge suggested that any of the statements by defendants—focusing on the company as a whole—were issued with intent to deceive. Instead, the court credited the innocent inference “that Tesaro believed that statements about the sufficiency of its cash and cash equivalents were accurate and that those statements were not intended to foreclose the possibility of an imminent second public offering.”

Wang Yan v. ReWalk Robotics Ltd., Case No. 17-cv-10169 (FDS), 391 F. Supp. 3d 150 (D. Mass. May 16, 2019) – Post-Marketing Study and FDA Warning

ReWalk Robotics, Ltd. (“ReWalk”), formerly known as Argo Medical Technologies, Inc., which is incorporated in Israel and headquartered in Marlborough, MA, is a medical technology company that develops exoskeletons, devices which help patients suffering from spinal injuries. ReWalk sells two products: ReWalk Personal, designed for personal use, and ReWalk Rehabilitation, designed for clinical rehabilitation centers. ReWalk submitted the ReWalk Personal Device (the “device”) to FDA in 2014 for “de novo” classification, which allows manufacturers to market devices that are low-to-moderate risk and not substantially similar to devices already being marketed. FDA granted approval in June 2014; classified the device as a “Class II” device, which requires special controls; and, because of concerns that a malfunction could result in serious injury or death, or-

dered the company to conduct a “post-market surveillance” study to examine the product’s risk, as required by Section 522 of the Food, Drug, and Cosmetic Act (“FDCA”), and the results of which must be reported.

In advance of a September 2014 IPO, ReWalk filed a registration statement with the SEC, which did not disclose that FDA had ordered the post-market surveillance study. Two weeks after the IPO, FDA informed ReWalk that its proposed post-market surveillance study was deficient. But because less than six months had elapsed since the Section 522 order had issued, the study status would be marked as “Plan Pending” on FDA’s website, and FDA granted ReWalk 30 days to respond. ReWalk did not timely respond, and instead submitted a response in November 2014, which FDA found deficient in February 2015. After FDA granted ReWalk another 30 days to respond, ReWalk did not timely respond, and when it did in May 2015, it stated that it wanted to discuss an issue with FDA before submitting its formal response.

In September 2015, FDA warned ReWalk that it still had not submitted a revised study plan; and later that month, having still not received a response, FDA issued a warning letter explaining that ReWalk was obliged under the FDCA to begin its surveillance study within 15 months after issuance of the Section 522 order, and that period had expired. Accordingly, as FDA’s letter explained, ReWalk had “committed a prohibited act” under the FDCA, and the device was “currently misbranded.” In March 2016, the letter was disclosed by the FDA to the public, leading to a 13% drop in ReWalk’s stock price. In the meantime, from February 2015 to February 2016, ReWalk had held a series of earnings calls, during which the company did not disclose this correspondence with FDA or the Section 522 order. At the end of March 2016, FDA decided in its discretion to allow ReWalk to continue to market the device, provided that ReWalk began the post-market surveillance study by June 2016, and FDA approved the proposed protocol for the study in May 2016. ReWalk did not timely file required monthly reports in June and July 2016. By June 2017, ReWalk had not recruited the required number of subjects for the study, and FDA’s post-market surveillance studies webpage listed the status of ReWalk’s post-market surveillance study as “progress inadequate.”

Investors first filed a class action lawsuit against the company in California state court in September 2016, which was dismissed for lack of personal jurisdiction. Two investors then filed a second and third class action against defendants in Massachusetts Superior Court in October 2016 alleging violations of the 1933 Act, which were consolidated. Then, in January 2017, an investor filed suit in the District of Massachusetts, also alleging violations of Sections 11 and 15 of the 1933 Act, against ReWalk, the company’s officers and directors, and the underwriters for ReWalk’s IPO, based on defendants’ alleged concealment of material information in ReWalk’s IPO registration statement regarding compliance with FDA’s Section 522 order. While the Massachusetts state court action was pending, Wang Yan was appointed lead plaintiff in the federal action, and the amended complaint filed by Yan added claims against defendants pursuant to the 1934 Act, alleging that defendants issued materially misleading statements after ReWalk’s IPO. After the Massachusetts state court action was stayed, the federal district court granted defendants’ motion to dismiss the 1933 Act claims in 2018, holding that the amended complaint failed to identify a false statement in the registration statement. The court denied the motion as to the 1934 Act claims without prejudice, reasoning that because the lead plaintiff Yan had purchased shares only in September 2014—at the time of the IPO—and before the alleged misstatements that formed the basis of the 1934 Act claims, Yan could not assert the only remaining claims. Accordingly, the court allowed plaintiffs an opportunity to seek appointment of a supplemental or substitute lead plaintiff or otherwise establish standing. Plaintiffs moved to amend the amended complaint and add a second named plaintiff in 2018.

The court denied plaintiffs’ motion to amend, deemed defendants’ motion to dismiss renewed, and dismissed the amended complaint without prejudice. The court held that Yan, the original named plaintiff, did not have standing to assert claims under the 1934 Act, because he had purchased shares before the statements on which those claims were based, and rejected Yan’s arguments that he could cure the lack of standing by adding a second named plaintiff. Yan’s appeal of the dismissal to the First Circuit is pending.

In re Ocular Therapeutix, Inc. Securities Litigation, Case No. 17-cv-12288 (GAO), 2019 WL 1950399 (D. Mass. Apr. 30, 2019) – Manufacturing Issues

Ocular Therapeutix, Inc. (“Ocular”) is a Massachusetts-based biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. In September 2015, Ocular submitted a New Drug Application (“NDA”) to FDA seeking approval of Dextenza, its leading drug candidate for the treatment of post-surgical eye pain and inflammation. In February 2016, following a pre-NDA inspection of Ocular’s manufacturing facility, FDA issued a Form 483 identifying ten observations of non-compliance with certain FDA regulations. In its 2015 Form 10-K, Ocular disclosed that it had received the Form 483, and that it “addressed some observations before the inspection was closed and responded to the FDA with a corrective action plan to complete the inspection process.” In July 2016, Ocular received a complete response letter (“CRL”) from FDA rejecting Ocular’s NDA. Ocular disclosed that it had received the CRL and that the “concerns raised by the FDA [in the CRL] pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection” of Ocular’s manufacturing facility. In January 2017, Ocular resubmitted its NDA to FDA. In April and May 2017, FDA made additional pre-NDA visits to Ocular’s manufacturing facilities, and in May 2017, FDA issued another Form 483 identifying six observations. The next day, Ocular released its financial results for Q1 2017 and held an earnings call. On that call, Ocular disclosed the second Form 483 and stated that the company had “the situation under control” and it expected to be able to resolve the issues identified in the Form 483 “in a timely manner.” In July 2017, the website *Seeking Alpha* published the two Forms 483, and STAT published an article asserting that Dextenza could be rejected by FDA due to product contamination. Later that month, FDA issued a second CRL rejecting Ocular’s NDA. The company received a subpoena from the SEC seeking documents and information concerning Dextenza, including related communications with FDA, investors, and others.

Upon a drop in Ocular’s share price following the second CRL, investors filed a federal securities class action in the District of Massachusetts under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that Ocular, its CEO, and a second officer made materially false and misleading statements regarding Dextenza and the Forms 483. Specifically, the amended complaint alleged that defendants issued false and/or misleading statements regarding Ocular’s significant manufacturing issues related to Dextenza and the drug’s prospects for FDA approval.

The district court granted defendants’ motion to dismiss with prejudice, holding that the amended complaint failed to plead an actionable misstatement or omission, and independently, that plaintiffs failed to allege a strong inference of scienter. The court considered three categories of alleged misstatements and omissions. First, the court rejected plaintiffs’ allegations as to generalized statements in Ocular’s Forms 10-K attesting that it used current good manufacturing practices (“cGMP”) at its multi-product manufacturing facility. The court noted that the amended complaint did not allege any contemporaneous facts supported by emails, internal documents, or reports to suggest that Ocular did not in fact use cGMP, and rejected plaintiffs’ exclusive reliance on the Forms 483 because they did not represent a final agency determination regarding compliance. Further, the court emphasized that the “challenged statements about compliance with cGMP cannot be considered in isolation” and noted that it was “undisputable that the company promptly disclosed its receipt of the two Forms 483.” Second, the court held that a statement by Ocular’s CEO in response to the first CRL—“we’ve adequately we think addressed the issues that [FDA] raised”—was a protected statement of opinion. Last, the court held that the company’s statement that it “expect[ed]” to resolve the issues identified in the second Form 483 “in a timely manner” was “clearly a forward-looking forecast about a future event,” accompanied by meaningful cautionary language, and therefore protected under the PSLRA’s safe harbor provision. Independently, the court held that the amended complaint failed to allege particularized facts supporting a strong inference that defendants intentionally or recklessly issued misleading statements about the Forms 483 and their importance to the Dextenza NDA. The court rejected plaintiffs’ reliance on the core operations theory and the related SEC investigation as

“non sequiturs” because “defendants knew about the [Forms] 483[] and disclosed them.” The court criticized the amended complaint for “ignor[ing] the disclosures about the Forms 483,” overlooking the progress the company made in addressing FDA’s concerns, and failing to mention that Ocular’s CEO purchased company stock during the class period, which undercut an inference of fraudulent intent. The court also noted that several months before it rendered its decision, FDA had accepted the Dextenza NDA for review and approved the drug.

Karth v. Keryx Biopharmaceuticals, Inc., Case No. 16-cv-11745 (DJC), 2019 WL 4605276 (D. Mass. Sept. 23, 2019) – Supply Issues/Contract Manufacturers and Class Certification

Keryx Biopharmaceuticals, Inc. (“Keryx”) is a biopharmaceutical company that sells Auryxia, a treatment for hyperphosphatemia, which involves elevated phosphorus levels in patients with chronic kidney disease. As disclosed in its 2012 Form 10-K, Keryx relied upon a single third-party contract manufacturer to convert Auryxia’s active ingredient into a tablet, but the company stated that in the future it would seek to obtain FDA approval for additional contract manufacturers in order to minimize production risk. In subsequent financial disclosures and verbal statements from 2014 through 2016, however, the company periodically removed the reference to a single contract manufacturer, stating instead that it relied on “third parties” and “manufacturers.” The Company again disclosed that it relied on a single manufacturer in its in February, April, and August 2016 disclosures. In August 2016, the company withdrew its 2016 financial guidance and announced that it was halting the distribution of Auryxia for at least two months because its only production manufacturer had been experiencing production difficulties in “the past few months.” Following this announcement, Keryx’s stock price fell 36%.

Investors filed a class action in the District of Massachusetts alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5, claiming that Keryx and four of its officers issued false and misleading statements in three principal ways. First, in their amended complaint, plaintiffs alleged that defendants misled investors by repeatedly referring to multiple contract manufacturers even though the company had contract-

ed with only one firm, at the time of the statements, to convert Auryxia’s active ingredient into tablet form. Second, plaintiffs alleged that the company’s April 2016 Schedule 14A indicated that the goal of obtaining FDA approval for a second contract manufacturer had been completed, even though that did not occur until more than six months later. And third, in their proposed second amended complaint submitted after defendants moved to dismiss the amended complaint, plaintiffs alleged that the individual defendants continued to provide positive forward-looking guidance in February and April 2016, despite knowledge of their sole contract manufacturer’s production difficulties.

In 2018, the district court denied defendants’ motion to dismiss as to the first two categories of alleged misstatements and granted their motion to dismiss as to the third category. The court rejected defendants’ argument that the disclosures referencing “contract manufacturers”—plural—were literally true because they concerned manufacturers of Auryxia at all stages of production, rather than just the manufacture of the treatment’s active ingredient into tablet form. In so concluding, the court explained that literally accurate statements can nevertheless mislead investors through “context and manner,” and concluded that Auryxia’s removal of language concerning a single contract manufacturer in its 2012 Form 10-K and use of language referring to multiple manufacturers in subsequent filings was sufficient to mislead a reasonable investor.

A year later, however, the district court denied plaintiffs’ motion for class certification and granted defendants’ motion for judgment on the pleadings. The court’s decision hinged on a single critical fact—the lead plaintiff made his only purchases of Keryx stock during the class period in July 2016, which was after the company indisputably disclosed its reliance on a single manufacturer for Auryxia. Noting that defendants had neglected to bring the February and April 2016 disclosures to the court’s attention in the context of their motion to dismiss, the court nevertheless denied plaintiffs’ motion for class certification because the lead plaintiff’s post-disclosure purchases rendered him an inadequate and atypical representative for the class. The court reasoned that the lead plaintiff, who purchased shares only in July 2016, “purchased Keryx shares in a markedly different disclosure environment than other proposed

class members.” Having denied plaintiffs’ motion for class certification, the court granted defendants’ motion for judgment on the pleadings and dismissed the lead plaintiff’s remaining individual claims. Given the company’s disclosures regarding Auryxia’s reliance on a sole contract manufacturer prior to the lead plaintiff’s purchase of Keryx stock, the court held that the amended complaint failed to plausibly allege (i) reliance, and (ii) loss causation. Finally, the court denied plaintiffs’ motion for leave to amend the complaint, finding that any such amendment would be futile in light of the lead plaintiff’s stock purchases in relation to the corrective disclosures.

Wu v. Tokai Pharmaceuticals, Inc., Case No. 2016-3725-BLS2, 2019 WL 938924 (Mass. Super. Ct. Jan. 9, 2019) – Enrollment Numbers and Trial Discontinuation

Tokai Pharmaceuticals, Inc. (“Tokai”) was a Boston-based biopharmaceutical company. On May 11, 2017, Tokai merged with Otic Pharma, Inc. to form Novus Therapeutics, Inc. As of its 2014 IPO, Tokai was focused on the development and commercialization of Galeterone, an androgen receptor targeted therapy (“ATT”) intended to treat a specific class of cancer patients with metastatic castration-resistant prostate cancer (“CRPC”). Xtandi and Zytiga, two competitor ATT drugs, had already obtained FDA approval by the time Galeterone entered Phase 2 clinical trials. However, research published in 2014 showed that the competitor ATT drugs were ineffective for treating “AR-V7 positive” patients, a subcategory of CRPC patients. Rather than initiating a new Phase 2 trial focused on these patients, Tokai conducted a retrospective analysis of its Phase 2 trial results, and specifically, the 7 of 87 CRPC patients that were AR-V7 positive. Based on this retrospective analysis of 7 patients, Tokai concluded that Galeterone was successful in the AR-V7 patient population, and elected to proceed to Phase 3 trials focused on AR-V7 patients, and to fund those trials with a \$105 million IPO. Tokai’s registration statement described the “treatment limitations” of Xtandi and Zytiga with respect to AR-V7 positive patients and the resulting “unmet need” that Galeterone could address. But due to severe difficulties in patient enrollment, Tokai discontinued the Phase 3

trials, after which the company’s stock price fell well below its IPO price. At the time of discontinuation, Tokai had discovered only 73 CRPC patients that were AR-V7 positive, and of those 73, only 38 enrolled in the trial.

Investors filed suit in the Massachusetts Superior Court on behalf of all holders of Tokai stock issued in connection with the IPO, alleging that the company’s registration statement and prospectus included misrepresentations and omissions in violation of Sections 11 and 15 of the 1933 Act. Specifically, plaintiffs alleged that Tokai omitted, among other things, certain facts suggesting that Tokai would face difficulties in enrolling AR-V7 patients for Phase 3 trials—such as that one-third of the AR-V7 positive patients from the Phase 2 trials declined to continue treatment, and that an alternative “taxane chemotherapy” treatment was a more viable alternative to Galeterone.

The Superior Court denied Tokai’s motion to dismiss, concluding that plaintiffs adequately alleged actionable misrepresentations and omissions in the registration statement. At the outset, the court noted that the heightened pleading standards of Rule 9(b) did not apply because the complaint alleged only negligent misrepresentations. The court concluded that four categories of allegations in the complaint supported plausible violations of the 1933 Act. First, the complaint had alleged that Tokai launched the Phase 3 trials for AR-V7 positive patients without first having performed a Phase 2 trial focused on those patients; instead, the Phase 2 trial involved a much larger group of patients, and the data only retrospectively analyzed AR-V7 positive patients. Although Tokai’s registration statement disclosed the retrospective analysis, the court concluded that this disclosure did not adequately convey the alleged inadequacy of the data to support proceeding to Phase 3. Second, while the registration statement disclosed that 6 of 7 AR-V7 positive patients in the Phase 2 trial demonstrated positive results, 2 of those 6 patients ceased treatment after participating in Phase 2. The court concluded that plaintiffs adequately alleged that the non-disclosure of this fact failed to inform investors that it would be difficult to recruit enough patients to generate statistically sufficient data for more demanding Phase 3 trials. Third, although the registration statement suggested there was an unmet need for

treatment of AR-V7 positive patients, the court found that it failed adequately to disclose the risk that existing alternative treatments (such as taxane chemotherapy) could inhibit patient enrollment in Phase 3 trials. Finally, although the registration statement disclosed that the Phase 3 trials would have to demonstrate a “statistically persuasive large relative and absolute magnitude of improvement” for FDA approval, and that Phase 3 trials would involve a “randomized” trial comparing Galeterone to Xtandi in “up to 170” AR-V7 positive patients, it did not disclose that the Xtandi and Zytiga Phase 3 trials had each enrolled nearly 1,200 patients, suggesting that there would not be statistically sufficient data for approval.

The court rejected Tokai’s arguments for dismissal. Although Tokai contended that it was not aware of taxane chemotherapy’s effectiveness at the time of the IPO, the complaint alleged otherwise, and Tokai improperly—according to the court—attempted to refute its allegations through documents not referenced in the complaint. Tokai also argued that the number of participants in the Xtandi and Zytiga Phase 3 trials was publicly available information, but the court found that the question could not be decided on the face of the complaint, and that the mere public availability of the information could not necessarily preclude liability at the pleading stage. As to whether Tokai’s Phase 2 analysis supported proceeding to Phase 3 trials, the company argued that the registration statement included non-actionable opinion statements. The court noted, however, that “the line between an opinion and a statement of fact is not an easy one to draw,” and that the alleged misleading statements could nevertheless be actionable if the company had possession of information that undermined its opinion.

The court noted, however, that “the line between an opinion and a statement of fact is not an easy one to draw,” and that the alleged misleading statements could nevertheless be actionable if the company had possession of information that undermined its opinion.

2020 CASES TO WATCH

In re Ocular Therapeutix, Inc. Securities Litigation, No. 19-1557 (1st Cir.) – Manufacturing Issues

Ocular Therapeutix, Inc. (“Ocular”) is a Massachusetts-based biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. In September 2015, Ocular submitted an NDA to FDA seeking approval of Dextenza, its leading drug candidate for the treatment of post-surgical eye pain and inflammation. In February 2016, following a pre-NDA inspection of Ocular’s manufacturing facility, FDA issued a Form 483 identifying ten observations of non-compliance with certain FDA regulations. In its 2015 Form 10-K, Ocular disclosed that it had received the Form 483, and that it “addressed some observations before the inspection was closed and responded to the FDA with a corrective action plan to complete the inspection process.” In July 2016, Ocular received a complete response letter (“CRL”) from FDA rejecting Ocular’s NDA. Ocular disclosed that it had received the CRL and that the “concerns raised by the FDA [in the CRL] pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection” of Ocular’s manufacturing facility. In January 2017, Ocular resubmitted its NDA to FDA. In April and May 2017, FDA made additional pre-NDA visits to Ocular’s manufacturing facilities, and in May 2017, FDA issued another Form 483 identifying six observations. The next day, Ocular released its financial results for Q1 2017 and held an earnings call. On that call, Ocular disclosed the second Form 483 and stated that the company had “the situation under control” and it expected to be able to resolve the issues identified in the Form 483 “in a timely manner.” In July 2017, the website *Seeking Alpha* published the two Forms 483, and STAT published an article asserting that Dextenza could be rejected by FDA due to product contamination. Later that month, FDA issued a second CRL rejecting Ocular’s NDA. The company received a subpoena from the SEC seeking documents and information concerning Dextenza, including related communications with FDA, investors, and others.

Upon a drop in Ocular’s share price following the second CRL, investors filed a federal securities class action in the District of Massachusetts under Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act, alleging that Ocular, its CEO, and a second officer made materially false and misleading statements regarding Dextenza and the Forms 483. Specifically, the amended complaint alleged that defendants issued false and/or misleading statements regarding Ocular’s significant manufacturing issues related to Dextenza and the drug’s prospects for FDA approval.

The district court granted defendants’ motion to dismiss, holding that the amended complaint failed to plead an actionable misstatement or omission, and independently, that plaintiffs failed to allege a strong inference of scienter. The court considered three categories of alleged misstatements and omissions. First the court rejected plaintiffs’ allegations as to generalized statements in Ocular’s Forms 10-K attesting that it used current good manufacturing practices (“cGMP”) at its multi-product manufacturing facility. The court noted that the amended complaint did not allege any contemporaneous facts supported by emails, internal documents, or reports to suggest that Ocular did not in fact use cGMP, and rejected plaintiffs’ exclusive reliance on the Forms 483 because they did not represent a final agency determination regarding compliance. Further, the court emphasized that the “challenged statements about compliance with cGMP cannot be considered in isolation” and noted that it was “undisputable that the company promptly disclosed its receipt of the two Forms 483.” Second, the court held that a statement by Ocular’s CEO in response to the first CRL—“we’ve adequately we think addressed the issues that [FDA] raised”—was a protected statement of opinion. Last, the court held that the company’s statement that it “expect[ed]” to resolve the issues identified in the second Form 483 “in a timely manner” was “clearly a forward-looking forecast about a future event,” accompanied by meaningful cautionary language, and therefore protected under the PSLRA’s safe harbor provision. Independently, the court held that the amended complaint failed to allege particularized facts supporting a strong inference that defendants intentionally or recklessly issued misleading statements about the Forms 483 and their importance to the Dextenza NDA. The

court rejected plaintiffs’ reliance on the core operations theory and the related SEC investigation as “non sequiturs” because “defendants knew about the [Forms] 483[] and disclosed them.” The court criticized the amended complaint for “ignor[ing] the disclosures about the Forms 483,” overlooking the progress the company made in addressing FDA’s concerns, and failing to mention that Ocular’s CEO purchased company stock during the class period, which undercut an inference of fraudulent intent. The court also noted that several months before it rendered its decision, FDA had accepted the Dextenza NDA for review and approved the drug.

Plaintiffs appealed the dismissal to the First Circuit. Briefing was completed in December 2019.

Angelos v. Tokai Pharmaceuticals, Inc., No. 1:17-cv-11365 (D. Mass.) – Enrollment Numbers and Trial Discontinuation

Tokai Pharmaceuticals, Inc. (“Tokai”) was a clinical-stage biopharmaceutical company focused on developing therapies for prostate cancer and other hormonally driven diseases, including its lead drug candidate, Galeterone, an oral treatment for patients with metastatic castration-resistant prostate cancer (“mCRPC”). On July 26, 2016, Tokai disclosed that it had discontinued its Phase 3 clinical trial of Galeterone on the recommendation of the trial’s independent data monitoring committee. Following the announcement, the company’s stock price dropped by more than 78%. Subsequently, the company announced that it would not proceed with its planned study of Galeterone in mCRPC patients and that the board of directors was considering strategic alternatives for the company, including a possible dissolution. On May 11, 2017, Tokai merged with Otic Pharma, Inc. to form Novus Therapeutics, Inc.

On September 29, 2016, investors filed a federal securities class action against Tokai, several of its former executives and directors, and its underwriters, alleging that Tokai made false and misleading statements regarding galeterone’s prospects for FDA approval, in violation of Sections 10(b) and 20(a) and Rule 10b-5 of the 1934 Act and Sections 11, 12(a)(2), and 15 of the 1933 Act. The complaint alleged that Tokai’s IPO registration statement, press releases, and periodic reports were

misleading because they expressed optimism about the clinical development of Galeterone and its advantages over competing therapies, while failing to disclose deficiencies in the drug’s clinical trials that made it “virtually certain” FDA would not approve the drug. Soon after, three additional putative class actions based on substantially similar allegations were filed against Tokai (two in federal court and one in Massachusetts state court). Opposing motions to consolidate were filed and briefed throughout 2016 and into 2017. On September 25, 2017, a new class action based on substantially similar allegations as those in the previous complaints was filed against Tokai in federal court. On September 28, 2017, the court consolidated the various class actions into one class action, *Angelos v. Tokai*.

On September 7, 2018, the lead plaintiff appointed by the court filed a consolidated amended complaint. In addition to the allegations in the previous complaints, the amended complaint alleges that defendants misled investors that there were 148 viable test subjects in its Phase 3 trial when, in fact, there were only four. The consolidated amended complaint alleges that this information did not become public until June 7, 2017, when the American Society of Clinical Oncology (“ASCO”) disclosed that the study only had 38 test subjects when the study was stopped and of those 38 patients, 35 patients did not meet the eligibility criteria to remain in the study. The consolidated amended complaint alleges that several alleged statements by former Tokai employees were false and misleading because defendants never disclosed that its Phase 3 study failed for lack of test subjects, and instead repeatedly stated that it anticipated 148 viable test subjects with over 953 patients enrolled in the study. As evidence of scienter, the consolidated amended complaint alleges that the “insider selling of the [c]ompany’s shares was rampant,” including by the CEO, CFO, and COO” during the relevant time period.

Defendants moved to dismiss the action in October 2018, the motion is fully briefed, and argument on the motion is set for February 18, 2020. While defendants’ motion to dismiss in the *Angelos* matter has been pending, the Massachusetts Superior Court denied a motion to dismiss in a similar matter against Tokai.

Mehdi v. Karyopharm Therapeutics Inc., 1:19-cv-11972 (D. Mass.) & Allegheny County Employees’ Retirement System v. Karyopharm Therapeutics Inc., 1:19-cv-11597 (D. Mass.) – Disclosure of Safety Concerns in FDA Briefing Document

Karyopharm Therapeutics Inc. (“Karyopharm”) is a clinical-stage pharmaceutical company focused on the development of drugs for the treatment of cancer. Its lead drug candidate was selinexor, which is principally intended for the treatment of blood cancers. The company conducted a Phase 2 SOPRA trial (“SOPRA”), which evaluated selinexor for treatment of patients with acute myeloid leukemia (“AML”), as well as a Phase 2b STORM trial (“STORM”), which evaluated the safety and efficacy of selinexor in treating patients with multiple myeloma (“MM”).

In March 2017, Karyopharm reported interim results from the SOPRA study, and announced that the study had not demonstrated statistical significance for overall survival among AML patients, the study’s primary endpoint. As a result, the company halted the trial, but it assured investors that selinexor was “well-tolerated” by patients and stated that there were “no new clinically significant adverse events in the patients receiving selinexor.” The company proceeded with the STORM study and continued to describe selinexor’s safety profile positively, including in press releases, conference calls, and various SEC filings. In April 2017, Karyopharm executed a secondary public offering of common stock (the “2017 offering”); and in May 2018, it executed a follow-on offering of common stock pursuant to a shelf registration (the “2018 offering”). The registration statements and supplemental materials incorporated various SEC filings that positively described selinexor’s safety profile.

In February 2019, in advance of an FDA advisory committee meeting to review the company’s New Drug Application (“NDA”) for selinexor and assess the drug’s risks and benefits, FDA released a briefing document expressing concerns about the drug’s safety and efficacy. The report stated that the SOPRA trial had resulted in “worse overall survival” for AML patients treated with selinexor, which “highlight[ed] the toxicity of this drug.” The report also stated that the toxicity observed with selinexor in AML patients was “similar” to that observed in MM patients in the STORM study. The report con-

cluded that “[t]reatment with selinexor is associated with significant toxicity,” and that the drug “has limited efficacy.” In the wake of the release of the FDA briefing document, Karyopharm’s stock price fell by more than 43%. Plaintiffs’ complaint does not address the FDA advisory committee meeting or FDA’s decision regarding the NDA.

In the summer and fall of 2019, plaintiffs filed two class actions against the company, various company officers and board members, and (in the *Allegheny* action) the underwriters of the 2017 and 2018 offerings. The complaints alleged, on behalf of a class of purchasers of the company’s stock between March 2, 2017 and February 22, 2019, as well as purchasers of stock traceable to the 2017 and 2018 offerings, that the company’s positive statements regarding the safety profile of selinexor, including those incorporated in the registration statements and supplemental materials for the 2017 and 2018 offerings, were materially false, in violation of Sections 11, 12(a)(2) (in the *Allegheny* action only), and 15 of the 1933 Act, as well as Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder. The statutory lead plaintiff process is currently underway.

Hackel v. Aveo Pharmaceuticals, Inc., No. 1:19-cv-10783 (D. Mass.) – Delay of NDA Filing Following FDA Concerns

Aveo Pharmaceuticals, Inc. (“Aveo”) is a biopharmaceutical company based in Cambridge, MA, that develops and commercializes a portfolio of targeted medicines for oncology and other areas of unmet medical need. Its lead drug candidate is tivozanib (registered under the trademarked name FOTIVDA), an oral, once-daily medication for treating renal cell carcinoma (“RCC”). In June 2013, FDA deemed tivozanib insufficient for approval, due to reported concerns regarding the negative trend in overall survival (“OS”) in the company’s first phase 3 trial (the “TIVO-1 trial”). The announcement caused a significant drop in the company’s stock price, and, in addition to securities class action cases being filed, in March 2016, the SEC brought fraud charges against the company’s CEO, CFO, and Chief Medical Officer (“CMO”) during the relevant period (all of these officers later left the company). In May 2016, Aveo announced the dosing of its first patient in the “TIVO-3

trial,” a phase 3 randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib. The company issued public statements that the TIVO-3 trial was designed to address FDA’s OS concerns with respect to the TIVO-1 trial. In November 2018, Aveo announced that tivozanib had successfully “met its primary endpoint of demonstrating a statistically significant benefit in progression-free survival (PFS)” through the TIVO-3 trial. According to the November 2018 press release, the company planned to submit a New Drug Application (“NDA”) to FDA in approximately six months based on results from the TIVO-3 trial, together with the previously completed TIVO-1 trial. But in January 2019, the company announced that, in accordance with FDA’s recommendation, it would not be submitting an NDA for tivozanib with the preliminary OS data, because “these preliminary OS results do not allay [the FDA’s] concerns about the potential detriment in OS outline in the complete response letter dated June 6, 2013.” The announcement also stated that Aveo had “identified the survival status of a group of patients that were previously lost to follow up.” Enrollees “lost to follow up” are those who were at one time actively participating but are no longer part of the data set, either because they became unreachable or because of mechanical error. The company’s stock price fell over 60% following these disclosures.

Investors filed suit in the Southern District of New York in February 2019, but the case was transferred to the District of Massachusetts in April 2019. Plaintiffs filed an amended complaint in July 2019, naming the company, its CEO, its CFO, its former CFO, and CMO as defendants. The amended complaint alleged violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b promulgated thereunder, on behalf of a class of those who purchased Aveo stock from May 4, 2017 through January 31, 2019. The amended complaint alleged that various public statements by defendants regarding the TIVO-3 trial—including the timing of when results would be reported; the existence of patients “lost to follow-up” at the time preliminary results were reported; and, descriptions of preliminary results—were misleading, and that defendants failed to disclose that the TIVO-3 trial was inadequately designed to address FDA’s OS concerns.

Defendants moved to dismiss the amended complaint in September 2019. Defendants argued that the alleged misleading statements and omissions were not actionable, because they were either accurate or not false when made, and because defendants were not obligated to characterize the trial results as plaintiffs would prefer. Defendants also argued that the complaint did not plead any particularized facts that would support a strong inference of scienter, and instead relied on “must have known” allegations. Briefing on defendants’ motion to dismiss was completed in January 2020.



SECOND CIRCUIT AND NEW YORK DISTRICT COURTS

In re Express Scripts Holdings Company Securities Litigation, 773 F. App'x 9 (2d Cir. 2019) – Deteriorating Contract Renewal Negotiations with Customer

Express Scripts Holdings Company (“Express Scripts”) is a pharmacy benefit management corporation. In April 2009, Express Scripts entered into an agreement with Anthem, Inc. (“Anthem”), a health insurance provider, under which Express Scripts was to act as Anthem’s exclusive pharmacy benefits manager. As a result of the agreement, Anthem became the most important customer of Express Scripts, accounting for 12% to 17% of Express Scripts’s revenues between 2012 and 2016. Express Scripts classified the agreement as an intangible asset, thus requiring the company to amortize the agreement over its “useful life” and update the useful life based on any material changes. Because Express Scripts anticipated renewing the 10-year agreement with Anthem, it amortized the agreement over a 15-year period in its SEC filings.

The agreement provided that Anthem could conduct a periodic pricing review every three years. The first periodic pricing review occurred in 2011, lasted nearly a year, and strained the relationship between Anthem and Express Scripts. During the course of the next periodic pricing review, which began in 2014, the relationship further deteriorated. In March 2016, Anthem sued Express Scripts for breaching the agreement. Express Scripts disclosed the suit, updated the useful life of the agreement, and adjusted its amortization of the agreement based on the assumption that it would not be renewed beyond its 10-year term.

Following a decline in the price of Express Scripts’s stock price following this disclosure, investors filed suit

in the Southern District of New York against the company, its CEO, president, CFO, and several other executives, alleging violations of Sections 10(b) and 20(a) of the 1934 Act. Specifically, plaintiffs alleged that defendants issued several misleading positive statements about Express Scripts’s relationship and negotiations with Anthem, even as the relationship and negotiations were deteriorating, during the approximately one-year class period. Plaintiffs also alleged that the company’s accounting for the agreement was incorrect under GAAP in light of the deteriorating relationship. After dismissing plaintiffs’ amended complaint without prejudice, the district court dismissed the second amended complaint with prejudice, concluding that plaintiffs failed to plead (i) an actionable misstatement, and (ii) a strong inference of scienter (fraudulent intent).

Plaintiffs appealed the district court’s dismissal, arguing that Express Scripts made three categories of actionable misstatements or omissions: (i) misrepresentations of the state of the relationship and negotiations with Anthem; (ii) failure to disclose the “true state” of the relationship and negotiations; and (iii) accounting misstatements related to the company’s decision to amortize the agreement over 15 years, rather than 10. In a non-precedential summary order, the Second Circuit affirmed the district court’s dismissal on both lack of misstatement and lack of scienter grounds.

As to alleged misrepresentations, the Second Circuit concluded that defendants’ statements regarding the Anthem relationship and negotiations—such as that the relationship was “great,” “very solid,” and a “two-way street,” and that Express Scripts was “excited to continue very productive discussions” with Anthem—were generalized expressions of corporate optimism or puffery, and therefore not materially misleading. Inde-

pendently, the court credited numerous disclosures by Express Scripts throughout the class period—warning investors of the possibility that the negotiations could fail and result in non-renewal of the agreement—in concluding that defendants’ statements were not actionable, emphasizing that courts must consider not only the “literal truth” of statements, but also the “context and manner of presentation.” Likewise, the Second Circuit rejected plaintiffs’ attempt to proceed on a pure omissions theory, holding that because the discussions with Anthem were in fact ongoing, Express Scripts did not have a duty to disclose more about the uncertain state of the negotiations. Finally, the court held that the company’s accounting treatment for the agreement was not actionable because, even though perhaps “overly optimistic,” its decision not to reduce the useful life of the agreement was not necessary until Anthem informed Express Scripts that it did not intend to renew the agreement, which did not occur until a full year after the end of the class period.

Independently, the Second Circuit held that even if plaintiffs had pleaded an actionable misstatement or omission, the second amended complaint did not allege facts giving rise to a strong inference of scienter. The court concluded that plaintiffs’ allegations amounted to impermissible fraud by hindsight—defendants could not have known at the time of their statements that negotiations would necessarily fail and result in non-renewal of the agreement, especially given the fact that the first periodic pricing review, which was contentious and lasted a year, ultimately concluded successfully.

Gagnon v. Alkermes PLC, 368 F. Supp. 3d 750 (S.D.N.Y. 2019) – Statements Concerning Organic Sales Growth and Drug’s Effectiveness

Alkermes PLC (“Alkermes”) is a global pharmaceutical company that develops and commercializes treatments designed to address unmet medical needs of patients in major therapeutic areas, such as schizophrenia, addiction, and multiple sclerosis. As the opioid crisis worsened, in 2010 Alkermes obtained FDA-approval for Vivitrol, a once-monthly, non-narcotic, injectable treatment for the prevention of relapse to opioid dependence, following opioid detoxification. Unlike other well-established agonist opioid treatments like methadone and buprenorphine, both of which reduce drug cravings and

withdrawal symptoms by activating opioid receptors in the brain, Vivitrol is an antagonist treatment, meaning it blocks the ability of opioids to activate those opioid receptors in the brain. While Alkermes primarily educated physicians and other healthcare personnel about Vivitrol, it also educated other stakeholders involved in the treatment of opioid dependence, including drug courts and criminal justice professionals. These stakeholders are critical members of the treatment ecosystem for opioid dependence, which is highly prevalent among defendants in the criminal justice system, and many of them reached out to Alkermes seeking information on Vivitrol. As an antagonist that was non-addictive and had no history of diversion, Vivitrol was a particularly attractive treatment option for participants in drug court initiatives and criminal justice reentry programs. In 2017, several media articles criticized Alkermes’s marketing, and Senator Kamala Harris announced an investigation into Alkermes’s sales practices related to Vivitrol. Upon the combination of these disclosures, Alkermes’s stock price declined.

Investors filed a class action in the Southern District of New York, alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5, claiming that Alkermes, its CEO, and its CFO issued materially misleading statements regarding: (i) Alkermes’s sales practices for Vivitrol (e.g., touting “organic” growth); (ii) Vivitrol’s effectiveness in preventing relapse to opioid dependence; and (iii) Vivitrol’s efficacy relative to agonist treatments. Following a pre-motion letter briefing process and hearing, plaintiffs elected to file a 175-paragraph second amended complaint that alleged 18 material misrepresentations and omissions across a 34-month class period culminating in June 2017.

The district court granted defendants’ motion to dismiss the second amended complaint with prejudice, holding that 17 of the 18 alleged misstatements were not actionable, and as to the single arguable “half truth,” the court held that plaintiffs failed to allege facts supporting a strong inference that defendants issued the statement with intent to defraud or extreme recklessness. The court explained that none of the alleged misstatements concerning Vivitrol’s efficacy—such as statements that Vivitrol “prevents relapse to opioid dependence”—were misleading, rejecting plaintiffs’ “assertion that these challenged statements constitute ironclad guarantees of Vivitrol’s effectiveness in perpetuity.” The court noted that the efficacy statements could not be

“read literally and in a vacuum,” and that defendants’ statements when read in context were statements regarding how Vivitrol was intended to work, including by reference to the drug’s FDA-approved label. Likewise, the court concluded that none of the statements concerning Vivitrol’s performance in comparison to agonists were actionable, finding that the statements delineated differences between how agonists and antagonists functioned, but did “not leave any impression as to which treatment is more effective.” The court concluded that a single statement regarding Vivitrol’s organic growth was potentially misleading because it did not disclose the influence of the company’s marketing and lobbying efforts for Vivitrol. Nevertheless, the court agreed with defendants that plaintiffs’ theory of scienter was not compelling, explaining that the stock sales by defendants were “neither suspicious nor unusual,” and that the second amended complaint—lacking any confidential witness allegations, internal documents, admissions, or any similar particularized allegations—failed to allege that any defendant “knew contrary facts or had access to information contradicting” the single plausible alleged misstatement.

Micholle v. Ophthotech Corporation, Case No. 17-cv-210 (VSB), 2019 WL 4464802 (S.D.N.Y. Sept. 17, 2019) – Clinical Trial Eligibility Modification

Ophthotech Corporation (“Ophthotech”) is a clinical-stage biopharmaceutical company focused on developing the drug Fovista for the treatment of wet age-related macular degeneration (“wet AMD”). Wet AMD is a degenerative eye disease that occurs when areas of abnormal blood vessels and abnormal tissue—i.e., lesions—form in the retina and leak fluid or blood, causing patients to experience blurred vision and blind spots in their visual field. Ophthotech designed Fovista to be used in combination with anti-vascular endothelial growth factor drugs, including Lucentis, which are commonly used to treat wet AMD.

In June 2012, Ophthotech completed a Phase 2b trial of Fovista, which evaluated the efficacy of Fovista administered in combination with Lucentis, as compared to Lucentis alone. In selecting individuals to participate in the Phase 2b trial, Defendants analyzed wet AMD patients’ lesions using an imaging technique called flu-

orescein angiography (“FA”). Potential participants were divided into subgroups on the basis of whether their lesions contained “classic” or “occult” components, as measured by FA. “Classic” refers to the portion of the lesion that is well-defined and typically located above the retinal pigment epithelium (“RPE”) layer of the retina, while “occult” refers to the portion of the lesion that is poorly defined and typically located below the RPE layer of the retina. Classic and occult subtypes represent a spectrum, with “pure classic” lesions containing no occult components and “pure occult” lesions containing no classic components. Importantly, patients with “pure occult” lesions were not eligible to participate in the Phase 2b trial.

On June 13, 2012, Ophthotech announced the results of the Phase 2b trial, which measured improvement in participants’ visual acuity by counting the number of additional letters trial participants gained on a standardized chart used for vision testing at the conclusion of the 24-week trial period. A press release announcing the trial’s results stated that those patients “receiving the combination of Fovista. . .and Lucentis gained a mean of 10.6 letters of vision” as “compared to 6.5 letters for patients receiving Lucentis” alone, “representing a 62% additional benefit.” The June 13, 2012 press release did not disclose that, at the start of the trial, those patients who received Lucentis alone had lesions which, on average, were approximately 17% larger than the lesions of those patients in the Fovista combination therapy group. The company had disclosed in its 2014 and 2015 Forms 10-K, however, that patients in the control group, on average, had larger lesions than those in the Fovista group, and later disclosed the specific 17% lesion size difference in the Journal of the American Academy of Ophthalmology on October 31, 2016.

After announcing the seemingly favorable Phase 2b trial results, the company conducted an IPO in September 2013, the proceeds of which the company used to finance a Phase 3 trial of Fovista that it had initiated in August 2013. The company disclosed publicly that the Phase 3 trial’s parameters involved certain changes from the Phase 2b trial, including a larger patient group, a greater amount of time over which patients’ visual acuity was measured, and a modification to the “methodology used to determine a patient’s eligibility.” The company did not disclose in detail what these particular eligibility modifications entailed, namely, that for the

Phase 3 trial, the company: (1) used spectral domain optical coherence tomography (“SD-OCT”) imaging to analyze potential trial participants’ lesions; and (2) determined patients’ eligibility based on the presence of sub-retinal hyper-reflective material (“SHRM”), as opposed to categorizing patients based on “classic” and “occult” lesions and excluding “pure occult” patients. In response to analyst questions concerning the changes made, defendants stated that there “aren’t any differences that are material or significant in any way,” and that the Phase 3 trial involved the “same group of patients” as the Phase 2b trial.

In December 2016, the company announced that the Phase 3 trial results showed no benefit in the addition of Fovista to a monthly Lucentis regimen for the treatment of wet AMD. On this news, the price of Ophthotech common stock fell approximately 86%, from a closing price of \$38.77 per share on Friday, December 9, 2016 to a closing price of \$5.29 per share on Monday, December 12, 2016. Putative investors filed a securities class action against the company and its former CEO and CFO, asserting violations of Sections 10(b) and 20(a) of the 1934 Act, and Rule 10b-5, alleging material misstatements and omissions falling into two categories—(i) failure to disclose the specific differences in lesion size between the control group and the combination group which rendered statements concerning the success of the Phase 2b trial misleading; and (ii) failure to disclose a material change in the enrollment criteria for the Phase 3 trial. Defendants moved to dismiss, and the district court granted in part and denied in part that motion.

The district court first addressed whether plaintiffs identified any material misstatements or omissions. The district court concluded that plaintiffs failed to adequately allege that any statement defendants made was rendered materially misleading by defendants’ failure to disclose that patients in the Phase 2b control group had larger lesions and poorer vision at the beginning of the trial than patients in the Fovista combination therapy group. In particular, the court held that defendants actually had repeatedly disclosed in the company’s 2014 and 2015 Forms 10-K that patients in the control group, on average, had larger lesions than those in the Fovista group.

The court held that “the fact that information regarding the specific difference in baseline lesion size between Fovista combination therapy group and the Lucentis monotherapy group ‘might have provided useful context for investors does not rise to the level of an actionable omission.’”

The court held that “the fact that information regarding the specific difference in baseline lesion size between Fovista combination therapy group and the Lucentis monotherapy group ‘might have provided useful context for investors does not rise to the level of an actionable omission,’” and that plaintiffs failed to allege facts establishing that the omission of the specific difference in average lesions size rendered any of defendants’ statements actionably misleading. The court further held that plaintiffs alleged no facts, as opposed to unsupported conclusions, establishing that the Phase 2b control group’s alleged poorer visual acuity at the outset of the trial affected the Phase 2b results, particularly where the results actually established that Fovista’s relative treatment benefit was evident regardless of patients’ baseline visual acuity.

By contrast, the district court held that plaintiffs adequately alleged that defendants’ generic statements concerning the modifications of the Phase 3 trial parameters relative to the Phase 2b trial parameters were rendered materially misleading by defendants’ omission of the fact that the Phase 3 trial did not exclude “pure occult” patients. In particular, the court found that defendants’ characterization of the trial parameter modifications as “not meaningful,” and other similar statements downplaying the significance of the trial parameter updates, were potentially materially misleading given defendants’ admissions that at least 17% of all wet AMD patients would have been eligible to participate in the Phase 3 trial but not the Phase 2b trial. The court concluded that the “full significance of these statements must await discovery,” but that the “17% overlap between lesions classified as ‘pure occult’ and those that demonstrate the presence of SHRM” were sufficient to support plaintiffs’ claims at the pleading stage, as an “investor may well have considered the degree of simi-

larity between the parameters of a new clinical trial and those of a recently completed—and purportedly very successful—clinical trial important in deciding whether to invest in a developmental drug.”

As to scienter, the court held that plaintiffs failed to allege facts plausibly suggesting that defendants had a motive and opportunity to commit fraud. The court rejected scienter notwithstanding that the individual defendants sold 82% and 66% of their company shares during the alleged class period, for proceeds exceeding \$22 million for each defendant. The court held that defendants’ alleged trading during the class period was consistent with their trading practices before the class period, and plaintiffs’ allegations concerning the proceeds of defendants’ stock sales included “few of the additional facts courts have found relevant when considering stock sales by insiders,” including actual profits.

However, the court held that plaintiffs adequately alleged facts establishing circumstantial evidence that defendants engaged in misbehavior or recklessness, namely, that plaintiffs’ allegations strongly suggested that defendants were aware that they lacked a reasonable basis for their repeated representations that the change in methodology following the Phase 2b trial did not alter the pool of patients eligible to participate in the Phase 3 trial. The court again relied on plaintiffs’ allegations that defendants knew that 17% of the wet AMD population would have been eligible to participate in the Phase 3 trial, but not the Phase 2b trial, yet defendants repeatedly stated that no meaningful modifications had been implemented.

Finally, the court held that plaintiffs adequately alleged loss causation, holding most notably that “it is a logical inference that changing a key variable in a subsequent iteration of a clinical trial increases the risk that the previous trial’s results will not be replicated,” and that the “direct connection” between that undisclosed risk and plaintiffs’ alleged losses was “plausibl[e].” The court allowed plaintiffs to proceed with claims concerning alleged misrepresentations and omissions related to the modifications implemented in the Phase 3 trial’s design, but dismissed plaintiffs’ claims concerning alleged omissions related to lesion sizes between the Phase 2b trial’s Fovista combination and control groups.

2020 CASES TO WATCH

Tung v. Bristol-Myers Squibb Company, Case No. 18-cv-1611 (JPO), 2019 WL 4805852 (S.D.N.Y. Sept. 30, 2019) – **Description of Clinical Trial Eligibility**

Bristol-Myers Squibb Company (“BMS”) is a pharmaceutical company that develops various drugs, including Opdivo, a type of immuno-oncology drug. Opdivo helps patients fight cancer by inhibiting cancer cells from expressing a particular protein, PD-L1, which, when expressed, can prevent the body’s immune system from attacking such cancer cells by binding to PD-1 proteins on T-cells. The effectiveness of Opdivo depends on the extent to which a patient’s cancer cells express PD-L1: if the cancer cells do not express that protein, then inhibiting PD-L1 expression likely would not make a difference. In January 2014, BMS commenced a Phase 3 clinical trial, Checkmate-026, to determine whether Opdivo is more effective than chemotherapy for patients with non-small cell lung carcinoma whose cancer cells “strongly” expressed PD-L1. BMS did not disclose at the time how much PD-L1 expression was required for a patient to “strongly” express PD-L1. Later, in May 2014, Merck, a competitor, announced a similar study in which it limited eligibility to patients with “PD-L1 strong expressing tumor,” which Merck defined as meaning at least 50% of the patients’ cancer cells expressed PD-L1.

On August 5, 2016, BMS announced that Checkmate-026 failed to demonstrate that Opdivo had outperformed chemotherapy, and disclosed for the first time that the patient population that “strongly” expressed PD-L1 was comprised of patients whose tumors expressed PD-L1 at rates of at least 5%. On this news, BMS’s stock price dropped approximately 16%. On October 9, 2016, Bristol-Myers further disclosed that the study’s design precluded the researchers from reaching any conclusions about the efficacy of Opdivo for patients whose expression of PD-L1 was higher than 5%, and that BMS “had no means under acceptable statistical methodologies of finding a significant difference between the performance of Opdivo and chemotherapy.” On this news, BMS’s stock price dropped more than 10%.

Thereafter, plaintiffs brought a class action complaint against BMS and its officers under Sections 10(b) and 20(a), and Rule 10b-5 of the 1934 Act, alleging that defendants mischaracterized the design of the trial when they used “strong” to describe a 5% cut-off for PD-L1 expression. Defendants moved to dismiss the complaint. Notably the court bypassed any analysis of the alleged misstatements and omissions at issue, and granted defendants’ motion to dismiss based exclusively on plaintiffs’ failure to adequately allege scienter.

First, the court rejected plaintiffs’ argument that defendants had motive and opportunity to commit fraud because they wanted to protect proprietary information and inflate the company’s stock price in preparation for selling shares. The court held that these allegations were inadequate, concluding that plaintiffs did not allege any concrete benefits from the protection of proprietary information other than the maintenance of profitability, which would be true for any company. The court also rejected plaintiffs’ argument that defendants were motivated to drive up the stock price to sell their shares, reasoning that two of the individual defendants did not sell any of their shares during the relevant period, and that all defendants either retained the same amount of company stock, or increased their holdings, during the relevant period.

The court also rejected plaintiffs’ argument that defendants were motivated to drive up the stock price to sell their shares, reasoning that two of the individual defendants did not sell any of their shares during the relevant period, and that all defendants either retained the same amount of company stock, or increased their holdings, during the relevant period.

Plaintiffs also argued that defendants acted knowingly or recklessly because defendants allegedly knew that the 5% PD-L1 expression rate was not a “strong” PD-L1 expression, based on their alleged knowledge of industry practices, Merck’s study concerning a similar

drug, and defendants’ own prior studies. The court disagreed, holding that plaintiffs failed to allege facts establishing any industry-wide consensus that a 5% cut-off cannot mean “strong” PD-L1 expression. The court also held that BMS’s descriptions of 5% expression rates as “positive” rather than strong in other trials did not mean that BMS had previously taken a “categorical position” that “‘strong’ compelled a cut-off of more than 5%.” The court further held with respect to the Merck study that plaintiffs failed to allege facts establishing that Merck’s definition of strong set forth any definition of what that term “must mean, as a matter of industry practice,” and that “[a]t best, the Merck study could have informed Defendants only of Merck’s definition of ‘strong’ PD-L1 expression, and only in the context of a particular study.” Accordingly, the court dismissed plaintiffs’ complaint in its entirety, with leave to amend.

On October 29, 2019, plaintiffs filed a second amended complaint. On December 13, 2019, defendants filed a motion to dismiss plaintiffs’ second amended complaint. Briefing on the motion to dismiss is scheduled to conclude in February 2020.

In re Mylan N.V. Securities Litigation, Case No. 16-cv-7926 (JPO), 379 F. Supp. 3d 198 (S.D.N.Y. March 29, 2019) – **Medicaid Misclassification and Antitrust Violations**

Mylan N.V. (“Mylan”) is a pharmaceutical developer, manufacturer and distributor. Mylan’s products include the EpiPen Auto-Injector (“EpiPen”) and various generic drugs such as doxycycline hyclate delayed release (“Doxo DR”), albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, doxycycline monohydrate, glipizide-metformin, and verapamil. Mylan allegedly misclassified the EpiPen as a generic drug for the Medicaid Drug Rebate Program (“MDRP”), was repeatedly informed that the EpiPen was misclassified, was investigated by the U.S. Department of Justice (“DOJ”) in November 2014 concerning this misclassification, and entered into a \$465 million settlement with the DOJ on October 7, 2016 concerning this misclassification. Until this settlement announcement, Mylan and its executives allegedly did not disclose the misclassification, its impact on Mylan’s reported revenues, or the risk it created that Mylan would be required to pay regulatory penalties as a result of the misclassification.

Mylan also allegedly engaged in multiple antitrust violations. It allegedly entered into numerous agreements for “pay for delay,” exclusive dealing, market allocation, and price fixing with its competitors and customers with regard to the EpiPen and various generic drugs. On October 31, 2017, attorneys general from 47 states issued a press release concerning an amended complaint alleging antitrust violations against Mylan (“State AG Action”). Following the filing of the State AG Action, Mylan’s stock price fell \$2.53, or 6.62%.

Plaintiffs filed a putative class action complaint against Mylan and its officers, alleging violations of Sections 10(b) and 20(a), and Rule 10b-5 of the 1934 Act, and Section 1 of the Israeli Securities Law. Defendants moved to dismiss, and the court granted the motion to dismiss in part. Plaintiffs subsequently filed a second amended complaint, which included allegations based on a confidential witness’s accounts, as well as allegations concerning Mylan’s misclassification of the EpiPen; the sale of the EpiPen on a rebate to third-party payors on the condition that they refuse to reimburse a competing product, Auvi-Q; and certain anticompetitive agreements into which Mylan entered to block competitors from the market and inflate the prices of various generic drugs. Plaintiffs alleged that defendants made multiple misleading statements concerning (1) Mylan’s historical income and the drivers underlying Mylan’s income, and (2) the competitiveness of the generic drug market, which plaintiffs alleged were misleading by virtue of Mylan’s failure to disclose its own anticompetitive conduct and potential risk of regulatory action. Defendants again moved to dismiss.

The court dismissed plaintiffs’ claims concerning Mylan’s statements of historical income, holding that those statements did not give rise to a duty to disclose any illegal conduct that may have contributed to the income disclosed in those statements. The court also dismissed all claims relating to Mylan’s reported income to the extent predicated on an alleged failure to disclose the risk of future regulatory action. Specifically, the court held that even though “the concealment of the risk of regulatory scrutiny may contribute to the materiality of the omissions for investors, the statements explaining income were not themselves misleading for failing to disclose a risk of future regulatory scrutiny.” However, the court held that Mylan’s statements were actionable if they placed Mylan’s income at issue but failed to disclose the effect that Mylan’s allegedly unlawful activities

had on the income. The court held: “Mylan’s statements explaining income” could be “actionable because the statements put its sources of income at issue” without disclosing “the extent to which Mylan’s income was inflated by its misclassification of the EpiPen and its other alleged anticompetitive activities.”

The court next addressed whether plaintiffs adequately pled actionable omissions based on defendants’ failure to disclose the alleged EpiPen rebate scheme and certain price-fixing arrangements concerning three particular generic drugs. The court held that such alleged omissions could be actionable only if plaintiffs adequately alleged that the alleged anticompetitive conduct occurred and violated the antitrust laws. The court held that plaintiffs sufficiently alleged such an actionable omission with respect to the alleged EpiPen rebate scheme, based on plaintiffs’ factual allegations explaining how the scheme blocked Mylan’s competitor, Sanofi, from accessing the market for epinephrine autoinjectors, and increased the ultimate price of the EpiPen, even with the rebate. By contrast, the court held that plaintiffs did not adequately allege an actionable omission based on an allegedly underlying antitrust violation related to Mylan’s alleged generic drug price-fixing practices. In particular, the court held that plaintiffs failed to adequately allege that such practices existed, and instead relied on insufficient allegations based on a single purported phone call during which unidentified employees of Mylan and a competitor allegedly discussed price-fixing, without alleging who in particular participated on the call, where the call occurred, or any contours of the alleged price-fixing agreements reached.

Defendants also argued that plaintiffs failed to adequately allege loss causation based on statements made between February 2012 and February 2013. Specifically, defendants argued that the PSLRA’s 90-day bounce-back rule required that plaintiffs should recover nothing based on any purchases made during this period because the price at which any such purchases were made were lower than the mean trading price during the 90-day period following any later alleged corrective disclosure. The court declined to adopt defendants’ argument, and instead ruled that plaintiffs’ allegation that Mylan’s stock price dropped after its alleged fraud was revealed was sufficient at the pleadings stage, deferring any ruling on whether certain class members could demonstrate loss causation and damages.

The court also considered plaintiffs’ claims against Mylan’s President. Of particular note, the court held that plaintiffs did not allege facts sufficient to establish the President’s scienter with respect to statements concerning the EpiPen and price-fixing schemes. The court explained that plaintiffs’ allegations were devoid of confidential witness accounts tying the President to either scheme. The court also concluded that the fact that the EpiPen was a “core business” for Mylan was not sufficient, on its own, to establish the President’s intent. By contrast, the court concluded that plaintiffs had alleged the President’s intent with respect to separate statements concerning a separate scheme involving unlawful market allocation for a separate product, reasoning that plaintiffs were entitled to rely on allegations taken from the State AG Action concerning the President’s direct involvement in that scheme. The court also imputed the President’s scienter with respect to this scheme to Mylan itself.

On June 17, 2019, plaintiffs filed a third amended complaint. On July 31, 2019, defendants filed a motion to dismiss the third amended complaint. On August 30, 2019, plaintiffs filed a motion to certify the class. The court has not yet ruled on either motion.

In re Allergan PLS Securities Litigation, Case No. 18 Civ. 12089 (CM), 2019 WL 4686445 (S.D.N.Y. Sept. 20, 2019) – Potential Link Between Product and Certain Type of Cancer

Allergan plc (“Allergan”) is a pharmaceutical company that develops, manufactures, and distributes branded pharmaceutical and medical-aesthetics products, including Naturelle 410 and Biocell breast implant products. From January 30, 2017 to December 19, 2018, Allergan made various statements concerning the quality of its breast implant products, its compliance with regulatory requirements, and the possible association between its breast implants and anaplastic large cell lymphoma (“ALCL”). In terms of the quality of its breast implants, Allergan’s executives described the company’s breast implant offerings as “robust,” “number one in breast implants,” and “very strong.” They also claimed that the “breast [implant] business . . . is doing incredibly well” and had “a strong quarter” in Q3 2017. Moreover, they issued statements concerning the safety of the company’s breast implants, noting that there is a “pos-

sible association” between breast implants and ALCL, but that “the medical community has not been able to establish causality.” Allergan also reported that it “complies with applicable regulations relating to the reporting of” the link between its breast implants and ALCL (“BIA-ALCL”) “to the FDA.” Allergan further stated that it was “actively working to help advance the knowledge of this disease, understand the association of [BIA-ALCL] and textured implants, and educate the community, including” by “working closely with the FDA and global regulatory bodies[,]” “convening global medical experts and researchers,” and “supporting ongoing research.”

Between 2015 and 2018, multiple studies found that a plurality or majority of relevant cases involved a link between breast implants to ALCL involved Allergan’s implants. On December 14, 2018, the European regulatory body responsible for certifying medical devices (“GMED”) decided not to renew its certification of Allergan’s breast implants (i.e., CE mark), which was set to expire on December 16, 2018. Four days later, France’s medical product regulator cited the GMED’s decision when requesting Allergan to recall its breast implants. On December 19, 2018, Allergan issued a press release announcing that it would no longer sell textured breast implants in Europe. That same day, Allergan’s stock price fell \$10.20 per share, or nearly 7%.

Plaintiffs thereafter filed a putative class action against Allergan and its executives, asserting claims under Sections 10(b) and 20(a), and Rule 10b-5 of the 1934 Act, alleging that defendants omitted to disclose a “definitive” link between the company’s breast implants and ALCL, misrepresented that they complied with regulatory obligations, and misrepresented that they supported further research on the link while working to undermine such work. Defendants moved to dismiss.

The court analyzed the statements at issue and held that defendants did not omit a “definitive” link between their products and ALCL, because no such link had been definitively established, and defendants actually repeatedly warned of a possible connection. The court also dismissed plaintiffs’ claims predicated on defendants’ optimistic statements regarding Allergan’s breast implant products, such as statements that Allergan was “number one in breast implants” and “doing incredibly well,” as puffery and corporate optimism that were too general to be actionable.

By contrast, the court denied defendants’ motion to dismiss claims based on their statements suggesting that Allergan’s breast implants were no more likely to be linked to ALCL than any other implants. Given the results of alleged studies conducted between 2015 and 2018 finding that a plurality or majority of ALCL cases involving breast implants related to Allergan’s implants, the court held that defendants potentially could be subject to 1934 Act liability based on even generalized statements concerning the link between breast implants and ALCL if defendants gave investors the false impression that Allergan’s breast implants were no more closely linked to ALCL than other implants.

Plaintiffs also alleged that Allergan did not comply with FDA requirements because it submitted a number of adverse event reports (“AERs”) with incorrect manufacturer names and also submitted alternative summary reports (“ASRs”) covering multiple adverse events at once. The court held that these allegations did not support a claim, reasoning that plaintiffs alleged only one AER with incorrect manufacturer information, which was filed a decade before the class period, and that defendants’ use of the ASRs was lawful at the time. The court similarly rejected plaintiffs’ claims based on Allergan’s support of BIA-ALCL research. Specifically, the court held that even if Allergan conducted no independent research and closed down the facility where such research was allegedly conducted, Allergan still had done a number of other things to advance the understanding of BIA-ALCL.

Finally, the court considered whether plaintiffs adequately alleged scienter, reliance and loss causation with regard to alleged misstatements concerning the link between Allergan’s breast implants and ALCL. The court held that plaintiffs pled strong circumstantial evidence of scienter because they had alleged that defendants were aware that Allergan’s breast implant products were more closely linked to ALCL than other products in the market, yet failed to say so and instead disclosed only a general, possible association between Allergan’s products and ALCL. The court also held that because plaintiffs’ allegations related to omissions concerning the relationship between Allergan’s breast implants and ALCL, plaintiffs did not need to plead specific proof of reliance. Finally, the court held that plaintiff adequately pled loss causation by alleging that the non-renewal of Allergan’s CE mark and the recall of its breast implants were the materialization of the undisclosed link

between Allergan’s breast implants and ALCL, which allegedly caused a 7% stock drop when revealed. On October 18, 2019, defendants answered the complaint. Discovery commenced on December 4, 2019, and summary judgment motions are due by November 5, 2020.

Salinger v. Sarepta Therapeutics, Inc., Case No. 19-CV-08122 (S.D.N.Y.) – FDA Concerns

Sarepta Therapeutics, Inc. (“Sarepta”) is a biopharmaceutical company focused on developing treatments for rare and infectious diseases, including, among other drug candidates, golodirsen for the treatment of Duchenne muscular dystrophy (“DMD”). On September 6, 2017, Sarepta announced positive muscle biopsy results from its 4053-101 Phase 1/2 first-in-human study, which included twenty-five patients treated with golodirsen. On February 14, 2019, Sarepta announced that the FDA Neurology Division had accepted for filing its New Drug Application (“NDA”) seeking accelerated approval for golodirsen and provided a regulatory action date of August 19, 2019. On August 19, 2019, Sarepta disclosed that it received FDA’s complete response letter, denying approval of the NDA and citing two concerns: “the risk of infections related to intravenous infusion ports and renal toxicity seen in pre-clinical models of golodirsen and observed following administration of other antisense oligonucleotides.” After this news, the price of Sarepta’s stock fell 15.16% on August 20, 2019.

An investor filed a putative class action complaint against Sarepta and two of its officers on August 30, 2019, alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder. Plaintiff alleged that Sarepta knowingly or recklessly made untrue or misleading statements with the intent to deceive the investing public and artificially inflate the price of Sarepta’s securities, by championing the positive results of golodirsen in Forms 10-K and press releases between 2017 and 2019, without addressing any potential safety concerns and the possibility that the drug would not receive accelerated FDA approval. On December 17, 2019, the court appointed the lead plaintiff and approved lead counsel. The lead plaintiff has until February 17, 2020 to file a second amended complaint, after which defendants will have sixty days to respond.

Rosi v. Aclaris Therapeutics, Inc., Case No. 19-CV-07118 (S.D.N.Y.) – False Advertising

Aclaris Therapeutics, Inc. (“Aclaris”) is a biopharmaceutical company that identifies, develops, and commercializes therapies to address unmet needs in medical and aesthetic dermatology and immunology. Its lead product, ESKATA, is a hydrogen peroxide topical solution to treat raised seborrheic keratosis, a common non-malignant tumor. On May 8, 2018, Aclaris announced that ESKATA was officially available for physicians and patients. From then until June 20, 2019, Aclaris stated through quarterly press releases that sales of ESKATA were positively impacting company revenue and that risk factors had not changed materially since 2017. On June 20, 2019, the FDA stated that a direct-to-consumer ESKATA advertisement made false and misleading claims, in particular that it failed to include information about ESKATA’s serious risks. On June 21, 2019, the share price of Aclaris fell \$0.57 per share, over 11%.

On July 30, 2019, an investor filed a putative class action complaint against Aclaris, its CEO, and its CFO and alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder. Plaintiff alleges that Aclaris artificially inflated its stock price through false and misleading statements about ESKATA and the company’s overall financial health by failing to disclose that (i) its advertising materials minimized the risks and overstated the efficacy of ESKATA to generate sales, and (ii) this advertising campaign was reasonably likely to lead to regulatory scrutiny.

The lead plaintiff has until January 24, 2020 to file a the consolidated amended complaint, and defendants’ motion to dismiss is to be fully briefed by July 14, 2020.

Skiadas v. Acer Therapeutics Inc., Case No. 1:19-cv-06137 (S.D.N.Y.) – FDA Denial of New Drug Application

Acer Therapeutics Inc. (“Acer”) is a development-staged pharmaceutical company focused on creating therapies for rare and life-threatening diseases. Its most advanced drug candidate is celiprolol, also known as “EDSIVO,” which is used to treat a rare genetic disorder called vascular Ehlers-Danlos Syndrome (“vEDS”). On

December 13, 2016, Acer acquired data from a clinical study of celiprolol (“Ong Trial Data”) from a French hospital, which showed, according to Acer, that celiprolol reduced the risk of a cardiac or arterial event by 64% for patients with vEDS. In a Prospectus Supplement for a public offering filed on December 12, 2017, Acer announced that it met with FDA in September 2015, and “FDA agreed that additional clinical development [beyond the Ong Trial Data] is not needed and that [Acer] may submit a 505(b)(2) NDA for EDSIVO.” Acer also conducted two public offerings to raise funds for its operations in December 2017 and August 2018. In the offering documents, Acer represented that it had an “agreement” with FDA that further clinical trials beyond the Ong Trial Data “is not needed” or “is not likely needed.” Acer raised \$12.56 million from the December 2017 offering and \$46 million from its August 2018 offering.

On October 29, 2018, Acer submitted its New Drug Application (“NDA”) for EDSIVO based only on the Ong Trial Data, its own analysis of the data, and supplemental patient registry data. On June 25, 2019, FDA denied Acer’s NDA for EDSIVO. According to Acer, FDA required Acer to “conduct an adequate and well-controlled trial” after finding the data Acer submitted insufficient. Following this news, Acer’s stock price fell over 78%.

On July 1, 2019, an alleged investor filed a putative class action lawsuit against Acer and its executives, alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder. The allegations were based on plaintiff’s claims that defendants misrepresented the prospects of FDA approval of the EDSIVO NDA because there was allegedly no agreement between FDA and Acer that the Ong Trial Data would be sufficient. On September 25, 2019, the court appointed a lead plaintiff, and the lead plaintiff filed an amended complaint on December 3, 2019. Defendants filed a motion to dismiss the amended complaint on February 7, 2020.



NINTH CIRCUIT AND CALIFORNIA DISTRICT COURTS

HsingChing Hsu v. Puma Biotechnology, Inc. et al., Case No. SACV 15-00865 AG (SHKx), 2019 WL 4295285 (C.D. Cal. Feb. 4, 2019)
— Inaccurate Clinical Trial Results

Puma Biotechnology, Inc. (“Puma”) is a pharmaceutical company that acquires and develops new drugs. Puma had focused its efforts for many years on a breast cancer treatment drug, neratinib (also called Nerlynx), which it owns the right to license. Puma’s Phase III clinical trial for neratinib, known as the ExteNET trial, was completed in October 2013. The primary endpoint for the ExteNET trial was improved disease-free survival (“DFS”) of patients taking the drug versus placebo at two years. On July 22, 2014, defendants announced that the ExteNET trial demonstrated that the absolute difference in DFS rates between neratinib patients versus placebo patients was 5% – approximately 91% compared to 86% – and, as a result, “treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo.” Defendants further stated that the drug and placebo DFS rates were “in line” with prior similar studies and that the DFS Kaplan-Meier curves widened year-over-year, meaning that the absolute difference between neratinib and placebo was actually improving over the course of the trial. Defendants also told investors that they “ha[d] not seen the safety results from the ExteNET trial,” but that the rate of diarrhea for neratinib patients was expected to be approximately 30%, and the dropout rate due to adverse events was only 5% to 10%. On July 23, 2014, Puma’s stock price went from \$59.03 to on the prior trading day to \$233.43 per share. In January 2015, defendants sold 1.15 million shares of Puma stock for proceeds of \$218.5 million in a secondary offering to cover the company’s escalating overhead costs.

On May 13, 2015, it was announced in Reuters that Abstract #508 for the ExteNET trial was posted on the American Society of Clinical Oncology (“ASCO”) website, which revealed that the difference in DFS rates between ExteNET trial patients on neratinib versus placebo was not 5%, but only 2.3%, and, therefore, there was not a 33% improvement in DFS over placebo. Abstract #508 also revealed that 39.9% of the neratinib patients in the ExteNET trial suffered from severe diarrhea. The following day, Puma’s stock price fell 18.6%, or \$39.05 per share. In addition, at a June 1, 2015 presentation at the ASCO conference, a doctor involved with the ExteNET trial disclosed that the Kaplan-Meier curves for the actual DFS rates from the ExteNET trial did not widen year-over-year and that the DFS rates for ExteNET were not close to being “in-line” with prior similar studies. The doctor further revealed that the study discontinuation rate of neratinib patients due to severe diarrhea alone was 16.8%, significantly higher than the total dropout rate of 5% to 10% defendants previously claimed. Over June 1 and 2, 2015, Puma’s stock price dropped by an additional \$48.80 per share, or approximately 24%.

On June 3, 2015, investors filed a putative securities class action against Puma and two of its officers alleging violations of Section 10(b) and 20(a) of the 1934 Act. In October 2015, the lead plaintiff filed a consolidated complaint which defendants moved to dismiss in November 2015. In September 2016, the court denied the motion and the case proceeded to the discovery phase. Plaintiff amended its complaint, in June 2017, adding new theories based on evidence received through discovery. Defendants again sought (unsuccessfully) to dismiss the operative complaint. In October 2018, the court narrowed the issues by granting, in part,

cross-summary judgment motions by the parties. Thereafter, the case proceeded to trial.

In just the 15th securities class action to reach a jury verdict since the passage of the PSLRA, on February 4, 2019, the jury found that Puma executives knowingly made materially false statements about the results of the ExteNET trial by stating that the disease-free survival rate of a breast cancer treatment was 91% compared to 86% for those who were treated with a placebo.

In just the 15th securities class action to reach a jury verdict since the passage of the PSLRA, on February 4, 2019, the jury found that Puma executives knowingly made materially false statements about the results of the ExteNET trial by stating that the disease-free survival rate of a breast cancer treatment was 91% compared to 86% for those who were treated with a placebo. The jury found that the difference in disease-free survival rates between those treated and those who were given a placebo—a 2.3% swing as compared to the 5% that Puma had represented—was material and played a substantial role in causing Puma’s stock price to decline and awarded damages of \$4.50 per share. Although the jury found defendants liable, this damages award reflected only approximately 5% or less of the damages sought. Jurors found for Puma on three other alleged misrepresentations, finding that Puma did not make material misstatements regarding the grade 3+ diarrhea rate, Kaplan-Meier curves, or the discontinuation rate due to adverse events. For life sciences companies reporting clinical trial results, the verdict underscores that there is no wiggle room for accurate reporting of data results, as even a relatively small difference between disclosed and actual results can be viewed as significantly impacting stock price and expose the company to potential liability under securities laws.

In re Regulus Therapeutics Inc. Securities Litig., Case No. 3:17-cv-0182-BTM-RBB, 2019 WL 4242485 (S.D. Cal. Sept. 5, 2019) — Serious Adverse Events In Clinical Trial

Regulus Therapeutics, Inc. (“Regulus”) is a biopharmaceutical company, which was developing a drug, RG-101, to treat hepatitis C. In late 2015 and early 2016, Regulus initiated its first clinical trials. On February 17, 2016, Regulus issued a press release in which it announced interim results from one of the Phase 2 trials stating, among other things, that “[t]o date, RG-101 has been generally well tolerated with the majority of adverse events considered mild or moderate, and with no study discontinuations.” In a conference call that same day, Regulus disclosed two serious adverse events (each, an “SAE”) experienced during the study and that an independent investigator had determined that one of the SAEs was “possibly” related to RG-101. The company downplayed the importance of these SAEs, stating that the SAEs were “not concerning.” On June 27, 2016, Regulus disclosed that FDA placed the trial on hold as a result of these safety issues, asking for additional information, Regulus announced in early 2017 four additional SAEs and later the resignation of the company’s CEO. On January 27, 2017, Regulus announced that, despite having submitted a complete response to FDA’s request for information and a proposal to mitigate this risk, FDA decided to maintain its clinical hold until it received a final preclinical study safety report, final results from certain clinical trials, and additional expert feedback and that Regulus anticipated providing additional information to FDA in the fourth quarter of 2017. On June 12, 2017, Regulus announced it would discontinue development of the RG-101. Over the alleged class period, Regulus’ stock price decreased approximately 78% from \$5.01 on June 27, 2016 to \$1.10 on June 12, 2017.

On January 31, 2017, investors brought a putative class action alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 on the grounds that Regulus misled investors about the safety of RG-101 by downplaying the potential connection between the drug and serious adverse events of liver toxicity and jaundice in two patients.

On September 5, 2019, the court dismissed the consolidated complaint, with leave to amend, holding that plaintiffs failed to plead both falsity and scienter. Plaintiffs attempted to plead each of these elements of securities fraud based on the company’s alleged possession of internal preclinical and nonclinical results that plaintiffs claimed should have alerted defendants to a stronger link between the drug and liver toxicity than what they publicly disclosed. But the court held that in view of plaintiffs’ “vague and impressionistic” claims, it was “unable to determine whether the complained-of statements differed materially from the actual state of affairs that existed at the time they were made and whether a reasonable investor would have considered the disclosure of such results to significantly alter the total mix of information made available.” With respect to scienter, the court likewise held that alleged internal reports were “too vague and impressionistic to provide any indication of conscious misconduct or deliberate recklessness.” Plaintiffs’ other scienter allegations—routine business objectives and the CEO’s resignation—also did not give rise to the requisite strong inference of intent because the complaint did not include specific facts to tie these allegations to the alleged misstatements.

Plaintiffs filed their first amended complaint on October 1, 2019, but the parties reached a settlement soon thereafter which is pending court approval.

Lu v. Align Technology, Inc., et al., Case No. 5:18-cv-06720, 2019 WL 5579520 (N.D. Cal.) – Impact of Discounts on Future Financial Results

Align Technology, Inc. (“Align”) is a medical device company that designs, manufactures and sells Invisalign clear dental aligners and iTero 3D digital scanners for use in orthodontic treatment. The company owned a virtual monopoly over the clear aligner market until 2017 when its patents began to expire. As the company’s patents began to expire, competition from new industry players exerted pressure on the company’s revenue. Between April 2018 and September 2018, the company made a number of statements concerning industry competition and significantly increased promotional and marketing efforts. On October 24, 2018, the company informed investors of a drop in average sales price figures of approximately \$85, which it attributed to a combination of promotional programs, unfavorable

exchange and product mix, and “partially offset by price increases across all regions.” The next day, the company’s stock price declined by approximately \$58 a share or nearly 20%.

A putative investor filed a securities class action complaint against Align and its officers, alleging violations of Sections 10(b) and 20(a), and Rule 10b-5 of the 1934 Act on the grounds that defendants made false and misleading statements and/or omissions concerning industry competition. Plaintiff cited significant changes to the company’s promotional and marketing strategy to support its contention that the company knew, but intentionally “down-played,” the competitor’s impact on sales.

On October 29, 2019, the court dismissed the consolidated amended complaint, with leave to amend, because the complaint failed to identify any false or misleading statements or adequately plead scienter (fraudulent intent). As an initial matter, the court could not discern which specific statements plaintiff contended to be false or misleading, noting that plaintiffs conceded that many of the alleged misstatements were nonactionable forward-looking statements or were included in the complaint “only for context.”

The court also found that plaintiff repeatedly drew “unwarranted conclusions” from selective portions of defendants’ statements and concluded statements were false without explanation while ignoring the actual content or context of the statements.

The court also found that plaintiff repeatedly drew “unwarranted conclusions” from selective portions of defendants’ statements and concluded statements were false without explanation while ignoring the actual content or context of the statements. Lastly, plaintiff failed to show that the company was impacted by the industry competition because it failed to address how other factors, such as an unfavorable foreign exchange rate and global price increases, may have explained the decrease.

With respect to scienter, the court held that plaintiff’s reliance on former employee statements did not give rise to any inference of scienter because they bore no connection to the allegedly false or misleading nature of defendants’ statements. Relatedly, the court held that plaintiff failed to plead with particularity what specific data defendants had that would raise an inference of scienter and defendants’ stock sales likewise did not establish scienter because nothing about the timing of the sales was suspicious.

Plaintiffs filed an amended complaint on November 29, 2019, and defendants again moved to dismiss on January 17, 2020. The hearing on this motion to dismiss is scheduled for May 28, 2020.

Oklahoma Police Pension and Retirement System v. Nevro Corp. et al., Case No. 3:18-cv-05181 (N.D. Cal. Aug. 1, 2019) – Intellectual Property Rights

Nevro Corporation (“Nevro”) is a medical device company that designs, develops, and manufactures treatments for patients suffering from debilitating chronic pain. Nevro’s principal products are its HF10 therapies delivered by Nevro’s Senza systems. On February 22, 2018, Nevro filed its 2017 Form 10-K, which (consistent with the company’s prior Form 10-K’s and 2014 IPO offering documents) stated that its Senza systems were “novel and proprietary.” During an investor call on the same day, Nevro’s CEO described the company’s positive financial results. In April 2018, Boston Scientific Corporation (“BSC”) filed an action against Nevro, asserting claims for patent infringement, usurpation of trade secrets, and tortious interference with contract related to the Senza systems (“BSC Litigation”). In May 2018, Nevro reported a 31% year-over-year increase in quarterly operating expenses, attributed largely to legal expenses associated with BSC Litigation. Nevro’s stock price declined by approximately 16%.

On August 23, 2018, an alleged investor filed a securities class action complaint against Nevro and its officers, alleging violations of Section 10(b) and 20(a), and Rule 10b-5 of the 1934 Act, based on defendants’ alleged failure to disclose that Nevro had improperly used confidential and proprietary trade secrets and stolen documents to develop its Senza systems.

On August 1, 2019, the court dismissed the amended complaint, with leave to amend, on the grounds that plaintiff failed to allege a materially false or misleading statement or scienter, and noted that the complaint was also likely deficient as to loss causation. The court explained that even assuming that some of Nevro’s statements about its competitive advantage and about the proprietary nature of the Senza technology were not puffery, it does not follow from allegations in the BSC Litigation that some former BSC employees had taken confidential documents with them to Nevro, or from the trade secret claims made by BSC in the wake of that revelation, that Nevro’s technology enjoyed no intellectual property protection. It further held that attorney emails and letters revealing the fact that former BSC employees took documents was not equivalent to knowledge that Nevro lacked a proprietary interest in Senza or its high frequency technology and thus was insufficient to allege scienter.

On August 15, 2019, plaintiff filed a notice of its intent not to amend its complaint, and on August 23, 2019, the court entered judgment in favor of defendants.

Evanston Police Pension Fund v. McKesson Corporation, No. 18-cv-06525-CRB, 2019 WL 5587311 (N.D. Cal. Oct. 30, 2019) – Anticompetitive Agreements

McKesson Corporation (“McKesson”) is a pharmaceutical wholesaler. McKesson’s wholesale activities include the resale of some generic drugs and it also manufactures certain generic drugs through its subsidiary, NorthStar Rx (“NorthStar”). In May 2019, 49 states’ Attorneys General filed a complaint (“State AG Complaint”) against multiple entities in the generic drug industry, but did not name McKesson as a defendant, alleging that the generics industry is “rife” with unlawful price-fixing and market allocation agreements. As prices of other companies’ generic drugs dropped, McKesson’s earnings declined. Between October 27, 2016 and January 25, 2017, there were three financial announcements concerning a drop in McKesson’s earnings, and two articles concerning the government investigations in Bloomberg and Reuters. Each of these disclosures allegedly was followed by a significant decrease in McKesson’s stock price of 22.67%, 4.59%, and 8.3%, respectively.

Plaintiffs brought a class action complaint against McKesson, its former CEO and its former CFO for concealing anticompetitive activity in the generic drug industry in violation of Sections 10(b) and 20(a), and Rule 10b-5 of the 1934 Act. Plaintiffs also alleged that the CEO violated Section 20A by selling stock while possessing material nonpublic information. Plaintiffs alleged that because the State AG Complaint alleged that certain generic drug manufacturers conspired to allocate the market for Doxy DR, a drug that McKesson distributed, McKesson “must have” entered into anticompetitive agreements. Plaintiffs also alleged that Northstar colluded to fix the price of other drugs. Plaintiffs further alleged that even if McKesson did not directly participate in anticompetitive conduct, it nonetheless made false and misleading statements that: (1) attributed its increased profitability to “supply disruption”; (2) advertised McKesson’s role as a negotiator for its purchasers; (3) characterized the generic drug market as competitive; (4) characterized NorthStar as a “growth driver”; (5) announced McKesson’s financial results; and (6) characterized McKesson’s earnings as de-risked. Defendants moved to dismiss plaintiffs’ complaint in its entirety.

On October 30, 2019, the court denied defendants’ motion to dismiss. The court first considered whether the statements at issue were false and misleading because of McKesson’s alleged participation in the price-fixing agreements. The court held that plaintiffs pled no direct evidence of McKesson’s participation in any anticompetitive agreement. The court also rejected plaintiffs’ allegations of circumstantial evidence, which only suggested agreements between other generic drug manufacturers, but did not involve McKesson and Northstar. Finally, the court held that plaintiffs failed to adequately allege that McKesson’s participation in anticompetitive agreements could be inferred through parallel conduct and other factors.

Having rejected claims based on McKesson’s alleged failure to disclose its purported involvement in anticompetitive conduct, the court considered whether McKesson’s statements may still be false and misleading because McKesson allegedly knew that the conspiracy in the generic drug market caused generics manufacturers allegedly to collusively increase prices. The court held that McKesson’s statements concerning its finan-

cial results were adequately alleged to be misleading because such statements put the source of McKesson’s profits at issue and did not disclose the illegal activity that affected those profits. Similarly, McKesson’s statements characterizing the generics market as “competitive” were adequately alleged to be misleading based on plaintiffs’ allegations that McKesson knew that the generics market was not competitive. By contrast, the court held that McKesson’s statements concerning its role as a “negotiator” were not misleading because they described the value that McKesson added, and were not necessarily a guarantee that McKesson would obtain the best prices for its customers. Likewise, McKesson’s statements concerning NorthStar as a “growth vehicle,” and other statements attributing NorthStar’s success to legitimate causes, also were not misleading because plaintiffs failed to plead facts establishing that NorthStar was involved in any collusive activity. Finally, the statements concerning McKesson’s de-risked earnings were forward-looking statements accompanied by meaningful cautionary language that were protected by the PSLRA’s safe harbor, given plaintiffs’ failure to allege facts establishing that McKesson made those statements with knowledge of their actual falsity.

The court also held that plaintiffs’ allegations, as a whole, established that McKesson’s CEO’s and CFO’s scienter could be presumed given their admitted knowledge of the generic drugs market and high-level positions, the widespread nature of the anticompetitive conduct, and its significance to McKesson’s earnings. The court also held that plaintiffs’ detailed allegations identifying the CEO’s and CFO’s compensation, including from stock and cash awards, establishing a “strong correlation” between their incentive compensation and company’s financial results, supported an inference of scienter.

Finally, the court held that the same evidence that supported the inference of scienter also supported plaintiffs’ Section 20A claim that the CEO sold his shares of McKesson stock while in possession of material nonpublic information.

Discovery has commenced and the parties filed a joint case management statement on January 3, 2020.

New York Hotel Trades Council & Hotel Association of New York City, Inc. Pension Fund v. Impax Laboratories Inc., No. 16-cv-06557-HSG, 2019 WL 3779262 (N.D. Cal. Aug. 12, 2019) – Anticompetitive conduct concerning generics

Impax Laboratories Inc. (“Impax”) is a pharmaceutical company that develops, manufactures and distributes generic and brand name drugs. In November 2013, Impax allegedly entered into anticompetitive agreements with its competitors to fix the prices for two of its generic drugs, digoxin and pyridostigmine bromide. Impax stated thereafter that the market for generic drugs was highly competitive, and disclosed Impax’s sales figures and financial performance without disclosing its purported anticompetitive conduct that allegedly inflated those numbers. Impax disclosed in May 2015 that it had received a grand jury subpoena from the DOJ concerning four generic drugs. In 2016, Impax made statements concerning two of its drugs: diclofenac sodium gel 3% (“diclofenac”) and budesonide. As to diclofenac, Impax: (1) stated in May 2016 that it was reaffirming optimistic revenue guidance based in part on “higher sales” of diclofenac; (2) stated between May and June 2016 that Impax had “defended share,” which later fell precipitously; and (3) allegedly failed to disclose a \$15 million shelf-stock adjustment related to diclofenac. As to budesonide, Impax had acquired that drug and other drugs from a competitor, and ascribed a particular valuation to the acquisition at a time when the budesonide market was experiencing increased competition and price erosion.

Plaintiffs filed a class action against Impax and its officers, asserting claims under Sections 10(b) and 20(a) of the 1934 Act, and Rule 10b-5. On September 7, 2018, the district court dismissed plaintiffs’ first amended complaint, with leave to amend, for failure to plead scienter and loss causation with respect to plaintiffs’ price fixing allegations, and failure to allege falsity and scienter with respect to price erosion allegations. Plaintiffs filed a second amended complaint and defendants again moved to dismiss.

On August 12, 2019, the court dismissed the second amended complaint with prejudice. As to plaintiffs’ price-fixing allegations, the court held that plaintiffs had failed to plead loss causation, reaffirming the Ninth Circuit’s holding in *Loos v. Immersion Corp.*, 762 F.3d 880

(9th Cir. 2014) that “the mere existence of a regulatory investigation is insufficient to show cognizable fraud,” and finding that plaintiffs failed to identify any corrective disclosure linked to a decrease in Impax’s stock price.

The court next held that plaintiffs failed to plead falsity with respect to defendants’ statements concerning diclofenac. In particular, the court held that defendants’ revenue guidance-related statements were forward-looking and cabined with meaningful cautionary language, and that instead of alleging facts establishing that defendants knew such guidance statements were false as required to take such statements outside the protection of the PSLRA’s safe harbor, plaintiffs only alleged that defendants’ guidance was “unreasonable based on past performance,” which was inadequate. The court further held that defendants’ optimistic and general statements about “defending share” in the diclofenac market were non-actionable puffery, and that plaintiffs failed to adequately allege that Impax had a duty to disclose the \$15 million diclofenac-related shelf-stock adjustment. The court also dismissed plaintiffs’ claims based on budesonide-related statements, holding that plaintiffs alleged no facts establishing that defendants’ initial valuation of the budesonide acquisition were objectively or subjectively false. Likewise, the court held that plaintiffs failed to allege facts establishing that any defendant knew that the acquisition was overpriced yet pursued it anyway. In view of plaintiffs’ failure to cure the pleading deficiencies that the court had identified when dismissing plaintiffs’ first amended complaint, the court dismissed the second amended complaint with prejudice.

On September 5, 2019, plaintiffs appealed the district court’s dismissal of their complaint to the Ninth Circuit.

In re Obalon Therapeutics, Inc., No. 3:18-cv-0352-AJB-WVG, 2019 WL 4729461 (S.D. Cal. Sept. 25, 2019) – Declining sales to new customers and revenue recognition correction

Obalon Therapeutics, Inc. (“Obalon”) is a medical device manufacturer with a single product, the Obalon balloon system, which is an intragastric balloon that helps patients with weight loss by simulating a feeling of fullness.

In connection with Obalon’s October 12, 2016 IPO, Obalon disclosed information about the Obalon balloon and the Six-Month Adjunctive Weight Reduction Therapy (“SMART”) trial, which was conducted to assess the safety and efficacy of the balloon. In particular, Obalon stated that, in comparison to its competitors, the Obalon balloon had “ease of placement,” “favorable safety profile,” and “simple and convenient placement.” Obalon also disclosed that: (1) “90.8% of patients who received the Obalon balloon system experienced an event that [] FDA classifies as an adverse device event”; (2) Obalon patients on average lost 15.1 pounds in a six-month period; and (3) “7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached despite success swallowing a placebo that did not have a catheter attached.”

On June 21, 2017, a short-seller, Northland Securities, Inc., published a report (“the Northland Report”) that challenged Obalon’s disclosures as they related to the ease of placement, safety, and effectiveness of the Obalon balloon. After the release of the Northland Report, Obalon’s stock price dropped from \$10.96 per share to \$10.12 per share. Thereafter, between October 1 and December 29, 2017, Obalon ran a holiday promotion that resulted in strong Q4 2017 sales. Subsequently, on January 16, 2018, Obalon announced a secondary offering of \$35 million, after which Obalon’s stock price fell from \$7.93 to \$5.24 per share.

On January 23, 2018, Obalon disclosed that a whistleblower lodged a complaint with the company’s independent auditors concerning alleged “improper revenue recognition during the Company’s fourth fiscal quarter of 2017,” and Obalon cancelled its planned secondary offering. Obalon’s stock price dropped 33%, from \$5.19 to \$3.46 per share. On February 20, 2018, Obalon announced that it had investigated the whistleblower’s allegations, and found that they had no merit. On March 5, 2018, Obalon filed its 10-K for 2017 with a correction that deferred \$147,000 of revenue from Q4 2017 to 2018. Then, on May 10, 2018, Obalon announced its Q1 2018 earnings, which were the lowest for any quarter in the company’s history. Following this announcement, Obalon’s stock price fell 34%, from \$4.32 to \$2.85 per share.

On February 14, 2018, plaintiffs filed a class action complaint against Obalon and certain of its executives, as well as the underwriters of Obalon’s IPO, alleging vi-

olations of Sections 10(b) and 20(a) of the 1934 Act, and Rule 10b-5, and Section 11 of the 1933 Act. Defendants moved to dismiss. With respect to the 1934 Act claims, plaintiffs alleged that defendants misrepresented the ease of use, safety and effectiveness of the Obalon balloon, and Obalon’s financial condition, and concealed certain GAAP violations.

On September 25, 2019, the court granted the underwriter defendants’ motion to dismiss with prejudice, and granted the remaining defendants’ motion to dismiss in part and denied it in part. The court held that statements describing the Obalon balloon as “easy to place” and “simple and convenient” were statements of corporate optimism and puffery that were not actionable. The court also held that plaintiffs failed to plead any actionable omission of adverse facts concerning the safety of the Obalon balloon given that such facts actually were disclosed, including that “90.8% of patients who received the Obalon balloon system experienced an event that the FDA classifies as an adverse device event.”

However, the court held that plaintiffs alleged facts sufficient to establish for pleading purposes that Obalon’s disclosures concerning its financial condition were materially false and misleading. In particular, plaintiffs alleged that Obalon had made several statements concerning customers increasing reorder sales of the Obalon balloon, while omitting the fact that there were decreasing sales of starter kits and that the reorder sales were concentrated in a small group of customers. The court held that plaintiffs adequately alleged that this statement was misleading because the statement could give a reasonable investor the impression that sales were healthy and evenly distributed. The court also denied defendants’ motion to dismiss as to Obalon’s statements concerning alleged GAAP violations because it concluded that plaintiffs’ allegation that the company overstated its revenue by 5% in Q4 2017 and then corrected those numbers after whistleblower allegations was sufficient to establish, at the pleading stage, that defendants could have concealed a revenue overstatement scheme.

The court also found that plaintiffs adequately had alleged that the individual defendants acted with scienter with respect to the financial condition statements based on the so-called “core operations” doctrine, because the Obalon balloon was the company’s only product

and the individual defendants represented that they “closely” monitored the company’s financial condition. Moreover, the court held that scienter was sufficiently alleged with respect to defendants’ alleged concealment of GAAP violations because the company’s alleged use of its favorable Q4 2017 financials to buoy its secondary offering, coupled with the close-in-time whistleblower allegations concerning defendants’ improper revenue recognition, suggested that defendants were aware of the alleged GAAP violations while disclosing their financials.

The court further held that plaintiffs adequately alleged loss causation by asserting that the disclosure of the whistleblower allegations, the cancelling of the company’s secondary offering, and the disclosure of Obalon’s unfavorable Q1 2018 financials were corrective disclosures that caused subsequent stock price drops and losses for investors.

Finally, the court dismissed plaintiffs’ Section 11 claims against all defendants, including the underwriter defendants, as time-barred under the one-year statute of limitations set forth in Section 13 of the 1933 Act (which provides not only a one-year statute of limitations that triggers upon actual or constructive discovery of allegedly untrue statements, but also a three-year statute of repose that provides an absolute bar against 1933 Act claims related to misstatements or omissions made more than three years in the past). The court concluded that the Section 11 claims were not filed within one year of the time that plaintiffs discovered, or should have discovered based on the exercise of reasonable diligence, the allegedly untrue statements. According to the court, plaintiffs should have discovered the facts underlying their claims upon publication of the Northland Report that was published in June 2017 (more than one year before plaintiffs filed their lawsuit), which first revealed the issues that patients had experienced with the Obalon balloon.

On October 25, 2019, defendants answered the complaint. A case management conference has been scheduled for March 3, 2020. In the meantime, the parties have agreed to privately mediate the dispute.

Khoja v. Orexigen Therapeutics, Inc., No. 15-CV-540 JLS (JLB), 2019 WL 4599882 (S.D. Cal. Sept. 23, 2019) – Terminated clinical trial

Orexigen Therapeutics, Inc. (“Orexigen”) is a biotechnology company focused on the development of pharmaceuticals used in the treatment of obesity. Its primary treatment candidate is Contrave, which is designed to treat patients who are both obese and at high risk for major adverse cardiovascular events (“MACE”). Orexigen conducted a study testing the cardiovascular risks associated with Contrave (the “Light Study”). In order to obtain FDA approval, the Light Study’s interim results needed to show that Contrave did not increase the risk of MACE by 40% or more. In November 2013, the interim results of the Light Study showed that Contrave reduced MACE by 41%. Orexigen agreed not to share the interim results beyond a core group pursuant to a data access plan (“DAP”). At around the same time, Orexigen filed a patent application (the “’810 Application”) with the USPTO to cover a new cardiovascular benefit of Contrave based on the Light Study, and consistent with the DAP, Orexigen requested that the ‘810 Application be kept confidential.

On September 10, 2014, FDA approved Contrave for commercial use and, in December 2014, the advisory committee for the European Medicines Agency adopted a positive opinion for Contrave and recommended that it be granted centralized marketing authorization. On January 5, 2015, Orexigen removed its confidentiality request concerning the ‘810 Application. On March 3, 2015, the USPTO issued U.S. Patent No. 8,969,371 (“’371 Patent”) from the ‘810 Application, and Orexigen filed an 8-K the same day to announce the ‘371 Patent and the interim results from the Light Study. The 8-K stated that the ‘371 Patent “incorporate[d] data from [the Light Study],” and “contain[ed] claims related to a positive effect of Contrave on [cardiovascular] outcomes.” Two days later, on March 5, 2015, Forbes published a news article reporting that “[t]here is widespread speculation that Orexigen used the excuse of the patent filing to reveal the interim results of the trial.” FDA also criticized the released data as “unreliable,” “misleading” and “likely false,” and stated that Orexigen could face regulatory penalties for its actions. On this news, Orexigen’s stock price dropped from \$8.01 to \$7.10.

On March 26, 2015, further results from the Light Study showed that the cardiovascular benefits seen in the interim results were not replicated when the sample size increased, and the study was terminated. Orexigen then refused to authorize a draft press release prepared by the Light Study monitoring committee that would have announced the study’s termination. Instead, on May 8, 2015, Orexigen filed an 8-K with its financial results from Q1 2015, and a 10-Q noting that its share price may be affected by “announcements regarding [its] clinical trials.” That same day, Orexigen held an earnings call where its executives represented that the “Light Study is continuing” and “if there was a decision to terminate the [Light Study,] that would be a disclosure that we would make.” On May 12, 2015, Orexigen announced the termination of the Light Study, but did not disclose its results. Shortly thereafter, the committee conducting the Light Study published the study’s results, which showed that Contrave did not have any statistically significant cardiovascular benefits. On this news, Orexigen’s stock price fell 25%, from \$6.75 to \$5.02.

Investors filed a putative class action complaint alleging violations of Sections 10(b) and 20(a) of the 1934 Act, and Rule 10b-5, against the company and its officers. Defendants moved to dismiss, and the court, considering only the elements of falsity and materiality, dismissed plaintiffs’ complaint, with leave to amend. Plaintiffs appealed, and the Ninth Circuit affirmed in part and reversed in part the district court’s dismissal order. In particular, the Ninth Circuit held that plaintiffs plausibly alleged that: (1) Orexigen’s March 3, 2015 8-K was materially false because it failed to disclose that the Light Study’s interim results were unreliable, and that Orexigen had asked that the USPTO publish its patent containing these results; and (2) defendants’ statements on May 8, 2015 were materially misleading because they represented that the Light Study was ongoing and failed to disclose the then-known findings that Contrave did not have any statistically significant cardiovascular benefits. Upon remand back to the district court, plaintiffs did not amend their complaint. Defendants moved to dismiss on the basis that plaintiffs failed to plead scienter (fraudulent intent) and loss causation.

The district court held that plaintiffs sufficiently alleged scienter with respect to the March 3, 2015 statements of Orexigen’s CEO and Head of Global Development, but not as to Orexigen’s CFO’s March 3, 2015 state-

ments. The court held that the CEO and Head of Global Development both had allegedly participated in a June 2014 meeting with FDA where FDA reminded them that the interim results have “a high degree of uncertainty,” such that they had a duty to disclose that the results were unreliable once they decided to publish their positive implications. The CFO, by contrast, did not attend the June 2014 meeting, and had no contact with FDA, so the court held that it was unclear whether he knew about the potential unreliability of the interim results. The court also held that plaintiffs adequately alleged scienter with respect to the May 8, 2015 statements as to all defendants because all defendants knew that the Light Study had been terminated, yet still represented that it was continuing. The court also held that all defendants had a duty to disclose the final Light Study results, having previously relied on the interim positive results.

The court also held that plaintiffs adequately alleged loss causation based on their allegation that the March 5, 2015 Forbes article was a corrective disclosure that revealed an aspect of fraud to the market, namely that Orexigen could face regulatory penalties for its actions. By contrast, the court held, the May 12, 2015 press release was not a corrective disclosure because it did not reveal any new information about the unreliability of the Light Study interim results or Orexigen’s filing of the ‘371 Patent that was not previously revealed.

On October 17, 2019, plaintiffs filed an amended complaint to explicitly identify the May 12, 2015 press release as a corrective disclosure. On November 15, 2019, defendants filed a motion to dismiss the amended complaint. Briefing on the motion to dismiss is complete, and the court has taken the matter under submission without oral argument.

In re Restoration Robotics, Inc. Securities Litigation, No. 5:18-CV-03712-EJD, 2019 WL 5295059 (N.D. Cal. Oct. 18, 2019) – Product defect and declining product use-related revenue

Restoration Robotics, Inc. (“RR”) is a medical technology company that develops and commercializes a robotic device, the ARTAS System, which assists physicians in performing follicular unit extraction surgery, a type of hair restoration procedure. RR generates its revenue from the sale of ARTAS Systems, on per-follicle and per-procedure bases, and from various service

and support fees. RR conducted an IPO in September 2017 at a price of \$7.00 per share. Thereafter, when RR announced its Q1 2018 earnings on May 14, 2018, RR reported a decline in revenue quarter-over quarter, from \$5.5 million to \$5.0 million. On this news, RR’s stock price fell by 14.42%. Later, on November 5, 2018, RR announced its Q3 2018 earnings, reporting a decline in its procedure-based revenue. On this news, RR’s share price fell to \$1.13 per share, reflecting an 86% decrease from the company’s IPO price.

Investors filed a putative class action against RR, its executives, venture capital investors, and RR’s IPO underwriters, asserting non-fraud claims under Sections 11 and 15 of the 1933 Act, based on allegedly material misstatements and omissions in RR’s IPO offering documents, including material adverse trends that plaintiffs alleged were required to be disclosed under Item 303 of Regulation S-K. Generally, the misstatements and omissions that plaintiffs identified related to RR’s collaboration with physicians, its belief in increasing procedure-based revenues, its sales of the ARTAS System, the ARTAS System’s quality and design, and the number of ARTAS Systems installed. RR and its executives moved to dismiss for failure to state a claim.

On October 18, 2019, the court granted defendants’ motion to dismiss in part and denied the motion in part. First, the district court held that several statements that plaintiffs challenged were non-actionable “puffery” and/or forward-looking statements protected by the PSLRA’s safe harbor, including statements concerning defendants’ “belief[f]” that they could “help” customers, their goal to “expand the commercialization of the ARTAS System,” and their “inten[t]” to work with and support customers.

The district court next held that plaintiffs failed to allege any facts establishing that several other generic statements, which accurately described the company’s business and strategy, were materially false or misleading. In particular, the court concluded that defendants’ statement that they “sell the ARTAS System” could not be misleading where plaintiffs themselves had alleged that defendants sold the ARTAS Systems. Likewise, the court concluded that RR’s statement that the ARTAS System “allow[s] physicians to perform hair restoration procedures with fewer staff” was true, given that traditional hair-restoration procedures require a team of “between four and eight technicians,” whereas an

ARTAS System procedure requires “at least four” technicians, which the court concluded was “‘fewer’ than eight.”

By contrast, the district court held that plaintiffs adequately had alleged that certain other statements that defendants made were false or materially misleading. First, the court held that plaintiffs adequately alleged falsity with respect to RR’s statement the ARTAS System’s needle’s speed “provides targeted precision and a cleanly scored incision” on patients. In so holding, the district court credited plaintiffs’ allegations that a confidential witness had stated that RR’s physician customers were abandoning the ARTAS System because the System’s needles “suffered from a material defect” that caused the System not to provide targeted precision or a cleanly scored incision on patients. The court also held that plaintiffs adequately alleged falsity with respect to RR’s statement that in 2016, RR had “sold 27 additional systems representing an aggregate installed base growth of approximately 34% from December 31, 2015, or 174 to 233 systems.” Specifically, the court held that plaintiffs had alleged facts sufficient to establish for pleading purposes that this statement was materially misleading, given plaintiffs’ allegations that a significant portion of ARTAS Systems “sold” internationally were not, in fact, “installed” and thus would not yield procedure-based revenue.

Notably, the court concluded that plaintiffs failed to adequately allege that defendants violated Item 303 based on the omission in the IPO offering documents that: (1) RR’s overseas distributors were bulk-purchasing and then warehousing ARTAS Systems before the IPO; (2) physicians were discontinuing use of the ARTAS System in light of their allegedly widespread discontent with the product; and relatedly (3) sales of ARTAS Systems were stalling leading up to the IPO. With respect to distributors’ alleged pre-IPO warehousing of ARTAS Systems, the court found no Item 303 violation pleaded, as plaintiffs alleged only one instance of this practice, rather than an “observed pattern that accurately reflects persistent conditions of the particular registrant’s business.” The court also held that plaintiffs alleged no facts establishing that any defendant knew at the time of the IPO of a trend that physicians were discontinuing use of the ARTAS Systems. Finally, the district court held that plaintiffs alleged no facts establishing that physicians were stalling purchases leading up to the IPO and, in

fact, sales actually were increasing leading up to the IPO. Moreover, the district court held that plaintiffs’ confidential witness account regarding an RR executive’s alleged concern about a continued decline in sales seven months after the IPO was inadequate to plead that any defendants knew that physicians were stalling purchases before the IPO.

The case now is proceeding into discovery based on the claims that the district court declined to dismiss. Defendants answered the complaint on December 9, 2019, and summary judgment motions are due to be filed by October 8, 2021.

Paciga v. Invuity, Inc., Case No. C 17-01005 JSW, 2018 WL 7286503 (N.D. Cal. Aug. 12, 2019) – Missed and Revised Guidance

nvuity, Inc. (“Invuity”) is a medical technology company that develops, markets, and sells single-use and reusable medical technology for use during surgery. In 2016, Invuity announced a two-pronged strategy to generate compounding growth: first, adding new customers through pre-existing connections to medical facilities, and second, going “deeper” by expanding to additional specialties within an existing hospital customer. On February 24, 2016, defendants represented during a quarterly earnings call that Invuity was “successfully going deeper into accounts,” that they expected “seasonality” with “the first quarter being the most difficult and the fourth quarter being the strongest,” and that their business model provided both predictability and profitability. In subsequent quarterly earnings calls, the company reiterated that the two-pronged strategy for growth was going as planned.

On November 3, 2016, Invuity reported lower revenue than expected for the third quarter 2016, reduced its full year 2016 guidance, and presented 2017 guidance that was below analyst expectations. The company attributed the shortfall to lower than anticipated revenue per active account and difficulties “going deeper” with existing accounts as the company added new accounts. It further stated that most of its growth was in its breast division and while “we do see little bit of seasonality” it probably is “not that dramatic uptick that maybe some people [who] are solely focused on spine and ortho [divisions] would see.” The next day, Invuity’s stock dropped approximately \$4 per share, or nearly 45%.

Plaintiff filed a second amended complaint on October 26, 2018. On February 27, 2017, an investor filed a putative class action lawsuit against Invuity and two of its executives, alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 thereunder. Plaintiff claimed that defendants (a) made false and/or misleading statements that Invuity could achieve compounding growth because defendants failed to disclose the existence of a “step-back” pattern (a dip in sales between a new customer’s first and second purchase), (b) misrepresented the impact of seasonality, and (c) misled investors through its 2016 revenue guidance.

On September 26, 2018, the court dismissed the first amended complaint, with leave to amend. On August 12, 2019, the court dismissed plaintiff’s operative complaint, for a second time, with leave to amend, holding that plaintiff failed to plead falsity and scienter. First, the court found that plaintiff failed to allege falsity because the existence of a step-back pattern was not inconsistent with defendants’ disclosed plan to sell more in depth to existing customers and defendants did disclose the existence of the step-back pattern and did increase sales to existing customers. It held further that statements regarding seasonality were accurate. Lastly, it noted that plaintiff changed his theory that the 2016 guidance was misleading after the prior dismissal to now contend that representations about the quality of Invuity’s data and defendants’ ability to use that data accurately to predict profitability were materially false when made, which was similarly deficient. The court reasoned that the amended complaint did not specifically identify any statement made by defendants regarding the magnitude or scale of Invuity’s growth plan and, with specific 2016 revenue guidance figures omitted from the claims of misrepresentations, there was no specific allegation of false representations in the statements actually made by defendants. It also rejected, for a second time, plaintiff’s repeated allegations that the company’s offers of incentives or special deals artificially inflated Invuity’s actual sales numbers for its single-use products.

The court held that plaintiff failed allege scienter, explaining that plaintiff offered only confidential witness allegations that the individual defendants attended regular meetings and had access to financial forecast reports. The court deemed these allegations insufficient because plaintiff failed to identify specific negative information that the speakers learned from those

meetings or reports about Invuity’s sales data or temporary dip in sales which was sufficiently troubling that they must have known that the company was going to be unable in the long term to go deeper with existing customers.

On September 12, 2019, plaintiff filed his third amended complaint which is substantially the same as the complaint dismissed by the court one month prior except that it adds information regarding the confidential witnesses and adds a new confidential witness. Defendants moved to dismiss this complaint on October 22, 2019, which is now fully briefed and set for hearing on February 7, 2020.

2020 CASES TO WATCH

Zaidi v. Adamas Pharmaceuticals, Inc., Case No. 4:19-cv-08051 (N.D. Cal.) – Commercialization and Insurance Coverage for Pharmaceutical Drug

Adamas Pharmaceuticals, Inc. (“Adamas”) is a pharmaceutical company that develops drug treatments for chronic neurological disorders. Its primary drug is GOCOVRI, which has been approved by FDA to treat levodopa-induced dyskinesia. From August 2017 to November 2018, Adamas and its executives allegedly made various representations concerning the adoption of GOCOVRI by physicians, insurance coverage for GOCOVRI, and the market share that GOCOVRI is expected to attain. In reality, plaintiffs allege that GOCOVRI did not become the go-to drug for physicians due to its high price and lack of insurance coverage, insurers were excluding GOCOVRI from prescription formularies or requiring patients to use “step therapy” prior to covering GOCOVRI, and there was impending competition from other pharmaceutical companies.

On October 5, 2018, a Bank of America/Merrill Lynch analyst downgraded its rating of Adamas, highlighting the drop rate of doctors using GOCOVRI and its lack of insurance coverage. That day, Adamas’s stock prices fell 8%. Then, on March 4, 2019, during Adamas’s Q4 2018 conference call, it lowered its growth estimates for GOCOVRI, warned that there would be a continued slow-down in prescriptions and declined to make any additional predictions on market share. Following the call, Adamas’s stock price fell 32.84%. Finally, on

September 30, 2019, a Bank of America/Merrill Lynch analyst downgraded Adamas’s rating to “underperform” because of “reimbursement hurdles” with GOCOVRI. Subsequently, Adamas’s stock price fell 42.83%.

On December 10, 2019, investors filed a putative class action lawsuit against Adamas and its executives alleging violations of Sections 10(b) and 20(a) of the 1934 Act based on alleged false and misleading statements concerning GOCOVRI’s insurance coverage and commercialization potential. The statutory lead plaintiff process is underway, with a hearing on lead plaintiff motions scheduled for March 27, 2020.

Bucks County Employees Retirement Fund v. Merit Medical Systems, Inc., Case No. 8:19-cv-02326 (C.D. Cal.) – Acquisition and Integration of Companies

Merit Medical Systems, Inc. (“Merit”) is a manufacturer and marketer of medical devices used in interventional, diagnostic and therapeutic procedures. In 2018, Merit acquired three other companies in the pharmaceutical and medical devices space. On February 21, 2018, Merit acquired Becton, Dickinson and Company for \$100 million. On November 13, 2018, Merit acquired Cianna Medical, Inc. (“Cianna”) for \$200 million, the company’s largest acquisition to date. On December 14, 2018, Merit acquired Vascular Insights, LLC (“Vascular Insights”) and its ClariVein product for \$60 million.

On February 26, 2019, Merit reported financials for the fourth quarter of 2018 and the fiscal year 2018. It forecasted significant revenue growth for 2019 and 2020 due to its recent acquisitions. On April 23, 2019, Merit reported financials for the first quarter of 2019. Merit’s CFO told investors that “[t]he Cianna transition is complete and sales continue to grow according to our expectations” and reiterated its 2019 and 2020 revenue forecasts. However, Merit and its executives allegedly failed to disclose that the integration of Cianna and Vascular Insights were delayed and resulted in operational disruptions and delayed sales. On July 25, 2019, Merit reported its second quarter 2019 financials, which missed analyst consensus estimates. As a result, Merit reduced its 2019 guidance which it attributed to “short term” issues like “slower anticipated conversion and

uptake of acquired products.” Following this announcement, Merit’s stock price fell more than 25%, from \$54.84 per share to \$41.00 per share. Subsequently, on October 30, 2019, Merit announced its third quarter 2019 financial results, which were once again below analyst estimates. Merit also reduced revenue guidance for 2019 by 20% and disclosed that there were significant issues such as delays in the integration of the acquired companies and a reduction in headcount to offset the costs of integration. That same day, Merit’s stock price fell more than 29%, from \$29.11 per share to \$20.66 per share.

On December 3, 2019, an investor filed a putative class action lawsuit against Merit and two of its executives alleging violations of Sections 10(b) and 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder on the grounds that defendants made various misrepresentations concerning the impact that the acquisitions had on the company. Motions seeking the appointment of a lead plaintiff and lead counsel were filed on February 3, 2020, are scheduled to be heard on March 3, 3020.

Mulquin v. Nektar Therapeutics, et al., Case No. 4:18-cv-06607 (N.D. Cal.) – Short Seller Allegations concerning Safety and Efficacy

Nektar Therapeutics (“Nektar”) is a research-based biopharmaceutical company that discovers and develops innovative medicines, including treatments for cancer, autoimmune diseases, and chronic pain. Nektar developed the biologic NKTR-214, an immune-oncology candidate with biased signaling through one of the IL-2 receptor subunits that stimulates proliferation and growth of tumor-killing immune cells. IL-2 has a short half-life and is known to have unintended biologic consequences. NKTR-214 adds polyethylene glycol molecules to IL-2 (i.e., pegylation), which potentially extends the half-life and causes fewer side effects. In November 2017, Nektar issued a press release announcing the first presentation of data from the PIVOT-02 Phase ½ Study, which was designed to evaluate the combination

of Bristol-Myers Squibb’s (“BMS”) Opvido with NKT-214. The release reported that the initial findings from the study underscored the potential benefit of the combination. In March 2018, Nektar reported its financial results for the fourth quarter and year ended December 31, 2017, in which Nektar described its collaboration with BMS, and its plans to conduct clinical studies of NKTR-214 in a series of registration-enabling trials in more than 20 indications in nine tumor types. Nektar later announced in April 2018 that it had initiated dosing patients in a Phase 1/2 REVEAL clinical study evaluating the efficacy and safety of the combination of investigational medicines NKTR-262 and NKTR-214 in the treatment of solid tumors. On October 1, 2018, Plainview LLC, a short-seller, published a report stating that the core conceptual underpinnings of NKTR-214 have never worked in practice, that prior studies assessing pegylated IL-2 failed to establish positive results, that NKTR-214 resulted in a 0% objective response rate in the company’s studies, that in the PIVOT trial, NKTR-214 failed to sufficiently induce an increase in lymphocytes to trigger a successful clinical response, and that NKTR-214’s extended half-life does not improve its efficacy and created safety concerns. Following the release of the report, Nektar’s stock price fell by more than 9%.

An investor filed a securities class action complaint on October 20, 2018, alleging that Nektar and its officers violated Sections 10(b) and 20(a), of the 1934 Act and Rule 10b-5 thereunder, by making materially false and misleading statements and/or by failing to disclose that (i) prior studies which attempted to pegylate IL-2 failed; (ii) NKTR-214’s extended half-life was unlikely to result in efficacy and created additional safety concerns; (iii) NKTR-214 was less effective than IL-2 alone; and (iv) the combination of NKTR-214 with Opvido had not yet demonstrated significant positive results.

On March 15, 2019, the lead plaintiff filed its consolidated amended complaint. On August 2, 2019, defendants moved to dismiss the complaint, which is fully briefed and under submission.

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SECURITIES SNAPSHOT

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