2021 Year in Review

Securities Litigation Against Life Sciences Companies

GOODWIN

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Introduction – Summary of 2021 Trends, Themes, and Takeaways

We are proud to present our sixth annual Securities Litigation Year in Review publication, in which we analyze data for securities class actions filed nationally against publicly traded pharmaceutical, biotechnology, medical device and healthcare product and services companies (collectively referred to herein as "life sciences companies") and summarize important decisions issued by courts in 2021 in key jurisdictions in these cases. These cases are typically filed by shareholders, on behalf of a putative class, 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, suspensions or terminations, negative clinical data results, 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/or, if the alleged misstatements or omissions are made in connection with a registered securities offering, under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "1933 Act").

Securities Class Action Filings Across All Industries in 2021

For the first time in many years, in 2021, the number of new securities class action filings in federal and state courts dropped precipitously, falling from 333 actions in 2020 to **218 filings in 2021** — **a 35% drop** and below the 1997-2020 average of 228 actions.[1] This decline was largely due to a dramatic drop (82%) in M&A-related class action filings, but was also due to a 17% decline in federal "core" class action filings alleging Rule 10b-5 claims under the 1934 Act.[2] Given the enormous volume of special purpose acquisition company ("SPAC") initial public offerings and transactions over the last two or so years, "core" class action filings related to SPACs not surprisingly increased more than sixfold from 2020 to 2021.[3] As in 2020, there also were a significant number of class actions filings related to the COVID-19 pandemic in 2021 — *i.e.*, filings against companies that were particularly impacted by the pandemic or companies involved in the development of products (*e.g.*, therapeutics, vaccines, and testing products) to address COVID-19 — although the number of COVID-19-related cases dropped significantly in the second half of 2021.[4] After a substantial drop in 2020, the total number of 1933 Act filings in connection with registered offerings further declined slightly (3%) in 2021.[5] The majority of these 1933 Act filings — 62%, the highest percentage since 2014 and as compared to 37% in 2020[6] — were exclusively filed in federal courts, presumably due to exclusive federal forum selection provisions in corporate charters or bylaws many Delaware corporations have implemented requiring 1933 Act

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[1] Cornerstone Research, Securities Class Action Filings 2021 Year in Review (the "Cornerstone Report"), available at Securities Class Action Filings 2021 Year in Review (cornerstone.com).

[2] Cornerstone Report, at 1, 4.

[3] Cornerstone Report, at 1, 5.

[4] Cornerstone Report, at 2, 5.

[5] Cornerstone Report, at 4.

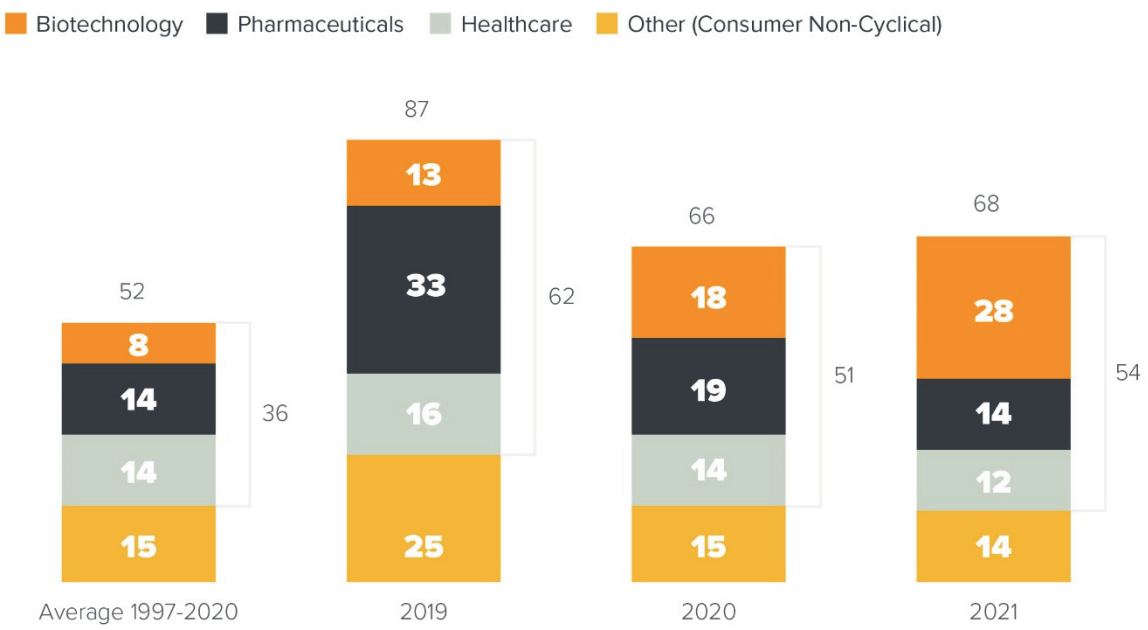
[6] Cornerstone Report, at 4.

claims against them to be filed in federal courts, the validity of which provisions have been upheld by the Delaware Supreme Court and various other state courts since March 2020.[7]

Securities Class Actions Filed Against Life Sciences Companies in 2021

While the overall number of cases across all industries declined substantially, the Consumer Non-Cyclical sector, primarily composed of life sciences companies, once again had by far the greatest number of securities class action filings in 2021 as compared to other sectors.[8] This is likely due to the inherently volatile nature of the stock prices of life sciences companies and the many event-driven disclosures made by such companies and, thus, the continued focus by the plaintiffs' bar on life sciences companies. As depicted in **Figure 1** below, the number of core federal filings against companies in the Consumer Non-Cyclical sector actually *increased* from 66 securities class actions in 2020 to 68 actions in 2021. Notably, cases against biotechnology companies jumped from 18 cases in 2020 to 28 cases in 2021.

Figure 1: Filings by Industry — Core Federal Filings

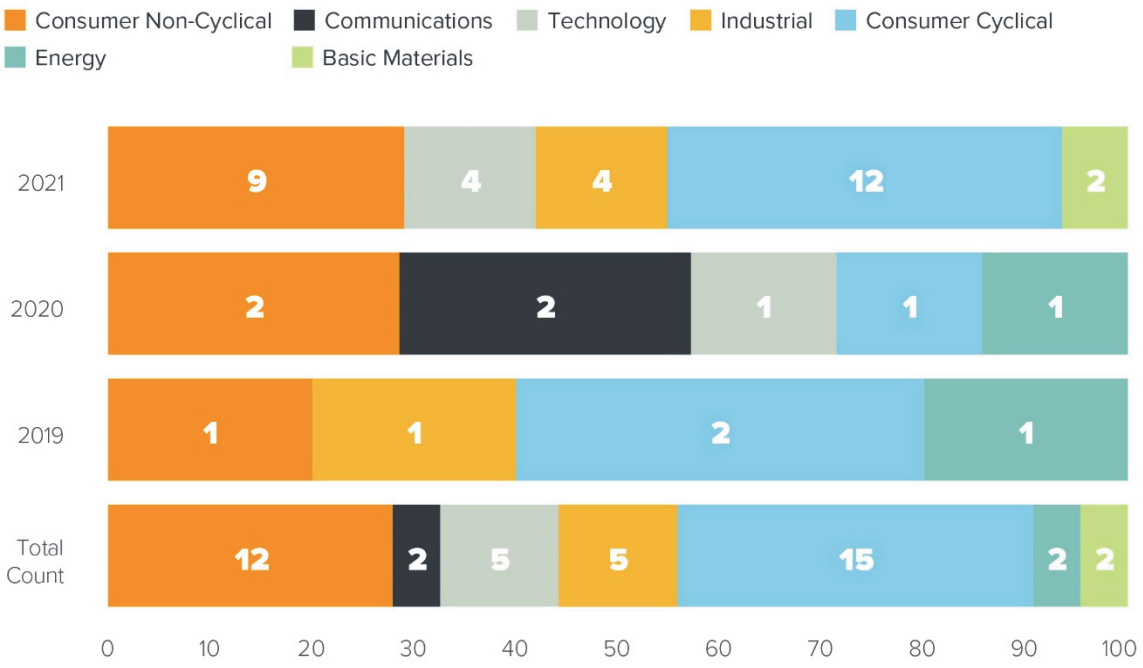


[7] *See e.g.*, *Salzberg v. Sciabacucchi*, 227 A.3d 102 (Del. 2020); *Wong v. Restoration Robotics, Inc.*, No. 18-CIV-02609 (Cal. Super. Ct. Sept. 1, 2020); *In re Uber Technologies, Inc. Securities Litigation*, No. CGC-19-579544 (Cal. Super. Ct. Nov. 16, 2020); *In re Dropbox, Inc. Securities Litigation*, No. 19-CIV-05089 (Cal. Super. Ct. Dec. 4, 2020); *In re Sonim Technologies Inc. Securities Litigation*, No. 19-CIV-05564 (Cal. Super. Ct. Dec. 7, 2020).

[8] *See* Cornerstone Report, at 29 (depicting 68 filings against companies in the Consumer Non-Cyclical industry, followed by 29 filings against companies in each of the Technology industry).

In addition, as depicted in **Figure 2**, the Consumer Non-Cyclical sector was the second most common sector targeted in federal SPAC-related class action filings in 2021 (second to Consumer Cyclical, which includes the automobile industry), with six total federal class actions filed against life sciences companies.[9] Given that many life sciences (particularly, biotechnology) companies are entering into transactions with SPACs, we expect this SPAC filing trend as to such companies to continue into 2022 and beyond.

Figure 2: Filings by Industry — All Federal SPAC Filings



[9] Cornerstone Report, at 6.

While life sciences companies continued to be a prominent target of the plaintiffs' bar in 2021, the percentage of cases filed in 2021 that were dismissed by year-end increased from 2020. Specifically, as detailed in **Figure 3**, 11.1% of federal core filings against life sciences companies were dismissed by December 31, 2021, as compared to a *de minimis* 1.9% year-end dismissal rate in 2020 (likely the result of COVID-19-related court closures and docket backups).

Year	Filings	Circuit					Case Status				
		1st	2nd	3rd	9th	Other	Percent Dismissed	Percent Settled	Percent Remanded	Percent Ongoing	Percent Trial
2005	32	5	4	4	3	16	56.3%	43.8%	0.0%	0.0%	0.0%
2006	25	0	5	3	3	14	44.0%	56.0%	0.0%	0.0%	0.0%
2007	29	0	11	2	7	9	58.6%	41.4%	0.0%	0.0%	0.0%
2008	25	5	5	2	2	11	40.0%	60.0%	0.0%	0.0%	0.0%
2009	22	1	1	2	11	7	36.4%	63.6%	0.0%	0.0%	0.0%
2010	33	3	7	2	15	6	45.5%	51.5%	3.0%	0.0%	0.0%
2011	21	0	5	0	6	10	57.1%	38.1%	4.8%	0.0%	0.0%
2012	28	2	5	5	5	11	57.1%	42.9%	0.0%	0.0%	0.0%
2013	34	2	10	5	11	6	41.2%	58.8%	0.0%	0.0%	0.0%
2014	38	3	8	11	11	5	52.6%	47.4%	0.0%	0.0%	0.0%
2015	42	6	4	5	18	9	52.4%	38.1%	7.1%	0.0%	2.4%
2016	65	5	22	8	20	10	44.6%	43.1%	1.5%	10.8%	0.0%
2017	65	7	17	15	13	13	60.0%	32.3%	3.1%	4.6%	0.0%
2018	56	3	15	11	15	12	51.8%	26.8%	0.0%	21.4%	0.0%
2019	62	3	23	12	11	13	41.9%	32.3%	0.0%	25.8%	0.0%
2020	51	1	12	9	21	8	33.3%	7.8%	0.0%	58.8%	0.0%
2021	54	1	13	8	20	12	11.1%	0.0%	0.0%	88.9%	0.0%
Average (1997–2020)	36	3	8	5	10	11	45.5%	45.7%	0.9%	7.8%	0.1%

As in past years, we have continued to focus our Year in Review on jurisdictions that are epicenters for life sciences companies and, thus, have been among the most active jurisdictions in the country for securities class actions filed against such companies: the First Circuit and District of Massachusetts; the Second Circuit and New York District Courts; and the Ninth Circuit and California District Courts. This year, we have also added the Third Circuit and the District of New Jersey to our Year in Review, given the life sciences activity in these jurisdictions. The Second and Ninth Circuits were particularly active in 2021, comprising 72% of all core federal class action filings (across all industries) in 2021, with filings in the Second Circuit increasing by 8% and filings in the Ninth Circuit decreasing by 26% as compared to 2020 filings.[10]

In 2020, federal courts in the jurisdictions of our focus 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 often face, including negative clinical trial results, enrollment issues and clinical trial delays, discussions with FDA, supply and manufacturing issues, drug side effects, adverse events and other safety issues, acquisition-related activity, and future growth prospects and revenue projections. We have highlighted and summarized a selection of key decisions in each of these jurisdictions below.

The decisions in these jurisdictions were a mixed bag in 2021. For example, of the decisions resolving motions to dismiss filed by defendants, almost half denied the motion in whole or in part, allowing the case to proceed to discovery. Moreover, almost all of the decisions granting defendants' motions to dismiss gave the plaintiffs another opportunity to replead their dismissed claims, continuing a trend in these jurisdictions — particularly in the federal district courts of California — of giving plaintiffs leeway to amend their deficient pleadings multiple times to try to state a cognizable claim. Consistent with prior years, of the complaints that were dismissed, most of the dismissals were based on a failure to adequately plead scienter, with a failure to plead a materially misleading statement or omission coming in a close second.

[10] Cornerstone Report, at 30.

First Circuit and District of Massachusetts

Karth v. Keryx Biopharmaceuticals, Inc., No. 19-1964, 6 F.4th 123 (1st Cir. July 9, 2021)

Plaintiff-appellant alleged that Keryx Biopharmaceuticals, Inc. ("Keryx") and certain of its officers violated the 1934 Act by making inadequate disclosures about Keryx's manufacturing defects with respect to manufacturing Auryxia, a drug used to treat chronic kidney disease and Keryx's sole product during the proposed class period. Manufacturing Auryxia involved a two-step process consisting of (1) manufacturing the active pharmaceutical ingredient ("API") and (2) converting the API into its finished tablet form. Plaintiff-appellant alleged that defendants failed to disclose that Keryx only had one third-party contractor for the second step of the manufacturing process, which created a much greater risk of supply interruption than was disclosed. Plaintiff-appellant alleged that this risk eventually materialized when Auryxia disclosed a supply interruption resulting from issues with the second-stage manufacturer. The district court granted defendant-appellees' motion to dismiss, and the U.S. Court of Appeals for the First Circuit affirmed. It held that plaintiff-appellant failed to plausibly allege that the statements at issue were false or misleading at the time that they were made. In particular, the First Circuit focused on Keryx's risk warnings from public filings made during the class period (and prior to plaintiff-appellant's purchase of Keryx stock) that Keryx "currently depend[ed] on a single supply source for Auryxia" and "[i]f any of our suppliers, including the source of Auryxia drug product, were to … otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations." The court further concluded that plaintiff-appellant failed to allege that a supply interruption was "looming" at the time these disclosures were made such that the disclosures would be misleading by omission.

Leavitt v. Alnylam Pharmaceuticals, Inc., No. 18-12433-NMG, 2021 WL 965052 (D. Mass. Mar. 3, 2021)

Plaintiff alleged that Alnylam Pharmaceuticals, Inc. ("Alnylam") and certain of its officers violated the 1934 Act by making false and misleading statements regarding the efficacy and marketability of Patisiran, Alnylam's injection treatment for hereditary transthyretin-mediated (hATTR) amyloidosis. Plaintiff alleged that Alnylam made material misstatements regarding Patisiran's potential dual treatment indication, for both polyneuropathy and cardiomyopathy, following completion of a Phase 3 clinical trial. FDA approved Patisiran only for treatment of polyneuropathy manifestations of hATTR amyloidosis, and released a report which certain analysts characterized as critical of Alnylam for providing insufficient cardiac efficacy data to support a cardiomyopathy indication. The European Medicines Agency approved the drug for all manifestations of the disease (in patients with polyneuropathy) and authorized inclusion of cardiac data on the drug label. The court previously granted defendants' motion to dismiss the first amended complaint in March of 2020 for failure to "plead specific facts demonstrating that defendants either knew broad label FDA approval for Patisiran was 'impossible' or otherwise fraudulently mischaracterized the purpose or potential of" the clinical trial, and for failure to plead scienter based on insider-trading-based allegations. Plaintiff filed a motion for leave to file a second amended complaint, which attempted to bolster the scienter allegations by narrowing the focus of the allegations and adding the opinion of a purported expert. The court denied the motion with prejudice, holding that the second amended complaint still failed to allege scienter, as it contained no allegations that defendants were informed of any alleged criticism when they made the statements at issue, defendants' expertise in the field was not

sufficient proof that they should have known facts contradicting their statements, and their eventual market benefit did not prove that they acted on a specific, fraudulent motive.

Dahhan v. Ovascience, Inc., No. 1:17-cv-10511-IT, 2021 WL 2186466 (D. Mass. May 28, 2021)

Plaintiffs alleged that Ovascience, Inc. ("Ovascience") and certain of its officers violated the 1934 Act by representing throughout 2015 that the company was "on track" and "expected" to have 1,000 paying patients for its Augment fertility treatment during the year 2015, before announcing in September 2015 that it had made only 35 sales up to that point. In a previous decision in July 2018, the court denied defendants' motion to dismiss, holding that the complaint adequately alleged that the statements at issue were misleading and did not qualify for the PSLRA's safe harbor for forward-looking statements, and that defendants acted with scienter. In December 2019, plaintiffs filed an amended complaint adding three new defendants, Longwood Fund L.P., Longwood Fund G.P, and Richard Aldrich, claiming they violated the control person provision of the 1934 Act, Section 20(a). Defendants moved to dismiss and to strike the second amended complaint, asserting that plaintiffs' claims against these new defendants were untimely. In May 2021, the court denied the motion, holding that the limitations period does not begin to run until plaintiffs discover (or should have discovered) facts constituting the violation — and not at the point when plaintiffs are on notice that they should investigate further a potential violation. Here, the court held that the limitations period did not run because plaintiffs only knew the Longwood funds were active investors who had the *potential* to control Ovascience's operations, not that the Longwood funds *actually controlled* Ovascience's operations. Upon discovering actual control, plaintiffs brought the claims, which were therefore timely.

In Re Karyopharm Therapeutics, Inc. Securities Litig., No. 19-11972, 2021 WL 3079878 (D. Mass. July 21, 2021)

Plaintiff alleged that the Karyopharm Therapeutics, Inc. ("Karyopharm") and certain of its officers and directors violated the 1934 Act and 1933 Act by making misleading statements in connection with two public offerings and other public filings regarding the safety and efficacy of selinexor, Karyopharm's leading drug candidate, which allegedly were revealed when FDA released a briefing document citing toxicity and limited efficacy of selinexor, and when an FDA advisory committee voted to delay approval of selinexor. Plaintiff alleged that defendants failed to disclose information about the toxicity of selinexor in relation to two clinical trials, and by making statements regarding the inclusion of data collected outside the context of clinical trials in its NDA (which data were later rejected by FDA). The court granted the motion to dismiss with leave to amend, holding that (1) statements regarding one selinexor trial were not misleading by omitting additional information about toxicity, (2) the complaint failed to plead facts supporting the allegation that statements regarding real-world data were known to be false or methodologically unsound, and (3) with respect to plausibly misleading statements about a second trial, the complaint failed to raise a strong inference of scienter because it failed to show that the failure to disclose toxicity data in the disclosures at issue was reckless (*i.e.*, highly unreasonable). Finally, the court also held that the 1933 Act claims failed for lack of standing because the complaint did not plausibly trace plaintiff's shares to the two secondary offerings at issue.

Second Circuit and New York District Courts

Midwest Operating Eng'rs Pension Tr. Fund v. Alkermes Pub. Ltd. Co., No. 21-801-cv, 2021 WL 5782079 (2d Cir. Dec. 7, 2021)

Plaintiff alleged Alkermes plc ("Alkermes") and certain of its officers violated the 1934 Act by misrepresenting FDA's feedback on Alkermes's new drug, ALKS 5461, an opioid combination product originally intended to treat major depressive disorder and cocaine dependence. The district court dismissed the complaint in full for failing to plead facts supporting a strong inference of scienter (*see* pp. 11-12 for more detail on the district court's decision). The U.S. Court of Appeals for the Second Circuit affirmed, holding that Alkermes' correspondences and disclosures supported the primary nonfraudulent interference that defendants were optimistic about the FDA's review and encouraged that the FDA was seriously considering its "novel approach to providing evidence of efficacy for a new drug," and not, as plaintiff alleged, that the FDA had rejected Alkermes' novel approach and that defendants had mischaracterized that rejection in its public disclosures. The court noted that the FDA had told Alkermes that the approach appeared "reasonable" and Alkermes disclosed that there was a risk that FDA would not accept it. The Second Circuit concluded that rather than support an inference of fraud, the circumstances, including Alkermes's disclosures, "reflect[ed] the iterative process between a company and the FDA, particularly when the agency must evaluate a novel study methodology" and that Alkermes "viewed ALKS 5461's chances of FDA approval with optimism, yet still made honest attempts to disclose the FDA's feedback where relevant and to caution the market as to the risks inherent in proposing new study designs." The court also affirmed the district court's denial of leave to further amend the complaint.

Abu Dhabi Inv. Auth. v. Mylan N.V., No. 20-CV-1342 (JPO), 2021 WL 516310 (S.D.N.Y. Feb. 10, 2021)

Plaintiff alleged Mylan N.V. and Mylan Inc. (collectively, "Mylan") violated the 1934 Act by making false and misleading statements between 2012 and 2019 related to Mylan's alleged misclassification of the EpiPen as a generic drug. Mylan moved to dismiss to the extent plaintiff's claims were based on statements from before February 14, 2015 — five years before the complaint was filed — based on the 1934 Act's statute of repose. Plaintiff argued that a "violation" under the statute of repose is subject to the continuing violation doctrine and covers statements made on a continuing basis. The court disagreed, holding the plain language of the 1934 Act does not indicate a "violation" under the 1934 Act's means a defendant's *last* culpable act or misstatement. The court granted the partial motion because the text of the statute does not support treating a "violation" as encompassing a series of misstatements and omissions.

In Re Alkermes Pub. Ltd. Co. Securities Litig., No. 18-CV-7410 (LDH) (RML), 2021 WL 768134 (E.D.N.Y. Feb. 26, 2021)

Plaintiff alleged that Alkermes and certain of its officers violated the 1934 Act by making false or misleading statements about FDA's approval process and feedback relating to Alkermes's ALKS 5461 (discussed above). Specifically, plaintiff alleged that the FDA briefing document presented a roadmap showing that defendants

purposely failed to disclose concerns FDA had expressed to Alkermes about its studies' trial designs and statistical analysis plan. The court dismissed the complaint with prejudice, holding that it failed to plead facts supporting an inference that defendants did not honestly believe that their "statements of optimism" were true. The court further concluded that plaintiff overstated FDA's concerns, referring to plaintiff's "blatant mischaracterization" of the FDA briefing document and assertions based on the document "border[ed] on pure fantasy." Finally, the court found that the alleged interactions between FDA and Alkermes were relatively standard and reflected a "collective expectation that the process was an iterative one and that Alkermes would continue to respond to feedback," and could not support a strong inference of scienter.

Gordon v. Vanda Pharms., Inc., No. 1:19-cv-01108-FB-LB, 2021 WL 911755 (E.D.N.Y. Mar. 10, 2021)

Plaintiffs alleged that Vanda Pharmaceuticals, Inc. ("Vanda") and certain of its officers violated the 1934 Act in connection with a campaign to promote Vanda's drugs, Fanapt (a schizophrenia treatment) and Hetiloz (a treatment for a rare circadian rhythm disorder), off-label. Vanda's alleged off-label marketing campaign was revealed in a short-seller report, causing Vanda's stock price to drop. The court held that the complaint adequately alleged the existence of an off-label marketing campaign, which rendered misleading certain statements, including statements related to the company's marketing practices which failed to disclose the off-label marketing. The court held that one individual defendant acted with scienter, in that he actively participated in trainings in which Vanda's salesforce was directed to engage in off-label marketing, and that his scienter could be imputed to the company. The court dismissed claims against the other individual defendants for lack of scienter.

Rosi v. Aclaris Therapeutics, Inc., No. 19-cv-7118 (LJL), 2021 WL 1177505 (S.D.N.Y. Mar. 29, 2021)

Plaintiffs alleged that Aclaris Therapeutics, Inc. ("Aclaris") and certain of its officers violated the 1934 Act by making misstatements about the efficacy of ESKATA — Aclaris's only FDA-approved product during the relevant period, indicated to treat seborrheic keratosis, colloquially known as age spots — and failing to disclose its undesirable side effects, including "eye disorders" up to blindness and "local skin reactions" up to scarring. Plaintiffs alleged that after defendants had received a letter from FDA warning defendants to revise their marketing materials to ensure that risks were sufficiently disclosed, a paid Aclaris spokesperson went on The View and discussed ESKATA, making statements about its efficacy and a few potential side effects. FDA sent a second letter asserting that The View appearance contained false/misleading claims by failing to include warnings about side effects and including misleading photos regarding efficacy. Aclaris stopped marketing ESKATA and discontinued the commercialization in the U.S. The court found the complaint failed to allege that statements about (1) patient experience, (2) sales of ESKATA, (3) Aclaris's disclosed Risk Factors, and (4) the individual defendants' SOX certifications were misleading. However, the court found that the complaint adequately pled claims based on statements about Aclaris's marketing campaign and The View appearance. Among other things, the court held that plaintiffs adequately pled scienter through a "recklessness" theory, and pled loss causation through both a corrective disclosure and a "materialization of the risk."

Alpha Cap. Anstalt v. Intellipharmaceutics Int'l Inc., No. 19cv9270, 2021 WL 2896040 (S.D.N.Y. July 9, 2021)

Plaintiff alleged Intellipharmecutics International Inc. ("IPCI") and certain of its officers violated the 1933 Act by omitting the fact that its CFO was leaving the company in its registration statement for a secondary public offering. The court previously denied, in large part, defendants' motion to dismiss. At the summary judgment stage, defendants asserted the affirmative defense of negative loss causation. In particular, an expert witness engaged by defendants demonstrated, using an event study, that there was no statistically significant change in the securities' price after the CFO announced his resignation because the price drop "was statistically indistinguishable from normal daily fluctuations in the value of IPCI's stock that occurred because of broader market developments." Thus, defendants argued that the decline in the value of the securities at issue was not caused by the disclosure of the omitted fact. The court granted defendants' motion for summary judgment, holding that Alpha's rebuttal of IPCI's expert failed to create a genuine issue of material fact because it was inadmissible under *Daubert* in relying on speculation and conjecture (or alternatively, simply failed to raise a genuine issue of material fact on that basis), and because plaintiff's expert focused on the wrong legal standard by examining whether the market for IPCI's securities was efficient, which the court held was not relevant to negative loss causation.

In re Perrigo Co. PLC Securities Litig., No. 19cv70 (DLC), 2021 WL 3005657 (S.D.N.Y. July 15, 2021)

Plaintiffs alleged Perrigo Company PLC ("Perrigo") and certain of its officers violated the 1934 Act by failing to disclose a potential €1.6 billion tax liability owed to the Irish Office of Revenue Commissioners and instead only disclosing they were contesting the Irish Revenue's position and "the amount of adjustments . . . that may be ultimately asserted . . . cannot be quantified at this stage." In granting plaintiffs' summary judgment motion on the issue of falsity, the court concluded defendants had a duty under GAAP to disclose the potential €1.6 billion liability because there was a reasonable probability that they may incur this loss, and under SEC rules, financial statements not prepared in accordance with GAAP are presumptively misleading. Moreover, in granting plaintiffs' summary judgment motion on the issue of materiality of the omissions in defendant's 10-Q, the court stated the amount of potential exposure could be quantified because the Irish Revenue provided in-depth calculations regarding its €1.6 billion figure, and omission of this tax liability was unquestionably material to investors. Finally, the court held that whether defendants' acted with the requisite scienter was a question of fact for a jury to resolve.

Villare v. Abiomed, Inc., No. 19 Civ. 7319 (ER), 2021 WL 4311749 (S.D.N.Y. Sept. 21, 2021)

Plaintiff alleged that Abiomed, Inc. ("Abiomed") and certain of its officers violated the 1934 Act by making misstatements regarding Abiomed's growth rate, ability to grow sustainably and penetrate the market, and execution of its five-year growth plan. Specifically, plaintiff alleged that defendants failed to disclose material adverse facts about Abiomed's business, including a stalling growth rate upon hospital saturation, a failure to convince doctors to prefer its products, unattainable growth expectations, and lack of a plan to stem the decline in revenue growth. The court held that, analyzing the complaint under an omissions theory, plaintiff had

failed to allege an actionable omission, and a plaintiff cannot attempt to hold defendants liable simply for failing to acknowledge the unsustainability of their business model. The court also found that certain of the statements at issue were corporate puffery, protected forward-looking statements, or non-actionable opinions, and that plaintiff had failed to allege scienter. The court granted leave to amend the complaint.

In Re Synergy Pharmaceuticals, Inc. Securities Litig., No. 18-CV-873, 2021 WL 4480625 (E.D.N.Y. Sept. 30, 2021)

Plaintiffs alleged that Synergy Pharmaceuticals Inc. ("Synergy") and certain of its officers violated the 1934 Act by making misstatements about the side-effect profile of Trulance (Synergy's sole commercial product during the alleged class period, a chronic idiopathic constipation treatment) and about a $300 million loan that Synergy secured from a private equity firm. With respect to the side-effect profile, plaintiffs alleged that defendants made statements to the effect that Trulance did not have the same side effects as its competitors without having conducted any head-to-head trials. With respect to the loan, plaintiffs alleged that defendants failed to disclose certain material aspects of the loan, such as a requirement that Synergy keep $128 million in cash or cash equivalents to receive the second $100 million. The court held that the side-effect profile statements were not comparative statements and plaintiffs failed to allege sufficiently that they were actually false or misleading. The court also held that plaintiffs had failed to allege loss causation. While the court found that certain statements about the loan that were phrased in present tense could be actionably misleading, it ultimately concluded that plaintiffs failed to adequately plead scienter, including because the statements at issue were accompanied by a commitment to publicly disclose the full loan agreement in Synergy's next 10-Q, which defendants later carried out — undercutting any inference of fraudulent intent. The court's dismissal was with prejudice, as plaintiffs had amended their complaint twice and had not requested another opportunity to amend.

Third Circuit and District of New Jersey

Aly v. Valeant Pharms. Int'l Inc., No. 19-3326, 1 F.4th 168 (3d Cir. June 16, 2021)

Plaintiffs, shareholders of Valeant Pharmaceuticals International ("Valeant") and formerly part of a class action against Valeant, opted out of the class action and brought the same claims in their individual capacities, before the district court had certified a class in the class action lawsuit. Defendants asserted that the new complaint was untimely, and that *American Pipe & Construction Company v. Utah* did not toll the statute of limitations period governing individual claims of putative class members that are filed before a class certification decision is made. The district court agreed and dismissed the complaint under the statute of limitations. The U.S. Court of Appeals for the Third Circuit reversed, holding that *American Pipe* automatically tolls the limitations period of putative class members' claims upon a filing of a class complaint. In holding that tolling applied, the court followed various other circuits that have reached the same conclusion, including the Second, Ninth and Tenth Circuits, and rejected a case from the Sixth Circuit holding otherwise.

In re Galena Biopharma, Inc. Securities Litig., No. 17-929, 2021 WL 50227 (D.N.J. Jan. 5, 2021)

Plaintiffs alleged that Galena Biopharma, Inc. ("Galena") and certain of its officers violated the 1934 Act by making misstatements about Galena's drug, Abstral, and its marketing of the drug, including failing to disclose that Abstral's increased sales were allegedly the product of an illegal rebate scheme. More specifically, plaintiffs asserted that defendants made misstatements that (1) attributed Abstral's earnings to sustainable business practices and (2) asserted Abstral's sales were "growing" and "trending" in the right direction. While the court concluded that the complaint adequately alleged both statements were material misstatements made with scienter, it ultimately held that plaintiffs failed to allege loss causation under a "materialization of the risk" theory, and dismissed the complaint with leave to replead one final time. The parties thereafter reached a settlement, and on January 26, 2022, filed a motion seeking the court's approval of the settlement.

Smith v. Antares Pharma, Inc., No. 17-8945 (MAS) (DEA), 2021 WL 754091 (D.N.J. Feb. 26, 2021)

Plaintiff alleged that Antares Pharma, Inc. ("Antares") and certain of its officers violated the 1934 Act by downplaying and misstating the incidence of certain adverse events (*i.e.*, hypertension, suicidality, and depression) observed in Phase 3 clinical studies of Antares' product QuickShot Testosterone (also known as Xyosted), an auto-injector product designed for testosterone replacement therapy. The court found that the third amended complaint suffered from the same deficiencies that the court had identified in granting a motion to dismiss plaintiff's second amended complaint, and that additional allegations failed to support falsity, materiality, or scienter. For example, the court held that statements from a confidential witness reflecting widespread knowledge at Antares of adverse events were insufficient to support scienter because such confidential witness allegations were not sufficiently specific to satisfy the requirements of the PSLRA. The court granted plaintiff one additional opportunity to amend the complaint.

Schwab Capital Trust v. Celgene Corporation, No. 20-3754, 2021 WL 1085474 (D.N.J. Mar. 22, 2021)

Plaintiffs — opt-outs from a parallel class action — alleged that Celgene Corporation ("Celgene") and certain of its officers violated the 1934 Act by making misleading statements about two drugs in Celgene's pipeline — Otezla and Ozanimod. Plaintiffs alleged that Celgene allegedly touted these drugs to mitigate its anticipated revenue drop following the impending expiration of Celgene's patent for its multiple myeloma drug Revlimid, which accounted for over 60% of Celgene's total sales between 2014 and 2016. With respect to Otezla, the complaint challenged statements about projected net sales made after Celgene allegedly received explicit warnings that the guidance was unattainable, which ultimately led to revised downward guidance. With respect to Ozanimod, which Celgene had acquired, the complaint alleged that Celgene projected annual sales and stated that it would be filing an NDA on a specific timetable, despite allegedly encountering difficulties in a Phase I trial, which ultimately resulted in a refuse to file letter from FDA. The court dismissed most of the alleged Otezla-related misstatements as non-actionable puffery and/or protected forward-looking statements, but allowed forward the claims with respect to one opinion statement, finding that plaintiffs had sufficiently alleged that the opinion lacked a reasonable basis and was not honestly believed when made. The court held that certain Ozanimod-related alleged misstatements also survived the motion to dismiss, and rejected defendants' arguments that the statements were primarily forward-looking. However, the court declined to extend the "corporate scienter" doctrine to statements made by Celgene and not attributed to a specific defendant, and only allowed Ozanimod-related claims to continue against certain individual defendants. The dismissed claims were dismissed without prejudice, and the court allowed plaintiffs to file a new amended complaint.

In re Amarin Corp. PLC Securities Litig., No. 3:19-cv-06601 (BRM) (TJB), 2021 WL 1171669 (D.N.J. Mar. 29, 2021)

Plaintiffs asserted that Amarin Corporation, PLC ("Amarin") and certain of its officers violated the 1934 Act by failing to disclose two issues that occurred during Amarin's REDUCE-IT trial, assessing its drug, Vascepa's, ability to reduce major adverse cardiac events in patients: (1) the placebo did not appear to act as an inert placebo, and (2) trial data could not explain how the drug actually reduced negative cardiac events. In granting defendants' motion to dismiss, the court concluded that plaintiffs failed to allege any actionable misstatements or omissions, including because (1) defendants warned the placebo may not be inert after disclosing the trial's top-line results, (2) disclosing top-line results does not trigger a duty to disclose full trial results, and (3) plaintiffs failed to identify a misstatement regarding the mechanism responsible for the benefit reflected in the REDUCE-IT trial. The court also held that plaintiffs failed to allege scienter, including because defendants' stock sales highlighted in the complaint as allegedly demonstrating motive were made pursuant to Rule 10b5-1 trading plans. The court granted plaintiffs an additional opportunity to amend the complaint.

TIAA-CREF Large-Cap Growth Fund v. Allergan plc, No. 17-cv-11089 (KSH) (CLW), 2021 WL 4473156 (D.N.J. Sept. 30, 2021)

Plaintiffs — opt-outs from a parallel class action — alleged that Allergan plc ("Allergan") and certain of its officers and directors violated the 1933 Act and the 1934 Act by failing to disclose purported participation in a

generic drug price-fixing conspiracy. The lawsuit followed a number of governmental investigations into the generic pharmaceutical industry, including DOJ criminal charges and a civil anticompetitive MDL brought by the attorneys general of 20 states. The court denied defendants' motion to dismiss, which relied primarily on statute of limitations and failure to plead scienter grounds. With respect to the statute of limitations, the court held that the complaint sufficiently pled that plaintiffs were unaware of their claims until certain media reports were issued and, thus, were timely. The court held that the complaint adequately pled scienter on a "market-allocation theory" based on a "core operations" inference, which "allows scienter to be imputed to individual defendants if the misconduct at issue involves 'core business' activities."

Ninth Circuit and California District Courts

In re Merit Medical Systems, Inc. Securities Litig., No. 8:19-02326 DOC (ADSx), 2021 WL 1258590 (C.D. Cal. Mar. 16, 2021)

Plaintiffs alleged that Merit Medical Systems, Inc. ("Merit") and certain of its officers violated the 1934 Act by making misstatements regarding Merit's acquisitions of Cianna and ClariVein. Specifically, plaintiffs allege the following statements, *inter alia,* about Merit's acquisition of Cianna were misleading: (1) "[t]he Cianna transition is complete," while half the integration allegedly was not yet complete; (2) "sales continue to grow according to our expectations," while they allegedly were not; and (3) claims about maintaining the sales force despite over 20% of the sales force allegedly quitting. With respect to ClariVein, plaintiffs alleged misleading statements concerning projected sales and insurance reimbursements. Although the magistrate judge concluded some of defendant's statements were non-actionable puffery, the court recommended the district judge deny defendants' motion to dismiss. The court held that certain statements regarding the acquisitions were sufficiently alleged to be misleading, and that plaintiffs sufficiently alleged scienter by demonstrating defendants were regularly made aware of sales data and problems, the reimbursement issues were serious and directly communicated to Merit's executive sale force, and both acquisitions were an important part of defendant's revenue growth strategy. Moreover, the court held that by asserting defendant's stock price dropped by 25.25% after defendants disclosed they did not receive any ClariVein orders and "Cianna's sales force suffered attrition," plaintiffs sufficiently alleged loss causation. The district judge adopted the magistrate judge's report and recommendation.

Derr v. Ra Med. Systems, Inc., No. 19cv1079-LAB-AHG, 2021 WL 1117309 (S.D. Cal. Mar. 24, 2021)

Plaintiffs alleged Ra Medical Systems, Inc. ("Ra") and certain of its officers and directors violated 1933 Act and the 1934 Act by making false or misleading statements beginning with the registration statement for Ra's September 2018 IPO. Specifically, plaintiffs alleged that defendants failed to disclose problems with Ra's DABRA system (Ra's sole product, a medical device approved by FDA for use in ablating a channel in occlusive peripheral vascular disease, a form of peripheral artery disease), financial reporting, and sales training programs that, when revealed, caused Ra's stock to price to collapse. The court denied defendants' motion to dismiss plaintiffs' 1934 Act claims, holding that the complaint alleged facts supporting the inference that defendants hid defects in Ra's production of catheters behind vague and misleading insinuations that "production issues were merely a question of insufficient capacity to meet demand," and that Ra's risk factor disclosures were rendered misleading because they failed to disclose that the risks posed as hypothetical had already materialized. The court further held that scienter could be inferred because the two individual defendant founders of the company held all primary officer roles within the company and the DABRA system was Ra's primary product, so it would be "absurd" to suggest they were without knowledge of the issues. However, the court dismissed plaintiffs' 1933 Act claims, holding that plaintiffs failed to plead facts demonstrating that the shares they purchased were issued pursuant to the misleading registration statement.

In re Align Tech. Inc. Securities Litig., No. 20-cv-02897-MMC, 2021 WL 1176642 (N.D. Cal. Mar. 29, 2021)

Plaintiffs alleged that Align Technology, Inc. ("Align") and certain of its officers violated the 1934 Act by making allegedly false and misleading statements about Align's business in China. The court held that some of the statements at issue — such as, "[t]he dynamics in China are really good for us" and "the appetite for growth and new technology adoption in China has been great for us" — were mere puffery and optimism during a time when Align's business in China was growing. The court held that certain other statements were not puffery, but concluded that they were not adequately alleged to be false. For example, the court held that statements reflecting that "China is our second largest market, and our fastest growing country market with approximately 70 [percent] annual growth rate," did not give a false impression that growth in China, which had been around 70%, was *continuing* to pace at that level. In addition, the court noted that certain optimistic statements at issue were made before sales in China slowed down. The court granted defendants' motion to dismiss, but also granted plaintiffs leave to amend.

Kuhne v. Gossamer Bio, Inc., No. 20-cv-649-DMS-DEB, 2021 WL 1529934 (S.D. Cal. Apr. 19, 2021)

Plaintiff alleged that Gossamer Bio, Inc. ("Gossamer"), certain of its officers and directors, and the underwriters for Gossamer's February 2019 IPO violated the 1933 Act by misleading investors in connection with Gossamer's IPO materials with respect to (1) the purported clinical validation of a competitor's oral antagonist of prostaglandin D2 receptor 2 ("DP2 antagonist"); (2) Gossamer's purported plan to release the results of its interim analysis of the Phase 2 clinical trial; and (3) Gossamer's plan to launch a Phase 3 trial for its own oral DP2 antagonist (GB001). The court held that, with respect to statements about the competitor's oral antagonist — which later failed a Phase 3 trial — defendants' statements cited to information the competitor itself had reported which plaintiff did not allege was inaccurate at the time of the IPO, and, even if there were a misrepresentation, it would be immaterial. With respect to Gossamer's own clinical trials, the court held that the alleged statements concerning a potential Phase 3 trial for GB001 were not materially misleading and were protected by the bespeaks caution doctrine, as the statements did not guarantee a trial and there were specific risk disclosures about clinical trials. However, the court found that reasonable minds could differ with respect to Gossamer's statements concerning the availability of Phase 2 trial results, and allowed plaintiff's 1933 Act claim to proceed on those allegations.

Oracle Partners, L.P. v. Concentric Analgesics, Inc., No. 20-cv-03775-HSG, 2021 WL 2322351 (N.D. Cal. June 7, 2021)

Plaintiffs alleged that Concentric Analgesics, Inc. ("Concentric") and certain of its officers violated the 1934 Act by falsely representing clinical trial results related to Concentric's "flagship pain product," CA-008. Specifically, plaintiffs' buyers alleged that defendants falsely represented that CA-008 "had successfully achieved both efficacy end points at high levels of statistical significance," but, as defendants conceded, the interim data available had not demonstrated statistically significant success. The court granted defendants' motion to dismiss the 1934 Act claims and denied the motion to dismiss Delaware common law fraud claims. With respect to the former, the court held that the complaint failed to plead loss causation. Specifically, the court

held that although plaintiffs alleged that the price of the securities at issue was inflated as a result of defendants' misrepresentations concerning the trial, plaintiffs failed to plead facts demonstrating that they had actually suffered a loss — an inflated purchase price, without more, was insufficient under Rule 9(b). Moreover, with respect to one of the individual defendants, the court held that the complaint failed to adequately plead scienter. However, the court denied defendants' motion to dismiss plaintiffs' common law fraud claim, and gave plaintiffs leave to replead their 1934 Act claims.

Kendall v. Odonate Therapeutics, Inc., No. 3:20-cv-01828 2021 WL 3406271 (S.D. Cal. Aug. 4, 2021)

Plaintiff alleged that Odonate Therapeutics, Inc. ("Odonate") and certain of its officers violated the 1934 Act, alleging that defendants made false and misleading statements about Odonate's sole drug candidate, tesetaxel, an oral chemotherapy agent. Plaintiff alleged that defendants knew about, but failed to disclose, significant safety concerns that arose during a Phase 3 study of tesetaxel, including higher than expected rates of neutropenia (a lower than normal amount of neutrophils, a type of white blood cell). Those issues allegedly led to increased withdrawals from the trial by participants, and in turn to changes in the trial protocol and presentations to trial investigators that were also not disclosed to shareholders. The court largely denied defendants' motion to dismiss. The court held that the complaint sufficiently alleged that certain disclosures, while perhaps literally true, were rendered misleading by the omissions, including statements reflecting that trial enrollment had been completed and positive statements about the potential of the drug, which allegedly "created an impression" that the trial "was proceeding as expected, with no significant setbacks." With respect to scienter, the court held that the complaint sufficiently alleged that the risk of the statements at issue misleading investors was either known to defendants, or so obvious that they must have been aware of it.

Hayden v. Portola Pharms., Inc., No. 20-cv-00367-VC, 2021 WL 3506614 (N.D. Cal. Aug. 10, 2021)

Plaintiffs brought suit against Portola Pharmaceuticals, Inc. ("Portola"), certain of its officers and directors, and the underwriters for Portola's August 2019 secondary public offering, alleging violations of the 1933 Act and the 1934 Act. Plaintiffs alleged that Portola made materially misleading statements regarding the company's revenue in its March 1, 2019 Form 10-K, which was incorporated by reference into the registration statement for the company's secondary public offering, by (1) disclosing Portola's revenue from Andexxa (a coagulant) but failing to disclose the percentage of that revenue that the company expected to lose for customer returns, despite knowing more than a year before the end of the customer return window that almost all of the company's return reserves had already been depleted, and (2) by certifying compliance with GAAP standards despite the undisclosed, higher than expected returns. The court dismissed the 1934 Act claims, holding that the complaint adequately pled misleading statements and scienter, but failed to plead loss causation, because it did not demonstrate that Portola's stock price dropped when the inadequate reserves were revealed, or that the specifics regarding the reserve issue were disclosed in the first place. The court denied defendants' motion to dismiss the 1933 Act claims based on the secondary public offering pursuant to a registration statement that incorporated the misleading 10-K, allowing those claims to proceed because 1933 Act claims do not require a plaintiff to establish loss causation. The court also granted plaintiffs another opportunity to amend to replead the 1934 Act claims.

Ferraro Fam. Found. Inc. v. Corcept Therapeutics Inc., No. 19-CV-01372, 2021 WL 3748325 (N.D. Cal. Aug. 24, 2021)

Plaintiffs alleged Corcept Therapeutics Inc. ("Corcept") and certain of its officers violated the 1934 Act by making false and misleading statements regarding Corcept's drug, Korlym (a treatment for treats endogenous Cushing Syndrome), and an alleged off-label marketing scheme. The court denied defendants' motion to dismiss in part, holding that plaintiffs alleged facts supporting the existence of an off-label marketing campaign (including through the use of confidential witness statements, records of payments made to physicians, and insurance companies tightening restrictions on reimbursing claims for Korlym prescriptions), in which physicians pushed Korlym for non-Cushing Syndrome uses, such as diabetes and obesity. The court held that this campaign conflicted with statements made by defendants (e.g., that they did not promote Korlym off-label, amongst others) and, when revealed to the market, caused the stock price to fall.

In re Progenity, Inc. Securities Litig., No. 20-cv-1683-CAB-AHG, 2021 WL 3929708 (S.D. Cal. Sept. 1, 2021)

Plaintiffs alleged that Progenity, Inc. ("Progenity"), certain of its officers and directors, and the underwriters for Progenity's June 2020 IPO violated the 1933 Act by omitting from Progenity's IPO registration statement (1) the fact that Progenity owed a refund to government payors for an overpayment due to billing errors of $10.3 million, and (2) negative trends in Progenity's testing volumes, average selling prices, and revenues. With respect to the $10.3 million overpayment, the court found that the mere fact of some overbilling was not itself material, and since the magnitude of the liability was unknown when the registration statement was issued, the omission was not actionable. With respect to the allegations concerning negative trends, the court found that a reasonable investor reviewing the registration statement in its entirety would not be misled, as the filing warned that testing volume declines could continue. Further, the court found that the complaint failed to identify any misleading statements regarding the average selling price decline, and plaintiffs failed to plead defendants were required to disclose this negative trend to make other statements in the registration statement not misleading. Lastly, the court dismissed plaintiffs' assertion that the entire registration statement was false and misleading for omitting information concerning negative trends in revenue, because defendants did disclose the negative trends, and plaintiffs' allegations to the contrary were conclusory. The court also dismissed similar claims based on Items 105 and 303 of Regulation S-K. The court granted plaintiffs an additional opportunity to amend the complaint.

Carr v. Zosano Pharma Corp., No. 20-cv-07625-EMC, 2021 WL 3913509 (N.D. Cal. Sept. 1, 2021)

Plaintiffs asserted that Zosano Pharma Corp. ("Zosano") and certain of its officers violated the 1934 Act by making materially false and misleading statements about the likelihood of gaining FDA approval for the company's new drug, Qtrypta, a formulation of a previously approved drug delivered using Zosano's proprietary technology for treatment of migraine headaches. FDA issued Discipline Review Letter ("DRL") identifying issues with the NDA, followed by a complete response letter from FDA rejecting the NDA, leading to the company's share price falling over 70%. Plaintiffs alleged that defendants' optimistic statements about the likelihood of approval of Qtrypta were rendered misleading by the omission of the issues identified by FDA in its DRL. The court granted defendants' motion to dismiss, holding that plaintiffs failed to raise a strong

inference that defendants acted with scienter. The court held that the complaint failed to establish the individual defendants knew about the allegedly omitted issues in the Qtrypta clinical trials or believed them to be material to FDA's approval of the drug, and that scienter could not be inferred because defendants did not engage in any insider trading or suspicious financial activity within the company. The court emphasized that plaintiffs' theory — under which defendants made optimistic statements about approval of Qtrypta while knowing FDA would reject or delay its approval — did not make sense. The court granted plaintiffs an opportunity to amend the complaint.

In Re AnaptysBio, Inc. Securities Litig., No. 20-CV-565 TWR (DEB), 2021 WL 4267413 (S.D. Cal. Sept. 20, 2021)

Plaintiff alleged that AnaptysBio, Inc. ("AnaptysBio") and certain of its officers violated the 1934 Act by making various misleading statements concerning the results of two of AnaptysBio's Phase 2 trials for ANB020, a drug intended to treat "severe inflammatory disorders with unmet medical needs" like "atomic dermatitis, peanut allergies, and asthma." The court held that plaintiff failed to plead any material misleading statements about the different clinical trials — primarily because the challenged information had actually been disclosed. The court further found that the plaintiff failed to plead scienter, finding the allegations related to stock sales and confidential witnesses insufficient. The court granted defendants' motion to dismiss, with leave to amend.

Evanston Police Pension Fund v. McKesson Corporation, No. 18-cv-06525, 2021 WL 4902420 (N.D. Cal. Oct. 21, 2021)

Plaintiffs alleged that McKesson Corporation ("McKesson") and two executives violated the 1934 Act, based on allegations that McKesson benefited from a price-fixing conspiracy among manufacturers of generic drugs (in which the complaint did not plead McKesson participated), and that McKesson misleadingly attributed strong performance caused by the conspiracy to other factors. After a class was certified, defendants moved for partial summary judgment. The complaint alleged two different corrective disclosures, and defendants moved for partial summary judgment based on only one of the corrective disclosures — specifically, November 2016 reports from media publications that regulators were investigating generic drug manufacturers for price-fixing. The court granted partial summary judgment, agreeing with defendants that plaintiffs failed to show loss causation with respect to the November 2016 corrective disclosure because the media reports did not suggest any wrongdoing by McKesson, and McKesson had previously disclosed that generic drug prices would wane.

In re Sona Nanotech, Inc. Securities Litig., No. 2:20-cv-11405-MCS-MAA, 2021 WL 5504758 (C.D. Cal. Oct. 28, 2021)

Plaintiffs alleged that Sona Nanotech, Inc. ("Sona") and certain of its officers violated the 1934 Act by making false and misleading statements in connection with Sona's ultimately failed attempt to develop an antigen test for COVID-19. In particular, plaintiffs challenged numerous optimistic statements defendants made about the test's development and prospects for FDA approval over a one-year period that allegedly omitted deficiencies in Sona's clinical trial designs, among other things, causing the company's stock price to increase by 14,545%, followed by a precipitous decline when FDA declined to issue an emergency use authorization. The court dismissed the complaint for failure to adequately plead falsity or scienter. With respect to falsity, the court held that the complaint failed to plead that any of the development-related statements were literally untrue — for

example, a statement that Sona had brought its test "to fruition" would not have been understood, in context, to mean that Sona had an FDA-ready test, and instead meant the company had developed a test with positive results. And a statement by Sona's CEO during an interview that he was "100% confident" the test would be approved was non-actionable because it was "vague" and "optimistic," and there were no allegations the CEO knew it was false when the statement was made. With respect to scienter, the court highlighted the lack of allegations concerning financial or other motivations for fraud, observed that the theory that Sona would lie to temporarily boost its stock price for no benefit made no sense, and ultimately concluded that the more logical inference was simply that Sona tried, and failed, to obtain FDA approval but its predictions did not come to fruition. The court granted leave to amend.

In re Sorrento Therapeutics, Inc. Securities Litig., No. 20-cv-00966-AJB-DEB, 2021 WL 6062943 (S.D. Cal. Nov. 18, 2021)

Plaintiffs alleged that Sorrento Therapeutics, Inc. ("Sorrento") and certain of its officers violated the 1934 Act by making false and misleading statements regarding Sorrento's development of an antigen treatment for COVID-19, including statements by officers in publications that, with respect to the treatment, "there is a cure," "there is a solution that works 100 percent," and "if we were approved [by FDA] today, everyone who gets that antibody can go back to work and have no fear of catching COVID-19." Plaintiffs alleged that such statements were false because Sorrento's treatment was in pre-clinical testing only. The court granted defendants' motion to dismiss, holding that the complaint failed to adequately plead falsity or a strong inference of scienter. As to falsity, the court held that the publications in which the statements were made clearly disclosed that the treatment was in pre-clinical testing, and certain statements (including "there is a solution that works 100 percent") amounted "to no more than generalized assertions of corporate optimism as to the initial success of STI-1499 against COVID-19." With respect to scienter, the court held that the complaint failed to plead facts indicating defendants knew the statements at issue were false, and financial motives stemming from the company's desire to raise capital were insufficient, without more, to create a strong inference. The court granted plaintiffs an opportunity to amend the complaint.

In re Vaxart, Inc. Securities Litig., No. 20-cv-05949-VC, 2021 WL 6061518 (N.D. Cal. Dec. 22, 2021)

Plaintiffs alleged Vaxart, Inc. ("Vaxart"), certain of its officers, and a hedge fund that owned a significant stake in Vaxart stock violated the 1934 Act by claiming Vaxart had been selected by the U.S. government for Operation Warp Speed ("OWS") funding and was partnering with Attwill Medical Solutions ("AMS") to manufacture one billion doses of COVID-19 vaccine per year. In denying defendants' motion to dismiss, the court concluded defendants misled the public because AMS lacked the regulatory certifications, personnel, or wherewithal to produce one dose, much less one billion doses of the purported vaccine. The court further held that defendants' headline statement that Vaxart had been selected for OWS was misleading because the company in fact was only selected for a primate study. While the company did disclose the limited nature of its selection in its OWS press release, the court noted that it was only disclosed in small font below the headline, was presented in a misleading manner, and came while investors were waiting for the U.S. government to announce the companies that would receive funding. The court held that plaintiffs sufficiently pled scienter because AMS played such a central role in defendants' plan that it would be absurd for defendants not to know about its regulatory and personnel deficiencies, and defendants' OWS headline created a strong inference of intent to deceive as defendants knew the company was not in fact selected for OWS. However, the court

granted the motion to dismiss filed by the defendant hedge fund investor, with leave to amend, holding that plaintiffs' allegations failed to demonstrate the hedge fund was involved in a scheme to pop defendant's stock price or assisted in disseminating any of the allegedly misleading statements, and in fact had sold most of its shares before the class period.

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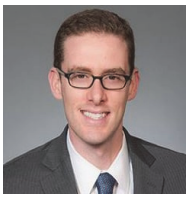

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