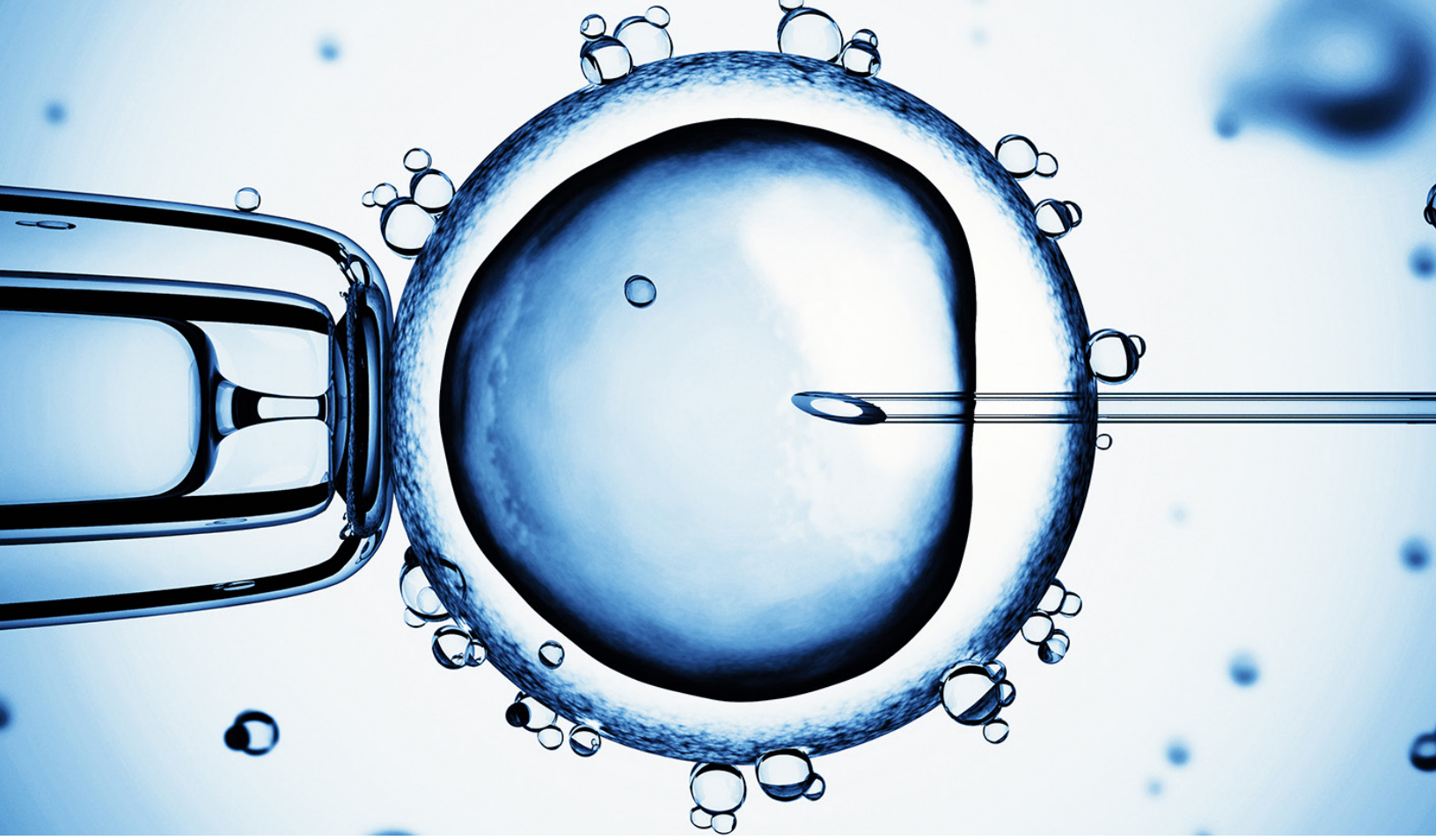
DECHERT SURVEY: DEVELOPMENTS IN SECURITIES FRAUD CLASS ACTIONS AGAINST LIFE SCIENCES COMPANIES

2020 Edition

Dechert LLP

Table of contents



Introduction

In 2020, securities class action litigation on the whole remained at a steady high, and life sciences companies were, once again, popular targets of such lawsuits.[1] In this White Paper, we analyze and discuss trends identified in last year's filings and decisions so that prudent life sciences companies can continue to take heed of the results.

Plaintiffs filed a total of 80 securities class action lawsuits against life sciences companies in 2020. Filings against life sciences companies in 2020 represented a 17.5% decrease from the previous year, but a 19.4% increase from five years prior. Of these cases, the following trends emerged:

- Consistent with historic trends, the majority of suits were filed in the Second, Third and Ninth Circuits, with a 92.3% increase in suits filed in the Ninth Circuit. The Third Circuit, on the other hand, saw a 27.5% decrease in filings from the previous year—from 40 in 2019 to 29 in 2020. Despite this decrease in the Third Circuit, the District of Delaware continued to see numerous filings due, in part, to a rise in merger litigation filed in federal court; that district alone accounted for approximately 72.4% of all suits filed in the Third Circuit and about 26.3% of all securities class action lawsuits against life sciences companies generally.
- A few plaintiff law firms were associated with about two-thirds of the filings against life sciences companies: Rigrodsky & Long, P.A. (23 complaints, 22 of which RM Law, P.C. joined as co-counsel), Pomerantz LLP (17 complaints), and The Rosen Law Firm (11 complaints).
- Slightly more claims were filed in the second half of 2020 than in the first half, with 36 complaints filed in the first and second quarters, and 44 complaints filed in the third and fourth quarters.

1. 2017 saw a record increase of class action securities litigation overall with 411 cases, up from the 271 securities class actions filed in 2016. In 2020, 324 securities class actions were filed.

– A growing number of lawsuits were filed against cannabis companies, with approximately 7.5% of all life sciences securities class actions filed against cannabis companies in 2020, most of which were incorporated in Canada.

– 19 cases were filed against non-U.S. issuers incorporated across eight countries. Of the 19 cases, eight were incorporated in Canada and four in the Netherlands.

An examination of the types of cases filed in 2020 reveals continuing trends from previous years.

– About 33.8% of claims involved alleged misrepresentations regarding product efficacy and safety, with many of these cases involving alleged misrepresentations regarding negative side effects related to leading product candidates, which could at times impact the likelihood of FDA approval.

– About 21.3% of the claims arose from alleged misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.

– Approximately 22.5% of the claims alleged misrepresentations regarding purported unlawful conduct in both the United States and abroad, including, but not limited to, illegal kickback schemes, anticompetitive conduct, tax issues, and inadequate internal controls in financial reporting.

– About 46.3% of the claims involved alleged misrepresentations of material information made in connection with proposed mergers, sales, IPOs, offerings and other transactions.[2]

Courts throughout the country issued a large number of decisions in 2020 involving life sciences companies, including:

– Claims that arose in the development phase—such as cases involving products failing clinical trials that are required for FDA approval or products not approved by the FDA— where courts were more likely to grant motions to dismiss in full as they were to deny them, either in whole or in part.

– Claims that were independent of or arose after the development process, which courts overwhelmingly dismissed.

– Claims based on the financial management of life sciences companies, which generally split between plaintiff and defendant-friendly outcomes.

Given the numbers from this and recent years' filings, and accounting for the 2020 COVID-19 pandemic, there is no indication that the filing of securities claims against life sciences companies is going to slow down any time soon. The decisions this year resulted in mixed outcomes, with 25 opinions decided in favor of defendants,[3] eight opinions denying motions to dismiss (including one reversal of dismissal on appeal), and 10 opinions in which only partial dismissal was achieved.[4] In addition, appellate courts also rendered opinions. Of the eight appellate decisions we reviewed, the Court of Appeals affirmed the district court's order in six of those cases. In one case, the Court of Appeals reversed an order of dismissal and remanded for further proceedings. In another case, the Court of Appeals affirmed in part, vacated in part, and remanded for further proceedings. Accordingly, in 18 of the 43 decisions rendered in 2020 that Dechert reviewed, the plaintiffs' claims were allowed to proceed (at least in part). These numbers illustrate how life sciences companies remain attractive targets for class action securities fraud claims. Therefore, companies should continue to stay abreast of recent developments and implement best practices to reduce their risk of being sued.

2. It should be noted that 30 of all 2020 filings fell in more than one of these four categories.

3. Throughout this White Paper, the terms "company" or "defendants" may be used to also include individual officers or directors.

4. The cases were compiled through Westlaw searches of dispositive orders involving the Private Securities Litigation Reform Act ("PSLRA") between January 1 and December 31, 2020, and were cross-referenced against filters in the Securities Class Action Clearinghouse filings by "Healthcare." In many cases, the court dismissed the operative complaint without prejudice and amended complaints are anticipated.

Life Sciences Companies Remain Popular Targets for Securities Fraud Litigation

In recent years, life sciences companies have increasingly been targets of securities fraud lawsuits, and 2020 was no exception. This survey is intended to give an end-of-year overview of life sciences securities lawsuits in 2020. First, we analyze the number of cases filed, including trends relating to the location, the types of companies targeted, and the parallels between underlying claims. Next, we analyze the securities class action decisions rendered in 2020 and how they impact the legal landscape of life sciences claims. Finally, we set forth issues and best practices life sciences companies should consider to reduce the risk of being subject to such suits.

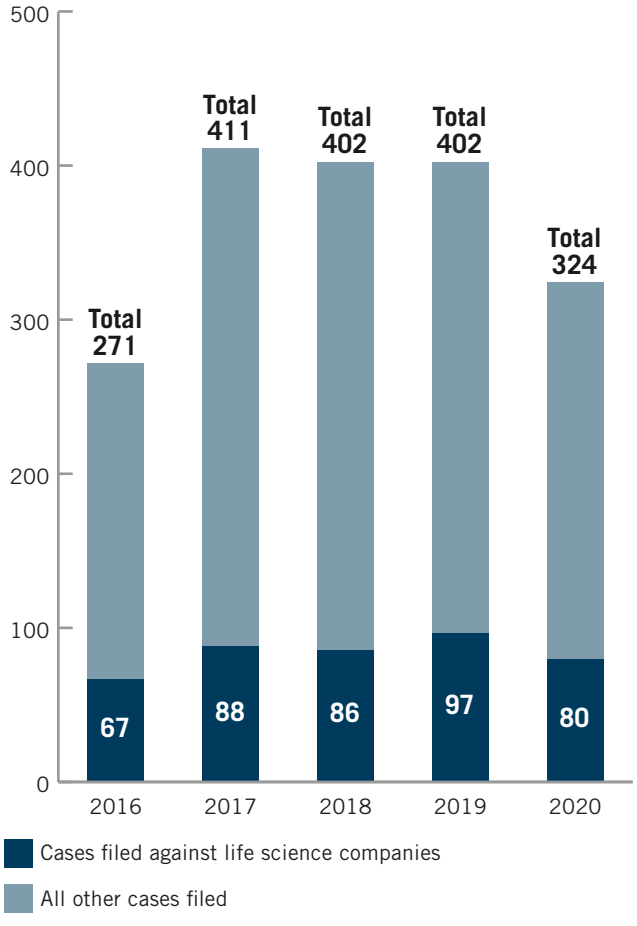
Increased Filings Involving Life Sciences Companies

The number of securities fraud class action lawsuits in general has been increasing steadily since 2012, peaking in 2017 before reaching a plateau in 2018. Naturally, the coronavirus pandemic upended the recent trend: "only" 324 securities fraud class action lawsuits were filed in 2020. While this total pales in comparison to the 411, 402, and 402 suits filed in 2017 through 2019, respectively, it marks the fifth-highest number of filings since 1996.[5] The average number of suits filed in the period 2017-2020 remains a healthy 386.[6]

Although the overall number of securities lawsuits filed has decreased since last year, the proportion of such actions brought against life sciences companies has remained unchanged. Indeed, a total of 80 class action securities lawsuits were filed against life sciences companies in 2020—almost one out of four of all securities fraud class action lawsuits. This percentage is similar to 2019, where 97 out of 402 securities fraud class actions—24%—were filed against life sciences companies.

Figure 1

Number of class action securities fraud cases filed from 2016–2020 (Total cases filed compared to cases filed against life science companies)



5. Throughout this survey, data from prior years is derived from Dechert LLP's 2019 survey on the same topic. David Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies*, Dechert LLP (Jan. 21, 2020). The number of securities fraud class actions filed and decided in 2020, as well as the number of those brought against life sciences companies, are based on information reported by the *Securities Class Action Clearinghouse in collaboration with Cornerstone Research, Stanford Univ., Securities Class Action Clearinghouse: Filings Database*, Securities Class Action Clearinghouse (last visited Jan. 12, 2021). This survey includes litigation and cases involving drugs, devices, deal litigation, and hospital management. As of January 12, 2021, the *Securities Class Action Clearinghouse* has reported a change in securities class action filing totals since Dechert published its previous survey in January 2020. In the 2019 Dechert survey, the Clearinghouse had listed the following totals for the years 2016-2020, respectively: 270, 412, 403, and 404.

6. *See id.*

Filing Trends

Over the past year, the number of claims filed against life sciences companies decreased numerically but remained proportional relative to the past three years. The coronavirus pandemic—and the attendant disruptions to business—likely contributed to the decrease in total filings in 2020. The percentage of filings brought against life sciences companies, however, remained the same. In 2020, one out of every four securities fraud class action suits targeted a life sciences company, while 2019 and 2018 finished with 24.1% and 21.4%, respectively.[7]

Despite the disruption in 2020, common patterns from previous years emerged once again, particularly relating to when and where suits were filed, and the claims involved. Indeed, 2020 continued to bring about new and noticeable variations within these larger trends.

– Increase in percentage of claims against large cap companies from previous year. In 2020, about 59.5% of the life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.[8] This filing trend[9] represents an increase from 2019 filings[10] and is in line with figures from 2018.[11] About 42.5% of the total cases filed in 2020 were against life sciences companies with a market capitalization of US$1 billion or more.[12] Of these complaints, about two in five were filed against companies with a market capitalization of US$5 billion or more[13], making up one sixth of the total cases filed.[14] The increased percentage of complaints filed against large cap companies shows that life sciences companies continued to be a popular target in 2020.

7. In 2020, 80 out of a total of 324 lawsuits were brought against a life sciences company, or 24.7%. In 2019, 97 out of a total of 402 lawsuits were brought against a life sciences company, or 24.1%. In 2018, 86 out of a total of 402 lawsuits were brought against a life sciences company, or 21.4%. These filings were tallied by filtering all Securities Class Action Clearinghouse filings by Healthcare, then sorting them by life sciences company named as defendant. *See Securities Class Action Clearinghouse in collaboration with Cornerstone Research, Stanford Univ., Securities Class Action Clearinghouse: Filings Database*, Securities Class Action Clearinghouse (last visited Jan. 12, 2021) (these figures are based on information publicly available through January 12, 2021). The filings include litigation and cases involving drugs, devices, financial management, deal litigation, and hospital management. Cases that were subsequently consolidated or amended were only counted once, unless the subsequent filing received a new docket number, in which case both filings were counted separately.

8. In 2020, 74 different life sciences companies were named in class action securities fraud complaints. Of these, 44 had a market capitalization of US$500 million or more, or 59.5%. Market capitalization figures are current as of the filing date and were compiled with Yahoo! Finance and Bloomberg. Yahoo! Finance, Yahoo.com, (last visited Jan. 12, 2021); Bloomberg (last visited Jan. 12, 2021).

9. In contrast, 70% of filings, or 56 of 80, were against life sciences companies with a market capitalization of US$2 billion or less. Of these 56 companies, 25 had a market capitalization of less than US$250 million.

10. In 2019, 51% of life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.

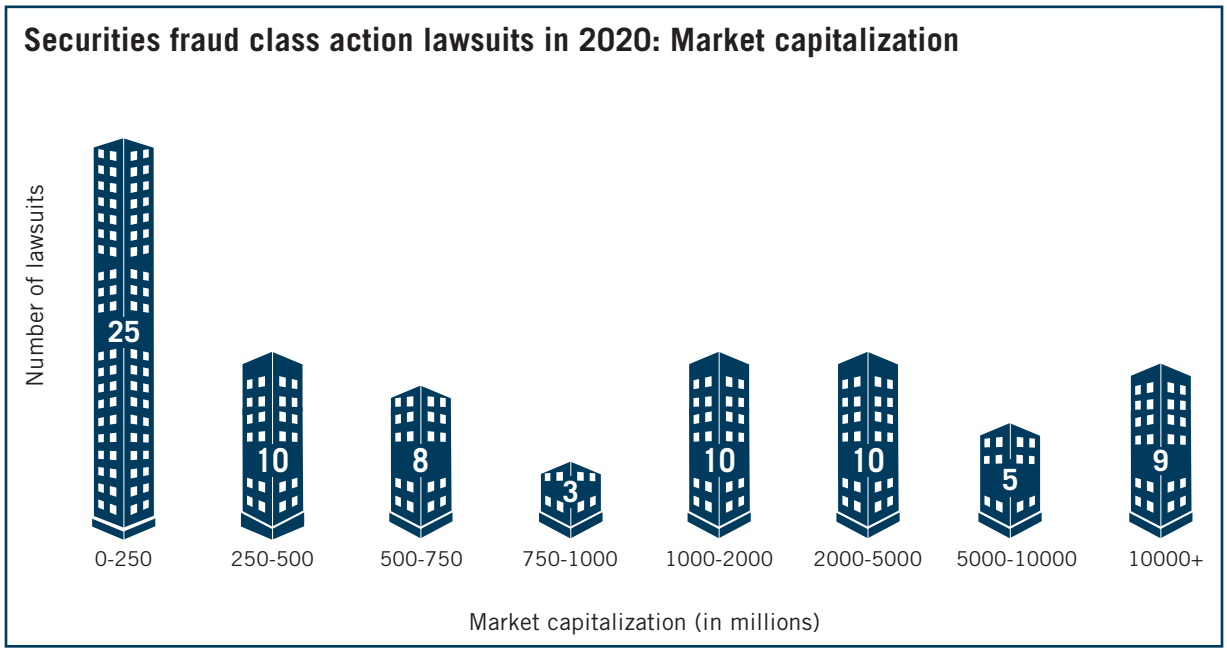
11. In 2018, 60% of life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.

12. In 2020, 34 of 80 cases were filed against these companies. In 2019, this number was 37 of 96, or 38.5%. In 2018, this number was 37 of 77, or 48.1%.

13. In 2020, 14 of 34 complaints were filed against life sciences companies with a market capitalization of US$5 billion or more, or 41.2%. In 2019, that number was 16 of 37, or 43.2%.

14. 14 of 80 is 17.5%.

Figure 2



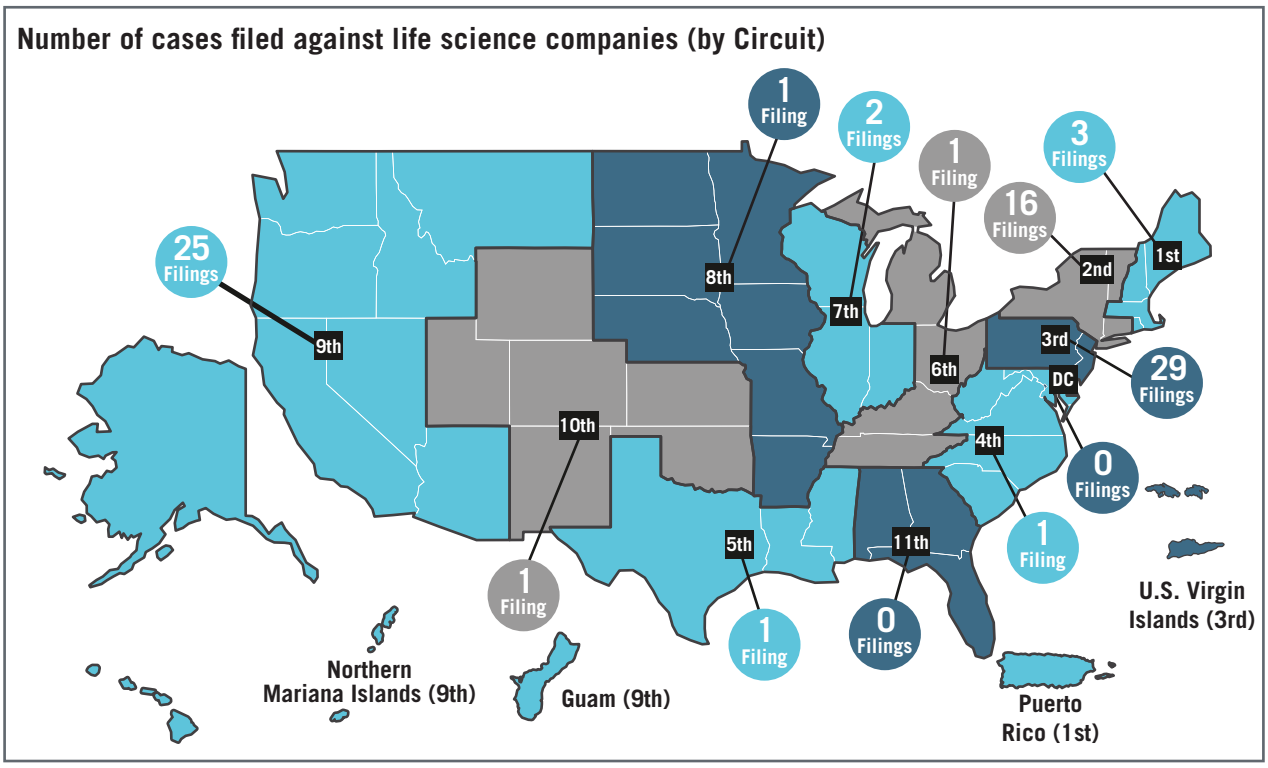
– The Third Circuit saw the highest number of filings again, and the District of Delaware saw the highest number of filings among district courts. Consistent with historic trends, the majority of the 80 class action securities fraud suits brought against life sciences companies were again filed in courts in three federal circuits: the Third Circuit with 29; the Ninth Circuit with 25; and the Second Circuit with 16. There were some notable shifts: The Third Circuit saw a 27.5% decrease in complaints filed in its district courts. The Second Circuit saw a similar decrease of 36%. The Ninth Circuit witnessed a rise in numbers: 25 in 2020 as opposed to 13 in 2019. Within these circuits, the District of Delaware had the most filings, with 21 overall. All 21 of these filings challenge mergers under Section 14 of the Exchange Act.[15] After Delaware, district courts in California were the second most popular with 24 total filings, 12 of which were in the Northern District of California alone. In 2020, over half of all cases were brought in the federal district courts of two states. Unlike in 2019, California and Delaware accounted for the greatest number of filings.[16] The Third Circuit, while accounting for the most filings against life sciences companies in 2020, also saw a shift in the distribution of filings among its federal district courts: Delaware with 21 (or 72.4%), New Jersey with four (13.8%), the Eastern District of Pennsylvania with three (or 10.3%), and the Western District of Pennsylvania with one (or 3.5%).[17]

15. Since 2016, plaintiffs have moved M&A challenges away from Delaware state court and into federal court. In *In re Trulia Stockholder Litigation*, 129 A.3d 884 (Del. Ch. 2016), the Delaware Court of Chancery rejected a settlement of a merger challenge where the plaintiffs only sought enhanced proxy disclosures. The Court of Chancery took a dim view of these "disclosure settlements," stating that it would meet such future settlements with "continued disfavor." *Id.* at 898. As a result, plaintiffs' counsel have instead opted to file in Delaware federal court, or in other jurisdictions entirely.

16. In 2016, 36 of 67 cases were filed in district courts in California and New York, or 53.7%. In 2017, this number was 35 out of 88, or 39.8%. In 2018, this number was 39 of 86, or 45.3%. In 2019, 53 of 97 cases were filed in district courts in Delaware and New York, or 54.6%. In 2020, 45 of 80 cases were filed in district courts in California and Delaware, or 56.3%.

17. In 2019, filings in the Third Circuit were as follows: the District of Delaware with 29, or 72.5%; the District of New Jersey with nine, or 22.5%; and the Western and Eastern Districts of Pennsylvania with one each, or 5% collectively. In 2018, eight of 18 filings brought in the Third Circuit were filed in the District of New Jersey, or 44%, and seven of those 18 were brought in the District of Delaware, or 38.9%.

Figure 3



– Three law firms were associated with about two thirds of filings against life sciences companies. In 2020, the three firms with the most filings of securities fraud lawsuits against life sciences companies were Rigrodsky & Long, P.A., RM Law, P.C., and Pomerantz LLP. These firms were listed on 23, 22[18] and 17 complaints respectively, and Pomerantz LLP was selected as lead or co-lead counsel in eight cases thus far. The Rosen Law Firm had the fourth most filings in 2020, accounting for 11 of the complaints filed, and serving as lead or co-lead counsel in five. The rise in lawsuits filed by RM Law, P.C. and Rigrodsky & Long, P.A., firms noticeably less visible in previous years in the context of securities lawsuits against life sciences companies, is attributable to the increase in merger litigation in Delaware, where those firms are particularly active.

– Slightly more claims were filed in the second half of 2020 than in the first half. Of the 80 complaints filed against life sciences companies in 2020, 36 were filed in the first half of the year, and 44 were filed in the second half. When broken down by quarter, 18 complaints were filed in the first quarter, 18 in the second, 28 in the third, and 16 in the fourth. This slight redistribution of the number of filings from the first half of the year to the second half of the year is consistent with 2019 figures.[19]

These figures are generally consistent with historic trends overall, but there were some notable changes in 2020. Companies with market capitalizations of more than US$500 million continued to be popular targets of class action complaints filed against life sciences companies—with those against companies with market capitalizations more than US$1 billion accounting for about 42.5% of the total cases filed. Three federal circuits dominated filings, consistent with recent years, and three states within those circuits led the pack: Delaware, California and New York, in that order. The increase of deal litigation in Delaware also corresponded with shifts in law firm filing trends, with

18. Rigrodsky & Long, P.A. appeared together with RM Law as co-counsel on 22 cases. Rigrodsky & Long, P.A. appeared with Grabar Law Office in one other filing in 2020.

19. In 2019, 46 of 97 securities fraud class action complaints filed against life sciences companies were filed in the first two quarters, or 47.4%.

RM Law and Rigrodsky & Long, the firms responsible for bringing the majority of 2020 deal litigations, accounting for the greatest number of law firm filings against life sciences companies.

Causes of Action

Although the total number of filings brought against life sciences companies in 2020 decreased, the legal issues alleged in those complaints against life sciences companies remained consistent with past years. As with other industries, deal litigation also continued to be at the forefront of securities fraud complaints filed against life sciences companies. However, the onset of the coronavirus pandemic has provided new allegations that are likely to continue into 2021.

Similar to previous years, one group of cases filed against life sciences companies in 2019 involved allegations unique to life sciences companies: misrepresentations regarding product efficacy and safety, especially negative side effects of leading product candidates, which could at times impact the likelihood of FDA approval. For example, MEI Pharma, a late-stage pharmaceutical company, was sued in a securities class action alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") for making materially false and misleading statements. Specifically, the complaint against MEI Pharma, a company that develops therapies for cancer treatment, alleged that: (1) MEI Pharma had overstated the potential efficacy of Pracinostat, a treatment for acute myeloid leukemia ("AML"), for the target population; and that (2) consequently, the Phase 3 Pracinostat Trial was unlikely to meet its primary endpoint of overall survival.[20] In June 2017, MEI Pharma initiated a Phase 3 Pracinostat Trial on 500 adults with newly diagnosed AML who were unfit to receive intensive chemotherapy. The primary endpoint of the trial was overall survival.[21] From August 2017 through June 2020, MEI Pharma made numerous public statements promoting the efficacy of Pracinostat as a treatment for the AML population.[22] In July 2020, the company announced in a press release that it was discontinuing the Phase 3 Pracinostat Trial based on a lack of overall efficacy.[23] Following MEI Pharma's announcement, the company's stock price fell US$0.78 per share, or 18.27%, closing at US$3.49 per share.[24]

Another group of complaints unique to life sciences companies arose from misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA unrelated to safety.[25] For example, investors sued LogicBio a genome editing company focused on developing medicines to treat rare diseases in patients with unmet medical needs using their GeneRide technology platform, alleging violations of Sections 10(b) and 20(a) of the Exchange Act. According to the complaint, LogicBio allegedly failed to disclose that its rushed, behind-schedule Investigational New Drug submission for LB-001, a treatment for methylmalonic academia, did not answer certain pertinent clinical and nonclinical questions posed by the FDA, and as a result, the FDA was likely to hold or deny the IND submission of LB-001 for treatment of MMA.[26] LogicBio's lead product candidate is LB-001 for the treatment of Methylmalonic Acidemia ("MMA"), a life-threatening disease that presents at birth.[27] Throughout 2019, LogicBio stated that it

20. *See* Compl., *Bahat v. MEI Pharma Inc.*, No. 3-20-cv-01543-WQH-LL ¶ 4 (S.D. Cal. Aug. 10, 2020).

21. *See id.* at ¶ 21.

22. *Id.* at ¶¶ 22-35.

23. *Id. at ¶ 37.*

24. *Id.* at ¶ 38; *see also, e.g.*, Am. Cons. Compl., *Junge v. Geron Corp.*, No. 3:20-cv-00547-WHA ¶¶ 3-9 (N.D. Cal. Oct. 22, 2020) (alleging that Geron misled investors regarding a drug called imetelstat and its corresponding clinical study, IMbark); Compl., *Kristal v. Mesoblast Ltd.*, No. 7:20-cv-08430-PMH ¶¶ 2-8 (S.D.N.Y. Oct. 8, 2020) (alleging that Mesoblast failed to disclose to investors: (1) that comparative analyses between Mesoblast's Phase 3 trial and three historical studies did not support the effectiveness of remestemcel-L, a stem cell therapy, for steroid refractory aGVHD due to design differences between the four studies; (2) that, as a result, the FDA was reasonably likely to require further clinical studies; and (3) that, as a result, the commercialization of remestemcel-L in the U.S. was likely to be delayed); Am. Compl., *Kim v. Allakos, Inc.*, No. 4:20-cv-01720-JSW ¶¶ 2-10 (N.D. Cal. Aug. 28, 2020) (alleging Allakos made numerous material misstatements about positive results it achieved in a clinical trial it conducted in 2019 regarding a drug named AK002 that it was going to submit to the FDA for approval).

25. Such suits comprised 17 of the 80 cases filed, or 21.3%.

26. *See* Compl., *Afinowicz v. LogicBio Therapeutics, Inc.*, No. 2:20-cv-03009-MCA-LDW ¶¶ 25-28 (D.N.J. Mar. 18, 2020).

27. *See id.* at ¶ 7.

expected to file an IND for LB-001 in the fourth quarter of 2019 and initiate a Phase 1/2 trial in 2020.[28] In January 2020, the company announced it had submitted the IND to the FDA with the goal of beginning the trial in the first half of 2020.[29] In February 2020, however, LogicBio announced that the FDA had placed a clinical hold on the IND submission for LB-001 pending the resolution of certain clinical and nonclinical questions.[30] This, according to plaintiffs, constituted material misstatements and omissions.[31] Following the press release, stock prices fell US$3.34 per share, or almost 32%, to close at US$7.11 per share.[32]

Another group of complaints alleged other unlawful conduct, including but not limited to, illegal kickback schemes, anticompetitive conduct, tax issues, and other forms of financial malfeasance.[33] In one case, investors sued Progenity, a biotech firm specializing in molecular testing products and precision medicine applications. The plaintiffs alleged that Progenity negligently prepared its initial public offering, failing to disclose until after its IPO that:

- separate from its US$49 million payment to the government for improper billing practices, Progenity had overbilled government payors by a previously unknown US$10.3 million in 2019 and early 2020, materially overstating its revenues;
- Progenity would need to refund this overpayment in the second quarter of 2020; and
- Progenity was suffering from accelerating negative trends.[34]

The plaintiffs alleged that as a result of the belated disclosure, Progenity stock closed nearly 50% below the US$15 per share price investors paid for the stock in the IPO less than two months previously.[35]

Notably, almost half of the class action securities fraud claims filed against life sciences companies in 2020 alleged misrepresentations and omissions related to proposed mergers, sales, IPOs, offerings, and other transactions.[36] Many of these complaints arising from transactions contain similar allegations,[37] and such

28. *Id.* at ¶ 17.
29. *Id.* at ¶¶ 22-23.
30. *Id.* at ¶ 26.
31. *Id. at ¶¶ 25-28.*
32. *Id.* at ¶ 27; *see also*, e.g., Compl., *Gonzalez v. Neovasc, Inc.*, No. 7:20-cv-09313 ¶¶ 3-9 (S.D.N.Y Nov. 5, 2020) (alleging that problems in Neovasc's clinical study meant that the FDA would require additional premarket clinical data before approving its cardiovascular treatment, and alleging that statements the company made about submitting its pre-market application without needing to gather further evidence was materially false and/or misleading); Compl., *Chapman v. Fennec Pharms. Inc.*, No. 1:20-cv-00812-UA-JLW ¶ 3 (M.D.N.C. Sept. 3, 2020) (alleging that defendants failed to disclose to investors that the manufacturing facilities for the company's sole product candidate did not comply with current good manufacturing practices; and that as a result, regulatory approval for the candidate was reasonably likely to be delayed; when defendants disclosed that it had received a Complete Response Letter from the FDA identifying deficiencies in a list of conditions or practices that are required to be resolved prior to the approval of Fennec's product candidate); Compl., *Himmelberg v. Vaxart, Inc.*, No. 3:20-cv-05949-VC ¶¶ 8-11 (N.D. Cal. Aug. 24, 2020) (alleging that defendant engaged in a fraudulent scheme to profit from artificially inflating the Company's stock price by announcing misleadingly that Vaxart's oral COVID-19 vaccine candidate had been been chosen for funding by U.S. "Operation Warp Speed" when it was merely selected to participate in preliminary government studies to determine potential areas for possible partnership and support).
33. Such complaints comprised 18 of the 80 filings reviewed, or 22.5%. Ten of these 18 cases involved allegations of false or misleading statements due to material weaknesses in life sciences companies' internal controls over financial reporting.
34. *See* Compl., *Soe v. Progenity, Inc.*, 3:20-cv-01683-WQH-AHG ¶¶ 27-37 (S.D. Cal. Aug. 28, 2020).
35. *See id.* at ¶ 38.
36. Such suits comprised 37 of 80 of the cases filed, or 46.3%.
37. *See, e.g.*, Compl., *Curtis v. Principia Biopharma Inc.*, No. 1:20-cv-01164-UNA (D. Del. Sept. 1, 2020) (alleging that defendant violated Sections 14 and 20 of the Exchange Act when, after a tender offer by Sanofi, defendant filed a Solicitation Statement with the SEC that purportedly omitted material information with respect to the Transaction, including material information regarding the Company's financial projections, financial analyses performed by Centerview Partners, and the like); Compl., *Thompson v. Qiagen N.V.,* No. 1:20-cv-00728 (D. Del. May 29, 2020) (alleging similar violations as in *Curtis,* but where the acquiring company was Thermo Fisher and the financial advisors were Barclays and Goldman Sachs); Compl., *Assad v. Arqule Inc.*, No. 1:19-cv-02383-UNA (D. Del. Jan. 2, 2020) (alleging similar violations as in *Curtis* but where the acquiring company was Merck and the financial advisor was Centerview Partners).

allegations are also similar to complaints filed against companies in other industries.[38] For example, investors sued Align Inc., the maker of Invisalign, for allegedly misrepresenting about the "tremendous" sales growth of Invisalign braces in one of its most important markets, China. Allegedly, the defendants repeatedly told investors that its sales growth in China remained at 70% annual growth, the same growth it had experienced in the prior two years. However, the plaintiff alleged that the defendants knew, or were deliberately reckless in disregarding, that the company's sales growth in China had materially decreased to a range of 20%-30%.[39] Accordingly, Align was alleged to have violated Sections 10(b), 20(a), and 20A of the Exchange Act.[40]

The COVID-19 pandemic has upended daily business across the world, forcing many companies, especially life sciences companies, to consider new litigation risks. Although fewer securities class actions were filed in 2020, there were at least seven complaints alleging issues with a company's COVID-19 antibody or vaccine development.[41] For example, investors alleged that Co-Diagnostics Inc. made willful misstatements about a COVID-19 diagnostic test to inflate the price of its stock while the executive officers exercised low priced options and sold their stock into the market.[42] Co-Diagnostics announced that it had received regulatory clearance to sell its tests in the European Union in February 2020. Then, in April 2020 the company announced that it had received emergency use authorization for its tests from the FDA. Throughout that time, Co-Diagnostics allegedly made unequivocal statements to the market that its COVID-19 tests were 100% accurate, which allowed Co-Diagnostic's stock price to soar.[43] By May 2020, however, it was revealed that Co-Diagnostic's test was only 95% accurate, an allegedly material discrepancy.[44]

Last, another noteworthy trend has been the number of life sciences companies that are incorporated abroad but still have been subject to securities lawsuits in the United States, which is in line with general securities litigation trends across all industries.[45] While many of the allegations seem to cover topics similar to those discussed above, at least five of these suits involve cannabis companies. For example, Cronos Group, a Canadian medical and legal cannabis producer, was sued for alleged accounting improprieties.[46] The plaintiffs allege that Cronos Group reported artificially inflated revenues by booking certain transactions with a service provider as sales.[47] Cronos was later forced to issue massive restatements based on the fraudulent accounting, reducing its first-quarter 2019 and third-quarter 2019 revenues by 39% and 40%, respectively.[48] The company also was forced to disclose a material weakness in its internal controls by an auditor.[49]

Similar to years past, the common themes of these complaints show the unique challenges life sciences companies face as issuers, but also commonalities with securities litigation filings on the whole. First, these filings continue to show that negative side effects in clinical trials can create a claim for securities fraud when management attempts to conceal or downplay these effects, subsequently overstating the trial's results and

38. 26 of 80 cases filed against life sciences companies, or 32.5%, challenge a merger or acquisition under Section 14 of the Exchange Act. This percentage is the same in the overall number of cases: 105 of the 324 cases filed this year are M&A litigations, or 32.4%.

39. *See* Am. Compl., *In re Align Tech., Inc. Sec. Litig.*, No. 3:20-cv-02897-MMC ¶ 1 (N.D. Cal. Aug. 4, 2020).

40. *See id.* at ¶ 15.

41. *See, e.g.*, First Am. Consol. Compl., *McDermid v. Inovio Pharm., Inc.*, No. 2:20-cv-01402-GJP (E.D. Pa. Sept. 21, 2020) (alleging that defendants misled investors about creating a COVID-19 vaccine within three hours in February 2020 and then again between March and May 2020 regarding its ability to produce one million doses of the INO-4800 vaccine by the end of 2020, and also alleging that defendants misled investors about being selected for Operation Warp Speed).

42. *See* Am. Compl., *Gelt Trading, Ltd. v. Co-Diagnostics, Inc.*, No. 2:20-cv-00368-CMR ¶ 5 (D. Utah July 15, 2020).

43. *See id.* at ¶¶ 6-7.

44. *Id.* at ¶¶ 8, 74-83.

45. Approximately 24%, or 19 of 80 cases, filed in 2020 were against non-U.S. issuers incorporated across eight countries. In 2019, 22 of 97 cases, or 22.7%, were filed against non-U.S. issuers.

46. *See* Consol. Am. Compl., *In re Cronos Group Inc. Sec. Litig.*, No. 2:20-cv-01310-ENV-SIL (E.D.N.Y Nov. 23, 2020).

47. *See id.* at ¶¶ 7-10.

48. *Id.* at ¶ 14.

49. *Id.* at ¶ 16.

prospects of FDA approval. The filings also continue to indicate that companies cannot inflate investors' expectations of FDA approval and must ensure that the company's risk disclosures and cautionary warnings are robust, and, as important, that executives' statements regarding the likelihood of approval are measured and in no way misleading. Moreover, the filings show life sciences companies also face challenges similar to those faced by other non-life sciences issuers, particularly challenges relating to disclosures in the sale or merger of life sciences companies. In addition, similar to other non-U.S. issuers, those life sciences companies with headquarters located outside of the U.S. may still be targets of securities class actions in the U.S. While these filings show that life sciences companies face unique challenges when it comes to securities fraud, they also reveal how these companies are still at risk from more common forms of securities fraud claims as well.

2020 Class Action Securities Fraud Decisions in the Life Sciences Sector

There was only a slight decline in securities fraud decisions by courts involving life sciences companies in 2020, especially in light of the coronavirus pandemic and resulting court closures. Compared to 2019, where Dechert identified 51 such decisions, Dechert identified 43 decisions under the same criteria. These decisions fall under three broad categories:

- cases involving claims that arose in the development phase, such as cases involving a drop in stock price after the failure of a clinical trial, and cases involving overly optimistic statements regarding FDA approval of a drug or device;
- cases involving claims arising independent of or after the development process; and
- cases involving the financial management of life sciences companies (e.g., alleged market manipulation or improper accounting).

As in the previous two years, the majority of these decisions address claims based on Sections 10(b) and 20(a) of the Exchange Act.

Court Decisions Regarding Alleged Misrepresentations During Product Development

Life sciences companies face significant risk during the developmental stage of a drug or device. Companies naturally want to promote new products and ensure that potential investors are aware of attractive opportunities. When those products perform well during trials and are ultimately approved by the FDA, they may then succeed in the market and reward the company and its investors. When new products fail clinical trials, or if the FDA declines to approve the new product, life sciences companies can (and should) expect plaintiffs' firms to mine public filings in order to prepare for litigation based on alleged mischaracterizations or exaggerations of trial results.

In 2020, courts issued 43 opinions—a slight decline from 51 decisions identified using the same criteria in 2019. Of those 43 opinions analyzed under the PSLRA, 24 include allegations of misrepresentations during product development. In some cases, stock prices fell after a drug or device did not meet efficacy or safety expectations, resulting in claims that the company misrepresented test results in order to improperly bolster stock prices. In others, plaintiffs' claims focus upon alleged misrepresentations regarding the likelihood of a product's FDA approval, including allegations that the companies withheld or mischaracterized FDA advice or warnings during development.

Though life sciences companies and their investors would prefer that all clinical trials succeed from the outset, many products in development underperform or outright fail during clinical trials. When this happens, plaintiffs' firms around the country pursue securities fraud class actions to recover for the alleged harm to investors, typically by alleging that the defendant company somehow misled the public.

Unlike in 2019, when courts were "almost as likely to deny defendants' motions to dismiss . . . as they were to grant them,"[50] courts in 2020 dismissed nearly all of the claims related to alleged misrepresentations during product

50. Kistenbroker, et al., *supra* note 5 at 11.

development. Of the 24 identified opinions, courts dismissed 15 in whole[51] and five in part[52] (including appellate decisions affirming lower courts' dismissal orders).

Defendants frequently challenge and defeat securities class action claims by arguing that they did not act with scienter when making statements during product development. One of the more notable cases from 2020, *Nguyen v. Endologix*,[53] centered on the "critical element of scienter"[54] in depth when it affirmed a dismissal under Federal Rule of Civil Procedure 12(b)(6). In *Endologix*, the Court of Appeals for the Ninth Circuit addressed allegations that Endologix, a company that manufactures and sells medical devices to treat aortic disorders, misled investors regarding the likelihood that one of its new products—"Nellix"—would receive FDA approval. In May 2016, Endologix first reported positive clinical trial data and expressed optimism that its product would receive FDA approval. The company later disclosed that FDA approval would be delayed due to efficacy concerns arising during the second year of clinical trials. By May 2017, Endologix announced that it was no longer seeking FDA approval of Nellix and was pivoting its attention to other products.[55] Following this announcement, the plaintiffs filed a complaint alleging that Endologix and its officers knew of Nellix's efficacy issues and, therefore, knew that the product would never receive FDA approval when the company made its initial optimistic announcement in May 2016.[56] The plaintiffs' complaint primarily relied on a confidential witness referencing various clinical complaints and incident reports to support its allegations of fraud.[57] The confidential witness, or "CW1," specifically referenced a "stream of complaint and incident reports," explained that the clinical study issues were the "biggest thing we had going at the company," recalled "thousands of pages of paper with studies and reports" related to the clinical issues, and described conversations with Endologix consultants.[58] Despite the breadth of CW1's recollections, the court found them insufficient.[59] Specifically, the court explained that CW1's information "lack[ed] any detail" about Endologix's problems; instead, it was "high on alarming adjectives" but "short on the facts."[60] Affirming the dismissal, the Ninth Circuit bolstered the PSLRA's "exacting" requirement that a complaint must establish a strong inference of scienter.[61] Relying heavily on pragmatism, the Ninth Circuit noted that the complaint did not allege any motive by the individual defendants, asking the question, "Why would defendants promise the market that the FDA would approve Nellix if defendants knew the FDA would eventually figure out that Nellix could not be approved due to 'intractable' and 'unresolvable' device migration problems?"[62] Indeed, the court explained that

51. *See Janies v. Cempra*, 816 F. App'x 747 (4th Cir. 2020) (affirming dismissal in whole); *Mehta v. Ocular Therapeutix, Inc.*, 955 F.3d 194 (1st Cir. 2020) (affirming dismissal in whole); *Nguyen v. Endologix, Inc.*, 962 F.3d 405 (9th Cir. 2020) (affirming dismissal in whole); *Spizzirri v. Zyla Life Sciences*, 802 F. App'x. 738 (3d Cir. 2020) (affirming dismissal in whole); *Yan v. ReWalk Robotics Ltd.*, 973 F.3d 22 (1st Cir. 2020) (affirming dismissal in whole); *Leavitt v. Alnylam Pharms., Inc.*, 451 F. Supp. 3d 176 (D. Mass. 2020) (dismissal without prejudice); *Khoja v. Orexigen Therapeutics, Inc.*, No. 15-CV-540 JLS (JLB), 2020 WL 6395629 (S.D. Cal. Nov. 2, 2020) (dismissal without prejudice); *Angelos v. Tokai Pharms., Inc.*, No. CV 17-11365-MLW, 2020 WL 5995598 (D. Mass. Oct. 9, 2020) (dismissal without prejudice); *Tung v. Bristol-Myers Squibb Co.*, No. 1:18-cv-01611 (MKV), 2020 WL 5849220 (S.D.N.Y. Sept. 30, 2020) (dismissal with prejudice); *Callinan v. Lexicon Pharms., Inc.*, No. CV H-19-0301, 2020 WL 4740487 (S.D. Tex. Aug. 14, 2020) (dismissal without prejudice); *Hackel v. Aveo Pharms., Inc.*, 474 F. Supp 3d 468(D. Mass. 2020) (dismissal without prejudice); *Immanuel Jun Shi v. Ampio Pharms., Inc.*, No. 2:18-cv-07476-RGK-RAO, 2020 WL 5092910 (C.D. Cal. June 19, 2020) (dismissal with prejudice); *Schaeffer v. Nabriva Therapeutics PLC*, No. 19 Civ. 4183 (VM), 2020 WL 7701463 (S.D.N.Y. Apr. 28, 2020) (dismissal without prejudice); *Smith v. Antares Pharma, Inc.*, No. 17-8945 (MAS) (DEA), 2020 WL 2041752 (D.N.J. Apr. 28, 2020) (dismissal without prejudice); *Lake v. Zogenix, Inc.*, No. 19-cv-01975-RS, 2020 WL 3820424 (N.D. Cal. Jan. 27, 2020) (dismissal without prejudice).

52. *See Abramson v. Newlink Genetics Corp.*, 965 F.3d 165 (2d Cir. 2020) (affirming in part and vacating in part); *Tomaszewski v. Trevena, Inc.*, No. 18-4378, 2020 WL 5095865 (E.D. Pa. Aug. 28, 2020); *Okla. Police Pension Fund and Ret. Sys. v. Teligent, Inc.*, No. 19 Civ. 3354 (VM), 2020 WL 3268531 (S.D.N.Y. June 17, 2020); *Skiadas v. Acer Therapeutics Inc.*, No. 1:19-cv-6137-GHW, 2020 WL 3268495 (S.D.N.Y. June 16, 2020); *In re Acadia Pharms. Inc. Sec. Litig.*, No. 18-CV-01647-AJB-BGS, 2020 WL 2838686 (S.D. Cal. June 1, 2020).

53. 962 F.3d 405 (9th Cir. 2020).

54. *Id.* at 414.

55. *See id.* at 408–13.

56. *Id.* at 412–13.

57. *See id.* at 417.

58. *Id.* at 409–10.

59. *Id.* at 416.

60. *Id.*

61. *Id.* at 414.

62. *Id.* at 415.

"[t]he theory does not make a whole lot of sense" and that there was "no basis in logic or common experience" for the notion that a company would heavily invest in a product and clinical trials if it knew—from the beginning—that the product was doomed to fail.[63] The more plausible inference, according to the court, was that the defendants made promising statements about FDA approval based on early clinical results but then "modulated their optimism when the results began to raise more questions."[64] By its reasoning, the *Endologix* court importantly recognizes that companies want their products to succeed and that a statement that turns out to be optimistic because its U.S. testing looked promising is not a fraudulent one.[65]

In the context of alleged misrepresentations during product development, courts also dismissed cases on grounds that the alleged misrepresentations were protected by the PSLRA's safe harbor for forward-looking statements. The PSLRA generally prevents statements from being actionable by applying a safe harbor for forward-looking statements when those statements are "accompanied by meaningful cautionary language."[66] For example, in *Hackel v. AVEO Pharmaceuticals*, plaintiffs brought allegations against AVEO Pharmaceuticals that the company made misleading statements related to its efforts to display the effectiveness of a drug designed to treat renal cancer.[67] Specifically, the court addressed the plaintiff's claims that purported forward-looking statements were not protected by the PSLRA's safe harbor because they were boilerplate and because certain statements in press conferences merely alluded to documents that contained the cautionary language, rather than provide the language directly.[68] Discarding these arguments, the court first noted that AVEO prefaced its statements with the comments that "forward-looking statements of AVEO . . . involve substantial risks and uncertainties" and "readers are cautioned not to place undue reliance on these expectations and estimates. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors."[69] AVEO also directed readers to refer to public filings containing "even more extensive cautionary language."[70] Characterizing AVEO's statements as "far from being boilerplate," the court explained that the language clearly expressed uncertainty and noted that it would be difficult for AVEO to have more explicitly warned the public about possible uncertainties in light of the statements highlighted above.[71] As to the indirect references to additional cautionary language, the court found the move appropriate. In doing so, the court explained that the PSLRA's safe harbor is "less exacting" in the context of oral statements and allows a speaker to reference written documents' cautionary language.[72] The court disposed of the remaining claims on materiality grounds.[73]

Oftentimes, courts will dispose of cases on grounds that the alleged misrepresentations were not material. Section 10(b) of the Exchange Act and its related Rule 10b-5 require a plaintiff to plead "a material misrepresentation or omission."[74] Aside from the nonactionable forward-looking statements in *AVEO Pharmaceuticals* discussed above, the court also disposed of certain claims due to materiality. Specifically, in *AVEO Pharmaceuticals*, the court addressed allegations that AVEO failed to disclose that certain clinical trial participants had been unaccounted for as the trial concluded and that AVEO had a duty to share complete data with the public.[75] The court disagreed. Aside from finding that AVEO made sufficient disclosure of this information, the court also found that the information would not have "significantly alter[ed] the total mix of information available to shareholders" and that the plaintiffs failed to prove what effect the omitted information would have in the first place.[76] Another case,

63. *Id.* at 408, 415 (noting, among other things, that ". . . [t]he allegation does not resonate in common experience. And the PSLRA neither allows nor requires us to check our disbelief at the door.").

64. *Id.* at 419.

65. *See id.*

66. 15 U.S.C. § 78u-5.

67. 474 F. Supp. 3d 468, 472 (D. Mass. 2020).

68. *See id.* at 478.

69. *Id.* at 478–79.

70. *Id.* at 479.

71. *Id.* at 480.

72. *Id.*

73. *Id.* at 481–83.

74. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005).

75. *See AVEO Pharms., Inc.*, 474 F. Supp 3d at 481.

76. *Id.*

Leavitt v. Alnylam Pharmaceuticals, Inc., similarly found limited data as insufficient to find materiality.[77] In *Alnylam Pharmaceuticals*, the court addressed a claim that defendants knowingly misrepresented data by not disclosing that its drug candidate was related to a higher frequency of cardiac arrest.[78] Refuting the claim, the court highlighted that the small number of cardiac arrest occurrences (only seven) did not warrant disclosure—a conclusion also reached by the FDA. Accordingly, the court found the alleged omissions immaterial in light of the FDA's safety evaluation and findings, particularly "the data analysis limitations inherent in a small sample size."[79]

Court Decisions Regarding Alleged Misrepresentations After Product Development

Life sciences companies can still face liability after a product is developed. Recalling the slight drop from 51 opinions in 2019 to 43 in 2020, Dechert identified only six instances of a court addressing fraud claims that arose after a drug or device's development process. Of the six cases, five were dismissed in whole[80] and one was dismissed in part.[81]

One of the cases, *Yan v. ReWalk Robotics Ltd.*, concerned alleged misstatements in ReWalk's IPO registration statement and subsequent investor phone calls related to a post-market surveillance study demanded by the FDA.[82] The court dismissed the complaint in whole and the decision was subsequently affirmed by the First Circuit. The *ReWalk* case included claims under both the Securities Act and the Exchange Act and stemmed from ReWalk's development of an exoskeleton product used to aid individuals with spinal cord injuries.[83] Prior to its IPO, ReWalk received FDA approval to market its product—known as ReWalk Personal—so long as it subjected itself to a post-market surveillance study in which the FDA continued to investigate potential safety risks.[84] As part of the post-market study, ReWalk issued a proposed study plan to the FDA for approval. Before receiving the FDA's approval, however, ReWalk issued a registration statement in August 2014.[85] The registration statement highlighted ReWalk Personal's success in "rigorous trials" and was supported by "compelling clinical data."[86] Though the registration statement noted that the FDA ordered a post-market study, it did not specifically disclose that the study was necessitated by the FDA's concern that the device's failure "would be reasonably likely to have serious adverse health consequences."[87] Instead, the company only included elsewhere that device failure generally could cause death or serious injury.[88]

During the course of the post-market surveillance study, ReWalk missed deadlines for submitting plans to the FDA and the plans it eventually submitted were "repeatedly deemed inadequate."[89] In September 2015, the FDA issued a warning letter advising ReWalk that the company was misbranding its product, that sanctions would result absent remedial action, and that ReWalk was failing to meet requirements ahead of a statutorily-imposed deadline.[90] The consequences of ReWalk's misbranding threatened product seizure, injunctions against the product's sale, prosecution, and monetary penalties.[91] Despite these struggles, ReWalk failed to include the details in either

77. 451 F. Supp. 3d 176, 185 (D. Mass. 2020).

78. *See Id.*

79. *Id.*

80. *See Yan v. ReWalk Robotics Ltd.*, 973 F.3d 22 (1st Cir. 2020) (affirming dismissal in whole); *Ferraro Fam. Found., Inc. v. Corcept Therapeutics Inc.*, No. 19-CV-01372-LHK, 2020 WL 6822916 (N.D. Cal. Nov. 20, 2020) (dismissal without prejudice); *In re Aceto Corp. Sec. Litig.*, No. 2:18-cv-2425-ERK-AYS, 2020 WL 4452059 (E.D.N.Y. Aug. 3, 2020) (dismissal with prejudice); *Hou Liu v. Intercept Pharms., Inc.*, No. 17-cv-7371 (LAK), 2020 WL 1489831 (S.D.N.Y. Mar. 26, 2020) (dismissal without prejudice); *Alberici v. Recro Pharma, Inc.*, No. CV 18-2279, 2020 WL 806719 (E.D. Pa. Feb. 14, 2020) (dismissal without prejudice).

81. *See In re Mylan N.V. Sec. Litig.*, No. 16-CV-7926 (JPO), 2020 WL 1673811 (S.D.N.Y. Apr. 6, 2020).

82. 973 F.3d 22 (1st Cir. 2020).

83. *See id.* at 27.

84. *Id.*

85. *Id.* at 28–29.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.* at 29.

90. *Id.*

91. *Id.*

their August 2014 registration statement or subsequent phone calls with investors.[92] The plaintiffs claimed that this lack of disclosure rendered ReWalk's filings and statements misleading.[93]

Assessing the plaintiffs' claims under the Securities Act and the Exchange Act, the court found ReWalk to have sufficiently disclosed available information. As to the Securities Act claims, the court was unconvinced by the plaintiffs' claims that ReWalk should have expounded on the product's risks more broadly, explored other potential risk scenarios, such as risks in different physical settings, or that ReWalk misled investors when it called its development a "breakthrough product."[94] As to the Exchange Act claims, the court found that the lead plaintiff lacked standing because he acquired ReWalk shares *after* the alleged misrepresentations and was unable to prove any "common scheme" tying pre- and post-acquisition statements together.[95]

Court Decisions Regarding Financial Management

Though life sciences companies must obviously navigate the risks associated with development of new drugs and devices, they also encounter securities-law risks common to all public companies. In 2020, courts issued 15 opinions in cases involving allegations of financial management, including: improper accounting, price fixing, and disclosures relating to mergers or spin-offs, among other claims. Of the cases Dechert identified, the outcomes varied, with six being dismissed in whole,[96] five more being dismissed in part,[97] and one in which dismissal was reversed and remanded for proceedings that have yet to take place.[98]

Three of the opinions issued in 2020 in this category concern allegations of illicit sales tactics or market manipulation.[99] One of those cases—*Higgins*—had previously been discussed by Dechert's 2019 edition of this report and has resurfaced following a second amended complaint.[100] The plaintiffs alleged Depomed, Inc. (now Assertio Therapeutics, Inc.) and certain of its officers made numerous false or misleading statements that described recent marketing achievements as successes but "did not disclose that the growth in sales was due in part to an illicit off-label marketing campaign" relating to the opioid drug NUCYNTA.[101] The plaintiffs further alleged that the company's public filings with the SEC were misleading because they disclosed a general risk from off-label marketing without indicating that the company itself was involved in the practice.[102] The plaintiffs also alleged new allegations in their second amended complaint that Depomed's statements that the company was well-positioned in the market were misleading in light of CDC guidelines and changing attitudes towards opioids causing decreased sales.[103] As before, the court disagreed with the plaintiffs because they did not sufficiently allege that the company materially misstated the likelihood or extent of the regulatory risks. Indeed, although the court agreed that plaintiffs sufficiently alleged a scheme in which sales representatives were *instructed* to make

92. *Id.*

93. *Id.* at 30.

94. *Id.* at 31–33.

95. *Id.* at 35–36.

96. *See Walleye Trading LLC v. AbbVie Inc.*, 962 F.3d 975 (7th Cir. 2020) (affirming dismissal in whole); *Inchen Huang v. Higgins*, 443 F. Supp. 3d 1031 (N.D. Cal. 2020) (dismissal without leave to amend); *In re Keryx Biopharms., Inc.*, 454 F. Supp. 3d 407 (D. Del. 2020) (dismissal without prejudice); *Zhang Yang v. Nobilis Health Corp.*, No. 4:19-CV-145, 2020 WL 5512456 (S.D. Tex. Sept. 14, 2020) (dismissal without prejudice); *Yaron v. Intersect ENT, Inc.*, No. 19-cv-02647-JSW, 2020 WL 6750568 (N.D. Cal. June 19, 2020) (dismissal without prejudice); *Teamsters Local 456 Pension Fund v. Universal Health Servs.*, No. 17-2817, 2020 WL 2063474 (E.D. Pa. Apr. 29, 2020) (denying motion to amend or alter order granting dismissal without prejudice).

97. *See Pelletier v. Endo Int'l PLC*, 439 F. Supp. 3d 450 (E.D. Pa. 2020); *In re Perrigo Co. PLC Sec. Litig.*, 435 F. Supp. 3d 571 (S.D.N.Y. 2020); *In re Aphria, Inc. Sec. Litig.*, No. 18 Civ. 11376 (GBD), 2020 WL 5819548 (S.D.N.Y. Sept. 30, 2020); *SEB Inv. Mgmt. AB v. Align Tech., Inc.*, No. 18-CV-06720-LHK, 2020 WL 5408056 (N.D. Cal. Sept. 9, 2020); *In re Mylan N.V. Sec. Litig.*, No. 16-CV-7926 (JPO), 2020 WL 1673811 (S.D.N.Y. Apr. 6, 2020).

98. *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204 (2d Cir. 2020).

99. *Inchen Huang v. Higgins*, 443 F. Supp. 3d 1031 (N.D. Cal. 2020); *In re Mylan N.V. Securities Litigation*, No. 16-CV-7926 (JPO), 2020 WL 1673811 (S.D.N.Y. Apr. 6, 2020); *Pelletier v. Endo International, 439 F. Supp.* 3d 450 (E.D. Pa. 2020).

100. Kistenbroker, et al., *supra* note 5 at 14–15; *Higgins*, 443 F. Supp. 3d. at 1040.

101. *Higgins*, 443 F. Supp. 3d at 1044.

102. *See id.*

103. *Id.* at 1054–55.

off-label statements regarding product usage, the revised allegations failed "to establish that this kind of off-label marketing actually took place, much less that it was part of a widespread campaign of off-label marketing."[104] As with the plaintiffs' first amended complaint, the second amended complaint contained numerous accounts from confidential witnesses but little evidence of any actual off-label marketing.[105] Specific to the allegations related to CDC guidelines and anti-opioid sentiment, the court found those statements also dependent on actual proof of off-label marketing.[106] Addressing scienter, the court first relied upon its conclusion that there was insufficient evidence of a scheme in the first instance and, therefore, little evidence of collective scienter.[107] Turning to individual scienter, the court looked to the core operations doctrine, individual motive, and the plaintiffs' presentation of a 2018 Senate report on the opioid industry.[108] Holding no single factor sufficient, the court found "at most a weak inference of individual scienter."[109] Though the plaintiffs' second amended complaint added 120 pages of new allegations, the result remained the same as before: dismissal (without providing a third opportunity to amend).[110]

Another case regarding financial management, *Nutriband, Inc. v. Kalmar*, uniquely featured a company as the plaintiff asserting allegations against individual defendants and their company. Nutriband, Inc. is a company that develops transdermal pharmaceutical products.[111] The complaint asserts that Nutriband entered into a partnership agreement with the defendant company at the behest of its CEO (Kalmar).[112] The agreement was motivated in part by one of the individual defendants' representations that he had extensive industry connections and a team of sales representatives.[113] Under the agreement, *Nutriband* issued 5 million shares of stock to the individual defendants and two other individuals.[114] In exchange, the individual defendants agreed to transfer all shares of their company and its portfolio of products to Nutriband.[115] A little over a year later, Nutriband discovered that the defendants had failed to effectuate their responsibilities under the partnership agreement, that one of the individual defendants had actually transferred certain company assets to his personal control, and that the defendants had misrepresented their capabilities and connections.[116] Nutriband alleged securities fraud claims under Sections 10(b) and 20(a) of the Exchange Act.[117] After addressing jurisdiction, the court turned to the fraud claims. First, the court found the defendants' representations regarding industry connections and the strength of their corporate teams were misleading.[118] The court also found misleading the fact that one of the individual defendants failed to disclose his criminal history—with multiple convictions for "passing bad checks."[119] Next, the court addressed materiality. The court largely abstained from assessing materiality at the pleading stage, instead framing the issue as a fact-specific one "more appropriate for summary judgment or trial."[120] Lastly, addressing scienter, the court examined Nutriband's allegations that scienter was satisfied under a "motive and opportunity" theory—at least at the pleading stage.[121] The court outlined Nutriband's allegations that the defendants' made numerous misrepresentations and that the misrepresentations made their company "seem more desirable to Nutriband."[122] Despite providing contrary explanations, the court declined to adopt the defendants' arguments and found that Nutriband met the PSLRA's standard that scienter allegations must be "at least as compelling as any opposing inference one could draw from the facts alleged."[123]

104. *Id.* at 1046, 1050, 1051.

105. *Id.*

106. *Id.* at 1055.

107. *Id.* at 1056.

108. *Id.* at 1056–57.

109. *Id.*

110. *Id.* at 1044, 1060.

111. *See Nutriband, Inc. v. Kalmar*, No. 19-CV-2511 (NGG) (SJB), 2020 WL 4059657 at *1 (E.D.N.Y. July 20, 2020).

112. *See id.*

113. *Id.* at *8.

114. *Id.* at *2.

115. *Id.*

116. *Id.*

117. *Id.* at *1.

118. *Id.* at *8–9.

119. *Id.* at *10.

120. *See id.* at *10–11.

121. *Id.* at *11.

122. *Id.*

123. *Id.*

Minimizing Securities Fraud Litigation Risks

Life sciences companies continue to be a popular target for class action securities fraud claims. While many of the companies discussed above were successful in defending against these claims, companies should take steps to reduce the risk of being targeted in a securities fraud class action. Below is a list of practices that life sciences companies should consider:

- Life sciences companies in particular deal with regulatory setbacks, negative side effects in clinical trials, clinical trial failures, etc. which, when disclosed, may trigger a stock drop. Be particularly cognizant when making disclosures or statements to disclose both positive and negative results, including after preliminary results are issued. Ensure that a disclosure regimen and processes are well documented and consistently followed.
- Smaller life sciences companies have been particularly susceptible to securities class actions and should work with counsel to ensure that they adopt a disclosure plan. Disclosure plans should not only cover written disclosures made in press releases or SEC filings, but also any statements made by executives during analyst calls. Websites should also be continually updated.
- Life sciences companies are not immune to issues that may cut across all industries and should be prepared to make appropriate disclosures relating to transactions, consolidated financials, internal controls, conflicts of interest, anticompetitive conduct, quality control etc.
- Because deal litigation has been at the forefront in filings against life sciences and other companies, materials to investors relating to the transaction should contain detailed explanations about the history of the transaction, alternatives to the transaction, reasons for recommendation, the terms of the transaction, fairness opinions, and conflicts of interest, among other issues.
- Even if incorporated abroad, life sciences companies that are also non-U.S. issuers may be targeted in the U.S. despite events occurring that may not be U.S.-specific.
- Regarding statements made in public filings, courts continue to weigh in on opinion statements and the law is continuing to evolve. Be aware that opinion statements should not conflict with information that would render the statements misleading.
- Forward-looking information about a drug or device should be clearly identified as such and distinguished from historical fact. Analyst calls and webcasts should also identify disclosures as a forward-looking statement.
- Risk disclosures that are current, relevant and upfront help to ward off securities class actions. Ensure that public statements and filings contain not only general disclaimers relating to forward-looking statements but also appropriate "cautionary language" or "risk factors" that are specific and meaningful, and cover the gamut of risks throughout the entire drug product life cycle—from development to commercialization.
- Be aware that former employees in all departments, not just those relating to clinical trials, may become confidential witnesses for shareholder plaintiffs. Educate employees about not sharing confidential information with others and limiting social media about the company.
- Develop and publish an insider trading policy to minimize the risk of inside trades, including 10b5-1 trading plans and trading windows. Class action lawyers aggressively monitor trades by insiders to develop allegations that a company's executives knew "the truth" and unloaded their shares before it was disclosed to the public and the stock plummeted.
- Work with insurers to hire experienced counsel with significant experience defending securities class action litigation on a full-time basis.

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The authors would also like to thank paralegal Austen Boer for his invaluable assistance in the preparation of this article.