Dechert LLP

DECHERT SURVEY: DEVELOPMENTS IN SECURITIES FRAUD CLASS ACTIONS AGAINST U.S. LIFE SCIENCES COMPANIES: 2023 EDITION

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Introduction

Last year marked an increase in federal securities class action filings, with plaintiffs filing 213 cases in 2023, up from 197 in 2022 and ending an overall decline in filings since 2019. Life sciences companies remained popular targets, accounting for approximately one in five of these filings.[1] In this white paper, we examine 2023's filing and decision trends, providing insights for life sciences companies to prudently navigate the litigation landscape.

Plaintiffs filed a total of 43 securities class action lawsuits against life sciences companies in 2023, which represented almost one in five securities class action lawsuits. Filings against life sciences companies in 2023 remained stable from the previous year but represent an approximately 50% decrease from five years prior in 2018. 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 20% increase in suits filed in the Ninth Circuit – 10 in 2022 and 12 in 2023. Notably, the Third Circuit saw a 160% increase in filings from the previous year – from five in 2022 to 13 in 2023. For district courts within these circuits, the District of New Jersey had the most filings, with 10 overall.
- A few plaintiff law firms were associated with almost half of the first filed complaints against life sciences companies: Pomerantz LLP (11 complaints), Glancy Prongay & Murray LLP (9 complaints), Levi & Korsinsky, LLP (7 complaints), and The Law Offices of Frank R. Cruz (6 complaints).
- Significantly more claims were filed in the second half of 2023 than in the first half, with 28 complaints filed in the third and fourth quarters, and 15 complaints filed in the first and second quarters.

An examination of the types of cases filed in 2023 reveals continuing trends regarding the underlying claims from previous years.

- About 46.5% of complaints, or 20 of 43 complaints, involved alleged misrepresentations regarding product efficacy and safety, with many of these cases involving alleged misrepresentations regarding certain negative side effects or the general ineffectiveness associated with leading product candidates, which could potentially impact the likelihood of Food and Drug Administration ("FDA") approval.
- About 27.9% of the complaints, or 12 of 43 complaints, arose from alleged misrepresentations involving regulatory hurdles, the timing of FDA approval, or the sufficiency of applications submitted to the FDA.
- About 11.6% of the complaints, or five of 43 complaints, involved misrepresentations related to COVID-19 related vaccines, products, or services.
- About 9.3% of the complaints, or four of 43 complaints, alleged misrepresentations regarding purported underlying unlawful conduct that gave rise to a securities fraud claim.
- About 16.3% of the complaints, or seven of 43 complaints, were against non-U.S. issuers incorporated abroad.
- About 34.9% of the complaints, or 15 of 43 complaints, involved alleged misrepresentations related to the company's financial reporting.
- About 18.6% of the complaints, or eight of 43 complaints, involved alleged misrepresentations of material information made in connection with proposed mergers, sales, initial public offerings ("IPOs"), offerings and other transactions.[2]

1 Throughout this survey, data from prior years is derived from Dechert LLP's 2023 survey on the same topic. *See* David Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies*, Dechert LLP (Feb. 2023). The number of securities fraud class actions filed generally and in particular against life sciences companies is based on information reported by Cornerstone Research, Securities Class Action Filings: 2023 Year in Review (last visited Feb. 21, 2024). This survey includes litigation and cases involving drugs, devices, deal litigation, and hospital management. These figures are based on the first complaint filed.

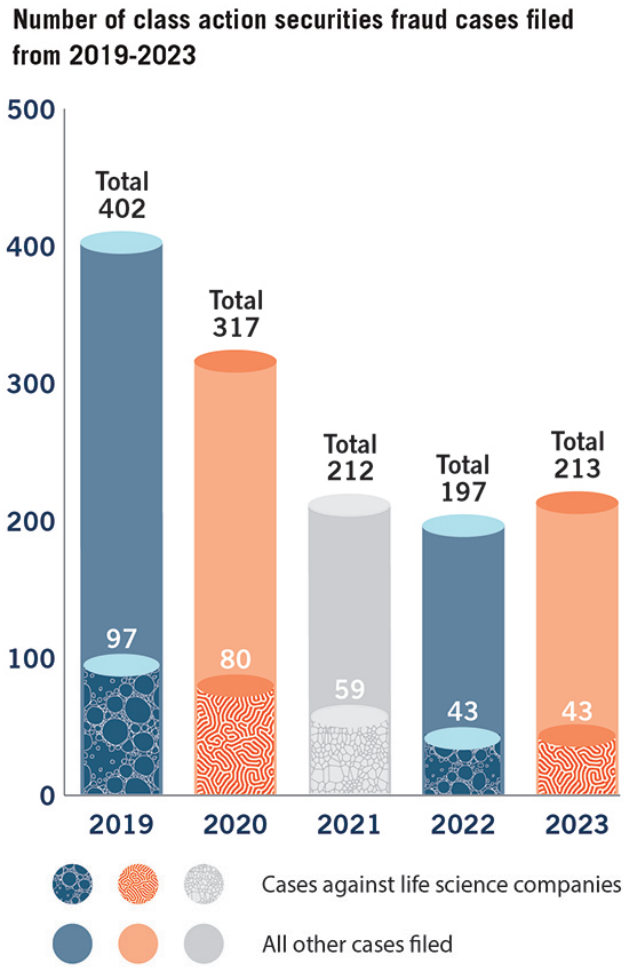
2 It should be noted that the majority of all 2023 filings against life sciences companies fell in more than one category.

Life Sciences Companies Remain Popular Targets for Securities Fraud Litigation

In recent years, life sciences companies have been targets of securities fraud lawsuits, and 2023 was no exception. This survey provides a comprehensive review of 2023's life sciences securities lawsuits. First, we analyze the number of cases filed, exploring jurisdictional trends, targeted companies, and underlying claim similarities. Next, we analyze the securities class action decisions rendered in 2023 and how they impact the legal landscape of life sciences claims. Finally, we set forth issues key considerations and best practices for life sciences companies to mitigate the risk of future lawsuits.

Approximately One in Five Securities Class Action Filings Are Against Life Sciences Companies

Figure 1

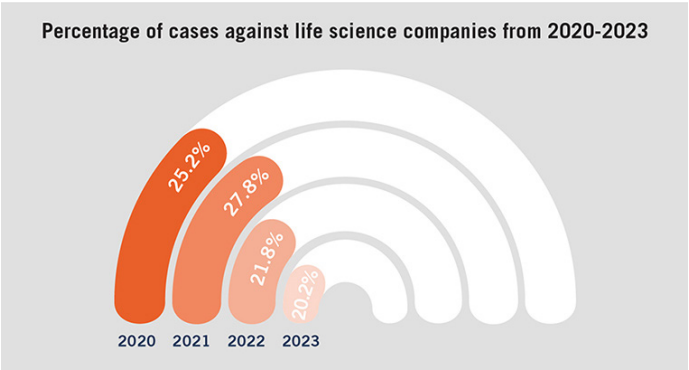


Last year marked an increase in federal securities class action filings, marking the end to an overall decline in filings since 2019 while still remaining below the historic filing peak of 2017-2019. In 2023, 213 lawsuits were filed, slightly more than the 197 filings in 2022 and comparable to the 211 filings in 2021. However, these numbers are significantly lower in comparison to the 411, 402, 402 suits filed in 2017 through 2019, respectively.

While there was a slight uptick in the number of overall filings, the proportion of such actions brought against life sciences companies has marginally decreased. Indeed, a total of 43 class action securities lawsuits were filed against life sciences companies in 2023 – approximately one out of five of all securities fraud class action lawsuits (or 20.2%). This percentage is slightly lower than 2022, where 43 out of 197 securities fraud class actions (or 21.8%) were filed against life sciences companies. Despite this slight decrease in proportion of actions against them, life sciences companies continue to remain a common target in securities fraud class action filings.

Filing Trends

Figure 2

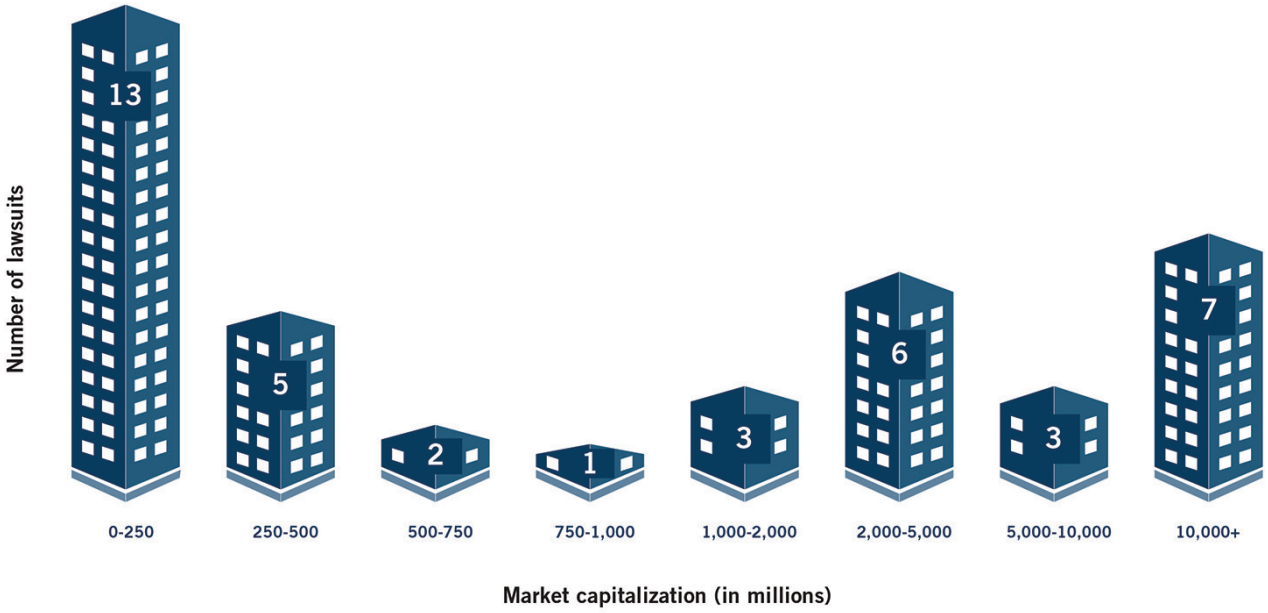


In 2023, while the numerical count of complaints filed against life sciences companies held steady, the proportion relative to the total securities fraud class action filings slightly decreased as compared to the past three years. Now, nearly one in five such lawsuits target a life sciences company (20.2%), as compared to 21.8% in 2022

and 28% in 2021.[3] The filings in 2023 brought about variations within larger trends, particularly relating to the timing and location of filings, and the claims involved.

Figure 3

Breaking Down the Lawsuits By Market Capitalizations*



*The market capitalization figures derive from 40 of the 43 companies. These figures exclude three companies whose market capitalization is unknown.

- **Slight increase in percentage of claims against large cap companies from previous year, and slight decrease in the percentage of claims against small cap companies.**[4] In 2023, at least 16.3% of the life sciences companies named in class action securities fraud complaints were large cap companies, or companies with a market capitalization of more than US$10 billion.[5] This is an increase from 2022 when 11.6% of companies were large cap companies.
  In looking at companies with a market cap of US$5 billion and above, in 2023, approximately 23.3% of complaints were filed against these companies.[6]
  This is an increase from the previous year.[7] In 2023, 13 in 43 cases, or 30.2%, included small cap companies between US$250 million to US$2 billion. This is a slight decrease from 2022, when 15 in 43, or 34.9%, complaints were filed against small cap companies.
- **The Third Circuit saw the highest number of filings against life sciences companies, but among district courts, the District of New Jersey saw the highest number of filings against life sciences companies.**

3 In 2023, 43 out of a total of 213 lawsuits were brought against a life sciences company, or 20.2%. In 2022, 43 out of a total of 197 lawsuits were brought against a life sciences company, or 21.8%. In 2021, 59 out of a total of 212 lawsuits were brought against a life sciences company, or 28%. In 2020, 80 out of a total of 317 lawsuits were brought against a life sciences company, or 25.2%. *See Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies 2022 (citing Securities Class Action Clearinghouse* in collaboration with *Cornerstone Research*, Stanford Univ., *Securities Class Action Clearinghouse: Filings Database*, Securities Class Action Clearinghouse.) 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.

4 The market capitalization figures derive from 40 of the 43 companies. These figures exclude three companies whose market capitalization is unknown.

5 In 2023, at least seven of 43 companies had a market capitalization of US$10 billion or more. In 2022, 5 of 43 companies had a market capitalization of US$10 billion or more.

6 In 2023, 10 of 43 companies had a market cap of US$5 billion and above.

7 In 2022, seven of 43 companies had a market cap of US$5 billion and above.

In 2023, there were noticeable shifts in the distribution of life science cases amongst the circuits and district courts from the previous year, but were still consistent with general overall trends prior to the pandemic. First, in 2023, the Third Circuit saw the greatest number of securities fraud case filings against life sciences companies, a shift from 2022 when the Second Circuit had the most filings. Specifically, the Third Circuit experienced a 160% increase in complaints, while the Second Circuit saw a 30.8% decrease.[8] Second, the majority of the 43 securities class action suits against life sciences companies in 2023 were filed in the same three federal circuits as in previous years: the Third Circuit (13 filings), the Ninth Circuit (12 filings), and the Second Circuit (nine filings). The District of New Jersey, which sits in the Third Circuit, had the most filings with 10, followed by district courts in California with 12. Also, half of all securities class action complaints against life science companies in 2023 were brought in federal courts of two states: California and New Jersey. This was a change from previous years when California and New York typically accounted for the greatest number of filings. The Third Circuit, historically the circuit accounting for the most securities actions filed against life sciences companies, saw an overall increase in the distribution of filings among its federal district courts, more specifically in New Jersey, from the outlier years of 2021 and 2022: Delaware with one (or 7.7%), New Jersey with 10 (76.9%), the Eastern District of Pennsylvania with one (or 7.7%) and the Western District of Pennsylvania with one (or 7.7%).[9]

- **Four law firms were associated with almost half of the filings against life sciences companies.** In 2023, the four firms with the most first filed complaints against life sciences companies were Pomerantz LLP, Glancy Prongay & Murray LLP, Levi & Korsinsky, LLP, and The Law Offices of Frank R. Cruz. Pomerantz LLP has been selected as lead or co-lead counsel in nine cases filed in 2023 and Levi & Korsinsky, LLP has been selected as lead or co-lead counsel in three.
- **More claims were filed in the second half of 2023 than in the first half, which was a shift from 2022.** Of the 43 complaints filed against life sciences companies in 2023, 15 were filed in the first half of the year, and 28 were filed in the second half. The number of complaints filed against life sciences companies per quarter in 2023 was as follows: eight in Q1, seven in Q2, 14 in Q3 and 14 in Q4. This pattern in 2023 contrasts with 2022, when more claims were filed in the first half of the year.[10]

Overall, 2023 saw notable changes in securities class action filings against life sciences companies. While the total number of complaints remained consistent, there was a geographical redistribution of filings resulting in the Third Circuit, particularly the District of New Jersey, experiencing an increase. Additionally, four law firms were associated with nearly half of the filings, indicating a concentration in the market in these cases. These trends continue to highlight the dynamic nature of securities fraud litigation against life sciences companies.

Causes of Action

The total number of securities fraud class actions brought against life sciences companies remained stable in 2023, and the legal issues alleged in those complaints remained consistent with past years.

Consistent with complaints filed in 2022, the largest category of cases filed against life sciences companies

8 In 2022, there were five complaints filed in the Third Circuit and 13 complaints filed in the Second Circuit. In 2023, there were 13 complaints filed in the Third Circuit and nine complaints filed in the Second Circuit.

9 In 2022, filings in the Third Circuit were as follows: Delaware with one or 20%; New Jersey with 10 or 40%; Eastern District of Pennsylvania with one or 40%; and the Western District of Pennsylvania with none. In 2021, filings in the Third Circuit were as follows: Delaware with one or 11.1%; the District of New Jersey with five or 55.6%; the Eastern District of Pennsylvania with three or 33.3%; and the Western District of Pennsylvania with none. In 2020, filings in the Third Circuit were as follows: Delaware with 21 or 72.4%; the District of New Jersey with four or 13.8%; the Eastern District of Pennsylvania with three or 10.3%; and the Western District of Pennsylvania with one or 3.5%. 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%.

10 In 2022, 24 of 43 securities fraud class action complaints filed against life sciences companies were filed in the first two quarters, or 55.8%.

in 2023 involved purported misrepresentations regarding product efficacy and safety, including negative side effects of leading product candidates and/or issues with clinical trials, which could at times impact the likelihood of FDA approval.[11]

For instance, plaintiffs brought suit against Scynexis Inc. ("Scynexis") and certain of its officers in the District of New Jersey.[12] Per the complaint, Scynexis is a biotechnology company primarily engaged in the development of ibrexafungerp, a broad-spectrum, intravenous (IV)/oral agent for fungal indications.[13] The company's development pipeline includes ibrexafungerp tablets, already approved by the U.S. Food and Drug Administration ("FDA") for the treatment of vulvovaginal candidiasis.[14] In addition, the company is also engaged in clinical investigation for treatment of invasive fungal infections in hospitalized patients and additional pre-clinical and discovery phase investigations.[15]
The plaintiffs alleged that Scynexis' public filings were purportedly false and/or misleading because they failed to disclose, among other things, that the equipment used to manufacture ibrexafungerp was also used to manufacture a non-antibacterial beta-lactam drug substance, presenting a risk of cross-contamination.[16] The plaintiffs

11 Such complaints comprised 20 of the 43 filings reviewed, or 46.5%. *See* Compl., *In re Y-mAbs Therapeutics, Inc. Sec. Litig.*, No. 23-CV-00431 (S.D.N.Y. Jan. 18, 2023); Compl., *Ali Hadian, et al. v. Fate Therapeutics, Inc., et al.*, No. 23-CV-00111 (S.D. Cal. Jan. 20, 2023); Compl., *Ron Bergman, et al. v. Caribou Biosciences, Inc., et al.*, No. 23-CV-01742 (N.D. Cal. Feb. 10, 2023); Compl., *Gerald Celano, et al. v. Fulcrum Therapeutics, Inc., et al.*, No. 23-CV-11125 (D. Mass. Apr. 28, 2023); Compl., *William E. Bazzelle, Sr., et al. v. NovoCure Ltd., et al.*, No. 23-CV-05146 (S.D.N.Y. June 19, 2023); Compl., *Grover J. Kelley, et al. v. Baxter Int'l, Inc., et al.*, No. 23-CV-04497 (N.D. Ill. Jul. 12, 2023); Compl., *Myo Thant, et al. v. Rain Oncology Inc., et al.*, No. 23-CV-03518 (N.D. Cal. Jul. 14, 2023); Compl., *Juliana Paice, et al. v. Aldeyra Therapeutics, Inc., et al.*, No. 23-CV-11737 (D. Mass. Jul. 31, 2023); Compl., *Judith M. Soderberg, et al. v. Apellis Pharm., Inc., et al.*, No. 23-CV-00834 (D. Del. Aug. 2, 2023); Compl., *Pembroke Pines Firefighters & Police Officers Pension Fund, et al. v. Integra LifeSciences Holdings Corp., et al.*, No. 23-CV-20321 (D.N.J. Sept. 12, 2023); Compl., *Brian Feldman, et al. v. SCYNEXIS, Inc., et al.*, No. 23-CV-22082 (D.N.J. Nov. 7, 2023); Compl., *Abduladhim A. Alghazwi, et al. v. The Beauty Health Co., et al.*, 23-CV-09733 (C.D. Cal. Nov. 16. 2023); Compl., *Laura L. Brill, et al. v. Invivyd, Inc., et al.*, No. 23-CV-10254 (D. Mass. Jan. 31, 2023); Compl., *Zachary Salzman, et al. v. ImmunityBio, Inc., et al.*, No. 23-CV-01216 (S.D. Cal. June 30, 2023); Compl. *Katelyn Martin, et al. v. BioXcel Therapeutics, Inc., et al.*, No. 23-CV-01055 (D. Conn. July 7, 2023); Compl., *James Hammond, et al. v. Kenvue Inc., et al.*, No. 23-CV-20998 (D.N.J. Oct. 9, 2023); Compl., *Joe Naclerio, et al. v. DocGo Inc., et al.*, No. 23-CV-09476 (S.D.N.Y. Oct. 27, 2023); Compl., *Eli Sporn, et al. v. Brainstorm Cell Therapeutics Inc., et al.*, No. 23-CV-09630 (S.D.N.Y. Nov. 1, 2023); Compl., *City of Hollywood Firefighters' Pension Fund, et al. v. Inspire Medical Systems, Inc., et al.*, No. 23-CV-03884 (D. Minn. Dec. 12, 2023); Compl., *Ramzy Alsaidi, et al. v. Outlook Therapeutics, Inc., et al.*, No. 23-CV-21862 (D.N.J. Nov. 3, 2023).

12 Compl., *Brian Feldman, et al. v. SCYNEXIS, Inc., et al.*, No. 23-CV-22082 (D.N.J. Nov. 7, 2023).

13 *Id.* ¶ 2.

14 *Id.*

15 *Id.* ¶ 2.

16 *Id.* ¶ 5.

also alleged Scynexis did not have effective internal controls and procedures, as well as adequate internal oversight policies to ensure that its third-party vendor complied with current Good Manufacturing Practices (cGMP).[17] Per the complaint, due to the substantial risk of cross-contamination, Scynexis was reasonably likely to recall its ibrexafungerp tablets and halt its clinical studies.[18] Thus, the complaint alleged that as a result of the foregoing, the defendants' positive statements about the company's business, operations, and prospects were materially misleading.[19] According to the complaint, Scynexis' stock experienced a "precipitous decline" in the market value after a series of press releases revealed the truth behind the alleged misrepresentations.[20]

In another case, misrepresentations regarding product efficacy and safety negatively impacted the ability to secure FDA approval for the product. Plaintiffs brought suit against Y-mAbs Therapeutics, Inc. ("Y-mAbs") and certain of its officers in the Southern District of New York.[21] Y-mAbs is a clinical-stage biopharmaceutical company focused on developing antibody therapeutics and medicines for the treatment of cancer patients.[22] According to the original complaint, Y-mAbs requested FDA approval to distribute omburtamab through a Biologics License Application ("BLA").[23] The plaintiffs alleged that on October 5, 2020, after the close of trading, Y-mAbs issued a press release informing investors that it had received a refusal to file ("RTF") letter from FDA regarding its BLA for omburtamab.[24] The plaintiffs further alleged that in public statements the defendants assured investors that the RTF was issued merely because the FDA wanted additional information rather than because of any substantive deficiencies with the BLA, but in truth, the defendants purportedly knew but failed to disclose that FDA had determined that the "application did not contain substantial evidence consisting of adequate and well-controlled investigations that 131I-omburtamab is safe and effective."[25] Per the complaint, the truth was purportedly revealed later when the FDA published its briefing document for an advisory committee meeting with the committee voting 16-0 against recommending approval of ombutamab, after which shares dropped from US$15.17 per share to US$3.61 per share a few days later.[26]

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.[27]

For instance, plaintiffs initially brought suit against ImmunityBio, Inc. and certain officers ("ImmunityBio") in the Southern District of California.[28] ImmunityBio is a clinical-stage biotechnology company that develops therapies and vaccines to combat cancers and infectious diseases in the U.S. and Europe.[29] The company's proprietary platform includes the antibody cytokine fusion protein N-803, commercially known as "Anktiva."[30] In May 2022, ImmunityBio submitted a Biologics License Application ("BLA") for Anktiva to the FDA.[31] The plaintiffs alleged that throughout the putative class period, the company assured investors of its Good Manufacturing Practice (GMP) capabilities at scale, with cutting-edge cell manufacturing expertise and

17 *Id.*
18 *Id.*
19 *Id.*
20 *Id.*
21 *In re Y-mAbs Therapeutics, Inc. Sec. Litig.*, No. 23-CV-00431 (S.D.N.Y. Jan. 18, 2023).
22 *Id.* ¶ 9.
23 *Id.* ¶ 49.
24 *Id.*
25 *Id.* ¶¶ 50–54, 57.
26 *Id.* ¶¶ 47, 48.
27 Such suits comprised 12 of the 43 cases filed, or 27.9%. *See* Compl., *Zachary Salzman, et al. v. ImmunityBio, Inc., et al.*, No. 23-CV-01216 (S.D. Cal. June 30, 2023); Compl. *Katelyn Martin, et al. v. BioXcel Therapeutics, Inc., et al.*, No. 23-CV-01055 (D. Conn. July 7, 2023); Compl., *Eli Sporn, et al. v. Brainstorm Cell Therapeutics Inc., et al.*, No. 23-CV-09630 (S.D.N.Y. Nov. 1, 2023); Compl., *In re Y-mAbs Therapeutics, Inc. Sec. Litig.*, No. 23-CV-00431 (S.D.N.Y. Jan. 18, 2023); Compl., *Gerald Celano, et al. v. Fulcrum Therapeutics, Inc., et al.*, No. 23-CV-11125 (D. Mass. Apr. 28, 2023); Compl., *State Tchr. Ret. Sys. of Ohio, et al. v. Charles River Lab'y Int'l, Inc., et al.*, No. 23-CV-11132 (D. Mass. May 19, 2023); Compl., *Juliana Paice, et al. v. Aldeyra Therapeutics, Inc., et al.*, No. 23-CV-11737 (D. Mass. Jul. 31, 2023); Compl., *Pembroke Pines Firefighters & Police Officers Pension Fund, et al. v. Integra LifeSciences Holdings Corp., et al.*, No. 23-CV-20321 (D.N.J. Sept. 12, 2023); Compl., *Joseph Zappia, et al. v. Myovant Sci., Ltd., et al.*, No. 23-CV-08097 (S.D.N.Y. Sept. 13, 2023); Compl., *Ramzy Alsaidi, et al. v. Outlook Therapeutics, Inc., et al.*, No. 23-CV-21862 (D.N.J. Nov. 3, 2023); Compl., *Ron Bergman, et al. v. Caribou Biosciences, Inc., et al.*, No. 23-CV-01742 (N.D. Cal. Feb. 10, 2023).
28 Compl., *Zachary Salzman, et al. v. ImmunityBio, Inc., et al.*, No. 23-CV-01216 (S.D. Cal. June 30, 2023).
29 *Id.* ¶ 2.
30 *Id.*
31 *Id.* ¶ 3.

ready-to-scale facilities.[32] Per the complaint, on May 11, 2023 Immunity Bio announced that the FDA had rejected the BLA for Anktiva, citing deficiencies related to the FDA's pre-license inspection of the company's third-party CMOs.[33] The plaintiffs brought suit, alleging that the company made false and/or misleading statements and/or failed to disclose GMP deficiencies at its third-party CMOs for Anktiva.[34] According to the complaint, this failure to disclose the GMP deficiencies led to a significant drop in ImmunityBio's stock price—falling US$3.43 per share, or 55.14%, to close at US$2.79 per share.[35]

Compared to 2022, there was a significant decrease in the number of actions against companies in relation to either a COVID-19-related products or services. [36]

For example, investors brought suit against Catalent, Inc. ("Catalent").[37] Catalent is a global provider of development and manufacturing solutions for drugs, biologics, cell and gene therapies, vaccines, and consumer health products and, according to the complaint, represented itself as a key player in the COVID-19 response, taking on large-scale projects including filling vaccines into syringes for Moderna and AstraZeneca.[38] The plaintiffs alleged Catalent made false and misleading statements in connection with its financial performance, including but not limited to materially overstating its revenue and earnings by prematurely recognizing revenue in violation of GAAP, having material weaknesses in its internal control over financial reporting, falsely representing demand, disregarding regulatory rules at key production facilities, among other things.[39] Despite not having any new projects at the time, Catalent had reported record-high quarterly revenues averaging approximately US$940 million between April 2020 and March 2021, a 40% jump over pre-COVID revenues.[40] The investors alleged that Catalent failed to disclose a drop in demand, despite their knowledge that one had occurred as the pandemic wore on and vaccinations had been administered to a large number of potential patients.[41] The investors also alleged that the defendants' purported fraud inflated Catalent's share price and caused Catalent stock to trade at a record high of US$142.64 per share on September 9, 2021 but pointed to stock drops, including one with more than a 68% decline.[42]

Another group of complaints alleged other unlawful conduct, involving purported misrepresentations stemming from an initial breach of legal or regulatory standards.[43]

In one case, plaintiffs brought suit against Charles River Laboratories International, Inc. ("Charles River") and certain of its officers in the District of Massachusetts.[44] Charles River is a full-service, non-clinical global drug development partner with a mission to create healthier lives, incorporated in Delaware with headquarters in Massachusetts.[45] As part of Charles River's operations, the company had been importing non-human primates from Cambodia for research.[46] According to the complaint, on February 22, 2023, before the market opened, Defendants issued a press release where it revealed that Charles River had received a subpoena from the U.S. Department of Justice ("DOJ"), in relation to an ongoing investigation by the U.S. Fish and Wildlife Service

32 *Id.*

33 *Id.* ¶ 5.

34 *Id.* ¶ 4.

35 *Id.* ¶ 6.

36 Such complaints comprised 5 of the 43 filings reviewed, or 11.6%. *See* Compl., *Brenda Hawkins, et al. v. Danaher Corp., et al.*, No. 23-CV-02055, (D.D.C. July 17, 2023); Compl., *City of Warwick Ret. Sys., et al. v. Catalent, Inc., et al.*, No. 23-CV-01108 (D.N.J. Feb. 24, 2023); Compl., *Laura L. Brill, et al. v. Invivyd, Inc., et al.*, No. 23-CV-10254 (D. Mass. Jan. 31, 2023); Compl., *United Ass'n of Plumbers and Pipefitters, Journeymen, Local #38 Defined BenefitPension Plan, et al. v. Syneos Health, Inc., et al.*, 23-CV-06548 (S.D.N.Y. July 27, 2023); *Carey Lowe, et al. v. Tandem Diabetes Care, Inc., et al*, No. 23-CV-01657 (S.D. Cal. Sept. 8, 2023).

37 Compl., *City of Warwick Retirement System, et al. v. Catalent, Inc., et al.*, No. 23-CV-01108 (D.N.J. Feb. 24, 2023).

38 *Id.* ¶¶ 3, 4.

39 *Id.* ¶ 1–2.

40 *Id.*

41 *Id.* ¶¶ 5–6.

42 *Id.* ¶ 6.

43 Such complaints comprised 4 of the 43 filings reviewed, or 9.3%. *See* Compl., *Roofers Local No. 149 Pension Fund, et al. v. Amgen Inc., et al.*, No. 23-CV-02138 (S.D.N.Y. March 13, 2023); Compl., *State Tchr. Ret. Sys. of Ohio, et al. v. Charles River Lab'y Int'l, Inc., et al.*, No. 23-CV-11132 (D. Mass. May 19, 2023); Compl., *City of Warwick Ret. Sys., et al. v. Catalent, Inc., et al.*, No. 23-CV-01108 (D.N.J. Feb. 24, 2023); Compl., *Kenneth S. Grossman, et al. v. Sin, et al.*, No. 23-CV-09501 (C.D. Cal. Nov. 9, 2023).

44 Compl., *State Tchr. Ret. Sys. of Ohio, et al. v. Charles River Lab'y Int'l, Inc., et al.*, No. 23-CV-11132 (D. Mass. May 19, 2023).

45 *Id.* ¶ 2.

46 *Id.* ¶ 3.

("USFWS") into the supply chain and illegal importation of non-human primates for research, and that it would be voluntarily suspending shipments of primates.[47] The plaintiffs brought suit, alleging that the announcements had disclosed the DOJ investigation while concealing the illegal importation of non-human primates for research.[48] According to the complaint, this failure to disclose illegal activities and the subsequent suspension of primate shipments led to a significant drop in Charles River's stock price, fell US$24.51, or 10%, to close at US$219.09 per share.[49] The plaintiffs also alleged that the voluntary suspension of non-human primates for research negatively impacted Charles River's earnings for the year and would reduce revenue growth by 200 basis points to 400 basis points.[50]

Another noteworthy trend in 2022 has been the number of life sciences companies that are incorporated abroad but have been subject to securities lawsuits in the United States.[51] For instance, plaintiffs originally brought suit against NovoCure Limited (NovoCure) and certain of its officers.[52] NovoCure is a company incorporated in the Baliwick of Jersey and headquartered in Switzerland with operating offices around the world, including in New Hampshire. It trades on the Nasdaq under the symbol "NVCR".[53] According to the complaint, NovoCure is a global oncology company with a proprietary platform technology called Tumor Treating Fields ("TTFields"), which are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms.[54] According to the original complaint, one of NovoCure's key priorities has been to drive the commercial adoption of Optune and Optune Lua, the Company's commercial TTFields devices.[55] As part of NovoCure's efforts, the Company had commissioned the LUNAR study.[56] On January 5, 2023, the defendants announced favorable results from the Company's LUNAR Study.[57] The plaintiffs brought suit, alleging that the announcements had disclosed positive results from the studies, while failing to disclose confounding factors that affected the study's results.[58] The plaintiffs alleged that the purported truth was not revealed until exactly five months later, during the ASCO Annual Meeting.[59] In particular, the plaintiffs alleged that, the company revealed that a relatively small percentage of study participants had been receiving standard of care therapy (i.e., immune checkpoint inhibitors), thereby rendering the study's results unreliable in terms of demonstrating clinical efficacy.[60] According to the complaint, when the purported truth was revealed about the LUNAR study, NovoCure's shareholders "immediately lost billions of dollars on extremely heavy volume."[61]

Some cases filed against life sciences companies included purported misrepresentations related to financial reporting.[62]

47 *Id.*

48 *Id.* ¶ 5.

49 *Id.* ¶¶ 4–5.

50 *Id.* ¶ 3.

51 Approximately 16.3%, or seven of 42 cases, filed in 2023 were against non-U.S. issuers incorporated across six countries. *See* Compl., *In re BioLineRx Ltd. Sec. Litig.*, No. 23-CV-00041 (D.N.J. Jan 5, 2023); Compl., *Christopher Turpel, et al. v. Canopy Growth Corp., et al.*, No. 23-CV-04302 (S.D.N.Y. May 23, 2023); Compl., *William E. Bazzelle, Sr., et al. v. NovoCure Ltd., et al.*, No. 23-CV-05146 (S.D.N.Y. June 19, 2023); Compl., *Cont'l Gen. Ins. Co., et al. v. Mallinckrodt plc, et al.*, No. 23-CV-03662 (D.N.J. Jul. 7, 2023); Compl., *John Kelk, et al. v. Bausch Health Co., Inc., et al.*, No. 23-CV-03996 (D.N.J. Jul. 26, 2023);); Compl., *Joseph Zappia, et al. v. Myovant Sciences, Ltd., et al.*, No. 23-CV-08097 (S.D.N.Y. Sept. 13, 2023); Compl., *Kenneth S. Grossman, et al. v. Sin, et al.*, No. 23-CV-09501 (C.D. Cal. Nov. 9, 2023). In 2022, 13.9%, or 6 of 43 cases, were against non-U.S. issuers.

52 Compl., *William E. Bazzelle, Sr., et al. v. NovoCure Ltd., et al.*, No. 23-CV-05146 (S.D.N.Y. June 19, 2023).

53 *Id.* ¶ 11.

54 *Id.* ¶ 20.

55 *Id.*

56 *Id.*

57 *Id.* ¶ 22.

58 *Id.* ¶ 2.

59 *Id.* ¶ 3.

60 *Id.*

61 *Id.* ¶ 4.

62 Such complaints comprised 15 of the 43 filings reviewed, or 34.9%. *See* Compl., *Erie County Emp.' Ret. Sys., et al. v. Cutera, Inc., et al.*, No. 23-CV-02560 (N.D. Cal. May 24, 2023); Compl., *Cont'l Gen. Ins. Co., et al. v. Mallinckrodt plc, et al.*, No. 23-CV-03662 (D.N.J. Jul. 7, 2023); Compl*., Tyler Dilbarian, et al. v. Infinity Pharm., Inc., et al.*, No. 23-CV-11865 (D. Mass. Aug. 15, 2023); Compl., *Sergio Vazquez, et al. v. Masimo Corp., et al.*, No. 23-CV-01546 (S.D. Cal. Aug. 22, 2023); Compl., *Carey Lowe, et al. v. Tandem Diabetes Care, Inc., et al*, No. 23-CV-01657 (S.D. Cal. Sept. 8, 2023).; Compl., *James Hammond, et al. v. Kenvue Inc., et al.*, No. 23-CV-20998 (D.N.J. Oct. 9, 2023); Compl., *Mika Bagheri, et al. v. DermTech, Inc., et al.*, No. 23-CV-01885 (S.D. Cal. Oct. 16, 2023); Compl., *Allegheny Cnty. Emp.' Ret. Sys., et al. v. AdaptHealth Corp., et al.*, 23-CV-04104 (E.D. Pa. Oct. 24, 2023). Compl., *Carla Aramouni, et al. v. ACELYRIN, Inc., et al.*,

For instance, plaintiffs brought suit against Cutera Inc. ("Cutera") and certain of its officers and directors in the Northern District of California.[63] Cutera is a Delaware corporation with its principal executive offices in Brisbane, California.[64] Cutera designs, develops, and manufactures aesthetic medical devices used for a variety of laser and energy-based beauty treatments.[65] The complaint alleges that throughout the putative class period, Cutera overstated the sustainability of its revenue growth in the wake of the COVID-19 pandemic, failed to disclose significant conflicts among members of the company's senior leadership and the board of directors, and failed to disclose several material weaknesses in the company's internal control over financial reporting.[66] The plaintiffs alleged that as a result of these misrepresentations, the price of Cutera stock declined from US$40.45 on January 6, 2023 to US$14.14 per share as of May 11, 2023.[67]

Last, another group of the cases involved alleged misrepresentations and omissions related to proposed mergers, acquisitions, IPOs, offerings and other transactions.[68]

For example, shareholders brought suit against Emisphere Technologies, Inc. and certain of its directors ("Emisphere") in the District of New Jersey.[69] Emisphere is a pharmaceutical and drug delivery company, known for developing proprietary technologies for oral formulations of therapeutic agents.[70] The plaintiffs alleged that Emisphere had disseminated false and misleading statements related to certain merger documents.[71] According to the complaint, during the time of its merger with Novo Nordisk, Emisphere was involved in the development of the Type 2 diabetes drug Rybelsus using Emisphere's proprietary SNAC drug delivery technology.[72] The Merger arose in the context of a longstanding business relationship between Emisphere and Novo Nordisk in which Emisphere licensed its patented SNAC drug delivery technology to Novo under a royalty agreement executed between the companies in 2008.[73] Following an intellectual property dispute that arose after Emisphere alleged that Novo had breached the royalty agreement by disclosing confidential information, Novo Nordisk initiated discussions about the potential acquisition of Emisphere.[74] The plaintiffs alleged that Defendants characterized the Merger as being "fair to and in the best interests of" Company shareholders based on discounted financial projections that, among other things:

- assumed a decrease in Rybelsus-related royalty payments from Novo to Emisphere beginning in 2027;
- wholly ignored the lucrative impact of the intellectual property dispute between Novo and Emisphere that was integral to the initial Merger negotiations and implicated significant royalty payments to the company; and
- discounted the possibility of success for FDA approval of the expanded use of Emisphere product Rybelsus.[75]

No. 23-CV-09672 (C.D. Cal. Nov. 15, 2023). Compl., *Brenda Hawkins, et al. v. Danaher Corp., et al.*, No. 23-CV-02055, (D.D.C. July 17, 2023); Compl., *United Ass'n of Plumbers and Pipefitters, Journeymen, Local #38 Defined BenefitPension Plan, et al. v. Syneos Health, Inc., et al.*, 23-CV-06548 (S.D.N.Y. July 27, 2023); Compl., *S/M Merger Arbitrage, L.P., et al. v. Emisphere Techs., Inc., et al.*, No. 23-CV-20898 (D.N.J. Oct. 4, 2023); Compl., *Abduladhim A. Alghazwi, et al. v. The Beauty Health Co., et al.*, 23-CV-09733 (C.D. Cal. Nov. 16. 2023); Compl., *Nicholas Miller, et al. v. Eagle Pharmas., Inc., et al.*, 23-CV-23011 (D.N.J. Dec. 11, 2023); Compl., *Christopher Turpel, et al. v. Canopy Growth Corp., et al.*, No. 23-CV-04302 (S.D.N.Y. May 23, 2023).

63 Compl., *Erie Cnty. Emp.' Ret. Sys., et al. v. Cutera, Inc., et al.,* No. 23-CV-02560 (N.D. Cal. May 24, 2023).

64 *Id.* ¶ 24.

65 *Id.* ¶ 31.

66 *Id.* ¶ 3.

67 *Id.* ¶¶ 4–17.

68 Such suits comprised eight of the 43 cases filed, or 18.6%. *See* Compl., *Joseph Zappia, et al. v. Myovant Scis., Ltd., et al.*, No. 23-CV-08097 (S.D.N.Y. Sept. 13, 2023); Compl., *S/M Merger Arbitrage, L.P., et al. v. Emisphere Techs., Inc., et al.*, No. 23-CV-20898 (D.N.J. Oct. 4, 2023); Compl., *Leslie Kangas, et al. v. Illumina, Inc., et al.*, No. 23-CV-02082 (S.D. Cal Nov. 10, 2023); Compl., *In re BioLineRx Ltd. Sec. Litig.*, No. 23-CV-00041 (D.N.J. Jan 5, 2023); Compl., *Robert Ciarciello, et al. v. Bioventus Inc., et al.*, No. 23-CV-00032 (M.D.N.C. Jan 12, 2023); Compl., *Jason Taylor, et al. v. Viatris Inc., et al.*, No. 23-CV-00812 (W.D. Pa. May 12, 2023); Compl., *Roofers Loc. No. 149 Pension Fund, et al. v. Amgen Inc., et al.*, No. 23-CV-02138 (S.D.N.Y. March 13, 2023); Compl., *Kenneth S. Grossman, et al. v. Sin, et al.*, No. 23-CV-09501 (C.D. Cal. Nov. 9, 2023.

69 Compl., *S/M Merger Arbitrage, L.P., et al. v. Emisphere Techs., Inc., et al.*, No. 23-CV-20898 (D.N.J. Oct. 4, 2023).

70 *Id.* ¶ 28.

71 *Id.* ¶ 1.

72 *Id.* ¶ 3.

73 *Id.*

74 *Id.* ¶ ¶ 6–7.

75 *Id.* ¶ 10

The merger documents suggested that unless there was a significant downturn, Emisphere would be able to proceed with the US$1.8 billion merger with Novo Nordisk within a short period of the announcement.[76]

The plaintiffs alleged that the defendants' material misstatements and omissions of material facts artificially depressed the company's stock price during the putative class period.[77] The defendants allegedly used this artificial stock price deflation to falsely assert that the Merger Consideration was "fair" to Emisphere shareholders and was the best way to maximize shareholder value when in fact, it did not reflect the true and accurate financial position of the company.[78] The plaintiffs further alleged that Emisphere's actions served to deflate Emisphere's stock price and justify the inadequate per share consideration offered to company shareholders under the merger.[79] The plaintiffs alleged that the defendants' material misrepresentations caused them to sell their Emisphere shares into the merger for the inadequate consideration of US$7.83 per share.[80]

Life sciences companies continue to face unique challenges in securities litigation, particularly around negative clinical trial results, product safety, and FDA approval expectations. Despite facing industry-specific issues, these companies also encounter common securities fraud risks, such as those related to disclosures in sales or mergers and are not immune to class actions in the U.S., even if incorporated abroad.

76 *Id.* ¶ 8; ¶¶ 11–16.
77 *Id.* ¶ 21.
78 *Id.*
79 *Id.*
80 *Id.* ¶ 22.

2023 Class Action Securities Fraud Decisions in the Life Sciences Sector

There was a slight increase in securities fraud decisions by courts involving life sciences companies in 2023, compared to 2022 when Dechert identified 43 decisions using the same criteria.[81] 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 or general mismanagement of life sciences companies (e.g., alleged market manipulation or improper accounting).

As in the previous years, the majority of these decisions address alleged violations of 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. However, when products in development underperform or outright fail during clinical trials, plaintiffs' firms around the country pursue securities fraud class actions to recover for the purported harm to investors arguing that the defendants somehow misled the public. Thus, 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 review public filings in an effort to bring forth allegations that the life science company mischaracterized or exaggerated trial results and/or failed to warn investors of significant risks that the product would not be approved.

In 2023, courts issued 49 opinions – a slight uptick from the 43 decisions identified using similar criteria in 2022.[82] Of those 49 opinions, 21 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 alleged that defendants made false or misleading misrepresentations regarding the likelihood of a product's FDA approval including that the companies withheld or mischaracterized FDA advice or warnings during development.[83] Similar to

81 *See supra* note 1.

82 Kistenbroker, et al. at 10.

83 *Id.*

2022, the courts in 2023 favored granting the motions to dismiss in their entirety with 17 of 21 motions granted,[84] and three motions were denied in part and granted in part.[85]

Similar to 2022, defendants frequently challenge and defeat securities class action claims regarding statements during product development. In *Zhou v. NextCure, Inc.,*[86] a court in the Southern District of New York granted the defendants' motion to dismiss the plaintiff's Amended Complaint ("AC") with prejudice due to the plaintiffs' failure to adequately plead any actionable misrepresentation or omission. In *NextCure,* the court addressed allegations in the plaintiffs' AC that the defendants created a misleading impression in its abstract regarding the efficacy of NC318, a drug designed to block the immunosuppressive properties of Siglec-15 ("S15"), a protein present on some cancerous tumors and made "false and misleading" statements in its prospectus regarding the FIND-10 platform, a three-dimensional imaging platform to develop immune-oncology therapies.[87] Specifically, the plaintiffs alleged that the defendants made "(1) omissions of updated Phase 1 Trial data from the November 5th Abstract; (2) statements and omissions, made in a variety of fora after November 5, 2019, generating 'false optimism' regarding the efficacy of NC318, when [NextCure Inc.] allegedly knew that the Phase 1 Trial could not support those conclusions; and (3) statements made in the IPO and SPO Prospectuses describing the FIND-IO Platform and failing to disclose the allegedly improper nature of its development."[88]

The court granted the defendants' motion to dismiss, explaining that the plaintiff's main allegations "that NextCure failed to disclose negative response data on three additional NSCLC patients on the publication date of the Abstract, creating a misleading impression of the efficacy of NC318…are confusing, and appear to contain fragments of two separate, mutually exclusive claims."[89] The plaintiffs alleged that by the time NextCure released its Abstract on "November 5, 2019, NextCure had a significant amount of additional negative data undercutting [its] representations of efficacy" regarding NC318 sometime between August and November, and failed to properly disclose the additional data in its November abstract.[90] The court found that the plaintiffs' argument failed because "although the Abstract was released on November 5, [NextCure] made clear that its results were current only through the previous August."[91] Thus, the plaintiff failed to identify any actionable misrepresentation or omission.

Regarding the plaintiffs' allegations "that [NextCure], in their IPO and SPO prospectuses, falsely characterized the FIND-IO Platform as 'unique', 'novel', 'proprietary', and 'the result of our industrialization, expansion, and optimization of a predecessor platform that Dr. Chen used to discover the immunosuppressive properties of

84 *Abady v. Lipocine, Inc.*, No. 19-cv-00906, 2023 WL 2938210 (D. Utah Apr. 13, 2023); *Berlinger v. Bienaime*, No. 21-cv-008254, 2023 WL 322899 (N.D. Cal. Jan. 19, 2023); *Dresner v. Silverback Therapeutics, Inc.*, No. 21-cv-01499, 2023 WL 2913755 (W.D. Wash. Apr. 12, 2023); *Employees' Retirement System of the City of Baton Rouge and Parish of East Baton Rouge v. MacroGenics, Inc.*, 61 F 4th 369 (4th Cir. 2023); *Golla v. Neovasc, Inc.*, No. 22-cv-00361, 2023 WL 2469770 (2d Cir. Mar. 13, 2023); *Goucher v. Iterum Therapeutics PLC*, 648 F. Supp. 3d 962 (N.D. Ill. 2023); *Gru v. Axsome Therapeutics, Inc.*, No. 22-cv-03925, 2023 WL 6214581 (S.D.N.Y Sep. 25, 2023); *In re Bristol-Myers Squibb Company CVR Sec. Litig.*, 658 F. Supp. 3d 220 (S.D.N.Y. 2023); *In re Ocugen, Inc. Sec. Litig.*, 659 F. Supp. 3d 572 (E.D. Penn. 2023); *Lewakowski v. Aquestive Therapeutics, Inc.*, No. 21-cv-03751, 2023 WL 2496504 (D.N.J. Mar. 14, 2023); *Nandkumar v. AstraZeneca PLC*, No. 22-cv-02704, 2023 WL 3477164 (2nd Cir. May 16, 2023); *Pitman v. Immunovant, Inc.*, No. 21-cv-00918, 2023 WL 1995018 (E.D.N.Y. Feb. 14, 2023); *Quinones v. Frequency Therapeutics, Inc.*, No. 21-CV-10933, 2023 WL 2693901 (D. Mass. Mar. 29, 2023); *Richfield v. PolarityTE, Inc.*, No. 21-cv-00561, 2023 WL 3010208 (D. Utah Apr. 19, 2023); *Shapiro v. TG Therapeutics, Inc.*, 652 F. Supp. 3d 416 (S.D.N.Y. 2023); *Spar v. Celsion Corp.*, No. 20-cv-15228, 2023 WL 2069725 (D.N.J. Feb. 6, 2023); *Zhou v. NextCure, Inc.*, No. 20-cv-07772, 2023 WL 4493541 (S.D.N.Y. July 12, 2023). In another motion, the magistrate made a recommendation for the district court to grant the motion to dismiss with prejudice. *In re Athenex, Inc. Securities LitigationNew*, No. 21-cv-00337, 2023 WL 7690175 (W.D.N.Y Sep. 29, 2023).

85 *Homyk v. ChemoCentryx, Inc.*, No. 21-cv-03343, 2023 WL 3579440 (N.D. Cal. Feb. 23, 2023); *In re Cassava Sciences, Inc. Securities Litigation*, No. 21-cv-00751, 2023 WL 3442087 (W.D. Tex. May 11, 2023); *Shash v. Biogen, Inc.*,84 F.4th 1 (1st Cir. 2023).

86 *Zhou v. NextCure, Inc.*, No. 20-cv-07772, 2023 WL 4493541 (S.D.N.Y. July 12, 2023).

87 *Id.*

88 *Id.* at *6.

89 *Id.* at *7.

90 *Id.*

91 *Id.*

S15,'"[92] the court found the plaintiffs failed to provide sufficient support for their fraud claim. These claims by the plaintiffs were directly drawn from a prior complaint that was voluntarily withdrawn. Thus, the court found these claims insufficient "because recitations of unproven allegations made in other complaints do not, on their own, constitute factual allegations sufficient to survive a motion to dismiss."[93] In sum, the plaintiffs' Section 10(b) claim failed because the plaintiff did not allege sufficient facts to support an actionable misrepresentation or omission, or a strong inference of scienter.

In the context of alleged misrepresentations relating to product development, courts also found additional and independent grounds to dismiss cases when plaintiffs fail "to adequately allege scienter in accordance with the PSLRA's ("Private Securities Litigation Reform Act") heightened standard."[94] For allegations of scienter, the PSLRA imposes a heightened pleading requirement, requiring that "complaints shall, with respect to each act or omission alleged to violate [Section 10(b)], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."[95] "[T]o establish scienter in a securities fraud case alleging non-disclosure of potentially material facts, the Plaintiff must demonstrate: (1) the Defendant knew of the potentially material fact, and (2) the Defendant knew that failure to reveal the potentially material fact would likely mislead investors."[96] For example, *Abady v. Lipocine, Inc.* plaintiffs brought suit against biopharmaceutical company, Lipocine, regarding the development of TLANDO, an oral capsule containing testosterone replacement therapy in a lipid formulation.[97] After submitting its initial New Drug Application ("NDA"), "Lipocine received a Complete Response Letter ("CRL") from the FDA indicating that its initial NDA for TLANDO could not be approved in its current form because the dosing regime in Lipocine's SOAR study differed significantly from the dosing regimen proposed in the 2015 NDA."[98] To address FDA concerns, Lipocine conducted two additional clinical studies, the Dosing Validation Study ("DV Study") and the Dosing Flexibility Study ("DF Study"), and resubmitted its NDA in 2017 based on the results from the DV Study.[99] Lipocine's 2017 TLANDO NDA was not approved and Lipocine subsequently submitted its third TLANDO NDA in May 2019 which was also rejected.[100] The plaintiffs alleged that Lipocine's stock price fell following the announcement that the May 2019 TLANDO NDA had been rejected by the FDA due to false or misleading statements "about Lipocine's ability to satisfy the FDA's concerns regarding secondary endpoint excursions in the DV Study and TLANDO's overall chances of approval by the FDA."[101] The plaintiffs alleged that the defendants made nine public statements that included materially false or misleading information during the class period between January 28, 2019 and November 11, 2019. For example, the plaintiffs alleged, among other things, that Lipocine's statements in its annual and quarterly SEC reports during the class period "regarding the TLANDO's secondary endpoints in the DV and DF Studies" were materially false or misleading because they "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA ... which were known to Defendants or recklessly disregarded by them."[102]

The District Court of Utah found that the complaint should be dismissed because the allegations failed to satisfy the PSLRA's heightened pleading standard of scienter which requires particularized facts giving rise to a strong inference.[103] Over the course of the clinical trials and the submissions to the FDA for the TLANDO NDAs, the defendants made statements regarding the status and potential efficacy of TLANDO and its anticipated NDA approval, which the plaintiffs claimed were knowingly

92 *Id.* at *11 (*citations omitted*).
93 *Id.*
94 *See, e.g.*, *Abady v. Lipocine, Inc.*, No. 19-cv-00906, 2023 WL 2938210 at *25 (D. Utah Apr. 13, 2023).
95 *Id.* at *23 (citing 15 U.S.C. § 78u-4(b)(2)).
96 *Id.* (citing *City of Phila. v. Fleming Cos., Inc.*, 264 F.3d 1245, 1260 (10th Cir. 2001)).
97 *Abady v. Lipocine, Inc.*, 2023 WL 2938210.
98 *Id.* at *1.
99 *Id.*
100 *Id.* at *4.
101 *Id.* at *6.
102 *Id.* at *7.
103 *Id.* at *23.

materially false and misleading.[104] For example, the plaintiffs allege that the defendants "had a motive to deceive investors into believing the prospects of TLANDO's approval was greater than it was" because "Lipocine was desperate to raise capital at the beginning of and throughout the class period in order to service its debt obligations under the SVB Loan."[105] Specifically, the court found that the plaintiffs' motive allegations were insufficient to meet the standards for pleading scienter.[106] The court explained that "while allegations regarding motive and opportunity may be relevant to establishing a defendant's scienter, they are not sufficient by themselves to satisfy the PSLRA's pleading requirement."[107] According to the court, "allegations of generalized motives shared by all companies that are not specifically and uniquely related to [the Defendants] in particular, are unavailing" and "while Plaintiff has alleged specific facts regarding Lipocine's particular debt situation, the need to raise capital for operations or to service debt is not unique to Lipocine."[108] Further, the court found that the plaintiffs' motive allegations were undermined by nearly identical statements made by Lipocine before the need to obtain the SVB Loan.[109]

Additionally, the court found the defendants' suggested alternative inference of scienter cogent and more plausible than the plaintiffs' inference. According to the defendants, their "statements were made in an attempt to explain to investors how Lipocine intended to address the deficiencies identified in the 2018 CRL" and "with respect to TLANDO's secondary endpoint deficiencies, to explain how Lipocine intended to justify the non-applicability of the FDA's secondary endpoint standard by performing additional analysis of existing data."[110] The court ultimately found the defendants' inference "more plausible, given the facts, than Plaintiffs' generalized and conclusory allegations that Defendants' intended to deceive investors regarding the likelihood of FDA approval." [111] Ultimately, the court granted the defendants' motion to dismiss with prejudice.

104 *Id.* at *24.
105 *Id.*
106 *Id.*
107 *Id.* (referencing *City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1263 (10th Cir. 2001).
108 *Id.*
109 *Id.* at *25 ("If it was the need to service the SVB Loan that motivated Lipocine to misrepresent the results of the DV Study by emphasizing the per dose measure of TLANDO's secondary endpoints over the per day measure, Plaintiffs have offered no explanation of why Lipocine made nearly identical statements before that need ever arose.").
110 *Id.* at 25.
111 *Id.*

Court Decisions Regarding Alleged Misrepresentations After Product Development

While statements made during product development are carefully monitored by the plaintiffs, life sciences companies can still face liability after a product is developed. Dechert identified 26 instances of a court addressing fraud claims that arose after a drug or device's development process. Of the 26 cases, nine of the motions to dismiss were granted in whole,[112] 12 were dismissed in part[113] and five motions to dismiss were denied.[114]

In one of the cases, *Oklahoma Firefighters Pension and Retirement System v. Biogen Inc.*, plaintiffs brought suit in the District of Massachusetts, alleging that the defendants violated the Exchange Act.[115] Biogen Inc. ("Biogen") is a global biopharmaceutical company focused on the development of treatments for serious neurological diseases.[116] The plaintiffs alleged that Biogen and its executives failed to disclose relevant information concerning the unsuccessful commercial rollout of its Alzheimer's disease therapy, Aduhelm.[117] The plaintiffs alleged that Biogen made 25 false and misleading statements, which the plaintiffs characterized as falling within six categories[118]

- First, the plaintiffs alleged that on June 7, 2021, the defendants made statements asserting that more than 900 healthcare sites were "ready" to implement treatment with Aduhelm.[119] The plaintiffs alleged that six weeks later, the defendants announced that only 325 of the 900 sites were ready to implement Aduhelm treatment.[120]
- Second, the plaintiffs alleged the defendants announced a partner to increase testing capacity for cerebrospinal fluid, stating that most physicians would want to determine the presence amyloid beta in a patient before prescribing Aduhelm.[121] The plaintiffs alleged the defendants failed to disclose the resistance received from doctors when suggesting CSF analysis as a means to test for the amyloid beta.[122]
- Third, the plaintiffs alleged the defendants made statements that Medicare coverage was "automatically presumed" following FDA approval.[123] Ultimately, Medicare coverage was limited to patients enrolled in CMS-approved randomized clinical trials.[124]
- Fourth, the plaintiffs alleged the defendants made false statements concerning Aduhelm's price, stating that the price per patient would be set at

112 *See In re Eargo, Inc. Sec. Litig.*, 656 F. Supp. 3d 928 (N.D. Cal. 2023); *Kong v. Fluidigm Corp.*, No. 22-CV-15396, 2023 WL 2134394 (9th Cir. Feb. 21, 2023); *Okla. Firefighters Pension & Ret. Sys. v. Biogen Inc.*, 665 F. Supp. 3d 125, 131 (D. Mass. 2023); *In re Mylan N.V. Sec. Litig.*, No. 16-CV-07926, 2023 WL 2711552 (S.D.N.Y. March 30, 2023); *Plumbers & Pipefitters Local Union #295 Pension Fund v. CareDx, Inc.*, No. 22-CV-03023, 2023 WL 4418886 (N.D. Cal. May 24, 2023); *Sneed v. AcelRx Pharmaceuticals, Inc.*, No. 21-CV-04353, 2023 WL 4412164 (N.D. Cal. July 7, 2023); *Turnofsky v. electroCore, Inc.*, No. 19-CV-18400, 2023 WL 4527553 (D.N.J. July 13, 2023); *In re Eargo, Inc. Sec. Litig.*, No. 21-CV-08597, 2023 WL 5663154 (N.D. Cal. Aug. 31, 2023); *In re Cronos Grp. Inc. Sec. Litig.*, No. 20-CV-01310, 2023 WL 8003324 (E.D.N.Y. Nov. 11, 2023).

113 *See In re Bos. Scientific Corps. Sec. Litig.*, 646 F. Supp. 3d 249 (D. Mass.2022); *Zaidi v. Adamas Pharms., Inc.*, 650 F. Supp. 3d 848 (N.D. Cal. 2023); *Reginald T. Allison, et al. v. Oak Street Health, Inc., et al.*, No. 22-CV-00149, 2023 WL 1928119 (N.D. Ill. Feb. 10, 2023); *In re Teva Sec. Litig.*, No. 17-CV-00558, 2023 WL 3186407 (D. Conn. May 1, 2023); *In re Mylan N.V. Sec. Litig.*, No. 20-CV-00955, 2023 WL 3539371 (W.D. Pa. May 18, 2023); *In re Vaxart, Inc. Sec. Litig.*, No. 20-CV-05949, 2023 WL 3637093 (N.D. Cal. May 25, 2023); *Hattaway v. Apyx Med. Corp.*, No. 22-CV-01298, 2023 WL 4030465 (M.D. Fla. June 15, 2023); *Roofer's Pension Fund v. Papa*, No. 16-CV-2805, 2023 WL 5287783 (D.N.J. Aug. 17, 2023); *Michele DeLuca, et al. v. Instadose Pharma Corp., et al.*, No. 21-CV-00675, 2023 WL 5489032 (E.D. Va. Aug. 24, 2023); *In re Aurora Cannabis Inc. Sec. Litig.*, No. 19-CV-20588, 2023 WL 5508831 (D.N.J. Aug. 24, 2023); *In re Emergent BioSolutions Inc. Sec. Litig.*, No. 21-CV-00955, 2023 WL 5671608 (D. Md. Sept. 1, 2023); *Phoenix Ins. Co., Ltd., et al. v. ATI Physical Therapy, Inc., et al.*, No. 21-CV-04349, 2023 WL 5748359 (N.D. Ill. Sept. 6, 2023).

114 This figure includes one case where Plaintiff's motion to leave to amend was denied and one appellate case where the district court had granted a motion to dismiss which was reversed upon appeal. *See Strougo v. Mallinckrodt Pub. Ltd. Co.*, No. 20-CV-10100, 2023 WL 17740482 (D.N.J. Dec. 16, 2022); *In re Dentsply Sirona, Inc. Sec. Litig.*, No. 18-CV-07253, 2023 WL 2682905 (E.D.N.Y. Mar. 29, 2023); *Nizar S. Nayani, et al. v. LifeStance Health Group, Inc., et al.*, No. 22-CV-06833, 2023 WL 3260260 (S.D.N.Y. May 4, 2023); *Hunter v. Elanco Animal Health Inc.*, No. 20-CV-01460, 2023 WL 6295487 (S.D. Ind. Sept. 27, 2023); *Habelt v. iRhythm Techs., Inc.,* 83 F. 4th 1162(9th Cir. 2023).

115 *Okla. Firefighters Pension & Ret. Sys. v. Biogen Inc.*, 665 F. Supp. 3d 125, 131 (D. Mass. 2023).

116 *Id.* at 133.

117 *Id.* at 131.

118

119 *Id.* at 134.

120 *Id.* at 134–35.

121 *Id.* at 135.

122 *Id.*

123 *Id.*

124 *Id.*

US$56,000 per year.[125] Prices were ultimately set at US$28,200.[126]

- Fifth, the plaintiffs alleged the defendants made statements concerning a potential agreement with the Veterans Health Administration ("VA") to provide Aduhelm to veterans despite knowledge of opposition to the drug within the VA.[127] The plaintiffs alleged the defendants had stated that they were "working to finalize a multiyear agreement with the [VA] in order to support access for veterans to Aduhelm[128]
- Sixth, the plaintiffs alleged Defendants made statements in an open letter to the Alzheimer's disease community allegedly describing Biogen's interactions with the FDA.[129]

The court granted the defendants' motion to dismiss in its entirety, stating that the plaintiffs had failed to allege sufficient facts to show the false or misleading nature of the defendants' challenged statements with respect to the failed rollout of the drug.[130] Further, the court found that even if one or more of the defendants' challenged statements were materially false or misleading, The plaintiffs allegations about knowledge of company and executives were insufficient to raise the strong inference of scienter required under the PSLRA to state a securities fraud claim.[131] The plaintiffs' allegations of scienter had been primarily derived from the statements of eight former Biogen employees.[132] One employee claimed that the decreased site readiness was said to be "no big deal," which the court viewed as actually supporting a lack of knowledge on the part of management, because the decreased site readiness would have been a "big deal" for Biogen.[133] In another employee statement, the employee claimed that after speaking to an individual two levels removed from management, it was "intimated" that the issue was "conveyed to more senior individuals."[134] The court found that this statement was insufficient to establish actual knowledge by management.[135] In its finding against scienter, the court specifically noted the plaintiffs' failure to prove that the defendants — rather than low-ranking employees at the company — knew or recklessly disregarded that 900 infusion sites were not "ready" on June 7–8.[136] Further, lacking from the complaint was any evidence that these employees had directly communicated with the named defendants.[137] Additionally, the court noted that the plaintiffs had mischaracterized numerous of the defendants' statements.[138] In dismissing the claim, the court did not note any prejudice.[139]

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 2023, courts issued 23 opinions in cases involving allegations of financial management, including: financial reporting, business operations, and disclosures relating to mergers or IPOs, among other claims. Of the cases Dechert identified, the outcomes varied, with seven cases being dismissed in whole in favor of the defendants,[140] 11 more being dismissed in part,[141] and five in which the plaintiffs

125 *Id.*
126 *Id.*
127 *Id.*
128 *Id.* at 135.
129 *Id.* at 131.
130 *Id.* at 139; *id.* at 156.
131 *Id.* at 156.
132 *Id.*
133 *Id.* at 152–53 (internal quotes omitted).
134 *Id.* at 154.
135 *Id.*
136 *Id.* at 156.
137 *Id.* at 132.
138 *Id.* at 156.
139 *Id.*
140 *See In re Eargo, Inc. Sec. Litig.*, 656 F. Supp. 3d 928 (N.D. Cal. 2023).; *Kong v. Fluidigm Corp.*, No. 22-CV-15396, 2023 WL 2134394 (9th Cir. Feb. 21, 2023); *In re Ocugen, Inc. Sec. Litig.*, 659 F. Supp. 3d 572 (E.D. Pa. 2023); *Dresner v. Silverback Therapeutics, Inc.*, No. 21-CV-01499, 2023 WL 2913755 (W.D. Wa. April 12, 2023); *Plumbers & Pipefitters Local Union #295 Pension Fund v. CareDx, Inc.*, No. 22-CV-03023, 2023 WL 4418886 (N.D. Cal. May 24, 2023); *Sneed v. AcelRx Pharma., Inc.*, No. 21-CV-04353, 2023 WL 4412164 (N.D. Cal. July 7, 2023*); Turnofsky v. electroCore, Inc.*, No. 19-CV-18400, 2023 WL 4527553 (D.N.J. July 13, 2023).
141 *See Zaidi v. Adamas Pharms., Inc.*, 650 F. Supp. 3d 848 (N.D. Cal. Jan. 13, 2023); *Reginald T. Allison, et al. v. Oak Street Health, Inc., et al.*, No. 22-CV-00149, 2023 WL 1928119 (N.D. Ill. Feb. 10, 2023); *In re Teva Sec. Litig.*, No. 17-CV-00558, 2023 WL 3186407 (D. Conn. May 1, 2023); *In re Mylan N.V. Sec. Litig.*, No. 20-CV-00955, 2023 WL 3539371 (W.D. Pa. May

prevailed on the defendants' motions to dismiss.[142]

An example of an opinion in this category includes allegations that a company misrepresented its financial reporting. For example, in *Kong v. Fluidigm Corporation*, the plaintiff alleged that Fluidigm Corporation ("Fluidigm") and two of its officers violated the Exchange Act.[143] Fluidigm is a lab equipment manufacturer that manufactures microfluidics and mass cytometry equipment.[144] Specifically, the plaintiff alleged Fluidigm and its top executives received internal reports in 2018 that projected the sharp decline in mass cytometry sales, which occurred in the second half of 2019, but chose to conceal these projections.[145] In addition to concealing the reports, the plaintiff alleged that Fluidigm and its executives made several statements during quarterly revenue calls that misled investors to believe the company's cytometry pipeline would remain profitable and continue to grow.[146] The decline in sales purportedly led to a substantial drop in stock price in the second half of 2019.[147]

The Ninth Circuit affirmed the district court's previous dismissal of the Second Amended Complaint, finding that the statements challenged did not constitute material misrepresentations or omissions that could sustain a securities fraud claim.[148] The safe harbor provision of the PSLRA protected the statements as forward-looking statements due to the accompanied meaningful cautionary language in Fluidigm's SEC filings and analyst calls, which warned investors about potential increased competition and market fluctuations.[149] For example, the court characterized statements such as "[w]e have certainly strong growth throughout the back half of the year in general" and "[w]e see no reason why the trend lines won't continue to revert back towards the norm" as forward-looking statements.[150] Second, the court noted that while some statements fell outside of the safe harbor, most of the statements constituted inactionable puffery.[151] Indeed, the court found that such statements assuring that "[m]ass cytometry adoption is robust" and "thriving" and that the "mass cytometry portfolio has done outstanding;" are generalized, optimistic remarks and "precisely the kind of 'feel good monikers' that this Court has characterized as puffery."[152] Last, the court concluded that the concrete past-tense statements about present trends in the mass cytometry market were not misleading when made because the company was experiencing record growth during the period the comments were made and the company did not conceal real-time financial information.[153] Accordingly, the Ninth Circuit affirmed, holding that the statements were not materially misleading when made.

Another example of an opinion in this category includes allegations that a company made misrepresentations in its offering documents as part of an IPO. For example, plaintiffs brought suit in the Northern District of California against Eargo Inc. ("Eargo"), a hearing aid manufacturer based in San Jose.[154] The plaintiffs alleged that Eargo, its executives, directors, and IPO underwriters breached the Securities Act and the Exchange Act by failing to disclose conflicts between Eargo's business model and federal insurance reimbursement requirements in the offering

18, 2023); *In re Vaxart, Inc. Sec. Litig.*, No. 20-CV-05949, 2023 WL 3637093 (N.D. Cal. May 25, 2023); *Hattaway v. Apyx Med. Corp.*, No. 22-CV-01298, 2023 WL 4030465 (M.D. Fla. June 15, 2023); *Roofer's Pension Fund v. Papa*, No. 16-CV-2805, 2023 WL 5287783 (D.N.J. Aug. 17, 2023); *In re Aurora Cannabis Inc. Sec. Litig.*, No. 19-CV-20588, 2023 WL 5508831 (D.N.J. Aug. 24, 2023); *Michele DeLuca, et al. v. Instadose Pharma Corp., et al.*, No. 21-CV-00675, 2023 WL 5489032 (E.D. Va. Aug. 24, 2023); *In re Emergent BioSolutions Inc. Sec. Litig.*, No. 21-CV-00955, 2023 WL 5671608 (D. Md. Sept. 1, 2023); *Phoenix Ins. Co., Ltd., et al. v. ATI Physical Therapy, Inc., et al.*, No. 21-CV-04349, 2023 WL 5748359 (N.D. Ill. Sept. 6, 2023).

142 This figure includes one case where Plaintiff's motion to leave to amend was denied and one appellate case where the district court had granted a motion to dismiss which was reversed upon appeal. *See Strougo v. Mallinckrodt Pub. Ltd. Co.*, No. 20-CV-10100, 2022 WL 17740482 (D.N.J. Dec. 16, 2022); *In re Dentsply Sirona, Inc. Sec. Litig.*, No. 18-CV-07253, 2023 WL 2682905 (E.D.N.Y. Mar. 29, 2023); *Nizar S. Nayani, et al. v. LifeStance Health Group, Inc., et al.*, No. 22-CV-06833, 2023 WL 3260260 (S.D.N.Y. April 10, 2023); *Hunter v. Elanco Animal Health Inc.*, No. 20-CV-01460, 2023 WL 6295487 (S.D. Ind. Sept. 27, 2023).

143 *Kong v. Fluidigm Corp.*, No. 22-15396, 2023 WL 2134394 (9th Cir. Feb. 21, 2023).

144 *Id.* at 1.

145 *Id.*

146 *Id.*

147 *Id.*

148 *Id.*

149 *Id.*

150 *Id.* at 1.

151 *Id.* at 2.

152 *Id.*

153 *Id.*

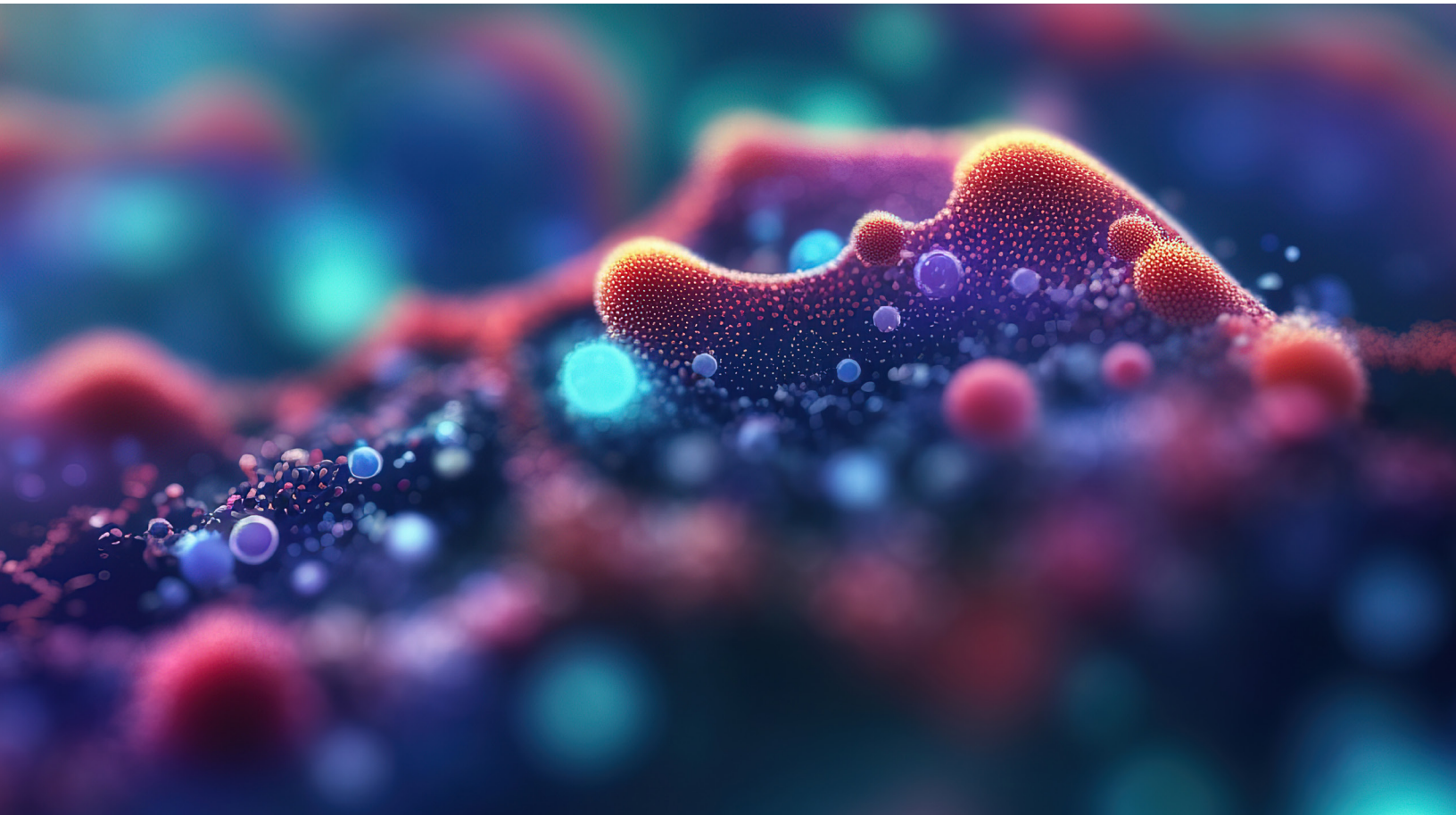
154 *In re Eargo, Inc. Sec. Litig.*, 656 F. Supp. 3d 928 (N.D. Cal. 2023).

documents and subsequent public filings.[155] The plaintiffs alleged that prior to the IPO, Eargo and its executives knew that Eargo's telecare business model for selling hearing aids was incompatible with federal insurance carrier policies, which require a diagnosis of "medical necessity."[156] Moreover, the plaintiffs alleged Eargo had made inflated revenue claims and fraudulent growth projections in public filings, leading to a Department of Justice ("DOJ") investigation following an insurance audit by Blue Cross Blue Shield ("BCBS"), Eargo's main third-party insurance provider.[157]

The plaintiffs argued that Eargo's alleged fraudulent practices led them to purchase the company's common stock at artificially inflated rates, resulting in significant losses.[158] The plaintiffs alleged the revelations about the BCBS audit and resulting DOJ investigation led to a substantial drop in Eargo's stock prices, exacerbating the plaintiffs' losses.[159] Among the claims that the plaintiffs alleged were false or misleading were Eargo's representation that it "validates customer eligibility and reimbursement amounts prior to shipping the product" and Eargo's characterization of the BCBS audit as "routine" or "pretty common."[160]

The court dismissed the plaintiffs' claims in their entirety.[161] The court held that the plaintiffs failed to adequately plead the falsity of the statements.[162] The court determined that Eargo's unaudited revenue numbers in the offering documents were not actionable and statements about targeting customers with qualifying insurance were shielded by the PSLRA' safe harbor clause.[163] Moreover, the court held that the plaintiffs did not sufficiently establish that Eargo's characterization of the insurer's audit as "routine" was misleading or false, nor did they adequately demonstrate the scienter necessary for a successful securities fraud claim.[164] The court granted the motion to dismiss with leave to amend.[165]

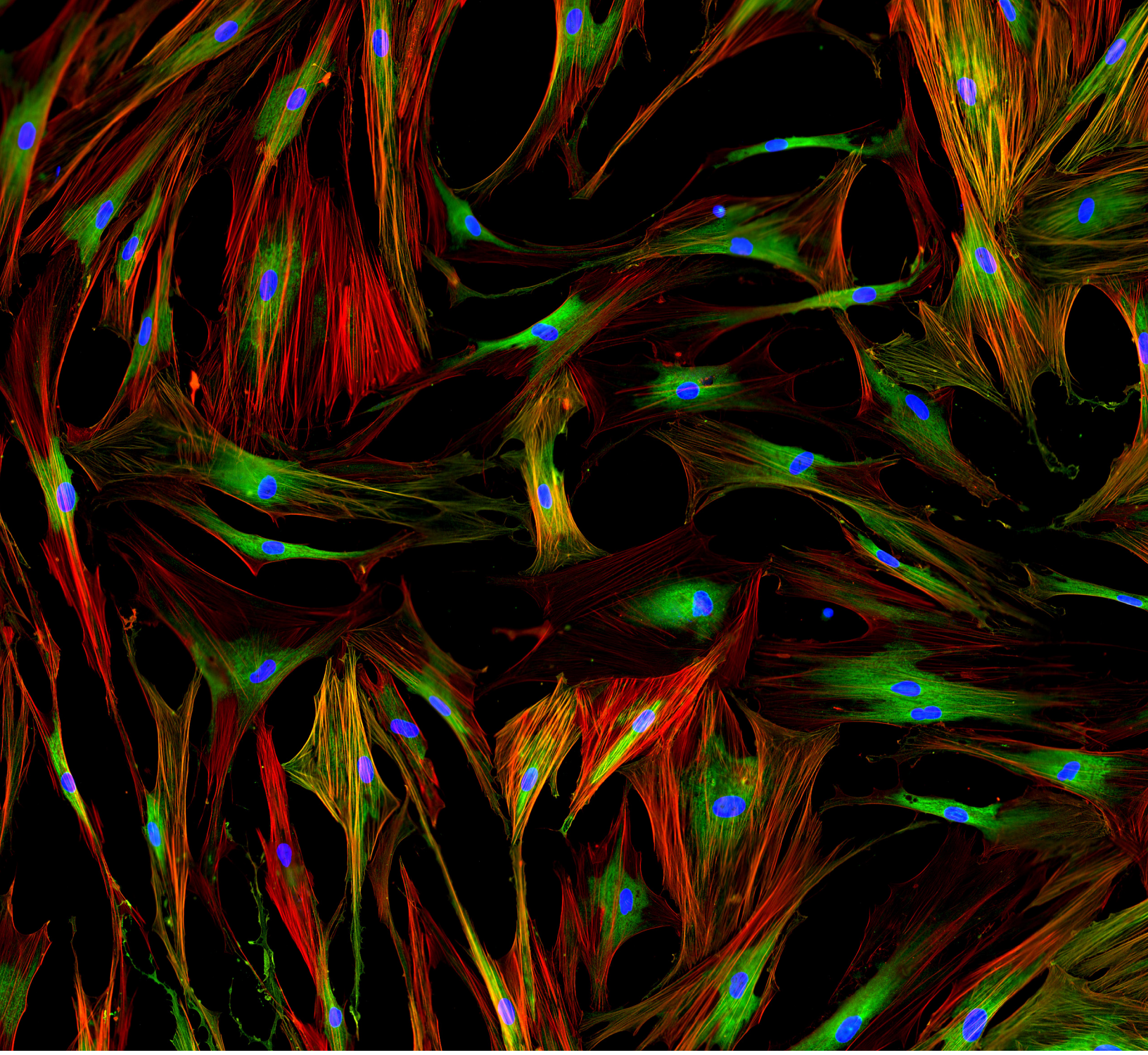
155 *Id.* at 933.
156 *Id.* at 937.
157 *Id.* at 933.
158 *Id.* at 934.
159 *Id.* at 933.
160 *Id.* at 944.
161 *Id.* at 948
162 *Id.* at 938; *id.* at 945.
163 *Id.* at 946.
164 *Id.* at 945.
165 *Id.* at 948.



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 be cautious and 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:

- Companies should strive to avoid any inconsistency in public statements and fight the urge to respond instinctively without identifying known risks or considering non-public information.
- In particular, many life sciences companies encounter regulatory setbacks, such as negative side effects in clinical trials, clinical trial failures, receipt of complete response letters, etc. When these are disclosed to the market, it may trigger a stock price drop. Companies should exercise care when making any disclosures to ensure that they disclose both the positive and negative results, including potentially negative information learned after the preliminary results are issued. Companies should ensure that internal disclosure regimens and processes are well documented and consistently followed.
- Smaller life sciences companies are susceptible to securities class actions and should work with counsel to ensure that they adopt a disclosure plan. Disclosure plans should not be limited to reviewed and written disclosures made in press releases or SEC filings, but should also include any statements made by executives during analyst calls. Company websites should also be continually updated.
- Life sciences companies are not immune to issues that may cut across all industries, and accordingly they should be prepared to make appropriate disclosures relating to transactions, business prospects, operations, financials, etc. Companies should ensure they are staying informed regarding the acts of third-party contractors and manufacturers, and public statements are consistent with the actions of such parties.
- Courts often have the benefit of hindsight to determine whether a product is defective by considering what defendants could or should have done differently. For example, courts often consider the existence of safer alternatives and the ability of the defendant to eliminate a product's dangerous characteristics. Companies should consider not only whether a given product is defective on its own, but how it compares to potential alternative designs or formulations and how its benefits balance the risks.
- Because deal litigation and other combinations and partnerships continue with regarding to life sciences companies, material disclosures to investors relating to the transaction should contain detailed explanations about the history of the transaction, alternatives to the transaction, reasons for the recommendation, the terms of the transaction, fairness opinions, and conflicts of interest, among other issues.
- Even if incorporated abroad, life sciences companies that are 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 be reasonably held and 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 certain disclosures as forward-looking statements.
- Risk disclosures that are current, relevant and upfront help to ward off securities class actions. Companies should 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.

- 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. Regulators are also cautious that corporate insiders use Rule 10b5-1 plans in ways that are not consistent with the objectives of the rule and will start monitoring 10b5-1 trading plans that are canceled or terminated based on later-obtained material nonpublic information.

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