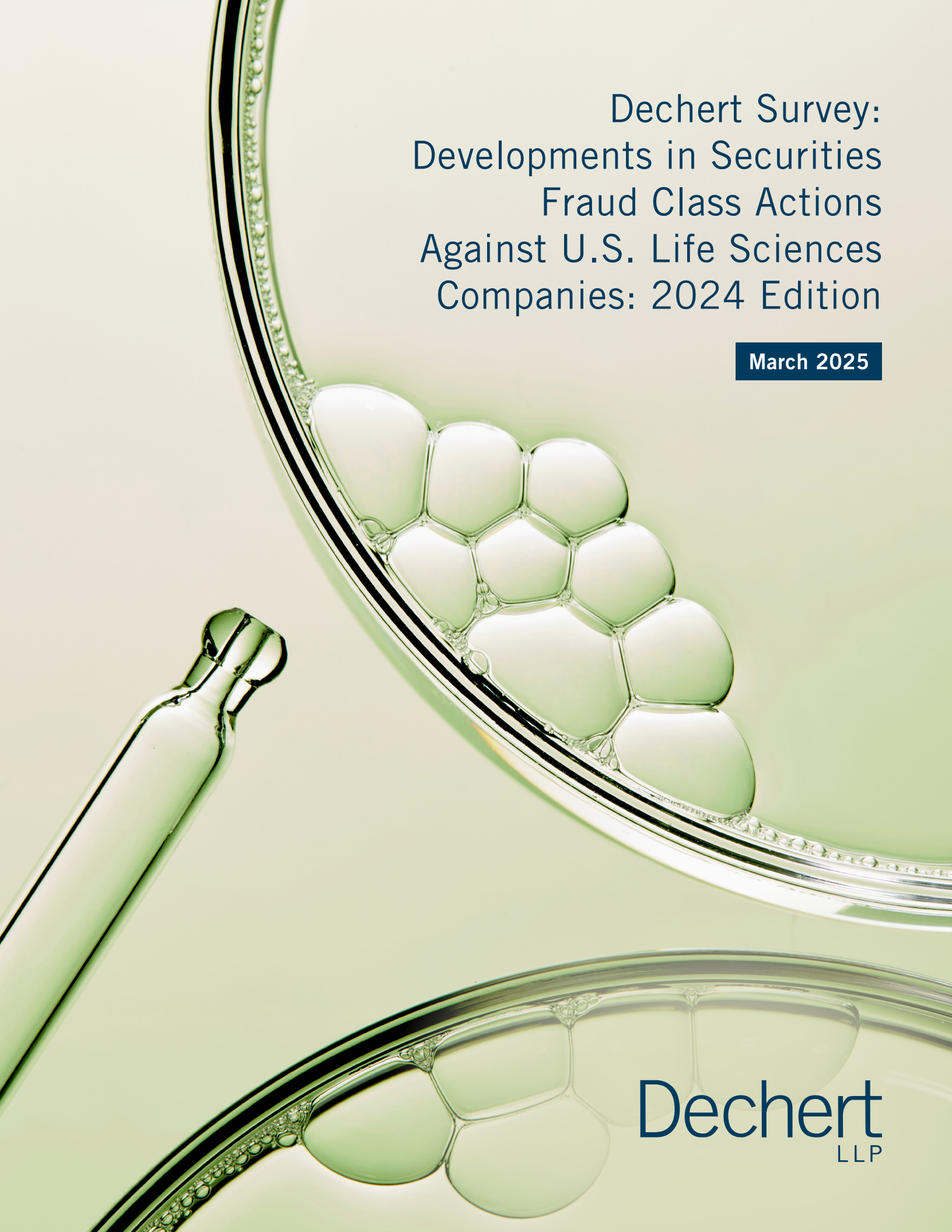


# Dechert Survey: Developments in Securities Fraud Class Actions Against U.S. Life Sciences Companies: 2024 Edition

**March 2025**

Dechert LLP

# Table of Contents

# Introduction

Last year marked an increase in federal securities class action filings, with plaintiffs filing 225 cases in 2024, up from 215 in 2023. Life sciences companies remained popular targets, accounting for approximately one in five of these filings.[1] In this report, we examine 2024's filing and decision trends, providing insights for life sciences companies to prudently navigate the litigation landscape.

**Plaintiffs filed a total of 50 securities class action lawsuits against life sciences companies in 2024, which represented over one in five securities class action lawsuits. Filings against life sciences companies in 2024 represent an increase of over 15% from the prior year. Of these cases, the following trends emerged:**

- The majority of suits were filed in the First, Second, and Ninth Circuits, continuing a trend of increased numbers of complaints being filed in the Ninth Circuit – 10 in 2022, 12 in 2023, and 14 in 2024. For district courts within these circuits, the Southern District of New York had the most filings, with 12 overall.
- A few plaintiff law firms were associated with about three-quarters of the first filed complaints against life sciences companies: Pomerantz LLP (22 complaints), Levi & Korsinsky, LLP (nine complaints), The Schall Law Firm (seven complaints), and The Rosen Law Firm, P.A. (six complaints).
- Moderately more claims were filed in the second half of 2023 than in the first half, with 29 complaints filed in the third and fourth quarters, and 21 complaints filed in the first and second quarters.

**An examination of the types of cases filed in 2024 reveals continuing trends regarding the underlying claims from previous years.**

- About 52% of complaints, or 26 of 50 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 34% of the complaints, or 17 of 50 complaints, arose from alleged misrepresentations involving regulatory hurdles, the timing of FDA approval, or the sufficiency of applications submitted to the FDA.
- About 6% of the complaints, or three of 50 complaints, involved misrepresentations related to COVID-19 related vaccines, products, or services.
- About 14% of the complaints, or seven of 50 complaints, were against non-U.S. issuers incorporated abroad.
- About 34% of the complaints, or 17 of 50 complaints, involved alleged misrepresentations related to the company's financial reporting.
- About 20% of the complaints, or 10 of 50 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 2024 survey on the same topic. *See* David Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in Securities Fraud Class Actions Against U.S. Life Sciences Companies,* Dechert LLP (Apr. 2024). 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: 2024 Year in Review* (last visited Feb. 28, 2025). 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 2024 filings against life sciences companies fell into more than one category.

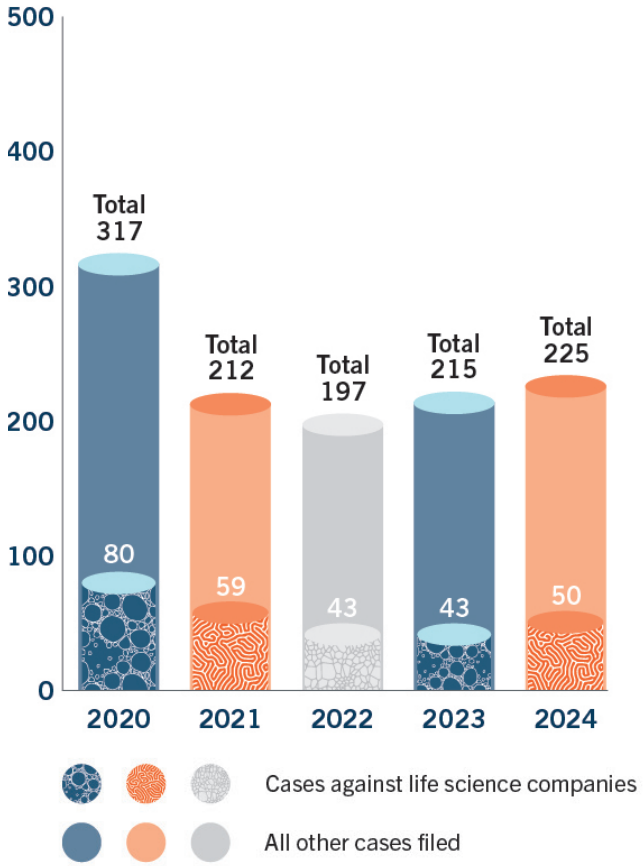
# Life Sciences Companies Remain Popular Targets for Securities Fraud Litigation

In recent years, life sciences companies have been targets of securities fraud lawsuits, and 2024 was no exception. This survey provides a comprehensive review of 2024's life sciences securities lawsuits. First, we analyze the number of cases filed, exploring jurisdictional trends, and underlying claim similarities. Next, we analyze the securities class action decisions rendered in 2024 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.

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

### Figure 1

**Number of class action securities fraud cases filed from 2020-2024**



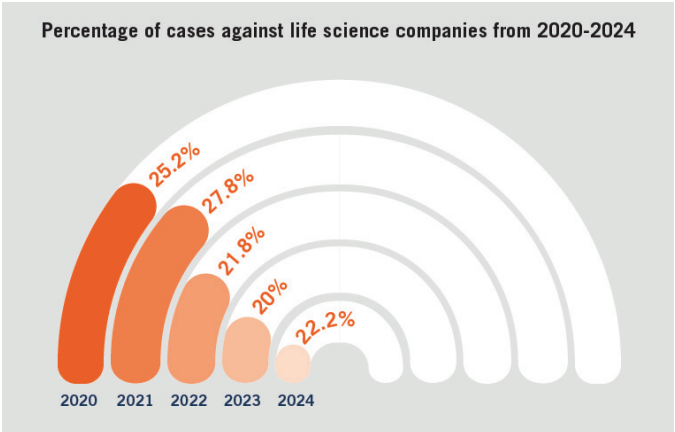

Last year marked a continued increase in federal securities class action filings, with the highest number of filings since 2020. In 2024, 225 lawsuits were filed, slightly more than the 215 lawsuits filed in 2023, the 197 filings in 2022, and the 212 filings in 2021. However, these numbers remain significantly lower in comparison to the 402, 402, 317 suits filed in 2018, 2019 and 2020, respectively.

The slight uptick in the number of overall filings has been accompanied by a corresponding slight increase in the proportion of actions brought against life sciences companies. A total of 50 class action securities lawsuits were filed against life sciences companies in 2024 – over one of five of all securities fraud class action lawsuits (or 22.2%). This percentage is slightly higher than in 2023, when 43 out of 215 securities fraud actions (or 20%) were filed against life sciences companies, and in 2022, when 43 out of 197 securities fraud class action lawsuits (or 21.8%) were filed against life sciences companies. Thus, life sciences companies continue to remain a common target in securities fraud class action filings.

## Filing Trends

### Figure 2

**Percentage of cases against life science companies from 2020-2024**




In 2024, the numerical count of complaints filed against life sciences companies slightly increased while the proportion relative to the total securities fraud class action filings similarly increased as compared to the past three years. Roughly in line with the prior three years,

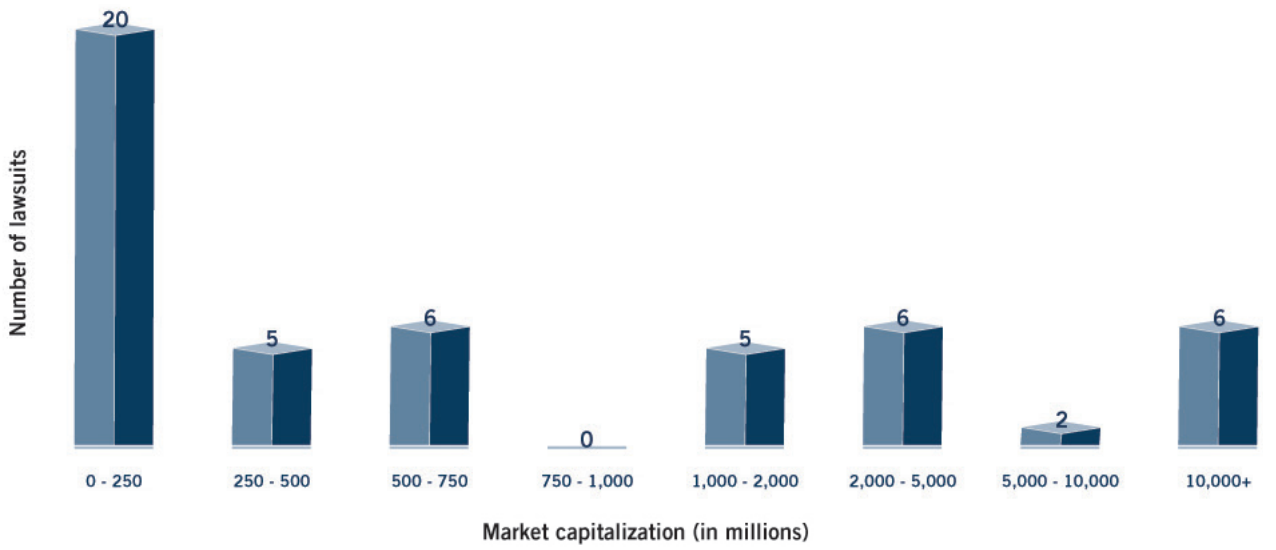
over one in five such lawsuits target a life sciences company (22.2%), as compared to 20% in 2023 and 21.8% in 2022.[3] The filings in 2024 brought about variations within larger trends, particularly relating to the timing and location of filings, and the claims involved.

- **There was a moderate decrease in the percentage of claims against large cap companies from the previous year, while the percentage of claims against small cap companies saw a slight increase.**[4] In 2024, six of 50, or 12%, of life science companies named in class action securities fraud complaints were large cap companies (companies with a market cap of more than US $10 billion).[5] This reflects a slight decrease from 2023 when 16.3% of the companies were large cap companies. For companies with a large market cap of US$5 billion and above, in 2024, approximately 16% of complaints were filed against these companies, representing a significant decrease from the year prior.[6] In 2024, 16 in 50 cases (or 32%) of life science companies named in class action securities fraud complaints were small cap companies between US $250 million to US $2 billion. This is a slight increase from 2023, when 13 in 43 cases, or 30.2%, involved small cap companies between US$250 million to US$2 billion.

- **Overall, courts within the Ninth Circuit saw the highest number of filings against life sciences companies, while the Southern District of New York was the district court with the highest number of such filings.** This marks a shift from 2023 and general trends. First, in 2024, the Ninth Circuit saw the greatest number of securities fraud case filings against life sciences companies, a change from 2023 when the Third Circuit had the most filings. The Ninth Circuit experienced a 16.7% increase in complaints, while the Third Circuit saw a drastic 83% decrease. Second, in a departure from historic trends, the majority of the 50 securities class action suits against life science companies in 2023 were filed in the First (three filings), Second (12 filings),

## Figure 3

**Breaking Down the Lawsuits By Market Capitalizations**




[3] In 2024, 50 out of the total of 225 lawsuits were brought against a life sciences company, or 22.2%. In 2023, 43 out of a total of 215 lawsuits were brought against a life sciences company, or 20%. In 2022, 43 out of a total of 197 lawsuits were brought against a life sciences company, or 21.8%. *See Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies 2023 (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 49 of the 50 companies. These figures exclude one company, Taro Pharmaceutical Industries, Ltd., whose market capitalization is unknown.

[5] In 2024, at least six companies had a market capitalization of US$10 billion or more. In 2023, seven companies had a market capitalization of US$10 billion or more.

[6] In 2024, eight of 50 companies had a market cap of US$5 billion and above. In 2023, 10 of 43 companies had a market cap of US$5 billion and above.

and Ninth (14 filings) Circuits. the Third Circuit, which had the most filings in 2023 (13 filings), only had three actions filed in 2024.[7] The Southern District of New York, which sits in the Second Circuit, had the most filings of any district court with 12, followed by Northern District of California with nine and the District of Massachusetts with eight. This reflects a change from 2023, when the District of New Jersey had the highest number of filings.[8] Additionally, over half of all securities class action complaints against life science companies in 2024 were brought in the federal courts in California and New York.[9] This brings filings back in accordance with previous trends, following the outlier year of 2023 where the majority of cases were brought in California and New Jersey.

- **Four law firms were associated with about three-quarters of the first filed complaints against life sciences companies.** The following firms were associated with the most first filed complaints: Pomerantz LLP (22 complaints), Levi & Korsinsky, LLP (nine complaints), The Schall Law Firm (seven complaints), and The Rosen Law Firm, P.A. (six complaints). Additionally, Pomerantz LLP has been selected as lead counsel in nine cases. Levi & Korsinsky LLP has been selected as lead counsel in five cases. The Rosen law Firm, P.A. has been selected as lead in four cases. The Schall Law firm has been selected as lead counsel in two cases.

- **More claims were filed in the second half of 2023 than in the first half, which continues the trend seen in 2023.** Of the 50 complaints filed against life sciences companies in 2024, 21 were filed in the first half of the year, and 29 were filed in the second half. The number of complaints filed against life sciences companies per quarter in 2024 was: 10 in Q1, 11 in Q2, 18 in Q3 and 11 in Q4. This pattern aligns with the pattern seen in 2023, when more claims were also filed in the second half of the year.[10]

Overall, in 2024, securities class action filings against life sciences companies saw notable changes. The total amount of complaints increased, with a geographical shift leading to more filings in the Ninth Circuit and fewer in the Third Circuit, compared to the previous year. Four law firms were associated with about three-quarters of the filings, indicating market concentration. Additionally, 2024 saw a moderate decrease in actions against large cap companies and a slight increase in cases against small cap companies. These trends continue to underscore the dynamic nature of securities fraud litigation in the life sciences sector.

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7 In 2023, the following circuits had the greatest amount of securities class actions filed against life science companies: Third Circuit (13 filings), the Ninth Circuit (12 filings), and the Second Circuit (nine filings).

8 In 2023, the District of New Jersey had 10 filings.

9 14 of 50 actions were brought in California federal courts, and 12 of 50 actions were brought in New York federal courts, exclusively in the Southern District of New York.

10 In 2023, 28 securities fraud class action complaints filed against life sciences companies were filed in the second two quarters, or 65.1%.

## Causes of Action

The total number of securities fraud class actions brought against life sciences slightly increased in 2024, with legal issues remaining consistent with previous years. The largest category of cases involved misrepresentations of produce efficacy and safety, which could at times impact the likelihood of FDA approval.[11]

For instance, plaintiffs brought suit against Caribou Biosciences, Inc. ("Caribou") and certain of its officers in the Northern District of California.[12] Caribou is a clinical-stage biopharmaceutical company that purports to develop genome-edited allogeneic cell therapies for the treatment of hematologic malignancies in the U.S. and internationally.[13] The plaintiffs alleged that Caribou and its officers made materially false and misleading statements regarding the safety, efficacy, and durability of their lead product candidate, CB-010, overstated the clinical results and commercial prospects of CB-010, and failed to disclose significant risks to the company's liquidity and operational capability.[14] The plaintiffs alleged that on June 2, 2024, Caribou issued a press release claiming positive clinical data for CB-010, which was followed by a downgrade from analysts noting concerns about the competitive viability of CB-010.[15] The plaintiffs alleged that on July 16, 2024, Caribou disclosed in an SEC filing that it had discontinued preclinical research activities associated with its allogenic CAR-NK platform and reduced its workforce by 12%.[16] Caribou's stock purportedly dropped.[17]

In another case, plaintiffs sued Moderna, Inc. ("Moderna") in the District of Massachusetts.[18] The plaintiffs accused Moderna of overstating mRNA-1345's efficacy and failing to disclose its true clinical performance.[19] After Moderna announced FDA approval of mRNA-1345, revealing a lower-than-expected efficacy rate, Moderna's stock purportedly fell.[20]

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[11] Such complaints comprised 26 of the 50 filings reviewed, or 52%. *See* Compl., *In re BioVie Inc. Sec. Litig.,* No. 24-CV-00035 (D. Nev. Jan. 19, 2024); Compl., *Zerbato v. AlloVir, Inc.,* No. 24-CV-10152 (D. Mass. Jan. 19, 2024); Compl., *Glazing Emps. & Glaziers' Union Local #27 Pension & Ret. Fund v. iRhythm Techs., Inc.,* No. 24-CV-00706 (N.D. Cal. Feb. 6, 2024); *Compl., Yuksel v. Ventyx Biosciences, Inc.,* No. 24-CV-00415 (S.D. Cal. Mar. 1, 2024); Compl., *Huey v. Anavex Life Scis. Corp.,* No. 24-CV-01910 (S.D.N.Y. Mar. 13, 2024); Compl., *Gill v. Bluebird Bio, Inc.,* No. 24-CV-10803 (D. Mass. Mar. 28, 2024); Compl., *In re Checkpoint Therapeutics, Inc. Sec. Litig.,* No. 24-CV-02613 (S.D.N.Y. Apr. 5, 2024); Compl., *Mogan v. Altimmune, Inc.,* No. 24-CV-01315 (D. Md. May 6, 2024); Compl., *Gray v. Biogen Inc.,* No. 24-CV-12691 (D. Mass. May 22, 2024); Compl., *Bishins v. Marinus Pharms., Inc.,* No. 24-CV-02430 (E.D. Pa. June 5, 2024); Compl., *Rodriguez v. Gritstone Bio, Inc.,* No. 24-CV-03640 (N.D. Cal. June 7, 2024); Compl., *Nesterenko v. Bolt Biotherapeutics, Inc.,* No. 24-CV-03985 (N.D. Cal. July 2, 2024); Compl., *Wells v. SeaStar Med. Holding Corp.,* No. 24-CV-01873 (D. Colo. July 5, 2024); Compl., *Crain v. MacroGenics, Inc.,* No. 24-CV-02184 (D. Md. July 26, 2024); Compl., *Klobus v. Akero Therapeutics, Inc.,* No. 24-CV-02534 (N.D. Cal. Apr. 26, 2024); Compl., *Wentz v. Moderna, Inc.,* No. 24-CV-12058 (D. Mass. Aug. 9, 2024); Compl., *Korver v. Sage Therapeutics, Inc.,* No. 24-CV-06511 (S.D.N.Y. Aug. 28, 2024); Compl., *Oldroyd v. Verve Therapeutics, Inc.,* No. 24-CV-12218 (D. Mass. Aug. 27, 2024); Compl., *Olsen v. Agenus Inc.,* No. 24-CV-12299 (D. Mass. Sept. 6, 2024); Compl., *Mukeljic v. Allarity Therapeutics, Inc.,* No. 24-CV-06952 (S.D.N.Y. Sept. 13, 2024); Compl., *Barpar v. Elanco Animal Health Inc.,* No. 24-CV-02912 (D. Md. Oct. 7, 2024); Compl., *N. Collier Fire Control & Rescue Dist. Firefighters' Ret. Plan v. Dentsply Sirona Inc.,* No. 24-CV-09083 (S.D.N.Y. Nov. 26, 2024); Compl., *Crocker v. Cassava Scis., Inc.,* No. 24-CV-01525 (W.D. Tex. Dec. 12, 2024); Compl., *Rondini v. Kyverna Therapeutics, Inc.,* No. 24-CV-08869 (N.D. Cal. Dec. 9, 2024); Compl., *Alexandru v. Applied Therapeutics, Inc.,* No. 24-CV-09715 (S.D.N.Y. Dec. 17, 2024); Compl., *Saylor v. Caribou Biosciences, Inc.,* No. 24-CV-09413 (N.D. Cal. Dec. 24, 2024).

[12] Compl., *Saylor v. Caribou Biosciences, Inc.,* No. 24-CV-09413 (N.D. Cal. December 24, 2024).

[13] *Id.* ¶ 2.

[14] *Id.* ¶ 4.

[15] *Id.* ¶¶ 5-6.

[16] *Id.* ¶ 8.

[17] *Id.* ¶ 9.

[18] Compl., *Wentz v. Moderna, Inc.,* No. 24-CV-12058 (D. Mass. Aug. 9, 2024).

[19] *Id.* ¶ 4.

[20] *Id.* ¶¶ 5-6.

Another distinct group of complaints involve misrepresentations regarding regulatory hurdles, the timing of FDA approval, or the sufficiency of applications submitted to the FDA.[21]

Plaintiffs brought suit against Ardelyx, Inc. ("Ardelyx") in the District of Massachusetts.[22] Per the complaint, Ardelyx is a biotechnology company focused on developing and commercializing therapies for, among other things, patients with chronic kidney disease ("CKD").[23] According to Ardelyx, 550,000 people in the U.S. suffer from end stage renal disease ("ESRD"), which is the final stage of CKD and is characterized by a progressive loss of kidney function.[24] The plaintiffs alleged that despite indicating plans to apply for a critical Medicare adjustment, Ardelyx shocked investors by disclosing it had not intended to apply, which purportedly led to a 30% stock price decline.[25]

The trend of declining actions against companies in relation to COVID-19 products or services that was seen in 2023 continued in 2024.[26] Further, the referenced actions were all filed in the first half of the year. Thus, life sciences companies can likely expect these types of actions to decrease further as more time passes since the pandemic.

For example, plaintiffs brought suit against BioNTech SE ("BioNTech") in the Southern District of New York.[27] BioNTech is a biotechnology company that in collaboration with Pfizer Inc. ("Pfizer"), developed Comirnaty, the first messenger RNA ("mRNA") COVID-19 vaccine authorized for human use.[28] As part of BioNTech's collaboration agreement with Pfizer, BioNTech has and continues to develop Comirnaty, a COVID-19 vaccine.[29] The plaintiffs alleged that BioNTech made false and misleading statements and failed to disclose that BioNTech overstated demand for Comirnaty and its commercial prospects, that BioNTech had accumulated excess inventory of raw materials and vaccine doses for non-XBB.1.5 variants, and as a result, BioNTech was at increased risk of recording significant inventory write-offs and other charges related to Comirnaty.[30] These inventory write offs purportedly led to stock drops.[31]

Another noteworthy trend in 2024 has been the number of life sciences companies that are incorporated abroad but have still been subject to securities lawsuits in the United States.[32]

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21 Such complaints comprised 17 of the 50 cases filed, or 34%. *See* Compl., *Cement Masons' & Plasterers' Local No. 502 Pension Fund v. InMode Ltd.,* No. 24-CV-01219 (C.D. Cal. Feb. 14, 2024); Compl., *Shih v. Amylyx Pharms., Inc.,* No. 24-CV-12068 (D. Mass. Feb. 9, 2024); Compl., *Gill v. Bluebird Bio, Inc.,* No. 24-CV-10803 (D. Mass. Mar. 28, 2024); Compl., *In re Checkpoint Therapeutics, Inc. Sec. Litig.,* No. 24-CV-02613 (S.D.N.Y. Apr. 5, 2024); Compl., *Wells v. SeaStar Med. Holding Corp.,* No. 24-CV-01873 (D. Colo. July 5, 2024); Compl., *Olsen v. Agenus Inc.,* No. 24-CV-12299 (D. Mass. Sept. 6, 2024); Compl., *Mukeljic v. Allarity Therapeutics, Inc.,* No. 24-CV-06952 (S.D.N.Y. Sept. 13, 2024); Compl., *Barpar v. Elanco Animal Health Inc.,* No. 24-CV-02912 (D. Md. Oct. 7, 2024); Compl., *Kachrodia v. Acadia Healthcare Co., Inc.,* No. 24-CV-01238 (M.D. Tenn. Oct. 16, 2024); Compl., *Cutshall v. Humacyte, Inc.,* No. 24-CV-00954 (M.D.N.C. Nov. 18, 2024); Compl., *N. Collier Fire Control & Rescue Dist. Firefighters' Ret. Plan v. Dentsply Sirona Inc.,* No. 24-CV-09083 (S.D.N.Y. Nov. 26, 2024); Compl., *Alexandru v. Applied Therapeutics, Inc.,* No. 24-CV-09715 (S.D.N.Y. Dec. 17, 2024); Compl., *Porcelli v. Outset Med., Inc.,* No. 24-CV-06124 (N.D. Cal. Aug. 29, 2024); Compl., *Korver v. Sage Therapeutics, Inc.,* No. 24-CV-06511 (S.D.N.Y. Aug. 28, 2024); Compl., *Yarborough v. Ardelyx, Inc.,* No. 24-CV-12119 (D. Mass. Aug. 16, 2024); Compl., *Wentz v. Moderna, Inc.,* No. 24-CV-12058 (D. Mass. Aug. 9, 2024); Compl., *Oldroyd v. Verve Therapeutics, Inc.,* No. 24-CV-12218 (D. Mass. Aug. 27, 2024).

22 Compl., *Yarborough v. Ardelyx, Inc.,* No. 24-CV-12119 (D. Mass. Aug. 16, 2024).

23 *Id.* ¶ 2.

24 *Id.*

25 *Id.* ¶¶ 13-14.

26 Such complaints comprised three of the 50 filings reviewed, or 6%. See Compl., *Rodriguez v. Gritstone Bio, Inc.,* No. 24-CV-03640 (N.D. Cal. June 7, 2024); Compl., *Bristol Cnty. Ret. Sys. v. QuidelOrtho Corp.,* No. 24-CV-02804 (S.D.N.Y. Apr. 12, 2024); Compl., *Adriano Ladewig v. BioNTech SE,* No. 24-CV-05310 (S.D.N.Y. Jan. 12, 2024).

27 Compl., *Ladewig v. BioNTech SE,* No. 24-CV-05310 (S.D.N.Y. Jan. 12, 2024).

28 *Id.* ¶ 2.

29 *Id.*

30 *Id.* ¶ 4.

31 *Id.* ¶ 12.

32 Approximately 14%, or seven of 50 cases, filed in 2024 were against non-U.S. issuers incorporated across four countries. *See* Compl., *Ladewig v. BioNTech SE,* No. 24-CV-05310 (S.D.N.Y. Jan. 12, 2024); Compl., *Cement Masons' & Plasterers' Local No. 502 Pension Fund v. InMode Ltd.,* No. 24-CV-01219 (C.D. Cal. Feb. 14, 2024); Compl., *In re Glob. Cord Blood Corp. Sec. Litig.,* No. 24-CV-03071 (S.D.N.Y. Apr. 22, 2024); Compl., *In re Exscientia P.L.C. Sec. Litig.,* No. 24-CV-05692 (D.N.J. Apr. 26, 2024); Compl., *Herbst Cap. Mgmt., LLC v. Indivior PLC,* No. 24-CV-00554 (E.D. Va. Aug. 2, 2024); Compl., *Mitchell v. Taro Pharm. Indus. Ltd.,* No. 24-CV-06818 (S.D.N.Y. Sept. 9, 2024); Compl., *Saleh v. AstraZeneca PLC,* No. 24-CV-11021 (C.D. Cal. Dec. 23, 2024). In 2023, 16.3%, or seven of 43 cases, were against non-U.S. issuers.

For example, plaintiffs brought suit against AstraZeneca PLC ("AstraZeneca") and certain of its officers.[33] Per the complaint, AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in oncology, rare diseases, and Biopharmaceuticals.[34] The plaintiffs alleged that AstraZeneca misled investors by making false and misleading statements about its compliance with legal and regulatory requirements and associated legal risks, particularly regarding its business operations in China.[35] The plaintiffs alleged that AstraZeneca failed to disclose that AstraZeneca was engaged in insurance fraud in China, which resulted in heightened legal exposure and the eventual detention of the AstraZeneca China President.[36] Thus, AstraZeneca was alleged to have misrepresented its legal risks and potential material harm to its business activities in China, which subsequently purportedly led to further stock drops.[37]

Some cases filed against life sciences companies included purported misrepresentations related to financial reporting.[38]

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33 Compl., *Saleh v. AstraZeneca PLC,* No. 24-CV-11021 (C.D. Cal. Dec. 23, 2024).

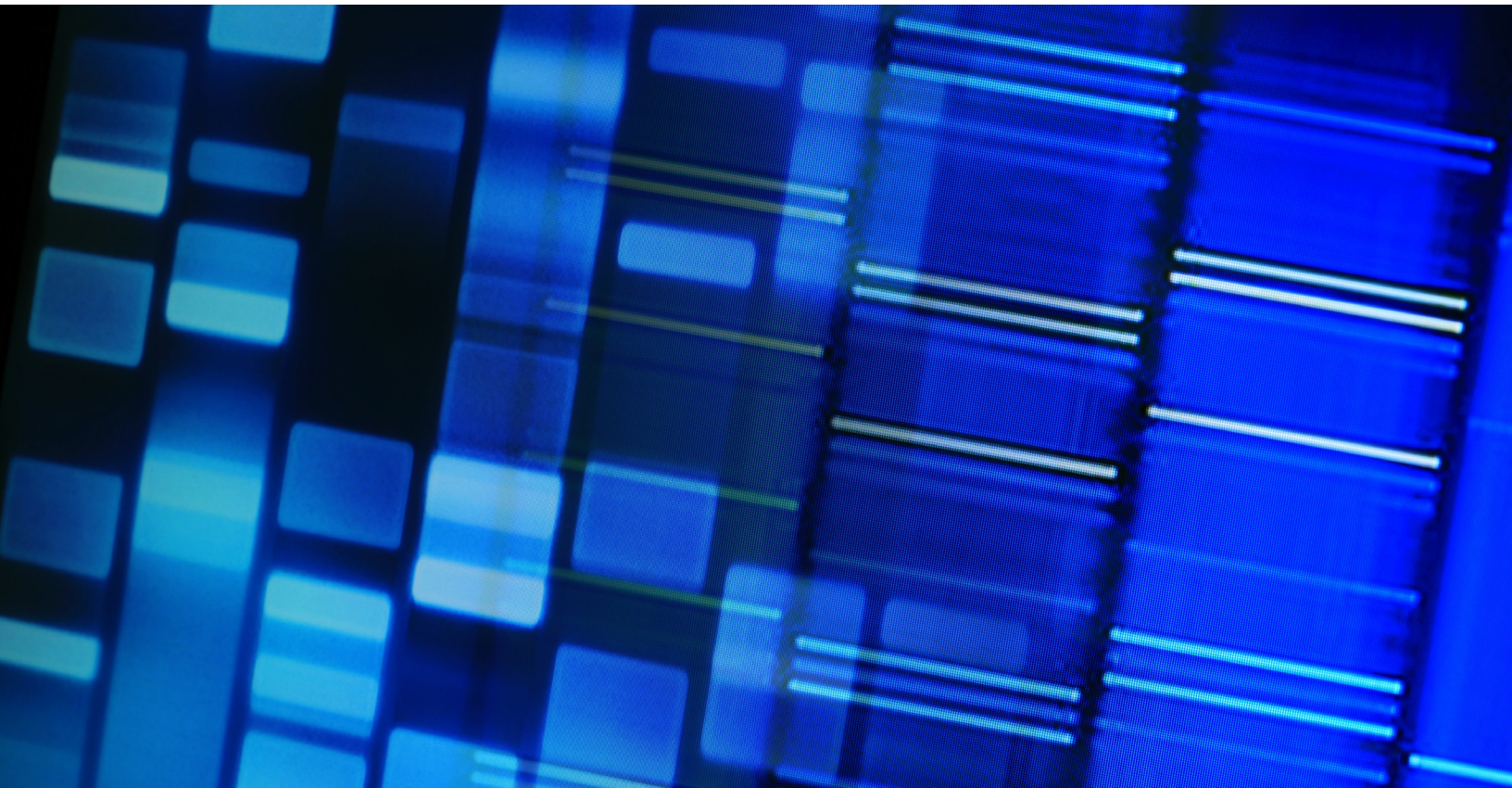
34 *Id.* ¶ 7.

35 *Id.* ¶¶ 18-33.

36 *Id.* ¶ 33.

37 *Id.* ¶¶ 35, 38.

38 Such complaints comprised 17 of the 50 filings reviewed, or 34%. *See* Compl., *Shapiro v. Assertio Holdings, Inc.,* No. 24-CV-00169 (N.D. Ill. Jan. 5, 2024); Compl., *Ladewig v. BioNTech SE,* No. 24-CV-05310 (S.D.N.Y. Jan. 12, 2024); Compl., *In re BioVie Inc. Sec. Litig.,* No. 24-CV-00035 (D. Nev. Jan. 19, 2024); Compl., *Shih v. Amylyx Pharms., Inc.,* No. 24-CV-12068 (D. Mass. Feb. 9, 2024); Compl., *In re Ocugen Inc. Sec. Litig.,* No. 24-CV-01500 (E.D. Pa. Apr. 11, 2024); Compl., *Michiana Area Elec. Workers' Pension Fund v. Inari Med., Inc.,* No. 24-CV-03686 (S.D.N.Y. May 13, 2024); Compl., *Bishins v. Marinus Pharms., Inc.,* No. 24-CV-02430 (E.D. Pa. June 5, 2024); Compl., *Wells v. SeaStar Med. Holding Corp.,* No. 24-CV-01873 (D. Colo. July 5, 2024); Compl., *Carew v. Lifecore Biomedical, Inc.,* No. 24-CV-03028 (D. Minn. July 29, 2024); Compl., *Herbst Cap. Mgmt., LLC v. Indivior PLC,* No. 24-CV-00554 (E.D. Va. Aug. 2, 2024); Compl., *Alonzo v. DexCom, Inc.,* No. 24-CV-01485 (S.D. Cal. Aug. 21, 2024); Compl., *Porcelli v. Outset Med., Inc.,* No. 24-CV-06124 (N.D. Cal. Aug. 29, 2024); Compl., *Kachrodia v. Acadia Healthcare Co., Inc.,* No. 24-CV-01238 (M.D. Tenn. Oct. 16, 2024); Compl., *Patel v. Edwards Lifesciences Corp.,* No. 24-CV-02221 (C.D. Cal. Oct. 14, 2024); Compl., *Barpar v. Elanco Animal Health Inc.,* No. 24-CV-02912 (D. Md. Oct. 7, 2024); Compl., *Ellington v. Paragon 28, Inc.,* No. 24-CV-02712 (D. Colo. Sept. 30, 2024); Compl., *Manchin v. PACS Grp., Inc.,* No. 24-CV-08636 (S.D.N.Y. Nov. 13, 2024).



For instance, plaintiffs brought suit against Lifecore Biomedical, Inc. ("Lifecore") and certain of its officers and directors in the District of Minnesota,[39] alleging the company made materially false and misleading statements regarding the Company's business, operations, and prospects.[40] Specifically, the plaintiffs alleged that Lifecore failed to disclose that it maintained deficient internal controls over financial reporting, issued inaccurate financial statements needing restatement, and had ineffective remediation efforts.[41] On September 14, 2022, Lifecore filed an Annual Report revealing a material weakness in internal control over financial reporting and the need to restate several financial statements.[42] This was the first in a series of 16 disclosures in an 18-month period, which purportedly led to multiple stock price declines.[43]

Last, another group of the cases involved alleged misrepresentations and omissions related to proposed mergers, acquisitions, IPOs, offerings and other transactions.[44]

For example, plaintiffs brought suit against Orthofix Medical Inc. ("Orthofix") and certain of its officers in the Eastern District of Texas.[45] Per the complaint, Orthofix is a global spine and orthopedics company that offers biologics, spinal hardware, bone growth therapies, and specialized orthopedic solutions, among other products and services, to healthcare professionals throughout the world.[46] The plaintiffs alleged that during the merger between Orthofix and SeaSpine, a global medical technology company focused on surgical solutions for the treatment of spinal disorders, Orthofix made false and misleading statements or failed to disclose adverse facts about the company's management.[47] The plaintiffs alleged that Orthofix's leadership falsely assured investors about the newly combined company's adherence to the "highest ethical and legal standards" and a strong performance-based culture.[48] However, following an investigation that purportedly revealed "that each of these executives engaged in repeated inappropriate and offensive conduct that violated multiple code of conduct requirements and was inconsistent with the Company's values and culture[,]" the independent directors voted to terminate for cause executives Valentine, Bostjancic, and Keran.[49] On this news, the Orthofix's stock purportedly dropped.[50]

Life sciences companies face unique challenges in securities litigation, particularly arising from negative clinical trial results, product safety, and FDA approval expectations. Despite facing industry-specific issues, they also encounter risks of securities fraud claims faced by all companies, such as those related to disclosures in mergers or acquisitions, or financial reporting. Moreover, life science companies are not immune to class actions in the U.S., even if incorporated abroad.

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39 Compl., *David Carew v. Lifecore Biomedical, Inc., et al.,* No. 24-CV-03028 (D. Minn. July 29, 2024).

40 *Id.* ¶ 4.

41 *Id.*

42 *Id.* ¶ 5.

43 *Id.* ¶¶ 5-33.

44 Such suits comprised 10 of the 50 filings reviewed, or 20%. *See* Compl., *Perry Shapiro v. Assertio Holdings, Inc.,* No. 24-CV-00169 (N.D. Ill. Jan. 5, 2024); Compl., *Bristol Cnty. Ret. Sys. v. QuidelOrtho Corp.,* No. 24-CV-02804 (S.D.N.Y. Apr. 12, 2024); Compl., *In re Glob. Cord Blood Corp. Sec. Litig.,* No. 24-CV-03071 (S.D.N.Y. Apr. 22, 2024); Compl., *Oleg Nesterenko v. Bolt Biotherapeutics, Inc.,* No. 24-CV-03985 (N.D. Cal. July 2, 2024); Compl., *Joseph Zappia v. Morphic Holding, Inc.,* No. 24-CV-04486 (N.D. Cal. July 25, 2024); Compl., *Kevin Vreeland v. Metagenomi Inc.,* No. 24-CV-06765 (N.D. Cal. Sept. 26, 2024); Compl., *Neal A. Mitchell v. Taro Pharm. Indus. Ltd.,* No. 24-CV-06818 (S.D.N.Y. Sept. 9, 2024); Compl., *Matthew Bernal v. Orthofix Med. Inc.,* No. 24-CV-00690 (E.D. Tex. Aug. 21, 2024); Compl., *Christopher Manchin v. PACS Grp., Inc.,* No. 24-CV-08636 (S.D.N.Y. Nov. 13, 2024); Compl., *Angelo Rondini v. Kyverna Therapeutics, Inc.,* No. 24-CV-08869 (N.D. Cal. Dec. 9, 2024).

45 Compl., *Matthew Bernal, et al. v. Orthofix Medical Inc.,* et al., No. 24-CV-00690 (E.D. Tex. Aug. 21, 2024).

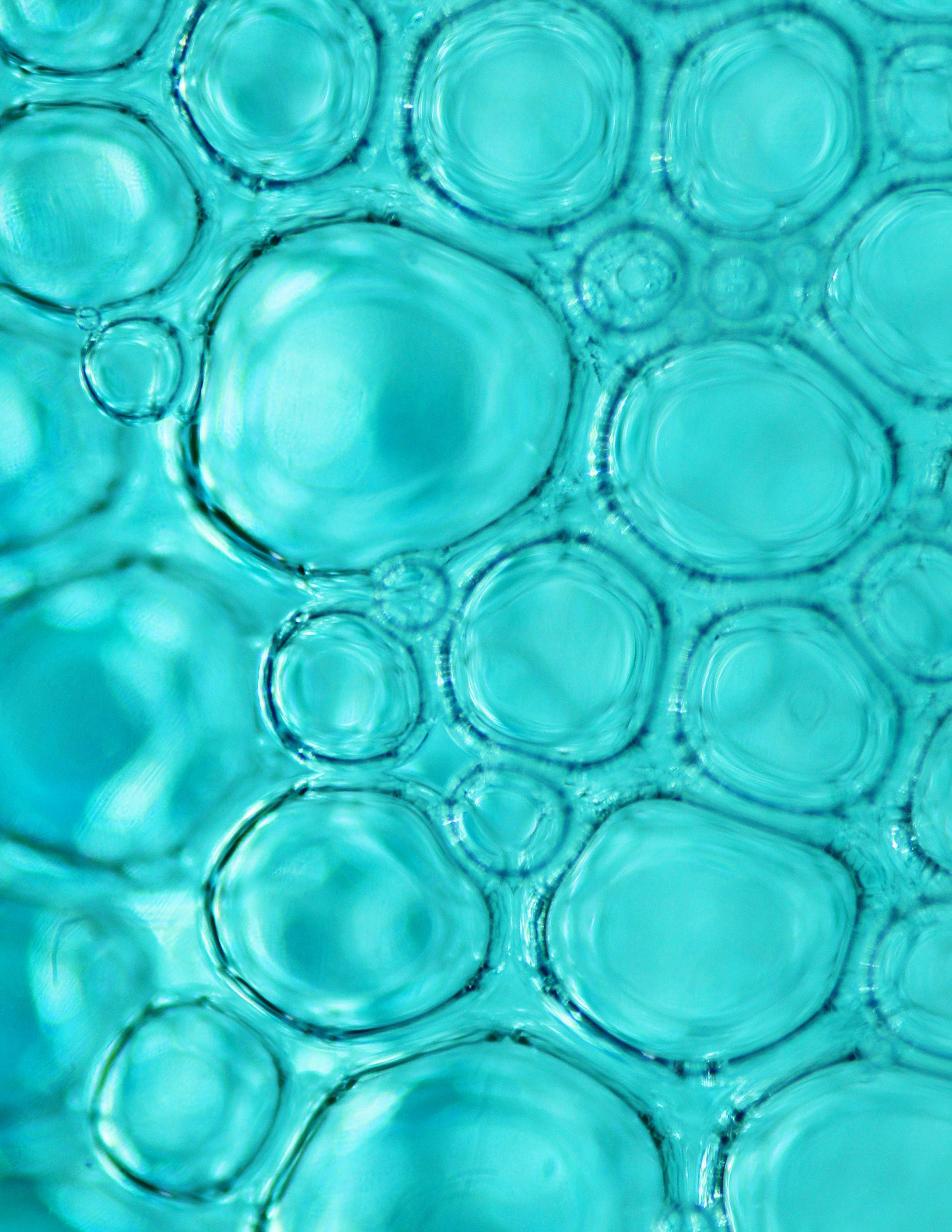
46 *Id.* ¶ 2.

47 *Id.* ¶¶ 3-6.

48 *Id.* ¶ 25.

49 *Id.* ¶ 27.

50 *Id.* ¶ 28.



# 2024 Class Action Securities Fraud Decisions in the Life Sciences Sector

In 2024, there was a significant decrease in securities fraud decisions by courts involving life sciences companies, with Dechert identifying 19 decisions in 2024 compared to 49 in 2023.[51] These decisions fall under three broad categories:

- Claims arising during 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;
- Claims arising independent of or after the development process; and
- Claims involving the financial management or general mismanagement of life sciences companies (e.g., alleged market manipulation or improper accounting).

Most 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 products fail clinical trials or are not ultimately approved by the FDA, securities class actions often follow, alleging the company mischaracterized or exaggerated trial results and/or failed to warn investors of significant risks that the product would not be approved.

In 2024, courts issued 19 opinions – a decrease from the 49 decisions identified using similar criteria in 2023.[52] Of those 19 opinions, eight 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.[53]

In 2024, the courts granted four of the eight motions to dismiss in their entirety,[54] and four motions were denied in part and granted in part.[55]

Defendants challenge and defeat securities class action claims regarding statements during product development in approximately half of these actions. In *Fernandes v. Centessa Pharmaceuticals PLC,*[56] a court in the Southern District of New York granted the defendants' motion to dismiss. The plaintiffs alleged that the defendants made misstatements and omissions in their Registration Statement regarding lixivaptan's comparative safety profile relative to tolvaptan, and overstated lixivaptan's clinical and commercial prospects.[57] The court granted the defendant's motion to dismiss stating that, "'[i]n reviewing the Registration Statement 'in [its] entirety,'… Plaintiffs have failed to adequately plead 'the existence

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51 *See supra* note 1.

52 Kistenbroker, et al. at 11.

53 *Id.*

54 *See In re BioLineRx Ltd. Sec. Litig.,* No. 23-cv-00041, 2024 WL 3409800 (D.N.J. July 15, 2024); *Fernandes v. Centessa Pharmaceuticals PLC,* No. 22-cv-08805, 2024 WL 3638254 (S.D.N.Y. Aug. 2, 2024); *Merritt v. Molecular Partners AG,* No. 22-cv-5925, 2024 WL 495140 (S.D.N.Y. Feb. 5, 2024); *In re Spero Therapeutics, Inc., Sec. Litig.,* No. 22-cv-3125, 2024 WL 4593422 (E.D.N.Y. Oct. 28, 2024).

55 *See Christiansen v. Spectrum Pharms., Inc.,* No. 22-cv-10292, 2024 WL 246020 (S.D.N.Y. Jan. 23, 2024); *Gorlamari v. Verrica Pharms., Inc.,* No. 22-cv-2226, 2024 WL 150341 (E.D. Pa. Jan. 11, 2024); *Pardi v. Tricida, Inc.,* No. 21-cv-00076, 2024 WL 1056013 (N.D. Cal. Mar. 11, 2024), *opinion clarified,* No. 21-cv-00076, 2024 WL 3262615 (N.D. Cal. July 1, 2024); *In re Y-mAbs Therapeutics, Inc. Sec. Litig.,* No. 23-cv-00431, 2024 WL 451691, (S.D.N.Y. Feb. 5, 2024).

56 *Fernandes v. Centessa Pharmaceuticals PLC,* No. 22-cv-08805, 2024 WL 3638254 (S.D.N.Y. Aug. 2, 2024).

57 *Id.*

of either a misstatement or an unlawful omission' that was material" and nearly all challenged statements were statements of opinion.[58]

In the context of alleged misrepresentations relating to product development, courts also found additional and independent grounds to dismiss cases when the complaint fails to "satisfy the pleading requirements included in the Private Securities Litigation Reform Act ("PSLRA").[59] For example, in *In re Spero Therapeutics, Inc., Sec. Litig.,* the Eastern District of New York also granted the defendants' motion to dismiss. The plaintiffs alleged the defendants acted with scienter by continuing to make positive statements about the ongoing trial and the drug's prospects despite knowing it would fail to meet the necessary criteria for FDA approval. The plaintiffs pointed to decisions to enroll fewer patients than recommended by the data review committee, the extensive interactions with the FDA, and the various internal steps taken by Spero's leadership such as making certain FDA submission documents confidential as evidence of scienter.[60] The plaintiffs also allege insider transactions and increased executive compensation were indications of motive.[61] The court found that the plaintiffs failed to sufficiently allege scienter, determining that the defendants' decision to proceed with fewer enrolled patients was made in consultation with the FDA due to operational challenges presented by the COVID-19 pandemic, a decision that was not "highly unreasonable."[62] Further, the court found the plaintiffs did not provide specific content from FDA meetings that unequivocally flagged concerns about the patient population or showed a near certainty of non-approval.[63]

The court also found the frequency of FDA meetings typical for Fast Track Designation and saw no compelling indication of defrauding intent behind the timing and nature of the alleged suspicious actions, such as retaining resigning employees or making certain submission documents confidential.[64] The court held that the plaintiffs failed to establish a connection between the defendants' alleged awareness of trial deficiencies and the alleged insider benefits, ruling out the allegations of scienter through motive and opportunity.[65] Ultimately, the court dismissed the plaintiffs' claims under Section 10(b) and 20(a) of the Exchange Act, and Rule 10b-5.

## Court Decisions Regarding Alleged Misrepresentations After Product Development

While statements made during product development are carefully monitored by plaintiffs, life sciences companies can still face liability after a product is developed. Dechert identified 11 instances of a court addressing fraud claims that arose after a drug or device's development process. Of the 11 cases, six of the motions to dismiss were granted in whole,[66] three motions to dismiss were denied,[67] and two were dismissed in part.[68]

In *Ortmann v. Aurinia Pharms., Inc.,* the plaintiff brought suit in the District of Maryland, alleging Defendants violated Section 10(b), Section 20(a) of the Securities and Exchange Act, and Rule 10b–5.[69] The plaintiff claimed that the defendants misled its investors about the success of LUPKYNIS and its future prospects.

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58 *Id.* at *18.

59 *In re Spero Therapeutics, Inc., Sec. Litig.,* No. 22-CV-3125, 2024 WL 4593422, at *4 (E.D.N.Y. Oct. 28, 2024).

60 *Id.* at *5-6.

61 *Id.* at *7.

62 *Id.* at *5.

63 *Id.* at *6.

64 *Id.*

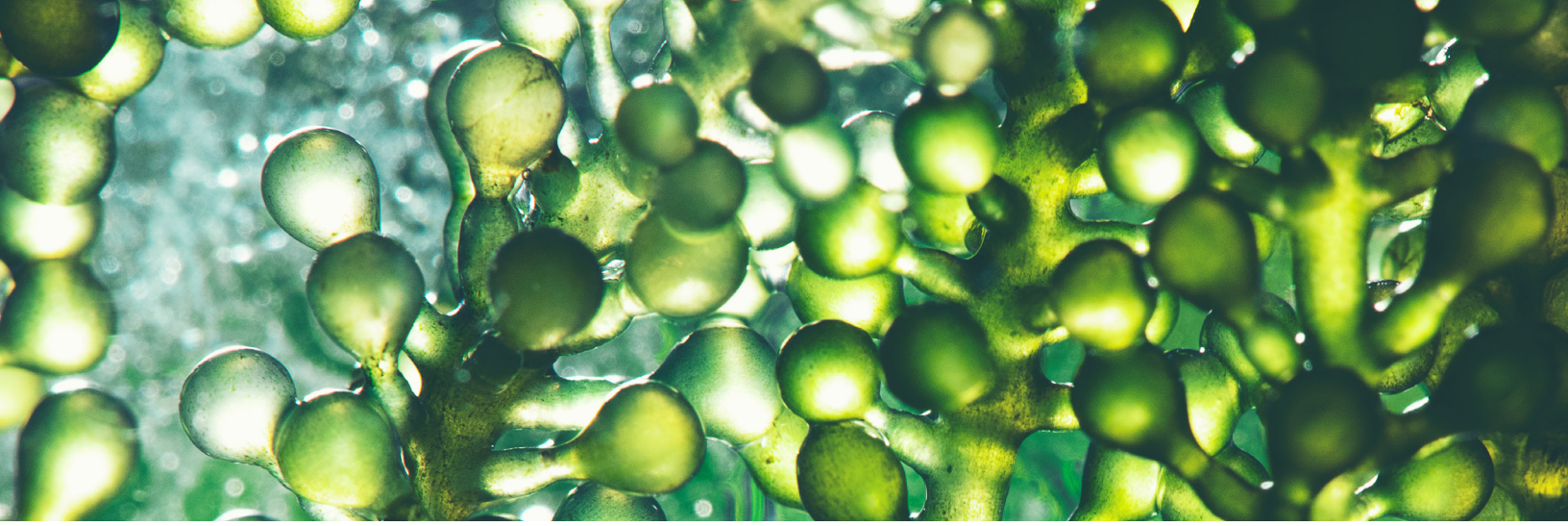
65 *Id.* at *8.

66 *See In re Acutus Medical, Inc. Securities Litigation,* No. 22-cv-00206, 2024 WL 2868276 (S.D. Cal. Apr. 29, 2024); *Ortmann v. Aurinia Pharms., Inc.,* No. 22-cv-1335, 2024 WL 3784566 (D. Md. Aug. 13, 2024); *Gonzalez v. Cano Health, Inc.,* No. 22-cv-20827, 2024 WL 4415216 (S.D. Fla. Oct. 4, 2024); *In re Canopy Growth Sec. Litig.,* No. 23-cv-4302, 2024 WL 3445436 (S.D.N.Y. July 17, 2024), *appeal withdrawn sub nom. In re Canopy Growth Securites Litig.,* No. 24-cv-2121, 2024 WL 4763225 (2d Cir. Oct. 9, 2024); *State Tchrs. Ret. Sys. of Ohio v. Charles River Lab'ys Int'l, Inc.,* No. 23-cv-11132, 2024 WL 3258293 (D. Mass. July 1, 2024); *In re Viatris Inc. Sec. Litig.,* No. 2:23-cv-00812, 2024 WL 4252060 (W.D. Pa. Sept. 20, 2024).

67 *See Roofers Loc. No. 149 Pension Fund v. Amgen Inc.,* No. 23-cv-2138, 2024 WL 4354809 (S.D.N.Y. Sept. 30, 2024); *In re Inotiv, Inc. Sec. Litig.,* No. 22-cv-00045, 2024 WL 1344784 (N.D. Ind. Mar. 29, 2024); *Cont'l Gen. Ins. Co. v. Olafsson,* No. 23-cv-3662, 2024 WL 4263211 (D.N.J. Sept. 23, 2024).

68 *See Plumbers & Pipefitters Local Union # 295 Pension Fund v. CareDx, Inc. et al,* 22-cv-03023 (N.D. Cal. Sep. 18, 2024); *City of Warwick Ret. Sys. v. Catalent, Inc.,* No. 23-cv-1108, 2024 WL 3219616 (D.N.J. June 28, 2024).

69 *Ortmann v. Aurinia Pharms., Inc.,* No. 22-cv-1335, 2024 WL 3784566 (D. Md. Aug. 13, 2024).



The amended complaint alleged the defendants' touted its success while simultaneously "failing to notify members of the class that:

- Despite the fact that LN is typically treated by nephrologists, Aurinia mainly focused on engaging with rheumatologists;
- The social and economic backgrounds of LN patients[] made them hard patients to reach;
- LN patients were often non-compliant with their drug regimens;
- Practitioners found the paperwork involved in initiating a prescription for LUPKYNIS to be tedious and believed that LUPKYNIS was too expensive; and
- Concerns over insurance coverage limitations deterred practitioners from prescribing LUPKYNIS."[70] (internal citations omitted).

The court granted the defendants' motion to dismiss finding that although the amended complaint alleged statements made by the defendants were "materially false and misleading statements and omissions," the amended complaint failed to assert that any particular statement was false.[71] Regarding the first alleged omission, the court found, "Defendants repeatedly noted that they were engaging both rheumatologists and nephrologists, beginning on May 6, 2021, the date of the first allegedly misleading statement."[72] The court also rejected the plaintiff's second alleged omission finding "Defendants repeatedly emphasized that LN patients came from underserved and under-resourced communities beginning on May 6, 2021, and continuing throughout the purported class period."[73] As with alleged omission number three, the court found, "Defendants continually referenced the fact that LUPKYNIS's target population is underserved and under-resourced, meaning that the target population is one that has difficulty accessing ongoing care."[74] Regarding the fourth alleged omission, the court found, "Defendants repeatedly noted that some doctors expressed hesitancy about prescribing LUPKYNIS."[75] Finally, the court rejected the plaintiff's allegation that "Defendants omitted concerns over 'insurance coverage limitations' deterred practitioners from prescribing LUPKYNIS."[76] Because the plaintiff's Section 10(b) and 20(a) claims failed, the court granted the defendants' motion to dismiss with prejudice.

## Court Decisions Regarding Financial Management

Though life sciences companies must navigate the risks associated with development of new drugs and devices, they also encounter securities-law risks common to all public companies.

In 2024, courts issued 14 opinions in cases involving allegations of financial and/or general management, including financial reporting, business operations, and disclosures relating to mergers or IPOs, among other claims. Of the cases Dechert identified, the outcomes varied:

70 *Id.* at *11.
71 *Id.*
72 *Id.*
73 *Id.* at *12.
74 *Id.*
75 *Id.* at *13.
76 *Id.*

- Nine cases were dismissed in whole in favor of defendants.[77]
- Three cases saw plaintiffs prevailed on defendants' motions to dismiss.[78]
- Two cases were dismissed in part.[79]

An example of an opinion in this category includes allegations that a company misrepresented its financial position. In *In re BioLineRx Ltd. Sec. Litig.,* the plaintiffs alleged the defendants' statements during the putative class period "regarding their belief that BioLineRx had sufficient capital to meet its projected needs through the first half of 2024 were false and misleading because BioLineRx raised capital in September 2022 by entering into a US$40 million loan agreement and selling certain ADS to certain institutional investors."[80] Specifically, the plaintiffs alleged that during the putative class period, the defendants made a series of misstatements and omissions regarding "the following information in certain SEC filings and press releases:

- BioLineRx 'did not have enough funds to execute its strategy to develop Motixafortide in SCM, while at the same time advancing other pipeline programs, through the first half of 2024'; and
- BioLineRx 'would need significant additional funding by 2022 in order to fund its operations and pipeline programs.'"[81]

The District Court of New Jersey found the plaintiffs failed to satisfy the heightened pleading requirements of the PSLRA because "it does not sufficiently allege a material misrepresentation or omission by Defendants."[82] The plaintiffs' alleged, "Defendants misled investors to believe BioLineRx had sufficient funds through the first half of 2024 to achieve various milestones when it must not have had sufficient funds because it disclosed in September 2022, over a year earlier, that it would be raising additional capital through a loan and a direct securities offering."[83] The court found the FAC did not allege sufficient facts to show that the defendants' statements regarding having sufficient funds were false. Instead, the plaintiffs "rel[ied] on the implied assumption that Defendants would not have raised capital in September 2022 unless they had insufficient funds to last them into 2024, and because Defendants raised capital in September 2022, they must have lied about having enough cash on hand to last them into 2024."[84] The court found the plaintiffs' allegations "hinge[d] on the implied assumption that a company would not raise capital unless it was in dire or immediate need of money, and as Defendants note, '[t]aken to its logical extreme, Plaintiffs' position would require [BioLineRx] to wait to the end of its cash runway before it could raise additional capital for future operations.'"[85] The court further noted "the FAC did not adequately allege facts showing BioLineRx did not have the amount of funds it stated it had at the time Defendants' statements were made or that those funds were not sufficient to last into 2024, irrespective of the additional capital obtained in September 2022."[86] Therefore, the court found the implied assumption without adequate supporting underlying facts was insufficient to satisfy the heightened pleading standards for a case alleging violations of Section 10(b), Section 20(a), and Rule 10b-5, and granted the motion to dismiss with leave to amend.[87]

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77 *See In re Acutus Medical, Inc. Securities Litigation,* No. 22-cv-00206, 2024 WL 2868276 (S.D. Cal. Apr. 29, 2024), *appeal dismissed sub nom. Weinberg v. Acutus Med., Inc.,* No. 24-3537, 2024 WL 4100260 (9th Cir. July 2, 2024); *Ortmann v. Aurinia Pharms., Inc.,* No. 22-cv-1335, 2024 WL 3784566 (D. Md. Aug. 13, 2024); *In re BioLineRx Ltd. Sec. Litig.,* No. 23-cv-00041, 2024 WL 3409800 (D.N.J. July 15, 2024); *Gonzalez v. Cano Health, Inc.,* No. 22-cv-20827, 2024 WL 4415216 (S.D. Fla. Oct. 4, 2024); *In re Canopy Growth Sec. Litig.,* No. 23-cv-4302, 2024 WL 3445436 (S.D.N.Y. July 17, 2024), *appeal withdrawn sub nom. In re Canopy Growth Securites Litig.,* No. 24-cv-2121, 2024 WL 4763225 (2d Cir. Oct. 9, 2024); *Fernandes v. Centessa Pharms. PLC,* No. 22-cv-8805, 2024 WL 3638254 (S.D.N.Y. Aug. 2, 2024); *State Tchrs. Ret. Sys. of Ohio v. Charles River Lab'ys Int'l, Inc.,* No. 23-cv-11132, 2024 WL 3258293 (D. Mass. July 1, 2024); *Merritt v. Molecular Partners AG,* No. 22-cv-5925, 2024 WL 495140 (S.D.N.Y. Feb. 5, 2024); *In re Viatris Inc. Sec. Litig.,* No. 2:23-cv-00812, 2024 WL 4252060 (W.D. Pa. Sept. 20, 2024).

78 *See Roofers Loc. No. 149 Pension Fund v. Amgen Inc.,* No. 23-cv-2138, 2024 WL 4354809 (S.D.N.Y. Sept. 30, 2024); *In re Inotiv, Inc. Sec. Litig.,* No. 22-cv-00045, 2024 WL 1344784 (N.D. Ind. Mar. 29, 2024); *Cont'l Gen. Ins. Co. v. Olafsson,* No. 23-cv-3662, 2024 WL 4263211 (D.N.J. Sept. 23, 2024).

79 *See Plumbers & Pipefitters Local Union # 295 Pension Fund v. CareDx, Inc. et al,* 22-cv-03023 (N.D. Cal. Sep. 18, 2024); *City of Warwick Ret. Sys. v. Catalent, Inc.,* No. 23-cv-1108, 2024 WL 3219616 (D.N.J. June 28, 2024).

80 See, e.g., *In re BioLineRx Ltd. Sec. Litig.,* No. 23-cv-00041, 2024 WL 3409800, at *6 (D.N.J. July 15, 2024).

81 *Id.* at *4.

82 *Id.* at *10.

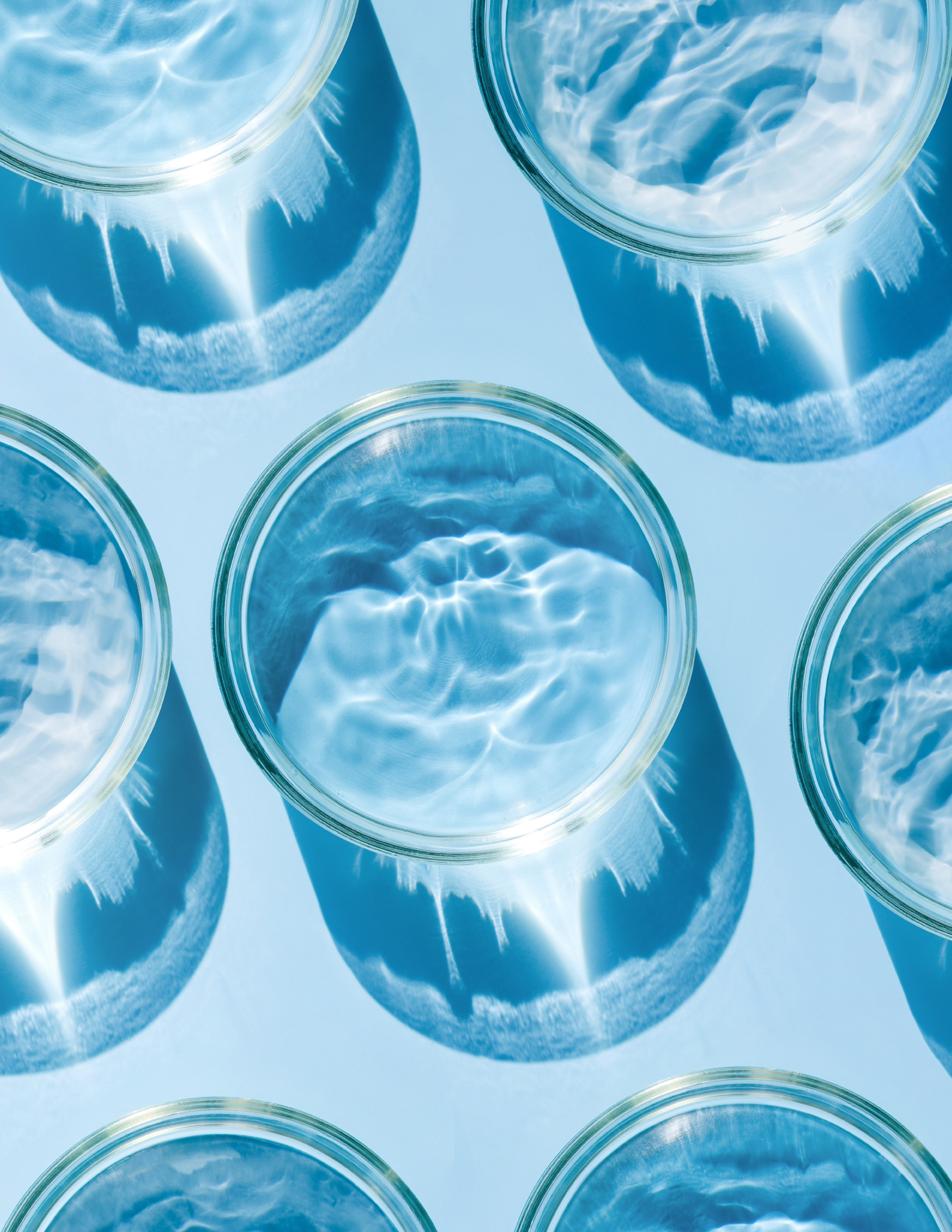
83 *Id.*

84 *Id.*

85 *Id.*

86 *Id.*

87 *Id.* at *12.



# 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:

- **Consistency in Public Statements.** 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.
- **Disclosure of Regulatory Setbacks.** 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 accurately describe any negative results, including potentially negative information learned after the preliminary results are revealed. Companies also should ensure that internal disclosure regimens and processes are well documented and consistently followed.
- **Adoption of a Disclosure Plan.** 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.
- **Appropriate Disclosures that Cut Across Industries.** 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.
- **Consideration of Product Defects and Alternatives.** 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 defendants 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 weigh against any potential risks.
- **Disclosures in Transactions.** 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, conflicts of interest, among other issues.
- **Non-U.S. Issuers.** 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.

- **Opinion Statements in Public Filings.** 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.** Forward-looking information about a drug or device should be clearly identified as such and distinguished from historical fact.
- **Relevant Risk Disclosures.** 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.
- **Insider Trading Practices.** 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.
- **Engage Experienced Legal Counsel.** Work closely with experienced legal counsel who specialize in securities litigation and life sciences to help navigate and provide guidance on litigation risks.
- **Evaluate Insurance Coverage.** Review and evaluate the company's and directors and officers insurance coverage to ensure it is adequate to cover potential litigation costs.

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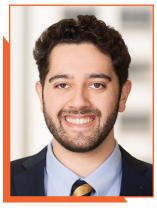

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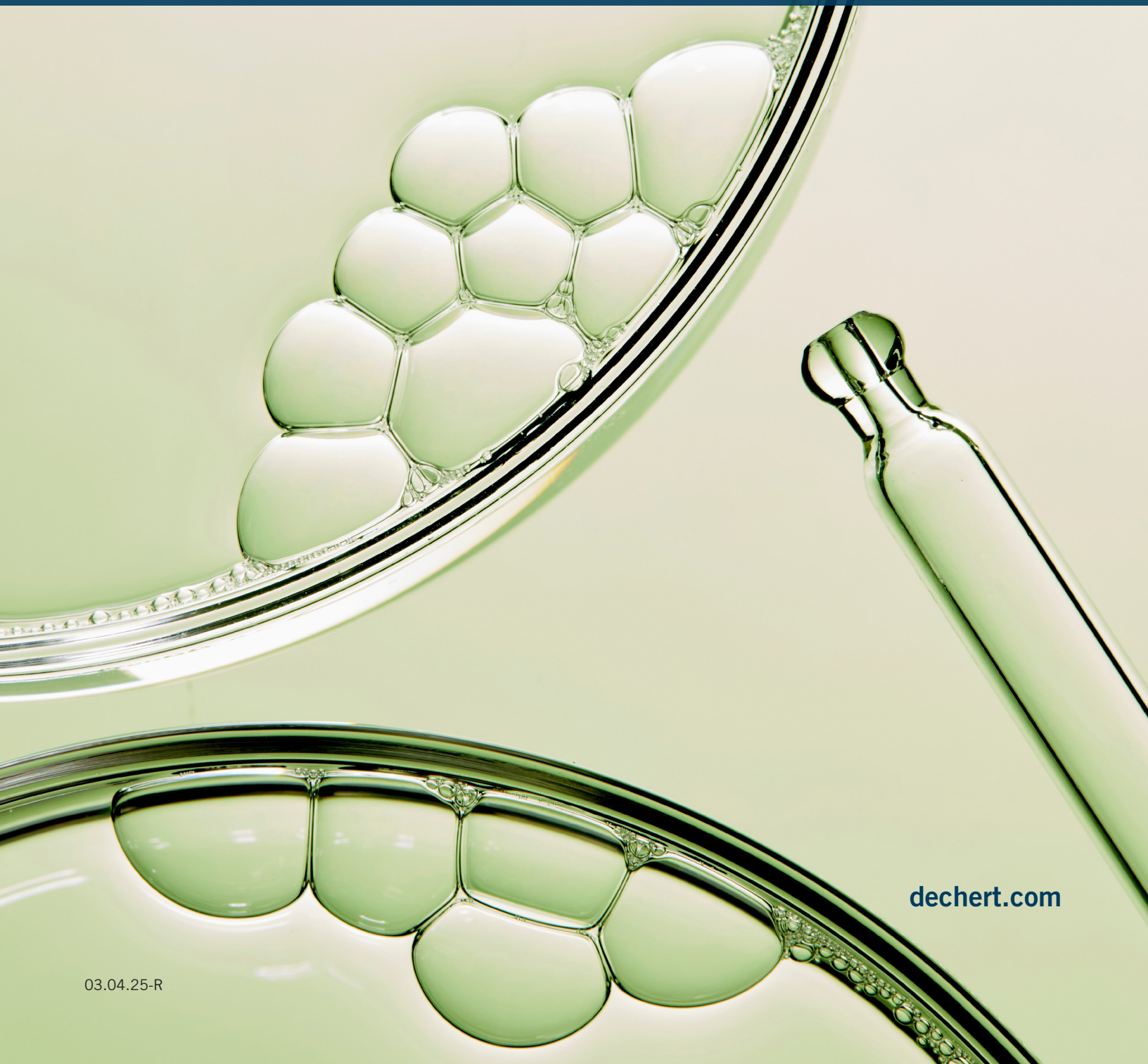

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