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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

In re: REVANCE THERAPEUTICS, INC. SECURITIES LITIGATION	Case No. 3:21-cv-09585-AMO CLASS ACTION
This Document Relates To:	**SECOND AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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TABLE OF DEFINED TERMS

Term	Definition
BLA	Biologics License Application
CAPA	Corrective Action and Preventative Action
CEO	Chief Executive Officer
CFO	Chief Financial Officer
cGMP	Current Good Manufacturing Practices
CMC	Chemistry, Manufacturing, and Controls
Company	Revance Therapeutics, Inc.
COO	Chief Operating Officer
CRL	Complete Response Letter
DAXI	DaxibotulinumtoxinA
DS	Drug Substance
EIR	Establishment Inspection Report
Exchange Act	Securities and Exchange Act of 1934
FDA	United States Food and Drug Administration
Foley	Mark J. Foley, Revance's Chief Executive Officer During The Class Period
Joshi	Abhay Joshi, Revance's Chief Operating Officer and President, R&D and Product Operations During The Class Period
Lead Plaintiffs	Chonghao Tang, Shengzhen Tang, Qiuyan Liu
MCB	Master Cell Bank
PDUFA	Prescription Drug User Fee Agreement
PSA	Performance Stock Award
RSA	Restricted Stock Award

SEC	United States Securities and Exchange Commission
Schilke	Tobin C. Schilke ("Schilke") served as the Company's Chief Financial Officer ("CFO") and Principal Accounting Officer During The Class Period
WCB	Working Cell Bank

BASIS FOR ALLEGATIONS

The allegations in this Second Amended Class Action Complaint are based on the personal knowledge of Lead Plaintiffs Chonghao Tang, Shengzhen Tang, and Qiuyan Liu (the "Tang Family Investor Group" or "Plaintiffs") as to Plaintiffs' own acts and are based on information and belief as to all other matters alleged herein. Plaintiffs' information and belief is based upon the substantial investigation by Plaintiffs' counsel into the facts and circumstances alleged herein, including the following: (i) review and analysis of public filings referenced herein made by Revance Therapeutics, Inc. ("Revance" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (ii) review and analysis of public statements made by Defendants Revance, Chief Executive Officer ("CEO") Mark J. Foley, Chief Financial Officer ("CFO") and Principal Accounting Officer Tobin C. Schilke ("Schilke"), and Chief Operating Officer ("COO") and President, R&D and Product Operations Abhay Joshi ("Joshi") in press releases, conference calls, SEC filings, and in media outlets; (iii) review and analysis of analyst reports, news articles, and other publications referenced herein; (iv) review and analysis of filings made by Revance with the U.S. Food and Drug Administration ("FDA") and documents issued by the FDA regarding Revance referenced herein obtained through Freedom of Information Act requests; and (v) review and analysis of other documents referenced herein. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Revance securities between August 5, 2021 and October 15, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Revance is a biotechnology company that for years had been developing its lead product candidate called DaxibotulinumtoxinA for Injection ("DAXI") that combines a proprietary peptide with botulinum toxin to treat frown lines, forehead lines and lateral canthal lines ("crows feet"), among other things. It is an injectable drug that would compete with Botox and similar products to smooth wrinkles for cosmetic reasons. According to the Company's clinical trials, patients treated with DAXI showed no or only mild frown lines for up to 6 months, which was touted by Defendants as differentiating DAXI from other botulinum toxin products that were effective for 3-4 months.

3. The Company and analysts believed that once approved by the FDA, DAXI would have a significant impact on the neurotoxin market, which in 2019 was over $4 billion. Neuromodulator products remained largely unchanged since botulinum toxin Type A treatments were first introduced nearly 30 years ago and they continued to provide short-term treatment. Because DAXI is longer lasting, it was seen as filling a significant and unmet demand.

4. In order to transition from researching and developing DAXI to commercial production, Revance had to obtain approval from the FDA based on the FDA's review of Revance's Biologics License Application ("BLA") and an inspection of the Company's manufacturing facility. The goals of this inspection are: (1) to assess readiness for commercial manufacturing; (2) to ensure conformance with the submitted application; and (3) to ensure the integrity of data submitted in conjunction with the application.

5. After a prior delay in filing the BLA early in 2019, the Company publicly set a goal that it would file the BLA with the FDA by the end of November 2019.

6. On November 25, 2019, Revance announced that it had finally filed its BLA for DAXI to treat moderate to severe glabellar (frown) lines. Defendants represented to investors that the BLA marked the beginning of the Company's transition from a development company to a commercial organization that would produce and market DAXI. Revance repeatedly expressed confidence that it would sail through the pre-approval inspection.

7. The FDA's on-site inspection was delayed due to COVID-19 in November 2020, and would ultimately begin in June 2021.

8. After learning of the June 2021 inspection date, an analyst asked Foley at a conference how much visibility he would give between the inspection and the approval decision. Foley responded that "***[o]bviously if there was something that was not favorable, we would certainly release that***."

9. According to Confidential Witness 2 ("CW2"), who served as Deputy Chief of Staff at Revance for approximately five months from July 2021 to December 2021, all energy was focused on approval of DAXI, and most of the activities of Foley, Schilke, Joshi, and other top executives at Revance centered around the development and approval of DAXI. As a member of the Senior Leadership Team, Joshi was in constant contact with Defendant Foley regarding progress with the FDA and the approval process with the FDA.

10. The FDA's inspection was finally completed on July 2, 2021 and the results were disastrous for the company. Joshi was present during the inspection. Despite the Company's years-long touting of its manufacturing facilities and capabilities, Revance did not pass inspection. Instead, the FDA inspectors issued a Form 483, which is used to "notify[] the inspected establishments' top management in writing of significant objectionable conditions . . . observed during the inspection." Foley, Schilke, and Joshi received the Form 483 promptly after it was issued.

11. The Form 483 reflected five significant objectionable conditions, two of which are extremely serious deficiencies.

12. The first observation pertained to the Working Cell Bank, which is used to provide cells for the manufacturing process. According to the Form 483, Revance's Working Cell Bank (which was used to produce DAXI's active ingredient) ***was ineffective and a new one had not yet been qualified.*** The FDA requires that newly prepared Working Cell Banks should be appropriately qualified by characterization and testing, and that this data be submitted with the product's BLA.

13. The second observation provided that Revance was using a ***different process to manufacture DAXI than the process that had been specified in the BLA***. This different process was made to manufacture and qualify the new Working Cell Bank.

14. When the FDA issues a Form 483 to a company, the FDA allows the company to file a response to the observations listed. This is true whether or not the observations are actually fixable without amending or resubmitting the BLA application. While Revance was able to fix some of the relatively minor deficiencies the FDA identified, there was no way for Revance to resolve the fact that its Working Cell Bank was ineffective and a new one had not yet been qualified, as the Company's internal projected completion date for qualification was December 31, 2021. Additionally, there was no way for Revance to resolve the fact that it was now proposing to use a different process to manufacture DAXI than the process contained in the BLA. Indeed, during the inspection, the FDA told Revance that its "assumption" that the manufacturing process changes were consistent with the BLA was "***incorrect***," and that the FDA inspector "***recommended that an approval . . . be withheld for lack of commercial readiness***."

15. Despite the disastrous inspection and Foley's earlier promise to the market that Revance would update investors if something "not favorable" arose between the inspection and approval decision, Defendants chose to mislead the market by concealing the truth about the FDA inspection and the likelihood that the BLA would be approved as submitted.

16. Indeed, on the first day of the Class Period, August 5, 2021, ***after*** Revance secretly received its undisclosed failing grade from the FDA on July 2, 2021, one analyst noted during the first earnings call following the preliminary approval inspection, "you're expressing a high degree of confidence in the launch. And so I'm assuming that the FDA inspection is going swimmingly." Rather than correct the analyst, Foley stated, *inter alia*, "I think you're sensing consistency with our tone around the ***expected approval before year-end***. We've taken advantage of this time to keep up sort of our readiness for the inspection and continue to advance our commercial preparation plans."

17. In fact, on September 9, 2021, rather than disclose the disastrous results of the FDA inspection and the fact that it they could not qualify a new Working Cell Bank in time to obtain "***approval before year-end,"*** Foley stated during an earnings call that they were waiting to hear the FDA's decision, and that Revance is continuing "to actively prepare for approval. We ***continue building inventory. We've got our launch strategy and everything in place. And so we're ready to flip the switch as soon as we receive notice from the agency. So nothing really incremental that we have from them in terms of timing***."

18. On October 12, 2021, Revance's lies were exposed when a portion of the FDA's negative inspection findings were made public because of a Freedom of Information Act ("FOIA") request. Because of that FOIA request, the FDA posted on its website the Form 483 issued to Revance on July 2, 2021, that notified Revance of the significant objectionable conditions that the FDA had observed during its inspection of the Company's Northern California DAXI manufacturing facility. According to CW2, Foley, Schilke and Joshi were immediately made aware of the release of the Form 483 on October 12, 2021 and extremely engaged in managing the internal crisis at the company that the release of the Form 483 created.

19. As would be expected, the market reacted negatively to the completely unexpected bad news that the Form 483 revealed and the partial exposure of the truth, causing Revance's stock price to fall precipitously by $6.85 per share, or ***25%***, to close at $20.45 per share on October 12, 2021.

20. Defendants responded to the disclosure of the Form 483 by falsely claiming that they remained confident in the quality of Revance's BLA and continued to anticipate approval in 2021. Some analysts reached out to regulatory consultants regarding the FDA's observations' potential impact on the BLA. For example, two regulatory consultants for Guggenheim Securities LLC reported that they were "surprised" that the changes in the manufacturing process had not been reported to the FDA.

21. Then, on October 15, 2021, Revance disclosed after market that it received a Complete Response Letter ("CRL") from the FDA, indicating that "the FDA has determined it is

unable to approve the BLA in its present form, and indicated that there are deficiencies related to the FDA's onsite inspection at Revance's manufacturing facility."

22. On this news, Revance's stock price fell dramatically again, dropping $8.90 per share, or ***39.19%,*** to close at $13.81 per share on October 18, 2021. Analysts viewed this news as unexpected given Defendants' numerous positive statements, including ones made after the Form 483's release. A Piper Sandler analyst stated in his report, "Only days after expressing a high degree of confidence in an FDA approval of daxibotulinumtoxinA (daxi') in the near-term, Revance received a complete response letter (CRL) from the agency. That is undoubtedly frustrating, even maddening. ***Though we have questions regarding how this came to pass*** (*e.g.*, did management simply misread the agency?), that is for another time."

23. Despite Defendants' repeated assurances to the market that DAXI would be approved in 2021, it was not approved by the FDA until September 9, 2022, and only after huge stock price drops occurred as the true state of the Company's internal problems came to light.

24. As a result of Defendants' fraudulent acts, statements and omissions, which led to the price of Revance stock being grossly over inflated before precipitous declines in market value, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

25. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

26. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

27. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Defendants conduct business in this Judicial District and a significant portion of Defendants' actions took place within this Judicial District.

28. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not

limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

29. Lead Plaintiffs Chonghao Tang, Shengzhen Tang, and Qiuyan Liu, as set forth in their respective shareholder certifications and incorporated by reference herein (ECF No. 20-3), purchased Revance common stock and options at artificially inflated prices during the Class Period and have been damaged thereby.

30. Defendant Revance is a Delaware corporation with a manufacturing facility located at 7555 Gateway Blvd, Newark California 94560 and its principal executive offices located at 1222 Demonbreun Street, Suite 2000, Nashville, Tennessee, 37203. Prior to January 1, 2021, Revance's principal executive offices were located at 7555 Gateway Boulevard, Newark, California 94560. Revance's common stock trades in an efficient market on the NASDAQ Global Market ("NASDAQ") under the ticker symbol "RVNC."

31. Defendant Foley served as the Company's CEO and a Director at all relevant times.

32. Defendant Schilke served as the Company's CFO and Principal Accounting Officer at all relevant times.

33. Defendant Joshi served as the Company's COO and President, R&D and Product Operations at all relevant times until March 31, 2022. According to Revance's proxy filings, Dr. Joshi was responsible for management and leadership of clinical development, regulatory and manufacturing, steering committees for partner collaborations, and the filing of Revance's BLA. *See* Revance, Proxy Statement (Schedule 14A), 36 (filed Mar. 26, 2020); Revance, Proxy Statement (Schedule 14A), 45 (Mar. 24, 2021); Revance, Proxy Statement (Schedule 14A), 42 (Mar. 24, 2022).

34. Defendants Foley, Schilke, and Joshi are sometimes referred to herein as the "Individual Defendants."

35. The Individual Defendants possessed the power and authority to control the contents of Revance's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Revance's SEC filings and press releases and other materials alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions within Revance, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

36. Revance and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

I. FACTUAL BACKGROUND

A. Company Background & DAXI

37. Revance, a biotechnology company, engages in the development, manufacture, and commercialization of neuromodulators for various aesthetic and therapeutic indications in the United States and internationally.

38. Neuromodulators come in a variety of forms, including medicines injected into the muscle to interrupt the signal between the nerve and the muscle, causing it to relax. *See* Liesa Goins, *Injectables: Are Fillers and Neuromodulators Right for You?* (June 5, 2019), WebMD, https://www.webmd.com/beauty/features/injectables-fillers-neuromodulators (last visited May 1, 2024). They can be used for aesthetic purposes, such as addressing wrinkles that are caused by the flexing of muscles, or therapeutic purposes, such as addressing migraine headaches. *See id.*; Sashank Reddy, M.D., Ph.D., *Botulinum Toxin Injectables for Migraines*, Johns Hopkins, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/botulinum-toxin-injectables-for migraines (last visited May 1, 2024).

39. The Company's lead drug candidate, DAXI, is made from botulinum toxin, a protein and neuromodulator produced by the bacteria clostridium botulinum, as well as a proprietary stabilizing peptide. Revance, Annual Report (Form 10-K) 1, 8 (filed Feb. 26, 2020). It contains no human or animal-based components. *Id.*

40. Botulinum toxins interfere with neural transmission by blocking the release of acetylcholine, a principal neurotransmitter, causing muscle paralysis and therefore preventing the formation of glabellar lines or wrinkles caused by muscle movement. *See BOLUTLINUM TOXIN Abstract*, PK Nigam and Anjana Nigam (Mar. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2856357/ (last visited May 1, 2024).

41. A peptide is a short chain of two or more amino acids, which combine to form proteins within the body. *See* National Library of Medicine, *Biochemistry, Peptide*, Jessica Forbes and Karthik Krishnamurthy (Aug. 28, 2023), https://www.ncbi.nlm.nih.gov/books/NBK562260.

42. According to Revance, the combination of the neuromodulator (botulinum toxin) with its proprietary stabilizing peptide is what gives DAXI a longer-lasting effect than competitors such as Botox. *See* Revance, Company Conference Presentation, 4-6 (Nov. 13, 2019). In clinical trials, DAXI demonstrated a 24-28 week duration for mild glabellar lines. *See* Revance, Press Release, *Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar (Frown) Lines* (Nov. 25, 2019). Botox, by contrast, typically lasts 3-4 months (12-16 weeks). *See* Revance, Company Conference Presentation, 6 (Nov. 13, 2019) (S&P Global, Inc. transcript).

B. Revance's Biologics License Application and Manufacturing Capabilities

43. Defendants were under significant pressure to submit the Biologics License Application ("BLA") to the FDA for DAXI, as Individual Defendants and other representatives from the Company told the market that the BLA would be filed during the first half of 2019. *See* Revance, Q4 2018 Earnings Call, 5 (Feb. 26, 2019) (S&P Global transcript) ("We are laser-focused on submitting our BLA package to FDA for DAXI in the treatment of glabellar lines in

the first half of this year."); Revance, Q4 2018 Earnings Call, 13 (Feb. 26, 2019) (S&P Global transcript) ("So basically, it's a procedural thing for us, and we hope that we can wrap it up in the next few months."); Revance, Special Call, 5 (Mar. 13, 2019) (S&P Global transcript) ("We plan to submit our BLA for glabellar lines in the first half of 2019, with a launch in first half of 2020.").

44. Finally, on November 25, 2019, Revance announced that it submitted its Biologics License Application ("BLA") to the FDA for DAXI, seeking approval for the treatment of glabellar (frown) lines. *See* Revance, Press Release, *Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar (Frown) Lines* (Nov. 25, 2019).

45. As one analyst put it, "[t]he Daxi BLA submission will be welcomed news for RVNC investors given a prior delay that pushed BLA filing out to Fall 2019 (from 1H19). Needham, *Daxi BLA Submission Starts Clock on Potential Approval/Launch in 2H20*, at 1 (Nov. 25, 2019).

46. A BLA "is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce." FDA, *Biologics License Application (BLA) Process* (CBER), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last visited May 1, 2024).

47. A "biologic product" is made from living sources, like bacteria. Benita Lee, MPH, *What Are Biologics?*, GoodRX Health (June 16, 2022), https://www.goodrx.com/healthcare-access/medication-education/biologics-biological-drugs-examples (last visited May 1, 2024).

48. Biologics like DAXI are subject to the Current Good Manufacturing Practices, or cGMP, regulations, which are found in 21 C.F.R. §§ 210, 211, and the Biologics regulations, 21 C.F.R. §§ 600-680. Compliance Program Guidance Manual, Chapter – 45 Biological Drug Products, Inspection of Biological Drug Products (CBER) 7354.848 ("Chap. 45"), at 5, available at https://www.fda.gov/media/73834/download (last visited May 1, 2024).

49. The requirements for a BLA are set forth in 21 C.F.R. § 601.2. *See* FDA, *Biologics License Application (BLA) Process* (CBER), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-processcber (last visited Nov. 4, 2022).

50. 21 C.F.R. § 601.2 requires that a BLA include, *inter alia*, "a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product for introduction or delivery for introduction into interstate commerce; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); specimens of the labels, enclosures, and containers, . . . ; and the address of each location involved in the manufacture of the biological product shall be listed in the biologics license application." 21 C.F.R. §601.2(a). Information concerning manufacturing is set forth in the chemistry, manufacturing, and controls ("CMC") section of the BLA. *See* FDA, *Form 356h*, at ¶30, *available at* https://www.fda.gov/about-fda/reports-manuals-forms/forms (last visited May 1, 2024).

51. As part of the BLA approval process, Revance was required to demonstrate that its manufacturing and quality assurance systems, or those of its third-party contract manufacturers and suppliers, complied with cGMPs. *See* Chap. 45 at 5; *see also* FDA, Contract Manufacturing Arrangements for Drugs: Quality Agreements, Guidance for Industry (Nov. 2016) ("Quality Agreement Guidance"), at 3, https://www.fda.gov/media/86193/download (last visited May 1, 2024).

52. To determine whether an applicant's manufacturing facilities comply with cGMPs and other applicable regulations, the FDA typically conducts a pre-approval or pre-license inspection.[1] *See* Chap. 45 at 5.

53. Even before submitting its BLA, Revance touted the readiness of the Company's manufacturing facility to withstand the FDA's BLA pre-approval inspection. For example, on

[1] "Pre-approval" and "pre-license" inspection are used interchangeably herein.

December 4, 2018, Revance's co-founder Browne stated that "one of Revance's strongest and most durable assets is our state-of-the-art manufacturing facility to manufacture both drug substance and drug product in the United States in the San Francisco Bay Area. We have a sophisticated CMC and analytics capability, along with the capacity and capability to immediately ship at commercial scale upon approval . . . ." Revance, Special Call, 10-11 (Dec. 4, 2018) (S&P Global transcript).

54. During the Company's Q4 2018 earnings call conference on February 26, 2019, COO Joshi and Browne continued to tout the Company's manufacturing capabilities and readiness for a pre-approval inspection. In response to an analyst's question, Joshi stated, ". . . with regards to the FDA inspection, as you guys all know, that once we file the BLA, we will receive a PI, or post -- pre-approval inspection, and that can happen any time within 3 to 6 months of our BLA filing. So we anxiously wait for that. ***We are fully prepared to accept the FDA facility***." Revance, Special Call, 10 (Dec. 4, 2018) (S&P Global transcript). Browne stated, "If I could come back to the facility, we think this is an asset that has tremendous shareholder value. There probably won't be another commercial-scale botulinum facility ever built in the United States again. It's-- the barriers to entry are just so high. We go through annual select agent approval. ***And so to Abhay [Joshi]'s point, we feel very confident in pre-approval inspection***. Quality, analytics has really been at the forefront of our manufacturing operation. And I think when you look at the Mylan partnership and the Fosun partnership, what really resonated with them was the quality and our intense focus on drug substance and drug product at commercial scale. So we feel very confident with our capability, not only in those relationships but as we build our own commercial business." *Id.*

55. Shortly before Revance submitted its BLA, Browne stated, in relevant part:

> [Analyst]: And with respect to the filing in the U.S., what are you finishing up before submitting the application? And what's your level of confidence of an approval on first cycle review?
>
> [Browne]: Our conviction is very high. We've been manufacturing both drug substance and drug product at commercial scale for nearly 10 years. And doing that in the United States under the U.S. Select Agent Review, that's a very

> rigorous review, that not only looks at the processes that used to manufacture drug substance and drug product, it goes beyond that to your standards, your employee safety. Doing that out of the San Francisco Bay Area was a strategic commitment that we wanted to understand our molecule, our formulation, our supply chain in a way that very few companies other than Allergan had been able to do. And we thought that we could satisfy that demand out of a U.S. operation. The thing that has tripped up many companies in the neurotoxins has been on the CMC, the Chemistry, Manufacturers and Controls (sic) [Chemistry, Manufacturing, and Controls]. It's something that under the leadership, it's been a focus. And for us, as we believe that we'll file our BLA here in the fall, which is defined between now and the Thanksgiving time period without some of the other issues that have been problematic for some of the other companies.
>
> And I think it's -- this intense focus not only in clinical development, but on your manufacturing quality systems that I think will become a strategic advantage for Revance over time.

Revance, Company Conference Presentation, 7 (Sept. 10, 2019) (S&P Global transcript).

56. On November 13, 2019, just two weeks before Revance submitted its BLA, Schilke stated during a Company Conference Presentation that "we make our drug substance and our drug product based in the San Francisco Bay Area. And we have the option to scale our drug product manufacturer with partnership agreements in the U.S. as well. So we're well set up to commercialize DAXI from a manufacturing perspective and have a very thoughtful supply chain." Revance, Company Conference Presentation, 5 (Nov. 13, 2019) (S&P Global transcript). During this call, Schilke also stated that Revance "undergo[es] rigorous annual inspections for our manufacturing plant, which gives us confidence that we'll be able to go through our prior approval inspections for our DAXI approval for the BLA. Given sort of the nature and the scrutiny that we have on making such a toxic molecule that the C[DC], we have very detailed inspections with them." *Id.* at 8

57. The "rigorous review" and "annual inspections" to which Browne and Schilke referred were the inspections required by the Federal Select Agent Program. Revance is a part of this program because it manufactures a product containing botulinum toxin—a "select agent." *See* Revance, Company Conference Presentation, 7 (Sept. 10, 2019) (S&P Global Transcript).

58. This Program "oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products." Federal Select Agent Program, Centers for Disease

Control, https://www.selectagents.gov/ (last visited May 1, 2024). Registered spaces where select agents are stored or used are required to be inspected on an annual basis. *See* 42 C.F.R. § 73.9(a)(6); *see also* Federal Select Agent Program Annual Inspection Guidance, Centers for Disease Control, https://www.selectagents.gov/compliance/guidance/annual-inspection/index.htm (last visited May 1, 2024).

59. Revance's BLA was accepted by the FDA on February 5, 2020, with an initial Prescription Drug User Fee Act, or PDUFA, "target action date" of November 25, 2020. *See* Revance, Form 10-K at 7 (Feb. 25, 2021).

60. The PDUFA "target action date" is the date by which the applicant can expect the FDA to render its decision regarding whether to approve or deny its BLA. *See* 21 U.S.C. § 379 *et seq*. Based on the PDUFA timeline, Defendants touted that they anticipated potential product approval in the second half of 2020.

61. While waiting for the FDA to give it an inspection date, Revance continued to express confidence that DAXI would be approved by the November 25, 2020 PDUFA date. Analysts picked up on the Company's confidence about approval by year end. For example, on February 26, 2020, an analyst from H.C. Wainwright & Co, stated, "This should be an eventful for the year for the company with approval of Daxi expected on the November 25 PDUFA date." H.C. Wainwright Co., Revance Gets Ready for Lift off, at 1 (Feb. 26, 2020).

62. On November 24, 2020, the FDA deferred its decision on Revance's BLA for DAXI, postponing the original PDUFA target action date of November 25, 2020. Revance, Press Release, *FDA Defers Approval of DaxibotulinumtoxinA for Injection in Glabellar Lines Due to COVID-19 Related Travel Restrictions Impacting Manufacturing Site Inspection* (Nov. 25, 2020). This was due to restrictions related to COVID-19, which prevented the FDA from conducting an inspection of Revance's manufacturing facility. *See id.* The FDA did not set a PDUFA date this time.

63. Revance assured the market that it was ready for the pre-approval inspection whenever the FDA was. *See, e.g.*, Revance, Press Release, *FDA Defers Approval of*

DaxibotulinumtoxinA for Injection in Glabellar Lines Due to COVID-19 Related Travel Restrictions Impacting Manufacturing Site Inspection (Nov. 25, 2020) (Foley stating we "***remain ready to support FDAs pre-approval inspection as soon as possible"***).

64. Based on Defendants' public statements, analysts continued to assume that the inspection would be uneventful and result in immediate approval of DAXI. *See, e.g.*, Barclays, *RHA Launch Trending Ahead of Consensus; PipelineIntact; Awaiting FDA Site Inspection*, at 1 (Jan. 7, 2021) ("Revance noted it is confident in its submission and continues to work proactively with the FDA on a pre-approval inspection as soon as possible in 2021. We currently assume an inspection will take place in 1Q21 with a late Q1/early Q2 launch, and revenues beginning Q2 onwards.); H.C. Wainwright & Co., *Teoxane Beats Expectation but Daxi Inspection not yet Scheduled*, at 1 (May 11, 2021) (Management "plans to issue a press release when the inspection is scheduled while building inventory ahead of the launch. We have little doubt that the Daxi is going to be approved based on the strong clinical data[.]"); William Blair, *First-Quarter Earnings; Strong RHA Launch Continues as DAXI Inspection Expected in the Near Term, Maintain Outperform*, at 1 (May 11, 2021) ("Given the positive interactions in the past, the clean data to date that includes the largest neurotoxin data set produced pre-approval, and a state-of-the art manufacturing facility, we expect an approval of DAXI within a relatively short period following inspection.").

C. The FDA Inspection Of Revance's Manufacturing Facility And The Resulting Form 483

1. The Pre-Approval Inspection

65. On May 26, 2021, Revance announced that the FDA planned to initiate an inspection of Revance's manufacturing facility by the end of June 2021. Revance, Current Report (Form 8-K) (filed May 26, 2021).

66. Analysts reported their view that based on Company public statements, the Company would pass the inspection. *See, e.g.*, William Blair, *Highlights From William Blair's 41st Annual Growth Stock Conference* (June 2, 2021) ("Regardless of the timeline, management

noted that the company is ready for a launch whenever an approval decision is issued. Indeed, the company was prepared to launch following its original PDUFA date in November 2020, and has therefore had an additional 6+ months to refine its messaging, marketing materials, and strategy ahead of launch."); H.C. Wainwright Co., *Daxi Enters the Homestretch: Preapproval Inspection to Occur by End of June*, at 1 (May 27, 2021) ("Given the amount of time that Revance has had to prepare, we're optimistic that the inspection should go well."); Barclays, *2021 DAXI approval looking more certain with FDA inspection date in June*, at 1 ("This had been an overhang on the stock since the FDA inspection/approval expected in Q4 2020 did not materialize and management had limited visibility on the inspection until now. We believe this provides incremental comfort around a likely 2021 approval and a launch soon thereafter.").

67. On June 8, 2021, the Company participated in the Goldman Sachs 42nd Annual Global Healthcare Conference, during which Foley once again expressed confidence in approval and promised to inform investors if "there was something that was not favorable" about the inspection:

> [Analyst]: Okay, okay, understood. And then -- so then would -- how much more visibility would you give us between now and then? Or is it pretty much just going to be, when you get the approval decision, that's kind of the next update we'll have in terms of the Street?
>
> [Foley]: ***That will be the next update. Obviously if there was something that was not favorable, we would certainly release that, but really the next update would be approval***. Again, we broke sort of our traditional protocol, which hopefully investors can appreciate, which is normally when you're in those, those are confidential discussions. There's a lot of back and forth, a lot of things. Typically we wouldn't make those comments. We obviously did before PDUFA date because, at that point in time, it was obvious they weren't going to show up in time for that to happen given everything going on with the pandemic. And we also thought it was important, given this uncertainty of, okay, there is no clear path forward, that we at least tell people, hey, this is what's happening. This is the last gating item. ***And so the next announcement would be approval.***

Revance, Company Conference Presentation, 10 (Jun. 8, 2021) (S&P Global Transcript).

68. The FDA conducted a pre-license inspection of Revance's manufacturing facility in Newark, CA on June 21-25 and 28-30, and again on July 1-2, 2021. Ex. A at 1.

69. The pre-license inspection had three primary objectives: (1) to assess readiness for commercial manufacturing; (2) to ensure conformance with the submitted application; (3) to ensure the integrity of data submitted in conjunction with the application. *See* Ex. B, Establishment Inspection Report ("EIR") at 1;[2] FDA Compliance Program 7346.832, Chap. 46—New Drug Evaluation ("Chap. 46"), at 13.

2. The Form 483

70. As a result of the inspection, the FDA issued a Form 483 on July 2, 2021 to COO Joshi indicating the company did not pass the inspection. A copy of the Form 483 is attached hereto as Exhibit A.

71. A Form 483 is "intended for use in ***notifying the inspected establishment's top management in writing of significant objectionable conditions***, relating to products and/or processes, or other violations . . . which were observed during the inspection." FDA, Inspections and Operations Manual (2022),§ 5.2.3, https://www.fda.gov/media/113432/download (last visited May 1, 2024). Form 483s "should be issued to the most responsible person available at the close of the inspection[,]" ***with a copy to the "top management of the firm***." *Id.* at 5-26.

72. According to the FDA's Inspections Operation Manual, "observations should be ranked in order of significance" and "observations of questionable significance should not be listed[.]" *Id.* at 5-20.

73. The Form 483 issued to Revance contained five "inspectional observations," two of which are relevant here. Ex. A at 1.

[2] The EIR was obtained by Lead Counsel through a Freedom of Information Act Request to the FDA. It is the FDA's final written report of an inspection. Because most of its pages are not numbered, PDF pagination is used when referring to the EIR (with page 1 following the exhibit cover page).

a) Observation 1

74. The first observation pertained to a working cell bank, or WCB, that was produced by Revance in November 2012. Ex. A at 1.

75. A WCB is derived from one or more master cell banks ("MCB"). *See* International Conference on Harmonisation; Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability, 63 Fed. Reg. 182 (Sept. 21, 1998) ("Cell Substrate Guidance"). The WCB is used to provide cells for the manufacturing process. *Id.*

76. According to applicable FDA regulatory guidance, a newly prepared WCB must be appropriately qualified by characterization and testing and presented in the product's marketing application—*e.g.*, a BLA. *See id.*; *see also* Ex. D ("Sensabaugh Decl."). "[I]t is well-established that cell substrates and events linked to the cell substrate can affect resultant product quality and safety, and further, that effective quality control of these products requires appropriate controls on all aspects of handling the cell substrate." Cell Substrate Guidance.

77. According to the Form 483, Revance's WCB was used to produce "DS" (*i.e.*, "Drug Substance") lots that were rejected. Ex. A at 1. A Drug Substance is the drug's "active ingredient." 21 C.F.R. § 314.3(b). The Drug Substance lots that were rejected were manufactured in August 2020 and September 2020, well before Revance's initial PDUFA date of November 2020. Ex. B at 5.

78. Specifically, on August 21, 2020, Revance manufactured its first drug substance batch of 2020 from its WCB. Ex. B at 21. It was rejected, which meant that Revance had not produced a commercial scale drug substance lot since September 6, 2019. *Id.* at 23, 50. An investigation concluded that the WCB "did not possess expected performance traits." *Id.* at 21.

79. To confirm that there were issues with the WCB, Revance attempted to manufacture a second drug substance batch on September 25, 2020, which was also rejected. *Id.* at 1, 21.

80. In response to the rejected lots, Revance initiated a quality investigation in September 2020 that ultimately determined in or around December 2020 that the root cause of the issue was the effectiveness of the previously qualified WCB. Ex. A at 1; Ex. B at 22; Ex. C, Revance's Form 483 Response ("Form 483 Response") at 2.[3]

81. After determining the root cause, Revance needed to take action to correct the problem (corrective action) and prevent it from occurring in the future (preventative action) (collectively, "CAPA"). Ex. A at 1. Federal regulations require drug manufacturers to have procedures for implementing CAPA. 21 CFR § 820.10. Revance implemented CAPA in May 2021 and determined that a new WCB should be manufactured and qualified. Ex. A at 1.

82. Notably, the "projected timeline" for completing qualification of the new WCB ***was December 31, 2021—nearly six months after the pre-approval inspection***. Ex. B at 22. With a new WCB not yet qualified, and a previous WCB that produced rejected Drug Substance lots, the FDA determined that Revance's current release and stability testing methods were insufficient to monitor the quality and shelf-life of its WCBs. Ex. A. at 1. Consequently, Revance's manufacturing facility was not ready for commercial production. *See generally* Ex. A; Ex. B; *see also* Chap. 46 at 15.

b) Observation 2

83. The Form 483's second observation provides that "[t]he current manufacturing process is not the process proposed for licensure." Ex. A at 1. This refers to a change from the manufacturing process that Revance submitted in its BLA, which was made as part of the CAPA process initiated after determining deficiencies with its WCB. *Id.*

[3] Revance's Form 483 Response was previously submitted in this litigation by Defendants. *See* ECF No. 65-29. It is submitted herewith as Exhibit C without Defendants' exhibit cover page or highlighting.

84. Revance's quality control team approved the change on June 15, 2021, and it became effective on June 25, 2021, in the middle of the FDA's inspection of Revance's facility. Ex. A at 1.

85. According to the Form 483, the CAPA process was still open during the FDA's inspection, meaning that the manufacturing process observed by the FDA during the inspection was subject to even further revision. Ex. A at 1-2.

86. Further, the FDA observed that recent Drug Substance lots manufactured by Revance were using the new process, instead of the process included in Revance's BLA. Ex. A at 1.

87. One of the goals of a pre-approval inspection is to ensure that the manufacturing methods employed are consistent with those submitted with the Company's BLA. *See* Chap. 46 at 27 ("Objective 2: Conformance to Application Verify that the formulating, manufacturing, or processing methods; analytical (or examination) methods); and batch records are consistent with descriptions contained in the CMC section of the application."). According to the FDA, the changes made with respect to the WCB "represent a significant deviation from the [Drug Substance] manufacturing process on file." Ex. B at 22.

88. The remaining three observations pertained to issues involving lack of oversight of outsourced activities for the quality control unit; lack of indicators of process performance; and lack of written responsibilities and procedures for the quality control unit. Ex. A at 2-3.

89. When the FDA issues a Form 483 to a company, the FDA allows fifteen (15) business days to provide a response to the observations contained in the Form 483. *See* Review of Post-Inspection Responses, 74 Fed. Reg. 40211 (Aug. 11, 2009).

90. Revance responded to the Form 483 in July 2021. *See* Revance, Press Release, *Revance Continues to Anticipate FDA Approval of DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines in 2021* (Oct. 12, 2021).

91. According to FDA procedures, substantive communication between the FDA and an applicant, such as Revance, are discouraged from the time an FDA reviewer receives a pre-

approval inspection report through the time a Complete Response Letter is issued by the FDA. *See* FDA Center for Drug Evaluation and Research, *Guidance for Review Staff and Industry Good Review Management Principles and Practices for PDUFA Products*, 8-9 *available at* https://www.fda.gov/media/132157/download (last visited May 1, 2024).

92. Despite being in possession of the Form 483 and the FDA inspector's statements during the inspection that Revance's assumption that the manufacturing process changes were consistent with the BLA was "incorrect," and that the initial recommendation was to withhold approval of the BLA "for lack of commercial readiness[,]" Defendants failed to disclose this information and continued to express confidence that they would receive approval shortly. For example, during the August 5, 2021 earnings call, Foley stated, "[w]ith the FDA having initiated their pre-approval inspection of our manufacturing facility in June, we continue to anticipate the approval of our lead product, DaxibotulinumtoxinA for injection for the treatment of glabellar lines ***this year***. In the meantime, the Revance team is actively building inventory and solidifying our commercial launch plans for innovative neuromodulators." Revance, Q2 2021 Earnings Call, 4 (Aug. 5, 2021) (S&P Global transcript). An analyst commented, "you're expressing a high degree of confidence in the launch. And so I'm assuming that the FDA inspection is going swimmingly." *See id*. at 7. Rather than correct the analyst, Foley stated, *inter alia*, "I think you're sensing consistency with our tone around the expected approval before year-end. We've taken advantage of this time to keep up sort of our readiness for the inspection and continue to advance our commercial preparation plans." *See id.* at 8.

93. The next day, on August 6, 2021, William Blair issued an analyst report stating in relevant part, ". . . the company recently announced that the FDA had conducted the agency's inspection of Revance's manufacturing facility that produces DAXI, one of the final steps prior to a regulatory decision that had been delayed due to the pandemic. ***Management's tone on the call was confident of an approval*** and we believe that when the original timing setback was communicated in 2020, labeling discussions were well underway and there ***remained no other outstanding issues. Given the positive interactions in the past, the clean data to date that***

includes the largest neurotoxin data set produced pre-approval, and a state-of-the-art manufacturing facility, we expect an approval of DAXI in the near term with the first meaningful sales in the fourth quarter." William Blair, *Second-Quarter Earnings; Strong RHA Launch Continues as We Wait for DAXI Approval and Launch, Remain Outperform*, at 1 (Aug. 6, 2021).

94. Defendants did nothing to correct this impression, with Foley informing investors during a September 9, 2021 presentation of his continued confidence that it would receive approval shortly. *See* Revance, Company Conference Presentation, 6 (Sept. 9, 2021) (S&P Global transcript).

95. On October 7, 2021, Barclays stated, ". . . 2021 approval expectations for DAXI are still intact, and we currently factor revenues trickling in from Q4 onward." Barclays, *ABBV Lawsuit Looks Tactical; Framing Our Grey-Sky Scenario*, at 2 (Oct. 7, 2021).

II. MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD[4]

A. Defendants Conceal Receipt Of The Form 483

96. As noted above, the FDA issued the Form 483 containing the five observations of significant objectionable conditions to Revance on July 2, 2021. *See* Ex. A.

97. Despite Foley's earlier statement that Defendants would tell investors if anything "not favorable" happened during the inspection, Defendants not only concealed receipt of the Form 483 from investors but also misled the market that there were no issues from the inspection that could delay launching DAXI in 2021. *See* S&P Global Tr. at 10 (June 8, 2021) (quoted at ¶67, *supra*).

[4] In this section, bold and italicized text indicates what statements are alleged to be false and/or misleading by way of omission. They are shown in context.

98. On August 5, 2021, the Company issued a press release announcing the Company's Q2 2021 results and providing a corporate update. The press release stated, in relevant part:

> ***The FDA initiated their pre-approval inspection of our manufacturing facility in June, and we continue to anticipate approval of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines in 2021. We are actively preparing for the launch*** and once approved, expect DaxibotulinumtoxinA for Injection to underpin our aesthetics franchise and set the standard for neuromodulator performance in therapeutic indications. In the second half of this year, we look forward to the topline results from our ASPEN-OLS Phase 3 open-label, long-term safety study of DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia, as well as an end-of-Phase 2 meeting with the FDA to discuss DaxibotulinumtoxinA for Injection for the treatment of adult upper limb spasticity.
>
> * * *
>
> **Second Quarter Highlights and Subsequent Updates**
>
> **Aesthetics Franchise**
>
> * * *
>
> - **Status of the Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection in the treatment of glabellar lines.** ***Consistent with the company's previous disclosure on the status of the pre-approval inspection, the FDA initiated the inspection of the company's manufacturing facility in June 2021. Revance continues to anticipate receiving approval for DaxibotulinumtoxinA for Injection in 2021 and is actively building inventory and preparing for commercial launch.***

Revance, Press Release, *Revance Reports Second Quarter 2021 Financial Results, Provides Corporate Update* (Aug. 5, 2021).

99. The statements in ¶98 above were materially false and/or misleading because Revance and Foley knowingly and/or recklessly made the statements while omitting the following facts:

(a) Defendants had received a Form 483 identifying five significant objectionable conditions on July 2, 2021;

(b) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted; and

(c) These omissions rendered the statements concerning the status of the DAXI BLA and commercial launch misleading to a reasonable person reading the statements fairly and in context.

100. That same day, August 5, 2021, Revance filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2021 (the "Q2 2021 10-Q"). The Q2 2021 10-Q was signed by Foley and Schilke. The Q2 2021 10Q Risk Factors warned in relevant part: "Even though filed with the FDA, ***our BLA may receive a Complete Response Letter or another response from the FDA identifying deficiencies that must be addressed, rather than an approval***." *See* Revance, Quarterly Report (Form 10-Q), 48 (filed Aug. 5, 2021).

101. Appended to the Q2 2021 10-Q as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Foley and Schilke, attesting that, "[t]he information contained in the [Q2 2021 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company. *See* Revance, Quarterly Report (Form 10-Q), Exs. 32.1, 32.2 (filed Aug. 5, 2021).

102. The statements in ¶¶100-01 were materially false and/or misleading because Revance, Foley, and Schilke knowingly and/or recklessly made the statements while omitting the following facts:

(a) Defendants had received a Form 483 identifying five significant objectionable conditions on July 2, 2021;

(b) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted; and

(c) These omissions rendered the statements that Revance "may" get a Complete Response Letter or "another response from the FDA identifying deficiencies that must be addressed" misleading to a reasonable person reading the statements fairly and in context.

103. That same day, August 5, 2021, Revance hosted an earnings call with investors and analysts to discuss the Company's Q2 2021 results (the "Q2 2021 Earnings Call"). Foley and Schilke were among the attendees. During the scripted portion of the Q2 2021 Earnings Call, Defendant Foley stated, in relevant part:

> ***With the FDA having initiated their pre-approval inspection of our manufacturing facility in June, we continue to anticipate the approval of our lead product, DaxibotulinumtoxinA for injection for the treatment of glabellar lines this year***.
>
> ***In the meantime, the Revance team is actively building inventory and solidifying our commercial launch plans for innovative neuromodulators***. We look forward to introducing the first true innovation in the neuromodulator category in over 30 years. And once approved, DaxibotulinumtoxinA for injection will not only anchor our aesthetics portfolio and also lay the foundation for our therapeutics franchise.
>
> * * *
>
> ***In closing, we're very proud of our performance in the first half of the year and anticipate a strong finish in the second half with the potential approval of DaxibotulinumtoxinA for injection*** and further advancement in our therapeutics pipeline. We also remain in a solid financial position with division cash to support our growth initiatives into 2024.

Revance, Q2 2021 Earnings Call at 4, 6 (Aug. 5, 2021) (S&P Global, Inc. transcript).

104. During the Q2 2021 Earnings Call, an analyst stated, "you're expressing a high degree of confidence in the launch. And so I'm assuming that the FDA inspection is going swimmingly." Foley did not correct the analyst, but instead responded, in relevant part:

> [Analyst]: Great. And then just as the second question very quickly on just obviously, you're expressing a high degree of confidence in the launch. And so I'm assuming that the FDA inspection is going swimmingly. Maybe you could just give us a general sense of how you would encourage us to think about the launch and uptake, obviously, given your premium strategy in the fourth quarter

> versus how we should think about the rollout through the balance and maybe just without guiding specifically, but just kind of the rollout through the balance of 2022.
>
> [Foley]: ***Yes.*** Thanks for asking that. First, on the FDA process and where we're at, consistent with prior commentary, we indicated that prior to our PDUFA date, everything had been addressed except for the onsite inspection as part of our PAI, where we press released that an inspection date had not been scheduled yet. And then due to the FDA delays, we were in a bit of a holding pattern waiting for that to occur. Given that this is our first drug approval, remote inspection without possibility and they're going to need to physically inspect the plant. We then in the spring, put out a press release that we've been given an inspection date to occur before the end of Q2. And obviously, in our press release and in our remarks, the FDA has shown up at our facility. ***So we continue to feel very good that they're following sort of through with the expected inspection plan.***
>
> ***I think you're sensing consistency with our tone around the expected approval before year-end. We've taken advantage of this time to keep up sort of our readiness for the inspection and continue to advance our commercial preparation plans.***
>
> In terms of the launch trajectory, we've also tried to be consistent. This will be the first time that our product has been used outside of clinical trials. And as a result, we're going to be sort of very thoughtful and intentional in the first phase of our launch, similar to what we did with the RHA filler line. And so I think for the balance of this year likely and post approval, we're going to spend most of our time focusing on ensuring that we're going to get really good, reproducible outcomes that are consistent with our clinical trial data. And that commercial launch is likely to be much more of a 2022 phenomenon.
>
> So that's how we're thinking about it, but there will be this stub period post approval, where we are going to need to spend some time with a select group of customers, getting real low commercial experience before going through a more traditional launch.

Revance, Q2 2021 Earnings Call, 7-8 (Aug. 5, 2021) (S&P Global, Inc. transcript).

105. In response to additional analyst questions during the August 5, 2021 earnings call about the BLA's status and DAXI manufacturing, Defendant Foley stated, in relevant part:

> [Analyst]: Maybe just one follow-up, Mark, on the DAXI manufacturing side. In the past, I think you've noted about a 6- to 10-week time line for a turnaround from the agency. Just wondering if that's still your expectation. And then obviously, a strong quarter for the filler side here. So -- and obviously, breadth contributed, but just wondering what you're seeing from the reorder side of things.
>
> [Foley]: Yes. So first off, we intentionally didn't give sort of a set time frame because we're outside of the PDUFA clock, where within the PDUFA framework, everything is moving towards the deadline. It's hard to know exactly the time frame that the agency is going to work under as it relates to the inspection. Clearly, they're trying their best, I think, to resolve any of these outstanding issues. ***And so we continue to pick our commentary that we're focused on an***

> ***approval certainly before the end of 2021, and have full preparation and build schedule going on in the interim***. . . .
>
> * * *
>
> [Analyst]: Just a little bit more on the commercial preparations you're doing ahead of the approval. What are you able to do? You've obviously penetrated a decent amount of accounts. Is there anything that you can do outside of potential training and education such as commercial work, contracting work, preliminary contracting, preliminary negotiation? Is there any of that stuff that can happen ahead of time that could potentially smooth the process for the launch and not pull away too much of the energy from the filler momentum that you're having? And then on the manufacturing side, I realize that you said that this is a process. And so I imagine that means that there's a bit of a back and forth, if there are any issues that do come up, would you be telegraphing any of that? Or is this just -- you're keeping it as part of the process and you're still on board for second half, and that's about what you're going to say.
>
> [Foley]: So first on the commercial prep, obviously, in the absence of approval, there's not much that we can do from a promotional standpoint or anything until we have approval. So when we talk about commercial prep, it's all around -- we continue to refine our pricing strategy and more market research work that we've been doing. I think that we've taken advantage of this gap between the launch of the filler and the expected approval of neuromodulator to build further relationships with physicians at the customer level. So we're continuing to establish the prestige Revance for aesthetics brand. I think people see us now as a company that's working towards a broader range of products, both from a services and a product stage.
>
> And then obviously, we talked about building inventory in advance of launch. So one of the launch preps is internal activities, getting all our sales materials ready and everything to support that. So that's kind of more of what we're doing on the commercial prep side. On the manufacturing side, we kind of broke protocol in commenting on where we were in our FDA journey, given the pandemic when we talked about the fact that inspection had not been scheduled prior to the PDUFA. And then again, putting out a press release that one had been scheduled for the end of June. ***So I wouldn't read into my commentary about process. This is sort of a <u>standard piece</u> that needs to happen before approval. So the next communication you'll hear from us is kind of once we get the decision. But again, come back to the fact that we feel very good about our prep and where we were in that process and we continue all of our preparations in the hopeful approval of the product.***

Revance, Q2 2021 Earnings Call, 8-9 (Aug. 5, 2021) (S&P Global, Inc. transcript).

106. The statements in ¶¶103-05 were materially false and/or misleading because Revance and Foley knowingly and/or recklessly made the statements while omitting the following facts:

(a) Defendants had received a Form 483 identifying five significant objectionable conditions on July 2, 2021;

(b) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted; and

(c) These omissions rendered the statements concerning the status of the DAXI BLA, the pre-approval inspection, and the timing of approval misleading to a reasonable person reading the statements fairly and in context.

107. On September 9, 2021, Revance attended the Wells Fargo Securities 2021 Virtual Healthcare Conference. Foley and Schilke were in attendance. During the conference, Defendant Foley made no mention of the Form 483 the Company received over a month prior, stating, in relevant part:

> ***Obviously, the most notable thing that we're waiting on is the approval of our neuromodulator.*** I'm sure we'll get into that a little bit more in the Q&A. ***But we feel really good about where we are in that process. The last thing that had to be completed as part of our approval was the on-site inspection, which did happen at the end of [Q2].*** We're now within -- in sort of a holding pattern or waiting game until we get final news from the agency on that.

Revance, Presents at Wells Fargo 2021 Virtual Healthcare Conference, 4-5 (Sep. 9, 2021) (S&P Global, Inc. transcript).

108. The statements in ¶107 were materially false and/or misleading because Revance and Foley knowingly and/or recklessly made the statements while omitting the following facts:

(a) Defendants had received a Form 483 identifying five significant objectionable conditions on July 2, 2021;

(b) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted; and

(c) These omissions rendered the statements concerning the status of the DAXI BLA and the pre-approval inspection misleading to a reasonable person reading the statements fairly and in context.

109. During that same conference, Defendant Foley responded to an analyst's question on the launch timing, stating, in relevant part:

> [Analyst]: Okay. Perfect. I appreciate that intro. Well, why don't we get the first out of the way, which, of course, on everyone's mind is the BLA that's in front of the FDA. Thank you for confirming on the inspection that was supposed to happen at the end of Q2. And you didn't provide this timetable, but I think you were speaking more generally around a 6- to 10 weeks time frame. And you anticipate getting a decision in the second half of '21. But is there any further update on this front? Has there been any additional dialogue with FDA about when this could occur?
>
> [Foley]: Yes, great question. So as you referenced, we did have the FDA at our facility end of Q2, as we indicated. A typical inspection is 1 to 2 weeks of sort of on-site inspection activities. Ours was a very typical inspection. And as you pointed out, we did reference sort of this 6- to 10-week time frame post inspection as being what is normal and traditional within the PDUFA process, right? So the challenge that we've got here is we're outside of the normal PDUFA process.
>
> Again, our approval got delayed because the FDA was not able to physically travel to visit our site. And so we were in a holding pattern until they scheduled it for the end of Q2. So that's sort of the normal timing. We don't know in this current environment, whether or not that time frame is going to apply to us or whether or not it will be different. This is the division as well that is overseeing vaccines. So I'm sure there's some other competing priorities.
>
> From a planning standpoint, we continue to actively prepare for approval. We ***continue building inventory. We've got our launch strategy and everything in place. And so we're ready to flip the switch as soon as we receive notice from the agency. So nothing really incremental that we have from them in terms of timing***. We're just -- we're sort of just waiting.

Revance, Presents at Wells Fargo 2021 Virtual Healthcare Conference, 6 (Sep. 9, 2021) (S&P Global, Inc. Transcript).

110. The statements referenced in ¶109 were materially misleading because Revance and Foley knowingly and/or recklessly omitted the following facts:

(a) Defendants had received a Form 483 identifying five significant objectionable conditions on July 2, 2021;

(b) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted;

(c) These omissions rendered the statements concerning the status of the DAXI BLA, the preapproval inspection, and the building of inventory misleading to a reasonable person reading the statements fairly and in context.

111. When the Form 483 was revealed to the market on October 11, 2021, Revance's stock price fell $6.85 per share, or 25%, to close at $20.45 per share on October 12, 2021.

B. Defendants Continue to Mislead The Market About The Likelihood of Approval

112. On October 12, 2021, Revance issued a press release entitled, "Revance Continues to Anticipate FDA Approval of DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines in 2021." The press release stated, in relevant part:

> [Revance] responds to the public disclosure of its Form 483 pursuant to a Freedom of Information Act (FOIA) request that was directed to the FDA. The Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection remains under FDA review ***and the company continues to anticipate FDA approval of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines in 2021.***
>
> Revance notes that the issuance of a Form 483 following the conclusion of an on-site inspection is not uncommon. A Form 483 lists observations made by FDA representatives during the inspection of a facility. A Form 483 does not constitute a final agency determination.
>
> Revance provided its response to the Form 483 in July 2021 following a pre-approval inspection and is currently awaiting the FDA's decision on its BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines. ***The company remains confident in the quality of its BLA submission and continues to anticipate FDA approval in 2021***.

Revance, Press Release, *Revance Continues to Anticipate FDA Approval of DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines in 2021* (Oct. 12, 2021).

113. The statements in ¶112 above were materially false and/or misleading because Revance knowingly and/or recklessly made the statements while omitting the following facts:

(a) Observations 1 and 2 identified in the Form 483 regarding the Working Cell Bank and changed manufacturing process materially decreased the likelihood that the BLA would be approved by the FDA as submitted; and

(b) The Working Cell Bank was not projected to be qualified until December 31, 2021;

(c) These omissions rendered the statements concerning the likelihood of approval in 2021 misleading to a reasonable person reading the statements fairly and in context.

114. At no point during the Class Period did Defendants correct or update the aforementioned false and/or misleading statements listed in ¶¶98, 100-01, 103-05, 107, 109, 112.

III. THE FDA DENIES REVANCE'S BLA

115. Then, on October 15, 2021, Revance issued a press release entitled, "Revance Provides Regulatory Update on DaxibotulinumtoxinA for Injection for the Treatment of Moderate to Severe Glabellar (Frown) Lines." The press release stated, in relevant part:

> [Revance] today announced that the United States (U.S.) Food and Drug Administration (FDA) has issued a Complete Response Letter, or CRL, regarding the Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection, for the treatment of moderate to severe glabellar (frown) lines.
>
> In a communication received on October 15, the FDA has determined it is unable to approve the BLA in its present form, and indicated that there are deficiencies related to the FDA's onsite inspection at Revance's manufacturing facility. Revance plans to request a Type A meeting with the FDA as soon as possible to address the deficiencies raised. No other deficiencies were identified in the CRL.
>
> "We are very disappointed by this unanticipated response from the FDA and are seeking further clarity from the agency. We remain committed to bringing our next-generation neuromodulator product to market in both aesthetic and therapeutic indications," said Mark Foley, President and Chief Executive Officer

116. On this news, Revance's stock price fell $8.90 per share, or 39.19%, to close at $13.81 per share on October 18, 2021.

117. After Revance disclosed that it had received a Complete Response Letter ("CRL") from the FDA on October 15, 2021, some market analysts expressed shock at the news given the Company's prior representations. For example, industry publication *Seeking Alpha* published an article on October 29, 2021, juxtaposing the Company's optimistic statements in its August earnings call with the Company's receipt of the CRL. *See* Robert Falcone, *Revance Therapeutics: Repricing Shares After A CRL*, Seeking Alpha (Oct. 29, 2021) https://seekingalpha.com/article/4463615-revance-therapeutics-repricing-shares-after-crl. Specifically, the article quoted Defendant Foley's representation during the August earnings call that Revance had taken advantage of pandemic delays "to keep up sort of our readiness for the inspection and continue to advance our commercial preparation plans." *Id*. Comparing those statements with later developments, the article called "[t]he sequence of events baffling to say the least." *Id*. Critically, the article noted that Revance appeared to be aware of the manufacturing issues outlined by the FDA in advance of the FDA's pre-approval inspection. *Id.*

118. An analyst from Guggenheim reported that after speaking with external FDA manufacturing consultants, in ***the best case scenario***, it would take three months "to complete comprehensive analytical testing and qualify a new cell bank," but "typically" the FDA "wants to see 6 months of stability data, potentially bumping out the timeline to a late 2022/early 2023 PDUFA date." Guggenhiem, *RVNC: A Wrinkle in Time(lines); Our Consultants Lay Out an ~ 12 (Base Case) – 24-Month (Worse Case) Resolution to Approval . . . Lowering PT to $32* (Oct. 21, 2021). As the Establishment Inspection Report shows, qualification of Revance's Working Cell Bank was not projected to be complete until December 31, 2021. Ex. B at 22.

119. Following the FDA's determination that it was unable to approve Revance's BLA for DaxibotulinumtoxinA, Revance expressed its plan to request a "Type A" meeting with the FDA, which is a meeting that is "[i]mmediately necessary for an otherwise stalled drug development program to proceed." Revance, Press Release, *Revance Reports Third Quarter 2021 Financial Results, Provides Corporate Update* (Nov. 9, 2021); FDA, *Engaging with the FDA During New Drug Development*, https://www.accessdata.fda.gov/cder/sb-

navigate/topic3/topic3/da_01_03_0090.htm#:~:text=Type%20A%20Meetings&text=Immediately%20necessary%20for%20an%20otherwise,Appeals%20Above%20the%20Division%20Level.

120. On December 15, 2021, a Type A meeting was held between the FDA and Revance. *See* Press Release, *Revance Receives Clarity on Path to Resubmission of the BLA for DaxibotulinumtoxinA for Injection Following Type A Meeting with FDA* (Jan. 18, 2022); Q4 2021 Earnings Call, Feb. 28, 2022, at 5. Revance announced after the meeting that "a complete response to address the outstanding observations related to the WCB and the drug substance manufacturing process will require Revance to qualify its new WCB by producing three consecutive drug substance lots and one drug product lot." *See* Press Release, *Revance Receives Clarity on Path to Resubmission of the BLA for DaxibotulinumtoxinA for Injection Following Type A Meeting with FDA* (Jan. 18, 2022).

121. As a result of the Type A meeting, and as Foley stated in the Q4 2021 Earnings Call:

> As we've indicated previously, and based on our Type A meeting, a ***reinspection of our manufacturing facility will be necessary*** once our resubmission is accepted by the agency. Further, based on FDA regulations, once the resubmission is accepted, ***the agency has up to 6 months to complete its reinspection of our facility, along with the review of our resubmitted BLA***.

Q4 2021 Earnings Call, Feb. 28, 2022, at 5 (emphasis added). *See also* Q4 2021 Earnings Call, Feb. 28, 2022, at 8 ("And in that Type A meeting, coming out of that, what the FDA wanted to see was the qualification of the new working cell bank with 3 consecutive drug substance and 1 drug product lot. So that's what we've been working on providing.").

122. On March 8, 2022, following its "completion of the production of three consecutive drug substance lots and one drug product lot as part of the qualification of a new working cell bank (WCB)," Revance provided the FDA with its BLA resubmission. *See* Press Release, *Revance Resubmits Biologics License Application for DaxibotulinumtoxinA for Injection for Glabellar Lines to the FDA* (Mar. 8, 2022).

123. When a BLA is resubmitted to the FDA, it can be given one of two designations: Class 1 or Class 2. FDA, *Classifying Resubmissions of Original NDAs, BLAs, and Efficacy Supplements in Response to Complete Response Letters*, Manual Of Policies and Procedures, Center For Drug Evaluation And Research, MAPP 6020.4 Rev. 2, at 1 https://www.fda.gov/files/about%20fda/published/Classifying-Resubmissions-of-Original-NDAs--BLAs--and-Efficacy-Supplements-in-Response-to-Action-Letters.pdf. A resubmission's classification "is based on the information submitted by the applicant in response to an action letter." *Id.* at 1. A Class 1 resubmission has a review period of two (2) months, while a Class 2 resubmission has a review period of six (6) months. *Id.* at 2. Resubmissions that require a reinspection of an applicant's manufacturing facilities fall into Class 2. *Id.* at 4.

124. On April 21, 2022, Revance received FDA acceptance of its BLA Resubmission for DaxibotulinumtoxinA. Revance, Press Release, *Revance Receives FDA Acceptance of BLA Resubmission for DaxibotulinumtoxinA for Injection for Glabellar Lines* (Apr. 21, 2022). In accepting Revance's resubmission, "[t]he FDA designated the BLA as a Class 2 resubmission, which has a six-month review period and includes a required reinspection of the company's manufacturing facility." *Id*;*see also* Revance, Q1 2022 Earnings Call, 14 (May 10, 2022) (S&P Global transcript).

125. The FDA's designation of this resubmission as Class 2 and the necessity of a reinspection further confirmed how far from ready Revance's manufacturing was.
On July 15th, the FDA provided Revance with ***another*** Form 483 that contained another three observations. *See Revance Reports Second Quarter 2022 Financial Results, Provides Corporate Update* (Aug. 9, 2022).

126. In line with the FDA's Class 2 designation of Revance's resubmission, it was not until September 8, 2022, nearly six months after the FDA accepted Revance's BLA resubmission for DaxibotulinumtoxinA, that the FDA approved the drug "for injection for the temporary improvement of moderate to severe frown lines (glabellar lines) in adults." Revance Press Release, *Revance Announces FDA Approval of DAXXIFY™ (DaxibotulinumtoxinA-lanm) for*

Injection, the First and Only Peptide-Formulated Neuromodulator With Long-Lasting Results (Sept. 8, 2022). It took nearly one year from October 15, 2021, the date the FDA determined that it was unable to approve Revance's BLA for DaxibotulinumtoxinA – during which time a "Type A" meeting between Revance and the FDA was held, Revance resubmitted DaxibotulinumtoxinA to the FDA for approval (which the FDA classified as a Class 2 resubmission), and the FDA inspected Revance's manufacturing facility over the course of several days, revealing several additional observations – before the drug was finally approved.

IV. ADDITIONAL SCIENTER ALLEGATIONS

A. *Respondeat Superior*

127. Revance is liable for the acts of Defendants and other Company officers, directors, employees, and agents under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of the Individual Defendants and other Company officers, directors, employees, and agents is similarly imputed to Revance under *respondeat superior* and agency principles.

B. Defendants Had Access To And Possession Of Material Adverse Facts

1. The Form 483

128. Foley and Schilke necessarily received a copy of the Form 483 immediately after its issuance because FDA regulations provide that a copy must be sent to the firm's "top management[.]" *See* FDA, Inspections and Operations Manual (2022), §§ 5.2.3, 5.2.3.6, at 5-20, 5-26, https://www.fda.gov/media/113432/download (last visited May 1, 2024) (providing that Form 483s "should be issued to the most responsible person available at the close of the inspection[,]" with a copy to the "top management of the firm."); *see also* 21 C.F.R. § 211.180(f) ("Procedures shall be established to assure that responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any . . . reports of inspectional observations issued by the Food and Drug Administration . . . "). Foley is necessarily "top management" because he is the CEO and because he was described by the FDA

as "the most responsible person for the firm." Ex. B at 10. Schilke is also necessarily "top management" by virtue of his role as CFO.

129. Joshi necessarily received a copy of the Form 483 because the FDA inspectors provided it to him at the end of the inspection. *See* Ex. A at 1.

130. The Form 483 and EIR confirm that Defendants had access to and were in possession of the seriousness of Observations 1 and 2 and the fact that Revance was not ready for commercialization at the time of the pre-approval inspection. For one thing, Defendants had access to and were in possession of the fact that Revance's Working Cell Bank (or WCB) was ineffective—the subject of the Form 483's first observation. This was discovered after drug substance lots manufactured in August and September 2020 failed, which meant that the Company had not been able to manufacture a "commercial batch" of drug substance since September 6, 2019. Ex. B at 23-24, 50. Revance conducted a quality investigation in September 2020 and recommended CAPA (corrective action and preventative action) in May 2021 to manufacture and qualify a new WCB. *See* Ex. A at 1; Ex. B at 5, 7-8, 53-54. The CAPA was not approved until June 15, 2021 ***and was still not completed as of the pre-approval inspection***. Ex. A at 1; Ex. B at 5. In fact, Revance's "projected timeline" for the qualification of the WCB was December 31, 2021—nearly six months after the pre-approval inspection. *See* Ex. B at 22. At the very least, such an important issue would necessarily have been discussed during the meetings described below after receipt of the Form 483.

131. Defendants also had access to and were in possession of the fact that the changes in the manufacturing process necessitated by the CAPA were different from the process proposed in the BLA—the subject of the Form 483's second observation—because they necessarily had possession of their own BLA and the new process Revance initiated. *See* Ex. A at 1; Ex. B at 5.

2. The FDA's Statements During the Inspection and its Implications for Approval and Commercialization

132. Joshi was present at Revance's manufacturing facility during the pre-approval inspection. *See* Ex. A at 1; Ex. B at 1-12. The FDA described Joshi as the "most responsible person onsite" at the facility and as "responsible for overseeing site operations at the Newark, CA facility." Ex. B at 10. Additionally, Defendant Joshi was present at the close-out meeting with the FDA, during which (1) each observation in the Form 483 was read aloud; and (2) the FDA inspector said Revance's "assumption" that the manufacturing changes were consistent with the BLA was "incorrect"; and (3) the FDA inspector said that "[i]t is recommended that an approval . . . be withheld for lack of commercial readiness." Ex. B at 5, 52-53.

133. Joshi necessarily informed Foley and Schilke of the FDA inspectors' statements because Joshi reports to Foley, Ex. B at 12, and two former employees explained that Joshi, Foley, and Schilke had frequent meetings on this topic, as explained below.

134. Confidential Witness 1 ("CW 1") served as an Executive Assistant at Revance from September 2019 to September 2021. CW 1 served in that capacity for Chief Commercial Officer Dustin Sjuts and, for a short time, Foley. As their Executive Assistant, CW 1 coordinated their calendars. According to CW 1, Foley, Schilke, Joshi, and other C-Level executives had meetings at least once a week during this time. Some of these meetings concerned preparations for the FDA inspection. CW 1 said that at some point during the period from September 2019 to September 2021, Azita Nejad ("Nejad") joined the weekly meetings.

135. Nejad served as Senior Vice President of Technical Operations for Revance and was present during the pre-approval inspection. Ex. B at 9. She reports directly to Joshi. *Id.* at 12.

136. Confidential Witness 2 ("CW 2") served as Deputy Chief of Staff at Revance for approximately five months from July 2021 to December 2021. As Deputy Chief of Staff, CW 2 coordinated meetings that included Foley, Schilke, Joshi, and other executives (including both Board of Directors and/or Senior Executive leaders) at Revance. CW2 stated that most of the activities of Foley, Schilke, Joshi, and other top executives at Revance centered around the

development and approval of DaxibotulinumtoxinA for Injection ("DAXI"). CW2 stated that all energy was focused on approval of DAXI. FDA approval of DAXI would allow the company to compete with Botox in the multi-billion dollar aesthetics industry. In addition to the lucrative aesthetics industry, DAXI was also under clinical trial for therapeutic uses, including cervical dystonia and upper limb spasticity.

137. In CW2's opinion as Deputy Chief of Staff, the manufacture and approval of DAXI was the single most important thing happening at the company during CW2's time at Revance. The prospect for growth at the company after the approval of DAXI was a major factor in CW2's decision to join the company in July 2021.

138. CW2 recalls very clearly that an unexpected crisis erupted at the company on October 12, 2021, the day the truth about the FDA Form 483 inspection report was released to the public. CW2 was given the urgent task of locating Dustin Sjuts, the company's Chief Commercial Officer, and requesting him to return to the office immediately.

139. From October 12, 2021 until the end of CW2's time at the company, the company seemed to be in crisis management mode, with Foley spending an increasing amount of time talking to analysts and shareholders. CW 2's understanding of these analyst and shareholder calls was to provide background on what the Form 483 revealed about the PDUFA inspection and the overall impact/potential delay to FDA approval that would result in the go-to-market launch of DAXI. These delays would have financial impacts to the guidance the company would have publicly disclosed in earnings releases and industry/investor conferences.

140. Defendant Joshi was the head of R&D and from CW 2's recollection had been the only Revance executive in direct contact with the FDA (during the PDUFA inspection). As a member of the Senior Leadership Team, Joshi was in constant contact with Defendant Foley regarding progress with the FDA and the approval process with the FDA. Foley, Schilke and Joshi were immediately made aware of the release of the Form 483 on October 12, 2021 and extremely engaged in managing the internal crisis at the company that the release of the Form 483 created.

3. The BLA Approval Process

141. Defendants were very familiar with the BLA approval process. For example, Defendants Foley's and Schilke's statements before and during the Class Period evidenced a strong familiarity with the BLA, DAXI's manufacturing, and the preparations for and conduct of the pre-approval inspection, as well as their interactions and relationship with the FDA. For example, shortly before the BLA was filed, Schilke stated during the Credit Suisse 28th Annual Healthcare Conference:

> And most important to really note is our U.S.-based manufacturing process. Again, we're manufacturing botulinum toxin. This is inspected on an annual basis by the CDC under the U.S. select agents.
>
> So we undergo rigorous annual inspections for our manufacturing plant, which gives us confidence that we'll be able to go through our prior approval inspections for our DAXI approval for the BLA.
>
> Given sort of the nature and the scrutiny that we have on making such a toxic molecule that the CBC, we have very detailed inspections with them.
>
> So again, that facility not only makes the drug substance but is also able to make the drug product. So we're able to scale from that facility. And then we have -- as we continue to build out, we have already a relationship with another party to allow us to scale the business as we continue to scale commercially from a drug product manufacturing perspective.

Revance, Company Conference Presentation 8 (Nov. 13, 2019) (S&P Global transcript). *See also* ¶¶98-113, *supra* (Foley's and Schilke's statements about the status of the BLA, the manufacturing status, and the pre-approval inspection).

142. Additionally, when Foley was introduced as Revance's new President and CEO, he touted his "intimate familiarity with the business," the opportunity that DAXI presented, and his keen awareness of where Revance stood with obtaining BLA approval for DAXI, by stating in pertinent part: "My priorities for the next year are first and foremost making sure that we get the BLA filed on time and as we've committed, we remain on track to file the BLA by the fall in my discussions with the team, and based on my familiarity with where we are in that process, I have high confidence that we're going to deliver on that date." Revance, *Mark Foley – President*

and CEO of Revance Therapeutics, YouTube (Oct. 25, 2019), https://www.youtube.com/watch?v=K02V9jKNAQA.

143. Foley also described in detail Revance's preparations for the pre-approval inspection, further evidencing his intimate involvement with the process. For example, Foley stated:

> The process for an actual BLA approval is you have to go out and investigates [sic] the sites that do the clinical trial work to make sure that the quality of the clinical data, because that's typically done pretty early in the process. You then submit your package of CMC materials, which they review along the way. And then the final one is the actual physical inspection. And since we don't currently have a product approved at that manufacturing facility, that's why they have indicated that, hey, we need to do a physical inspection… And so we continue to feel like it's a good collaborative relationship and that we are very well-positioned"

Stifel Virtual Healthcare Conference (Nov. 17, 2020), at 2-3.

144. Additionally, Foley discussed that Revance hired "outside consultants and experts to do mock audits to pressure test [Revance's] systems" to help them prepare for the pre-approval inspection. *See* Revance, Q1 2021 Earnings Call 9 (May 10, 2021) (S&P Global, Inc. transcript). Specifically, during the Q1 2021 Earnings Call, Foley stated that Revance had been using the "downtime" afforded to it by the FDA's delay in conducting inspections to be even further prepared for the pre-approval inspection:

> [Analyst]: . . . And then wondering on the inspection, you've had a little bit of time now, more time to prepare. Just can you talk about what you've done behind the scenes? Are you having consultants do mock walk-throughs? Is there any kind of corrective action you've been able to take just to really make sure that we nail it the first time around?
>
> [Foley]: . . . ***On the overall preparation side of it, absolutely. Our team has done a great job of taking sort of advantage of this downtime where we have been engaged with outside consultants and experts to do mock audits to pressure test our systems. And we are actively building inventory in preparation for our launch. So things are changing there. We've actually trained our sales force as well. And so we continue to be leaning in, and we'll certainly be ready once approval comes.***

Id.

145. Additionally, Foley and Schilke discussed the Company's interactions with the FDA. *See* Goldman Sachs 41st Annual Global Healthcare Conference 7 (June 9, 2020) (S&P

Global, Inc. transcript) (Foley: "we've had good constructive ongoing dialogue with [the FDA]"); Stifel Virtual Healthcare Conference 3 (Nov. 17, 2020) (Foley: "we continue to feel like it's a good collaborative relationship [with the FDA] and that we are very well-positioned"); Credit Suisse 29th Annual Healthcare Virtual Conference 5 (Nov. 10, 2020) (Schilke: "we remain really confident in the overall strength of that BLA . . . we'll continue to work proactively and constructively with the agency to bring to market that innovation").

146. Analysts routinely sought out Foley and Schilke to discuss the upcoming pre-approval inspection. *See, e.g.*, Seamus Fernandez, Tarun Soni & Kushal Patel, *RVNC – Takeaways from our Fireside Chat with Management … Firing on All Cylinders as We Wait on FDA* 1, Guggenheim Securities, LLC (Jan. 10, 2021) ("Our meeting Friday with . . . Foley and . . . Schilke focused on (1) DAXI's potential approval and the pending on-site inspection . . . "); Tim Lugo, Lachlan Hanbury-Brown & John Boyle, *Highlights From William Blair's 41st Annual Growth Stock Conference* 1, William Blair (June 2, 2021) ("we hosted . . . Foley . . . and Schilke . . . . The discussion focused on the recently announced preapproval inspection to support potential approval of DAXI for the treatment of glabellar lines, including expectations for the timeline of an approval decision following that inspection, and launch plans . . .").

147. Joshi's position at Revance, ¶¶33, 132, 140, his own statements about the approval process, *see* ¶54, and his presence and role at the pre-approval inspection discussed above, ¶¶10, 129, 132, also demonstrate his knowledge of and involvement in the process.

148. Furthermore, Defendants knew or were deliberately reckless in not knowing the FDA regulations pertaining to BLAs because they frequently discussed the BLA and Revance's readiness for the pre-approval inspection. *See, e.g.*, ¶¶98-113, *supra.*

C. Core Operations

149. Because the fraud alleged herein relates to the core business of Revance, knowledge of the facts underlying the fraudulent scheme may be imputed to the Individual Defendants. Indeed, Revance repeatedly acknowledged the significance of DAXI as a core product, and its pending FDA approval as a pivotal moment for the company. Therefore, the

Individual Defendants, as senior level executives and/or directors, were in such positions at the company to access all material, non-public information concerning the ongoing manufacturing issues identified during the FDA's inspection, and the Form 483 itself.

150. As Foley put it, getting the "BLA approved" is "priority number one[.]" Stifel Virtual Healthcare Conference 10 (Nov. 17, 2021).

151. Indeed, throughout the Class Period, Revance emphasized the importance of DAXI to its overall business. In its SEC filings, Revance acknowledged that DAXI is its "lead product candidate" and that "[w]e are substantially dependent on the clinical and commercial success of our product candidate DAXI." *See, e.g.*, Revance, Annual Report (Form 10-K), 1, 22 (filed Feb. 26, 2020); *see also* Revance, Annual Report (Form 10-K), 31 (filed Feb. 25, 2021).

152. In Revance's press release announcing its submission of the DAXI BLA to the FDA, Defendant Foley stated, "[t]he submission of our BLA represents a significant milestone in the Company's history . . . . Revance enters a catalyst-rich calendar year of significant clinical trial readouts and meaningful Company milestones, which we believe will culminate in the approval and launch of DAXI..." acknowledging at the outset that the success of DAXI had wide ranging implications for the Company. *See* Press Release, *Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar (Frown) Lines* (Nov. 25, 2019).

153. During an earnings call held on August 6, 2020, Foley referred to DAXI as "our lead asset" and touted DAXI as "the world's first true next-generation long-acting neuromodulator[.]" Revance, Q2 2020 Earnings Call, at 5, 8 (Aug. 6, 2020) (S&P Global, Inc. transcript). Schilke also described DAXI as Revance's "core asset" and "key asset." Credit Suisse 29th Annual Healthcare Virtual Conference 3, 9 (Nov. 10, 2020).

154. Although Revance marketed the RHA Fillers beginning in June 2020, it did so in partnership with another company. As the Company's own product, DAXI had the most earning potential for the Company by far. While presenting at the Morgan Stanley 18th Annual Global Healthcare Conference on September 14, 2020, Defendant Schilke stated that "[c]learly, over time, from our [DAXI], we seek to get to sort of industry norms from sort of a gross margin

perspective. And you do that with scale as you kind of build your scale for [DAXI] and sort of build your scale for fillers. Clearly, the margins on [DAXI] will be greater than those on fillers, just simply because we're the innovator there and we control the manufacturing process for [DAXI]." Revance, Presents at Morgan Stanley 18th Annual Global Healthcare Conference, at 8 (Sept. 14, 2020) (S&P Global, Inc. transcript).

155. DAXI's importance to Revance is also made apparent by the amount of time the Company devoted to discussing it. DAXI and/or the status of its BLA approval is mentioned during every earnings call held during the Class Period. *See* Revance, Q4 2019 Earnings Call (Feb. 24, 2020) (S&P Global, Inc. transcript); Revance, Q1 2020 Earnings Call (May 7, 2020) (S&P Global, Inc. transcript); Revance, Q2 2020 Earnings Call (Aug. 6, 2020) (S&P Global, Inc. transcript); Revance, Q3 2020 Earnings Call (Nov. 9, 2020) (S&P Global, Inc. transcript); Revance, Q4 2020 Earnings Call (Feb. 22, 2021) (S&P Global, Inc. transcript); Revance, Q1 2021 Earnings Call (May 10, 2021) (S&P Global, Inc. transcript); Revance, Q2 2021 Earnings Call (Aug. 5, 2021) (S&P Global, Inc. transcript); Revance, Q3 2021 Earnings Call (Nov. 9, 2021) (S&P Global, Inc. transcript).

156. Foley continued to refer to DAXI as the Company's "lead product" during the Q2 2021 earnings call held on August 5, 2021. Revance, Q2 2021 Earnings Call, at 4 (Aug. 5, 2021) (S&P Global, Inc. transcript). On the same date, Revance issued a press release that stated that once DAXI was approved, they expected the product to "underpin our aesthetics franchise and set the standard for neuromodulator performance . . ." *See* Press Release, Revance Reports Second Quarter 2021 Financial Results, Provides Corporate Update (Aug. 5, 2021).

157. Revance has consistently advertised DAXI as a core product, maintaining it as a top priority before, during, and after the Class Period. On an earnings call held on August 9, 2022, Foley stated that obtaining FDA approval of DAXI "***remains*** our top corporate priority for 2022" and referred to DAXI as "our flagship drug product." Revance, Q2 2022 Earnings Call, at 5 (Aug. 9, 2022) (S&P Global, Inc. transcript).

158. Revance has a relatively small number of employees. Revance began the class period with 193 employees in 2019. Revance, Annual Report (Form 10-K), 21 (Feb. 26, 2020). That number grew to 470 during 2020, then to almost 500 by the end of 2021. Revance, Annual Report (Form 10-K), 26 (filed Feb. 25, 2021); Revance, Annual Report (Form 10-K), 29 (filed Feb. 28, 2022).

159. Accordingly, it is highly likely that the Form 483, the FDA's statements during the pre-approval inspection, and the implications of both would also have been directly reported from the person responsible for manufacturing—Joshi—to the other Individual Defendants.

160. Thus, the Individual Defendants were aware, or recklessly disregarded, that the challenged statements were made contemporaneously with knowledge of contradictory information, and were materially false and/or misleading when made.

D. Defendants' Financial Motive

1. Equity Grants and Other Incentive Compensation

161. Although the Individual Defendants knew, or recklessly disregarded that there were manufacturing issues that would preclude approval of the BLA for DAXI, they were motivated to tout the pending approval of DAXI and represent its readiness for commercialization to the public to maximize the value of their lucrative performance-based executive compensation through inflation of Revance's share price.

162. According to Revance's SEC filings, the Company's executive compensation program included base salary, performance-based annual bonus, and performance-based incentive equity. *See* Revance, Proxy Statement (Schedule 14A), 28-29 (Mar. 26, 2020). In making executive compensation decisions, the Compensation Committee of Revance's Board of Directors considered the performance and skills of each Named Executive Officers ("NEO") in addition to compensation paid to NEOs at similar companies. *Id.* at 29. The details of the components of Revance's executive compensation program during the Class Period are as follows:

a. Base Salary (fixed cash): Base salaries are generally reviewed annually and determined based on a number of factors such as individual performance, internal equity, retention, expected cost of living increases, and overall Company performance. *Id.* Additionally, market data provided by an independent compensation consultant was taken into account. *Id.*

b. Performance Bonus (at-risk cash): The Company believes that performance bonuses motivate and reward NEOs for attaining annual corporate performance goals. *Id.* Target bonus amounts, which are calculated as a percentage of each NEO's base salary, were reviewed annually and are "dependent on achievement of specific corporate performance goals established at the beginning of the year, and except with respect to [the] CEO, individual performance objectives that relate to the NEOs' role and expected contribution to reaching [Revance's] corporate goals." *Id.* Throughout the Class Period, one of the key corporate goals was the achievement of milestones and activities related to the BLA for DAXI and its subsequent commercialization. *Id*. at 35; *see also* Revance, Proxy Statement (Schedule 14A), 44 (filed Mar. 24, 2021); Revance, Proxy Statement (Schedule 14A), 41 (filed Mar. 24, 2022).

c. Long-Term Incentive (at-risk equity): According to the Company, the objective of Long-Term Incentives is to motivate and reward for long-term Company performance. *See* Revance, Proxy Statement (Schedule 14A), 29 (filed Mar. 26, 2020). The Company generally reviewed and determined equity opportunities on an annual basis. *Id.* Individual grants of equity are based on "a number of factors, including current corporate and individual performance, outstanding equity holdings and their retention value and total ownership, historical value of [Revance] stock, internal equity amongst executives and market data provided by [Revance's] independent compensation consultant." *Id.* Historically, the Company granted equity primarily in the form of stock options and Restricted

Stock Awards ("RSA"). *Id.* After Defendant Foley was hired in late 2019, the Company introduced Performance Stock Awards ("PSA"). *Id.* The Company granted PSAs to other NEOs in 2020. *Id.* Crucially, the award of PSAs to NEOs vests according to a schedule encompassing three corporate milestones: "(1) 25% of the PSA will vest on the earlier of the following events, if such event occurs on or before December 31, 2020: (a) approval by the FDA of the Company's BLA for DAXI for the treatment of glabellar lines; or (b) change in control (as defined in the Equity Plan); (2) 35% of the PSA will vest upon the earlier of the following, as confirmed by the Board or Compensation Committee on or before October 13, 2029: (a) the date that the closing share price of our common stock is at least $25 per share (representing more than a 100% increase in closing share price as compared to the closing share price on the grant date) and remains at or above $25 per share during any 90 consecutive trading-day period on a volume weighted average price (VWAP) basis; or (b) upon a change in control (as defined in the Equity Plan) in which the purchase of our common stock is at or above $25 per share; (3) 40% of the PSA will vest upon the earlier of the following, as confirmed by the Board or Compensation Committee on or before October 13, 2029: (a) the date that the closing share price of our common stock is at least $40 per share (representing more than a 200% increase in closing share price as compared to the closing share price on the grant date) and remains at or above $40 per share during any 90 consecutive trading-day period on a [volume weighted average price] (VWAP) basis; or (b) upon a change in control (as defined in the Equity Plan) in which the purchase of our common stock is at or above $40 per share." *Id.* at 38; *see also* Revance, Proxy Statement (Schedule 14A), 47-48 (filed Mar. 24, 2021).

163. As reflected in Revance's SEC filings, the Individual Defendants were motivated to conceal the truth by their executive compensation packages. For example, the chart below shows their executive compensation for 2019 through 2021:

Name and Principal Position(s)	Fiscal Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	Incentive Plan Compensation (3)	All Other Compensation (4)	Total
Mark J. Foley	2021	$ 660,000	$ —	$ 4,561,652	$ 1,141,226	$ 425,700	$ 317,338	$ 7,105,916
CEO	2020	$ 650,000	$ —	$ 7,794,350	$ —	$ 328,331	$ 8,255	$ 8,780,936
	2019	$ 189,764	$ 150,000	$11,728,370	$ 5,112,573	$ —	$ 9,723	$ 17,190,430
Tobin C. Schilke	2021	$ 429,802	$ —	$ 1,267,172	$ 634,014	$ 192,336	$ 11,470	$ 2,534,794
Chief Financial Officer	2020	$ 407,126	$ 25,000	$ 86,150	$ 299,781	$ 178,123	$ 11,078	$ 1,007,258
	2019	$ 64,644	$ 25,000	$ 449,280	$ 1,434,350	$ —	$ 233	$ 1,973,507
Abhay Joshi, Ph.D.	2021	$ 519,754	$ —	$ 1,267,172	$ 634,014	$ 154,081	$ 11,738	$ 2,586,759
Chief Operating Officer, President of R&D and Product Operations	2020	$ 514,608	$ —	$ 1,405,850	$ 1,913,759	$ 213,726	$ 11,731	$ 4,059,674
	2019	$ 485,479	$ —	$ 271,373	$ 939,314	$ 204,211	$ 9,520	$ 1,909,897

Revance, Proxy Statement (Schedule 14A), 49 (Mar. 24, 2022).

164. As illustrated above, most of the Individual Defendants' compensation came in the form of stock and options, providing ample motive to keep the Company's share price inflated during the Class Period.

c) Revance's Bonus and Equity Incentive Programs Caused the Individual Defendants To Be Aware of the Progress of the FDA Regulatory Process for DAXI

165. Given that 45% of the Individual Defendants' target bonuses during the Class Period were tied to regulatory approval of DAXI, the Individual Defendants were self-interested in the progress of the FDA approval process for DAXI, including the status of the FDA's pre-approval inspection of Revance's manufacturing facility. *See* Revance, Proxy Statement (Schedule 14A), 43 (filed Mar. 24, 2022) at 43 (providing that 45% of the Individual

Defendants' cash bonuses are tied to DAXI's approval). This was despite the Board's decision to extend eligibility for this bonus into 2021 from 2020. *Id*.

166. The Individual Defendants' personal stake in Revance's successful completion of the pre-approval inspection certainly would have caused them to monitor the preparations for such inspection, the results of the inspection, the FDA's comments during the inspection, and the implications of the FDA's issuance of a Form 483 in July 2021, putting their bonuses and personal compensation in jeopardy.

167. Additionally, with respect to Revance's grant of PSAs to the Individual Defendants, the vesting of 25% of those equity awards was directly tied to regulatory approval of DAXI. *See* Revance Proxy Statement (Schedule 14A), 38 (filed Mar. 26, 2020); *see also* Revance, Proxy Statement (Schedule DEF 14A), 47-48 (filed Mar. 24, 2021). This vesting requirement provides even further evidence that the Individual Defendants would have closely monitored the regulatory approval process including the FDA's pre-approval inspection.

d) Revance's Equity Incentive Grants Incentivized the Individual Defendants to Artificially Inflate the Company's Share Price

168. Revance's equity compensation program constituted a large portion of the Individual Defendants' annual compensation, causing the Individual Defendants to be highly motivated to increase the value of the Company's common stock during the Class Period. As the Company itself admitted, the equity incentives motivate and reward executives for long-term Company performance. *See* Revance, Proxy Statement (Schedule DEF 14A), 29 (filed Mar. 26, 2020). This is especially true given Revance's emphasis on PSAs, the vesting of large portions of which are directly tied to defined increases in Company share price. *Id*. at 38; *see also* Revance, Proxy Statement (Schedule 14A), 47-48 (filed Mar. 24, 2021). Therefore, the Individual Defendants were motivated to artificially inflate the price of Revance stock during the Class Period by misrepresenting the pre-approval inspection, the BLA's status, and the likelihood of approval.

2. Revance's Motive

169. During the Class Period, Defendants were further motivated to artificially inflate Revance's stock price because doing so allowed Revance to continue to fund its operations, including development and commercialization of DAXI.

170. In early 2019, Revance's primary sources of income were through collaboration and license agreements with third party companies. *See* Revance Quarterly Report (Form 10-Q), 9 (filed May 9, 2019); Revance, Annual Report (Form 10-K), F-16 (filed Feb. 26, 2020). In February 2018, Revance entered into the Botox biosimilar collaboration and license agreement with Mylan, which included an upfront payment of $25 million and subsequent incremental payments which constituted the bulk of Revance's revenue throughout 2019. *See* Revance, Annual Report (Form 10-K), 47 (filed Feb. 26, 2020). In January 2019, in connection with a License Agreement with Fosun that it executed in December 2018, Revance received from Fosun an upfront payment of $30.0 million. *See* Revance, Annual Report (Form 10-K), F-18 (filed Feb. 26, 2020); Revance, Quarterly Report (Form 10-Q), 10 (filed Nov. 4, 2019); Revance, Annual Report (Form 10-K), 66 (filed Feb. 26, 2020). In August 2019, Revance entered into the Amended agreement with Mylan, in order to continue the Botox biosimilar development program. *See* Revance, Annual Report (Form 10-K), 69 (filed Feb. 26, 2020). In its own SEC filing, Revance attributes "all of [its] revenue" to be from "Mylan under the Mylan Collaboration." *See id.* at 21.

171. This income was insufficient to fund Revance's operations. During the Class Period, Revance's operating costs were $164.872 million to $352.474 million annually, and it ran of deficit of $844 million to $1.4 billion during this time. *See* Revance, Annual Report (Form 10-K), 28, 34, 66, F-4, F-5, F-8 (filed Feb. 26, 2020); Revance, Annual Report (Form 10-K), 6, 44, F-5, F-6, F-9 (filed Feb. 25, 2021); Revance, Annual Report (Form 10-K), 34, 83, F-5, F-11 (filed Feb. 28, 2022).

172. As a result, the Company was depending on funding its operations through the sale and issuance of common stock. *See, e.g.*, Revance, Annual Report (Form 10-K) 29 (filed

Feb. 26, 2020). For example, in its quarterly filing for the first quarter of 2020, Revance stated that "[i]n recent years, we have funded our operations primarily through a combination of issuance and sale of common stock and issuance of convertible senior notes." *See* Revance, Quarterly Report (Form 10-Q), 7 (filed May 7, 2020).

173. In May 2021, shortly before the pre-approval inspection, Revance filed a Quarterly Report on Form 10-Q that stated "[i]n recent years, we have funded our operations primarily through the sale of common stock, convertible senior notes, and payments received from collaboration arrangements." *See* Revance, Quarterly Report (Form 10-Q), 7 (filed May 10, 2021).

174. Revance reiterated this position in its August 2021 Quarterly Report. *See* Revance, Quarterly Report (Form 10-Q) 8 (Aug. 5, 2021).

175. Defendants' repeated representations about the importance of common stock to the funding of the Company's operations provides strong financial motive to artificially inflate Revance's stock price during the Class Period.

176. Further, Defendants were motived to artificially inflate Revance's stock price because it allowed the Company to obtain more cash through public and private securities offerings.

177. For example, on December 4, 2019, Revance announced a public offering of 6,500,000 shares at $17.00 per share which closed on or about December 6, 2019, raising approximately $110.5 million. *See* Revance Current Report (Form 8-K), 1 (filed Dec. 4, 2019).

178. Defendants were motivated to artificially inflate Revance's stock so that they could use the funds obtained to commercialize DAXI. *See* Revance, Prospectus Supplement (Form 424B5), S-2 (filed Dec. 4, 2019) ("We intend to use the net proceeds from this offering to continue to fund the commercialization of DAXI, and the remainder for working capital, research and development and general corporate purposes.").

179. Then, on February 10, 2020, Revance announced a private placement of $200 million convertible senior notes due in 2027. *See* Revance, Current Report (Form 8-K), 1 (filed

Feb. 10, 2020). The notes were convertible into cash, shares of Revance, or a combination of the two. *Id.* at Ex. 99.1.

180. Notably, Revance stated that the proceeds of the offering would go to supporting the development and commercialization of DAXI. *Id.* at Ex. 99.1.

181. The offering ultimately resulted in the issuance of $287.5 million in convertible senior notes. *See* Revance Current Report (Form 8-K) 1 (Feb. 14, 2020)

182. Given that the notes could be converted into either cash or Revance common stock, there was an incentive to keep the Company's stock price high in order to encourage exchange for Revance common stock at a lower cost to the Company than a cash payout.

183. Additionally, Defendants were motived to artificially inflate Revance's stock price in order to fund acquisitions that allowed the Company to fund its operations and expand its commercialization efforts.

184. For example, in January 2020, Revance announced that it had entered into a deal with Teoxane SA ("Teoxane") for the right to sell and distribute Teoxane's line of Resilient Hyaluronic Acid dermal fillers *See* Revance Current Report (Form 8-K), 1 (filed Jan. 10, 2020). Revance financed the deal with the exchange of 2,500,000 shares of Revance common stock. *Id.*

185. Proceeds from this distribution agreement would later come to fund a portion of Revance's operations. *See* Revance, Quarterly Report (Form 10-Q) 8 (filed Aug. 5, 2021) ("In recent years, we have funded our operations primarily through the sale of common stock, convertible senior notes, payments received from collaboration arrangements, and sales of the RHA® Collection of dermal fillers."); *see also* Revance, Annual Report (Form 10-K), 34 (filed Feb. 28, 2022) ("We have funded our operations primarily through the sale of common stock, convertible senior notes, payments received from collaboration arrangements, and sales of the Current RHA® Collection of dermal fillers.").

186. With respect to Revance's commercialization efforts, Revance also acquired Hint, Inc. ("Hint"), a private company which had created an integrated financial technology platform for the aesthetics industry. *See* Revance Press Release, *Revance Announces Agreement to*

Acquire HintMD and its Proprietary Fintech Platform for Aesthetic Practices (May 19, 2020).. Revance's acquisition of Hint was completed on an all-stock basis. *Id*. Revance announced that the acquisition of Hint would strengthen the Company's ability to grow its aesthetics business, a key component of which was DAXI. *Id*.

187. Revance's commercialization efforts were exceedingly important to the Company, as evidenced by warnings in its regulatory filings that failure to properly execute the Company's commercialization strategy could adversely impact the Company and its business. *See*, e.g., Revance, Annual Report (Form 10-K), 22-24 (filed Feb. 26, 2020).

188. Consequently, as evidenced in detail above, Defendants had a strong financial motive to keep Revance's stock price artificially inflated during the Class Period so that the Company could continue to fund its operations and acquisitions.

E. Defendant's Experience and Education

189. During the Class Period, Defendants were highly experienced in the pharmaceutical, healthcare, and biotechnology industries, and were therefore well aware that their statements regarding the likelihood of DAXI BLA obtaining FDA approval within the timeframe Revance had represented to investors were false and/or misleading and that material information had been omitted.

190. As set forth below, Defendants are sophisticated pharmaceutical executives who are well-versed in the customs and practices of the pharmaceutical industry. For example, Defendant Foley has more than twenty-five (25) years of experience in the healthcare industry. Foley has been the President and Chief Executive Officer of Revance since October 2019, and has been a Director at Revance since September 2017. Revance, Proxy Statement (Schedule 14A), 8 (filed Mar. 24, 2021). The Company explains Foley's director qualifications as follows: "Our Board believes that Mr. Foley's leadership experience, financial expertise, experience at multiple public pharmaceutical companies, and his expertise with the development and commercialization in the aesthetics, medical device, and biotechnology and financial technology

industries make him qualified to serve on our Board." *See id.* at 8. His "key skills" include "manufacturing and supply chain." *See id.* at 7-8.

191. At the time Foley assumed the role of CEO, Revance's Chairman of the Board was quoted in a press release dated October 14, 2019, as saying that "Mark [Foley] is a seasoned aesthetic and medical device leader, having expertise in commercialization strategies that drive company growth and generate significant shareholder value." Revance, Press Release, *Revance Appoints Mark J. Foley as President and CEO, Replacing Dan Browne* (Oct. 14, 2019). Before Revance, Foley was the Chairman, President, and CEO of ZELTIQ Aesthetics, which manufactures medical devices, from April 2012 to April 2017. *See* Revance, Proxy Statement (Schedule 14A), 8 (filed Mar. 24, 2021). At ZELTIQ, Foley led the company through a period of significant growth that culminated with Allergan acquiring ZELTIQ. Revance, Current Report (Form 8-K), Ex. 99.1 (filed Oct. 14, 2019). Before ZELTIQ, Foley held various senior operating roles in both large public companies and ventured-backed startups, such as Perclose, U.S. Surgical Corporation, Devices for Vascular Intervention, Guidant Corporation, and Ventrica, the latter of which he was the founder and CEO. *See* Revance, Proxy Statement (Schedule 14A), 8 (filed Mar. 24, 2021). Foley has served on the Board of Directors of SI-BONE, Inc., a medical device company, and currently serves as a Board of Director for Glaukos Corp., a medical technology and pharmaceutical company that focuses on treatments for eye conditions. *See id.* Foley has also served as the Co-Chair of the Aesthetics Innovation Summit since September 2017, has been a Board Member and Chairman of uLab since June 2015, and has served as Chairman of the Board of HintMD. *See* LinkedIn, *Mark Foley*, https://www.linkedin.com/in/mark-foley-1615995/; Aesthetics Innovation Summit, *Mark Foley*, https://attendais.com/mark-foley/; uLab Systems, *uLab Team*, https://www.ulabsystems.com/ulab-team/; HintMD, Press Release, Mark Foley Joins HintMD as Chairman of the Board (Nov. 1, 2017). Further, Foley had served as a Managing Director of RWI Ventures, a life sciences and technology venture capital fund, from May 2004 through 2018. *See* Revance, Proxy Statement (Schedule 14A), 8 (filed Mar. 24, 2021).

192. Schilke has more than twenty (20) years of experience in the pharmaceutical and biotechnology industries. In a November 1, 2018 press release announcing Schilke's appointment as CFO, Revance stated that Schilke had "spent 13 years in senior management roles at Roche and Genentech, leading significant finance and strategic initiatives." Revance, Current Report (Form 8-K) Ex. 99.1 (filed Nov. 1, 2018). Before becoming Revance's Chief Financial Officer in November 2018, Schilke served as the CFO of Achaogen, Inc., a biopharmaceutical company, from July 2016 to October 2018. Revance, Proxy Statement (Schedule 14A), 33 (filed Mar. 24, 2021). Before Achaogen, Schilke was the Finance Director and Company Director of Roche Products Limited, a pharmaceutical company, from August 2014 to June 2016. *Id.*; LinkedIn, *Tobin Schilke*, https://www.linkedin.com/in/tobin-schilke/. Before Schilke assumed this role at Roche, he was the Director of the Commercial Finance BioOncology Business Unit of Genentech, a biotechnology company involved in the discovery and development of medicines and a member of the Roche Group, from September 2012 to August 2014, and previously was an associate director of commercial finance for Genentech from December 2009 to September 2012. Revance, Proxy Statement (Schedule 14A), 33 (filed Mar. 24, 2021).; Genentech, *About Us*, https://www.gene.com/about-us; https://www.linkedin.com/in/tobin-schilke/. Before working for Roche, Schilke was a process engineer at Pharmacia from August 1998 to August 2001. LinkedIn, *Tobin Schilke*, https://www.linkedin.com/in/tobin-schilke/. Schilke went to Lafayette College, where he earned a B.S. degree, the University of California, Berkeley, where he earned an M.S. Degree, and Cornell University's Johnson Graduate School of Management, where he earned an M.B.A. degree. Revance, Proxy Statement (Schedule 14A), 33 (filed Mar. 24, 2021).

193. Joshi has over 25 years of experience as a pharmaceutical and biotechnology executive. He served as Revance's Chief Operating Officer since December 2015 and as Revance's President, R&D and Product Operations since January 2020. Revance, Proxy Statement (Schedule 14A), 33 (filed Mar. 24, 2021). Before joining Revance, he served as the President and CEO of Alvine Pharmaceuticals, Inc., a pharmaceutical company developing

therapeutic products for the treatment of autoimmune and inflammatory diseases, where he was responsible for overseeing all aspects of the company's business. *Id.* His experience prior to Alvine includes serving as the Vice President of Global Technical Operations, Specialty Pharmaceuticals at Allergan plc, where he was responsible for Allergan's global biologics manufacturing operations for BOTOX®, among other things. *Id.* Joshi has served on the board of Genyous Biomed International, Sira Pharmaceuticals, Inc., and Sinopia Biosciences, Inc. He received his BTech in Chemical Engineering from the Indian Institute of Technology, New Delhi, an M.S.E. and a Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor, and an MBA from the University of California, Irvine. *Id.*

F. SOX Certifications

194. Defendants Foley and Schilke signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") that they filed with the SEC in connection with the filing of Revance's August 5, 2021 Form 10-Q . *See* Revance, Quarterly Report (Form 10-Q). The certifications state that the quarterly report "fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act," and that "[t]he information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company." *Id.* at Exs. 32.1, 32.2. Furthermore, the certifications also state, in relevant part:

> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

See id. at Exs. 31.1 and 31.2.

V. PLAINTIFFS' CLASS ACTION ALLEGATIONS

195. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Revance securities during the Class Period (the "Class"), and were damaged thereby. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

196. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Revance securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Revance or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

197. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

198. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

199. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Revance;
- whether the Individual Defendants caused Revance to issue false and misleading statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of Revance securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

200. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

201. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Revance securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentation and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiffs and members of the Class purchased, acquired and/or sold Revance securities between the time Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

202. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

203. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court *in Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

VI. LOSS CAUSATION

204. Defendants' wrongful conduct, as alleged herein, directly and proximately caused Plaintiffs and the Class to suffer substantial damages.

205. During the Class Period, Plaintiffs and other Class Members purchased or otherwise acquired Revance securities at artificially inflated prices and suffered substantial losses and damages when the true facts concealed by Defendants' fraud were revealed and/or when the risk concealed by those undisclosed facts materialized. The price of Revance securities declined significantly, causing Plaintiffs and other Class Members to suffer losses and damages when Defendants' misrepresentations, and/or information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, and/or the foreseeable risks that had been fraudulently concealed by Defendants materialized.

206. Defendants made false and misleading statements and material omissions regarding the status of the DAXI BLA, the pre-approval inspection, and the likelihood of approval. On the strength of these false and misleading statements and material omissions, the price of the Company's securities was artificially inflated to a Class Period high of $30.49 per share on August 5, 2021. Those misrepresentations and omissions that were not immediately

followed by an upward movement in the price of the Company's securities served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Revance's business, operations, performance, and prospects. When these statements were corrected and/or the risks concealed by them materialized, investors suffered losses as the price of Revance securities declined.

207. The true facts and risks regarding the status of the DAXI BLA, the pre-approval inspection, and the likelihood of approval which were omitted and/or misrepresented by Defendants eventually caused the price of Revance's securities to decline on October 12, 2021.

208. Defendants' statements were partially corrected, and the risks concealed by the undisclosed facts regarding the status of the DAXI BLA, the pre-approval inspection, and the likelihood of approval materialized on October 12, 2021, when the Form 483 was revealed to the market. This caused investors to suffer losses as the price of Revance's common stock dropped $6.85 per share, or 25%, to close at $20.45 per share on October 12, 2021.

209. Defendants' statements were further corrected, and the risks concealed by the undisclosed facts regarding the status of the DAXI BLA, the pre-approval inspection, and the likelihood of approval were fully revealed on Friday October 15, 2021, when, after market close, the Company announced the receipt of the CRL from the FDA, denying Revance's BLA. This caused investors to suffer losses as the price of Revance's common stock tumbled, dropping from a close of $22.71 per share on October 15, 2021 to close at $13.81 per share on the next trading day, October 18, 2021, a decline of approximately 39.19%.

210. Accordingly, as a result of their purchases of Revance's publicly traded securities during the Class Period, Plaintiffs and other members of the Class suffered economic losses and damages.

VII. NO STATUTORY SAFE HARBOR

211. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do

not apply to any of the materially false and misleading statements and omissions alleged in this Complaint.

212. First, many of the identified false and misleading statements and omissions herein are not forward-looking statements, but instead are statements of current or historic fact, or are actionable in context because they omit then-existing material facts.

213. Second, many of the identified false and misleading statements were not identified as forward-looking statements.

214. Third, to the extent there were any forward-looking statements that were identified as such at the time made, those statements also contained statements of present or past facts and so are not entitled to protection under the safe harbor.

215. Fourth, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningfully cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Such statements were also not accompanied by cautionary language that was meaningful because any such warnings or "risk" factors contained in, or incorporated by reference in, the relevant press release, SEC filings, earnings call, or other public statements described herein were general, "boilerplate" statements of risk that would affect any pharmaceutical company, and misleading contained no factual disclosure of any of the specific details concerning the problems with Revance's manufacturing and their impact on approval of the DAXI BLA, or similar important factors that would give investors adequate notice of such risks. Defendants are liable for those false and misleading forward-looking statements because at the time each of those statements were made, the particular speaker knew that the particular forward-looking statement was false, or by reason of what the speaker failed to note, was materially false and/or misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Revance who actually knew that each such statement was false or misleading when made.

VIII. CONTROL PERSON LIABILITY

216. The Individual Defendants, because of their positions with Revance, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each Individual Defendant possessed the power to direct or cause the direction of the management and policies of Revance. Each Individual Defendant had a duty to promptly disseminate complete, accurate, and truthful information with respect to the status of the FDA's pre-approval inspection and the impact of those facts on the approval of the DAXI BLA. Each Individual Defendant was provided with copies of the Company's SEC filings, press releases, and other documents alleged herein to be false or misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each Defendant knew or recklessly disregarded that the adverse facts and omission specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

217. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

218. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

219. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances

under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Revance securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Revance securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

220. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Revance securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Revance's finances and business prospects.

221. By virtue of their positions at Revance, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

222. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers

and/or directors of Revance, the Individual Defendants had knowledge of the details of Revance's internal affairs.

223. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Revance. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Revance's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Revance securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Revance's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Revance securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

224. During the Class Period, Revance securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Revance securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Revance securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Revance securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

225. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

226. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating false and misleading statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

227. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

228. During the Class Period, the Individual Defendants participated in the operation and management of Revance, and conducted and participated, directly and indirectly, in the conduct of Revance's business affairs. Because of their senior positions, they knew the adverse non-public information about Revance's misstatements with respect to the status of the DAXI BLA, the status of the FDA's pre-approval inspection, and the impact of those facts on the approval of the DAXI BLA.

229. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Revance's results of operations, and to correct promptly any public statements issued by Revance which had become materially false or misleading.

230. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Revance disseminated in the marketplace during the Class Period concerning Revance's results of operations. Throughout the Class Period, the Individual

Defendants exercised their power and authority to cause Revance to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Revance within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Revance securities.

231. Each of the Individual Defendants, therefore, acted as a controlling person of Revance. By reason of their senior management positions and/or being directors of Revance, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Revance to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Revance and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

232. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Revance.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all triable claims.[5]

Dated: May 1, 2024

By: */s/ James M. Wilson, Jr.*
James M. Wilson, Jr.

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[5] Pursuant to Section H.1. of this Court's Standing Order for Civil Cases, Plaintiffs submit herewith as Exhibit E a redline document showing the changes made to the previously filed complaint.