

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

_____, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

v.

REVANCE THERAPEUTICS, INC., MARK J.
FOLEY, and TOBIN C. SCHILKE,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1 Plaintiff _____ (“Plaintiff”), individually and on behalf of all others similarly situated, by
2 Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following
3 based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to
4 all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys,
5 which included, among other things, a review of the Defendants’ public documents, conference calls and
6 announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission
7 (“SEC”) filings, wire and press releases published by and regarding Revance Therapeutics, Inc.
8 (“Revance” or the “Company”), analysts’ reports and advisories about the Company, and information
9 readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will
10 exist for the allegations set forth herein after a reasonable opportunity for discovery.
11

12 **NATURE OF THE ACTION**

13
14 1. This is a federal securities class action on behalf of a class consisting of all persons and
15 entities other than Defendants that purchased or otherwise acquired Revance securities between
16 November 25, 2019 and October 11, 2021, both dates inclusive (the “Class Period”), seeking to recover
17 damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under
18 Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5
19 promulgated thereunder, against the Company and certain of its top officials.
20

21 2. Revance, a biotechnology company, engages in the development, manufacture, and
22 commercialization of neuromodulators for various aesthetic and therapeutic indications in the United
23 States and internationally. The Company’s lead drug candidate is DaxibotulinumtoxinA for injection
24 (“DAXI”), which has completed phase III clinical trials for the treatment of glabellar (frown) lines and
25 cervical dystonia; is in phase II clinical trials to treat upper facial lines, moderate or severe dynamic
26
27
28

1 forehead lines, and moderate or severe lateral canthal lines; and has completed Phase II clinical trials for
2 the treatment of adult upper limb spasticity and plantar fasciitis.

3 3. In November 2019, Revance issued a press release announcing that it had submitted a
4 Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) for DAXI
5 to treat glabellar (frown) lines (the “DAXI BLA”).
6

7 4. Throughout the Class Period, Defendants made materially false and misleading statements
8 regarding the Company’s business, operations, and compliance policies. Specifically, Defendants made
9 false and/or misleading statements and/or failed to disclose that: (i) quality control deficiencies existed
10 at the Company’s manufacturing facility for DAXI; (ii) the foregoing deficiencies decreased the
11 likelihood that the FDA would approve the DAXI BLA in its current form; (iii) accordingly, it was
12 unlikely that the DAXI BLA would obtain FDA approval within the timeframe the Company had
13 represented to investors; and (iv) as a result, the Company’s public statements were materially false and
14 misleading at all relevant times.
15

16 5. On October 12, 2021, Revance disclosed that on July 2, 2021, the FDA had issued a Form
17 483 notifying Revance of serious issues that the FDA had observed during its inspection of the
18 Company’s Northern California DAXI manufacturing facility. Among other deficiencies, the FDA
19 observed that “[t]he current manufacturing process is not the process proposed for licensure” and
20 Revance’s “Quality Unit lacks the responsibility and authority for control, review, and approval for
21 outsourced activities[.]” Significantly, the Form 483 only came to light as a result of a Freedom of
22 Information Act request directed to the FDA.
23
24

25 6. On this news, Revance’s stock price fell \$6.85 per share, or 25%, to close at \$20.45 per
26 share on October 12, 2021.
27
28

1 7. Then, on October 15, 2021, Revance issued a press release announcing that it had received
2 a Complete Response Letter (“CRL”) from the FDA, indicating that “the FDA has determined it is unable
3 to approve the BLA in its present form, and indicated that there are deficiencies related to the FDA’s
4 onsite inspection at Revance’s manufacturing facility.”
5

6 8. On this news, Revance’s stock price fell \$8.90 per share, or 39.19%, to close at \$13.81 per
7 share on October 18, 2021.

8 9. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the
9 market value of the Company’s securities, Plaintiff and other Class members have suffered significant
10 losses and damages.
11

12 JURISDICTION AND VENUE

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

16 11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §
17 1331 and Section 27 of the Exchange Act.
18

19 12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15
20 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Defendants conduct business in this Judicial District and a
21 significant portion of Defendants’ actions took place within this Judicial District.
22

23 13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly,
24 used the means and instrumentalities of interstate commerce, including, but not limited to, the mails,
25 interstate telephone communications, and the facilities of the national securities markets.
26
27
28

PARTIES

1
2 14. Plaintiff, as set forth in the attached Certification, acquired Revance securities at
3 artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged
4 corrective disclosures.

5
6 15. Defendant Revance is a Delaware corporation with principal executive offices located at
7 1222 Demonbreun Street, Suite 2000, Nashville, Tennessee, 37203. Prior to January 1, 2021, Revance’s
8 principal executive offices were located at 7555 Gateway Boulevard, Newark, California 94560.
9 Revance’s common stock trades in an efficient market on the NASDAQ Global Market (“NASDAQ”)
10 under the ticker symbol “RVNC.”

11
12 16. Defendant Mark J. Foley (“Foley”) served as the Company’s Chief Executive Officer
13 (“CEO”), and Director at all relevant times.

14 17. Defendant Tobin C. Schilke (“Schilke”) served as the Company’s Chief Financial Officer
15 (“CFO”) and Principal Accounting Officer at all relevant times.

16 18. Defendant Defendants Foley and Schilke are sometimes referred to herein as the
17 “Individual Defendants.”

18
19 19. The Individual Defendants possessed the power and authority to control the contents of
20 Revance’s SEC filings, press releases, and other market communications. The Individual Defendants
21 were provided with copies of Revance’s SEC filings and press releases alleged herein to be misleading
22 prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to
23 cause them to be corrected. Because of their positions with Revance, and their access to material
24 information available to them but not to the public, the Individual Defendants knew that the adverse facts
25 specified herein had not been disclosed to and were being concealed from the public, and that the positive
26
27
28

1 representations being made were then materially false and misleading. The Individual Defendants are
2 liable for the false statements and omissions pleaded herein.

3 20. Revance and the Individual Defendants are collectively referred to herein as “Defendants.”
4

5 **SUBSTANTIVE ALLEGATIONS**

6 **Background**

7 21. Revance, a biotechnology company, engages in the development, manufacture, and
8 commercialization of neuromodulators for various aesthetic and therapeutic indications in the United
9 States and internationally. The Company’s lead drug candidate is DAXI, which has completed phase III
10 clinical trials for the treatment of glabellar (frown) lines and cervical dystonia; is in phase II clinical trials
11 to treat upper facial lines, moderate or severe dynamic forehead lines, and moderate or severe lateral
12 canthal lines; and has completed Phase II clinical trials for the treatment of adult upper limb spasticity
13 and plantar fasciitis.
14

15 **Materially False and Misleading Statements Issued During the Class Period**

16 22. The Class Period begins on November 25, 2019, when Revance issued a press release
17 entitled, “Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar
18 (Frown) Lines.” The press release stated, in relevant part:
19

20 “The submission of our BLA represents a significant milestone in the Company’s history
21 and initiates our transition from a development company to a commercial organization. I’m
22 incredibly excited about the opportunity to introduce the first truly novel advancement in
23 neuromodulator products in over 30 years. We believe that a long-acting neuromodulator
24 product will fill a significant, unmet need in both aesthetics and therapeutics and that the
25 market is hungry for innovation,” said Mark Foley, President and Chief Executive Officer
26 of Revance. “As we manufacture our own product in the United States, the BLA filing
27 represents a monumental achievement for a company of our size, which was only made
28 possible through the incredible dedication and commitment of our employees. I would like
to sincerely thank all of those involved for their tireless efforts.” Foley further commented,
“Based on the SAKURA trial results, DAXI has the potential to provide patients with
lasting, natural-looking frown line correction all year long with just two treatments.
Following this submission, 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 in the aesthetic marketplace.”

1 * * *

2 Under the current Prescription Drug User Fee Agreement (PDUFA VI), the FDA has
3 agreed to file acceptable applications within 60 days of receipt and to review the majority
4 of BLAs within 10 months following the Day 60 filing date. Based on that timeline,
5 Revance anticipates potential product approval in the second half of 2020.

6 23. On January 9, 2020, Revance issued a press release providing a corporate update and
7 anticipated milestones for 2020. The press release stated, in relevant part:

8 **Corporate Updates**

- 9 • **Acceptance of BLA Submission for DaxibotulinumtoxinA for Injection**
10 **(DAXI) in Glabellar Lines Expected Q1 2020** – In November 2019, Revance
11 submitted its Biologics License Application (BLA) to the U.S. Food and Drug
12 Administration (FDA) for DAXI in the treatment of moderate-to-severe frown
13 lines. In the Phase 3 pivotal program, the median time to loss of none or mild
14 wrinkle severity was 24 weeks and the median time to return to baseline wrinkle
15 severity was approximately 28 weeks. Revance anticipates acceptance of the
16 submission in the first quarter and projects potential approval in the fourth quarter
17 of 2020. Subject to approval, the company plans to initiate commercialization
18 activities before year end.

19 * * *

20 “This is a very exciting and pivotal year for Revance, with not only a number of significant
21 clinical data read-outs, but also the expected U.S. approval and launch of our next-
22 generation neuromodulator product, DAXI,” said Mark Foley, President and Chief
23 Executive Officer of Revance. “Our near-term focus is on completing the BLA approval
24 process and finalizing our launch strategies to garner a meaningful share in the \$1.4 billion*
25 U.S. neuromodulator market. DAXI will create a new, long-lasting neuromodulator
26 product category, delivering a premium experience that could require as few as two
27 treatments per year and potentially provide patients with lasting, natural-looking frown line
28 correction all year long. Although DAXI will be commercialized first in an aesthetics
indication, we plan to unlock the long-term value of DAXI in an array of therapeutic
indications, with clinical trials currently underway in cervical dystonia, upper limb
spasticity and plantar fasciitis.”

29 **Near-Term Milestone Expectations**

30 **Aesthetics:**

- 31 • Acceptance by the FDA of BLA submission for DAXI in glabellar lines expected
32 in 1Q 2020. Potential approval anticipated in 4Q 2020.

1 24. On February 6, 2020, Revance issued a press release entitled, “Revance Announces U.S.
2 FDA Acceptance of Biologics License Application (BLA) for DAXI to Treat Glabellar (Frown) Lines.”

3 The press release stated, in relevant part:

4 Revance [. . .] today announced that the [DAXI BLA] has been accepted for review by the
5 [FDA]. In its correspondence, FDA stated that no potential filing review issues were
6 identified. The FDA set an action date of November 25, 2020 under the Prescription Drug
7 User Fee Act (PDUFA) VI program. The Agency also indicated in the BLA filing
8 communication letter that it is not currently planning to hold an advisory committee
9 meeting to discuss the application.

10 “The FDA’s acceptance of our BLA for our next-generation neuromodulator product,
11 DAXI, is a significant achievement for Revance and a crucial step forward as we look to
12 establish a new, premium, long-lasting neuromodulator category,” said Mark Foley,
13 President and Chief Executive Officer of Revance. “The patient experience has remained
14 largely unchanged since botulinum toxin type A treatments were first introduced over 30
15 years ago. If approved, we expect that patients treated with DAXI may achieve lasting,
16 natural-looking frown line correction all year long with as few as two treatments.”

17 25. On February 24, 2020, Revance issued a press release announcing the Company’s Q4 and
18 full year 2019 financial results and providing a corporate update. The press release stated, in relevant
19 part:

20 **Key Fourth Quarter 2019 Events and Subsequent Updates**

21 Commercial:

- 22 • **BLA for DAXI in Glabellar Lines Accepted by FDA, PDUFA Date
23 Announced.** In February, the company received U.S. Food and Drug
24 Administration (FDA) notification that its Biologics License Application (BLA)
25 for DAXI in the treatment of moderate to severe glabellar (frown) lines was
26 accepted for review. Revance has been given a target action date under the
27 Prescription Drug User Fee Act (PDUFA) of November 25, 2020.

28 ***

 “With the FDA’s recent acceptance of our BLA submission for DAXI in glabellar lines,
and the announcement of our distribution agreement for TEOXANE’s RHA® technology,
Revance has constructed an exceptional start to what we believe will be a transformational
year for the company. These milestones represent the first two of twelve potential value
inflection points for our company in 2020,” said Mark J. Foley, President and Chief
Executive Officer of Revance.

1 26. That same day, Revance hosted an earnings call with investors and analysts to discuss the
2 Company's Q4 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019
3 Earnings Call, Defendant Foley stated, in relevant part:

4
5 In 2019, Revance made significant progress in the initiation and enrollment of several
6 important clinical trials while also submitting a biologics license application to the U.S.
7 Food and Drug Administration for our neuromodulator, DaxibotulinumtoxinA for injection
8 or DAXI for short for the treatment of glabellar lines. This progress has set us up for a
9 transformational 2020, a year which we believe will be characterized by excitement and
10 execution. 2020 contains no less than 12 transformative clinical, regulatory and
11 commercial events that could generate significant value for our company and position
12 Revance to be an innovation leader in both aesthetics and therapeutics.

13 ***

14 Following on the heels of our TEOXANE deal, we were notified that our BLA for DAXI
15 for glabellar lines was accepted for review by the FDA. In its correspondence, the FDA
16 stated that no potential filing review issues were identified and that there are currently no
17 plans to hold an advisory committee meeting. The FDA also set the PDUFA target action
18 date of November 25, 2020. We remain focused on ensuring a successful FDA review
19 process and have confidence in the quality of our submission and the experience of our
20 team.

21 27. On February 26, 2020, Revance filed an Annual Report on Form 10-K with the SEC,
22 reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019
23 10-K"). The 2019 10-K stated, in relevant part:

24 Revance Therapeutics is a biotechnology company, developing new innovations in
25 neuromodulators for aesthetic and therapeutic indications. Our lead product candidate,
26 DaxibotulinumtoxinA for Injection (DAXI), combines a proprietary stabilizing peptide
27 excipient with a highly purified botulinum toxin that does not contain human or animal-
28 based components. We have successfully completed a Phase 3 program for DAXI in
glabellar (frown) lines. In November 2019, we submitted the Biologics License
Application ("BLA") to the U.S. Food and Drug Administration (the "FDA") for DAXI in
the treatment of moderate to severe glabellar (frown) lines. The FDA accepted the BLA on
February 5, 2020, and the Prescription Drug User Fee Act ("PDUFA") target action date
is November 25, 2020. If the BLA is approved on or by the target action date, we plan to
initiate commercialization activities for DAXI for the treatment of glabellar lines before
year end 2020. We are also evaluating DAXI in upper facial lines - glabellar lines, forehead
lines and crow's feet combined - as well as in three therapeutic indications - cervical
dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine.

1 ***

2 **Manufacturing and Operations**

3 We have established capabilities for the production of botulinum toxin type A,
4 including bulk drug substance and injectable finished drug product. Botulinum toxin is
5 regulated as a Tier 1 Select Agent under authority of the Centers for Disease Control and
6 Prevention (“CDC”), and as such requires that we obtain a select agent registration and
7 perform our operations in compliance with CDC regulations. We are in good standing
8 under our select agent registration with the CDC. We have assembled a team of
9 experienced individuals in the technical disciplines of chemistry, biology, biosafety, and
10 engineering and have appropriately equipped laboratory space to support ongoing research
11 and development efforts in our botulinum toxin product development platform. We have
12 the ability to manufacture our own botulinum toxin bulk drug substance to support our
13 clinical trial programs and eventually, our commercial production. We believe that having
14 direct control over our manufacturing processes will enable us to develop additional
15 pharmaceutical product configurations effectively and with a competitive cost structure.

16 ***

17 ***Drug Product Manufacturing***

18 Manufacture of dose forms to support the DAXI programs is currently performed
19 at our fill-finish facility. The manufacturing process consists of bulk compounding, liquid
20 fill and freeze-drying to support acceptable shelf-life duration. We plan to perform further
21 scale-up of DAXI drug product manufacturing to meet anticipated commercial demand
22 and may utilize internal capacity, a third-party manufacturer such as Althea or a
23 combination of both.

24 28. Appended to the 2019 10-K as exhibits were signed certifications pursuant to the
25 Sarbanes-Oxley Act of 2002 (“SOX”) by the Individual Defendants, attesting that, “[t]he information
26 contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results
27 of operations of the Company.”

28 29. On May 7, 2020, Revance hosted an earnings call with investors and analysts to discuss
the Company’s Q1 2020 results (the “Q1 2020 Earnings Call”). During the scripted portion of the Q1
2020 Earnings Call, Defendant Foley stated, in relevant part:

As we adapt to the new world shaped by the COVID-19 pandemic, Revance does so from
a position of financial, operational and product portfolio strength. We are very well funded
with more than \$0.5 billion in cash and investments as of March 31. We have an FDA-

1 approved RHA dermal filler portfolio, we are readying for launch in the U.S. in the third
2 quarter. Our PDUFA date for DaxibotulinumtoxinA for Injection remains on schedule for
3 November 25, and our key clinical development plans remain on track to deliver top line
4 results for multiple Phase II studies and a Phase III pivotal trial this year.

5 ***

6 Now let me cover DaxibotulinumtoxinA for Injection. To date, we have not received any
7 indication from the FDA that our PDUFA date will change and our commercial launch is
8 still planned for year-end. Revance is a vertically integrated manufacturer with
9 DaxibotulinumtoxinA for Injection produced at our headquarters in California. As a result,
10 we've been fortunate to avoid any supply chain or production issues related to the COVID-
11 19 situation, and we continue to work with the FDA toward our November 25 PDUFA
12 date. Once we combine DaxibotulinumtoxinA for Injection with our range of RHA dermal
13 fillers, we'll have a synergistic portfolio of products to establish a whole new prestige
14 segment in the facial injectables market and that will provide both physicians and
15 consumers with a truly differentiated alternative.

16 30. On August 6, 2020, Revance hosted an earnings call with investors and analysts to discuss
17 the Company's Q2 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2
18 2020 Earnings Call, Defendant Foley stated, in relevant part:

19 Now, let me make a brief statement on our lead asset DaxibotulinumtoxinA for Injection
20 given the COVID-19 environment. Our PDUFA date for DaxibotulinumtoxinA for
21 Injection in glabellar lines remains November 25th and as such we are busy preparing for
22 a potential commercial launch of our next-generation neuromodulator before year end.

23 ***

24 This is a pivotal and exciting time at Revance. Having created what we believe to be a
25 compelling portfolio of leading assets in aesthetics, we stand on the cusp of
26 commercialization not just of our RHA Collection of dermal fillers and HintMD fintech
27 platform, but also subject to approval of the world's first true next-generation long-acting
28 neuromodulator DaxibotulinumtoxinA for Injection.

31. On November 9, 2020, Revance issued a press release announcing the Company's Q3
2020 financial results and providing a corporate update. The press release stated, in relevant part:

Third Quarter 2020 and Subsequent Updates

Revance Aesthetics

- **Due to COVID-Related Travel Restrictions, Required Inspection of the Revance Manufacturing Site by the U.S. Food and Drug Administration (FDA) has Not Been Scheduled.** Today, Revance disclosed that, with 16 days left before its Prescription Drug User Fee Act (PDUFA) action date of November 25, 2020, the FDA has not scheduled a manufacturing site inspection related to the company’s Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection in the treatment of moderate to severe glabellar (frown) lines. The FDA has indicated that an inspection of the Newark, Calif. manufacturing site will be required prior to approval. Revance continues to work proactively with the FDA to secure an inspection at the earliest possible time.

“Finally, today, we shared that the FDA has not yet scheduled a site inspection at our Newark, CA manufacturing facility as part of our BLA submission. We understand this is due to COVID-19-related travel restrictions at the Agency. While there is still time for an inspection to take place before our PDUFA date of November 25th, and though the company continues to work proactively with the Agency, we felt it was appropriate to provide an update. Importantly, should the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines be delayed, we believe that Revance is in a strong position, both commercially and financially, to weather any near-term change in timing. Just as importantly, we remain confident in the strength of our BLA submission for DaxibotulinumtoxinA for Injection in the treatment of glabellar lines.”

32. On January 7, 2021, Revance issued a press release providing a corporate update and anticipated milestones for 2021. The press release stated, in relevant part:

In 2021, we hope to receive our first FDA approval for our next-generation neuromodulator, DaxibotulinumtoxinA for Injection, for the treatment of glabellar lines, further refine our therapeutics strategy and continue to execute on our focused and disciplined launch in aesthetics.

Aesthetics Franchise Update:

- **Biologics License Application (BLA) Approval for DaxibotulinumtoxinA for Injection in the Treatment of Glabellar Lines Anticipated in 2021.** On November 25, 2020, the company announced that the United States (U.S.) Food and Drug Administration (FDA) has deferred a decision on the BLA for DaxibotulinumtoxinA for Injection due to the FDA’s inability to conduct a required inspection of the company’s Northern California manufacturing facility as a result of COVID-19 pandemic travel restrictions. The inspection of the company’s manufacturing facility is required by the FDA as part of the BLA approval process. Though the company’s BLA is still under review, the FDA did not indicate any

1 further outstanding review issues beyond the pending on-site inspection. The
2 company remains confident in its BLA submission and continues to work
proactively with the FDA on a pre-approval inspection as soon as possible in 2021.

3 33. On February 25, 2021, Revance filed an Annual Report on Form 10-K with the SEC,
4 reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020
5 10-K"). The 2020 10-K stated, in relevant part:
6

7 Revance is a biotechnology company focused on innovative aesthetic and
8 therapeutic offerings, including its next-generation neuromodulator product,
9 DaxibotulinumtoxinA for Injection. DaxibotulinumtoxinA for Injection combines a
10 proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does
11 not contain human or animal-based components. We have successfully completed a Phase
3 program for DaxibotulinumtoxinA for Injection in glabellar (frown) lines and are
pursuing U.S. regulatory approval.

12 ***

13 **Manufacturing and Operations**

14 We have established capabilities for the production of botulinum toxin type A,
15 including bulk drug substance and injectable finished drug product. Botulinum toxin is
16 regulated as a Tier 1 Select Agent under authority of the Centers for Disease Control and
17 Prevention ("CDC"), and as such requires that we obtain a select agent registration and
18 perform our operations in compliance with CDC regulations. We are in good standing
19 under our select agent registration with the CDC. We have assembled a team of
20 experienced individuals in the technical disciplines of chemistry, biology, biosafety, and
21 engineering and have appropriately equipped laboratory space to support ongoing research
22 and development efforts in our botulinum toxin product development platform. We have
the ability to manufacture our own botulinum toxin bulk drug substance to support our
clinical trial programs and eventually, our commercial production. We also plan to use
third-party manufacturers to further scale-up DaxibotulinumtoxinA for Injection drug
product manufacturing to meet anticipated commercial demand in the event of BLA
approval.

23 ***

24 ***Drug Product Manufacturing***

25 Manufacture of dose forms to support the DaxibotulinumtoxinA for Injection
26 programs is currently performed at our fill-finish facility. The manufacturing process
27 consists of bulk compounding, liquid fill and freeze-drying to support acceptable shelf-life
28 duration. We plan to perform further scale-up of DaxibotulinumtoxinA for Injection drug
product manufacturing to meet anticipated commercial demand and may utilize current and

1 additional internal capacity, a third-party manufacturer such as ABPS or a combination of
2 both.

3 34. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by the
4 Individual Defendants, attesting that “[t]he information contained in the [2020 10-K] fairly presents, in
5 all material respects, the financial condition and results of operations of the Company.”

6 35. On May 10, 2021, Revance issued a press release announcing the Company’s Q1 2021
7 financial results and providing a corporate update. The press release stated, in relevant part:
8

9 “We are very pleased with our commercial execution in the first quarter, particularly given
10 the impact of COVID-19 and seasonality, where the first quarter is traditionally a slower
11 time of the year for the aesthetics market. We are also encouraged by the progress we are
12 making in our therapeutics franchise as we begin laying the groundwork for our first
13 anticipated approval in the treatment of muscle movement disorders,” said Mark Foley,
14 President and Chief Executive Officer. “Our FDA approval for DaxibotulinumtoxinA for
15 Injection for glabellar lines remains under review with a deferred action due to COVID-
16 related travel restrictions. We stand ready for the pre-approval inspection of our
17 manufacturing facility and are actively engaging with the FDA to schedule an inspection
18 date as soon as possible. We continue to anticipate an approval this year and, as we have
19 noted before, the FDA did not indicate that there were any other review issues beyond the
20 pending inspection.”

21 36. On August 5, 2021, the Company issued a press release announcing the Company’s Q2
22 2021 results and providing a corporate update. The press release stated, in relevant part:
23

24 The FDA initiated their pre-approval inspection of our manufacturing facility in June, and
25 we continue to anticipate approval of DaxibotulinumtoxinA for Injection for the treatment
26 of glabellar lines in 2021. We are actively preparing for the launch and once approved,
27 expect DaxibotulinumtoxinA for Injection to underpin our aesthetics franchise and set the
28 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.

26 **Second Quarter Highlights and Subsequent Updates**

27 **Aesthetics Franchise**

1 ***

- 2 • **Status of the Biologics License Application (BLA) for DaxibotulinumtoxinA**
3 **for Injection in the treatment of glabellar lines.** Consistent with the company’s
4 previous disclosure on the status of the pre-approval inspection, the FDA initiated
5 the inspection of the company’s manufacturing facility in June 2021. Revance
6 continues to anticipate receiving approval for DaxibotulinumtoxinA for Injection
7 in 2021 and is actively building inventory and preparing for commercial launch.

8 37. That same day, Revance hosted an earnings call with investors and analysts to discuss the
9 Company’s Q2 2021 results (the “Q2 2021 Earnings Call”). During the scripted portion of the Q2 2021
10 Earnings Call, Defendant Foley stated, in relevant part:

11 With the FDA having initiated their pre-approval inspection of our manufacturing facility
12 in June, we continue to anticipate the approval of our lead product, DaxibotulinumtoxinA
13 for injection for the treatment of glabellar lines this year.

14 In the meantime, the Revance team is actively building inventory and solidifying our
15 commercial launch plans for innovative neuromodulators. We look forward to introducing
16 the first true innovation in the neuromodulator category in over 30 years. And once
17 approved, DaxibotulinumtoxinA for injection will not only anchor our aesthetics portfolio
18 and also lay the foundation for our therapeutics franchise.

19 ***

20 In closing, we’re very proud of our performance in the first half of the year and anticipate
21 a strong finish in the second half with the potential approval of DaxibotulinumtoxinA for
22 injection and further advancement in our therapeutics pipeline. We also remain in a solid
23 financial position with division cash to support our growth initiatives into 2024.

24 38. When asked a question regarding the status of the FDA inspection of the DAXI
25 manufacturing site, Defendant Foley stated, in relevant part:

26 Given that this is our first drug approval, remote inspection without possibility and they’re
27 going to need to physically inspect the plant. We then in the spring, put out a press release
28 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.

1 39. The statements referenced in ¶¶ 22-38 were materially false and misleading because
2 Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts
3 about the Company’s business, operations, and compliance policies. Specifically, Defendants made false
4 and/or misleading statements and/or failed to disclose that: (i) quality control deficiencies existed at the
5 Company’s manufacturing facility for DAXI; (ii) the foregoing deficiencies decreased the likelihood that
6 the FDA would approve the DAXI BLA in its current form; (iii) accordingly, it was unlikely that the
7 DAXI BLA would obtain FDA approval within the timeframe the Company had represented to investors;
8 and (iv) as a result, the Company’s public statements were materially false and misleading at all relevant
9 times.
10

11
12 **The Truth Begins to Emerge**

13 40. On October 12, 2021, Revance issued a press release entitled, “Revance Continues to
14 Anticipate FDA Approval of DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines in
15 2021.” The press release stated, in relevant part:

16 [Revance] responds to the public disclosure of its Form 483 pursuant to a Freedom of
17 Information Act (FOIA) request that was directed to the FDA. The Biologics License
18 Application (BLA) for DaxibotulinumtoxinA for Injection remains under FDA review and
19 the company continues to anticipate FDA approval of DaxibotulinumtoxinA for Injection
for the treatment of glabellar lines in 2021.

20 Revance notes that the issuance of a Form 483 following the conclusion of an on-site
21 inspection is not uncommon. A Form 483 lists observations made by FDA representatives
22 during the inspection of a facility. A Form 483 does not constitute a final agency
determination.

23 Revance provided its response to the Form 483 in July 2021 following a pre-approval
24 inspection and is currently awaiting the FDA’s decision on its BLA for
25 DaxibotulinumtoxinA for Injection for the treatment of glabellar lines. The company
26 remains confident in the quality of its BLA submission and continues to anticipate FDA
approval in 2021.

27 Among other things, the Form 483 indicated that “[t]he current manufacturing process is not the process
28 proposed for licensure,” and “[t]he firm’s Quality Unit lacks the responsibility and authority for the

1 control, review, and approval of outsourced activities which includes defining the responsibilities and
2 communication processes for quality-related activities in a written agreement.”

3 41. On this news, Revance’s stock price fell \$6.85 per share, or 25%, to close at \$20.45 per
4 share on October 12, 2021.

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

8
9 [Revance] today announced that the United States (U.S.) Food and Drug Administration
10 (FDA) has issued a Complete Response Letter, or CRL, regarding the Biologics License
11 Application (BLA) for DaxibotulinumtoxinA for Injection, for the treatment of moderate
12 to severe glabellar (frown) lines.

13 In a communication received on October 15, the FDA has determined it is unable to
14 approve the BLA in its present form, and indicated that there are deficiencies related to the
15 FDA’s onsite inspection at Revance’s manufacturing facility. Revance plans to request a
16 Type A meeting with the FDA as soon as possible to address the deficiencies raised. No
17 other deficiencies were identified in the CRL.

18 “We are very disappointed by this unanticipated response from the FDA and are seeking
19 further clarity from the agency. We remain committed to bringing our next-generation
20 neuromodulator product to market in both aesthetic and therapeutic indications,” said Mark
21 Foley, President and Chief Executive Officer.

22 43. On this news, Revance’s stock price fell \$8.90 per share, or 39.19%, to close at \$13.81 per
23 share on October 18, 2021.

24 44. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the
25 market value of the Company’s securities, Plaintiff and other Class members have suffered significant
26 losses and damages.

27 **PLAINTIFF’S CLASS ACTION ALLEGATIONS**

28 45. Plaintiff brings 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

1 securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged
2 corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the
3 Company, at all relevant times, members of their immediate families and their legal representatives, heirs,
4 successors or assigns and any entity in which Defendants have or had a controlling interest.

5
6 46. The members of the Class are so numerous that joinder of all members is impracticable.
7 Throughout the Class Period, Revance securities were actively traded on the NASDAQ. While the exact
8 number of Class members is unknown to Plaintiff at this time and can be ascertained only through
9 appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed
10 Class. Record owners and other members of the Class may be identified from records maintained by
11 Revance or its transfer agent and may be notified of the pendency of this action by mail, using the form
12 of notice similar to that customarily used in securities class actions.
13

14 47. Plaintiff’s claims are typical of the claims of the members of the Class as all members of
15 the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is
16 complained of herein.
17

18 48. Plaintiff will fairly and adequately protect the interests of the members of the Class and
19 has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests
20 antagonistic to or in conflict with those of the Class.

21 49. Common questions of law and fact exist as to all members of the Class and predominate
22 over any questions solely affecting individual members of the Class. Among the questions of law and
23 fact common to the Class are:
24

- 25 • whether the federal securities laws were violated by Defendants’ acts as alleged
26 herein;
- 27 • whether statements made by Defendants to the investing public during the Class
28 Period misrepresented material facts about the business, operations and
management of Revance;

- whether the Individual Defendants caused Revance to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Revance securities during the Class Period were artificially inflated because of the 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.

50. 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.

51. Plaintiff 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 misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Revance securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

1 52. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a
2 presumption of reliance upon the integrity of the market.

3 53. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of
4 reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*,
5 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period
6 statements in violation of a duty to disclose such information, as detailed above.
7

8 **COUNT I**

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

11 54. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set
12 forth herein.

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

16 56. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of
17 conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and
18 courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the
19 Class; made various untrue statements of material facts and omitted to state material facts necessary in
20 order to make the statements made, in light of the circumstances under which they were made, not
21 misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and
22 sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the
23 investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate
24 and maintain the market price of Revance securities; and (iii) cause Plaintiff and other members of the
25 Class to purchase or otherwise acquire Revance securities and options at artificially inflated prices. In
26
27
28

1 furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the
2 actions set forth herein.

3 57. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the
4 Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and
5 annual reports, SEC filings, press releases and other statements and documents described above,
6 including statements made to securities analysts and the media that were designed to influence the market
7 for Revance securities. Such reports, filings, releases and statements were materially false and misleading
8 in that they failed to disclose material adverse information and misrepresented the truth about Revance's
9 finances and business prospects.
10

11 58. By virtue of their positions at Revance, Defendants had actual knowledge of the materially
12 false and misleading statements and material omissions alleged herein and intended thereby to deceive
13 Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless
14 disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal
15 the materially false and misleading nature of the statements made, although such facts were readily
16 available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless
17 disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts
18 were being misrepresented or omitted as described above.
19
20

21 59. Information showing that Defendants acted knowingly or with reckless disregard for the
22 truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors
23 of Revance, the Individual Defendants had knowledge of the details of Revance's internal affairs.
24

25 60. The Individual Defendants are liable both directly and indirectly for the wrongs
26 complained of herein. Because of their positions of control and authority, the Individual Defendants were
27 able to and did, directly or indirectly, control the content of the statements of Revance. As officers and/or
28

1 directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely,
2 accurate, and truthful information with respect to Revance's businesses, operations, future financial
3 condition and future prospects. As a result of the dissemination of the aforementioned false and
4 misleading reports, releases and public statements, the market price of Revance securities was artificially
5 inflated throughout the Class Period. In ignorance of the adverse facts concerning Revance's business
6 and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class
7 purchased or otherwise acquired Revance securities at artificially inflated prices and relied upon the price
8 of the securities, the integrity of the market for the securities and/or upon statements disseminated by
9 Defendants, and were damaged thereby.

11
12 61. During the Class Period, Revance securities were traded on an active and efficient market.
13 Plaintiff and the other members of the Class, relying on the materially false and misleading statements
14 described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the
15 integrity of the market, purchased or otherwise acquired shares of Revance securities at prices artificially
16 inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the
17 truth, they would not have purchased or otherwise acquired said securities, or would not have purchased
18 or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or
19 acquisitions by Plaintiff and the Class, the true value of Revance securities was substantially lower than
20 the prices paid by Plaintiff and the other members of the Class. The market price of Revance securities
21 declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class
22 members.

23
24
25 62. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or
26 indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
27
28

1 Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially
2 inflated the market price of Revance securities.

3 68. Each of the Individual Defendants, therefore, acted as a controlling person of Revance.
4 By reason of their senior management positions and/or being directors of Revance, each of the Individual
5 Defendants had the power to direct the actions of, and exercised the same to cause, Revance to engage in
6 the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control
7 over the general operations of Revance and possessed the power to control the specific activities which
8 comprise the primary violations about which Plaintiff and the other members of the Class complain.
9

10 69. By reason of the above conduct, the Individual Defendants are liable pursuant to Section
11 20(a) of the Exchange Act for the violations committed by Revance.
12

13 **PRAYER FOR RELIEF**

14 **WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

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

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

19 C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment
20 interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
21

22 D. Awarding such other and further relief as this Court may deem just and proper.
23

24 **DEMAND FOR TRIAL BY JURY**

25 Plaintiff hereby demands a trial by jury.
26
27
28