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SAN MATEO COUNTY

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN MATEO



Behalf of All Others Similarly Situated,

Plaintiff,

vs.

REVANCE THERAPEUTICS, INC.,
L DANIEL BROWNE,
LAUREN P. SILVERNAIL,
JACOB WAUGH,
ROBERT BYRNES,⁷
RONALD W. EASTMAN,⁸
PHYLLIS GARDNER,⁹
JAMES GLASHEEN,⁹
JONATHAN TUNNICLIFFE,¹⁰
RONALD WOOTEN,¹¹
COWEN AND COMPANY, LLC,¹²
PIPER JAFFRAY & CO.,¹³
BMO CAPITAL MARKETS CORP.,¹⁴
WILLIAM BLAIR & COMPANY, L.L.C.¹⁵
and DOES 1-25, inclusive,

Defendants.

VIA FAX

CIV533635

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

File By Fax

1 Plaintiff [REDACTED] (“plaintiff”), individually and on
 2 behalf of all others similarly situated, by plaintiff’s undersigned attorneys, for plaintiff’s complaint
 3 against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff’s
 4 own acts, and upon information and belief as to all other matters based on the investigation conducted
 5 by and through plaintiff’s attorneys, which included, among other things, a review of Revance
 6 Therapeutics, Inc.’s (“Revance” or the “Company”) press releases, Securities and Exchange
 7 Commission (“SEC”) filings, analyst reports, media reports and other publicly disclosed reports and
 8 information about defendants. Plaintiff believes that substantial evidentiary support will exist for the
 9 allegations set forth herein after a reasonable opportunity for discovery.

10 NATURE OF THE ACTION

11 1. This is a securities class action on behalf of all those who purchased Revance common
 12 stock in Revance’s June 19, 2014 follow-on public stock offering (the “Offering”), seeking to pursue
 13 remedies under the Securities Act of 1933 (the “1933 Act”)

14 JURISDICTION AND VENUE

15 2. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the 1933 Act, 15 U.S.C.
 16 §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the 1933 Act and venue is proper pursuant
 17 to §22 of the 1933 Act. Section 22 of the 1933 Act explicitly states that “[e]xcept as provided in section
 18 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be
 19 removed to any court in the United States.” Section 16(c) refers to “covered class actions,” which are
 20 defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting
 21 claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall
 22 within the definition of a “covered class action” under §16(b)-(c) and ***is therefore is not removable to***
 23 ***federal court***, under the Securities Litigation Uniform Standards Act of 1998 or otherwise. *See Luther*
 24 *v Countrywide Fin. Corp*, 195 Cal App. 4th 789, 792 (2011) (“The federal Securities Act of 1933 . . . ,
 25 as amended by the Securities Litigation Uniform Standards Act . . . , provides for ***concurrent***
 26 ***jurisdiction*** for cases asserting claims under the 1933 Act . . .”), *Luther v Countrywide Home Loans*
 27 *Servicing LP*, 533 F.3d 1031, 1032 (9th Cir 2008) (“Section 22(a) of the Securities Act of 1933 creates
 28 concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically

1 33,914 common shares underlying vested options exercisable within one month from the close of the
2 Offering at \$8.70 per share. Silvernail's residence is in Newport Coast, California.

3 8. Defendant Jacob Waugh ("Waugh") is, and was at the time of the Offering, a co-founder
4 of Revance and its Chief Scientific Officer. Immediately prior to the Offering, Waugh owned over
5 142,000 Revance shares, which included 53,333 common shares and 64,135 common shares underlying
6 vested options exercisable within one month from the close of the Offering at exercise prices of
7 between \$2.55 and \$9.15 per share. Waugh participated in the preparation of the Registration
8 Statement, including reviewing and approving statements contained in the Registration Statement
9 concerning RT001. Waugh's residence is in San Mateo County.

10 9 Defendant Ronald W. Eastman ("Eastman") is, and was at the time of the Offering, a
11 director of the Company. Immediately prior to the Offering, Eastman beneficially owned over 4.1
12 million Revance shares, or approximately 22% of the outstanding shares, consisting largely of over 3.7
13 million common shares held by Essex Woodlands Health Ventures Fund VIII, L.P. (including over
14 369,000 common shares underlying warrants exercisable at \$0.15 per share), over 270,000 common
15 shares held by Essex Woodlands Health Ventures Fund VIII-A, L.P. (including over 26,000 common
16 shares that were previously underlying warrants exercisable at \$0.15 per share), and over 117,000
17 common shares held by Essex Woodlands Health Ventures Fund VIII-B, L.P. (including over 11,000
18 common shares underlying warrants exercisable at \$0.15 per share). Eastman is a managing director of
19 Essex Woodlands Health Ventures VIII, LLC, a venture capital firm and general partner of the
20 aforementioned limited partnerships, and has (and had at the time of the Offering) shared voting power
21 and shared power to dispose of the shares held by the aforementioned limited partnerships. Eastman's
22 residence is in Carmel, California.

23 10. Defendant Phyllis Gardner ("Gardner") is, and was at the time of the Offering, a director
24 of the Company. Immediately prior to the Offering, Gardner beneficially owned over 462,000 Revance
25 shares, or approximately 2.4% of the outstanding shares, consisting largely of over 457,000 shares held
26 by Essex Woodlands Health Ventures Fund V, L.P. (including over 41,000 common shares that were
27 previously underlying warrants exercisable at \$0.15 per share) and over 5,300 common shares
28 underlying vested options exercisable within one month from the close of the Offering at exercise prices

1 of \$2.55 per share. Gardner is a partner at Essex Woodlands Health Ventures VIII, LLC, a venture
2 capital firm and general partner of the aforementioned limited partnership, and has (and had at the time
3 of the Offering) shared voting power and shared power to dispose of the shares held by that limited
4 partnership Gardner's residence is in Stanford, California, approximately seven and one-half miles
5 from San Mateo County Superior Court at 400 County Center.

6 11. Defendant Robert Byrnes ("Byrnes") is, and was at the time of the Offering, a director of
7 the Company. Immediately prior to the Offering, Byrnes owned over 24,000 Revance common shares
8 underlying vested options exercisable within one month from the close of the Offering at exercise prices
9 of between \$2.55 and \$9.15 per share. Byrnes's residence is in Canyon Lake, California.

10 12 Defendant James Glasheen ("Glasheen") is, and was at the time of the Offering, a
11 director of the Company. Immediately prior to the Offering, Glasheen beneficially owned over 726,000
12 Revance shares, or approximately 3.8% of the outstanding shares, consisting largely of over 709,000
13 shares held by Technology Partners Fund VII, L.P. (including over 50,000 common shares that were
14 previously underlying warrants exercisable at \$0.15 per share) and over 16,000 shares held by
15 Technology Partners Affiliates VII, L.P. Glasheen is a managing member of TP Management VII,
16 LLC, a venture capital firm and general partner of the aforementioned limited partnerships, and has
17 (and had at the time of the Offering) shared voting power and shared power to dispose of the shares
18 held by those limited partnerships. Glasheen's residence is in Corte Madera, California.

19 13. Defendant Jonathan Tunncliffe ("Tunncliffe") is, and was at the time of the Offering, a
20 director of the Company. Immediately prior to the Offering, Tunncliffe beneficially owned over 3.09
21 million Revance shares that were held by NovaQuest Pharma Opportunities Fund III, L.P., or
22 approximately 16.4% of the outstanding shares, consisting largely of over 2.4 million common shares
23 and over 658,000 common shares that were previously underlying warrants exercisable at \$0.15 per
24 share. Tunncliffe is also a director of the general partner to the general partner of the aforementioned
25 limited partnership, and has (and had at the time of the Offering) shared voting power and shared power
26 to dispose of the shares held by the limited partnership. Tunncliffe's residence is in Cary, North
27 Carolina.

28

1 14 Defendant Ronald Wooten (“Wooten”) is, and was at the time of the Offering, a director
2 of the Company. Immediately prior to the Offering, Wooten beneficially owned over 3.09 million
3 Revance shares that were held by NovaQuest Pharma Opportunities Fund III, L.P., or approximately
4 16.4% of the outstanding shares, consisting largely of over 2.4 million common shares and over
5 658,000 common shares that were previously underlying warrants exercisable at \$0.15 per share.
6 Wooten is also a director of the general partner to the general partner of the aforementioned limited
7 partnership, and has (and had at the time of the Offering) shared voting power and shared power to
8 dispose of the shares held by the limited partnership. Wooten’s residence is in Raleigh, North Carolina.

9 15. The defendants referenced above in ¶¶6-14 are referred to herein as the “Individual
10 Defendants.” The Individual Defendants each participated in the preparation of, and, with the exception
11 of Waugh, signed, the Registration Statement. Their participation in the solicitation of the Offering,
12 through preparation of the offering documents, was motivated by each of their financial interests in the
13 Company that were served by the Offering, and each of them financially benefited from the Offering in
14 numerous ways, including by substantially increasing the book value of Revance and the Individual
15 Defendants’ shares and by providing a further liquid market in which to sell their shares upon the
16 exercise of in-the-money options or otherwise. The defendants referenced above in ¶¶6-8 are
17 executives of Revance, participated in the roadshow to sell the Offering and are sometimes referred to
18 herein as the “Executive Defendants.” Defendant Revance and the Individual Defendants who signed
19 the Registration Statement are strictly liable for the materially false and misleading statements
20 incorporated into the Registration Statement.

21 16. Defendants Cowen and Company, LLC (“Cowen”), Piper Jaffray & Co. (“Piper”), BMO
22 Capital Markets Corp. (“BMO”) and William Blair & Company, L.L.C. are investment banking firms
23 that acted as underwriters of the Offering, helping to draft and disseminate the offering documents.
24 These defendants are referred to herein as the “Underwriter Defendants.” Pursuant to the 1933 Act, the
25 Underwriter Defendants are liable for the materially false and misleading statements in the Registration
26 Statement as follows:

27 (a) The Underwriter Defendants are investment banking houses which specialize,
28 *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the

1 Offering and shared more than \$7.3 million in fees collectively. The Underwriter Defendants
2 determined that in return for their share of the Offering proceeds, they were willing to merchandize
3 Revance stock in the Offering. The Underwriter Defendants arranged a multi-city roadshow prior to the
4 Offering during which they, and the Executive Defendants, met with potential investors and presented
5 highly favorable information about the Company, its operations, and its financial prospects.

6 (b) The Underwriter Defendants also demanded and obtained an agreement from
7 Revance that Revance would indemnify and hold the Underwriter Defendants harmless from any
8 liability under the federal securities laws. They also made certain that Revance had purchased millions
9 of dollars in directors' and officers' liability insurance.

10 (c) Representatives of the Underwriter Defendants also assisted Revance and the
11 Individual Defendants in planning the Offering, and purportedly conducted an adequate and reasonable
12 investigation into the business and operations of Revance, an undertaking known as a "due diligence"
13 investigation. The due diligence investigation was required of the Underwriter Defendants in order to
14 engage in the Offering. During the course of their "due diligence," the Underwriter Defendants had
15 continual access to confidential corporate information concerning Revance's operations and financial
16 prospects.

17 (d) In addition to availing themselves of virtually unbridled access to internal
18 corporate documents, agents of the Underwriter Defendants met with Revance's management, top
19 executives and outside counsel and engaged in "drafting sessions" throughout at least June 2014.
20 During these sessions, understandings were reached as to (i) the strategy to best accomplish the
21 Offering, (ii) the terms of the Offering, including the price at which Revance stock would be sold; (iii)
22 the language to be used in the Registration Statement; (iv) what disclosures about Revance would be
23 made in the Registration Statement; and (v) what responses would be made to the SEC in connection
24 with its review of the Registration Statement. As a result of those constant contacts and
25 communications between the Underwriter Defendants' representatives and management and top
26 executives, the Underwriter Defendants knew, or should have known, of Revance's existing problems
27 as detailed herein.

28

1 (e) The Underwriter Defendants caused the Registration Statement to be filed with
2 the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the
3 Class.

4 17. The true names and capacities of defendants sued herein under California Code of Civil
5 Procedure §474 as Does 1 through 25, inclusive, are presently not known to plaintiff, who therefore
6 sues these defendants by such fictitious names. Plaintiff will seek to amend this Complaint and include
7 these Doe defendants' true names and capacities when they are ascertained. Each of the fictitiously
8 named defendants is responsible in some manner for the conduct alleged herein and for the injuries
9 suffered by the Company as a result of defendants' wanton and illegal conduct.

10 SUBSTANTIVE ALLEGATIONS¹

11 18 Defendant Revance develops and manufactures dermatology and aesthetic medicines,
12 products and treatments. The Company, formerly known as Essentia Biosystems, Inc., was founded in
13 1999, commenced operations in 2002 and changed its name to Revance in 2005. Revance has never
14 had a product or treatment approved for commercial sale by the FDA.

15 19. Botox is a neurotoxic protein produced by the bacterium *Clostridium botulinum* and
16 related species. It is the most acutely lethal toxin known, with an estimated human median lethal dose
17 (LD-50) of 1.3-2.1 ng/kg intravenously or intramuscularly and 10-13 ng/kg when inhaled. Botox
18 exposure can cause botulism, a serious and life-threatening illness in humans and animals.

19 20 Despite its toxicity, forms of botulinum toxin types A and B are available commercially
20 for research and various medical and cosmetic procedures. Therapeutic indications include upper motor
21 neuron syndrome, focal hyperhidrosis, blepharospasm, strabismus, as well as a widely used cosmetic
22 treatments.

23 21. The FDA requires drug products containing the toxin that are sold in the United States to
24 carry a mandatory warning, which since 2009 has included the caution that effects of locally
25 administered botox may spread from the injection area to other areas of the body, causing symptoms
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28 ¹ All emphasis in bold and italics is added, unless otherwise noted.

1 similar to those of botulism. The warning was the result of documented deaths associated with botox's
2 therapeutic uses, especially unapproved (off-label) use in children.

3 22. Revance's lead product under development at the time of the Offering was RT001, a
4 physician-applied topical botulinum toxin type A for the treatment of wrinkles around the eyes,
5 colloquially referred to as "crow's feet." Revance claims that its RT001 is a topical neurotoxin or
6 "neuromodulator," which means that it decreases muscle activity. However, unlike other FDA-
7 approved neuromodulators for the treatment of crow's feet that are applied through injections, RT001 is
8 applied topically in the doctor's office, where it is left on the patient's skin for approximately 20
9 minutes. Although the more traditional botox injection treatments – such as Allergan's Botox® – are
10 fairly quick and cause minimal discomfort, Revance has consistently maintained that many people
11 avoid injectable botox treatments because of the needles, claiming, therefore, that there is a large,
12 unaddressed, multi-million dollar market available for its product.

13 23. "Clinical research" refers to studies, or trials, that are done in people and overseen by the
14 FDA. Drug developers, or "sponsors," must submit an Investigational New Drug ("IND") application
15 to the FDA before beginning clinical research. Though there can be some additional post-approval
16 clinical testing, there are three explicitly delineated, pre-approval phases of clinical trials.

- 17 • **Phase 1:** Once an IND has been approved by the FDA, drug candidates first undergo a
18 Phase 1 clinical trial which typically involves 20 to 100 healthy volunteers and lasts
19 several months. According to the FDA, the purpose of Phase 1 clinical testing is to
20 determine safety and dosage, and 70% of all drug candidates successfully complete this
21 phase.
- 22 • **Phase 2:** Phase 2 clinical trials typically involve up to several hundred people with the
23 disease or condition and last several months to two years. According to the FDA, the
24 purpose of a Phase 2 clinical trial is to demonstrate efficacy and to identify any side
25 effects, and only 33% of drug candidates successfully complete this phase.
- 26 • **Phase 3:** Phase 3 clinical trials typically involve 300 to 3,000 volunteers who have the
27 disease or condition and typically last one to four years. According to the FDA, the
28 purpose of a Phase 3 clinical trial is to gather more information about safety and
effectiveness, studying different populations and different dosages and using the drug in
combination with other drugs. This phase of the clinical research process continues
until the developer decides to end clinical testing or files a marketing application with
the FDA. Before filing a marketing application, a developer must have adequate data
from two large, controlled Phase 3 clinical trials.

24 Though drug developers are not required to obtain FDA consent of the design of their
28 Phase 3 clinical trials, because Phase 3 clinical trials involve hundreds of people and take years to

1 complete, making them very expensive, the FDA permits drug developers/sponsors to sit down with the
 2 agency following the conclusion of a Phase 2 trial to ensure that the size, design and endpoints selected
 3 for a Phase 3 clinical trial will demonstrate what the FDA requires for approval. According to the
 4 agency, “[a]t the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale
 5 studies in Phase 3 should be done,” and “Phase 3 studies [then] begin if evidence of effectiveness is
 6 shown in Phase 2.”² These meetings are referred to as EOP2 meetings.

7 25 Privately, Revance had been wrestling with the FDA for years over what clinical
 8 measures were appropriate to demonstrate efficacy of RT001. The outcome of these private disputes
 9 was that the FDA downgraded the status of an EOP2 meeting Revance was trying to achieve, indicating
 10 that in the FDA’s view Revance was not even ready for an EOP2 meeting. Unable to demonstrate
 11 successful completion of Phase 2, Revance used the FDA’s Formal Dispute Resolution process in an
 12 effort to justify completion of Phase 2 and proceed into Phase 3 trials. Revance’s letter to the FDA,
 13 never disclosed to investors in the Offering, stated in pertinent part as follows:

14 Pursuant to this formal dispute resolution process, Revance seeks FDA’s agreement
 15 with the following

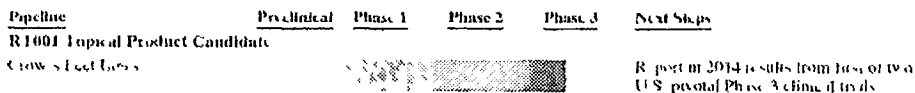
- 16 • Temporary Improvement in the severity of lateral canthal lines *at rest* is an acceptable indication for RT001
- 17 • The measurement of LCL *at rest is the appropriate primary clinical endpoint* (*i e* primary efficacy assessment) to support the proposed indication for RT001
 18 *Further, it is not required that Revance incorporates the assessment of LCL at*
 19 *smfile] in the primary endpoint.* Revance is willing to conduct the
 20 measurement of LCL at smile as an additional, descriptive endpoint (*i e* non-
 21 primary endpoint), if deemed necessary following this dispute resolution.
- 22 • The proposed IGA-LCL and PSA scales [with “IGA” referring to
 23 investigator/physician/physician’s assistant filled-out scales and “PSA” referring
 24 to a patient’s own severity assessment] are valid measurement tools for the
 25 primary endpoint. Revance may proceed with these scales, as currently defined,
 26 in Phase 3 clinical studies for [RT001]
- 27 • *With the resolution of these three issues, the RT001 program has completed*
 28 *End-of-Phase 2, no End-of-Phase 2 Meeting is required, and the RT001*
program may proceed with Phase 3 clinical development

27 ² See “The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective,” www.fda.gov (last
 28 visited April 29, 2015).

1 Underwriter Defendants priced the Offering and filed the final prospectus for the common stock
 2 Offering (the “Prospectus”), which forms part of the Registration Statement (the Prospectus and
 3 Registration Statement are collectively referred to herein as the “Registration Statement”)

4 29. The Registration Statement was negligently prepared and, as a result, contained untrue
 5 statements of material facts or omitted to state other facts necessary to make the statements made not
 6 misleading, and was not prepared in accordance with the rules and regulations governing its
 7 preparation.³

8 30. Concerning the then-present status of Revance’s clinical trial program, the Registration
 9 Statement repeatedly falsely stated that the Company was then “*in a Phase 3 clinical development*
 10 *program of RT001 in North America for the treatment of crow’s feet lines.*” Emphasizing that Phase
 11 3 trials had already started and Phase 2 was complete, the Registration Statement said immediately
 12 thereafter, “we plan to initiate an additional Phase 3 clinical trial in Europe and a second Phase 3
 13 clinical trial in the United States in 2015 ” The Registration Statement also displayed the misstatement
 14 graphically, purporting to show RT001 completed Phase 2 and was then in Phase 3 clinical testing, and
 15 misleadingly stating Revance would “[r]eport in 2014 results from first of two U.S. pivotal Phase 3
 16 clinical trials”:



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 21 31 With respect to Revance’s purported Phase 3 clinical trials, according to the Registration
 22 Statement, Revance had “initiated an open label Phase 3 clinical trial in the first quarter of 2014 to
 23 evaluate the long term safety and efficacy of repeat administration of RT001” and expected “to enroll
 24 up to 1,800 subjects in the study.” But this statement and the statements above were materially false
 25 and misleading and omitted material information, including the following No contract research
 26 organization (“CRO”) had been hired to conduct this trial and Revance did not have an RT001

27 ³ References to the “Registration Statement” include other SEC filings expressly incorporated by
 28 reference therein, including the 2013 annual financial report filed on Form 10-K on February 6, 2014,
 and the first quarter 2014 quarterly financial report filed on Form 10-Q on May 14, 2014

1 formulation it could administer in the trial. In fact, the RT001 Revance was using had a different
2 manufacturer (Revance, not the third party that manufactured the original RT001), process and
3 manufacturing site. And Revance had not confirmed the RT001 formulation had adequate stability to
4 support production for such a Phase 3 study. To the contrary, Revance had to conduct a secret trial to
5 ascertain whether the RT001 formulation it was using was even effective. By the time of the Offering,
6 Revance, at best, had no results from that secret trial demonstrating the RT001 formulation it was then
7 using was effective. Indeed, *after* the Offering Revance was forced to admit the RT001 formulation it
8 was using was not effective or suitable for large scale production and use in the Phase 3 clinical trial.
9 Revance was supposedly “in.” Investors and securities analysts recoiled upon learning this and
10 Revance’s stock lost nearly a quarter of its value.

11 32 The Registration Statement also asserted that the Company intended to “commercialize
12 RT001 for indications where topical application provides a *meaningful* advantage over injectable
13 administration,” and in Revance’s “Phase 2 clinical trials, RT001 has demonstrated a statistically
14 significant and *clinically meaningful* reduction in crow’s feet lines.” But these statements were
15 materially false and misleading and omitted material facts, including that the FDA did not agree that
16 Revance’s proposed primary endpoint for demonstrating efficacy (“at rest”) was in fact meaningful, and
17 that Revance’s RT001 formulation intended for the Phase 3 clinical trials was *not* the same formulation
18 or product from the Phase 2 clinical trials and therefore had not demonstrated any reduction in crow’s
19 feet lines, let alone a meaningful one. Indeed, Revance had yet to manufacture the same product used
20 in its Phase 2 trials, notwithstanding its statements to the contrary.

21 33 Revance had changed its formulation for RT001 in order to enhance stability but did not
22 see clinical improvement in trials for that new formulation. The Registration Statement made the point
23 that Revance was using its “original Phase 2b diluent formulation” that generated the purportedly
24 successful Phase 2 clinical trial results and that Revance had “confirm[ed]” that version of RT001 had
25 “adequate commercial stability” for large scale production. But these statements were materially false
26 and misleading and omitted material information. Revance was *not* using the original RT001
27 formulation, nor had Revance confirmed the product it was using had adequate stability. In fact, the
28 RT001 formulation Revance was using had a different manufacturer (Revance, not the third party that

1 manufactured the original RT001), process and manufacturing site. And Revance had *not* confirmed
2 the RT001 formulation had adequate stability. To the contrary, Revance had to conduct a secret trial to
3 ascertain whether the RT001 formulation it was using was effective. By the time of the Offering,
4 Revance, at best, had no results from that secret trial demonstrating the product it was then using was
5 effective. Indeed, *after* the Offering Revance was forced to admit the RT001 formulation it was using
6 was *not* effective or suitable for production and use in the Phase 3 clinical trial Revance was supposedly
7 “in.”

8 34. The Registration Statement represented that “[w]e have the ability to manufacture our
9 own botulinum toxin type A product to support our clinical trials” and “currently manufacture our own
10 clinical drug products to support both RT001 and RT002 exclusively in a single manufacturing and
11 laboratory facility and plan to utilize this facility in the future to support commercial production if our
12 product candidates are approved.” The Registration Statement further asserted Revance was
13 manufacturing its own “bulk drug substance and finished dose forms of drug product to support
14 [Revance’s] topical RT001 product candidate” and “we generally do not begin a clinical trial unless we
15 believe we have a sufficient supply of a product candidate to complete the clinical trial.” These
16 statements were materially false and misleading and omitted material facts as explained below
17 Defendants also put in the Registration Statement a number of generalized misleading “risk factors”
18 aimed at purported risks associated with Revance’s ability to manufacture at “full commercial scale if
19 [Revance’s] product candidates are approved” and “raw materials” and suggesting the next step for
20 Revance was merely commercial – not clinical – production. But defendants left out the following
21 material facts, including that Revance had never manufactured RT001 product at its own facility
22 effective enough to support a clinical trial, and specifically the Phase 3 clinical trial Revance was telling
23 investors it was in

24 35 Indeed, Revance did *not* have the RT001 product to support the Phase 3 clinical trial.
25 Moreover, Revance was *not* using the original RT001 formulation, nor had Revance confirmed the
26 product it was using had adequate stability. In fact, the “RT001” Revance was using had a different
27 manufacturer (Revance, not the third party that manufactured the original RT001), process and
28 manufacturing site. And Revance had *not* confirmed that the product had adequate stability. To the

1 contrary, Revance had to conduct a secret trial to ascertain whether the RT001 formulation it was using
 2 was effective. By the time of the Offering, Revance, at best, had no results from that secret trial
 3 demonstrating the RT001 it was then using was effective. Indeed, *after* the Offering Revance was
 4 forced to admit the formulation it was using was *not* effective or suitable for production and use in the
 5 Phase 3 clinical trial Revance was supposedly “in.”

6 36. The Registration Statement falsely claimed that Revance had successfully completed an
 7 EOP2 meeting, that the FDA had approved its Phase 3 clinical trial structure, and that the FDA had
 8 agreed that Revance did not need to demonstrate temporary wrinkle eradication “at smile” as a primary
 9 endpoint in that Phase 3 clinical trial, stating in pertinent part as follows:

10 [A]fter our Phase 2 clinical trials, we used the FDA’s Formal Dispute Resolution
 11 process to obtain *confirmation* from the FDA that our proposed indication, *primary*
 12 *endpoint assessment and primary endpoint measurement were acceptable for*
 13 *continued clinical trials*. . . [T]he FDA provided written confirmation that our
 14 proposed indication, primary endpoint assessment and primary endpoint measurement
 15 were acceptable for Phase 3 clinical trials .

16 Indeed, the Registration Statement materially falsely stated that Revance obtained “written
 17 confirmation” from the FDA approving Revance’s principal Phase 3 clinical trial designs for RT001,
 18 including allowing primary efficacy to be measured at rest, rather than at smile. In reality, the FDA
 19 merely responded that Revance was not legally required to successfully complete an EOP2 meeting
 20 with the FDA to proceed with its Phase 3 clinical trial. Acknowledging the unremarkable facts that “the
 21 FDA [does] not confirm[] . . . indication [and] primary endpoint[s] . . . are acceptable for regulatory
 22 approval” before the actual results from Phase 3 trials are obtained and “there is no assurance the FDA
 23 will approve our BLA for RT001,” the Registration Statement was materially misleading and omitted
 24 material facts because the FDA had in truth threatened that Revance’s Phase 3 plan was destined for
 25 significant delay or failure, as set forth below and in ¶¶25-26.

26 37. In fact, the Registration Statement indicated Revance’s Phase 3 clinical trial design met
 27 the FDA’s approval standards, *when the design did not*, stating in pertinent part that “[b]ased on . . .
 28 *discussions with the United States Food and Drug Administration*, . . . three Phase 3 pivotal clinical
 trials and the Phase 3 open label safety clinical trial, if successful, *[would] provide the efficacy and*
safety data to support . . . regulatory filing for approval of RT001 for the treatment of crow’s feet lines

1 in the United States.” These statements and the statements in the paragraph above were materially false
2 and misleading and omitted material facts because the FDA rejected Revance’s principal Phase 3
3 clinical trial designs for RT001 that Revance was leaving intact, including allowing primary efficacy to
4 be measured “at rest,” rather than “at smile.” In fact, the FDA’s letter threatened that Revance’s Phase
5 3 trial was destined for significant delay or failure, warning that “*if the requirement for muscle*
6 *paralysis in terms of efficacy is not demonstrated in some way, the potential exists for questioning the*
7 *need for botulinum toxin type A at all*” in RT001. Thus, the FDA explicitly warned Revance that the
8 agency was not approving a botox treatment unless Revance demonstrated efficacy with muscle
9 paralysis, necessitating that Revance demonstrate efficacy “at smile” as a primary endpoint. Revance
10 never disclosed the FDA’s letter. Indeed, when the FDA published the guidance consistent with what it
11 told Revance in private communications, Revance’s securities analysts and investors were surprised,
12 causing Revance’s stock price to drop nearly 30%.

13 38. The Registration Statement also contained thousands of lines of generalized “risk
14 factors,” including materially false and misleading statements about the “possible” future of Revance’s
15 business that omitted then-*current* material information. Defendants stated the “success” of Revance’s
16 product candidates depended on “timely completion of . . . clinical trials” and the “ability to
17 demonstrate” to the FDA “safety and efficacy;” Revance “may be unable to obtain regulatory approval
18 for RT001;” “there can be no assurance that the FDA will agree with our Phase 3 clinical trial protocol”
19 or “agree that the benefits of RT001 outweigh its risks;” clinical data “may not be sufficient to support
20 approval by the FDA;” “failure can occur;” and “later stage clinical trials” may not have the same
21 “positive results” as earlier trials. The “risk factors” on these matters were materially false and
22 misleading and omitted material information because of the true facts alleged above concerning
23 Revance’s communications with the FDA and the status of Revance’s Phase 3 clinical trials and ability
24 to manufacture RT001.

25 39. The statements referenced above in ¶¶30-34 and 36-38 were each materially false and
26 misleading and omitted the material facts as alleged above that existed at the time of the Offering, and
27 as a result the Company’s business and financial prospects were not what defendants had led the market
28 to believe they were in the Registration Statement.

1 maintained by Revance or its transfer agent and may be notified of the pendency of this action by mail,
2 using the form of notice similar to that customarily used in securities class actions

3 45 Plaintiff's claims are typical of the claims of the members of the Class as all members of
4 the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is
5 complained of herein

6 46. Plaintiff will fairly and adequately protect the interests of the members of the Class and
7 has retained counsel competent and experienced in class and securities litigation.

8 47 Common questions of law and fact exist as to all members of the Class and predominate
9 over any questions solely affecting individual members of the Class. Among the questions of law and
10 fact common to the Class are.

11 (a) whether defendants violated the 1933 Act;

12 (b) whether statements made by defendants to the investing public in the Registration
13 Statement and Prospectus misrepresented material facts about the business and operations of Revance;
14 and

15 (c) to what extent the members of the Class have sustained damages and the proper
16 measure of damages

17 48 A class action is superior to all other available methods for the fair and efficient
18 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the
19 damages suffered by individual Class members may be relatively small, the expense and burden of
20 individual litigation make it impossible for members of the Class to individually redress the wrongs
21 done to them. There will be no difficulty in the management of this action as a class action.

22 **FIRST CAUSE OF ACTION**

23 **For Violations of §11 of the 1933 Act**
24 **Against All Defendants (Except Waugh)**

25 49. Plaintiff incorporates ¶¶1-48 by reference.

26 50. This Cause of Action is brought pursuant to §11 of the 1933 Act, 15 U.S.C. §77k, on
27 behalf of the Class, against all defendants (except defendant Waugh). This is a non-fraud cause of
28

1 action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that
2 defendants acted with scienter or fraudulent intent.

3 51 The Registration Statement for the Offering was inaccurate and misleading, contained
4 untrue statements of material facts, omitted to state other facts necessary to make the statements made
5 not misleading, and omitted to state material facts required to be stated therein

6 52 The defendants named in this Cause of Action are strictly liable to plaintiff and the Class
7 for the misstatements and omissions

8 53 None of the defendants named herein made a reasonable investigation or possessed
9 reasonable grounds for the belief that the statements contained in the Registration Statement were true
10 and without omissions of any material facts and were not misleading

11 54. By reason of the conduct herein alleged, each defendant named herein violated, and/or
12 controlled a person who violated, §11 of the 1933 Act.

13 55 Plaintiff acquired Revance common stock in the Offering.

14 56. Plaintiff and the Class have sustained damages. The value of Revance common stock
15 has declined substantially subsequent to and due to these defendants' violations.

16 57 At the time of their purchases of Revance common stock, plaintiff and other members of
17 the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and
18 could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has
19 elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon
20 which this complaint is based to the time that plaintiff commenced this action. Less than three years
21 has elapsed between the time that the securities upon which this Cause of Action is brought were
22 offered to the public and the time plaintiff commenced this action.

23 **SECOND CAUSE OF ACTION**

24 **For Violation of §12(a)(2) of the 1933 Act Against**
25 **Defendants Revance, the Executive Defendants and the Underwriter Defendants**

26 58 Plaintiff incorporates ¶¶1-57 by reference.
27
28

