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[Additional Counsel on Signature Page]

#### UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

Caption Consistent With Order Appointing Lead Plaintiff dated April 22, 2020, ECF No. 49:	No. 3:20-cv-00367-VC
ALAMEDA COUNTY EMPLOYEES' RETIREMENT ASSOCIATION and OKLAHOMA FIREFIGHTERS RETIREMENT SYSTEM, Individually and on Behalf of All Others Similarly Situated, Plaintiffs,	THIRD AMENDED CONSOLIDATED COMPLAINT FOR VIOLATION OF SECURITIES LAWS CLASS ACTION
v. PORTOLA PHARMACEUTICALS, INC.; SCOTT GARLAND; MARDI C. DIER; SHELDON KOENIG; HOLLINGS C. RENTON; JEFFREY W. BIRD; LAURA BREGE; DENNIS FENTON; JOHN H. JOHNSON; DAVID C. STUMP; H. WARD WOLFF; GOLDMAN SACHS & CO. LLC; CITIGROUP GLOBAL MARKETS INC.; COWEN AND COMPANY, LLC; WILLIAM BLAIR & COMPANY, L.L.C.; and OPPENHEIMER & CO. INC.,	JURY TRIAL DEMANDED
Defendants.	

Original Caption:	
PAUL HAYDEN, Individually and on Behalf of All Others Similarly Situated,	
Plaintiff, v.	
PORTOLA PHARMACEUTICALS INC., SCOTT GARLAND, and MARDI C. DIER,	
Defendants.	
JOHN R. MCCUTCHEON, Individually and on Behalf of All Others Similarly Situated, Plaintiff,	No. 3:20-cv-00949-VC <u>CLASS ACTION</u>
VS.	
PORTOLA PHARMACEUTICALS INC., SCOTT GARLAND, SHELDON KOENIG, and MARDI C. DIER,	
Defendants.	
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY, on behalf of itself and all others similarly situated,	No. 3:20-cv-01501-VC <u>CLASS ACTION</u>
Plaintiff,	
V.	
PORTOLA PHARMACEUTICALS, INC., SCOTT GARLAND, MARDI C. DIER, SHELDON KOENIG, HOLLINGS C. RENTON, JEFFREY W. BIRD, LAURA BREGE, DENNIS FENTON, JOHN H. JOHNSON, DAVID C. STUMP, and H. WARD WOLFF,	
Defendants.	

## TABLE OF CONTENTS

I.	SUMMARY OF THE ACTION			
II.	JURISDICTION AND VENUE7			
III.	INTRADISTRICT ASSIGNMENT7			
IV. THE PARTIES			S7	
	A.	Lead P	laintiff7	
	B.	Additional Named Plaintiff		
	C.	Defendants		
		1.	The Company	
		2.	Officer Defendants	
		3.	Director Defendants	
		4.	Underwriter Defendants11	
V.	SUBS	TANTI	VE ALLEGATIONS12	
	A.	Company's Background and Drive For Cash12		
	B.	Backg	round of Andexxa14	
		1.	May 2018 FDA Approval of Andexxa (via the FDA Accelerated Approval Pathway)	
		2.	Alternative Treatments Such as Kcentra Were Neither Considered Nor Substantively Discussed as a Real Impediment to Andexxa Sales	
		3.	Andexxa's Early Supply Program15	
		4.	Approval of Generation 2 Andexxa and Full Commercial Launch16	
		5.	Despite the December 31, 2018 Approval For 24-Month Andexxa as Part of the Gen 2 Commercial Launch, Portola Continued to Sell and Ship 6-12 Month Short Shelf-Life Product Well Into The Class Period	
		6.	Portola's Formal Return Policy	
		7.	Change in Andexxa Distribution Model for Gen 2 Commercial Launch	
		8.	As the Class Period Wore On, Portola Released Data Attacking The Viability of 4F-PCCs, such as Kcentra	

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 4 of 114

	9.	Throughout the Class Period, in Public Filings, Portola Disclosed that Demand and Utilization Were Materially Important to the Company's and Andexxa's Success	19
C.		dants Touted Extraordinary Demand and Utilization (Both Depth and th) and Provided a Narrative of Andexxa's Unparalleled Ascension	20
D.	Defendants' Material Misrepresentations Regarding Demand and Utilization Were Made On and in Conjunction With Key Disclosure Dates During The Class Period		
	1.	January 8, 2019: Portola Announces the Broad Commercial Launch of Andexxa	21
	2.	May 8, 2019: Portola Announces Q1 2019 Financial Results	21
	3.	June 11, 2019: Goldman Sachs Global Healthcare Conference	23
	4.	August 7, 2019: Q2 2019 Financial Results	23
	5.	September 10, 2019: Morgan Stanley Global Healthcare Conference	23
	6.	November 5, 2019: Q3 2019 Financial Results	24
E.	E. Confidential Witnesses Report Fleeting Demand and Utilization In Stark Contrast to What Defendants Were Stating Publicly		
	1.	Both Salesperson and Hospital CWs Report that Cost Was A Barrier To Sales and Utilization, Particularly Given the Availability of a Cheaper Alternative Such as Kcentra	26
	2.	Andexxa's Relatively Unique Posture as an Orphan Drug Whose Patient and Treater Populations Were Not Easily Identifiable, and Whose Cost as an Inpatient Drug Was Part of the Hospital Pharmacy Budget, Posed Particular Sales Challenges	30
	3.	Hospital CWs Report That Data was Weak from Both the Initial Clinical Trial of Andexxa and Subsequent Studies Pushed By Portola Near the End of the Class Period	31
	4.	CWs Support the Notion that Portola's Generous Return Policy Together With Its Continued Sale of Short Shelf-Life Product Reduced Risk for Hospitals Considering the Purchase of That Soon- Expiring Product, as It Could Be Returned After Expiration Without Penalty	31
	5.	The Issues Described by Salesperson CWs Were Pervasive Throughout The Class Period, and In No Way Limited To Q4 2019	32
	6.	Salesperson CWs Were Geographically Diverse and Describe the Nature of Selling Andexxa in Their Territories and The Make-up of Their Potential Hearital Pass	20
		Their Potential Hospital Base	32

		7.	Both Salesperson and Hospital CWs Describe How Senior Management Knew about the Critical Demand and Utilization Impediments	33
	F.	The Tr	th Starts to be Revealed	36
		1.	Portola Admits that Andexxa Demand is Flat, Utilization is Decreasing, the Company Under-Reserved for Product Returns, and There was Excessive Product in the Distribution Channel	36
		2.	The Announcement of the Company's Q4 and Full-Year 2019 Results (1) Reveal that Andexxa is Floundering and Portola is Forced to Focus Like A "Laser" on it by Streamlining Organizationally and (2) Provide Disappointing Utilization Guidance Going Forward	38
		3.	Portola Issues its 2019 Form 10-K and Admits that the Marketing of Andexxa and Resistance to Utilization by Hospital Formulary Committees Was Adversely Impacted by Competition with Off- Label Use of 4F-PCCs	40
		4.	The Alexion Acquisition is Announced and Consummated	41
VI.	EXCH	IANGE	ACT VIOLATIONS	42
	A.	Defend	nts' Material Misrepresentations	42
		1.	Defendants Issued Materially Misleading Statements About Its Financial Reporting With GAAP	42
			a. Summary of Applicable GAAP	42
			<ul> <li>Defendants Issued Materially False and Misleading Statements Regarding Portola's Compliance With GAAP, ASC 606, and Its Own Internal Policy</li> </ul>	49
			c. Having Failed to Comply with GAAP and ASC 606, Defendants' Net Revenue Figures were Materially False and Misleading	61
			d. The Company's Internal Control Over Financial Reporting Failed to Prevent or Detect Portola's Violation of ASC 606 and Rendered Defendants Garland's and Dier's SOX Certifications Materially False and Misleading	63
		2.	Defendants Issued False and Misleading Statements About Demand and Utilization of Andexxa, Falsely Portraying the Commercial Launch of Andexxa as a Success	65
	B.	Additi	nal Allegations of Scienter	73
		1.	The Nature and Significance of the Problems with Andexxa, Which s the Company's Core Business, Further Support Scienter	74

		2.	Statements About Defendants' Knowledge of Demand and Utilization Issues in Light of Andexxa's Exorbitant Cost Further Support Scienter
		3.	The Defendants Consummated the August 2019 Offering to Exploit the Artificial Inflation in the Company's Common Stock77
		4.	The Defendants Were Motivated to Inflate Andexxa Sales to Access the \$62.5 Million Second Tranche of the Secured Term Loan77
		5.	Defendants' Insider Trading is not Relevant to Their Scienter Because They were Motivated by Efforts to Sell The Company, Not by Short-Term Stock Sales
	C.	Loss C	Causation
		1.	The Significant Declines in Portola's Common Stock Price (and Resulting Losses) were Causally Connected to Defendants' Class Period Misrepresentations and Omissions
			<ul> <li>a. Since the January 9 and 14, 2020 and February 26, 2020 Disclosures of Disappointing Q4 2019 and FY 2019 Net Revenue Figures Were the Result of the \$5 million Adjustment to Return Reserves and the Reversal of Revenue for Products Sold and Sales Reported in 2018 and 2019, They Are Causally Connected to the Misrepresentations and Omissions Regarding Compliance with ASC 606, Revenues, and Inadequate Reserves</li></ul>
			b. The January 9 and 14, 2020 and February 26, 2020 Disclosures of Problems with Utilization and Demand
			c. The Market Reacts to Defendants' January and February 2020 Disclosures, Causing Plaintiffs' Significant Losses
			(i) Market Reaction to the January 9, 2020 News
			(ii) Market Reaction to the February 26, 2020 News
		2.	Defendants' Materially False and Misleading Statements and Omissions Concealed Risks That Inevitably Materialized at the End of the Class Period, Thereby Causing Plaintiffs' Foreseeable Losses89
	D.	Presun	nption of Reliance
	E.	Excha	nge Act Counts92
		1.	Count One—Violations of Section 10(b) and Rule 10b-592
		2.	Count Two—Violations of Section 20(a) of the Exchange Act (Against the Officer Defendants)
VII.	SECU	RITIES	ACT VIOLATIONS

	A.	Summary of August 2019 Offering		
	B.	The M	aterially Untrue and Misleading Statements in the Offering Materials	95
	C.	The Se	ecurities Act Counts	98
		1.	Count One—Violations of Section 11 of the Securities Act (Against all Securities Act Defendants, Except Koenig)	98
		2.	Count Two—Violations of Section 12(a)(2) of the Securities Act (Against Portola and the Underwriter Defendants)	.100
		3.	Count Three—Violations of Section 15 of the Securities Act (Against the Officer and Director Defendants)	.101
VIII.	CLAS	S ALLE	EGATIONS	.103
IX.	NO SA	AFE HA	RBOR	.105
X.	PRAY	ER FO	R RELIEF	.106
XI.	DEMA	AND FC	DR TRIAL BY JURY	.106

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 8 of 114

Lead Plaintiff the Alameda County Employees' Retirement Association ("Lead Plaintiff" or "ACERA"), by and through its attorneys, and on behalf of all others similarly situated, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief are based on, among other things, their counsel's investigation, which includes without limitation: (i) a review and analysis of U.S. Securities and Exchange Commission ("SEC") filings by Portola Pharmaceuticals, Inc. ("Portola" or the "Company"), (ii) a review and analysis of press releases and other public statements, (iii) a review and analysis of securities analysis are ports and media reports about the Company, (iv) investigative interviews with former Portola employees and hospital customers/potential hospital customers, and (v) consultation with consulting experts.

#### I. SUMMARY OF THE ACTION

1. Lead Plaintiff brings claims for violations of two federal statutes: (1) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) (the "Exchange Act"), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b5"); and (2) Sections 11, 12(a)(2), and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77l(a)(2), and 77o (the "Securities Act"). The Securities Act claims allege strict liability and/or negligence and do not sound in fraud.

2. Lead Plaintiff asserts these claims individually and on behalf of investors who purchased or otherwise acquired common stock of Portola, including shares sold in an offering in August of 2019 (the "August 2019 Offering") (as described *infra* at ¶¶308-10), between January 8, 2019 and February 26, 2020, inclusive (the "Class Period"), and were damaged as a result (the "Class").

3. Portola is a relatively small company that develops pharmaceuticals. In 2018, it had developed two bet-the-company drugs—Bevyxxa and Andexxa—that it was bringing to market that addressed bleeding emergencies resulting from the use of certain anti-coagulants. Bevyxxa's launch failed spectacularly by September 2018, leaving just Andexxa.

4. And Andexxa's survival was fraught. While Andexxa was promoted from the start

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 9 of 114

as a breakthrough drug without competition, it had two things working against it. First, it cost an exorbitant amount—between approximately \$25,000 and \$50,000 per dose. Second, while no U.S. Food and Drug Administration ("FDA")-approved competitor existed for the specific types of serious bleeds that Andexxa was developed to address, at least one—a 4-factor Prothrombin Complex Concentrate ("4F-PCC") called Kcentra—did exist, was effective, and cost just a fraction of what Andexxa did, and it had been prescribed off-label regularly by doctors for years.

5. In the years prior to the one-plus-year Class Period, Portola had been burning through hundreds of millions of dollars per year and was keenly focused on cash and staying afloat. On a January 8, 2019 call to analysts, Defendant Scott Garland ("Garland") stated, "Cash is our fuel on this journey. We take it very seriously. It's what [it's] going to take to get us from this side to the other side of the river or the pond, and we're being very judicious with how we spend our money." Thus, Andexxa was Portola's key to success, with nothing waiting in the wings.

6. Therefore, from Defendants' perspectives, Andexxa had to produce revenue promptly; and in the meantime, Defendants had to keep Portola's coffers full. Defendants took two steps during 2019 to inject cash into Portola while waiting for Andexxa to succeed. One step was a public offering in August 2019 that provided gross proceeds of approximately \$250 million for Portola. But the more critical step was a credit agreement that the Company entered into an agreement on February 28, 2019 for a term loan of \$125.0 million to be advanced in two equal tranches of \$62.5 million each. The first tranche came immediately, but the second was to be made available near year's end—on November 15, 2019—and only if certain conditions were met, including that consolidated net revenue for the three fiscal quarter periods ending September 30, 2019 was at least \$50.0 million. In other words, Portola's only product, which was commencing a broader commercial launch, had to both perform and book immediate revenue.

7. Management therefore sang Andexxa's praises. Defendants touted extraordinarily "strong and growing" demand, sometimes evidenced by new hospital purchases as well as reorders. At a conference in September 2019, Chief Executive Officer ("CEO") Garland said that it "feel[s] like there's a lot of momentum, wind in our sales for Portola...." Defendants also touted

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 10 of 114

deep and broad utilization among hospital customers. As for depth, even well into the Class Period, in August 2019, Garland said that "[t]here's nothing that we're seeing today that makes us concerned about a lack of pull through or plateauing of our utilization." Portola also claimed wide breadth; in November 2019, one executive said on an analyst conference call that "Andexxa is being used in all ranges of bleeds." And Defendants touted Andexxa's ascension. Indeed, on August 7, 2019, Garland stated that "Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban."

8. These were not idle claims—Portola made verbosely clear in quarterly and annual public filings that demand and utilization were critical to Andexxa's success. Analysts commented on that in making recommendations, and the market reacted to Portola's claims.

9. Unfortunately, what Defendants were singing at the top of their lungs to the public was at complete odds with what was actually known internally. Geographically diverse salesperson and hospital confidential witnesses ("CWs") told a uniform story of stagnant demand—that the exorbitant cost of each dose was a barrier to sales, and that there were viable alternatives of other, cheaper drugs, such as Kcentra, that could be used off label. Andexxa's arrival in the marketplace was met with a tempered reaction—with what one former salesperson CW described as "shock" at the \$25,000 to \$50,000 price tag. Hospitals acted warily toward Andexxa. Many refused to purchase the drug. Others purchased it in limited quantities—e.g., one, two, six doses—while at the same time restricting use to only the most dire life-threatening bleeds.

10. Defendants knew this. On its own, it is absurd to suggest otherwise, where Andexxa was Portola's only viable product and the Company's complete success or utter failure rested on its ability to sell its product successfully. Defendant Garland admitted at the beginning of the Class Period to focusing on cash as the Company's "fuel," given that its burn rate was high; he would not be focused on cash without knowing about sales, demand, and utilization. Further, midway through the Class Period, he agreed with an analyst who said that the Company's story was "Andexxa, Andexxa, Andexxa"—there was little else to look at.

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 11 of 114

11. But there is also evidence of Garland's and others' specific knowledge. First, these issues were also regularly discussed on Company calls and at Company meetings, including national sales meetings in San Francisco that Garland attended and participated in. Second, salesperson CWs report that they used customer relationship management (CRM) software and Excel spreadsheets to track meetings, sales, and utilization (in great detail). Third, Defendants themselves conceded that they tracked key metrics, such as hospitals orders.

12. The announced revenues were also somewhat of a mirage. Even though Andexxa was approved as of January 2019's full commercial launch to sell with a 24-month shelf-life, Portola continued to sell its shorter-shelf-life product during the Class Period (6-12 month shelf-life when sold to distributors without visibility into when that got to the hospitals). And, Portola provided an extraordinarily generous return policy, allowing expiring product to be returned or exchanged by either distributors or hospitals without penalty up to three months after expiration. The tenor of the CWs' comments suggested that the shelf-life together with the return policy allowed hospitals to purchase the expensive product that was set to expire without fear of losing the money spent. Indeed, CWs reported an uptick in returns in Spring and Summer 2019.

13. In fact, the longer shelf-life product was only likely sold starting in November 2019. When the truth began to emerge about Portola's misrepresentations in January 2020, Defendant Chief Financial Officer ("CFO") Mardi Dier ("Dier") explained, in an apparent effort to minimize future damage, that longer 36-month shelf-life Andexxa had started shipping (only) in November 2019.

14. Meanwhile, Portola did not properly recognize revenue for Andexxa sales in accordance with generally accepted accounting principles ("GAAP"), given the Company's failure to properly account for significant uncertainties regarding the amount of product that might be returned.

15. GAAP and Accounting Standards Codification ("ASC"), Topic 606 ("ASC 606"), *Revenue from Contracts with Customers*, allows companies to recognize net product revenue "<u>only</u> to the extent that it is probable that a significant reversal in the amount of cumulative revenue

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 12 of 114

recognized will not occur when the uncertainty associated with the variable consideration is <u>subsequently resolved</u>."<sup>1</sup> ASC 606-10-32-11. As detailed *infra*, Defendants lacked a reasonable basis, including relevant historical evidence, to reach the conclusion that these sales would not be returned given the combination of what was known about demand and utilization, the existence of alternatives such as Kcentra, the short shelf-life product being sold, and the extraordinarily generous return policy. Thus, Portola was required to forestall recognizing revenue on product for which it was not probable that were would be a significant reversal of revenue upon return. Andexxa was a new product, and Defendants had no basis to determine otherwise.

16. This is not to say that no revenue could be recognized before the return period expired. Defendants could have, for example, recognized revenue on product that was used, or made a reasonable and appropriate estimate on product sold and used in a repeated pattern with a particular hospital, giving Portola license to rely on its estimation of return probability for that hospital. But Defendants failed to properly constrain revenue on any Andexxa product sold during the Class Period pursuant to ASC 606-10-32-11, and instead only applied modest reserves. As explained *infra*, determining whether revenue should be constrained under ASC 606 is an additional consideration beyond estimating reserves.

17. The Company's Annual Report on Form 10-K ("Form 10-K") for the year ended December 31, 2019, filed with the SEC on February 28, 2019 (the "2019 Form 10-K") bore out Portola's non-compliance with ASC 606 as Portola had to reverse a significant portion of the Andexxa revenue recognized in 2018, take a \$5 million adjustment to sales provisions, and increase its fourth quarter (or "Q4") 2019 reserves significantly.

18. However, the Company's improper recognition of revenue during the Class Period helped the Company exceed a \$50 million milestone, which was critical to accessing \$62.5 million of seriously-needed capital on November 15, 2019.

19. Notwithstanding Defendants' efforts to keep the truth from investors, as alleged in

<sup>&</sup>lt;sup>1</sup> All emphasis is added, unless otherwise noted.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 13 of 114

Section VI., *infra*, the truth started to be revealed on January 9, 2020 and/or risks began to materialize, when the Company announced its Q4 2019 results and issued a press release stating that total net U.S. Andexxa revenue was projected to be \$24 million, down from \$33 million the prior quarter—a decline of 27%; on January 14, 2020, in a follow-up analyst presentation by Portola given at an industry conference; on February 26, 2020 in a press release and analyst call; and on February 28, 2019 with the release of the 2019 Form 10-K.

20. On the January 9, 2020 news and conference call, Portola's share price plummeted by \$9.98 (or 40%) to close at \$14.76 per share on January 10, 2020 on heavy trading volume. After the February 26, 2020 presentation, the stock price fell, closing at \$10.17 per share—a decline of \$2.35 per share (or 19%) on heavy trading volume on February 27, 2020.

21. On the February 26, 2020 call, after the market closed, the Company revealed that the future of Andexxa was even more dire when it announced lower than expected full year ("FY") 2019 losses and that the Company would have to restructure its operations to be "laser focused" on Andexxa by, among other things, reorganizing the Andexxa operation and shutting down the final remnants of Bevyxxa. Portola further described a bleaker-than-expected future for Andexxa when it revealed that it expected to add 350 new hospitals in 2020 (down from 425 hospital additions in 2019), which caused analysts to lower their projections.

22. In its 2019 Form 10-K, issued two days later on February 28, 2020, Portola also finally admitted what it had otherwise refused to recognize since Andexxa's launch. Since Andexxa's launch in May 2018, Portola had disclaimed Kcentra as a viable competitor, the Company now added disclosures that made clear the opposite was true. The Company highlighted the precariousness of the initial FDA-approval medical study, ANDEXXA-4, which was based on the change from baseline in healthy volunteers only, rather than a randomized controlled trial which compares Andexxa to other types of care the enrolling institution would provide in the absence of Andexxa. In its 2019 Form 10-K, Portola admitted not just that it had been encountering material difficulties in selling Andexxa in 2019 due to competition from "widely used" 4F-PCCs such as Kcentra, a scenario Portola had downplayed at launch, but also to the

ANDEXXA-4 potential deficiencies.

## II. JURISDICTION AND VENUE

23. Lead Plaintiff's claims arise under 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, and Sections 11, 12, and 15 of the Securities Act, 15 U.S.C. §§ 77k, 77l, and 77o.

24. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and Section 22 of the Securities Act, 15 U.S.C. § 77v. This Court has jurisdiction over Defendants because each Defendant has sufficient minimum contacts with this district, particularly since Portola's principal place of business is located in South San Francisco, California.

25. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act and Section 22 of the Securities Act because many of the false and misleading statements were made in or issued from this district. Many of Defendants' acts and practices that give rise to this complaint substantially occurred in this district.

26. In connection with the acts, conduct, and other wrongs Lead Plaintiff alleges, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, and national securities markets.

## III. INTRADISTRICT ASSIGNMENT

27. Pursuant to Northern District of California Civil Local Rules 3-2(c) and 3-5(b), assignment to the San Francisco Division of this district is proper because a substantial part of the events or omissions, which give rise to the claims asserted herein, occurred in San Mateo County, and Portola's principal place of business is located in San Mateo County, California.

## IV. THE PARTIES

## A. Lead Plaintiff

28. Lead Plaintiff ACERA, a public pension fund located in Oakland, California, purchased Portola common stock during the Class Period (as set forth in its Certification attached

as Exhibit 1) and suffered damages as a result of the violations of the federal securities laws alleged herein.

## B. Additional Named Plaintiff

29. The Oklahoma Firefighters Pension and Retirement System ("OFPRS"), a public pension fund located in Oklahoma City, Oklahoma, purchased Portola common stock during the Class Period (as set forth in its certification attached as Exhibit 2), including shares issued pursuant to the August 2019 Offering, and was damaged as a result. Specifically, but not exclusively, OFPRS purchased 7,889 shares of Portola common stock on August 14, 2019 directly in the August 2019 Offering at the offering price of \$28.00 per share.

## C. Defendants

## 1. The Company

30. Defendant Portola is incorporated under the laws of Delaware with its principal executive offices located in South San Francisco, California. The Company is the issuer of the common stock sold in the August 2019 Offering. Portola's common stock traded on the NASDAQ exchange under the symbol "PTLA." As of February 20, 2020, the number of shares outstanding of Portola's common stock was 78,080,365.

## 2. Officer Defendants

31. Defendant Garland was at all relevant times the CEO and President of the Company, as well as a Director of Portola. Throughout the Class Period, he issued materially false and misleading statements for which he is liable under the Exchange Act. In addition, Garland signed and certified the Company's Form 10-K for the year ended December 31, 2018, filed with the SEC on March 1, 2019 (the "2018 Form 10-K"); Quarterly Report on Form 10-Q ("Form 10-Q") for the period ended March 31, 2019, filed with the SEC on May 8, 2019 (the "Q1 2019 Form 10-Q"); Form 10-Q for the period ended June 30, 2019, filed with the SEC on August 7, 2019 (the "Q2 2019 Form 10-Q"); and Form 10-Q for the period ended September 30, 2019, filed with the SEC on November 5, 2019 (the "Q3 2019 Form 10-Q"). Garland also signed the certifications pursuant to Sarbanes-Oxley Act of 2002 ("SOX" or "SOX Certifications") in the Form 10-Ks and

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 16 of 114

Form 10-Qs issued during the Class Period. Garland also signed the Registration Statement (as defined at  $\P309$ , *infra*) and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials (as defined at  $\P309$ , *infra*).

32. Defendant Dier was at all relevant times an Executive Vice President and the CFO of the Company. Throughout the Class Period, she issued materially false and misleading statements for which she is liable under the Exchange Act. In addition, Dier signed and certified the 2018 Form 10-K, Q1 2019 Form 10-Q, Q2 2019 Form 10-Q, and Q3 2019 Form 10-Q. Dier also signed the SOX Certifications in the Form 10-Ks and Form 10-Qs issued during the Class Period. Dier also signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials.

33. Defendant Sheldon Koenig ("Koenig") was at all relevant times an Executive Vice President and the Chief Commercial Officer of the Company. Throughout the Class Period, he issued materially false and misleading statements for which he is liable under the Exchange Act.

34. Defendants Garland, Dier, and Koenig (collectively, the "Officer Defendants"), because of their positions within the Company, 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, *i.e.*, the market.

35. The Officer Defendants were provided with copies of the Company's reports and press releases alleged to be materially 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 nonpublic information, the Officer Defendants knew or should have known that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made and financial results reported were thereby materially false and/or misleading. The Officer Defendants are liable for the false and/or misleading statements pleaded herein.

## **3.** Director Defendants

36. Defendant Hollings C. Renton ("Renton") served as Chairman of Portola's Board

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 17 of 114

of Directors ("Board") from March 2010 through July 2020. During the Class Period, Renton was a member of the Nominating and Corporate Governance Committee and the Commercial Advisory Committee. He was also a member of the Compensation Committee until he resigned September 18, 2019.

37. Defendant Jeffrey W. Bird ("Bird") served as a Director of Portola from November 2003 through July 2020. During the Class Period, Bird was a member of the Audit Committee and the Research and Development Advisory Committee.

38. Defendant Laura Brege ("Brege") served as a Director of Portola from January 2015 through July 2020. During the Class Period, Brege was a member of the Audit Committee and the Commercial Advisory Committee.

39. Defendant Dennis Fenton ("Fenton") served as a Director of Portola from February2015 through July 2020. During the Class Period, Fenton was a member of the CompensationCommittee and the Research and Development Advisory Committee.

40. Defendant John H. Johnson ("Johnson") served as a Director of Portola from March 2014 through July 2020. During the Class Period, Johnson was a member of the Compensation Committee, the Nominating and Corporate Governance Committee, and the Commercial Advisory Committee.

41. Defendant David C. Stump ("Stump") served as a Director of Portola from September 2015 through July 2020. During the Class Period, Stump was a member of the Nominating and Corporate Governance Committee and the Research and Development Advisory Committee.

42. Defendant H. Ward Wolff ("Wolff") served as a Director of Portola from November 2007 through July 2020. During the Class Period, Wolff was a member of the Audit Committee.

43. Defendants Garland, Renton, Bird, Brege, Fenton, Johnson, Stump, and Wolff are collectively referred to hereinafter as the "Director Defendants." They each signed the 2018 Form 10-K. Each of the Director Defendants also signed the Registration Statement and are therefore

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 18 of 114

liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. In addition, as directors and/or executive officers of the Company, the Director Defendants and the Officer Defendants participated in the solicitation and sale of Portola shares to investors in the August 2019 Offering for their own benefit and the benefit of Portola. The Director Defendants and the Officer Defendants, because of their positions within Portola, possessed the power and authority to control the contents of the Offering Materials.

44. Portola, the Officer Defendants, and the Director Defendants are collectively the "Exchange Act Defendants." The term "Defendants" on its own, used throughout, refers to the Exchange Act Defendants unless otherwise stated.

### 4. Underwriter Defendants

45. Defendant Goldman Sachs & Co. LLC ("Goldman Sachs") served as an underwriter in the August 2019 Offering. Goldman Sachs is a New York limited liability company with its headquarters at 200 West Street, New York, NY 10282.

46. Defendant Citigroup Global Markets Inc. ("Citigroup") served as an underwriter in the August 2019 Offering. Citigroup is a New York corporation with its headquarters at 388 Greenwich Street, New York, NY 10013.

47. Defendant Cowen and Company, LLC ("Cowen") served as an underwriter in the August 2019 Offering. Cowen is a Delaware limited liability company with its headquarters at 599 Lexington Avenue, 20th Floor, New York, NY 10022.

48. Defendant William Blair & Company, L.L.C. ("William Blair") served as an underwriter in the August 2019 Offering. William Blair is a Delaware limited liability company with its headquarters at 222 West Adams Street, Chicago, IL 60606.

49. Defendant Oppenheimer & Co. Inc. ("Oppenheimer") served as an underwriter in the August 2019 Offering. Oppenheimer is a New York corporation with its headquarters at 85 Broad Street, New York, NY 10004.

50. Defendants Goldman Sachs, Citigroup, Cowen, William Blair, and Oppenheimer are collectively referred to as the "Underwriter Defendants." The Exchange Act Defendants and

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 19 of 114

the Underwriter Defendants are referred to collectively as the "Securities Act Defendants."

51. The Underwriter Defendants acted as the underwriters of the August 2019 Offering by offering, selling, and distributing the Portola common stock offered to the investing public and purchased by Plaintiff, OFPRS, and members of the Class. As the underwriters of the August 2019 Offering, the Underwriter Defendants earned lucrative fees for their participation in the August 2019 Offering.

52. The chart below sets forth the number of shares purchased by each Underwriter Defendant in the August 2019 Offering:

Name	Number of shares
Goldman Sachs & Co. LLC	2,973,215
Citigroup Global Markets Inc.	2,330,358
Cowen and Company, LLC	1,767,857
William Blair & Company, L.L.C.	803,571
Oppenheimer & Co. Inc.	160,714
Total:	8,035,715

53. The federal securities laws obligated the Underwriter Defendants to conduct a reasonable investigation into the truthfulness and accuracy of the statements contained in or incorporated by reference into the Offering Materials. The Underwriter Defendants purported to conduct such an investigation into the operations of the Company, an undertaking known as "due diligence." During their due diligence, the Underwriter Defendants had continual access to confidential corporate information concerning the Company's business, financial condition, products, plans, assets, and growth prospects. A reasonable investigation into the truthfulness and accuracy of the Offering Materials, including statements incorporated by reference, would have revealed that the Offering Materials contained materially untrue and misleading statements and omissions, as alleged *infra*. None of the Underwriter Defendants made a reasonable investigation into the truthfulness and accuracy of the Offering Materials.

## V. SUBSTANTIVE ALLEGATIONS

## A. Company's Background and Drive For Cash

54. At the time of the Company's May 2013 initial public offering ("IPO"), the

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 20 of 114

Company had two lead therapeutics that it was focused on researching and developing with a goal of commercialization—Bevyxxa and Andexxa. Portola generated significant operating losses researching and developing Bevyxxa and Andexxa. The FDA approved Bevyxxa in June 2017 and Andexxa (at a 100 mg dose) in May 2018. Bevyxxa's launch failed spectacularly, and it was pronounced all but dead by September 2018, when the Company announced that it was curtailing efforts to commercialize this drug.

55. Portola burned through \$225 million in 2017 and \$326 million in 2018 for its operating activities. As of December 31, 2018, the Company had \$317 million in cash, cash equivalents, and investments, and an accumulated deficit of \$1.5 billion.

56. On February 28, 2019, the Company entered into the aforementioned (¶6) credit agreement for a \$125 million term loan to be advanced in two equal tranches of \$62.5 million subject to certain performance-based milestones related to Andexxa (the "Secured Term Loan"). The first tranche was to be (and was) drawn down immediately. The second tranche was to be available as of November 15, 2019 if, <u>and only if</u>, among other things, Andexxa's consolidated net revenue reported "in conformity with GAAP" for the three fiscal-quarter periods ending September 30, 2019 was at least \$50.0 million. On November 21, 2019, the Company announced that it had met that milestone and had drawn down the remaining \$62.5 million.

57. Similarly, in early August 2019, the Company took steps to announce a public offering to raise additional cash. In the Registration Statement filed with the SEC on August 7, 2019, Portola incorporated by reference the following Company documents: (i) the 2018 Form 10-K, (ii) Q1 2019 Form 10-Q, and (iii) Q2 2019 Form 10-Q. As noted *infra* at ¶309, these materials, along with the Registration Statement and Prospectus, are collectively referred to herein as the Offering Materials. As the Offering Materials stated, the "information incorporated by reference by reference is considered to be part of" the Registration Statement.

58. Portola sold 9,241,072 shares of common stock in the August 2019 Offering, which included 1,205,357 shares of common stock issued pursuant to the over-allotment option granted to the Underwriter Defendants, at a public offering price of \$28 per share. The total proceeds from

the August 2019 Offering and over-allotment, net of underwriting discounts and commissions of approximately \$14.2 million, were approximately \$244.5 million.

## B. Background of Andexxa

# 1. May 2018 FDA Approval of Andexxa (via the FDA Accelerated Approval Pathway)

59. On May 9, 2018, after the market closed, Portola revealed that its lead drug, Andexxa, had received accelerated approval by the FDA on May 3, 2019 as the "first and only antidote" indicated "for patients treated with rivaroxaban [(also known as Xarelto)] and apixaban [(also known as Eliquis)], when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding." In response to this news, shares of Portola traded up to close at \$42.44 per share on May 4, 2018 (up \$8.66 or 25.64%), on heavy volume.

60. Years prior, on February 26, 2015, Portola had announced in a press release that Andexxa "has been granted orphan drug designation" by the FDA, noting that orphan drug status is reserved for those drugs treating "diseases/disorders that currently affect fewer than 200,000 people in the United States." Andexxa's orphan drug status was relatively unique. Most other drugs have discrete and identifiable patient and treater populations and were often prescribed on an outpatient basis (generally covered by insurance and not carried on the hospital pharmacy's budget). Andexxa, instead, focused on a very small outlier subpopulation of hospital patients with severe bleeding-condition complications that would often arise in emergency departments and operating rooms—neither the patient population nor the treaters were easily identifiable, where Andexxa was being sold to be used only in the event of a very unlikely occurrence.

61. And exxa was approved under the FDA's Accelerated Approval pathway—one for drugs developed to treat an unmet medical need, where approval is substantially based on evidence of an effect on a biomarker endpoint that is considered reasonably likely to predict clinical benefit, rather than on a clinical endpoint.

## 2. Alternative Treatments Such as Kcentra Were Neither Considered Nor Substantively Discussed as a Real Impediment to Andexxa Sales

62. Prior to the availability of Andexxa, Kcentra and other coagulant factors were

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 22 of 114

widely used for the same indications for which Andexxa was approved, *i.e.*, reversing the anticoagulant activity of rivaroxaban and apixaban. Kcentra was the brand name of a 4F-PCC— an older and cheaper type of alternative off-label treatment. Despite Andexxa's mid-2018 FDA-approval, Kcentra and other anticoagulants continue to be "widely used." The approximate cost of Kcentra is \$5,000 compared to \$24,750 for a low dose of Andexxa and \$49,500 for a high dose.

63. Despite Kcentra's effectiveness at less cost, Portola did not publicly identify it as a viable threat to Andexxa's commercialization. During a May 4, 2015 conference call regarding Andexxa FDA approval, then-CEO William Lis described Andexxa as being launched to meet an "unmet medical need," and that its price "reflects its novel attributes as well as its orphan drug designation and the targeted population of high-risk patients that will benefit from the use of Andexxa." About Kcentra, CEO Lis stated: "[Y]ou have a drug called Kcentra, no biological plausibility. … I do—we do not think demand [for Andexxa] is going to be the issue."

64. Instead of considering Kcentra and other treatments, Portola tried to justify the cost of Andexxa by focusing on what would otherwise be an extended hospital stay. Then-CEO Lis continued: "Importantly, we are confident that we can build a successful Andexxa franchise by targeting just the select subpopulation of patients with the most severe life-threatening bleeds. ... [A]nd the cost to treat these patients in the hospital exceeds \$100,000."

## 3. Andexxa's Early Supply Program

65. Upon receiving FDA approval for Andexxa, the Company began a limited commercial launch in the United States in May 2018, referred to as the Early Supply Program (or "ESP"), using limited quantities manufactured under a clinical-scale process, referred to as Generation 1 (or "Gen 1") supply. The launch focused on approximately 30 to 40 hospitals that were predominantly clinical-trial sites for Andexxa, as well as and a limited number of Level I trauma centers and comprehensive stroke centers.

66. The hospitals in the ESP purchased Gen 1 Andexxa product directly from the Company at a wholesale price ranging from \$24,750 to \$49,500 depending on dosage. In a May 7, 2018 report, a William Blair analyst commented that the price was "noticeably above our expected

range of \$15,000 to \$20,000 per patient."

67. During an earnings call with investors on November 7, 2018, Garland commented that, after shifting from Bevyxxa to focus solely on Andexxa, the "top priority of Portola is Andexxa ensuring the approval of the Gen-2 supply and a successful launch."

## 4. Approval of Generation 2 Andexxa and Full Commercial Launch

68. On December 31, 2018, Portola announced in a press release that the FDA approved Portola's Generation 2 ("Gen 2") manufacturing process which provided commercial scale volume to support a global launch that could meet worldwide commercial demand over the next several years. According to the FDA Andexxa approval letter dated May 3, 2018, the FDA approved the Gen 2 product with a 24-month shelf-life. Gen 2 was to ship in 200 mg/vials compared to 100 mg/vials for Gen 1. In response to this news, shares of Portola were up \$2.43 per share (an increase of 14.22%) to close at \$19.52 on December 31, 2018, on heavy volume.

69. Prior to that approval, on a September 12, 2018 Morgan Stanley Global Healthcare Conference analyst call, Portola's Jeet Mahal, VP of Strategic Marketing (and Defendant Koenig's predecessor, who ran the ESP), talked about the process for drug utilization reviews / Pharmacy and Therapeutic ("P&T") Committee reviews (which are conducted at hospitals to consider whether and how drugs should be included in their formularies) and how long it would take to get the Gen 2 product online at hospitals. With the Gen 2 launch date set, Mahal stated that "we're going to be able to go to the hospitals and just as you allude talk to those that are able to get the P&T process started ahead of that date or at least scheduled for the first P&T or second P&T Committee meeting post PDUFA date. A lot of times these take a few months to get that schedule in order. We don't have a number in terms of a strong percentage in terms of how does that break down, but we do think that a substantial portion of the hospitals we can reach will be able to either get the P&T done ahead of time or schedule within a couple months of the PDUFA date."<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> On a May 8, 2019 conference call Defendant Koenig updated analysts on the success Andexxa was having with P&T Committee approval, stating that "[t]he majority of hospitals have made P&T decisions…[and]

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 24 of 114

70. The full commercial launch of Andexxa was announced at the January 8, 2019 conference call with investors led by Garland, where he stated, "This is by far the most important destination for Portola and that is Andexxa. I tell folks internally all the time that <u>our first, second,</u> third priority, fourth priority, fifth priority are demonstrating that Andexxa can achieve the potential that we believe that it can achieve."

#### 5. Despite the December 31, 2018 Approval For 24-Month Andexxa as Part of the Gen 2 Commercial Launch, Portola Continued to Sell and Ship 6-12 Month Short Shelf-Life Product Well Into The Class Period

71. While Garland's January 8, 2019 statement about Andexxa being Portola's real priority was made on the heels of the commercial launch of Gen 2, which could have a 24-month shelf-life, Portola continued to sell and ship Andexxa with a 6-12 month short shelf-life.

72. The decision to continue to sell that shorter shelf-life product was explained after the fact by Defendant Koenig. During an analyst conference call on January 9, 2020, after the truth about the false and material misstatements was partially revealed, Koenig explained, "On the short-dated product, it was ... between 6 and 12 months. And the reason why the decision was made to go out with that dating was to get the medicine to patients as quickly as possible."

73. Indeed, that same January 9, 2020 conference call was the first time a longer shelflife product was identified as having been shipped—starting, at most, two months prior in "November of 2019" (depending on when in the month it shipped). In the context of discussing a \$5 million charge Portola was forced to take for return reserves, Defendant Dier explained, "[L]ike I said, <u>we're already starting to shift the long-dated 36-month product. We started that in</u> <u>November [2019]</u>." Dier later said, "I'll just reiterate again, the longer-dated product has already stated selling as of November [2019], and that's 36 months."

have the product on the protocol and are using the product...," and indicating that "the review as it relates to [P&T] committee is looking at the product ... it's typically a 6 to 9 month process. Defendant Garland stated, "[O]ne of the things we've said all along is that we expected that rate to continue at a pretty linear rate, which is exactly what we're seeing and totally in line with our expectations."

## 6. Portola's Formal Return Policy

74. Portola's formal return policy, effective January 1, 2019, provided, *inter alia*:

## **Returnable Products**

Product returns will be accepted from direct (specialty distributor) and non-direct (specialty distributor's customers i.e., hospitals, clinics and pharmacies) accounts under the following conditions:

- Product returned within three (3) months prior to and six (6) months past expiration date
- Product in its original, unopened vial and bearing its original label

## 7. Change in Andexxa Distribution Model for Gen 2 Commercial Launch

75. The commercial launch of Gen 2 also resulted in a change in the Company's distribution model (where Andexxa was previously sold directly to hospitals) by selling to specialty distributors who would in turn fill Andexxa orders for hospitals. Explaining the change, Dier stated during the January 8, 2019 conference call: "[I]t is important to know that [this] is a change in how we'll recognize revenue. Everything will be recognized when we sell into the distributors."

# 8. As the Class Period Wore On, Portola Released Data Attacking The Viability of 4F-PCCs, such as Kcentra

76. On July 8, 2019, Portola issued a press release announcing new in vitro data establishing the relationship between concentrations of the direct oral anticoagulants apixaban and rivaroxaban and the ability of 4F-PCC to correct inhibition of thrombin generation, compared with warfarin anticoagulation reversal by 4F-PCCs, such as Kcentra. This was the first press release issued by Portola attacking 4F-PCCs during Andexxa's commercial launch.

77. On November 15, 2019, Portola issued a press release announcing that the Annals of Emergency Medicine, the journal of the American College of Emergency Physicians ("ACEP"), published a multidisciplinary anticoagulant reversal and replacement guidance statement. In the guidance statement, ACEP highlighted Andexxa as a first-in-line, FDA-approved reversal agent for patients treated with apixaban or rivaroxaban, "as compared to 4F-PCC [*e.g.*, Kcentra], which

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 26 of 114

are highlighted as a second-in-line option for Factor Xa reversal and recommended for use only if Andexxa is not available."

### 9. Throughout the Class Period, in Public Filings, Portola Disclosed that Demand and Utilization Were Materially Important to the Company's and Andexxa's Success

78. Throughout the Class Period, in quarterly and annual public filings with the SEC, Portola disclosed that issues surrounding demand and/or utilization were materially important to both the Company's and Andexxa's success. In each filing, Portola made clear that failure to meet expected demand and/or broad utilization (where utilization is part of marketing and sales goals) could impact Company operations, Andexxa, and the shareholders.

79. For example, in the 2018 Form 10-K filed on March 1, 2019, under Part I, Item 1A, entitled "Risk Factors," Portola warned: "If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment."

80. Under Subsection (1) to Item 1A, Portola advised that risks regarding the "<u>level of</u> <u>demand and market acceptance</u>" related directly to the Company's "<u>Financial Condition</u>" and "<u>need for additional capital</u>." This Section also noted that Andexxa product sales and the degree and rate of market acceptance of its products were risks that could affect its financing requirements.

81. Under Subsection (2) to Item 1A, Portola stated that its success depended on the launch and commercialization of its products, which depended on product "acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe." Portola explained that this included the risks of (i) "the willingness of physicians and healthcare organizations to change their current treatment practices," (ii) "the willingness of hospitals and hospital systems to include our products as treatment options," and (iii) the willingness of third party payers to pay for the Andexxa.

82. Under Subsection (7) to Item 1A, the Company flagged risks regarding (i) "the timing and amount of revenues generated from sale of our products or product candidates," and

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 27 of 114

(ii) "our ability to meet the expectations of investors related to the commercialization of our products...."

83. All of Portola's public SEC filings during the Class Period (and immediately before) contain identical or similar disclosures of risk relating to demand and/or utilization.

## C. Defendants Touted Extraordinary Demand and Utilization (Both Depth and Breadth) and Provided a Narrative of Andexxa's Unparalleled Ascension

84. As detailed in Section VI.A.2., *infra*, Defendants worked to spin a narrative to investors and analysts of extraordinary success quarter after quarter. For example:

a. **Defendants touted demand.** At the beginning of the Class Period in January 2019 and carrying through for a good part of the year, Portola and its executives were saying that demand was strong and growing. These were not disparate, static statements, but rather a consistent, constructed narrative that spun how Andexxa was excelling and thriving. They repeated this mantra over and over again. For example, on a May 8, 2019 analyst conference call, Garland stated that "enthusiasm and the desire from what we might call a nontarget hospital to stock this drug," which therefore "speaks both to the significant value of the drug as well as the desire to use the product as quickly as possible." Four months later, at a conference in September 2019, Garland said that it "feel[s] like there's a lot of momentum, wind in our sales for Portola...." Two months later in November 2019, Portola gave a presentation to analysts that stated, "Andexxa Demand is Strong and Growing."

b. **Defendants touted utilization—depth and breadth.** With regard to depth, even in August 2019, Mr. Garland said that "[t]here's nothing that we're seeing today that makes us concerned about a lack of pull through or plateauing of our utilization." And nearer the end of the Class Period, on November 5, 2019, Garland stated, "What we have seen is that, that utilization per hospital per month stays—has been staying consistent in 2019. That is with—in the context of us broadening the hospital-base to include more Tier 2 and Tier 3 accounts." And with regard to breadth, in November 2019, one executive

said on an analyst conference call, in line with similar claims made throughout the Class Period, that "Andexxa is being used in all ranges of bleeds."

c. They touted Andexxa's ascension. On August 7, 2019, Garland stated that

"Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban."

## D. Defendants' Material Misrepresentations Regarding Demand and Utilization Were Made On and in Conjunction With Key Disclosure Dates During The Class Period

85. Defendants' false and misleading representations regarding demand and utilization of Andexxa (identified, along with their reasons for falsity, in Sections V.C. and VI.A.2., *supra*) were made on dates in conjunction with the following key announcements and presentations.

# 1. January 8, 2019: Portola Announces the Broad Commercial Launch of Andexxa

86. On a January 8, 2019 conference call ("Jan. 8, 2019 Conference Call"), the date the Class Period commences, Portola announced the broad commercialization of Andexxa. The Jan. 8, 2019 Conference Call was accompanied by a slide presentation ("Jan. 8, 2019 Presentation"). On the call, the Company reported the FDA's December 31, 2018 approval of the Gen 2 manufacturing process and that the Company had officially begun shipping Andexxa to specialty distributors.

87. Garland told investors about the positive outlook of the broad commercial launch of Andexxa. Garland reported that since Andexxa first began shipping to select hospitals at the end of May 2018 through the ESP, Portola had stocked 200 hospitals, doubling the number of sites that it had begun stocking in the previous quarter.

## 2. May 8, 2019: Portola Announces Q1 2019 Financial Results

88. On May 8, 2019, the Company issued a press release announcing its financial results for the first quarter (or "Q1") ended March 31, 2019 ("May 8, 2019 Press Release") and increased Andexxa product revenue.

89. Later that day, on a conference call ("May 8, 2019 Conference Call"), Koenig represented that the "daily demand [for Andexxa] continue[s] to grow" as "hospitals will continue

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 29 of 114

to come online at a rate that is approximately consistent with what we have seen in the last few quarters." Furthermore, Garland represented that there was "enthusiasm and the desire from what we might call a nontarget hospital to stock this drug," which "speaks both to the significant value of the drug as well as the desire to use the product as quickly as possible."

90. Koenig further stated that "the amount of inventory with our distributors remained relatively constant throughout the quarter and is in line with industry norms."

91. Koenig also noted that the Company is "seeing that the utilization of Andexxa is both in ICH bleeds and also in other bleeds ... outside of ICH. So we're seeing a mix of all types of bleeds that are currently being treated." Similarly, Garland represented that he was "pleasantly surprised by the fact that [the] drug is being used broadly."

92. Regarding the P&T Committee review process, Koenig represented that the majority of the Company's 300 hospital customers <u>had conducted those hospital protocol reviews</u> and made their P&T determinations. Specifically, Koenig told investors that "[t]he majority of <u>hospitals have made P&T decisions</u>. And so the majority of them have the product on the protocol and are using the product." Koenig had previously stated that Portola expected this approval process "to continue at a pretty linear rates." When asked about the P&T Committee review process for the "300 start hospitals," Garland stated, "The majority of hospitals have made P&T decisions. So the majority of them have the product on the product...."

93. On that same day, an analyst from Cowen noted that Andexxa's reported \$20.3 million in revenue was in-line with his estimate and consensus estimates of \$20 million. The Cowen analyst noted, "Management declined to quantify the revenue contribution from hospital stocking versus end-user demand, but indicated that in January specialty distributors purchased ~\$2MM in initial inventory and that inventory remained relatively constant throughout the quarter, in-line with industry norms." The Cowen analyst also recounted that "Portola has been adding ~100 hospitals per quarter … Andexxa continues to undergo P&T reviews at institutions, a process which Portola estimates typically takes 6-9 months."

## 3. June 11, 2019: Goldman Sachs Global Healthcare Conference

94. On June 11, 2019, Garland participated in the Goldman Sachs Global Healthcare Conference ("June 11, 2019 Goldman Sachs Global Healthcare Conference Call"). Garland represented that the Company "track[s] the number of accounts that have ordered at least once," stressed that on a quarter-on-quarter basis, Portola had "about 100 new hospitals ordering each quarter," and touted that there was "<u>enough data to feel very confident in both the short- and the</u> <u>long-term trajectory of Andexxa</u>," and "[w]e've now had 4 quarters of very solid revenue, the most recent of which was \$20.3 million net."

## 4. August 7, 2019: Q2 2019 Financial Results

95. On August 7, 2019, Portola announced its financial results for the second quarter (or "Q2") ended June 30, 2019 and increased Andexxa net revenue via press release ("Aug. 7, 2019 Press Release") and analyst conference call ("Aug. 7, 2019 Conference Call"). On this news, shares of Portola traded up \$3.22, or 11.9%, to close at \$30.36 per share on August 8, 2019, on heavy volume.

96. On the Aug. 7, 2019 Conference Call, Garland reported that Portola tracked the type of usage of Andexxa by hospitals as a metric of deepening utilization, saying, "We do track that, we do track it with a chart [or poll]." After Garland represented that they tracked that information, both Garland and Koenig made multiple statements about the depth and breadth of utilization of Andexxa that were materially false and misleading. Following prior statements about exceptional demand, Garland claimed, following a recent report, that "reports like these are making it clear that Andexxa is becoming the standard of care...."

97. In a report issued that same day, an analyst at Cowen noted that Andexxa's reported sales of \$27.1 million were above the consensus and his estimate. A Credit Suisse analyst commented that, "Management highlighted that 74% of revenues this quarter were from reorders, potentially reflecting real underlying demand and hospital utilization of Andexxa."

## 5. September 10, 2019: Morgan Stanley Global Healthcare Conference

98. On September 10, 2019, during the Morgan Stanley Global Healthcare Conference

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 31 of 114

Call ("Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call"), Garland announced "\$27.1 million in net revenues for Andexxa" and assured investors of Andexxa's "broad utilization" and emphasized that Portola was hearing "from our physicians ... a lot of enthusiasm for the drug, high unmet medical need, very limited treatment options and a very large and growing problem that is urgent and life-threatening." To bolster his assertion of Andexxa's "broad utilization," Garland cited internal metrics on the increasing number of hospitals making their first, second, and third purchases of Andexxa; <u>a "regular chart audit" of hospital records for patients who have been given Andexxa</u>.

### 6. November 5, 2019: Q3 2019 Financial Results

99. On November 5, 2019, Portola announced its financial results for the third quarter (or "Q3") ended September 30, 2019 via press release ("Nov. 5, 2019 Press Release") and analyst conference call ("Nov. 5, 2019 Conference Call"), reporting total global revenue of \$36.8 million, compared to \$14.2 million for the third quarter of 2018.

100. Garland represented during the Nov. 5, 2019 Conference Call that "demand for Andexxa was strong" because of continued execution on Andexxa's launch, the rapid growth of the Factor Xa inhibitor market, and Portola's success in establishing Andexxa as "the standard of care." Garland further represented, "Our revenue is being driven by new customer additions and positive utilization trends..." and that "[w]e also hit an exciting revenue milestone in the third quarter surpassing \$100 million in cumulative net sales since our launch in May of 2018."

101. Koenig stated that "[e]xisting accounts continued to show strong pull-through, with 76% of sales in the quarter coming from utilization or reorders compared to 74% in the previous quarter" and "[t]his is an important metric because it reflects demand and significant pull-through in hospitals where Andexxa is being used to treat patients." He further stated, "Inventory in the channel remained steady at approximately two weeks of demand" and described the U.S. market as "very data rich" for use in tracking orders. Answering an analyst question about charting the types of bleeds being seen, Koenig responded, "So we do still continue our chart review on the quarterly basis. And similar to what we've reported in our previous quarters, Andexxa is being

used in all ranges of bleeds."

102. A Cowen report issued that day stated that "Andexxa/Ondexxya sales of \$35.7MM (+32% Q/Q), above consensus of \$33.6MME and our \$32.0MME... 76% of Q3 U.S. sales were from re-orders reflecting genuine pull-through of the product."

103. On November 6, 2019, Oppenheimer issued a research report stating "Andexxa 3Q revenues of ~\$36M exceeded our estimate and consensus estimate, both at ~\$33M, by adding 125 new US hospitals for a total of 550 now stocking Andexxa." Further, "[m]anagement indicates US inventory levels were essentially constant during the quarter with no incremental stocking...."

## E. Confidential Witnesses Report Fleeting Demand and Utilization In Stark Contrast to What Defendants Were Stating Publicly

104. Accounts of thirteen (13) CWs contribute to the allegations of this complaint—

seven (7) from former Portola salespeople<sup>3</sup> and six (6) from hospital and potential hospital-

- CW4 was a Thrombosis Area Manager at Portola focusing on an area in Great Lakes region of the United States from February 2019 through the end of the Class Period. CW4 said that s/he joined Portola after the FDA-approved production of the 200 mg dosage of Andexxa (Gen 2).

- CW5 was employed as a Thrombosis Area Manager for Portola focusing on an area in the Great Lakes region of the United States from February 2019 through March 2020. CW5 said that s/he was responsible for sales of Andexxa within a particular state and reported to the Regional Business Director.

- CW6 was a Thrombosis Area Manager at Portola focusing on an area in the Rocky Mountain region of the United States from July 2017 until January 2019. His/her territory consisted of a state in that region, and s/he was the only sales rep responsible for that state. S/he was initially responsible for selling Portola's Bevyxxa and then Andexxa.

<sup>&</sup>lt;sup>3</sup> Salesperson CWs were:

<sup>-</sup> CW1 was a Thrombosis Area Manager for Portola focusing on a major metropolitan area in New England from September 2018 through November 2019.

<sup>-</sup> CW2 was employed as a Regional Sales Manager for Portola focusing on an area in the Far West region of the United States from June 2017 through August 2018.

<sup>-</sup> CW3 was an Area Thrombosis Manager at Portola focusing on an area in the Southwest region of the United States between 2018 and February 2019. CW3 said s/he was responsible for marketing and sales of Andexxa for the entirety of his/her Southwestern state.

<sup>-</sup> CW12 was employed in a support position at Portola's South San Francisco headquarters from prior to the Class Period through July 2020. S/he provided support to the Commercial Sales Division and the Medical Affairs Division.

customer representatives.<sup>4</sup> As detailed *infra*, both the salesperson CWs and the hospital CWs vary geographically from regions around the United States.

105. Remarkably, the stories from both sellers' and hospitals' CWs each individually show that what they know about the key issues complained about in this Complaint are at odds with what Portola was communicating publicly. What is even more remarkable is how consistent each of their accounts are with the others in telling a story of what was actually happening, and how different a story that was from the one that Defendants were telling publicly.

### 1. Both Salesperson and Hospital CWs Report that Cost Was A Barrier To Sales and Utilization, Particularly Given the Availability of a Cheaper Alternative Such as Kcentra

106. Both hospital and salesperson CWs explained that Andexxa's high price magnitudes higher than its quasi-competitor, Kcentra (which we now know was viewed by most hospitals as a viable form of alternative during the Class Period)—was the primary impediment to selling the product.

107. For example, salesperson CW4 reported that the cost was a shock to many pharmacy directors, particularly when compared to the price of Kcentra, and it was the reason for slow sales. Salesperson CW5 stated that sales of Andexxa were not increasing in 2019, which s/he knew from his/her own observations and discussions with other sales reps—that the biggest issues

<sup>&</sup>lt;sup>4</sup> Hospital CWs were:

<sup>-</sup> CW7 was the Clinical Specialist Formulary Management and Drug Information Coordinator at a healthcare system in the Southeast region of the United States. CW7 has been in this position since October 2018.

<sup>-</sup> CW8 was the Team Leader, Ambulatory Care, Emergency Department, and a member of the cardiology team for a large regional healthcare system in the Southeast region of the United States.

<sup>-</sup> CW9 was the Director of Pharmacy (and was previously the Assistant Director of Pharmacy) at a large hospital in the Great Lakes region of the United States since April 2013.

<sup>-</sup> CW10 was the Director of Pharmacy Services at a regional hospital in the Southeast region of the United States since January 2019.

<sup>-</sup> CW11 was the Director of Pharmacy Services at a metropolitan hospital in the Southeast region of the United States since 2003.

<sup>-</sup> CW13 was the Director of Pharmacy Services at a small, rural community hospital in the Northeast region of the United States since April 2017.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 34 of 114

Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra. Salesperson CW6 reported that when Andexxa first launched, it was almost impossible to sell due to its shockingly high price, with negative feedback from hospitals, most of whom pushed back on price. Salesperson CW3 reported that s/he had push-back from the hospitals from day one due to the high price of Andexxa, noting "the hospital pharmacists were terrified of [Andexxa], and not from a clinical point; strictly from a cost point." CW6 similarly explained that s/he called on approximately 40 hospitals and 90% responded with a "flat-out 'no," and that "[a]s soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer."

108. Salesperson CWs struggled to sell Andexxa. CW3 reported that "It was a struggle for me from day one to sell Andexxa." There were approximately 150 hospitals in CW3's state, and s/he concentrated on hospitals with reported bleeding events. Yet throughout his/her tenure at Portola, CW3 was able to sell and get Andexxa stocked at just six hospitals. CW4 said that s/he was only able to sell Andexxa to one hospital while at Portola, explaining that the price of Andexxa was a shock to hospital pharmacists. CW6, who sold Andexxa when it launched in limited capacity in 2018, reported that s/he sold the drug to two Level I trauma centers with large bed capacity in his/her district, though they pushed back on pricing. S/he noted that having two large accounts purchasing Andexxa was more than what the other sales reps were able to achieve, adding that Andexxa was an "extremely tough sell." CW1, describing the work environment as "stressful" and "toxic," reported that although s/he had been in the top quarter of performers earlier in 2019, s/he was told in an April 2019 meeting with his/her regional manager that if a particular one of his/her hospitals did not use Andexxa at least twice by November 2019, s/he would be let go. CW2 reported that, like CW1, sales representatives were threatened with losing their jobs if they did not get hospitals to stock the drug.

109. Salesperson CWs were aware that the availability of a cheaper and effective alternative such as Kcentra impeded both the ability to sell Andexxa and the will to use it. As previously reported, salesperson CWs 4 and 5 noted that the cost of Andexxa was a barrier to sales,

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 35 of 114

particularly in light of alternative treatments such as Kcentra. And salesperson CW5 stated that the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra. CW3 also identified Kcentra as a cheaper alternative at a cost of between \$7,000 and \$8,000 per dose. Indeed, CW3 hosted a speaker event for the Hospital Pharmacy Society on behalf of Portola in June 2018, which was attended by 55 hospital pharmacists, and Portola paid an honorarium to a noted professor of pharmacology and clinical specialist to speak about the benefits of Andexxa. Yet while the speaker spoke very favorably about Andexxa from a clinical perspective, he told his pharmacist audience that he would never use Andexxa because it cost too much and he was "going to use Kcentra."

110. CW12—a support employee at Portola's headquarters—stated that s/he was aware from "lunchroom" conversation with people in the Sales Division that the sales of Andexxa were not going well. Of note, s/he reported that in the Spring of 2019, s/he believed that sales had "come down," recalling lunchroom conversations with frustrated sales staff about why sales were slow and not going well.

111. Salesperson CW5 explained that pharmacies made the purchasing decisions, and they told doctors who wanted Andexxa that the drug was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary. Salesperson CW4 said that the high cost of Andexxa put a strain on hospital pharmacy budgets, with salesperson CW5 explaining that insurance coverage did not affect a hospital pharmacy department's decision about whether to purchase Andexxa because third-party reimbursement tended to go back to the general hospital accounts and it may not get refunded to the pharmacy department's budget.

112. Given Andexxa's price and the availability of alternatives such as Kcentra, hospital CWs either refused to purchase the drug or else purchased limited doses and restricted its utilization to the most severe intercranial bleeds.

113. On one hand, hospital CWs 9's, 10's, and 11's hospitals refused to carry Andexxa. CW9 reported that Andexxa was rejected for the hospital's formulary not because of effectiveness, but because it was determined to be too costly to carry when compared with other treatments, and

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 36 of 114

that other PCC treatments such as Kcentra and Feiba were effective for significantly less cost. CW9 said that the cost versus benefit analysis was the only reason Andexxa is not on his/her hospital's formulary. CW10 stated that his/her hospital's Chief Clinical Officer denied a proposal from medical staff to include it on the hospital's formulary, telling the proposing group that the cost of Andexxa was too prohibitive and that there was no justification for Andexxa's high cost when they could try other alternatives, including Kcentra. And CW11 stated that the reason Andexxa was kept off the hospital's formulary was its high cost, where a cheaper and more reasonable alternative was found in Feiba.

114. On the other hand, hospital CWs 7's, 8's, and 13's hospitals/systems did ultimately agree to carry Andexxa, but with significant reservations and restrictions on its use. CW7 reported that while s/he was the person responsible for bringing Andexxa to his/her hospital system, the system had restricted its use to only life threatening intercranial bleeding, which CW7 understood to be consistent with how hospitals throughout the country were utilizing Andexxa. CW7 said that his/her system only stocked a single high and low dose of Andexxa because usage was so limited. CW7 said that if Andexxa had been cheaper, it would have gotten more usage, particularly where the clinical data showed that Kcentra was as effective in treating gastrointestinal ("GI") bleeding (and where it was cheaper). CW8 said that the cost of Andexxa is a factor when evaluating cost versus benefit, explaining that treatments such as Kcentra and Feiba have been used in the past and have been shown to be effective for less cost. CW13 reported that use of Andexxa was very restricted, and that cost was the sole reason for it—it was only used for intercranial hemorrhaging and would not even be used to treat a life-threating GI bleeding event; its usage also required the CEO's approval due to the high cost of Andexxa.

115. Relatedly, hospital CW13 explained that it was thought that if the hospital did not include Andexxa on its formulary, it could be exposed to liability. Salesperson CW4 also said that s/he believed that hospitals were initially worried about being sued if it did not carry Andexxa and a patient died following a severe bleed, and salesperson CW1 explained that s/he believed that some hospitals carried Andexxa to have it on hand as a "CYA" without intending to use it.

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 37 of 114

116. Like the hospital CWs, Salespeople CWs also knew that Portola was not being broadly utilized. Salesperson CW1 reported that Andexxa was not being broadly utilized, given all the restrictions on usage imposed by hospitals that purchased it. One hospital that s/he covered had in place very restrictive use protocols for the drug, only allowing it to be used for life-threating intracranial bleeding and requiring several layers of approval before it could be administered. Salesperson CW3 sold Andexxa to the largest health system, who informed him/her that Andexxa would be restricted to their two flagship hospitals. Salesperson CW5 reported that "all" of his/her accounts placed restrictions on the use of Andexxa due to its cost. And while CW6 says that s/he sold the drug to two Level I trauma centers, these trauma centers pushed back on the pricing of Andexxa and restricted the drug's use.

117. And, in fact, salesperson CW5 reported that even while the sales numbers were steady, some hospitals were stocking up while doing little reordering. Hospital CW7 also attributed the early rise of Andexxa sales to hospitals "stocking up" on the drug.

## 2. Andexxa's Relatively Unique Posture as an Orphan Drug Whose Patient and Treater Populations Were Not Easily Identifiable, and Whose Cost as an Inpatient Drug Was Part of the Hospital Pharmacy Budget, Posed Particular Sales Challenges

118. Salesperson CW4 described the challenges of selling Andexxa given the <u>type</u> of orphan drug it was. CW4 noted that Andexxa was an orphan drug because of the limitations on its use and the minimal off-label indications, and that it was this limited number of possible patients that allowed Andexxa to be classified as an orphan drug. CW4 explained that in this way Andexxa was different from other orphan drugs: with others, one is generally aware of the number of patients with the rare indications (and, presumably, which specialists treat them). But Andexxa presented particular challenges, as CW4 explained, because Andexxa was an in-patient drug that comes out of the hospital pharmacy's budget, it caused hospitals to put strict procedures in place for when and how to allow the drug's use.

## 3. Hospital CWs Report That Data was Weak from Both the Initial Clinical Trial of Andexxa and Subsequent Studies Pushed By Portola Near the End of the Class Period

119. Hospital CWs said that the data on Portola was weak. Hospital CW7 said that the data presented in the clinical trial was "flimsy," and that the data on Kcentra indicated it was as effective in many of the same situations as Andexxa. And hospital CW8 attributed limitations in his/her hospital system's use of Andexxa to, in part, data presented in Portola's clinical trials. Even salesperson CW1 said that the data on the effectiveness of Andexxa was not supportive enough to justify the cost versus the potential benefit.

120. CWs also mentioned that Portola attempted to address lagging demand later in the Class Period by conducting new studies and releasing new data. For example, CW1 reported that Portola attempted to address the cost versus benefit problem by conducting a new study and presenting additional data on Andexxa's effectiveness, but said that s/he did not believe that data changed anyone's opinion of the drug. In line with that, CW8 stated that the results of an additional study that Portola conducted of Andexxa were presented at the American Society of Hospital Pharmacists convention in December 2019 in Las Vegas, Nevada, and that, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions.

## 4. CWs Support the Notion that Portola's Generous Return Policy Together With Its Continued Sale of Short Shelf-Life Product Reduced Risk for Hospitals Considering the Purchase of That Soon-Expiring Product, as It Could Be Returned After Expiration Without Penalty

121. Salesperson CWs statements support the notion that Portola's very generous return policy together with short shelf-life product obviated some risk for hospitals considering the purchase of that short shelf-life product. Salesperson CWs 1, 3, 5, and 6 all noted the Company's policy to allow for returns on expiring products. Salesperson CW5 explained that some of his/her smaller hospital accounts had expressed concern about the short shelf-life, and the return policy was a way to mitigate risk for that. Salesperson CW5 heard from other sales reps that beginning in the second half of 2019, there was an increase in the volume of returns, which s/he described as a large amount of returns of Andexxa. (Portola had continued to sell short shelf-life Andexxa into 2019 when Gen 2 was authorized for release (¶¶68,71-73).) Consistent with that, CW6 reported that Andexxa clients were told that if their order was fulfilled, they may receive some short-dated product, but that Portola offered to replenish any that went unused within the specified shelf-life. And while salesperson CW6 did not report many returns before s/he left in January 2019 just as Gen 2 was approved for selling, s/he heard about returns accelerating after s/he left Portola. S/he was told by "a lot of people across the country that there were large health systems that were returning Andexxa." These returns were not tied to Q4 2019 and happened before then.

122. Salesperson CW5 also reports that many hospitals that originally ordered the 100 mg dosage returned them to Portola for the larger dosage when it became available.

# 5. The Issues Described by Salesperson CWs Were Pervasive Throughout The Class Period, and In No Way Limited To Q4 2019

123. The salesperson CWs, in aggregate, stated that the difficulty selling Andexxa was a

pervasive problem throughout the Class Period (and before) and were not isolated incidents or ones that

surprised Portola and its management near the end of the Class Period.

- CW3 made clear that sales were stagnant throughout his/her time selling the drug at Portola (2018–February 2019).
- CW4 reported that sales of Andexxa were slow throughout the entire time that s/he worked at Portola and sold Andexxa (February 2019–end of Class Period).
- CW5 reported that, based on his/her own observations and discussions with other sales reps during his/her time at Portola (February 2019–March 2020), the rate of sales was not increasing during 2019 and that some hospitals were stocking up but did little reordering.
- CW6 stated that there were issues selling Andexxa throughout the time s/he was selling Andexxa until s/he left (in January 2019); further, during the limited ESP launch, it was almost impossible to sell due to its shockingly high price.
- CW12, who worked at headquarters throughout the Class Period, stated that, in the Spring of 2019, s/he understood that sales had "come down," recalling lunchroom conversations with sales staff about discussing that sales were not going well.

#### 6. Salesperson CWs Were Geographically Diverse and Describe the Nature of Selling Andexxa in Their Territories and The Make-up of Their Potential Hospital Base

124. While salesperson CWs were geographically diverse, their potential hospital-

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 40 of 114

customer base differed depending on their location. For example, CW3, responsible for marketing and sales to the entirety of his/her Southwest-region state, noted that there were approximately 150 hospitals in his/her state and that s/he concentrated on hospitals with reported bleeding events. Salesperson CW4, who focused on an area in the Great Lakes region of the United States, reported that there were 12-15 hospitals in his/her sales area and that s/he called on 5 or 6. S/he overlapped with two other salespeople, and there were 7 salespeople in his/her state. Salesperson CW5 stated that sales areas were determined by zip code, and that while s/he had no recollection of how many hospitals were in his/her region, s/he would have focused on Tier 1 hospitals and ultimately had 6 accounts that s/he covered. And salesperson CW6 was responsible for a state in the Rocky Mountain region of the United States, an area for which s/he was the only sales rep responsible, and that while she called on approximately 40 hospitals, the vast majority (approximately 90%) rejected him/her immediately.

#### 7. Both Salesperson and Hospital CWs Describe How Senior Management Knew about the Critical Demand and Utilization Impediments

125. Salesperson CWs report that Portola's senior management (including Garland) were aware of the lack of demand and utilization of such Andexxa. Salesperson CW1 said that Portola management "100%" knew that high cost versus benefit is why hospitals don't use Andexxa and that the few hospitals that carry Andexxa place restrictions on its use. Salesperson CW3 said that during a "one on one" meeting with his/her boss, an Area Business Director, they discussed the high cost of Andexxa and that the price of the drug was prohibitive. When CW3 suggested lowering the price, s/he reported that her boss's response was that the Company could not lower the price because it would cause the stock price to go down and drive away venture capital. Salesperson CW5 said that, from his/her perspective, the Portola sales force frequently advised management that the cost of the drug was hindering sales. According to CW5, the response from management was that the price was not going to be reduced. CW5 reported that s/he "always" informed his/her Regional Business Director of the issue. Salesperson CW6 reiterated that the high price of Andexxa was "absolutely" discussed at <u>all</u> sales meetings. CW6

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 41 of 114

stated that Portola was such a small company and that everyone was connected, so it would be impossible for the CEO and CFO to assert that they were unaware that sales of Andexxa were "nonexistent because of its egregious pricing."

126. Salesperson CW6 recalled reporting to management at the end of 2018 that hospitals balked at the high price of Andexxa. S/he had started selling Andexxa in May 2018 and had been part of a separate sales group that visited clients between May and June 2018. The feedback that his/her group had received from the hospitals was that Andexxa was too expensive. S/he then attended two meetings at the end of 2018 where the Company wanted the feedback from these hospitals and reasons for why Andexxa was not on their formulary. It was at that point that CW6 responded as reported.

127. The cost-as-barrier-to-sales was discussed at regional and national calls and meetings, some (if not all) of which Garland attended.

128. Salesperson CW5 reported that there were national sales calls organized by the Vice President of Sales, Randy St. Laurent (who reported directly to Defendant Koenig), and that Defendant Garland spoke at some. Salesperson CW4 reported that s/he participated in Portola national sales calls, describing them as "rah rah" sessions. Salesperson CW5 also said that during these calls, cost as the cause of slow sales and the implementation of restrictions was "always" discussed. When Garland addressed the issue, CW5 said that he would articulate value of the drug over the issue with cost.

129. Salesperson CW5 also reported that there was a national sales meeting held in San Francisco. CW5 recalled that Defendant Garland spoke there (as did VP of Sales Randy St. Laurent), who again articulated value over cost, just as on sales calls. Salesperson CW4 also reported attending a companywide national sales meeting in San Francisco.

130. CW6 stated that s/he attended four sales meetings a year, some district meetings and some national meetings. These meetings were generally held in a hotel in San Francisco near Portola's headquarters. The executives at these meetings always asked, "Where is our take? What are the customers saying? What are the issues?" S/he indicated that everyone knew what the

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 42 of 114

feedback was from the hospitals. CW6 explained that there were open discussions about issues, particularly the cost. S/he and other sales reps had discussions with managers, and s/he believes that the managers shared those concerns with the executive management. During breakout sessions by region, cost was a big concern. CW6 reported that sales reps were asked "what we were hearing [about cost] and how did we respond to the customers."

131. Portola employee CW12 reported on "town hall" meetings consistent with the description of national meetings described *supra*. CW12 stated that the meetings were generally held after quarterly analyst calls and announcements, and were led by Garland and others. Garland was accompanied by other members of the senior executive team, including Defendant Dier. They were held in the San Francisco headquarters with conference lines open for those calling in from other locations. CW12 stated that during "many town hall meetings," slow Andexxa sales were discussed as was the high price of the drug, which was said to be hindering sales. CW12 stated that Defendant Garland "danced around" those issues and did not address them directly.

132. Hospital CWs were also confident that Portola was aware of the cost-asimpediment-to-sales and -utilization issue. Hospital CW7 stated that s/he told the Portola sales reps covering the system what restrictions the hospital system put in place on Andexxa, and the Portola salespeople would try to advocate for getting the restrictions expanded to include other indications, such GI bleeding. Hospital CW8 said Portola was aware that hospitals were restricting the use of Andexxa, that the cost of Andexxa was the reason the drug was not put on the hospital's formulary, and that Portola conducted an additional study on Andexxa and presented at a conference in December 2019 in Las Vegas, Nevada. Hospital CW9 said that s/he knew that his/her team communicated the cost issue directly to officials at Portola, and that it was his/her opinion that Portola knew that the issue with Andexxa is cost, and not efficacy. And hospital CW13 stated that s/he and others at his/her hospital pressed the Portola sales representative to get the price of Andexxa lowered, and that representative said that s/he would do his/her best to get the price lowered.

133. Salesperson CW6 explained that management used CRM software provided by

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 43 of 114

Salesforce to track sales and demand. CW6 explained that all management had access to the CRM and, based on his/her experience in the industry, they "absolutely" tracked sales number daily, if not hourly. And salesperson CW1 shed more light on what was tracked by the CRM software, explaining that sales reps were required to enter certain information into the system such as the name of the hospital, when the hospital was contacted, whether and when the P&T Committee is meeting about Andexxa, and, if Andexxa was purchased, what restrictions the hospital placed on prescribing Andexxa. CW1 said that Portola management knew that Andexxa is not widely used even by hospitals that carry it.

## F. The Truth Starts to be Revealed

# 1. Portola Admits that Andexxa Demand is Flat, Utilization is Decreasing, the Company Under-Reserved for Product Returns, and There was Excessive Product in the Distribution Channel

134. After market close on January 9, 2020, Portola issued a press release ("Jan. 9, 2020 Press Release") stating that total net U.S. Andexxa revenue was projected to be \$24 million for the fourth quarter of 2019, down from \$33 million the prior quarter (a 27% decline), and that global net revenue was projected to be \$28 million for the quarter, which was 32% lower than the \$41 million consensus estimate. The press release stated that fourth quarter Andexxa net sales in the U.S. were impacted primarily by two factors: (i) a "\$5 million gross to net adjustment due to a return reserve for short-dated product"; and (ii) "[f]lat quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts." Portola further stated that it "believes that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets."

135. During a conference call at 5:00 p.m. ET on January 9, 2020 ("Jan. 9, 2020 Conference Call"), Dier conceded that "[w]e haven't given our gross-to-net estimate publicly, but the \$5 million does represent short-dated product return reserve adjustment for this quarter. So obviously, that had an impact on the gross to net, but that represents a little bit of a catch-up and a little bit about what we project going forward for the short-dated product." Dier further explained that "[w]e do think this onetime adjustment takes in effect a little bit of what came back <u>during the</u>

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 44 of 114

year and what may come back going forward with some short-dated products still outstanding. But going forward, our reserves will be calculated into our gross to net on a more normalized basis. And like I said, we're already starting to shift to the long-dated 36-month product. We started that in November. So we feel good about this one adjustment." Dier further stated that the reserve addresses "both" "what's been returned, <u>it's a little bit of catch-up for the year</u>, and then you need to make an estimate of what you think may be returned based on what you've seen so far. <u>That's</u> just accounting for return reserves.... And then moving forward, we'll have our classic return reserve adjustment as part of our gross-to-net calculation.... I'll just reiterate again, the longerdated product has already stated selling as of November, and that's 36 months."

136. Koenig noted, "On the short-dated product, it was ... <u>between 6 and 12 months</u>. And the reason why the decision was made to go out with that dating was to get the medicine to patients as quickly as possible." Garland added, "I should emphasize that the dating of 6 to 12 months is when it got to the distributor. <u>What the actual dating was when it was shipped to the</u> <u>end customer, we don't have that visibility</u> ...."

137. On January 14, 2020, Garland participated in a corporate updated call ("Jan. 14, 2020 Corporate Update Call") where he revealed that, in addition to the two factors disclosed in the Company's fourth quarter 2019 earnings release, Andexxa's net <u>revenue was also impacted by</u> "lower distributor purchases to manage inventory" in order "to keep their inventory levels at a <u>constant level in the fourth quarter</u>." In doing so, Portola essentially admitted that its distributors were so overstocked with Andexxa product that they had stopped ordering new inventory or reduced their orders.

138. During this call, Portola used the same form of investor presentation used throughout the Class Period but removed the slide from the Company's three prior earnings presentations that "Andexxa Demand is Strong and Growing." The presentation materials used on the call also detailed the three factors that had "primarily" impacted fourth quarter sales: (i) "\$5 million gross to net adjustment due to return reserve for short-dated product," (ii) "[f]lat Q/Q demand due to a decrease in utilization, primarily in Tier 1 accounts," and (iii) "[1]ower distributor

purchases to manage inventory."

# 2. The Announcement of the Company's Q4 and Full-Year 2019 Results (1) Reveal that Andexxa is Floundering and Portola is Forced to Focus Like A "Laser" on it by Streamlining Organizationally and (2) Provide Disappointing Utilization Guidance Going Forward

After the close of market on February 26, 2020, Portola announced its financial 139. results for the fourth quarter and full year 2019 in a press release ("Feb. 26, 2020 Press Release") and held a conference call ("Feb. 26, 2020 Conference Call") that revealed in more detail the serious problems with hospitals' adoption of the Andexxa drug and further reinforced investors' concerns after the Company's pre-announcement of financial results the previous month. Portola reported in the Feb. 26, 2020 Press Release that total global revenues for the fourth quarter of 2019 were \$29.2 million and total revenues from sales of Andexxa/Ondexxya were \$28.4 million. Portola further reported that total global revenues for FY 2019 were \$116.6 million, \$111.5 million of which were from sales of Andexx/Ondexxya. Portola also reported that it had sustained a fourth-quarter loss of \$96.7 million (\$1.24 per share) and a FY 2019 loss of \$290.7 million (\$4.06 net loss per share). Portola noted that its outsized loss for the quarter encompassed a \$27.5 million charge, which it attributed to inventory and manufacturing write-offs in line with its decision to discontinue the final remnants of operations related to Bevyxxa (which had been limited to 10 hospitals after its catastrophic launch in May 2018). Id. In its press release, the Company explained that its internal restructuring was necessary in order "to align resources to drive Andexxa growth."

140. On the Feb. 26, 2020 Conference Call, Dier outlined the key financial results, including that total revenue for 2019 was \$116.6 million, \$111.5 million of which was revenue from Andexxa sales, and that total revenue for Q4 2019 was \$29.2 million, \$28.4 million of which was from Andexxa sales.

141. On the Feb. 26, 2020 Conference Call, Garland admitted that the Company was "disappointed" with Andexxa's fourth quarter performance, as it saw "variability" in its business operations:

# Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 46 of 114

While we are disappointed with the results in the fourth quarter, we gained important insights into the potential variability of our business and the impact that it can have at this stage of our launch. We are confident that Andexxa will continue to grow in 2020 and beyond. And it is our goal to provide annual revenue guidance once we have more visibility into these growth trends.

142. In an effort to assuage investors' concerns over the future of Andexxa, Garland outlined the "important steps" that the Company was taking, including an internal restructuring, to "realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share." He explained, "[W]e are laser focused on driving near-term revenue growth. To support this strategy, we have taken three important steps to realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share." This included a "completed ... internal restructuring that aligns with our strategic plans to support Andexxa and Ondexxya [the international version of Andexxa]. We are streamlining our efforts and reducing spend on early stage and development programs in order to focus our resources on the Andexxa revenue drivers and lifecycle management."

143. Also, during the Feb. 26, 2020 Conference Call, Koenig stated, "In 2019, we added 425 new hospital customers for a total of 640 accounts that have ordered Andexxa.... <u>As we progress in 2020, we expect to add approximately 350 new hospital accounts throughout the year.</u>"

144. During the Feb. 26, 2020 Conference Call, analysts repeatedly pressed the Company for more insight on Andexxa Q1 utilization trends, but Company refused to provide this insight. For example:

<u>Vikram Purohit - Morgan Stanley</u>: Two from my side. Both kind of focused on the utilization reviews that you alluded to when you pre-announced 4Q '19 sales. So first off, <u>I wanted to see if you have any visibility into how utilization is trended</u> in the Tier 1 centers that were reported to have and stated DURs [drug utilization reviews] in 4Q'19? And then, secondly, to the extent you have visibility on the topic. Do you have any additional centers year-to-date 2020 that have been stated similar DURs?

**<u>Garland</u>**: Thanks for the question, Vikram. So the focus of the call today is on Q4 and year-end. We look forward to giving you an update on both revenue and trends for Q1. And that's pretty much in line with our practice, which is to stick with the

quarter, when we're talking about the quarter call.

145. With regard to Portola's claim that drug utilization reviews (*i.e.*, P&T Committee reviews) somehow curtailed revenue, Koenig acknowledged his comments at Gen 2 launch about that process: "[A]s we talked about the drug utilization reviews [(*i.e.*, P&T Committee reviews)], when we did our pre-announce, first again, institutions are always going to conduct drug utilization reviews. This was common among all hospital products and not just Andexxa." Despite that, Koenig did not acknowledge in any way that he and Garland had <u>previously stated in Q1 2019 that</u> a majority of hospital accounts had already conducted such reviews, nor did he acknowledge why reviews would curtail usage at this time in Q4 2019.

# 3. Portola Issues its 2019 Form 10-K and Admits that the Marketing of Andexxa and Resistance to Utilization by Hospital Formulary Committees Was Adversely Impacted by Competition with Off-Label Use of 4F-PCCs

146. On February 28, 2020, after the market closed, Portola filed its 2019 Form 10-K. In this Form 10-K, the Company provides detailed figures regarding its \$5 million adjustment and additional provisions for returns as discussed in detail in Section VI.A.1.b., *infra*. The underlying figures detailed that the additional amount provisioned for return reserves for 2018 sales was \$2.373 million (or an additional 91% on top of the original \$2.611 million provision), and that as of December 31, 2018, only \$299,000 of the *original* \$2.611 million of reserves remained (*i.e.*, approximately 11.5%) for all future returns on 2018 sales—sales that could be returned for as long as an additional 18 months.

147. In its 2019 Form 10-K, the Company also added critical new language to its risk disclosures that highlighted that Portola's "ability to grow our company is critically dependent upon the commercial success of Andexxa" that did not appear in prior SEC filings, effectively admitting that Andexxa had been encountering material difficulties in selling Andexxa in 2019 due to competition from "widely used" 4F-PCCs, a common standard of care preceding Andexxa and potential inadequacies in the initial studies relied upon to obtain FDA approval of Andexxa through the Accelerated Approval process. The new language provides in relevant part:

For example, we do not have comparator arm data, including clinical head to head data against the treatment options which were used by hospitals prior to the availability of Andexxa, which we believe continue to be widely used, including off-label use of 4F-PCCs and other coagulation factors. In addition, the efficacy statements in our product label are limited as the result of our single-arm, open-label study. These limitations have a significant impact on our ability to market Andexxa and establish it as the standard of care, as pharmaceutical companies are generally prohibited from making product claims not set forth in their product labels. These limitations can also increase resistance to utilization by hospital formulary committees and may also negatively impact government pricing discussions in the EU and abroad.

148. The language from the 2019 Form 10-K cited in ¶147, *supra*, is a rigorous reworking and supplementation of a prior disclosure seen, for example, in the Q3 2019 Form 10-Q, which did not provide the critical examples of these limitations or that 4F-PCCs such as Kcentra continued to be widely used and the deficiencies in the original ANDEXXA-4 study.

# 4. The Alexion Acquisition is Announced and Consummated

149. Less than three months following the end of the Class Period, on May 5, 2020, Alexion Pharmaceuticals, Inc., a Delaware corporation ("Alexion"), and Portola issued a joint press release announcing the execution of an Agreement and Plan of Merger ("Acquisition Agreement") by and among Alexion as Parent and Portola relating to a planned tender offer of all of the outstanding shares and common stock of Portola (the "Acquisition") (the "Acquisition Announcement").

150. On May 27, 2020, Alexion filed its tender offer statement on Schedule T/O. Alexion offered to purchase the shares of Portola at \$18.00 per share net to the holder of each such share. This \$18 per share price was 231.96% more than the May 4, 2020 price of \$7.76 (the day before the Acquisition Announcement), but far lower than the trading prices between the Class Period start and the last trading date before the first partial disclosure, which ranged from \$22.18 to \$37.67. As discussed in ¶241, *infra*, this Acquisition price was only agreed to on February 27, 2020, after end of Class Period stock drops.

# VI. EXCHANGE ACT VIOLATIONS

# A. Defendants' Material Misrepresentations

151. Throughout the Class Period, Defendants repeatedly issued false and misleading statements that there was strong demand for Andexxa and that Andexxa was being broadly utilized by hospitals. These statements omitted substantial negative information concerning Andexxa, which it was under a duty to disclose when it made these statements.

152. During the Class Period, Defendants issued several categories of materially false and misleading statements regarding its financial results, namely materially false and misleading (i) misrepresentations regarding the Company's compliance with GAAP, including ASC 606, and its own revenue recognition policy ("Revenue Recognition Policy"), (ii) net revenue figures, and (iii) SOX Certifications ("Financial Reporting Statements"). These statements were false and misleading because the Company recognized revenue upon sell-in to its distributors without sufficient relevant historical sales and return data with which to conclude that it was "probable" that there would not be a significant reversal in the amount of reversal due to returns, in violation of ASC 606.

# 1. Defendants Issued Materially Misleading Statements About Its Financial Reporting With GAAP

153. The following provides the background regarding the applicable GAAP and then describes why Portola's Financial Reporting statements are materially false and misleading.

# a. Summary of Applicable GAAP

154. As an SEC registrant, Portola was responsible for issuing and fairly presenting its consolidated financial statements in accordance with GAAP and SEC Rules. Responsibility for preparing the financial statements in conformity with GAAP lies with management. *See, e.g.*, professional standards adopted by the Public Company Accounting Oversight Board ("PCAOB"), PCAOB Auditing Standards ("AS") 1001.

155. During the Class Period, authoritative GAAP were promulgated by the Financial Accounting Standards Board ("FASB") and contained within the FASB's ASC (or "FASB

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 50 of 114

Codification"). GAAP includes not only broad guidelines of general application, but also detailed practices and procedures, including implementation guidance and related examples. Those conventions, rules, and procedures provide a standard by which to measure financial presentations. Rules and interpretive releases of the SEC under the authority of the federal securities laws are also sources of relevant GAAP for SEC registrants, such as Portola. *See* ASC 105-10-05-01.

156. GAAP is established in recognition of the numerous financial reporting objectives, including providing "financial information about the reporting entity that is useful to existing and potential investors, lenders, and other creditors in making decisions about providing resources to the entity." *See Statement of Financial Accounting Concepts No. 8, Conceptual Framework for Financial Reporting*—Chapter 1, *The Objective of General Purpose Financial Reporting*, and Chapter 3, *Qualitative Characteristics of Useful Financial Information*, Financial Accounting Standards Board (Sept. 2010), at ¶OB2, OB12, BC1.24, QC6.

157. SEC Regulation S-X (17 C.F.R. § 210.4-01) provides that: "Financial statements filed with the [SEC] which are not prepared in accordance with [GAAP] will be presumed to be misleading or inaccurate." 17 C.F.R. § 210.4-01(a)(1).

158. Per ASC 250-10-S99-1, a misstatement or omission is material if there is "a substantial likelihood that a reasonable person would consider it important." ASC 250-10-S99 further notes that an "omission or misstatement of an item in a financial report is material if, in the light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item." *Id.* GAAP also notes that the formulation of materiality in the accounting literature is in substance identical to the formulation used by the courts in interpreting the federal securities laws. *Id.* Evaluating the importance of a misstatement or omission requires that materiality be evaluated using each of the following two lenses separately: (1) is the misstatement or omission quantitatively important; and (2) is the misstatement or omission qualitatively important? *Id.* 

159. Quantitatively, ASC 250-10-S99 acknowledges the practice of applying a "rule of

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 51 of 114

thumb" threshold (e.g., 5% of an item) to provide a "preliminary" basis for evaluating materiality.

160. <u>Qualitatively</u>, ASC 250-10-S99 recognizes that factors can render misstatements less than the 5% benchmark material, such as (i) "whether the misstatement concerns a segment or other portion of the registrant's business that has been identified as playing a significant role in the registrant's operations or profitability," and (ii) "whether the misstatement hides a failure to meet analysts' consensus expectations for the enterprise."

161. While companies may supplement GAAP earnings with non-GAAP measures, all SEC Registrants must report revenue figures in compliance with GAAP. *See*, *e.g.*, SEC Regulation G (17 C.F.R. §244.100).

162. Of importance here, the FASB issued ASC 606 (Financial Accounting Series, Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* [Topic 606]) on May 28, 2014 ("FASB Accounting Standards Update No. 2014-09"), and it became effective as a GAAP rule for annual and quarterly reporting periods beginning after December 15, 2017. ASC 606 sets forth the core principle that an entity may only recognize net revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services and thus requires an entity to evaluate every sales agreement in detail to recognize revenue.

163. The adoption of ASC 606 was a significant change in GAAP. Revenue recognition guidance prior to ASC 606 was comprised of broad revenue recognition concepts and included numerous, distinct revenue requirements for particular industries or transactions. *See* FASB Accounting Standards Update No. 2014-09, at p. 1. At times, the previous lack of a single revenue standard resulted in different accounting for economically similar transactions under GAAP. *Id.* ASC 606 was therefore established in part to: (i) create a more robust framework for addressing revenue recognition issues, (ii) remove inconsistencies and weaknesses in the legacy revenue recognition guidance, and (iii) reduce the complexity of applying revenue recognition guidance. *Id.* Of particular note, ASC 606 reduced the number of requirements to which an entity must consider in recognizing revenue. *Id.* Rather than referring to several locations for guidance within

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 52 of 114

the FASB Codification, ASC 606 provides companies like Portola with a single, comprehensive framework for determining and reporting its product revenue. FASB Accounting Standards Update No. 2014-09, at p. 2.

164. ASC 606-10-05-4 permits the recognition of revenue according to the following five step process: (i) identify the contract(s) with a customer (Step 1), (ii) identify the performance obligations in the contract (Step 2), (iii) determine the transaction price (Step 3), (iv) allocate the transaction price to the performance obligations in the contract (Step 4), and (v) recognize revenue when (or as) the entity satisfies a performance obligation (Step 5). <u>Step 3—the transaction price</u> is the relevant step here.

165. When rights of return exist, ASC 606-10-32-01 through ASC 606-10-32-14 impose additional requirements to determine the transaction price (Step 3). This is because the amount that a company will receive may vary. In these circumstances, there are two relevant considerations that generally must be accounted for when determining the transaction price and assessing whether to recognize revenue pursuant to ASC 606.

166. An entity generally begins by estimating the consideration it expects to receive from its customer contracts, giving consideration to estimated reductions in the contract price and related credits or refunds associated with product returns. Estimated reductions to the contract price for sales returns results in a reduction of the transaction price through the recognition of sales provisions" and a corresponding refund liability or "reserve."<sup>5</sup>

167. Then, the entity must further consider whether to limit or "constrain" the contract price, net of estimated reserve provisions, when a company is unable to <u>conclude that it is probable</u>

<sup>&</sup>lt;sup>5</sup> Portola only reports <u>net</u> revenue, that is, gross revenue (which is based on price charged to customers) minus reserves and related sales provisions for (i) estimated returns, (ii) government rebates and chargebacks, (iii) fees paid to specialty distributors and wholesales, and (iv) cash discounts. Reserves, as used in this context, generally represent refund liabilities that exist and are reflected on the Company's balance sheets. Reserves are generally established to account for future estimated product returns or credits. *See* 2019 Form 10-K at 52 and 2018 Form 10-k at F-13. Related sales "provisions" are used to either establish additional reserves for future estimated product returns or account for product returns not previously reserved for. Unless otherwise stated, all references to revenue herein are to net revenue.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 53 of 114

that a significant revenue reversal will not occur in future periods once the uncertainty (*e.g.*, of product return) is resolved. To the extent an entity is unable to conclude that it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur, it is precluded from including such amounts in the transaction price and recognizing revenue (*i.e.*, the revenue recognition constraint). Therefore, the amount of constraint determined necessary as part of this second consideration may negate some, or all, of the estimated transaction price, net of product return reserves estimated as part of the first consideration described *supra*.

168. In assessing whether it is probable that a significant reversal in the amount of cumulative revenue will not occur, ASC 606-10-32-12 requires the consideration of both the likelihood and the magnitude of the potential revenue reversal, including consideration of whether: (i) the amount of consideration is highly susceptible to factors outside the entity's influence, including a high risk of obsolescence of the promised good or service, (ii) the uncertainty about the amount of consideration is not expected to be resolved for a long period of time, (iii) the entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value, (iv) the entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances, and (v) the contract has a large number and broad range of possible consideration amounts.

169. To be clear, this consideration (of whether it is probable that a significant reversal in the amount of cumulative revenue will not occur) is generally required even when the estimated transaction price is reduced by estimated sales reserves (*e.g.*, reserves for product returns, chargebacks, etc.). Stated differently, the ASC 606 constraint requires <u>additional</u> consideration beyond management's estimate of product return reserves.

170. This constraint assessment is generally to be performed at the transaction level, such that a particular contract may allow for recognition of some or all revenue while others may not allow for any recognition of revenue. However, an expected value may be an appropriate estimate of the amount of variable consideration if an entity has large numbers of contracts with

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 54 of 114

similar characteristics. ASC 606-10-32-8 defines the expected value as being the sum of probability-weighted amounts in a range of possible consideration amounts. Nevertheless, even when using the expected value method, appropriate consideration must still be given to reasonably conclude whether or not it is "probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

171. When ASC 606 was first issued, the FASB explained that: "Many respondents agreed that it was necessary to include some form of constraint on the recognition of revenue that results from variable consideration because a significant portion of errors in financial statements under previous revenue recognition guidance have related to the overstatement or premature recognition of revenue. ... This is because revenue is an important metric and users of financial statements explained that it is critical that those estimates of variable consideration be included in revenue only when there is a high degree of confidence that revenue will not be reversed in a subsequent reporting period." FASB Accounting Standards Update No. 2014-09, at ¶BC204.

172. Most companies can rely on product-specific historical evidence to reasonably estimate product returns, overcome the revenue constraints, and recognize revenue under ASC 606, but that is not always the case for entities selling new products. While only some portion of revenue may require constraint under ASC 606, GAAP explicitly recognizes that deferral of all revenue associated with a new product sale is deemed necessary where there exists "the right of return and the lack of relevant historical evidence." Indeed, Implementation Example 26 of 606-10-55, Implementation Guidance and Illustrations, at ¶606-10-55-229, states:

The entity does not recognize revenue when control of the product transfers to the customer. <u>This is because the existence of the right of return and the lack of relevant historical evidence means that the entity cannot conclude that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in accordance with paragraphs 606-10-32-11 through 32-13. Consequently, revenue is recognized after three months when the right of return lapses.</u>

173. ASC 606 does not mandate that a company lacking some historical evidence cannot recognize any revenue until the right of return lapses. However, sufficient relevant evidence must

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 55 of 114

exist to overcome that constraint, include amounts in the transaction price and recognize all or a portion of the revenue for one or more contracts either upfront or after the initial sale. Such evidence may include, for example, (i) the actual use of the product by a patient such that it cannot be returned, (ii) insights into distributor sell-through trends (orders or a lack thereof to specific hospitals/end-users) to identify and reduce, in part, the constraint impact based on the indicated exposure to short-dated product returns, and (iii) insights directly from the hospital/end-user channel from a salesforce and/or other sources, including communications with customers regarding consumption/usage, product-related concerns, and possibility of returns given the expected roll-out of longer-dated product. If the constraints are overcome with respect to some or all of the amounts, they may be included in the transaction price and that related amount may be reported as net revenue, provided that other revenue recognition requirements have been satisfied. And since an entity must update the estimated transaction price each reporting period pursuant to ASC 606-10-32-14, it can account for changes in transaction price and may report revenue that had been previously constrained.

174. As discussed in Section VI.A.1.b., *infra*, the facts here indicate that the factors did not permit Portola to overcome the constraints when it sold Andexxa to distributors, particularly given (i) that distributors <u>and hospitals</u> each had a right to return all Andexxa product sold before the end of the Class Period since it was short-dated, (ii) demand trends to which the CWs spoke, including that demand was limited due to price and availability of Kcentra and similar drugs, (iii) utilization trends to which the CWs spoke, including that even hospitals that purchased Andexxa limited its use to only the most dire life-threatening bleeds such as intercranial bleeds, (iv) the Company's February 2020 concession that it lacked visibility into what the expiration date was when product was sold by distributors to hospitals, (v) the Company's February 2020 concession that utilization had declined in 2019, (vi) the Company's February 2020 concession that it knew that Kcentra and other 4F-PCCs were still being used over Andexxa, and (vii) that excess supply had accumulated in the distribution channel. Accordingly, the embedded and omitted facts underlying Defendants' application of ASC 606 were false and misleading.

### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 56 of 114

175. As a practical matter, the fact that revenue recognition is constrained <u>does not</u> <u>prevent the Company from explaining</u> their product sales transactions to the market. If an entity, like Portola, is constrained from including amounts in its transaction price and recognizing related revenue, it can still report the amounts that had been constrained and not included in net revenue. It could do so through disclosures associated with related refund liabilities established on its balance sheet in connection with the constraint, including disclosure of the amounts excluded from its transaction price(s) and/or explanation of the nature of the related liability. Indeed, Portola understood this—it did constrain and disclose related amounts in connection with collaboration agreements entered into in 2014 and 2016 (*i.e.*, agreements for the development and commercialization of products) with both (i) BMS and Pfizer, and (ii) Daiichi Sankyo, as set forth in the 2019 Form 10-K at F-19 thru F-21.

176. Importantly, it appears that Portola <u>determined not to separately constrain any</u> of its Andexxa product revenue pursuant to ASC 606-10-32-11, as evidenced by two facts. First, unlike what it disclosed for the collaboration agreements with BMS and Pfizer and Daiichi Sankyo, Portola provided no disclosures regarding explicit constraints on transaction price and related product revenue for sales of Andexxa to its customers. Second, in its balance sheet and related disclosures, Portola only reported line items primarily for returns, chargebacks, and other distribution fee reserves, with no explicit mention of separate refund liabilities associated with the revenue constraint. That is, while refund liabilities may include both reserves and constraints on revenue, there is no indication that the refund liabilities figures included anything other than the estimated returns, chargebacks, and other distribution fee reserves.

# b. Defendants Issued Materially False and Misleading Statements Regarding Portola's Compliance With GAAP, ASC 606, and Its Own Internal Policy

177. Throughout the Class Period, the Company represented in each of its financial reports issued during the Class Period that it prepared its financials in compliance with GAAP, including its (i) 2018 Form 10-K, (ii) Q1 2019 Form 10-Q, (iii) Q2 2019 Form 10-Q, and (iv) Q3 2019 Form 10-Q (collectively, the "Financial Reports"):

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 57 of 114

a. The 2018 Form 10-K stated: "[t]he accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ('U.S. GAAP')."

b. The Q1 2019 Form 10-Q, the Q2 Form 10-Q and the Q3 2019 Form 10-Q each stated: "[t]he unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ('U.S. GAAP'), and follow the requirements of the Securities and Exchange Commission ('SEC') for interim reporting.... These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of our financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and related financial statements and the related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 1, 2019 with the SEC."

c. The August 7, 2019 Registration Statement incorporated by reference the 2018 Form 1-K, Q1 2019 Form 10-Q and Q2 2019 Form 10-Q and, thus, the false and misleading statements regarding compliance with GAAP.

178. In its 2018 Form 10-K, at 60-61, the Company issued false and misleading statements in its Revenue Recognition Policy regarding its compliance with ASC 606. It expressly stated that it would only recognize net revenue in compliance with ASC 606—that is, where it was "probable that a significant reversal" of the cumulative amount recognized would not occur and that it would deduct from gross revenue forms of various considerations as constrained:

#### *Revenue recognition*

On January 1, 2018, we adopted Accounting Standards Codification ("ASC"), Topic 606 (ASC 606), Revenue from Contracts with Customers, using the modified retrospective method to all contracts that were not completed as of January 1, 2018. ... The results for our reporting periods beginning on and after January 1, 2018 are presented under ASC 606....

Pursuant to ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. <u>To determine revenue</u> recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

# Product Revenue, Net

Prior to January 2018 we had no product revenues. <u>We sell Andexxa and Bevyxxa</u> to a limited number of specialty distributors and wholesalers in the United States ("Customers"). These Customers subsequently resell our products to hospitals, pharmacies and long-term care centers. ...

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances....

# Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, copay assistance and other allowances that are offered within contracts between us and our Customers, group purchasing organizations, payors and other indirect customers relating to our product sales. These reserves as detailed below are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net

### product revenue and earnings in the period such variances become known.

\* \* \*

*Product Returns*: We generally offer Customers a right of return based on the product's expiration date or other market-based factors for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities using available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel.

179. Because ASC 606 applies to all product sales, it applies to sales of Andexxa. During the Class Period, the Company reported revenues for both Andexxa and total revenue. Andexxa (including sales in Europe) represented 99.5% and 99.8% of total product sales in 2018 and 2019, respectively.

180. The representations in each of the Financial Reports that the Company complied with GAAP, ASC 606, and its stated Revenue Recognition Policy (¶¶178-79) in recognizing product revenue were materially false and misleading because the Company lacked a reasonable basis to recognize some or all the revenue reported under ASC 606. More specifically, Defendants lacked sufficient relevant historical evidence and other facts to conclude "that it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur," to report the net revenue reported upon sell-in to its distributors.

181. That Portola lacked a reasonable basis, including relevant historical evidence and other factual bases, to conclude it was "probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur" is demonstrated by a confluence of the following facts.

182. <u>First</u>, the Company did not have sufficient relevant historical sales and return data with which to conclude that it was "probable" that there would not be a significant reversal in the amount of reversal due to returns. While relevant historical evidence could be either company-specific (same product, similar product, etc.) or market-specific historical experience, the Company admittedly lacked both.

183. The Company lacked sufficient <u>company-specific</u> relevant historical sales data for

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 60 of 114

either Andexxa or any similar product. Indeed, as it admitted in its 2018 Form 10-K issued at the beginning of the Class Period, "We are an early stage commercial biopharmaceutical company. We launched our first commercial products in 2018." Andexxa only received FDA approval for limited ESP sales in May 2018 and for commercial sale on December 31, 2018. As stated in its 2018 Form 10-K, the Company's had no meaningful sales history for its products because "product revenue consists of the U.S. sales of Andexxa, which we began shipping to customers in May 2018, and the U.S. sales of Bevyxxa, which we began shipping to customers in January 2018. Prior to January 2018 we had no product revenues." Indeed, as of December 31, 2018, the Company only reported global product net revenue of \$24.1 million and net product revenue was reported as only \$111.6 million and its net product revenue for Andexxa was only \$104.5 million. In its 2018 Form 10-K, the Company further conceded that "[w]e are still in the early stages of developing our sales and marketing infrastructure."

184. The Company also lacked any <u>market-specific</u> historical data because it repeatedly claimed that there were no comparable products on the market from a sales perspective. As the Company noted in its 2018 Form 10-K, "there are no therapies other than Andexxa approved specifically as antidotes for Factor Xa inhibitors." The Company repeatedly pressed this position throughout the Class Period, including in each Form 10-Q issued during the Class Period and in its 2019 Form 10-K. At a November 14, 2019 Investor Day conference, Dr. Alvin Schmaier, an oncologist speaking on behalf of Portola, said that Andexxa "is focused towards an unmet need and that is correction of bleeding of individuals who are on these oral anti-Xa. There is no comparative." In Portola's Jan. 14, 2020 Corporate Update Call, Garland touted that "Andexxa is a unique drug. It's a highly innovative novel therap. It was granted breakthrough designation and orphan drug status by the FDA." He also noted that "Andexxa is a highly differentiated drug." During the Feb. 26, 2020 Conference Call, Garland further noted that "Andexxa is a novel product, addressing an unmet need in a large and growing market." While there were other drugs that were used off-label as such a therapy, none of these were sold at the exorbitant prices at which Portola

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 61 of 114

sold Andexxa, a fact that goes to the core of its (impeded) commercial marketability and, thus, the viability of its revenue.

185. <u>Second</u>, the Company could not overcome the constraints against revenue recognition when the factors set forth in ASC 606-10-32-12 regarding both the likelihood and the magnitude of the potential revenue reversal are considered, as demonstrated by the confluence of the following facts, all of which existed contemporaneously with the Company's decision to recognize revenue:

a. Because Portola's formal return policy dated January 1, 2019 (¶74), which was in effect throughout the Class Period, allowed for the return of product from distributors <u>or</u> hospitals between three months prior to six months past its expiration date, unused product sold during the Class Period was subject to return throughout the Class Period. Indeed, by way of example, a hypothetical 12-month dated product sold in December 2018 could be returned as late as June 2020. As Koenig explained during the Jan. 9, 2020 Conference Call, the Company was selling 6- to 12-month dated product during the Class Period because "the decision was made to go out with that dating ... to get the medicine to patients as quickly as possible." As CWs 5 and 6 explained, hospitals relied on the liberal return policy when purchasing short-dated product. *See* ¶121.

b. Defendants also knew that unused product sold prior to late 2019 would be subject to an additional heightened risk of return in Q4 2019 because Portola was ramping up a longer-dated (36-month) product, which the Company started selling in November 2019. ¶¶135-36. Given Portola's liberal return policy, this created an increased likelihood of return of the shorter-dated product as the longer-dated product became available, thereby creating further uncertainty as to whether a significant reversal of consideration would be required for short-dated Andexxa contracts. And, as noted *infra*, the Company lacked visibility into the date of products resold to hospitals.

c. The uncertainties surrounding market acceptance, due in part to the high cost of the drug and a viable alternative, further affected Portola's ability to conclude that

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 62 of 114

a significant reversal of revenue was not probable, thereby creating serious sales and product-use obstacles. Indeed, as the hospital and salesperson CWs reported, (i) the high price of Andexxa was hindering sales, (ii) demand for Andexxa was not strong since many hospitals refused to order Andexxa, choosing instead to purchase Kcentra and other alternatives due to cost (and potentially other) concerns, and (iii) hospitals that were ordering Andexxa were restricting its usage to life threatening bleeds both because of cost concerns and the lack of clinical data to support broader utilization. ¶¶106-18. As noted *supra*, Portola admitted in its SEC filings that its financial results were directly correlated to these very factors. ¶¶78, 80-83.

186. <u>Third</u>, that Defendants' lacked a reasonable basis to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur," thereby precluding upfront recognition of the reported revenue during the Class Period, is further demonstrated by the confluence of the following admissions by the Company at the end of the Class Period:

a. Portola did not track what the expiration date was when Andexxa was sold by distributors to hospitals. Garland disclosed that point on the Jan. 9, 2020 Conference Call: "I should emphasize that the dating of 6 to 12 months is when it got to the distributor. <u>What the actual dating was when it was shipped to the end customer, we don't have that</u> <u>visibility</u>, but that's essentially what it was when we shipped to our distributors." ¶136. This lack of visibility into the end-user customer channel created further uncertainties regarding the risk and magnitude of product returns.

b. The Company, on January 9, 2020 and February 26, 2020, admitted that there was a decrease in utilization, primarily in Tier 1 accounts (¶¶134-35, 139) (which is entirely consistent with what the CWs reported was occurring throughout the Class Period) (*e.g.*, ¶¶114-16), and that they lacked visibility into utilization trends going forward.

c. The Company issued new risk disclosures in the 2019 Form 10-K conceding, for the first time, that (i) Portola knew that Kcentra and other 4F-PCCs were

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 63 of 114

still being used over Andexxa (consistent with the CW reports), and (ii) the fact that Andexxa lacked clinical data comparing its efficacy with that of "widely used" 4F-PCCs like Kcentra had affected its ability to compete with a common standard of care preceding Andexxa. This alternative treatment gave rise to further uncertainty about market acceptance and use of Andexxa, thereby creating further uncertainty about whether the product would be returned.

d. Portola admitted that distributors had accumulated excess inventory by Q4
2019, reflecting weakness in market demand and heightening the risk of product returns. *See* ¶137. As the Company had admitted in its filings, it had "visibility into the inventory remaining in the distribution channel."

187. <u>Fourth</u>—and significantly—that Defendants lacked a relevant reasonable basis with which to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur" is further evidenced by the fact that, in its 2019 Form 10-K for FY 2019 audited financials (issued after the end of the Class Period), Portola did, in fact, make significant reversals of revenue previously recognized in 2018, made adjustments to its sales reserves and related provisions, and increased its percentage reserves in Q4 2019.

188. A review of the details of the FY 2019 reserves and adjustments demonstrates that the reserves taken in 2018 for sales in 2018 were <u>drastically insufficient</u>. This led Portola to reverse a significant amount of revenue previously recognized for sales in 2018 just after the Class Period ended in February 2020, as demonstrated by analyzing pages F-5, F-18, and F-39 of the 2019 Form 10-K filed at that time, copies of which are appended hereto as Exhibits 3, 4 and 5, respectively. The following describes this analysis.

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 64 of 114

189. In 2018, the Company reported a sales provision of \$3.533 million, \$2.611 million of which were for returns (Ex. 4 (F-18)), and net sales of \$24.117 million (Ex. 3 (F-5)), which adds up to estimated gross amounts invoiced of \$27.65 million. This means that, as of December 31, 2018, the Company established a return reserve of 9.4% of 2018's gross sales (\$2.6 million as a percentage of gross invoiced amounts of \$27.65 million). *See* excerpt of Ex. 4 (F-18):

	Returns		Chargebacks		Others		Total	
Balance at December 31, 2017	\$ _	\$	_	\$	_	\$	_	
Provision related to sales made in:								
Current period	2,611		289		633		3,533	
Prior period	_		_		_		_	
Payments and customer credits issued	(2,312)		(113)		(409)		(2,834)	
Balance at December 31, 2018	\$ 299	\$	176	\$	224	\$	699	
Provision related to sales made in:								
Current period	10,254		4,026		3,988		18,268	
Prior period	2,373		_		_		2,373	
Payments and customer credits issued	(5,366)		(3,303)		(1,550)		(10,219)	
Balance at December 31, 2019	\$ 7,561	\$	899	\$	2,661	\$	11,121	
		_		_				

190. What we also learn in the 2019 Form 10-K at page F-18 is that, as of December 31, 2018, (i) \$2,312,000 of that 2018 return reserve was for payments and customer credits issued (*i.e.*, returns already made), and (ii) the unused portion of the 2018 reserve for returns was only \$299,000. Ex. 4 (F-18). This means that only \$299,000 was left at the end of December 31, 2018 to cover credits or payments in connection with all future returns for 2018 sales. That is, as of December 31, 2018, 8.4% of 2018 sales had actually been returned during 2018, leaving only 1% remaining on the 9.4% reserved for future returns of product sold in 2018. Yet, product sold in 2018 could be returned for up to another 18 months beyond the end of 2018. This is particularly significant since over 58% of 2018 sales occurred in Q4 2018. *See* Ex. 3 (F-5) and Ex. 5 (F-39).

191. To be clear, the fact that there is an unused \$299,000 in the 2018 reserves as of December 31, 2018 does not mean that the reserves taken in 2018 were sufficient. Reserves are generally established to cover all returns on product sold in a particular year (here, 2018), including returns that come in after that year on sales made during that year.

192. Despite the obvious fact that the reserves for FY 2018 sales were critically

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 65 of 114

insufficient, Portola waited until the end of FY 2019 to address this. Portola's 2019 Form 10-K (filed February 28, 2020) demonstrated that the unused portion of the reserves as of December 31, 2018 proved to be insufficient due to returns made in 2019 of product originally sold in 2018, as follows.

193. Portola's 2019 Form 10-K discloses that an additional \$2.373 million of the Company's 2019 "provision related to sales" was designated for "prior period" sales, *i.e.*, sales made in 2018. *See* Ex. 4 (F-18). That means that, by December 31, 2019, an additional \$2.373 million of 2018 gross sales were returned or were expected to be returned on top of what had already been provisioned for initially in 2018 (\$2.611 million). *Id*.

194. Thus, while Portola's actual and future 2018 product-return provisions as of December 31, 2018 approximated just \$2.611 million, actual and expected product returns relating to 2018 sales were ultimately determined to be \$4.984 million as of December 31, 2019 (*i.e.*, the sum of the \$2.611 million provision established in 2018 plus the \$2.373 million additional provision <u>for 2018</u> and <u>established in 2019</u>). This equates to a provision for returns of 2018 sales of approximately 18% of 2018 gross invoiced sale amounts (\$4.984 as a percentage of gross sales).

195. This additional return reserve taken at December 31, 2019 means that Portola determined as of that date that its 2018 sales provisions were understated by 91%.

196. This significant reversal of Portola's originally reported 2018 net sales during 2019 is important in that the revenue constraint requirements established under ASC 606, with which the Company purported to comply, existed to avoid this very situation. As described by the FASB, this revenue constraint existed so that "those estimates of variable consideration be included in revenue only when there is a <u>high degree of confidence</u> that revenue <u>will not be reversed in a subsequent reporting period</u>." FASB, Accounting Standards Update No. 2014-09, at **(BC204**.

197. Portola's improper recognition of revenue in contravention of ASC 606 constituted a widespread, significant, and material overstatement of revenue (where Andexxa was Portola's sole viable product). This is, in part, evidenced by the significant reversal of Portola's originally reported 2018 net sales during 2019 (but which does not speak to the improper recognition of 2019 Andexxa

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 66 of 114

sales, which included a significant amount of short shelf-life product).

198. Moreover, recognizing the insufficiency of its prior reserves, the Company admitted on January 9, 2020 that it had to incur a \$5 million gross-to-net adjustment "due to a return reserve for short-dated product" in FY 2019, which Defendant Dier described as "a little bit of catch-up for the year." ¶¶134-35. As Defendant Dier further explained on the Jan. 9, 2020 Conference Call, this \$5 million "adjustment takes in effect a little bit of what came back during the year and what may come back going forward with some short-dated products still outstanding," and going forward reserves would be calculated on <u>a more normalized basis</u>." ¶135.

199. Even further, while the total sales provisions as a percentage of reported net revenue ranged between 10.5% to 13.5% in Q1 2019 and Q3 2019, respectively, they jumped to 24% in Q4 2019—just after the Class Period—a stark and obvious indication that the provisions established during the nine months ended September 30, 2019 were insufficient.<sup>6</sup>

200. In sum, the facts that (i) Portola had to take a \$5 million adjustment at FY 2019 year-end, (ii) a significant reversal in the amount of revenue previously recognized during 2018 was indeed necessary and reported in the FY 2019 audited financials, and (iii) and the significant increase in reserves taken in Q4 2019, combined with the facts demonstrating that revenue should have been constrained (including lack of sufficient, relevant historical experience, liberal rights of returns for all Class Period sales, issues regarding market acceptance of Andexxa as compared to Kcentra, and building inventories in the channel) collectively demonstrate that Defendants lacked the "high degree of confidence" necessary to conclude that "revenue would not be reversed" and violated ASC 606 in recognizing revenue.<sup>7</sup>

201. These false and misleading statements regarding the Company's compliance with GAAP, ASC 606, and Portola's stated Revenue Recognition Policy were both qualitatively and

<sup>&</sup>lt;sup>6</sup> These figures are derived from Portola's 2019 Form 10-K, at F-5, F-18, F-39; Q1 2019 Form 10-Q, at F-2, F-10; Q2 2019 Form 10-Q, at F-2, F-9, F-10; Q3 2019 Form 10-Q, at F-2, F-10.

<sup>&</sup>lt;sup>7</sup> Plaintiffs do not concede that even Portola's 2019 Form 10-K reserves and related sales provisions were adequate or sufficiently complied with GAAP. Indeed, since Portola merged with Alexion, it is unclear whether any adjustments to reserves taken in 2019 were necessary.

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 67 of 114

quantitively material.

202. From a <u>qualitative</u> perspective, the fact that the Company failed to comply with GAAP and ASC 606 was material in several ways.

a. First, revenue was a critical metric. The Company represented that sales and market acceptance of Andexxa were critical to the Company's financial results, operations and investor value. ¶¶78, 80-83.

b. Second, analysts focused on these issues, posed questions about these issues, and based their recommendations and price targets on this information. *E.g.*, ¶¶93, 97, 102-03, 143, 261-68, 272-77. Indeed, based on the revenue reported, Portola consistently met or beat consensus estimates for FY 2018 and in the first three quarters of 2019, as analysts noted. *See* ¶¶93, 97, 102-03.

c. Third, as discussed in Section VI.C., Loss Causation, *infra*, the market reacted to the January and February 2020 news that (i) Andexxa demand was flat due, in part, to a decline in utilization, (ii) a \$5 million adjustment to reserves due to a return reserve for both catch up of actual returns of short-date product and projected future returns, and (iii) preliminary results were significantly below consensus estimates due to the significant returns and truth about demand and utilization. The price drops were significant and based on unusually high trading volume.

d. Fourth, in connection with the Company's 2019 Form 10-K, its auditors, E&Y, flagged Portola's accounting practices for product return reserves as a "Critical Audit Matter" (or "CAM"). The language of the relevant SEC order makes clear that a CAM, by definition, amounts to an admission that reserves were "material" to Portola's financial statements.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> See Public Company Accounting Oversight Board; Order Granting Approval of Proposed Rules on the Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion, and Departures From Unqualified Opinions and Other Reporting Circumstances, and Related Amendments to Auditing Standards, SEC Release No. 34-81916, File No. PCAOB-2017-01, 82 Fed. Reg. 49886-01 (Oct. 23, 2017).

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 68 of 114

203. From a <u>quantitative</u> perspective, as noted *supra*, the Company's upfront recognition of revenue violated GAAP. That is, the absence of a relevant reasonable basis, including relevant historical evidence and other factual basis, with which to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur" precluded Portola from recognizing revenue upon delivery. As such, the Company's net revenue figures for both 2018 and 2019 were recognized out of period. Even assuming a portion of the net revenue could have been recognized under the ASC 606 constraints, as noted *supra*, a quantitatively material portion of 2018 revenue was reverse in 2019—that is, 9.8% of Portola's originally reported net product revenue, far above the rule-of-thumb 5% referenced by the SEC (\$2.373 million in reserves taken in 2019 as a percentage of the \$24.117 million net product revenue reported in 2018).

# c. Having Failed to Comply with GAAP and ASC 606, Defendants' Net Revenue Figures were Materially False and Misleading

204. Portola reported net revenue figures and other financial figures based on the net revenue figures. These include the following statements:

- The 2018 Form 10-K reported product revenue of \$24.1 million for 2018.
- The March 1, 2019 press release announced Andexxa net revenue of \$14 million for Q4 2018.
- At a March 1, 2019 conference call ("Mar. 1, 2019 Conference Call"), Garland touted that "I'm very pleased to report Q4 2018 net revenues of \$14 million. This is our third consecutive quarter of strong revenues for Andexxa and reflects solid demand."
- Dier stated at the Mar. 1, 2019 Conference Call that "total revenues were \$15.3 million for the fourth quarter and \$40.1 million for the full year 2018. Total revenues for the quarter included \$1.2 million in license and collaboration revenue."
- Dier stated at the Mar. 1, 2019 Conference Call that "net sales of Andexxa grew to \$14 million, a more-than-80% increase over the previous quarter and our third consecutive quarter of strong Andexxa revenues. This brings the 2018 revenues of Andexxa to \$24 million."
- The May 8, 2019 Press Release reported total net revenue of \$22.2 million for Q1 2019, as compared to \$6.6 million for the first quarter of 2018, and total net revenue of \$20.3 from Andexxa sales.

- At the May 8, 2019 Conference Call, Garland, Dier, and Koenig reported Q1 2019 Andexxa net revenue of \$20.3 million and Garland reported total net revenue of \$22.2 million.
- Dier stated on the May 8, 2019 Conference Call statement that Portola "had a strong first quarter with Andexxa revenues growing 45% of its fourth quarter and expenses in line with our guidance for the full year."
- The Q1 2019 Form 10-Q reported net revenue of \$20.3 million of Andexxa sales and revenue of \$22.2 million in Q1 2019.
- Garland stated at the June 11, 2019 Goldman Sachs Healthcare Conference Call that "[w]e've now had 4 quarters of very solid revenue, the most recent of which was \$20.3 million net."
- The Aug. 7, 2019 Press Release announced that "Andexxa® Net Product Revenues Grow to \$27.1 Million ... [t]otal revenues for the second quarter of 2019 were \$28.4 million, compared with \$4.0 million for the second quarter of 2018."
- On the Aug. 7, 2019 Conference Call, Garland stated that "our team's exceptional execution on the launch of Andexxa is driving continued revenue growth. For the second quarter, net product revenues for Andexxa were \$27.1 million, marking our fifth consecutive quarter of strong revenue."
- On the Aug. 7, 2019 Conference Call, Dier stated that "[t]otal revenues were \$28.4 million for the second quarter driven by \$27.1 million in net revenues of Andexxa."
- The Q2 2019 Form 10-Q reported revenue of \$27.1 million for Q2 2019.
- The August 7, 2019 Registration Statement incorporated by reference the following documents that contained materially false and misleading net revenue figures: (i) the 2018 Form 10-K, (ii) Q1 2019 Form 10-Q, and (iii) Q2 2019 Form 10-Q.
- Garland stated at the Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call that about \$27.1 million in net revenue for Andexxa.
- The Nov. 5, 2019 Press Release reported total net global revenue of \$36.8 million, compared to \$14.2 million for the third quarter of 2018, and that the total global net revenue included \$35.7 million in net product revenue from sales of Andexxa/Ondexxya.
- At the Nov. 5, 2019 Conference Call, Garland stated that "[i]n the third quarter, net product revenues for Andexxa were \$35.7 million. This includes \$33 million in net product sales for Andexxa in the United States and \$2.7 million in net product sales of Ondexxya in our wave 1 countries in Europe."
- At the Nov. 5, 2019 Conference Call, Garland stated that "[w]e also hit an exciting revenue milestone in the third quarter surpassing \$100 million in cumulative net sales since our launch in May of 2018."
- At the Nov. 5, 2019 Conference Call, Koenig stated that "[t]hese initial

revenues of \$2.7 million reflect demand since the majority of sales to date are direct to hospitals, unlike the U.S., where we distribute via wholesalers. All of this underscores the unmet need and demand in Europe for Andexxa."

- At the Nov. 5, 2019 Conference Call, Dier stated that "[t]otal revenues were \$36.8 million for the third quarter driven by \$35.7 million in global net revenues of Andexxa."
- The Q3 2019 Form 10-Q reported (i) \$32.95 million for Andexxa net product revenue for the Q3 2019, and (ii) \$80.33 million in net revenue for Andexxa for the nine-months ending September 30, 2019.

205. Each of these reported revenue and related financial figures were materially false and misleading because the Company failed to comply with ASC 606 when it recognized revenue up front despite its inability to reasonably conclude that a significant reversal in the amount of revenue would not occur for the same reasons as set forth in ¶¶180-96, 198-200 (falsity) and ¶¶197, 201-03 (materiality), *supra*, regarding the GAAP violations. *See also* Regulation S-X (17 C.F.R. § 210.4-01(a)(1)) (financial statements filed with the SEC which are not prepared in compliance with GAAP are presumed to be misleading or inaccurate, despite footnote or other disclosure).

# d. The Company's Internal Control Over Financial Reporting Failed to Prevent or Detect Portola's Violation of ASC 606 and Rendered Defendants Garland's and Dier's SOX Certifications Materially False and Misleading.

206. Garland and Dier each signed SOX Certifications attesting to the purported accuracy and completeness of the Company's financial and operational reports as well as statements concerning Portola's internal controls and procedures, in the 2018 Form 10-K, the Q1 2019 Form 10-Q, the Q2 2019 Form 10-Q and the Q3 2019 Form 10-Q. These SOX certifications were nearly identical:

- 1. I have reviewed this annual report on Form 10-K of Portola Pharmaceuticals, Inc.;
- 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;

- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.<sup>9</sup>
- 207. There were no qualifications or limitations in any of these SOX Certifications

<sup>&</sup>lt;sup>9</sup> In yet a further certification appearing as Exhibit 32.1 to the 2018 Form 10-K, both Garland and Dier certified that "[t]he information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 72 of 114

contained in the 2019 Form 10-Qs indicating that the 2018 Form 10-K could no longer be relied upon. As such, the direction to read the 2019 Form 10-Qs in conjunction with the 2018 Form 10-K constituted a continuing affirmation of those certifications.

208. Each of these SOX Certifications (including the representation that the Company's financial statements fairly present the Company's financial condition) were materially false and misleading for the same reasons as set forth in ¶¶180-96, 198-200 (falsity) and ¶¶197, 201-03 (materiality), *supra*, regarding the GAAP violations. For example, the absence of effective controls to prevent or detect Portola's failure to comply with GAAP during the Class Period was a material weakness in internal controls. Accordingly, management's assurances regarding the effectiveness of the Company's internal control over financial reporting, including the existence of no material weaknesses, were false and misleading.

#### 2. Defendants Issued False and Misleading Statements About Demand and Utilization of Andexxa, Falsely Portraying the Commercial Launch of Andexxa as a Success

209. Throughout the Class Period, Defendants created a false impression of the state of affairs at the Company. Defendants repeatedly reassured investors that Andexxa demand was "strong and growing" and was being "broadly" and "deeply" utilized by hospitals. As a result, the Company portrayed that it had "strong execution" on the Andexxa commercial launch and that Andexxa was becoming the standard of care as the treatment of life-threatening or uncontrolled bleeding in patients treated with rivaroxaban or apixaban. These statements were false. However, even if some are argued to be literally true—and they are not—the context and manner of their presentation make them false and misleading statements that do not have the ability to inform, but instead mislead, investors. *See, e.g.*, Section V.D., *supra*.

210. The following are a series of false and misleading statements that Andexxa demand was strong and growing and that growth was on a linear trajectory:<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> Underlined quoted statements are alleged to be false and misleading, while other statements are provided for context.

- "<u>Andexxa Demand is Strong and Growing</u>." (Jan. 8, 2019 Presentation.)
- "This is our third consecutive quarter of strong revenues for Andexxa and reflects solid demand." (Garland, Mar. 1, 2019 Conference Call.)
- That "our first quarter results continue to <u>reflect strong demand for</u> <u>Andexxa</u>, as well as focused execution on our commercial launch." (May 8, 2019 Press Release.)
- "Andexxa <u>Demand in the U.S. is Strong and Growing</u>." (May 8, 2019 presentation, which was used at the May 8, 2019 Conference Call.)
- That "<u>daily demand continue[s] to grow</u>." (Koenig, May 8, 2019 Conference Call.)
- "<u>This is our fifth consecutive quarter of strong revenue growth reflecting</u> our exceptional launch execution and <u>continued demand for Andexxa</u>." (Aug. 7, 2019 Press Release.)
- "<u>Andexxa Demand in the U.S. is Strong and Growing</u>." (Aug. 7, 2019 presentation, which used the Aug. 7, 2019 Conference Call.)
- "<u>There is continued strength and demand for Andexxa</u>...." (Garland, Aug. 7, 2019 Conference Call.)
- "Our second quarter results reflect the fifth consecutive quarter of strong launch, execution and growing demand for Andexxa." (Dier, Aug. 7, 2019 Conference Call.)
- That it "<u>feel[s] like there's a lot of momentum, wind in our sales</u> for Portola. We announced on our quarterly call \$27.1 million in net revenues for Andexxa. That was our fifth consecutive quarter of strong revenue growth and also expectation-beating revenues. So very solid there." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- "In Q3, we delivered <u>strong Andexxa revenue growth</u> in the United States ... our team's <u>strong execution on the launch</u> of Andexxa in the United States." (Garland, Nov. 5, 2019 Conference Call.)
- "<u>Our performance in the third quarter is a testament to the strong growth</u> since launch and <u>long-term potential of our business</u>." (Koenig, Nov. 5, 2019 Conference Call.)
- "Our financial results reflect strong growth of Andexxa in the U.S. and an initial demand in Europe." (Dier, Nov. 5, 2019 Conference Call.)
- "<u>Andexxa Demand is Strong and Growing</u>." (November 5, 2019 presentation, which was used at the Nov. 5, 2019 Conference Call.)
- 211. The following are a series of false and misleading statements that Andexxa was

being "deeply" utilized by hospitals:

- "[<u>U]tilization on a per hospital level [] deepen[s]</u> both as physicians get used to the product and as hospitals continue to go through their protocol development." (Garland, May 8, 2019 Conference Call.)
- "I do know that when we spoke to customers about <u>Q4 utilization, the</u> <u>number one reason was actually supply. That was probably the main reason</u> <u>why accounts did not order</u>." (Garland, Jan. 8, 2019 Conference Call.)
- "The majority of hospitals have made P&T decisions. So the majority of them <u>have the product on the protocol and are using the product</u>." (Koenig, May 8, 2019 Conference Call.)
- "So everything that we're seeing so far in terms of the launch kinetics points to a <u>deepening and a pull-through of utilization</u>." (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference Call.)
- "Also last week, the Joint Commission known as JCAHO, the oldest and largest accrediting body for hospitals and med care [ph] issued a new report on DOACs. The report directs accredited hospitals and critical care centers to stock anecdotes appropriate for the use with each type of anticoagulant. Reports like these are making it clear that Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban." (Garland, Aug. 7, 2019 Conference Call.)
- "[W]hat we're seeing is increased usage over time or deepening usage over time. There's nothing that we're seeing today that makes us concerned about a lack of pull through or a plateauing of our utilization." (Garland, Aug. 7, 2019 Conference Call.)
- "Adding new accounts is just one part of ensuring continued growth. The second component is <u>deepening utilization within existing accounts and we are seeing encouraging trends</u>." (Koenig, Aug. 7, 2019 Conference Call.)
- "I will tell you we're really happy with what we're seeing both in terms of new account adds as well as <u>deepening [ph] of utilization</u> and we'll certainly give you updates as we move forward." (Garland, Aug. 7, 2019 Conference Call.)
- "[W]hat we're seeing is increased usage over time or <u>deepening usage over</u> <u>time</u>." (Garland, Aug. 7, 2019 Conference Call.)
- "[W]hat we're seeing is real <u>pull-through at hospitals</u>." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- "What we have seen is that, <u>that utilization per hospital per month stays</u> <u>has been staying consistent in 2019</u>. That is with—in the context of us broadening the hospital-base to include more Tier 2 and Tier 3 accounts." (Garland, Nov. 5, 2019 Conference Call.)
- 212. The following are a series of false and misleading statements that Andexxa was

being "broadly" utilized by hospitals:

- Koenig also noted that the Company is "<u>seeing that the utilization of</u> Andexxa is both in ICH bleeds and also in other bleeds outside of ICH. So we're seeing a mix of all types of bleeds that are currently being treated." (Koenig, May 8, 2019 Conference Call.)
- Garland noted the Company is "pleasantly surprised by the fact that [the] <u>drug is being used broadly</u>, to the label, obviously. But it's definitely not being used in a specific type—bleed type like intracranial hemorrhage." (Garland, May 8, 2019 Conference Call.)
- "[W]e're actually seeing <u>broad usage across all bleed types</u> not necessarily focused on intracranial hemorrhage." (Garland, May 8, 2019 Conference Call.)
- "[W]e are definitely <u>seeing usage in patients outside of the intracranial</u> <u>hemorrhage space</u>." (Garland, Aug. 7, 2019 Conference Call.)
- "[W]e're seeing actually is <u>broad utilization</u>. We're not seeing it niched to just intracranial hemorrhage.... But like I said, <u>what we are seeing is usage broadly</u>." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- "<u>Andexxa is being used in all ranges of bleeds</u>. So not only intracranial hemorrhage, but also GI bleeds, trauma related compartmental bleeds. So we're seeing it being used across all bleed types." (Koenig, Nov. 5, 2019 Conference Call.)

213. The underlined statements in ¶210, that the Company was experiencing strong demand and linear growth were affirmative statements of present fact that were materially false and misleading when made because the Company was in fact facing substantial obstacles and significant negative feedback from hospitals in marketing Andexxa during the Class Period, suggesting neither strong ongoing demand nor linear growth.

214. The underlined statements in ¶¶211-12, that Andexxa was experiencing "broad" and "deepening" utilization and usage were affirmative statements of present fact that were materially false and misleading when made because contrary to the Company's statements Andexxa was encountering significant resistance from hospitals and their drug utilization review committees which placed severe restrictions on Andexxa usage when stocked because of the high cost coupled with limited clinical data and an available more cost-effective alternative.

215. The series of false and misleading statements identified in ¶¶210-12 are statements

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 76 of 114

of fact and not forward looking statements. Rather, references to such things as current "demand," utilization, and utilization trends (both depth and breadth) are informed by past information, current understanding, and current knowledge of what is expected in the future. Further, Defendants knew at the time they made their statements that demand and utilization trends were not expected to continue as they were suggesting, making them false and misleading present statements of fact. Finally, even if they are considered to contain forward looking statements—and they are not—they would be statements containing a mixture of past, current, and forward looking facts, making them actionable.

216. That demand was neither strong nor robust and that Andexxa was not "broadly" and "deeply" being utilized is evidenced by the following consistent statements by geographically diverse Portola (i) former employees, and (ii) hospital customers and potential hospital-customers:

a. statements by both salesperson and hospital CWs that cost was a barrier to both sales and utilization (¶106-09, 111-13, 116);

b. statements by both salesperson and hospital CWs that the availability of cheaper alternatives to Andexxa such as 4F-PCCs (*e.g.*, Kcentra) was a barrier to both sales and utilization (¶¶109, 111-13; *see generally* ¶¶106-07);

c. statements by hospital CWs that the data on Andexxa's initial clinical trials and then data pushed out for subsequent Portola studies later in the Class Period were "flimsy" and "not supportive enough to justify the cost" of Andexxa over any perceived benefit (¶¶119-20);

d. statements by hospital CWs whose hospitals / systems did purchase Andexxa (and salesperson CWs that sold to such hospitals) that they, for example, purchased a very thin supply (such as one of each dose size); limited utilization to the most life-threatening intercranial bleeds; had mechanisms in place for seeking approval, such as express authorization form the CEO; and (for hospital systems) had limitations on which hospitals in the system could and would carry Andexxa, such as two "flagship hospitals" for one hospital CW (¶¶114-16);

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 77 of 114

e. statements by salesperson CWs about Portola's generous return policy for Andexxa that, when taken together, demonstrate that (i) Portola used its policy to allow the Company to sell existing short shelf-life Andexxa (even after Gen 2 longer shelf-life had been authorized) and gave license to its hospitals to freely purchase that product, (ii) hospitals with lower-dose Andexxa returned it for a higher-dose Andexxa when it became available, and (iii) there was a significant uptick in returns in Spring and Summer 2019 (¶121-22);

f. statements by salesperson CWs that hospital pharmacies, and not doctors, made the purchasing decisions; that, as a drug used internally at hospitals, Andexxa put a strain on pharmacy budgets; and that even if insurance reimbursed for hospital usage, that reimbursement went to the hospital's general accounts and might not have been credited to the pharmacy account it was initially paid from (¶111; *see generally* ¶¶107-09);

g. a statement from a Portola employee CW at Company headquarters that the Sales Department articulated that sales were not going well and, by Spring of 2019, had "come down" (¶110);

h. a statement by a salesperson CW that, while Andexxa was an orphan drug, its presented "particular challenges" to selling it, where, with others, one is generally aware of the number of patients with the rare indications, but with Andexxa, because it was an inpatient drug that comes out of the hospital pharmacy's budget, it caused hospitals to put strict protocols in place for when and how to allow the drug's use (¶118);

i. statements by salesperson CWs that, when taken together, demonstrate that these issues with demand and utilization were pervasive throughout the Class Period and were not limited to the end of the Class Period in Q4 2019 (which would have been after an article critical of Andexxa was released) ( $\P$ 123);

j. statements by hospital CWs that Andexxa was purchased out of fear of liability for not carrying it, or as a "CYA" (¶115); and

k. statements by both a salesperson CW and hospital CW that Andexxa was

being stocked but not used (¶117).

217. The truth that demand was neither strong nor robust and that Andexxa was not "broadly" and "deeply" being utilized is further evidenced by the evasive responses by management to analyst questions during quarterly conference calls.

a. **[Analyst]**: [W]here Andexxa is available, is it your understanding that that is clearly the first line therapy for the Xa bleeds or might there be some hospitals that while they have Andexxa available, are still using some of the older methods like fresh frozen plasma or four-factor PCCs even though that Andexxa is available?

**[Garland]**: ... Certainly, we know hospitals are using PCCs and we expect they probably will continue to use PCCs although we believe that's inappropriate given the fact that we're the only approved agent. But in many ways you call it, it really does vary by hospital. <u>It's kind of hard to speak about it generally because each hospital is somewhat unique</u>. (Mar. 1, 2019 Conference Call);

b. **[Analyst]**: Does it concern among investors that over time as you get later doctors to stock a drug, their utilization is going to be less than the people who have stocked already. So the revenue curve is going to—going to begin to plateau or decelerate. What are your—what are your thoughts on that concern that's in the market.

**[Garland]**: ... What we are seeing is we've looked at a cohort of our institutions, large important institutions that came on earlier at E[S]P and actually what we're seeing is increased usage over time or deepening usage over time. <u>There's nothing that we're seeing today that makes us concerned about a lack of pull through or plateauing of our utilization</u>. (Aug. 7, 2019 Conference Call); and

c. [Analyst]: I'm just wondering if you could start to give some kind of on a comparison or, if it's high level even about the current utilization at some of those hospitals that have been online for at least a year maybe even over a year versus maybe some that have come online in the past six months....

**[Garland]**: [N]ow that we've got a couple of years under—or a year under our belt how does the utilization look[?] We aren't giving any detailed information around utilization per hospital per month. <u>What we have seen</u> is that, that utilization per hospital per month stays—has been staying <u>consistent in 2019</u>. (Nov. 5, 2019 Conference Call).

218. The truth that demand was neither strong and robust and that Andexxa was not "broadly" and "deeply" being utilized is further evidenced by the following:

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 79 of 114

a. the Company's ultimate admissions on January 9, 2020 that the Portola encountered "[f]lat quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts" and that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets"—the very issues that the CWs said existed throughout the Class Period (¶134);

b. the Company's admissions on the Jan. 14, 2020 Corporate Update Call that Andexxa sales had fallen because of "lower distributor purchases to manage inventory" in order "to keep their inventory levels at a constant level in the fourth quarter" (¶137);

c. the Company's acknowledgement on February 26, 2020 that the Company was "laser focused on driving near-term revenue growth [for Andexxa]" and was taking three important steps to "realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share" (¶142);

d. the Company's admission in its 2019 Form 10-K filed on February 28, 2020 that it knew since Andexxa was approved by the FDA in early 2018 via the Accelerated Approval Program that the ANDEXXA-4 study proffered and relied upon had "inherent limitations" that could impact the viability of Andexxa, where, for example, the Company was having significant difficulties competing with the off-label use of 4F-PCCs and other coagulation factors given a lack of comparative data and that hospital formulary committees were resistant to utilizing Andexxa because the Company lacked clinical trial data comparing it to treatments used before Andexxa's FDA approval (¶22, 147-48); and

e. the fact that Defendants lacked sufficient relevant historical evidence and other facts to recognize revenue upon sell-in, *i.e.*, upon shipment to its distributors, under ASC 606, and, thus, the revenue figures could not support these assertions of strong, growing or robust demand (*see* Section VI.A.1.b.).

219. These misstatements were material, non-puffery, because a reasonable investor would consider the fact that demand for Andexxa, Portola's only viable drug, was weaker than portrayed by the Company and meant that Andexxa's commercial launch was failing.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 80 of 114

220. When considering the context in which these statements were offered, these misstatements were important to investors and analysts. Throughout the Class Period, Portola had disclosed as material in public filings the critical importance to the viability of Andexxa of creating and maintaining strong demand and utilization, as well as procuring a hospital's willingness to pay for Andexxa. ¶¶78-83. Portola made repeated statements about demand throughout the Class Period, despite evidence to the contrary. *Id.*; *e.g.*, ¶210. Those statements were in that context materially misleading. Further, on the conference calls cited throughout, analysts repeatedly inquired directly into demand and factors meant to serve as indicators of demand. *E.g.*, ¶¶101, 216. And analysts noted in reports throughout the Class Period that demand and utilization of Andexxa were factors driving the commercial success of the Company. ¶¶93, 97, 102-03. Moreover, the significant stock drops, which revealed the weak demand and utilization of Andexxa, further demonstrate the materiality of these false and misleading statements. *See* Section VI.C., Loss Causation, *infra*. Further, analyst reports reacting to the news pointed specifically to issues of demand and utilization as factors for their downgrades. *Id*.

221. These statements about both demand and its trajectory as well as utilization and its breadth and depth were fundamentally based on quantifiable metrics, which were capable of objective verification and consideration. Thus, statements about demand were not statements of optimism, but rather statements premised on facts.

## B. Additional Allegations of Scienter

222. In addition to the detailed allegations *supra* supporting scienter (including, but not limited to, those regarding the CWs' descriptions of Defendants' knowledge of the true facts; Defendant's knowledge of the requirements of ASC 606 along with the lack of relevant historical sales data, the Company's liberal return policy, their visibility into the distribution and hospital channel, failure to track expiring dates of products sold by distributors, and data regarding demand and utilization; the widespread and material overstatement of revenue in contravention of ASC 606; and the pervasive nature of the GAAP violations and their magnitude), four key facts further support a strong inference of scienter as to the Company and each of the Officer Defendants.

# 1. The Nature and Significance of the Problems with Andexxa, Which is the Company's Core Business, Further Support Scienter

223. Andexxa was of crucial importance to the Company. It accounted for virtually all of the Company's sales. It would be absurd to suggest that the Officer Defendants and other senior executives were not intimately familiar with key demand and utilization metrics and sales information and updates publicized by them regularly during analyst calls.

224. At the outset of the Class Period, on January 8, 2019, Defendant Garland articulated his focus on the core business and operations of Portola and its single viable product, Andexxa. *See, e.g.*, ¶¶5, 10. Where Garland and his executive team (including Officer Defendants) were focused on the fact that cash was tight and were monitoring expenses and expenditures very carefully, they were also of course aware of how the Company's single product was performing as it was brought to market. It is absurd to suggest otherwise.

225. Portola tracked sales and utilization through CRM software by Salesforce, and also used an Excel spreadsheet to track additional information. That information was readily available to those in the Company whose position mandated that they have access to this information, and certainly Officer Defendants as well as their direct reports had access. Salesperson CW6 explained that all management had access to it and, based on his/her experience in the industry, they "absolutely" tracked sales number daily, if not hourly.

226. Indeed, Garland expressly touted the data at his disposal and the Company's sole focus on Andexxa. At the June 11, 2019 Goldman Sachs Global Healthcare Conference Call, Garland represented that the Company "track[s] the number of accounts that have ordered [Andexxa] at least once" and claimed that there was "enough data to feel very confident in both the short- and the long-term trajectory of Andexxa." When an analyst posited to Garland that, "for investors who are maybe new to the story, <u>it seems it's Andexxa, Andexxa, Andexxa</u>," Garland agreed, responding: "<u>Right now, as you just said, we're focused on Andexxa. And I think it's important we stay focused on Andexxa</u>...."

#### 2. Statements About Defendants' Knowledge of Demand and Utilization Issues in Light of Andexxa's Exorbitant Cost Further Support Scienter

227. The Officer Defendants' and a senior Portola executive's statements, as well as those by multiple CWs, offer further support for scienter of Garland and the Officer Defendants, demonstrating knowledge about demand, utilization, and cost as a barrier to sales.

228. The Officer Defendants closely monitored all aspects of Andexxa's commercialization, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential proprietary information concerning Andexxa. For example:

- <u>Portola Queried Hospitals Concerning the Bleeds that Andexxa Treated.</u> "But as we query multiple hospitals, we do see uses in other situations, GI patients with severe signs of shock or other critical bleeds. So we're happy that it's starting with the intracranial hemorrhages but then expanding to other labeled uses as well, as we expect." (Jeet Mahal, Jan. 8, 2019 Conference Call.)
- <u>Portola Talked to Hospitals about Utilization</u>.
  - "I do know that when we spoke to customers about Q4 utilization, ..." (Garland, Jan. 8, 2019 Conference Call.)
  - "<u>What we are seeing</u> is we've looked at a cohort of our institutions, large important institutions that came on earlier at [ESP] and actually what we're seeing is increased usage over time or deepening usage over time. <u>There's nothing that we're seeing today</u> that makes us concerned about a lack of pull through or plateauing of our utilization." (Garland, Aug. 7, 2019 Conference Call.)
- <u>Portola Tracked Hospital Purchases</u>. "We also track internally the number of hospitals who've made their first purchase, the number of hospitals who've made their second, the number of hospitals that have made their third and more purchases." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- <u>Portola Chart Audits</u>. "We do conduct a regular chart audit where we go out and pull records from patients who have been given Andexxa in the hospital. And what we're seeing ...." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.). *See also* Garland, Mar. 1, 2019 Conference Call ("[Portola uses] chart pulls to see if the actual—when the product ultimately gets used.... [W]e have is visibility into the hospital in terms of its use").
- <u>Portola Mined Electronic Records from Hospitals</u>. "[W]e mine electronic

medical records from hospitals to look at patients who are discharged that were—had as a primary diagnosis a Factor Xa-related bleed." (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference Call.)

- <u>Portola Tracked Andexxa Shipped to Hospitals from Distributors</u>. "So we certainly have visibility into the data that goes from our distributors to our hospitals. <u>We get that data on a relatively regular basis</u>,..." (Garland, Mar. 1, 2019 Conference Call.)
- <u>Garland Had Access To Critical Data</u>. Garland highlighted the data at his and the Company's disposal. On the June 11, 2019 Conference Call, Garland represented that the Company "track[s] the number of accounts that have ordered [Andexxa] at least once" and touted that there was "enough data to feel very confident in both the short- and the long-term trajectory of Andexxa." (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference Call.)

229. Multiple CWs stated that Andexxa's high cost was a barrier to sales (which directly impacted demand and utilization) (*e.g.*, ¶¶106-09, 111-13, 116) and was discussed regularly at Portola business meetings, both telephonically and in person (*e.g.*, ¶¶125; *see also* 11, 127-31).

230. Multiple CWs state that they raised the issue with their managers or regional managers. *E.g.*, ¶¶125-26.

231. Multiple salesperson CWs also discussed regularly held national sales calls and regional and national sales meetings in San Francisco and also town-hall meetings. *E.g.*, ¶¶11, 127-31. Cost as a barrier to sales was discussed regularly on these calls and meetings. And, salesperson CWs report that, rather than provide support to the sales team, Garland and management danced around these issues.

232. Salesperson CWs 1, 5, and 6 stated that they are confident that Portola and its management knew about demand and utilization issues and Andexxa costs' impact on them, as management tracked sales and utilization through CRM software and there were regular conversations with management. ¶¶125-26, 133.

233. Similarly, hospital CWs expressed confidence that Portola and its management knew about demand and utilization issues and Andexxa costs' impact on them. ¶132.

# 3. The Defendants Consummated the August 2019 Offering to Exploit the Artificial Inflation in the Company's Common Stock

234. Because of the substantial costs to manufacture and launch Andexxa along with other research and development projects, Portola had a significant cash burn even as it received monies from Andexxa sales. The Defendants' false and misleading statements concerning revenue and the commercialization of Andexxa enabled Portola to artificially inflate the price of its shares of common stock for its August 2019 Offering. Consequently, Defendants were motivated to continue to misrepresent the sales and demand for Andexxa in order to keep Portola's stock price artificially inflated and to generate sufficient funds in the August 2019 Offering.

## 4. The Defendants Were Motivated to Inflate Andexxa Sales to Access the \$62.5 Million Second Tranche of the Secured Term Loan

235. As alleged in  $\P\P6$ , 56, the Company entered into a \$125 million credit agreement on February 28, 2019, with one-half (or \$62.5 million) provided to Portola immediately and the other half provided on November 15, 2019, only if Andexxa net revenue "in conformity with GAAP" reached at least \$50 million by the end of the third quarter of 2019.

236. Since the Company's access to the \$62.5 million second tranche was essential to the Portola's survival, senior management was motivated to inflate Andexxa net revenue as much as possible in the first three quarters of 2019 to meet the milestone. The Company did this by recognizing revenue in violation of ASC 606.

#### 5. Defendants' Insider Trading is not Relevant to Their Scienter Because They were Motivated by Efforts to Sell The Company, Not by Short-Term Stock Sales

237. During the Class Period, several of the Officer and Director Defendants collectively sold millions of dollars of Portola stock.<sup>11</sup> However, whether their sales are deemed highly suspicious in amount or timing as compared to the pre-Class Period is irrelevant here and does not indicate that Defendants were not motivated to mislead the market.

<sup>&</sup>lt;sup>11</sup> Notably, because he only joined Portola in October 2018, Garland's shares were not fully vested during the Class Period. Portola, Garland's Statements of Changes in Beneficial Ownership (Form 4s) (Oct. 31, 2018, Feb. 4, 2019, Nov. 4, 2019, Feb. 4, 2020, Feb. 26, 2020).

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 85 of 114

238. Rather, Defendants were motivated to find a suitable acquiror for Portola to reap both the financial benefits that they would personally receive in an acquisition and the expected stock price bump up upon news of an acquisition, which would support the retention of shares.

239. Although the Acquisition occurred three months after the end of the Class Period, Defendants' efforts to find such a suitor commenced long before the end of the Class Period.

240. The documents filed with the SEC related to the Acquisition (the "Acquisition Documents") reveal that Portola had reached out to Alexion in Q2 2019 and Q3 2019 to discuss a potential strategic partnership and related business. According to the Acquisition Documents, while those discussions with Portola temporarily ended in September 2019, Garland and Dier resumed discussions with Alexion in mid-November 2019 and early December 2019. The Acquisition Documents further reveal that, without specifying a transaction price, Alexion's CFO sent Garland a letter on December 13, 2019 requesting access to due diligence materials in order to inform a potential bid for Portola. The closing price on December 13, 2019 was \$26.31.

241. The Acquisition Documents further disclose that, on February 27, 2020, the last day of the Class Period and the day that the stock price fell again after the revelations regarding the demand for and utilization of Andexxa, Alexion's CFO communicated with Garland and Dier that Alexion was interested in acquiring Portola for \$18.00 per share. Those discussions continued through the months leading up to the May 5, 2020 Acquisition announcement. The timing of these price discussions is highly suspicious and supports an inference that, during their Acquisition negotiations, Portola was required to make certain disclosures to correct the stock price.

242. Portola's Officer Defendants indeed benefited from the Acquisition in at least two ways, as revealed in its post-Class-Period Solicitation/Recommendation Statement on Schedule 14D-9, filed May 27, 2020 ("May 27, 2020 Schedule 14D-9").

243. First, as part of the Executive Severance Benefits Agreements included in the Acquisition, the executive officers received a continuation of their base salary and bonus/equity awards, including an additional bonus payment and equity award vesting acceleration benefits if terminated without "cause" or resignation for "good reason."

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 86 of 114

244. Second, beyond simply, *inter alia*, the continued salary and bonus payments, the Officer Defendants enjoyed other benefits in the form of "Golden Parachute Compensation" consisting of severance/bonus payments and the acceleration of vesting of Portola options, Portola restricted units ("RSUs") and Portola performance-based restricted stock units ("PSUs").

245. Portola's May 27, 2020 Schedule 14D-9 reveals the following significant "Golden Parachute Compensation" estimated to be received by the Officer Defendants:

			<b>Perquisites</b> /		
Defendant	Cash	Equity	Benefits	<b>Tax Reimbursement</b>	Total
Garland	\$2,548,156	\$6,069,057	\$79,389	\$3,125,221	\$11,811,823
Dier	\$1,079,066	\$1,945,550	\$27,626		\$3,052,242
Koenig	\$924,562	\$1,956,800	\$27,626	\$1,144,666	\$4,053,654

246. Further, the value of Defendants' options, RSUs, and PSUs increased significantly because they were scheduled to receive actual cash for them by reason of vesting <u>on an accelerated</u> <u>basis</u> due to the Acquisition. The following chart shows the total value and accelerated value which Defendants received for their options upon the Acquisition:

	Shares Underlving Vested In-the- Money	the-Monev	Accelerated In- the-Monev	Value of Accelerated In-the-Monev	Total
Defendant	Options	Options	Options	<b>Options</b>	Value
Garland	12,500	\$65,125	287,500	\$1,497,875	\$1,563,000
Dier	4.062	\$21,163	93,438	\$486,812	\$507,975
Koenig	4,062	\$21,163	93,438	\$486,812	\$507,975
Wolff	10,520	\$115,720	0		\$115,720

247. Certain other consideration to be received by the Officer Defendants, noted below, consisted of a right to convert shares underlying the Portola Rollover RSUs and PSUs into shares of Alexion at the accelerated values referenced below:

	Shares Underlying Portola Rollover	Acceleration Value of Portola Rollover	Shares Underlving Portola		Total Acceleration
Defendant	RSUs	RSUs	PSUs	<b>Portola PSUs</b>	Value
Garland	153,399	\$2,761,182	100,000	\$1,800,000	\$4,561,182
Dier	32,291	\$581,238	48,750	\$877,500	\$1,458,738
Koenig	32,916	\$592,488	48,750	\$877,500	\$1,469,988

248. Moreover, as expected, the Acquisition price of \$18 per share was 231.96% more

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 87 of 114

than the Company's \$7.76 stock price close the day before the Acquisition Announcement.<sup>12</sup> The following is a chart (based on the May 27, 2020 Schedule 14D-9 at 5) that shows the bump up on the value of the stock that they owned (excluding options, RSUs, and PSUs).

	Shares Held	Value On Day	Value of Shares Based on the		
	Prior to	Before	Acquisition		Percentage
Defendants	Acquisition	Acquisition	Price	Difference	Increase
Garland	24,529	\$190,345	\$441,522	\$251,177	231.96%
Dier	39,563	\$307,009	\$712,134	\$405,125	231.96%
Koenig	5,075	\$39,382	\$91,350	\$51,968	231.96%
Renton	16.020	\$124,315	\$288,360	\$164,044	231.96%
Bird	527,172	\$4,090,855	\$9,489,096	\$5,398,242	231.96%
Brege	13,194	\$102,385	\$237,492	\$135,107	231.96%
Fenton	13,194	\$102,385	\$237,492	\$135,107	231.96%
Johnson	13,194	\$102,385	\$237,492	\$135,107	231.96%
Stump	13,194	\$102,385	\$237,492	\$135,107	231.96%
Wolff	17,960	\$139,370	\$323,280	\$183,911	231.96%

## C. Loss Causation

249. As alleged above, at all relevant times, Defendants issued materially false and misleading statements and/or omitted to state material facts necessary to make the statements made about the Company's financial reporting and market demand for and utilization of Andexxa not materially misleading. As a result of these materially false and misleading statements and omissions, Portola's common stock price was artificially inflated during the Class Period.

250. As set forth below, the true facts regarding Defendants' materially false and misleading statements or omissions of material fact started to be revealed through a series of partial disclosures at the end of the Class Period, detailed in Section V.F., *supra*, which allegations are incorporated herein. As these true facts regarding the misrepresentations and concealed facts started to be revealed, the prior artificial inflation came out of its stock price and the Company's common stock declined significantly, resulting in damages to the Class members.

<sup>&</sup>lt;sup>12</sup> This \$18 per share price was far lower than the trading prices between the Class Period start and the last trading date before the first partial disclosure, which ranged from \$22.18 to \$37.67. Had there been no fraud, the Class members would not have paid as much as they did for their shares purchased at inflated prices during the Class Period but would have still benefited from any mark-up resulting from the Acquisition.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 88 of 114

251. In addition, or alternatively, as set forth below, the partial disclosures at the end of the Class Period resulted in the materialization of the foreseeable risks associated with the misrepresentations and omissions regarding both (i) compliance with ASC 606, including the improper recognition of revenue and related failure to recognize adequate sales reserves during the Class Period, and (ii) actual demand and utilization of Andexxa by distributor customers and hospitals. The market reacted to revelations of these materialized risks and, since Lead Plaintiff and other Class members purchased Portola's common stock at those artificially inflated prices, they suffered losses as the risks materialized.

- 1. The Significant Declines in Portola's Common Stock Price (and Resulting Losses) were Causally Connected to Defendants' Class Period Misrepresentations and Omissions
  - a. Since the January 9 and 14, 2020 and February 26, 2020 Disclosures of Disappointing Q4 2019 and FY 2019 Net Revenue Figures Were the Result of the \$5 million Adjustment to Return Reserves and the Reversal of Revenue for Products Sold and Sales Reported in 2018 and 2019, They Are Causally Connected to the Misrepresentations and Omissions Regarding Compliance with ASC 606, Revenues, and Inadequate Reserves

252. As alleged in ¶¶134-36, *supra*, after market close on January 9, 2020, Portola issued the Jan. 9, 2020 Press Release and held a Conference Call revealing, among other things, (i) that Andexxa revenue from U.S. sales was expected to be \$24 million for the fourth quarter of 2019, which was a 27% decline from Q3 2019, and that global net revenue was projected to be \$28 million for the quarter (32% lower than the \$41 million consensus estimate); and (ii) that these disappointing revenues were impacted, at least in part, by returns of short-dated products and by a \$5 million adjustment to return reserves for short-dated (6 to 12 month) product for both actual returns during 2019 and potential returns going forward. On January 14, 2020, the Company announced an additional factor, on top of the first two, that had impacted sales: "lower distributor purchases to manage inventory" in order "to keep their inventory levels at a constant level in the fourth quarter." Then, as alleged in ¶¶139-40, *supra*, on February 26, 2020, the Company revealed both in its press release and at the Feb. 26, 2020 Conference Call, among other things,

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 89 of 114

disappointing key financial results, including that total revenue for FY 2019 was \$116.6 million, \$111.5 million of which was revenue for Andexxa sales.

253. Since the disappointing revenues resulted from returns of product previously sold and the "\$5 million adjustment" due to decline in demand and returns, they demonstrate that Portola had failed to sufficiently provision for product returns for the short-dated product sold in both 2018 and 2019. While the Company only later disclosed in its 2019 Form 10-K (on February 28, 2020) that it had provisioned an additional \$2.373 million for previously unaccounted for 2018 sales-related product returns (as alleged at VI.A.1, *supra*), the \$5 million charge and related provisioning clearly implicated 2018 sales as well as 2019 sales for two overlapping reasons. First, when announcing the \$2.373 million provision on February 28, 2020, Portola indicated that it was for "prior period" sales, *i.e.*, sales made in 2018, because Portola had only reserved \$299,000 for future returns for reserves on 2018 sales. Second, given Portola's generous return policy (¶74) and Andexxa's six- (6) to twelve- (12) month product life, and given that 58% of 2018 sales were in 4Q 2018, a significant portion of the underlying product returned during Q4 2019 was likely originally sold in Q4 2018 as well as through Q2 2019.

254. Thus, the partial disclosures regarding disappointing Q4 2019 and FY 2019 results due to significant returns relate directly to the true facts regarding Portola's failure to comply with ASC 606 and the inadequacy of its return reserves (including at 2018 year-end a reserve balance of just \$299,000) and related provisions taken during the Class Period.

255. As set forth in more detail below, the market reacted negatively to this news, thereby causing Plaintiffs' substantial losses.

# b. The January 9 and 14, 2020 and February 26, 2020 Disclosures of Problems with Utilization and Demand

256. During the Class Period, Defendants also touted stellar demand for and hospital utilization of Andexxa throughout 2019, as alleged in ¶¶78-103; 209-12, *supra*. However, as alleged in ¶¶213-21, the statements about demand and utilization were materiality misleading because there was limited demand for Andexxa and it was not being well-utilized when purchased.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 90 of 114

Further, Defendants' alleged reliance on revenue results to make such statements was improper because, among other things, distributor customers and hospitals had a right of return, and Defendants were not properly reserving for returns of product sold prior to and during the Class Period, as evidenced by, among other things, the fact that only approximately 11.5% of its reserves set aside for 2018 product returns—or, \$299,000—remained at year-end 2018 when such product could be returned well into calendar year 2020 (*see, e.g.*, ¶¶189-95).

257. The end-of-Class-Period partial disclosures revealed true facts regarding demand and utilization. Indeed, as previously alleged at ¶¶134-36, on January 9, 2020, the Company disclosed flat demand quarter-over-quarter due to a decrease in utilization and that there was a \$5 million adjustment to return reserves due to actual returns in 2019 (which substantially included returns on sales from 2018) and projected returns. Then, as previously alleged at ¶137, on January 14, 2020, the Company disclosed that there were lower distributor purchases to manage inventory. Further, as previously alleged at ¶¶143-44, on February 26, 2021, the Company declined to provide any guidance to analysts when they pressed the Company for more insight on Andexxa utilization trends, and it provided disappointing guidance for new hospital adds. These disclosures, combined with the revelations of disappointing revenues, demonstrate that Defendants' representations regarding demand and utilization were materially false and misleading.

258. As discussed herein, and in more detail *infra*, when Portola disclosed flat demand and serious problems with hospitals' adoption of Andexxa in January 2020 and on February 26, 2020, the market reacted and Portola's common stock dropped precipitously, thereby establishing that the losses suffered by Class members were proximately caused by Defendants' misleading statements and omissions regarding demand and utilization.

## c. The Market Reacts to Defendants' January and February 2020 Disclosures, Causing Plaintiffs' Significant Losses

259. The market reacted to the January 9, 2020 and February 26, 2020 news (i) of Portola's disappointing Q4 2019 and FY 2019 revenues; (ii) that Portola needed to take a \$5 million adjustment to its return reserve for both catch up of actual returns of short-dated product

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 91 of 114

and projected future returns; (iii) that Andexxa demand was flat due, in part, to a decline in utilization; (iv) of serious problems with hospitals' adoption of Andexxa; and (v) of disappointing and reduced year-over-year figures for expected new hospital adds for Andexxa.

## (i) Market Reaction to the January 9, 2020 News

260. On January 10, 2020, the Company's share price plummeted by \$9.98, or approximately 40%, to close at \$14.76 per share on January 10, 2020 on unusually heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index decreased only 0.3% and 0.4%, respectively, on January 10, 2020.

261. Analysts reacted negatively in response to the relevant January 9, 2020 news, and Oppenheimer, Cowen, Credit Suisse, and Morgan Stanley downgraded their ratings and/or lowered their price targets on January 9 and January 10, 2020.

262. For example, Cowen issued a January 9, 2020 report noting that

"Portola attributed the disappointing Andexxa sales to two factors. During Q4, <u>there</u> was a \$5MM gross-to-net adjustment due to a return reserve for short-dated (6-12 month shelf life) product. ... Q4 sales were hurt by lower utilization at early-adopting Tier 1 hospitals. Management notes many held drug utilization reviews and these resulted in the requirement for a physician or pharmacy consult prior to use of Andexxa. Though management does not think the reviews produced specific restrictions on which patients can get Andexxa, the revenue numbers clearly suggest that the consults are resulting in fewer patients getting the antidote.... We are concerned by this decrease in utilization. Though management outlined a number of measures it will take to deepen utilization during 2020, we suspect that these will take time to have an impact. Moreover, as the reviews were undertaken by early-adopters, other hospitals could be expected to perform them over time. This implies Andexxa will ramp more slowly than we had projected. We are cutting our estimates for 2020-22."

263. On January 9, 2020, *Seeking Alpha* released a story titled <u>Portola down 39% after</u> <u>hours on weak Q4</u>, listing the "\$5M gross-to-net adjustment to a return reserve for short-dated product" as among the reasons for Portola's significant drop in price.

264. On January 10, 2020, *Bloomberg* issued a similar story titled <u>Portola Pharma Shares</u> <u>Falling After-Hours Following Guidance</u>, highlighting Portola's January 9, 2020 announcement and noting that the Company's "expected fourth-quarter global revenue of about \$28 million from sales of Andexxa, including \$24 million from U.S. sales" was impacted by two factors: "a \$5

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 92 of 114

million gross to net adjustment because of a return reserve for short-dated product and flat quarterover-quarter demand due to a decrease in utilization."

265. On January 10, 2020, Credit Suisse lowered its target price for Portola stock from \$35 per share to \$18 per share. Credit Suisse noted, "Portola reported Q4'19 revenue of ~\$28m, which came in substantially below FactSet consensus of ~\$41m, and was 22% lower than Q3 2019 revenue of ~\$36m." In noting how management explained the numbers, Credit Suisse pointed to Portola's claims about issues with drug utilization reviews, "which is in addition to a \$5m gross-to-net adjustment for the reassessment of a return reserve for shorter-dated product." Credit Suisse also raised concerns of a "high burn rate (2020 consensus OpEx of ~\$340m vs \$464m cash balance)."

266. Further, Oppenheimer issued a January 10, 2020 report on Portola stating it was "[m]oving to the [s]idelines on Andexxa [h]eadwinds" because the utilization reviews "signal hospital interest in Andexxa likely crossed a critical threshold." It expressly noted:

PTLA announced 4Q19 Andexxa revenues below expectations with commentary describing certain headwinds including: 1) drug utilization reviews at certain hospitals temporarily blunting demand, 2) slightly lower rate of new hospital adds, and 3) a onetime \$5M net sales adjustment for return of short-dated product that should be replaced by longer-dated product. Andexxa 4Q19 revenues of \$28M were well below our \$39M estimate and \$41M consensus. Backing out the reserve for short-dated returns, US revenues of \$24M would have been \$29M (-12% Q/Q) significantly missing our \$38M estimate and \$37M consensus. We update our model to reflect the latest Andexxa dynamics resulting in lower revenue and EPS estimates. These changes drive our new DCF-based PT to \$17 (vs \$40 prior) which reduces our rating to Perform.

267. Morgan Stanley issued a similar report on January 10, 2020, noting that Portola's Q4 2019 sales of \$28 million were approximately 30% below consensus expectations of approximately \$41 million and that management attributed "weak 4Q19 sales" to, *inter alia*, "a \$5M gross-to-net-adjustment for a return reserve."

268. In a January 10, 2020 report titled <u>Disappointing Andexxa Prerelease Resets</u> <u>Valuation as Concerns on Utilization Trends Grow</u>, William Blair stated, "The decreased utilization at tier-1 accounts is the most worrisome update, which management believes is due to hospital pharmacies curtailing the use of Andexxa following drug utilization reviews and

## Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 93 of 114

determining the impact on pharmacy budgets. Management continues to highlight that physician demand remains strong; however, the decline in utilization raises serious concerns regarding the growth trajectory of Andexxa, particularly in the near term."

269. Portola's stock price continued to fall on the next trading day, closing down 6.2% at \$13.84 on January 13, 2020 on heavy trading. Meanwhile, the Nasdaq Composite Index increased 1.0% and the Nasdaq Biotech Index fell only 1.2% on January 13, 2020.

#### (ii) Market Reaction to the February 26, 2020 News

270. On February 27, 2020, the Company's share price fell \$2.35 to close at \$10.17 per share, an approximate 19% decline on heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index only decreased 4.61% and 4.13%, respectively, on February 27, 2020. And on Monday, March 2, 2020, the first trading day following the Company's aftermarket-close filing of its 2019 Form 10-K on Friday, February 28, 2020, the Company's share price fell to a close of \$9.83, an approximate 3% decline from its previous close. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index increased 4.5% and 4.6%, respectively, on March 2, 2020.

271. While on February 26, 2020, the Company had also announced that it was restructuring its operations to be "laser focused" on Andexxa by, among other things, shutting down the already-stagnant Bevyxxa and reorganizing its Andexxa operation, analysts' questions and reports after that call focused primarily on <u>what the announcements meant for Andexxa</u>. Indeed, the Company had previously disclosed in September 2018 (more than 17 months earlier) that it was placing the Bevyxxa commercialization on the back-burner (and leaving it in just a handful of hospitals) to focus on Andexxa and had reported negligible sales of Bevyxxa in 2018 and 2019. Thus, as a as a William Blair analyst noted in a September 20, 2018 report 17 months earlier, "investor expectations [for Bevyxxa] had been essentially removed" from Portola' valuation by September 2018.

272. As *Bloomberg* noted in a February 27, 2020 report, the Q4 2019 loss of \$96.7 million, or \$1.24 per share, that the Company reported on February 26, 2020 was "wider than [the

average analyst] estimate" of \$0.88 per share.

273. Moreover, while analysts had lowered their expectations for Andexxa after the Company's January 2020 pre-announcement, management's refusal to provide any additional insight on Andexxa utilization trends during the Feb. 26, 2020 Conference Call was cause for even further alarm over the drug's true prospects. As a result, several analysts expressed further concern regarding their limited visibility going forward and further cut their target price even further down from their January 2020 cut.

274. For example, in its February 26, 2020 analyst report, Credit Suisse noted: "All About the Long-Term Opportunity for Andexxa. Management didn't provide any additional commentary on <u>Andexxa utilization trends in the beginning of 2020, the main area of investor focus following the Q4 revenue pre-announcement</u> that showed declining QoQ revenue. Instead, the earnings call focused on PTLA's strategy to capitalize on the LT opportunity for Andexxa/Ondexxya—the company is deprioritizing Bevyxxa and has postponed cerdulatinib's CELTIC-1 study pending partnership for the asset. ... In 2020, PTLA expects to add approximately 350 new hospital accounts, with a mix that will include hospitals in all tiers and non-target hospitals.... [T]his could drive the average revenue per account down slightly depending on reordering rates for existing accounts.... With limited visibility in the near-term drug utilization trends, and potential choppiness in ordering patterns, we continue to expect the stock to be volatile around earnings for the next few quarters until a clearer picture of the drug's utilization pattern emerges." Credit Suisse cut its target price for Portola stock even further down from its cut in January 2020.

275. Likewise, Cowen issued a report on February 26, 2020 stating, "Portola indicated that it expects to add approximately 350 ... new hospital accounts during 2020, implying a <u>deceleration</u> from the 425 hospitals added in 2019." Cowen decreased its 2020 and 2021 Andexxa estimates and further cut its Portola target price from its January 2020 price cut.

276. In its February 28, 2020 report, Morgan Stanley reported that "PTLA has faced significant pressure following 4Q19 earnings, which we suspect is likely related to (a) <u>the lack of</u>

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 95 of 114

<u>annual Andexxa sales guidance</u> that some investors may have been expecting and (b) <u>little</u> <u>additional visibility</u> into the utilization reviews that impacted 4Q19 Andexxa sales.... We would expect <u>continued scrutiny of quarterly Andexxa performance</u> until mgt. is able to provide sales guidance. We await mgt. commentary on the impact of recently instated initiatives to drive Andexxa growth, Ondexxya progress in the EU, and updates on partnership discussions for cerdulatinib."

277. In sum, analysts were concerned about and the market reacted to (i) overall revenue results, which reflected the \$5 million adjustment and the provisions for returns that occurred and for potential returns of product sold in both 2018 and 2019; and (ii) weak demand and utilization going forward.

\* \* \*

278. Thus, the economic loss suffered by Lead Plaintiff and Class members was a direct result of (i) Defendants' GAAP violations and materially false and misleading statements and omissions to artificially inflate the prices of Portola's common stock (including statements about compliance with GAAP and their inadequate reserves (including the failure to disclose that, as of December 31, 2018, just \$299,000 of reserves remained to cover an additional 18-month return period), and statements touting demand and utilization); and (ii) the subsequent decline in the value of Portola's common stock when true facts were revealed.

279. The timing and magnitude of the common stock price decline coupled with the market reactions negate any inference that the losses suffered by Lead Plaintiff and the Class were caused solely by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. To the contrary, the facts revealed in January and February were a foreseeable and substantial cause of the price decline. Accordingly, these false and misleading statements and omissions directly or proximately caused Lead Plaintiff and other Class members to suffer damages.

#### 2. Defendants' Materially False and Misleading Statements and Omissions Concealed Risks That Inevitably Materialized at the End of the Class Period, Thereby Causing Plaintiffs' Foreseeable Losses

280. As explained above, the main foreseeable risk stemming from the alleged misrepresentations and omissions regarding compliance with GAAP and ASC 606 was that a significant amount of reported revenue would be reversed in a future period. *See, e.g.*, ¶196.<sup>13</sup> Relatedly, the facts demonstrating that a significant amount of revenue would be reversed in a future period was also a foreseeable risk stemming from the alleged misrepresentations regarding demand and utilization. *See, e.g.*, ¶218(e).

281. Indeed, Defendants' reporting of inflated revenue in violation of ASC 606 during the Class Period (including Defendants' failure to disclose that, as of December 31, 2018, the Company had already depleted nearly 90% of its reserves for 2018 product returns such that just \$299,000 in reserves remained with well over a year left in the return window) concealed from the market the risk that product sold during the Class Period would be returned and that Portola's 2018 and 2019 sales would inevitably need to be reversed during future financial reporting periods to account for inadequacies in the Company's respective 2018 and 2019 sales reserves, which, in turn, would reduce Company's future financial reporting period net revenue and cause such revenue to come in lower than analysts' expectations.

282. While, as summarized in Section VI.A.1, *supra*, the details of the FY 2019 financials (including the additional provisions taken during 2019 to cover previously unreserved product returns relating to 2018 sales and the dramatic increase in sales provisions as a percentage of invoiced sales for Q4 2019 to 24%) were only revealed on February 28, 2020, the actual risk of a significant reversal of revenue had materialized, at least in large part, between January 9 and February 26, 2020. Moreover, the market reacted to this news and the stock price fell, causing the

<sup>&</sup>lt;sup>13</sup> Part of the purpose of ASC 606 is to avoid the reversal of sales, which is why those recognizing revenue (such as Defendants) must have a "high degree of confidence that revenue will not be reversed in a subsequent reporting period." *See* ¶171, *supra* (citing FASB, Accounting Standards Update No. 2014-09, at ¶BC204).

Class members' losses.

283. Indeed, as alleged in ¶¶250-55, *supra*, this risk of reversal partially materialized on January 9, 2020, when the Company announced (i) revenues of \$24 million for Q4 2019, which were far below the prior quarter and consensus estimates; (ii) that the disappointing revenues were due to returns for previously sold short-dated product for which revenue had been recognized; and (iii) that Portola had to take the \$5 million adjustment. While the public only learned in the 2019 Form 10-K that the Company had to increase its provisions for 2018 sales by \$2.373 million to account for product returns and effectively reverse revenue previously reported in 2018 (because its return reserves were woefully inadequate), this information was embedded in the Q4 2019 net revenue figure and the increases and adjustments to reserves.

284. Moreover, as further alleged in ¶¶250-55, *supra*, the risk of a significant reversal of revenue in future periods further materialized on February 26, 2020, when Portola announced its disappointing FY 2019 net revenue and higher than expected FY 2019 losses, which were caused, in part, by a significant reversal in the amount of revenue previously recognized during 2018 and the increases and adjustments to reserves.

285. Similarly, as alleged in ¶¶256-58, *supra*, because the misrepresentations and omissions regarding demand from and utilization by distributor customers and hospitals omitted facts that demonstrated that there was a substantial risk that revenues could be reversed in subsequent quarters, the information disclosed on January 9, January 14, and February 26 also constituted the materialization of the foreseeable risk of these misrepresentations and omissions.

286. In sum, reversal of revenue was within the foreseeable "zone of risk" caused by Defendants' misrepresentations and omissions and this risk eventually materialized between January 9, 2020 and February 26, 2020, causing Portola's common stock to decline disproportionately to the market and relevant peer indices, thereby eliminating the prior artificial inflation and causing the Class members' substantial losses.

## **D. Presumption of Reliance**

287. Lead Plaintiff is entitled to a presumption of reliance under the fraud-on-the-market

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 98 of 114

doctrine. At all times, the market for the Company's securities was an efficient market that promptly digested current information related to the Company from all publicly available sources and reflected such information in the prices of the Company's securities.

288. Throughout the Class Period: (i) Portola common stock was actively traded on the NASDAQ, (ii) the market price of Portola's common stock reacted promptly to the determination of public information regarding the Company, (iii) the Company's stock was followed by financial analysts, including those cited in this complaint, (iv) the average weekly trading volume for Portola stock during the Class Period was over 3.5 million shares, (v) as a regulated issuer, Portola filed with the SEC periodic public reports during the Class Period, (vi) Portola regularly communicated with public investors via established market communication mechanisms, and (vii) during the Class Period, the Company had over 78 million shares outstanding (and market capitalization reached as high as \$2.4 billion).

289. Throughout the Class Period, the Company was consistently followed by the market, including securities analysts. The market relies upon the Company's financial results and management to accurately present the Company's financial results. During this period, Portola and the Officer Defendants continued to pump materially false and misleading information into the marketplace regarding the Company. This information was promptly reviewed and analyzed by analysts and institutional investors, and assimilated into the price of the Company's securities.

290. As a result of the misconduct alleged herein, the market for Portola's common stock was artificially inflated. Thus, the presumption of reliance available under the "fraud-on-the-market" theory applies and Class members are presumed to have indirectly relied upon the misrepresentations and omissions for which Defendants are each responsible.

291. Lead Plaintiff and other Class members justifiably relied on the integrity of the market price for the Company's securities and were substantially damaged as a direct and proximate result of their purchases of Portola's common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

292. Lead Plaintiff and the other Class members are also entitled to a presumption of

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 99 of 114

reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted in this complaint against Defendants are predicated upon omissions of material fact for which there was a duty to disclose. Because this action involves Defendants' failure to disclose material adverse information regarding the utilization and adoption of Andexxa—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of hospital customers' utilization and adoption of Andexxa, that requirement is satisfied here.

293. Had Lead Plaintiff and other members of the Class known of the material adverse undisclosed information or been aware of the truth behind Defendants' material misstatements, they would not have purchased Portola's common stock at artificially inflated prices.

## E. Exchange Act Counts

#### 1. Count One—Violations of Section 10(b) and Rule 10b-5 (Against Portola and the Officer Defendants)

294. Lead Plaintiff repeats and realleges each and every allegation contained *supra* as if fully set forth herein.

295. Throughout the Class Period, the Exchange Act Defendants, directly or indirectly, by the use of means or instrumentalities of interstate commerce, the United States mails, interstate telephone communications, and a national securities exchange, made 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 engaged in acts, practices, and a course of business which operated as a fraud and deceit upon Lead Plaintiff and the other members of the Class in connection with their purchases of the common stock of Portola during the Class Period, all in violation of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 promulgated thereunder.

296. The Company and Officer Defendants, as the most senior officers of Portola during the Class Period, are liable as direct participants in all of the wrongs complained of through the

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 100 of 114

date they left the Company.

297. As detailed *supra*, Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts even though such facts were available to them.

298. Lead Plaintiff and other members of the Class relied upon Defendants' statements and/or on the integrity of the market in purchasing shares of Portola's common stock during the Class Period.

299. As a direct and proximate cause of the wrongful conduct described herein, Lead Plaintiff and the Class suffered damages in connection with their purchases of Portola's common stock at artificially inflated prices during the Class Period. Had Lead Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or been aware of the truth behind Defendants' materially false and misleading statements, they would not have purchased Portola's common stock at artificially inflated prices during the Class Period.

300. In addition to the duties of full disclosure imposed on the Officer Defendants, as a result of their responsibility for the Company's financial statements and making affirmative statements and reports to the investing public, the Officer Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's business operations, growth, and financial condition, so that the market price of the Company's securities would be based on truthful, complete, and accurate information.

301. By virtue of the foregoing, Defendants violated 10(b) of the Exchange Act and SEC Rule 10b-5(b) promulgated thereunder and are liable to Lead Plaintiff and the Class members who have been damaged as a result of such violations.

## 2. Count Two—Violations of Section 20(a) of the Exchange Act (Against the Officer Defendants)

302. Lead Plaintiff repeats and realleges each and every allegation contained *supra* as if fully set forth herein.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 101 of 114

303. The Officer Defendants acted as control persons of Portola within the meaning of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). By virtue of their high-level positions, agency, and their ownership and contractual rights, participation in and/or awareness of Portola's operations, and/or intimate knowledge of the false financial statements filed by Portola with the SEC and disseminated to the investing public, the Officer Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Portola, including the content and dissemination of the various statements that Lead Plaintiff contends are false and misleading. The Officer Defendants were provided with or had unlimited access to copies of Portola's reports, press releases, public filings, and other statements alleged by Lead Plaintiff to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

304. In particular, each Officer Defendant had direct and supervisory involvement in the day-to-day operations of Portola and therefore is presumed to have had the power to control or influence the particular transactions giving rise to the violations alleged and exercised that power.

305. As a direct and proximate result of the Officer Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Portola's common stock during the Class Period.

306. As set forth *supra*, Portola and the Officer Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint.

307. By reason of the conduct of Portola alleged in this complaint and their positions as control persons, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act.

## VII. SECURITIES ACT VIOLATIONS

#### A. Summary of August 2019 Offering

308. Lead Plaintiff and named representative, OFPRS, bring claims arising under the Securities Act, 15 U.S.C. §§ 77k, 77l(a)(2), and 77o, against all the Securities Act Defendants. The Securities Act claims asserted herein are brought on behalf of only those Class members who purchased or otherwise acquired shares of Portola common stock pursuant and/or traceable to the

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 102 of 114

Company's August 2019 Offering. The Securities Act claims solely allege strict liability and negligence causes of action, and do not sound in fraud. Accordingly, for the purpose of these Securities Act claims, Lead Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging fraud, intentional misconduct, or deliberately reckless misconduct. In addition, this disclaimer expressly excludes all allegations *supra* contained in (i) ¶¶7-12, 18-19, 22, 35, 63-64, 145, 148, 192, 209, and (ii) all paragraphs in Sections V.E.7., VI.B., VI.C., VI.D., and VI.E. in their entireties.

309. On August 7, 2019, the Company filed the Registration Statement on Form S-8 ("Registration Statement") with the SEC. The Registration Statement became effective on August 7, 2019. On August 12, 2019, Portola filed a Preliminary Prospectus Supplement on Form 424(b)(5) with the SEC, which preliminarily announced a public offering. On August 14, 2019, the Company filed a Prospectus Supplement on Form 424(b)(5) with the SEC. In the Registration Statement and Prospectus, Portola incorporated by reference the following Company documents: (i) the 2018 Form 10-K, (ii) Q1 2019 Form 10-Q, and (iii) Q2 2019 Form 10-Q (the "Offering Materials").

310. On August 14, 2019, shares of Portola common stock issued in connection with the August 2019 Offering commenced regular public trading. The Offering closed on August 16, 2019.

311. The Underwriter Defendants acted as the underwriters and book-running managers in connection with the August 2019 Offering. The Underwriter Defendants were granted a 30-day option to purchase an additional 1,205,357 shares of common stock at the offering price to cover over-allotments in connection with the August 2019 Offering. The Underwriter Defendants received a fee of \$14.2 million and exercised their over-allotment option in full. In total, the August 2019 Offering raised gross proceeds of approximately \$244.5 million for the Company.

## **B.** The Materially Untrue and Misleading Statements in the Offering Materials

312. The Underwriting Agreement, included as Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2019, represented that "the Registration

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 103 of 114

Statement and the Prospectus comply ... in all material respects with the Securities Act and the applicable rules and regulations of the [SEC] thereunder," and "did not contain ... any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading."

313. Contrary to this representation, the Offering Materials contain numerous untrue statements of material fact and omit material facts required to be stated therein in order to make the statements therein not misleading.

314. First, the Offering Materials incorporated by reference (i) the 2018 Form 10-K, (ii) Q1 2019 Form 10-Q, and (iii) Q2 2019 Form 10-Q, which included statements that Portola's reported revenue figures were reported in compliance with GAAP, including ASC 606, and its own Revenue Recognition Policy. However, the Company did not comply with ASC 606 in determining the "transaction price" for its sales of Andexxa when it reported its revenue figures during the Class Period.

315. Where, as here, customers have a right of return, <u>ASC 606 imposes an additional</u> requirement to limit or "constrain" the transaction price when a company <u>cannot conclude that it</u> is probable that a significant revenue reversal <u>will not</u> occur in future periods once the uncertainty associated with product returns is resolved. ASC 606-10-32-11 allows companies to recognize net revenue "<u>only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved."</u>

316. Here the factors to be considered under ASC 606-10-32-12 *et al.* did not permit Portola to overcome the constraints when it sold Andexxa to distributors because of (i) the Company's lack of sufficient relevant historical sales and return data to conclude that there would not be a significant reversal of revenue due to returns (¶¶182-84), (ii) the Company's return policies allowing distributors <u>and hospitals</u> to return the Andexxa product sold during those financial periods after the date of the August 2019 Offering (¶185(a)&(b)), (iii) the demand trends to which the CWs spoke, including that demand was limited due to price and availability of

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 104 of 114

Kcentra and other drugs (¶185(c)), (iv) the utilization trends to which the CWs spoke, including that the hospitals that did purchase Andexxa limited its use to only the most dire life-threatening bleeds such as cranial bleeds (¶185(c)), (v) the Company's February 2020 concession that it lacked visibility into what the expiration date was when product was sold by distributors to hospitals (¶186(a)), (vi) the Company's February 2020 concession that utilization had declined in 2019 (¶186(b)), (vii) the Company's February 2020 concession that it knew that Kcentra and other 4F-PCCs were still being used over Andexxa (¶186(c)), and (viii) the fact that distributors had amassed excess inventory by at least Q4 2019, which reduced sales (¶186(d)).

317. Moreover, that Defendants lacked a relevant reasonable basis with which to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur" is <u>further</u> demonstrated by the fact that (i) Portola had to take a \$5 million adjustment to reserves at FY 2019 year-end, (ii) there was significant reversal in the amount of revenue previously recognized as set forth in the FY 2019 audited financials, and (iii) Portola significantly increased its reserves as a percentage of gross product revenue in Q4 2019. ¶¶187-91, 193-95, 198-200. Thus, the exact situation that ASC 606 was designed to prevent—the reversal of recognition revenue in a later quarter—occurred. *See* ¶196.

318. As such, Portola was precluded from recognizing revenue upon sell-in, *i.e.*, upon shipment to its distributors, rendering materially untrue and/or misleading its (i) statements of compliance with GAAP, including ASC 606, and Portola's Revenue Recognition Policy, (ii) reported revenue figures in the 2019 Form 10-K, Q1 2019 Form 10-Q, and the Q2 2019 Form 10Q, and (iii) SOX Certifications regarding, among other things, the Company's internal controls.

319. These untrue and misleading statements were material as discussed in ¶¶201,202(a), 202(b), 202(d), and 203, *supra*.

320. Second, the Offering Materials included material omissions in violation of Item 303 of Regulation S-K (17 C.F.R. § 229.303(a)(3)(ii)), which requires that the Offering Materials disclose "any known trends or uncertainties that have had or that are reasonably likely to will have a material favorable or unfavorable impact on net sales or revenues or income from continuing

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 105 of 114

operations," and Item 105 of Regulation S-K (17 C.F.R. § 229.105), which requires that the Offering documents disclose a "discussion of the material factors that make an investment in the registrant or offering speculative or risky." *See Commission Statement About Management's Discussion and Analysis of Financial Condition and Results of Operations*, SEC Release No. 33-8056, 67 Fed. Reg. 3746-02 (Jan. 25, 2002).<sup>14</sup>

321. Specifically, the Offering Materials omitted to disclose (i) the demand trends to which the CWs spoke, including that demand was limited due to price and availability of Kcentra and other drugs, and (ii) the utilization trends to which the CWs spoke, including that even hospitals that purchased Andexxa limited its use to only the most dire life-threatening bleeds such as intercranial bleeds. ¶¶106-18, 120.

322. These omitted facts were material, as discussed in ¶¶219, 220 (excluding reference to Section VI.C.), *supra*.

## C. The Securities Act Counts

## 1. Count One—Violations of Section 11 of the Securities Act (Against all Securities Act Defendants, Except Koenig)

323. Lead Plaintiff repeats and realleges each and every allegation contained *supra* as if fully set forth herein, with the exception of any allegation that could be construed as alleging fraud, recklessness, or intentional misconduct. In addition, this disclaimer expressly excludes all allegations *supra* contained in (i) ¶¶7-12, 18-19, 22, 35, 63-64, 145, 148, 192, 209, and (ii) all paragraphs in Sections V.E.7., VI.B., VI.C., VI.D., and VI.E. in their entireties.

324. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who bought shares of Portola common stock pursuant and/or traceable to the Offering Materials, which includes the Registration Statement, against all Securities Act Defendants, other than Koenig. This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

<sup>&</sup>lt;sup>14</sup> Rules and interpretive releases of the SEC under the authority of the federal securities laws are also sources of relevant GAAP for SEC registrants, such as Portola. *See* ASC 105-10-05-01.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 106 of 114

325. As set forth at ¶¶312-322, *supra*, the Offering Materials contained untrue and/or misleading statements of material fact, omitted material facts which were necessary to make those statements not misleading, and omitted to state material facts required to be stated in it. The facts misstated and omitted would have been material to a reasonable person reviewing the Offering Materials.

326. Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials did not know, or in the exercise of reasonable diligence could not have known, of the untrue statements of material fact or omissions of material facts in the Offering Materials.

327. This action was commenced less than one year from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This action commenced less than three years from the time that the securities upon which this cause of action is brought were bona fide offered to the public.

328. Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials have sustained damages and are entitled to damages pursuant to 15 U.S.C. § 77k(e).

329. Portola is the registrant for the August 2019 Offering and, as issuer of the shares, it is strictly liable to Lead Plaintiff and to the members of the Class for materially untrue and/or misleading statements and omissions alleged herein.

330. None of the Securities Act Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Materials were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged in this Count.

331. Defendants Garland, Dier, and the Director Defendants signed or authorized the signing of the Registration Statement. By virtue of signing the Registration Statement, they issued, caused to be issued, and participated in the issuance of the Offering Materials, which contained

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 107 of 114

untrue statements of material fact, omitted to state other facts necessary to make the statements not misleading, and omitted to state material facts required to be stated therein. The Underwriter Defendants acted as the underwriters of the Offering within the meaning of Section 11 of the Securities Act by selling and distributing the Portola common stock offered to the investing public and purchased or otherwise acquired by Lead Plaintiff and members of the Class.

332. For the foregoing reasons, all Securities Act Defendants other than Koenig violated Section 11 of the Securities Act and are strictly liable to Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials.

## 2. Count Two—Violations of Section 12(a)(2) of the Securities Act (Against Portola and the Underwriter Defendants)

333. Lead Plaintiff repeats and realleges each and every allegation contained *supra* as if fully set forth herein, with the exception of any allegation that could be construed as alleging fraud, recklessness, or intentional misconduct. In addition, this disclaimer expressly excludes all allegations *supra* contained in (i) ¶¶7-12, 18-19, 22, 35, 63-64, 145, 148, 192, 209, and (ii) all paragraphs in Sections V.E.7., VI.B., VI.C., VI.D., and VI.E. in their entireties.

334. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of all members of the Class who purchased or otherwise acquired Portola common stock pursuant to the Offering Materials against Portola and the Underwriter Defendants. This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

335. Portola and the Underwriter Defendants were sellers, offerors, or solicitors of purchasers of the shares offered pursuant to the Offering Materials.

336. By means of the Offering Materials (as well as instruments of transportation and communication in interstate commerce and the mails), the Defendants named in this Count, through the public Offering solicited and sold Portola common stock to members of the Class.

337. As set forth at ¶¶312-322, *supra*, the Offering Materials contained materially untrue statements or omitted material facts which were necessary to make statements made not

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 108 of 114

misleading. The facts misstated and omitted would have been material to a reasonable person reviewing the Offering Materials.

338. Class members who purchased or otherwise acquired shares pursuant to the Offering Materials did not know, or in the exercise of reasonable diligence could not have known, of the materially untrue statements of fact or material omissions of facts in the Offering Materials.

339. This Action commenced less than one year elapsed from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This Action commenced less than three years elapsed from the time that the securities upon which this cause of action is brought were sold to the public.

340. As the issuer of the registered securities, Portola is strictly liable for the untrue statements and omissions of material facts contained in the Offering Materials.

341. None of the Underwriter Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Materials were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged in this Count.

342. By reason of the foregoing, Portola and the Underwriter Defendants are liable for violations of Section 12(a)(2) of the Securities Act to Class members who purchased or otherwise acquired securities sold pursuant to the Offering Materials. These Class members also have the right to rescind and recover the consideration paid for these securities upon tender of their stock to the Underwriter Defendants and to recover rescissory damages to the extent they have already sold the securities.

## **3.** Count Three—Violations of Section 15 of the Securities Act (Against the Officer and Director Defendants)

343. Lead Plaintiff repeats and realleges each and every allegation contained *supra* as if fully set forth herein, with the exception of any allegation that could be construed as alleging fraud, recklessness, or intentional misconduct. In addition, this disclaimer expressly excludes all

allegations *supra* contained in (i) ¶¶7-12, 18-19, 22, 35, 63-64, 145, 148, 192, 209, and (ii) all paragraphs in Sections V.E.7., VI.B., VI.C., VI.D., and VI.E. in their entireties.

344. This Count is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 770, on behalf of all Class members who bought shares of Portola common stock pursuant and/or traceable to the Offering Materials, which includes the Registration Statement and Prospectus, against the Officer and Director Defendants. This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

345. At all relevant times, the Officer and Director Defendants were controlling persons of Portola within the meaning of Section 15 of the Securities Act. As set forth herein, by reason of their positions of control and authority as officers and/or directors of Portola, the Officer and Director Defendants had the power to directly or indirectly control or influence Portola to engage in the acts described herein, including by causing Portola to conduct the August 2019 Offering pursuant to the Offering Materials, and exercised the same.

346. Specifically, the Officer Defendants each served as an executive officer of Portola prior to and at the time of the August 2019 Offering. As such, at all relevant times the Officer Defendants each participated in the operation and management of Portola, including participating in the preparation and dissemination of the Offering Materials, and/or otherwise participated in the process necessary to conduct the August 2019 Offering. By virtue of their positions as officers of Portola, and/or their status as signatories of the Registration Statement, each of the Officer Defendants had the power to control, and did control, Portola in its conduct of the August 2019 Offering, including controlling the contents of the Offering Materials, which contained materially untrue statements. As officers of a publicly owned company, the Officer Defendants had a duty to disseminate accurate and truthful information with respect to Portola's business operations, growth, and financial condition.

347. Similarly, each of the Director Defendants served as directors on Portola's Board at the time the August 2019 Offering was conducted. As directors of a publicly owned company, the Director Defendants had a duty to disseminate accurate and truthful information with respect

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 110 of 114

to the Portola's operations at the time of the August 2019 Offering. Each Director Defendant signed the Registration Statement disseminated to the investing public and were Directors of the Company at the time the August 2019 Offering was conducted. Thus, the Director Defendants controlled the contents and dissemination of the Offering Materials.

348. None of the Officer or Director Defendants conducted a reasonable investigation or possessed a reasonable basis for the belief that the statements contained in the Offering Materials were true, were without omissions of material fact, and were not misleading. By reason thereof, each of the Officer and Director Defendants is liable under Section 15 of the Securities Act, jointly and severally with, and to the same extent as the Company is liable under Sections 11 and 12(a)(2) of the Securities Act, to the Class members who purchased or otherwise acquired Portola common stock pursuant and/or traceable to the Offering Materials.

349. As a direct result of the aforementioned conduct, these Class members suffered damages in connection with their purchase of Portola common stock. This Action commenced less than one year elapsed from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This Action commenced less than three years elapsed from the time that the securities upon which this cause of action is brought were bona fide offered or sold to the public.

#### VIII. CLASS ALLEGATIONS

350. Lead Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a Class consisting of all persons and entities who purchased or otherwise acquired Portola common stock during the Class Period, including shares sold in the August 2019 Offering, and were damaged as a result (the Class). Excluded from the Class are: (i) Defendants, (ii) members of the immediate families of Defendants, (iii) the subsidiaries and affiliates of Defendants, (iv) any person who is an officer, director, or controlling person Portola, (v) any entity in which any Defendant has a controlling interest, (vi) Defendants' directors' and officers' liability insurance carriers, and any affiliates or subsidiaries thereof, and (vii) the legal representatives, heirs, successors, or assigns of any such excluded party.

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 111 of 114

351. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are thousands of members in the proposed Class. Indeed, as of February 20, 2020, Portola had 78,080,365 outstanding shares of common stock.

352. Members of the Class may be identified from records maintained by Portola or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

353. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class, including: (i) whether the federal securities laws were violated by Defendants' respective acts as alleged herein, (ii) whether the statements made were materially false or misleading, or omitted material facts, (iii) whether Defendants acted knowingly or with deliberate recklessness in issuing false and misleading financial statements in violation of the Exchange Act claims, (iv) whether the Underwriter Defendants exercised due diligence, (v) whether the prices of Portola's securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein, and (vi) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

354. Lead Plaintiff's claims are typical of the claims of other members of the Class and the other members of the Class sustained damages arising out of Defendants' wrongful conduct in violation of federal law as alleged in this complaint.

355. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and securities litigation. Lead Plaintiff has no interests antagonistic to, or in conflict with, those of the Class.

356. A class action is superior to other available methods for the fair and efficient adjudication of the controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by the individual Class members may be relatively

#### Case 3:20-cv-00367-VC Document 149 Filed 08/31/21 Page 112 of 114

small, the expense and burden of individual litigation makes it impracticable for the Class members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

357. Lead Plaintiff will rely, at least in part, on the presumption of reliance established by the fraud-on-the-market doctrine. All purchasers of Portola's securities during the Class Period suffered similar injuries, including injury through their purchase of the securities at artificially inflated prices. A presumption of reliance therefore applies.

## IX. NO SAFE HARBOR

358. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false and misleading statements pleaded in this complaint. The statements alleged to be false and misleading all relate to historical or then-existing facts and conditions.

359. In addition, to the extent certain of the statements alleged to be false may be characterized as forward-looking, they were not adequately identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

360. Alternatively, to the extent that the statutory safe harbor is intended to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker had actual knowledge that the particular forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Portola who knew that those statements were false, misleading, or omitted necessary information when they were made. In addition, to the extent any of the statements set forth *supra* were accurate when made, they became inaccurate or misleading because of subsequent events, and Defendants failed to update those statements which later became inaccurate.

## X. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiff as Class representative under Federal Rule of Civil Procedure 23, and appointing Lead Plaintiff's counsel as Class Counsel;

B. Awarding compensatory and/or rescissionary damages in favor of Lead Plaintiff and the other members of the Class against all Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre- and post-judgment interest thereon;

C. Granting equitable and/or injunctive relief as permitted by law, equity and federal law;

D. Awarding Lead Plaintiff and the Class their reasonable fees and expenses incurred in this action, including counsel fees and expert fees; and

E. Awarding such other and further relief as the Court may deem just and proper.

## XI. DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Lead Plaintiff hereby demands a trial by jury.

DATED: August 31, 2021

Respectfully submitted,

## **BERMAN TABACCO**

By: <u>/s/ Nicole Lavallee</u> Nicole Lavallee

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