**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| MAGNETAR CONSTELLATION FUND II-PRA LP, MAGNETAR SYSTEMATIC MULTI-STRATEGY MASTER FUND LTD, MAGNETAR PRA MASTER FUND LTD, MAGNETAR MSW MASTER FUND LTD, MPROVED SYSTEMATIC MERGER ARBITRAGE FUND, MPROVED SYSTEMATIC MULTI-STRATEGY FUND, AMX MASTER – MAGNETAR – PASSIVE RISK ARBITRAGE, BLACKSTONE ALTERNATIVE MULTI-STRATEGY SUB FUND IV LLC, AND BLACKSTONE DIVERSIFIED MULTI-STRATEGY FUND, | ) | |
| Plaintiffs, | ) | Case No. |
| v. | ) | JURY TRIAL DEMANDED |
| AKORN, INC., RAJAT RAI, DUANE A. PORTWOOD, ALAN WEINSTEIN, RONALD M. JOHNSON, AND BRIAN TAMBI, | ) | |
| Defendants. | ) | |

**COMPLAINT**

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Plaintiffs Magnetar Constellation Fund II-PRA LP, Magnetar Systematic Multi-Strategy Master Fund Ltd, Magnetar PRA Master Fund Ltd, Magnetar MSW Master Fund Ltd, MProved Systematic Merger Arbitrage Fund, MProved Systematic Multi-Strategy Fund, AMX Master – Magnetar – Passive Risk Arbitrage, Blackstone Alternative Multi-Strategy Sub Fund IV LLC, and Blackstone Diversified Multi-Strategy Fund (collectively, "Plaintiffs") are purchasers of the publicly traded securities of Akorn, Inc. ("Akorn," or the "Company"). Plaintiffs, through their undersigned attorneys, by way of this Complaint and Jury Demand, for their federal securities law claims against Akorn and its present or former executive officers and directors Rajat Rai, Duane A. Portwood, Alan Weinstein, Ronald M. Johnson, and Brian Tambi (the "Individual Defendants," and, collectively with Akorn, the "Defendants"), allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters.

Plaintiffs' information and belief is based on, *inter alia*, an investigation by their attorneys, which investigation includes, among other things, a review and analysis of: Akorn's filings with the United States Securities and Exchange Commission ("SEC"); public documents and media reports concerning Akorn; analyst reports concerning Akorn; transcripts of Akorn conference calls and earnings calls; federal regulations and interpretative guidance concerning pharmaceutical manufacturing data integrity requirements; documents filed in the matter *In re: Akorn, Inc. Data Integrity Securities Litigation*, Civ. A. No. 1:18-cv-01713 (N.D. Ill.) (the "Class Action"); and documents filed in the matter *Akorn, Inc. v. Fresenius Kabi AG, et al.*, C.A. No. 2018-0300-JTL (Del. Ch.) (the "Merger Litigation"). Many of the facts supporting the allegations contained herein are known only to Defendants or are exclusively within their

custody and/or control. Plaintiffs believe that further substantial evidentiary support will exist for the allegations in this Complaint after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is an action to recover significant investment losses suffered as a result of a massive fraud that has left Akorn – a once-vibrant multi-billion dollar pharmaceutical company – in ruins.

2. The facts of this case are already beyond dispute, having been established by the nation's leading business court (and affirmed on appeal) following a multiday trial where thousands of documents were introduced into evidence and hours of live witness testimony were presented to the trial court.

3. After considering all of this evidence, the court concluded that – contrary to Defendants' public representations that Akorn was complying with government regulations designed to protect the health and welfare of U.S. consumers – there was "***overwhelming evidence of widespread regulatory violations and pervasive compliance problems at Akorn***."[1] The court determined that – again, contrary to Defendants' public representations – "Akorn did not have a well-functioning quality system and lacked a meaningful culture of compliance."

4. The situation was so bad inside Akorn that one expert opined at trial that Akorn's compliance infrastructure was worse than what he would expect to see at "a company that made Styrofoam cups." A Company consultant issued a report stating that Akorn's data-integrity violations were so severe that senior management could be subject to criminal liability.

5. Akorn is a U.S. pharmaceutical company that specializes in the development and marketing of generic drugs. As a generic pharmaceutical company, Akorn is subject to the

[1] Unless otherwise noted, bold, italic emphasis has been added to quotations.

regulatory requirements of the United States Food and Drug Administration ("FDA"). Compliance with FDA regulations is an essential component of Akorn's business. Additionally, Akorn is a publicly traded company subject to the federal securities laws and regulated by the SEC.

6. The FDA's regulations include certain "data integrity" requirements with which pharmaceutical companies must comply. Under these requirements, Akorn is obligated to maintain data-integrity controls, including an effective information technology infrastructure, to ensure that the data it submits to the FDA in support of its applications to market drugs are based on reliable and accurate testing and manufacturing data. A pharmaceutical company's implementation of FDA-mandated data-integrity controls is critical to the protection of the patients who are prescribed FDA-approved drugs because those controls are designed to guarantee that medications are safe, effective, and will not endanger the public health.

7. Unbeknownst to Plaintiffs and the rest of the market, between 2016 and 2018, Defendants made material misrepresentations and omitted to disclose material information to investors. They did this by assuring investors that Akorn was compliant with FDA regulations, by emphasizing that the FDA had inspected and approved Akorn's manufacturing facilities, and by touting the "pipeline" of generic drugs that the FDA was supposedly on the verge of approving. These statements were materially false and misleading, and failed to disclose material information that Defendants were required to disclose.

8. When they made these misrepresentations, Defendants were acutely aware of widespread and serious data-integrity issues at Akorn, as well as a complete lack of quality assurance, compliance and disclosure controls at Akorn. Akorn senior management and its board of directors were apprised of these issues through employee surveys, internal audits, and

outside consultant reports. However, they intentionally decided not to remediate, or even try to remediate, these significant problems within the Company. At least one member of senior management knowingly submitted fabricated data to the FDA.

9. Defendants elected not to remediate these serious deficiencies – and to conceal the truth from the investing public – because they wanted to sell the Company for their own personal financial benefit. Each of the Individual Defendants held equity interests in the Company that would result in them receiving multi-million-dollar payouts if Akorn was acquired by another company. In 2017, Defendants took a big step toward achieving this goal when Akorn entered into a merger agreement with Fresenius, an international healthcare company. Fresenius agreed to purchase Akorn for $34 per share, which amounted to a total value of almost $5 billion.

10. After entering into the merger agreement, Defendants made additional misrepresentations to the investing public to keep Akorn's stock price inflated. They told investors that between the signing of the merger agreement and the consummation of the merger, Akorn would continue to operate its business in the ordinary course, including complying with FDA regulations. However, Defendants did anything but that. Rather than operating as a responsible pharmaceutical company that valued quality assurance and regulatory compliance, once the ink on the merger agreement was dry Akorn abandoned all of its quality control audits and ignored existing compliance issues so that Akorn's significant regulatory failures would not be disclosed until after the merger closed.

11. In late 2017, a corporate whistleblower sent Fresenius a letter revealing some of the widespread regulatory violations and pervasive compliance problems that Akorn was concealing from the public. In response, Fresenius hired a law firm and a FDA compliance

consultant to independently investigate the issues raised by the whistleblower. This investigation revealed severe noncompliance with FDA regulations and a complete lack of data-integrity controls at Akorn. In addition, Fresenius learned that Akorn had submitted a drug application with fabricated data to the FDA, and when the FDA questioned that application while the merger was pending, a senior Akorn "quality control" executive committed fraud in the Company's response to the FDA.

12. As a result of its investigation, Fresenius elected to terminate the merger. In response, Akorn filed suit in Delaware, seeking an injunction requiring Fresenius to consummate the merger. Fresenius countersued, claiming that it was entitled to terminate the merger and that Akorn was liable to it for damages incurred as a result of Akorn's breach of the merger agreement.

13. The Delaware Court of Chancery held a trial in July 2018, and issued its post-trial opinion on October 1, 2018. The court concluded that Fresenius properly terminated the merger because of, among other things, Akorn's false representations concerning FDA compliance. The Delaware Supreme Court affirmed the trial court's opinion in its entirety.

14. As the truth about Akorn's widespread noncompliance and data-integrity issues slowly leaked to the market as the merger fell apart, the price of Akorn securities plummeted. In February 2018, Akorn common stock was trading at over $30 per share. Today, the stock is trading at just a few dollars per share. Akorn went from being a multi-billion-dollar company to having a market capitalization of just a few hundred million dollars. As aptly summarized by the Delaware Court of Chancery: "Akorn has gone from representing itself as an FDA-compliant company . . . to ***a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance***."

15. Plaintiffs are investment funds that purchased Akorn common stock and Akorn common stock-based swaps in 2017 and 2018, during the time when, unbeknownst to them, Defendants were making materially false and misleading statements, and failing to disclose material information, which caused the price of these securities to be artificially inflated. As the truth was gradually disclosed and processed by the market, Akorn's stock price plummeted, and Plaintiffs suffered significant investment losses.

16. The revelation of this fraud has caused Plaintiffs significant harm. Plaintiffs therefore bring this action under the federal securities laws and under the common law to recover the losses they suffered as a result of this securities fraud.

## JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to Sections 10(b), 18 and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

18. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331.

19. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391. Many of the acts giving rise to the violations complained of herein, including the dissemination of false and misleading information, occurred in this District.

20. In connection with the acts, transactions and conduct alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of a national securities exchange and market.

## PARTIES

### I. Plaintiffs

21. Plaintiff Magnetar Constellation Fund II-PRA LP is a Delaware limited partnership whose investment adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit A.

22. Plaintiff Magnetar Systematic Multi-Strategy Master Fund Ltd is a Cayman Islands Exempted Company whose investment adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit B.

23. Plaintiff Magnetar PRA Master Fund Ltd is a Cayman Islands Exempted Company whose investment adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit C.

24. Plaintiff Magnetar MSW Master Fund Ltd is a Cayman Islands Exempted Company whose investment adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit D.

25. Plaintiff MProved Systematic Merger Arbitrage Fund is a fund of a Delaware statutory trust whose investment adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit E.

26. Plaintiff MProved Systematic Multi-Strategy Fund is a fund of a Delaware statutory trust whose investment adviser has its main office location in Evanston, Illinois. A list

of the dates on which it purchased Akorn common stock-based swaps in the United States during the relevant period is attached hereto as Exhibit F.

27. Plaintiff AMX Master – Magnetar – Passive Risk Arbitrage is a sub-fund of an Irish variable capital investment company whose investment sub-adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock in the United States during the relevant period is attached hereto as Exhibit G.

28. Plaintiff Blackstone Alternative Multi-Strategy Sub Fund IV LLC is a Delaware limited liability company, one of whose investment sub-adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock-based swaps in the United States during the relevant period is attached hereto as Exhibit H.

29. Plaintiff Blackstone Diversified Multi-Strategy Fund is a sub-fund of an umbrella fund established as an Irish UCITS, one of whose investment sub-adviser has its main office location in Evanston, Illinois. A list of the dates on which it purchased Akorn common stock-based swaps in the United States during the relevant period is attached hereto as Exhibit I.

30. At all relevant times, either Magnetar Financial LLC or Magnetar Asset Management LLC (collectively, "Magnetar") acted as either investment adviser or sub-adviser to Plaintiffs in connection with their purchases of Akorn securities.

## II. Defendants

31. Defendant Akorn is a Louisiana corporation with its headquarters in Lake Forest, Illinois. Akorn markets itself as "a niche pharmaceutical company that develops, manufactures and markets generic and branded prescription pharmaceuticals as well as animal and consumer health products." According to its corporate website, Akorn "specialize[s] in difficult-to-manufacture sterile and non-sterile dosage forms including: ophthalmics, injectables, oral liquids, otics, topicals, inhalants, and nasal sprays." In addition to its corporate headquarters,

Akorn has pharmaceutical research and development facilities in Vernon Hills, Illinois; Cranbury, New Jersey; and Copiague, New York. It also has drug manufacturing facilities in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Paonta Sahib, India; and Hettlingen, Switzerland. Akorn's common stock is publicly traded in the United States on the NASDAQ Global Select Market (the "Nasdaq") under the ticker symbol "AKRX."

32. At all relevant times, Defendant Rajat Rai ("Rai") was Akorn's former Chief Executive Officer ("CEO"). Rai joined Akorn as a strategic consultant in 2009 to help oversee the operations of the Company while it searched for a new CEO. Rai was appointed as interim CEO of Akorn later that year, and was handed the permanent CEO position in May 2010. Prior to Akorn, Rai spent several years serving as an executive at Option Care Inc. At the time of his initial retention by Akorn, the Company described him as "a veteran healthcare executive" with "extensive knowledge of operations, finance and sales and marketing." His employment with Akorn was terminated effective December 31, 2018, shortly after the release of the post-trial opinion in the Merger Litigation.

33. Defendant Duane A. Portwood ("Portwood") has served as Akorn's Chief Financial Officer ("CFO") since October 2015. Portwood is a Certified Public Accountant whom Akorn has described as "an accomplished executive with over 25 years of extensive accounting and finance experience."

34. Defendant Alan Weinstein ("Weinstein") has been a member of Akorn's Board of Directors (the "Board") since July 2009. He currently serves as Chairman of the Board. According to Akorn, "Weinstein brings to Akorn's Board in-depth knowledge of the provider side of the healthcare industry, specifically hospital management, materials management and channel partner relationships, as well as business leadership and innovative and strategic

planning skills gained from his years of service as a founder, and later a consultant, advisor and board member, for a number of privately held healthcare services/technology companies." At all relevant times, Weinstein served on the Board's Quality Oversight Committee.

35. Defendant Ronald M. Johnson ("Johnson") has been a member of Akorn's Board since 2003. According to Akorn, "Johnson brings to Akorn's Board extensive experience in managing regulatory and compliance requirements of the FDA, particularly in pharmaceutical, medical device, biologic and biotechnology industries, as well as a deep knowledge and understanding of FDA policies and procedures regarding cGMP compliance, quality control processes and outcomes reporting gained from his years of providing specialized consulting services to governments, pharmaceutical companies and healthcare institutions and working at the FDA." At all relevant times, Johnson served on the Board's Quality Oversight Committee.

36. Defendant Brian Tambi ("Tambi") has been a member of Akorn's Board since 2009. According to Akorn, "Tambi brings to Akorn's Board extensive pharmaceutical industry experience, particularly FDA knowledge and drug development and commercialization expertise, as well as business leadership skills gained from his experience as a founder, executive and board member of numerous public and private pharmaceutical companies." At all relevant times, Tambi served on the Board's Quality Oversight Committee.

## FACTUAL ALLEGATIONS

37. In addition to the sources discussed above and counsel's independent investigation, the following factual allegations draw heavily from the 246-page written opinion issued by Vice Chancellor J. Travis Laster in the Merger Litigation on October 1, 2018. *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347 (Del. Ch. Oct. 01, 2018). The opinion was released following a five-day bench trial in the Delaware Court of Chancery in July 2018, during which 1,892 exhibits were introduced into evidence, fifty-four deposition transcripts were

lodged, and sixteen witnesses testified live at trial (nine fact witnesses and seven expert witnesses). Vice Chancellor Laster's decision was affirmed by the Delaware Supreme Court on December 7, 2018. *Akorn, Inc. v. Fresenius Kabi AG*, 198 A.3d 724 (Del. 2018).

## I. Akorn's Regulation by the FDA

38. Akorn is a pharmaceutical company that, among other things, specializes in developing and manufacturing generic drugs. Generic drugs are a cheaper substitute for brand-name drugs. Generic drugs generally are named after the active ingredient in the drug as opposed to the brand-name of the drug.

39. U.S. pharmaceutical companies like Akorn are regulated by the FDA. Prescription drugs marketed in the United States must be approved by the FDA before they can be prescribed to patients.

40. Generic prescription drugs are submitted to the FDA for approval on a form known as an "Abbreviated New Drug Application" or "ANDA".

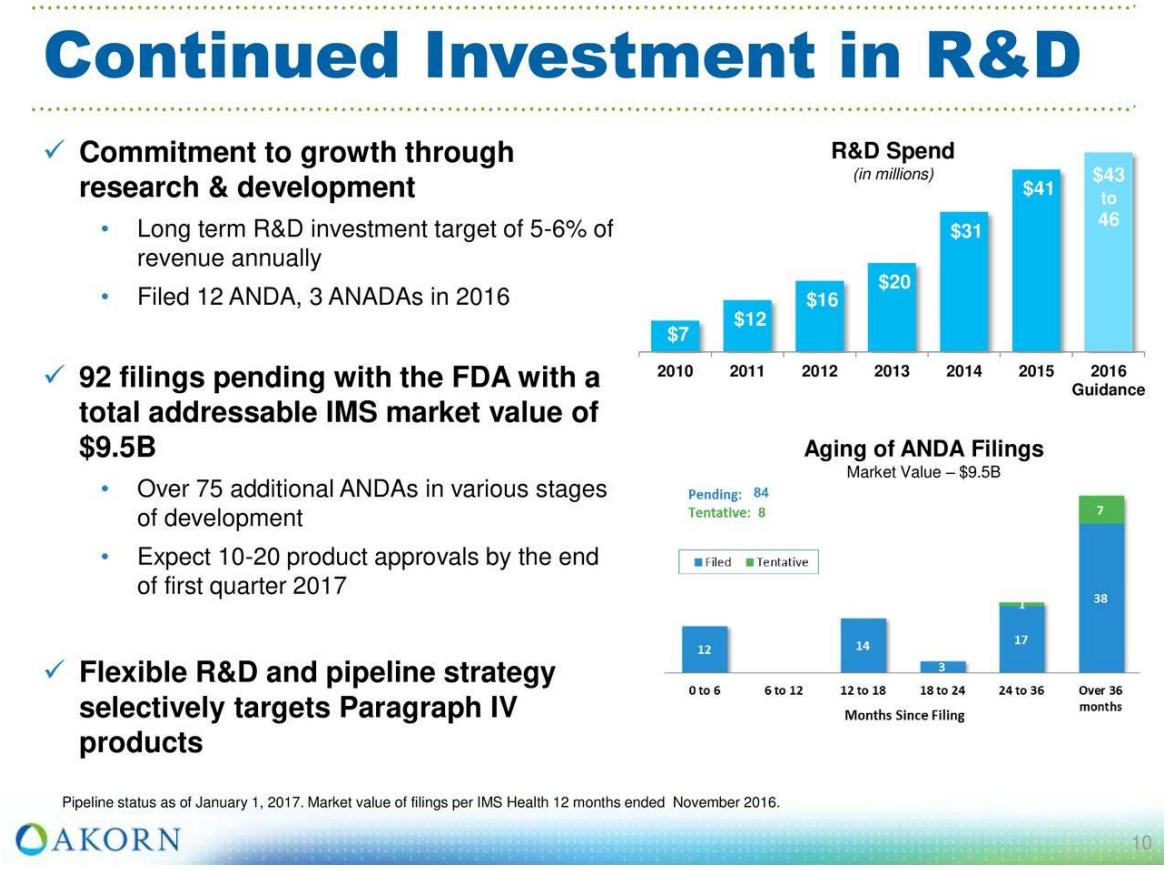
41. After the patent on a brand-name drug expires, the first manufacturer to gain FDA approval of its ANDA for a generic version of that drug is typically granted a 180-day exclusivity period during which it is the only company that can sell the cheaper generic alternative to the brand-name drug. After the expiration of that exclusivity period, other pharmaceutical companies with FDA-approved ANDAs may also market generic versions of the brand-name drug. Because such competition drives down prices as demand becomes saturated, a drug manufacturer's ability to continuously develop new generic drugs can be an important component of that company's earnings growth.

42. That was (and is) the case for Akorn. During the relevant period, Akorn's senior management consistently highlighted for investors the importance of Akorn's new product development and the "pipeline" of new generic drugs that the Company was planning to launch.

Thus, Akorn's management was acutely aware that Akorn's growth depended on the Company's ability to develop and successfully launch new pharmaceutical products, which required FDA approval.

43. For example, in a presentation to investors at the 35th Annual J.P Morgan Healthcare Conference in San Francisco, California on January 9, 2017, Akorn management emphasized how the Company's investment in research and development of new generic drugs and its pipeline of new product launches were a key component of its "compelling growth strategy."

44. That presentation included the following slide in which Akorn highlighted the importance of FDA approval of ANDAs to the Company's long-term profitability:



## II. Current Good Manufacturing Processes and the Importance of Data Integrity

45. ANDAs submitted to the FDA for approval of a generic drug must contain data to scientifically demonstrate that the medication performs in the same manner as the brand-name drug for which it is being offered as an alternative. Pharmaceutical companies have a duty to ensure that the information contained in the ANDA is true and accurate. Indeed, the FDA requires that the ANDA include a certification that the information contained in the ANDA has been reviewed by a "Responsible Official" signing the ANDA on behalf of the company, and that such information is true and accurate to the best of that Responsible Official's knowledge.

46. The accuracy of the data submitted in support of an ANDA is absolutely critical to the FDA, the applicant, and the public. The FDA relies on the accuracy and reliability of the data submitted to it by pharmaceutical companies in determining whether the drug is effective and safe for public consumption.

47. To ensure the reliability of the data submitted in ANDAs by companies like Akorn, and pursuant to section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, the FDA has promulgated "current good manufacturing practices," or "cGMPs," for the manufacturing of medications marketed to the public. Pharmaceutical companies like Akorn are legally obligated to abide by the FDA cGMPs.

48. FDA cGMPs are designed to create a formal system of controls at pharmaceutical companies that, if implemented, help prevent instances of contamination, error and fraud.

49. Among other things, cGMPs impose on pharmaceutical companies rigorous "data integrity" requirements.

50. The FDA defines data integrity as "the completeness, consistency, and accuracy of data." The governing principle applied by the FDA with respect to data integrity is known by

the acronym "ALCOA"; that is, data must be attributable, legible, contemporaneously recorded, original or a true copy, and accurate.

51. The cGMPs' data-integrity requirements are set forth in federal regulations and interpretive FDA guidance. They include the following requirements:

- "Backup data [must be] exact and complete" and "secure from alteration, inadvertent erasures, or loss."
- Data must be "stored to prevent deterioration or loss."
- Certain activities must be "documented at the time of performance" and laboratory controls must be "scientifically sound."
- Records must be retained as "original records," or "true copies," or other "accurate reproductions of the original records."
- Information, data derived from all tests, records of all data, and records of all tests performed must be "complete."
- Production and control records must be "reviewed" and laboratory records must be "reviewed for accuracy, completeness, and compliance with established standards."
- Records must be "checked," "verified," or "reviewed."

52. The FDA also prohibits pharmaceutical companies from "testing into compliance"; that is, a drug company may not repeatedly run tests and record only passing results.

53. Pharmaceutical companies are required to promptly investigate and remediate potential data integrity violations.

54. The FDA has resolutely stated that compliance with its data-integrity requirements is essential to ensuring "the safety, efficacy, and quality of drugs, and of [the] FDA's ability to protect the public health."

## III. FDA Enforcement

55. To help patrol compliance with its cGMPs, the FDA conducts onsite inspections of pharmaceutical manufacturing facilities.

56. If a FDA inspection reveals violations of cGMPs, the FDA may issue a "Form 483" documenting the violations that were discovered during the inspection. A drug company must respond within fifteen business days to a Form 483 with a corrective action plan to address the violations.

57. The submission of a satisfactory corrective action plan by a pharmaceutical company typically results in the FDA classifying the inspection as "voluntary action indicated," or "VAI," with no further action taken.

58. However, if the FDA is not satisfied with a company's response to a Form 483, it may classify the inspection as "official action indicated," or "OAI."

59. The classification of a FDA inspection as OAI may lead to further regulatory action, including the FDA's refusal to approve new ANDAs submitted by a company until the problems listed in the Form 483 have been resolved.

60. In addition to actions taken in response to site inspections, the FDA also can impose sanctions on a company that submits false data to the FDA in an ANDA.

61. When the FDA is dissatisfied with an ANDA, it will send the company a "complete response letter" or "CRL." The CRL identifies the deficiencies in the ANDA and advises the applicant of what actions to take to correct the deficiencies. The applicant can then resubmit the ANDA, request a hearing, or withdraw/abandon the ANDA.

62. When a company is found to have engaged in a pattern or practice of wrongful conduct that raises a significant question about the reliability of data in its ANDAs, the FDA may invoke is "Application Integrity Policy," or "AIP." If the AIP is invoked, the FDA

suspends its review of the drug company's pending ANDAs until the company has implemented remedial measures.

## IV. Akorn's Purported Compliance with FDA cGMPs

63. The FDA's power to clamp down on drug companies that fail to implement cGMPs means that compliance with the FDA's requirements – and submission of accurate data to the FDA – is essential to the successful operation of a pharmaceutical company such as Akorn.

64. Akorn's noncompliance with cGMPs could result in the FDA refusing to approve Akorn's pending ANDAs and/or prohibiting Akorn from submitting new ANDAs, which in turn would cut off the supply of new generic drugs that Akorn could market. An embargo of Akorn's ability to bring new drugs to market would be a death knell to its profitability and future growth.

65. The veracity of Akorn's public assurances concerning its compliance with FDA requirements was thus extremely important to Akorn's investors.

66. Because of the significance of FDA compliance to its success as a business and its shareholders, Akorn had a senior executive position – "Executive Vice President, Global Quality" – who was meant to be dedicated to and responsible for ensuring that Akorn's research labs and manufacturing plants met FDA data-integrity requirements. This senior executive was also supposed to make sure that Akorn's ANDAs submitted to the FDA contained accurate data and complied with FDA standards.

67. At all relevant times, Mark Silverberg ("Silverberg") held this important position at Akorn, and thus was in charge of Akorn's quality assurance function. Silverberg reported directly to Akorn's CEO, Defendant Rai.

68. During the relevant time period, Akorn publicly represented to investors that it was in compliance with FDA cGMPs and data-integrity requirements. For example, in mid-

2016, Akorn received a Form 483 from the FDA following an inspection of its Decatur, Illinois manufacturing facility. Defendant Rai told investors on a call that the FDA made only a "handful of observations" on the Form 483, and that those observations were "routine." In a subsequent investor call, Rai told investors that "no remediation" needed to be done at Decatur.

69. In a merger agreement publicly filed with the SEC a few months later, Akorn was even more strident in its assurances of compliance with FDA cGMPs. Akorn represented that it was materially compliant with FDA regulations (including data-integrity requirements), that it had conducted all trials and studies in accordance with standard medical, scientific and clinical procedures, and that its FDA submissions contained no material misstatements or omissions.

## V. Akorn's SEC Reporting Obligations

70. Under the federal securities laws and the regulations and guidance promulgated by the SEC pursuant to those laws, companies whose stock is publicly traded in the U.S. – such as Akorn – have important public reporting and disclosure obligations.

71. Public companies are required to file with the SEC certain disclosure documents containing comprehensive information about their business operations and their financial condition. The market relies on the accuracy and transparency of these disclosures, and the material information they disclose is reflected in the market prices of the companies' securities.

72. The following table sets forth the relevant filings that Akorn made with the SEC during the relevant period, the date they were filed with the SEC, which of the Defendants signed those filings, and how they will be referred to throughout this Complaint:

| Description of Filing | Date of Filing | Defendant Signatories | Abbreviation |
|---|---|---|---|
| Form 8-K dated December 12, 2016 | December 12, 2016 | Portwood | "December 12, 2016 Press Release" |
| Form 10-K for year ended December 31, | March 1, 2017 | All Defendants | "2016 Annual Report" |

| Description of Filing | Date of Filing | Defendant Signatories | Abbreviation |
|---|---|---|---|
| 2016 | | | |
| Form 8-K dated February 28, 2017 | February 28, 2017 | Portwood | "February 28, 2017 Press Release" |
| Form 8-K dated March 1, 2017 | March 1, 2017 | Portwood | "March 1, 2017 Press Release" |
| Form 8-K dated April 24, 2017 | April 24, 2017 | Portwood | "Merger Announcement" |
| Form 10-Q for quarter ended March 31, 2017 | May 4, 2017 | Portwood | "2017 First Quarter Report" |
| Schedule 14A Preliminary Proxy Statement | May 22, 2017 | Rai and "By Order of the Board of Directors" | "Merger Proxy Statement" |
| Schedule 14A Definitive Proxy Statement | June 14, 2017 | Rai and "By Order of the Board of Directors" | |
| Form 10-Q for quarter ended June 30, 2017 | July 31, 2017 | Portwood | "2017 Second Quarter Report" |
| Form 10-Q for quarter ended September 30, 2017 | November 1, 2017 | Portwood | "2017 Third Quarter Report" |
| Form 8-K dated February 27, 2018 | February 27, 2018 | Portwood | "February 26, 2018 Press Release" |
| Form 10-K for year ended December 31, 2017 | February 28, 2018 | All Defendants | "2017 Annual Report" |
| Form 10-Q for quarter ended March 31, 2018 | May 2, 2018 | Portwood | "2018 First Quarter Report" |
| Form 10-Q for quarter ended June 30, 2018 | August 1, 2018 | Portwood | "2018 Second Quarter Report" |

73. Public companies are required to follow the standards developed by the SEC governing what information must be disclosed in their public filings.

74. One of those standards is Item 303 of SEC Regulation S-K, which requires a public company's management to include a discussion and analysis of the company's financial condition and its results of operations in the company's periodic filings with the SEC. Among

other things, under Item 303, company management is required to describe to investors "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations."

75. In addition to these affirmative disclosure obligations required by the SEC, federal law prohibits a person from making a materially false or misleading statement in connection with the purchase or sale of a security. Moreover, when a company makes an incomplete statement that omits material information necessary to render the affirmative statement not misleading, that statement can be considered a violation of the federal securities laws even if the company did not have an independent duty to disclose the omitted information in the absence of the affirmative statement.

76. Public companies such as Akorn also are required to maintain effective disclosure controls and procedures to ensure compliance with their SEC reporting obligations. An issuer's top-ranking executives must be involved in creating and designing these controls, and must personally guarantee their effectiveness.

77. The Committee of Sponsoring Organizations of the Treadway Commission's *Internal Control – Integrated Framework* defines internal control as "a process, effected by an entity's board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives relating to operations, reporting and compliance." With respect to the reporting and compliance aspects of this definition, the *Integrated Framework* specifically states that "[w]hen internal control is determined to be effective, senior management and the board of directors have reasonable assurance [that] . . . the organization prepares reports in conformity with applicable laws, rules and regulations, and

standards established by legislators, regulators, and standard setters, . . . [and that] the organization complies with applicable laws, rules and regulations." *See* The Committee of Sponsoring Organizations of the Treadway Commission's *Internal Control – Integrated Framework* § 3 ("Requirements for Effective Internal Control").

78. Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") requires public companies to publish information in their annual reports concerning the scope and adequacy of their internal control structure and procedures for financial reporting, and also to assess the effectiveness of such internal controls and procedures. When management identifies a control deficiency, it cannot claim that its internal controls are effective if the control deficiency is deemed to be a material weakness.

79. Section 302 of SOX requires a public company's chief executive officer and chief financial officer to provide certifications concerning their review of, and disclosure of information about, the company's internal controls. Specifically, pursuant to rules promulgated by the SEC to implement Section 302 of SOX, the CEO and CFO are required to certify in each periodic report that:

- he or she has reviewed the report;
- based on his or her knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order 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 the report;
- based on his or her knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in the report;
- he or she and the other certifying officers:

- are responsible for establishing and maintaining "disclosure controls and procedures" [i.e., controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms] for the issuer;

- have designed such disclosure controls and procedures to ensure that material information is made known to them, particularly during the period in which the periodic report is being prepared;

- have evaluated the effectiveness of the issuer's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report; and

- have presented in the report their conclusions about the effectiveness of the disclosure controls and procedures based on the required evaluation as of that date;

- he or she and the other certifying officers have disclosed to the issuer's auditors and to the audit committee of the board of directors (or persons fulfilling the equivalent function):

  - all significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and

  - any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and

- he or she and the other certifying officers have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

*Certification of Disclosure in Companies' Quarterly and Annual Reports*, Exchange Act Release 46427, § II.A (Sept. 9, 2002) (footnotes omitted).

80. Defendants' Rai and Portwood provided these internal control certifications with each of Akorn's Form 10-Ks and Form 10-Qs filed with the SEC during the relevant period.

81. As explained in greater detail below, throughout the relevant period Akorn represented to investors that it was complying with its important public reporting obligations by timely disclosing truthful material facts about its business and by maintaining effective internal controls. However, unbeknownst to the market, in 2017 and 2018, Defendants made material misrepresentations and failed to disclose material information in order to artificially inflate the price of Akorn's stock for their own personal gain. They did this by, among other things, falsely and misleadingly stating that Akorn was complying with FDA regulations, including the FDA's data-integrity requirements. In connection with the Fresenius merger, Akorn also falsely represented that it would continue to operate its business in the normal course while the merger was pending. Furthermore, Defendants falsely represented to the market that they had designed a system of internal controls to ensure that material information was disclosed to investors. However, as was later revealed when the Fresenius merger fell apart and during the subsequent civil trial, Defendants misled the investing public in order to artificially inflate the value of Akorn's securities for their own financial gain, all the while knowing that their public representations were materially false and misleading.

## VI. Akorn's Significant Data Integrity Failures

82. Unbeknownst to investors, and contrary to Defendants' public representations, Akorn lacked the quality assurance functions necessary to ensure compliance with FDA cGMPs. As detailed below, Akorn had extensive and recurring internal quality and data-integrity problems.

83. Akorn's blatant disregard for its compliance obligations emanated from a toxic "tone at the top" of the Company. Although he was the chair of Akorn's Quality Oversight

Committee and its executive steering committee on data-integrity remediation, Defendant Rai consciously disregarded Akorn's quality issues, including widespread data-integrity failures. For example, Rai testified in the Merger Litigation that although he received Akorn's internal audit reports, he did not actually read them.

84. Moreover, Silverberg (the executive that the Company had placed in charge of quality control) was unqualified for his position and was (at best) indifferent to remedying glaring data-integrity problems at Akorn. According to Vice Chancellor Laster's post-trial opinion in the Merger Litigation, "Silverberg was not a suitable individual to be responsible for Akorn's quality efforts." In fact, by 2016, Rai and the Board had concluded that Silverberg was unsuitable for the job and needed to "retire." Nevertheless, they inexplicably allowed Silverberg to stay in this essential position until 2018.

85. During his ten-year tenure as head of the quality compliance function at Akorn, Silverberg placed pressure on employees to sacrifice quality assurance in order to increase production. One employee (who was based at Akorn's corporate headquarters) shockingly reported in January 2016 that:

> Our current Executive Vice President of Quality Assurance [Silverberg] is not fostering a willingness to change the current Akorn culture. Instead of acknowledging and embracing our compliance gaps and working collaboratively with other groups to change and mature our quality systems, he actively works to prevent collaboration and transparency. ***He has actually counselled his staff to not speak to Global Quality Compliance staff and to not share information with GQC***. . . . ***He has also provided misleading information to regulatory bodies including the US FDA***.

86. This comment was made in a survey that was sent to Defendant Rai and other members of Akorn senior management. However, Rai and the other executives took no action in response to this report.

87. The January 2016 employee disclosure regarding Silverberg is consistent with other evidence introduced at trial during the Merger Litigation. For example, Silverberg once instructed the head of quality for Akorn's European operations to disregard a quality issue reported to him, and then directed him not to put anything in writing concerning the quality issue.

88. During Silverberg's time at the helm, Akorn was not devoting sufficient resources to data integrity. Although Silverberg purported to oversee the preparation of a data-integrity plan for Akorn's Decatur facility in August 2017, he did so without ever intending to implement that plan. Silverberg expressly told Akorn employees that the purpose of the plan was so that Akorn would have a document it could furnish to keep the FDA at bay.

89. The Individual Defendants were aware of Silverberg's cavalier approach to quality assurance and the problems he was trying to cover up, but they took no remedial action and failed to put in place any quality assurance measures to fix Akorn's glaring compliance gaps.

90. In June 2016, Defendant Johnson wrote an email to Silverberg raising concerns:

> I continue to be concerned that our position always seems to be that FDA got it wrong and we are just fine. I do not think we are fine, I think there are signals that we are missing. As the leader of the quality function, I do not understand how you can tolerate the ***continued non-compliance by employees, supervisors and quality assurance staff***. . . . We have do[d]ged a bullet a number of times, but at some point, our number will be up unless we, once and for all, fix the underlying reasons why ***our people do not adhere to procedures***. Why do we not see an effort to do this?

91. Silverberg's response was to request that Johnson and he discuss these issues "on the phone." There is no evidence that any further action was taken.

92. Akorn's Global Quality Compliance ("GQC") team identified critical data-integrity failures at Akorn's facilities. Akorn's GQC team conducted periodic audits at Akorn in an attempt to ensure that Akorn's facilities met FDA requirements. However, as summarized by

Vice Chancellor Laster following the Merger Litigation trial, the GQC team discovered the following serious issues at Akorn's research and manufacturing facilities that Akorn did not remediate:

> - At [Akorn's corporate headquarters in Lake Forest, Illinois], in April 2016, GQC found that audit trails were not being reviewed for even "minimum criteria," including "data deletion" and "data manipulation." GQC also found that "multiple Akorn staff members" had unauthorized "system access allowances" that enabled them to modify data and to delete audit trails. When GQC visited Lake Forest again in December 2017, the problems had not been remediated.
>
> - At [Akorn's research and development facility in Vernon Hills, Illinois], in June 2016, a GQC audit identified a critical data integrity failure that permitted unauthorized personnel to "make changes in master production and control records." The internal audit also found that laboratory equipment was "unable to record audit trails" and could not identify the users performing tests. More than a year later, a September 2017 GQC audit found exactly the same problems. The report observed that corrective actions had "been halted and remain incomplete," and noted that Akorn's failure to remediate these deficiencies "presents undue risk to the site's ongoing operations." By the time of trial [in the Merger Litigation], the problems had still not been fixed, and Vernon Hills did not even have a data integrity compliance plan.
>
> - At [Akorn's manufacturing facility in Somerset, New Jersey], in April 2017, GQC identified critical problems involving access controls and audit trail reviews. When GQC returned in December 2017, the problems had not been remediated. By the time of trial, Somerset still did not have an approved data integrity compliance plan.
>
> - In 2017, GQC identified numerous other data integrity deficiencies at Akorn's sites, with seventeen at [Akorn's manufacturing facility in Hettlingen, Switzerland], five at [Akorn's manufacturing facility in Amityville, New York], and five at [Akorn's corporate headquarters in Lake Forest, Illinois].

93. In September 2016, John Avellanet of Cerulean Associates LLC ("Cerulean"), a data-integrity consultant, conducted a four-day inspection of Akorn's manufacturing facility in

Decatur, Illinois. Mr. Avellanet is an expert on FDA data-integrity compliance. He is trained in conducting FDA data-integrity inspections, and has been called the "best in the business" by former FDA officials.

94. In December 2016, Cerulean delivered its Compliance Gap Analysis Summary and Recommendation Report (the "Cerulean Decatur Report") to Akorn. The report was highly critical of Akorn, finding that the data-integrity controls at the inspected facility were "insufficient to support compliance with current data integrity expectations and [FDA] regulatory requirements."

95. Cerulean broke its noncompliance findings into three categories: (1) critical nonconformities; (2) major nonconformities; and (3) minor nonconformities. A critical nonconformity is one that is "reasonably likely to directly impact (e.g., either immediately cause, enable, or be a non-compliance) the regulatory compliance status of the organization."

96. Cerulean identified seven critical nonconformities, seven major nonconformities and five minor nonconformities at Akorn's Decatur facility.

97. The seven critical findings in the Cerulean Decatur Report were as follows:

(a) "Failure to exercise sufficient controls to prevent data loss."

(b) "Insufficient data integrity controls (both procedural and technical) to prevent unauthorized changes to electronic data."

(c) "Insufficient registered record archival controls and retention for records involved in drug product manufacture, testing and release, and quality records."

(d) "Failure to have sufficient controls over computerized equipment used in regulated processes and used to create, manipulate, edit, [and] store . . . regulated data for drug product safety and quality testing and release."

(e) "Inadequate validation of computerized systems to ensure the ongoing suitability of systems for Akorn processes, data, and personnel."

(f) "Inadequate control over approved specifications for drug product and raw materials, and failure to ensure that product testing data is derived from compliance with established specifications and standards."

(g) "Inadequate corrective action and preventative action and out-of-specification investigations, explanations, and corrective actions."

98. Cerulean found that all Akorn employees at Decatur had the ability to alter or delete electronic data, including test data concerning the drug products being manufactured at the facility. Additionally, Akorn had not established an audit trail at Decatur that would allow it to determine whether data had been manipulated.

99. In January 2017, Cerulean attempted to conduct an inspection of Akorn's manufacturing facility in Somerset, New Jersey. However, Akorn failed to provide Cerulean with adequate IT support for Cerulean to complete the inspection.

100. Nevertheless, in May 2017, Cerulean provided Akorn with a preliminary report (the "Cerulean Somerset Report") that identified three additional critical findings and three major findings.

101. The Cerulean Somerset Report stated that some of the violations at Somerset were so severe that members of Akorn's senior management were potentially subject to criminal liability because they had failed "to ensure an effective quality system" and because Akorn's IT department had failed to "ensure the reliability of the controls around data used to make, test, [and] release" safe and pure medication.

102. As a result of its inspection of the Decatur and Somerset facilities, Cerulean concluded that there were "serious questions about the reliability of any data integrity controls

and thus the trustworthiness of any electronic information ***used throughout Akorn*** to make safety, efficacy and quality decisions."

103. Mr. Avellanet testified at trial in the Merger Litigation that Akorn's data-integrity failures were among the "top three worst" he has ever seen. Avellanet further testified that he would not expect to see such data-integrity errors "at a company that made Styrofoam cups," never mind at a highly regulated pharmaceutical company.

104. The Cerulean reports confirmed (and added more detail to) what Akorn's senior management already knew. Akorn's Quality Oversight Committee was aware of quality control issues at the Company as early as 2014. Minutes from one of that committee's meetings from 2014 cited the need for a "change in culture" with respect to quality control.

105. At the trial of the Merger Litigation, Rai testified that he and other members of Akorn's Quality Oversight Committee were "aware of ***significant and repeat problems*** that Akorn was having in its quality function" as of November 2016. Rai further testified that Akorn was experiencing such problems across all of its sites at that time.

106. In December 2016, during a meeting of the Board's Quality Oversight Committee, Defendant Johnson "expressed his concern around the repetitiveness of issues between sites and across sites identified during audits & external inspections." Defendant Tambi separately recognized that "the implementation of corrective action is lacking or not timely."

107. The Cerulean reports confirmed these concerns, and should have prompted Akorn senior management to take immediate corrective action. However, upon receiving the Cerulean reports – rather than attempt to remedy numerous "critical" and "major" data-integrity issues identified by Cerulean – ***Akorn cancelled any further work by Cerulean***, including completion of the Somerset inspection and an upcoming inspection of Akorn's manufacturing facility in

Amityville, New York. According to Vice Chancellor Laster, Akorn's senior executives did so because "they did not want Cerulean to identify any more data integrity gaps that could jeopardize their efforts to sell the Company." Furthermore, "[t]he only interest that Akorn's executives showed in the Cerulean [Somerset Report] was a request by Joseph Bonaccorsi, Akorn's Executive Vice President, General Counsel, and Corporate Secretary, that Cerulean remove the reference to potential criminal liability for Akorn's executives."

## VII. The Fresenius Merger

108. Notwithstanding the serious data-integrity problems that were plaguing the Company (or perhaps because of those problems), Akorn began exploring strategic alternatives and, in July 2016, began a process of soliciting proposals to acquire Akorn. Fresenius emerged as part of that solicitation process.

109. Fresenius is a global healthcare company based in Germany. Its pharmaceutical subsidiary specializes in pharmaceuticals and technologies for infusion, transfusion and clinical nutrition.

110. After a series of negotiations between Fresenius and Akorn representatives, on April 2, 2017, Akorn's Board accepted Fresenius's bid to buy the Company for a price of $34 per share, at a total price of $4.75 billion.

111. On April 24, 2017, Akorn and Fresenius executed a merger agreement (the "Merger Agreement").

112. Akorn made various representations, warranties and covenants in the Merger Agreement. Among other things, Akorn falsely represented that it was not materially noncompliant with any FDA regulations, including:

- that Akorn was in "compliance with . . . all applicable Laws . . . relating to or promulgated by" the FDA;

- that Akorn was in "compliance with current good manufacturing practices";
- that all studies or tests had "been conducted in compliance with standard medical and scientific research procedures and applicable Law";
- that Akorn had not "made an untrue statement of a material fact or a fraudulent statement to the FDA"; and
- that all "ANDAs submitted by [Akorn] . . . are true, complete and correct."

113. In addition to these compliance representations, Akorn committed to use "commercially reasonable efforts to carry on its business in all material respects in the ordinary course of business" between signing of the Merger Agreement and the closing of the merger. Akorn's obligation included investigating and remediating quality control issues and data-integrity violations.

114. Akorn announced the merger in a Form 8-K filed with the SEC after the markets closed on April 24, 2017. The Form 8-K generally described the terms of the merger, and incorporated by reference the Merger Agreement, which was attached thereto as an exhibit.

115. On May 22, 2017, Akorn filed the Merger Proxy Statement with the SEC, seeking shareholder consent for the merger. In his cover letter accompanying the Merger Proxy Statement, Defendant Rai, "*By Order of the Board of Directors*," encouraged shareholders "to carefully read" the accompanying copy of the Merger Agreement attached to the Merger Proxy Statement. The Merger Proxy Statement also summarized some of the representations and warranties that Akorn had made in the Merger Agreement, including Akorn's representation that it was in material "compliance with applicable laws . . . , court orders and certain regulatory matters."

## VIII. Fresenius Discovers Akorn's Data Integrity Issues

116. On October 5, 2017, a whistleblower sent a letter to Fresenius raising issues with Akorn's product development processes at three of its facilities. The whistleblower sent Fresenius a more detailed version of the letter on November 2, 2017, which included information about flaws in Akorn's quality control processes.

117. On November 16, 2017, Fresenius executives called Rai to tell him about the whistleblower letters and to suggest that Fresenius and Akorn confidentially investigate the allegations in those letters. Fresenius sent the whistleblower letters to Akorn's Board.

118. Fresenius hired Sidley Austin LLP ("Sidley") to conduct a confidential investigation. Sidley retained Lachman Consulting Services ("Lachman") to assist with the investigation. Akorn hired Cravath, Swaine & Moore LLP ("Cravath") to shadow Sidley's investigation.

119. In December 2017 and January 2018, Sidley and Lachman conducted site visits of three Akorn facilities. They identified serious data-integrity issues during each of those site visits.

120. Sidley's investigation discovered that ***Akorn employees had no awareness of FDA requirements and compliance issues***.

121. Sidley concluded that there was ***no data integrity*** at Akorn's Decatur, Vernon Hills, and Somerset facilities.

122. Additionally, Lachman identified ***"major, systemic data integrity gaps" at every Akorn facility***. Lachman concluded that ***Akorn's compliance issues seriously undermined "the safety and efficacy of Akorn's products."***

123. A representative of Lachman made this point succinctly when testifying during the Merger Litigation trial:

> Everywhere that Lachman looked at policies, procedures, practices and data, we found noncompliance. And the unusual thing is, is when we go into a client's site, we might find one area where they're weak in compliance. ***But at Akorn, across the board, everything we looked at had significant noncompliance associated with it***.

124. On January 5, 2018, a third whistleblower letter was sent to Fresenius alleging that ***Akorn employees had concealed information*** from Sidley and Lachman during one of their site visits.

125. While preparing witnesses for interviews with Sidley and Lachman, Cravath learned of a serious issue concerning Akorn's ANDA for the generic drug azithromycin, and Silverberg's submission of a fraudulent response to the FDA's CRL for that ANDA. Vice Chancellor Laster recited the facts surrounding this fraudulent submission as follows:

- In 2012, Akorn began developing a topical ophthalmic form of azithromycin, a prescription antibiotic, at its Somerset site, but could not perform particulate matter stability testing due to its viscosity.

- In September 2012, an Akorn lab supervisor at Somerset named Jim Burkert entered stability testing data into the lab notebook of an Akorn chemist. There is no evidence that he had the data; he seems to have made it up.

- In December 2012, Akorn submitted to the FDA an ANDA for azithromycin which included the false data.

- In fall 2014, the stability testing issue came up again, and the chemist discovered the entries in her notebook. She also noticed other entries in the same notebook and in two other notebooks that were not in her handwriting. She reported it to Burkert, who did not ask any questions or follow up. The chemist next brought the issue to the attention of a quality manager who instructed all scientists to review their notebooks. The review discovered numerous instances of altered and missing data. In addition, two of Burkert's notebooks were missing.

- On December 30, 2014, Burkert resigned voluntarily.

- In July 2016, Silverberg visited Somerset. He interviewed the chemist and told her to note in her notebooks where the writing was not hers. She identified six additional products where the writing was not hers. After learning about the missing notebooks, Silverberg instructed that going forward, all notebooks would be stored in the quality manager's office and checked in and out. Employees expressed concern that Silverberg was not addressing the issues properly.

- In August 2017, Somerset was attempting to respond to a CRL that asked questions about the stability testing for azithromycin, albeit not specifically the fabricated test. When preparing the response, Akorn personnel identified the problems with the data and brought them to Misbah Sherwani [the Executive Director of Quality at Somerset]'s attention. She and a colleague, Michael Stehn, concluded that Akorn would need to withdraw the ANDA, and they elevated the issue to Silverberg.

- During Silverberg's discussion with Sherwani and Stehn, Silverberg was told that it was highly likely that there was false or fabricated data in the initial ANDA submitted to the FDA.

- During a meeting on August 17, 2017, Silverberg told Sherwani and Stehn that Akorn would not withdraw the ANDA and should instead pull samples and test them to see if the samples passed the test. Silverberg subsequently instructed Sherwani and Stehn to respond to the CRL, not to ask for an extension, and not to open an investigation in[to] the data issues.

- Sherwani believed it was essential to conduct an investigation and to obtain an extension from the FDA. Sherwani asked Silverberg whether he was "allowing Regulatory Affairs to continue to submit inaccurate information" to the FDA.

- Silverberg argued that the FDA was asking about different data.

- Sherwani disagreed with Silverberg's positon and declined to sign the CRL.

- Silverberg instructed Sherwani that there should be "[n]o more emails."

- Silverberg signed the CRL on Sherwani's behalf while she was out of the office.

- By signing off on the CRL, Silverberg validated the attachments, which were not yet attached to the form he signed. The attachments included the false stability data. Sherwani had made clear to Silverberg that signing the CRL would constitute a resubmission of the false data.

126. When Cravath started investigating this issue in December 2017, Silverberg went to Sherwani to get her to cooperate with him in harmonizing their stories. In response, Sherwani contacted Cravath to tell them that she was not comfortable with what Silverberg was asking her to do.

127. After hearing all of the evidence concerning the CRL response, Vice Chancellor Laster concluded that Silverberg had intended to defraud the FDA in order to avoid blowing up the merger. In his post-trial opinion, Vice Chancellor Laster found as follows:

> I am forced to conclude that ***Silverberg knew that the CRL would rely on fabricated data but authorized it anyway because he did not want to withdraw the ANDA and wave a red flag in front of Fresenius*** that would call attention to Akorn's data integrity problems while the Merger was pending.

128. In early 2018, Akorn hired Hyman, Phelps & McNamara, P.C. ("Hyman") to advise it about how the Company should tackle the azithromycin ANDA and Silverberg's CRL response.

129. Heeding the advice of Hyman, Akorn decided to go to the FDA to disclose the issue and withdrew the ANDA for azithromycin. Akorn also removed Silverberg as the head of quality control, and instead made him a "Quality Advisor," effective March 1, 2018. Shockingly, Akorn continued to pay Silverberg a significant salary in his demoted role.

130. In March 2018, Akorn hired NSF International ("NSF") to conduct an investigation of its data-integrity failures. NSF found extensive issues at the sites it examined, and confirmed the existence of widespread data-integrity problems at Akorn. Indeed, NSF found over 200 major deficiencies in the ANDAs that Akorn had submitted to the FDA.

## IX. Akorn Misleads the FDA

131. On March 16, 2018, Akorn representatives had an in-person meeting with the FDA during which Akorn misled the agency.

132. Akorn improperly characterized the investigation of Akorn's data-integrity issues as a joint investigation by Akorn and Fresenius into the whistleblower letters, when in fact it was Fresenius conducting an investigation that Akorn merely shadowed. Moreover, in its written presentation to the FDA, Akorn took credit for Sidley's and Lachman's investigatory work.

133. Perhaps most disconcertingly, Akorn attempted to excuse Silverberg's conduct vis-à-vis the CRL response. Akorn disingenuously stated to the FDA that Silverberg had authorized the August 2017 submission to the FDA without knowing that false data was being included with that submission. Internally, however, Akorn did not credit that explanation.

134. Finally, Akorn misled the FDA by informing it that Akorn had placed an "emphasis . . . on improving data integrity controls in the last few years," when Akorn's Board and its executives knew that was not true. Indeed, Akorn failed to inform the FDA of Cerulean's findings or its own employees' complaints about Silverberg.

## X. Fresenius Terminates the Merger

135. On February 26, 2018, after the markets closed, Fresenius and Akorn released conflicting statements concerning the discovery of potential data-integrity issues at Akorn.

136. Fresenius made the following statement to the market:

> Fresenius is conducting an independent investigation, using external experts, into alleged breaches of FDA data integrity requirements relating to product development at Akorn, Inc. The Management and Supervisory Boards of Fresenius will assess the findings of that investigation. The consummation of the transaction may be affected if the closing conditions under the merger agreement are not met. Fresenius does not intend to provide further updates as the investigation proceeds. Fresenius continues to seek FTC clearance.

137. Notwithstanding its knowledge of serious and widespread data-integrity flaws, Akorn responded with the following false and misleading statement:

> Akorn and Fresenius Kabi AG, with the assistance of outside consultants, are investigating alleged breaches of FDA data integrity requirements relating to product development at the Company. To date, ***the Company's investigation has not found any facts that would result in a material impact on Akorn's operations and the Company does not believe this investigation should affect the closing of the transaction with Fresenius***. The Company does not intend to provide further updates as the investigation proceeds. The Company is continuing to work to obtain regulatory clearance for the transaction.

138. On April 22, 2018, Fresenius gave Akorn notice that it was terminating the Merger Agreement, in part due to Akorn's breaches of representations and warranties regarding its compliance with FDA regulations.

139. Fresenius's press release announcing the termination stated in pertinent part:

> Fresenius has decided today to terminate the company's merger agreement with Akorn, due to Akorn's failure to fulfill several closing conditions.
>
> Fresenius' decision is based on, among other factors, material breaches of FDA data integrity requirements relating to Akorn's operations found during Fresenius' independent investigation. Fresenius offered to delay its decision in order to allow Akorn additional opportunity to complete its own investigation and present any information it wished Fresenius to consider, but Akorn has declined that offer.

140. The next day, before markets opened, Akorn issued the following misleading statement to investors:

> We categorically disagree with Fresenius' accusations. ***The previously disclosed ongoing investigation***, which is not a condition to closing, ***has not found any facts that would result in a material adverse effect on Akorn's business and therefore there is no basis to terminate the transaction***. We intend to vigorously enforce our rights, and Fresenius' obligations, under our binding merger agreement.

141. Later that day, Akorn filed suit against Fresenius in Delaware, asking the court to order Fresenius to close the merger.

142. Fresenius counterclaimed, contending that it validly terminated the merger and seeking damages from Akorn.

## XI. Akorn Loses the Merger Litigation

143. As noted above, a bench trial was held by the Delaware court in July 2018, during which large amounts of documentary and testimonial evidence were introduced by both Akorn and Fresenius.

144. During the course of the Merger Litigation, more negative information concerning Defendants' misrepresentations was revealed to the market.

145. On May 2, 2018, during trading hours, Reuters released an article summarizing the contents of Fresenius's previously sealed court filings. The article revealed that Fresenius believed that it had "uncovered 'blatant fraud at the very top level'" of Akorn. Reuters reported that "Fresenius [had] alleged that an Akorn executive vice president for quality assurance . . . knowingly directed the submission of fraudulent testing data to the U.S. Food and Drug Administration."

146. On August 23, 2018, Vice Chancellor Laster held post-trial oral argument. During the argument, the Vice Chancellor asked questions that led observers to believe and publicly report that things were not going well for Akorn.

147. On September 3, 2018, Akorn reported to the court that ***certain company documents had been spoliated***. On August 22, 2018, during the pendency of the FDA's investigation of Akorn, someone at Akorn in its Somerset, New Jersey facility erased electronic data relevant to issues raised in a recent FDA Form 483.

148. On October 1, 2018, Vice Chancellor Laster issued his post-trial decision. The court found that Fresenius had validly terminated the Merger Agreement because Akorn violated its compliance representations and its covenant to continue to conduct its business in the ordinary course during the pendency of the merger. The court determined that Akorn's breaches of its compliance representations were material because they amounted to approximately $900 million in economic harm.

149. On January 4, 2019, Akorn received a warning letter from the FDA related to an inspection of Decatur. Akorn disclosed the existence of this letter on January 9, 2019.

## DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

### I. Defendants Misrepresent Akorn's Compliance with FDA Regulations

150. In Akorn's 2016 Annual Report, Defendants stated: "We are subject to extensive government regulations which if they change and or we are not in compliance with, could increase our costs, subject us to various obligations and fines, or prevent us from selling our products or operating our facilities." This statement was repeated verbatim in the 2017 First Quarter Report, the 2017 Second Quarter Report, the 2017 Third Quarter Report, the 2017 Annual Report, the 2018 First Quarter Report, and the 2018 Second Quarter Report.

151. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. Specifically, it was misleading for Defendants to suggest that Akorn was materially compliant with FDA regulations and that noncompliance was merely a possibility that had not yet occurred. As demonstrated above, during the period when these statements were made, Akorn was engaged in rampant and widespread noncompliance with FDA regulations across all of its facilities, particularly with respect to FDA cGMPs and data-integrity requirements. Among other things:

(a) an Akorn chemist and Silverberg submitted false data to the FDA in connection with the azithromycin ANDA; (b) Silverberg actively worked to thwart quality compliance efforts at Akorn; (c) the Board expressed concern in June 2016 about continued noncompliance by employees, supervisors and quality-assurance staff; (d) Akorn's Global Quality Compliance team identified critical data-integrity failures at Akorn's facilities on numerous occasions in 2016 and 2017; (e) the Board's Quality Oversight Committee identified "significant and repeat problems that Akorn was having in its quality function" as of November 2016; (f) Cerulean found a number of "critical" and "major" data-integrity flaws at two of Akorn's manufacturing plants in 2016 and early 2017; and (g) Sidley and Lachman identified serious data-integrity issues at the three Akorn facilities they inspected in 2017 and 2018, determined that Akorn employees had no awareness of FDA requirements and compliance issues, and found there to be significant noncompliance everywhere they investigated at Akorn. Accordingly, it was materially misleading for Defendants to state that there would be consequences "if" Akorn was not in compliance with FDA regulations when they *affirmatively knew* that Akorn was not in compliance with those regulations.

152. Each of Akorn's 2016 Annual Report, 2017 First Quarter Report, the 2017 Second Quarter Report, the 2017 Third Quarter Report, and the 2017 Annual Report were also materially misleading because they failed to disclose the Company's regulatory noncompliance in violation of Item 303 of Regulation S-K. Item 303 requires disclosure of "any known trends or uncertainties that have had or that the registrant expects will have a material . . . unfavorable impact on net sales or revenues or income from continuing operations." Accordingly, these periodic filings should have disclosed that Akorn was engaged in rampant and widespread noncompliance with FDA regulations across all of its facilities, particularly with respect to FDA

cGMPs and data-integrity requirements, which exposed Akorn to significant regulatory and negative public perception risk that would materially and negatively impact Akorn's earnings.

153. Akorn appended the Merger Agreement to both the Merger Announcement and the Merger Proxy Statement filed with the SEC. In the Merger Agreement, Akorn represented that it was materially compliant with FDA regulations:

> The Company and its Subsidiaries are and, to the Knowledge of the Company, since July 1, 2013, (1) ***have been in compliance with*** (A) ***all applicable Laws (including all rules, regulations, guidance and policies) relating to or promulgated by the U.S. Food and Drug Administration*** . . . .

154. Akorn also expressly represented in the Merger Agreement that it was in material compliance with cGMPs:

> The Company and its Subsidiaries are and have been, since July 1, 2013, ***in compliance with current good manufacturing practices and have maintained appropriate mechanisms, policies, procedures and practices to ensure the prompt collection and reporting of adverse event or any other safety or efficacy data, notifications, corrections, recalls and other actions required by Law related to their products***, except where the failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
>
> Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, since July 1, 2013 (i) ***all preclinical and clinical studies or tests sponsored by the Company and its Subsidiaries have been conducted in compliance with standard medical and scientific research procedures and applicable Law (including Good Clinical Practices requirement*** . . . ) .

155. Finally, Akorn represented in the Merger Agreement that it had not submitted any false information to the FDA.

> ***All material reports, documents, claims and notices required or requested to be filed, maintained, or furnished to any Healthcare Regulatory Authority by the Company*** and its Subsidiaries since July 1, 2013, have been so filed, maintained or furnished and, to the Knowledge of the Company, ***were complete and correct in all***

> ***material respects on the date filed*** (or were corrected in or supplemented by a subsequent filing), except where the failure to do so (or the failure to be complete and correct) would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. . . .
>
> . . .
>
> Since July 1, 2013, ***neither the Company nor any of its Subsidiaries (i) have made an untrue statement of a material fact or fraudulent statement to the FDA or any other Governmental Authority, (ii) have failed to disclose a material fact required to be disclosed to the FDA or other Governmental Authority, (iii) have committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy*** or (iv) have been the subject of any investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy, except, in each case, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
>
> . . .
>
> Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect: (i) ***no*** new drug applications ("NDAs") or ***ANDAs submitted by the Company or any of its Subsidiaries to any Health Regulatory Authority for approval contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading***, (ii) ***all*** NDAs and ***ANDAs submitted by the Company or any of its Subsidiaries are true, complete and correct*** and none is deficient by virtue of any failure to submit a modification, amendment or supplement thereto or for failure to pay any requisite fee, penalty or other charge or expense, and (iii) neither the Company nor any of its Subsidiaries has used or engaged the services of any debarred individual in connection with the preparation or submission of any marketing applications for its products.

156. These representations in the Merger Agreement, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. Specifically, Akorn was not compliant with FDA regulations, was violating

cGMPs, and had submitted false data to the FDA. Among other things: (a) an Akorn chemist and Silverberg submitted false data to the FDA in connection with the azithromycin ANDA; (b) Silverberg actively worked to thwart quality compliance efforts at Akorn; (c) the Board expressed concern in June 2016 about continued noncompliance by employees, supervisors and quality-assurance staff; (d) Akorn's Global Quality Compliance team identified critical data-integrity failures at Akorn's facilities on numerous occasions in 2016 and 2017; (e) the Board's Quality Oversight Committee identified "significant and repeat problems that Akorn was having in its quality function" as of November 2016; (f) Cerulean found a number of "critical" and "major" data-integrity flaws at two of Akorn's manufacturing plants in 2016 and early 2017; and (g) Sidley and Lachman identified serious data-integrity issues at the three Akorn facilities they inspected in 2017 and 2018, determined that Akorn employees had no awareness of FDA requirements and compliance issues, and found there to be significant noncompliance everywhere they investigated at Akorn.

157. Akorn stated on a section of its website titled "Compliance" that it had "developed a Corporate Compliance Policy and Procedures Manual containing several policies and procedures regarding appropriate interactions with Health Care Professionals ('HCPs') consistent with 'Compliance Program Guidance for Pharmaceutical Manufacturers,' developed by the United States Department of Health and Human Services Office of Inspector General (OIG)," which Akorn referred to as its "Compliance Plan." Akorn further stated on that part of its website that it had "designated a Compliance Officer to implement and oversee the Compliance Program as a priority of the Company to ensure employee compliance with the Company's commitment to lawful conduct of its business." Moreover, "[t]he Compliance Officer will ensure that good faith reports of unlawful conduct relating to the Company's

operations or practices are duly investigated." "If evidence of a violation exists, the Compliance Officer will recommend an appropriate course of action to management. The Compliance Officer will relate the outcome of investigations and actions taken to the Board of Directors."

158. On another section of its website titled "Quality Policy," Akorn stated as follows:

> **Akorn Quality Policy Statement**
>
> It is Akorn's policy to preserve and improve patient health by ***consistently delivering high quality, safe and effective specialty pharmaceutical products, that meet or exceed customer expectations***.
>
> **Akorn Quality Mission Statement**
>
> Our management and employee workforce are committed to successfully deploying our company's Quality Policy to all aspects of our firm - assuring continued high quality, safe and effective Akorn products for our customers.
>
> ***This commitment will be maintained through having the right people doing the right things, the first time, every time***. This includes:
>
> - State of the art technology, which develops and commercializes safe pharmaceutical products that enhance the quality of life
> - An experienced workforce, equipped with continuing education in emerging Quality techniques and philosophy
> - ***A management team that is accountable for effective review and support of quality, through the prioritization, resourcing, and timely execution of quality-conscious decision-making***
> - Confirmation of our success based upon the testimony of our customers, shareholders, regulators, business partners, and employees

159. These statements on Akorn's website, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. Akorn's senior management was (at best) indifferent to compliance and quality assurance

issues. Silverberg – the senior executive who was put in charge of compliance and quality assurance at Akorn – actively worked to thwart quality compliance efforts at Akorn. Moreover, the Board and senior management were aware of serious compliance and quality assurance issues, but failed to take action to remediate those issues because they did not want to derail a potential acquisition from which they would personally financially benefit. Far from doing the "right things, the first time, every time," Akorn personnel, among other things, submitted false data to the FDA in order to get an ANDA approved for a new generic drug.

## II. Defendants' Misrepresentations Concerning Akorn's Manufacturing Facilities

160. In Akorn's 2016 Annual Report, Defendants stated that Akorn's manufacturing facilities in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; and Hettlingen, Switzerland "are Food and Drug Administration ("FDA") approved." Furthermore, Defendants stated that "[a]ll of our FDA approved facilities were inspected by the FDA in 2016" and "all of our FDA approved facilities . . . ultimately received satisfactory status from the FDA."

161. In Akorn's 2017 Annual Report, Defendants repeated that Akorn's manufacturing facilities in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; and Hettlingen, Switzerland "are Food and Drug Administration ("FDA") approved." Furthermore, Defendants stated that "[a]ll of our FDA approved facilities were inspected by the FDA in 2017" and "all of our FDA approved facilities . . . are in good standing with the FDA."

162. These statements in Akorn's 2016 Annual Report and 2017 Annual Report, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. It was misleading for Defendants to emphasize to investors the FDA's inspection and approval of the four manufacturing facilities when there were such serious regulatory deficiencies at those facilities. As demonstrated above, during the period when these statements were made, Akorn was engaged in rampant and widespread violations of

FDA regulations across all of its facilities, particularly with respect to FDA cGMPs and data-integrity requirements. Among other things: (a) an Akorn chemist and Silverberg submitted false data to the FDA in connection with the azithromycin ANDA; (b) Silverberg actively worked to thwart quality compliance efforts at Akorn; (c) the Board expressed concern in June 2016 about continued noncompliance by employees, supervisors and quality-assurance staff; (d) Akorn's Global Quality Compliance team identified critical data-integrity failures at Akorn's facilities on numerous occasions in 2016 and 2017; (e) the Board's Quality Oversight Committee identified "significant and repeat problems that Akorn was having in its quality function" as of November 2016; (f) Cerulean found a number of "critical" and "major" data-integrity flaws at two of Akorn's manufacturing plants in 2016 and early 2017; and (g) Sidley and Lachman identified serious data-integrity issues at the three Akorn facilities they inspected in 2017 and 2018, determined that Akorn employees had no awareness of FDA requirements and compliance issues, and found there to be significant noncompliance everywhere they investigated at Akorn.

163. In Akorn's 2016 Annual Report, Defendants stated that Akorn's "[r]esearch and development expertise" and its "manufacturing expertise" were two of its five competitive strengths. Defendants repeated this statement in Akorn's 2017 Annual Report.

164. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. It was misleading for Defendants to highlight Akorn's purported manufacturing and research and development "expertise" when there were such serious regulatory deficiencies at Akorn's facilities. As demonstrated above, during the period when these statements were made, Akorn was engaged in rampant and widespread noncompliance with FDA regulations across all of its facilities, particularly with respect to FDA cGMPs and data-integrity requirements. Among

other things: (a) an Akorn chemist and Silverberg submitted false data to the FDA in connection with the azithromycin ANDA; (b) Silverberg actively worked to thwart quality compliance efforts at Akorn; (c) the Board expressed concern in June 2016 about continued noncompliance by employees, supervisors and quality-assurance staff; (d) Akorn's Global Quality Compliance team identified critical data-integrity failures at Akorn's facilities on numerous occasions in 2016 and 2017; (e) the Board's Quality Oversight Committee identified "significant and repeat problems that Akorn was having in its quality function" as of November 2016; (f) Cerulean found a number of "critical" and "major" data-integrity flaws at two of Akorn's manufacturing plants in 2016 and early 2017; and (g) Sidley and Lachman identified serious data-integrity issues at the three Akorn facilities they inspected in 2017 and 2018, determined that Akorn employees had no awareness of FDA requirements and compliance issues, and found there to be significant noncompliance everywhere they investigated at Akorn. Far from giving Akorn a "competitive advantage," Akorn's manufacturing and research and development processes exposed the Company to regulatory and negative public perception risk.

165. Defendants made the following statements specific to the Decatur, Illinois manufacturing facility in response to a Form 483 issued by the FDA in mid-2016:

(a) On a November 3, 2016 earnings call, Defendant Rai stated in response to an analyst question that "there is no remediation per se that we have to do at our Decatur site."

(b) On November 29, 2016, Defendant Portwood told an analyst at the Piper Jaffray Healthcare Conference that "there's nothing really more for us to do other than just operate under cGMP type standards . . . and that work has been done" at Decatur.

(c) In the December 12, 2016 Press Release, Akorn announced that "the U.S. Food and Drug Administration (FDA) conducted a re-inspection of its Decatur, Illinois manufacturing facility from December 5, 2016 to December 9, 2016, with no Form 483 observations."

(d) On a March 1, 2017 earnings call, Rai stated that Akorn had achieved a "NAI, or no action indicated, status for Decatur."

(e) In the March 1, 2017 Press Release, Akorn highlighted that it had "[r]eceived FDA NAI status (No Action Indicated), the highest status level available, for the Company's Decatur facility, following the December 2016 re-inspection."

166. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. It was misleading for Defendants to highlight the FDA's reinspection of Decatur without revealing the significant data-integrity issues that existed at that facility. Indeed, at the time of these announcements, Cerulean had conducted an inspection of Decatur and provided Akorn with a report that disclosed seven critical and seven major data-integrity nonconformities. Decatur defined a critical nonconformity as one that is "reasonably likely to directly impact (e.g., either immediately cause, enable, or be a non-compliance) the regulatory compliance status of the organization." However, by concealing these findings from the investing public while stating that Decatur had received "the highest status level available" from the FDA, Defendants made materially misleading statements.

## III. Defendants Mislead Investors About Akorn's ANDA "Pipeline"

167. On January 10, 2017, Defendant Portwood attended the JPMorgan Healthcare Conference on behalf of Akorn. At that investor conference, Portwood spoke about Akorn's valuable drug pipeline, stating: "[W]e have a large pipeline of pending ANDAs and planned launches . . . . As of the end of 2016, our pending ANDA count stood at 92 filings, which represent a total addressable IMS market value of approximately $9.5 billion . . . . We are starting to see a steady stream of product launches from our deep ANDA pipeline."

168. The accompanying presentation included a slide highlighting Akorn's "large pipeline of pending ANDAs and planned launches," with "filings pending with the FDA with a total addressable IMS market value of $9.5B" and "[o]ver 75 additional ANDAs in various stages of development."

169. The February 28, 2017 Press Release announced that Akorn "has received approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Mycophenolate Mofetil for Injection, USP, 500 mg/vial. This approval is the first new product approval received out of Akorn's Decatur, Illinois manufacturing facility since the FDA re-inspection in December 2016."

170. On an earnings call the next day, Defendant Rai cited this ANDA approval as support for the Company's ability to obtain approval for its pipeline drugs. Rai stated: "As we announced yesterday, we have received the approval of Mycophenolate, our first ANDA approval from the Decatur facility since the reinspection. This implies that we should now expect to receive approvals for other filings, including ephedrine, from our Decatur facility that was delayed due to the compliance status." In response to a question from an analyst, Rai doubled-down that Akorn would be "getting [its] products approved this year more than ever."

171. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. It was misleading for Rai and Portwood to speak about Akorn's pipeline and assure investors that new ANDA approvals were coming down the pike when they knew of the widespread FDA violations and data-integrity problems at Decatur and Akorn's other facilities. Among other things: (a) an Akorn chemist and Silverberg submitted false data to the FDA in connection with the azithromycin ANDA; (b) Silverberg actively worked to thwart quality compliance efforts at

Akorn; (c) the Board expressed concern in June 2016 about continued noncompliance by employees, supervisors and quality-assurance staff; (d) Akorn's Global Quality Compliance team identified critical data-integrity failures at Akorn's facilities on numerous occasions in 2016 and 2017; (e) the Board's Quality Oversight Committee identified "significant and repeat problems that Akorn was having in its quality function" as of November 2016; (f) Cerulean found a number of "critical" and "major" data-integrity flaws at two of Akorn's manufacturing plants in 2016 and early 2017; and (g) Sidley and Lachman identified serious data-integrity issues at the three Akorn facilities they inspected in 2017 and 2018, determined that Akorn employees had no awareness of FDA requirements and compliance issues, and found there to be significant noncompliance everywhere they investigated at Akorn. Defendants' awareness of the serious impact of these issues on Akorn's ANDA pipeline rendered their statements materially misleading.

## IV. Defendants Misrepresent Akorn's Operations During the Pendency of the Merger

172. In the Merger Announcement, Akorn stated that it would "operate its business in the ordinary course of business in all material respects" until the merger was consummated. This statement was repeated in Acorn's periodic filings with the SEC during the pendency of the merger, including in the 2017 First Quarter Report, the 2017 Second Quarter Report, and the 2017 Third Quarter Report.

173. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading. Akorn did not operate its business in the ordinary course in all material respects after the Merger Agreement was signed because, among other things, Akorn: (a) cancelled its scheduled regular audits of its facilities and simply conducted "verification audits"; (b) cancelled Cerulean's scheduled inspection of the Somerset and Amityville facilities; (c) did not address the data-integrity issues identified by the GQC audits or

in the Cerulean reports; (d) submitted fabricated data to the FDA in response to a CRL; and (e) elected not to conduct an independent investigation in response to the whistleblower letters.

## V. Defendants Mislead Investors About Fresenius's Investigation

174. In the 2017 Second Quarter Report, Akorn stated that there was a "possibility that any or all of the various conditions to the consummation of the merger may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals)." Akorn repeated this statement in the 2017 Third Quarter Report.

175. In the February 26, 2018 Press Release, which was issued by Defendants in response to a statement from Fresenius that it was conducting an independent investigation, into alleged breaches of FDA data-integrity requirements at Akorn, the Company stated:

> Akorn and Fresenius Kabi AG, with the assistance of outside consultants, are investigating alleged breaches of FDA data integrity requirements relating to product development at the Company.
>
> To date, ***the Company's investigation has not found any facts that would result in a material impact on Akorn's operations and the Company does not believe this investigation should affect the closing of the transaction with Fresenius***. The Company does not intend to provide further updates as the investigation proceeds. The Company is continuing to work to obtain regulatory clearance for the transaction.

176. Then, when Fresenius disclosed to investors that it had provided Akorn with a notice terminating the Merger Agreement, Akorn stated:

> We categorically disagree with Fresenius' accusations. ***The previously disclosed ongoing investigation***, which is not a condition to closing, ***has not found any facts that would result in a material adverse effect on Akorn's business and therefore there is no basis to terminate the transaction***. We intend to vigorously enforce our rights, and Fresenius' obligations, under our binding merger agreement.

177. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading, and omitted to state material facts. It was misleading for Defendants to suggest that it was only a "possibility" that the terms of the Merger Agreement "may not be satisfied" when Defendants affirmatively knew that Akorn was engaged in rampant and widespread noncompliance with FDA regulations across all of its facilities, particularly with respect to FDA cGMPs and data-integrity requirements, which ultimately derailed the merger. It was also false for Defendants to state that the "investigation has not found any facts that would result in a material impact on Akorn's" business or operations because the investigation had revealed material FDA noncompliance across all of Akorn's facilities as well as Akorn's submission of false data to the FDA.

## VI. Defendants Misrepresent the Effectiveness of Akorn's Disclosure Controls and Procedures

178. Defendants repeatedly certified that they had established effective disclosure controls and procedures for Akorn, with one exception that related to a material weakness in financial reporting related to Akorn's accounting for in process research and development indefinite-lived intangible assets that existed as of year-end 2016 and during the first quarter of 2017.

179. In the 2016 Annual Report, Defendants disclosed that:

> Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

> As of December 31, 2016, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). ***Based on this evaluation, such officers have concluded that our disclosure controls and procedures were not effective as of December 31, 2016, solely because of the material weakness in our internal control over financial reporting described below***.[2]

180. In the 2017 First Quarter Report, Akorn disclosed that:

> Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, for the three month period ended March 31, 2017.
>
> ***Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, because of the material weakness in internal control over financial reporting described in our 2016 Form 10-K as filed on March 1, 2017, our disclosure controls and procedures were not effective as of March 31, 2017***.
>
> A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
>
> In prior filings, we identified and reported a material weakness in the Company's internal control over financial reporting related to our internal controls over the accounting for indefinite-lived IPR&D-related intangible assets, which still exists as of March 31, 2017. We are executing our remediation plan and testing procedures. In response to the identified material weakness, our management, with oversight from our audit committee, has

[2] The material weakness "described below" was the financial reporting related to Akorn's accounting for in process research and development indefinite-lived intangible assets.

dedicated resources to improve our control environment and to remedy the identified material weakness.

We believe that we have designed and implemented the appropriate controls to fully remediate the material weakness. These controls include additional procedures related to the review of assumptions and data inputs, as well as the review of the results and documentation of the IPR&D indefinite-lived intangible assets impairment analysis. However, the Company is required to demonstrate the effectiveness of the new processes for a sufficient period of time. Therefore, until all remedial actions as described fully in our 2016 Form 10-K, as filed on March 1, 2017, including the efforts to test the necessary control activities we identified, are fully completed, the material weakness identified will continue to exist.

During the three month period ended March 31, 2017, the Company commenced testing of the redesigned controls directly related to the identified material weakness. ***We are committed to achieving and maintaining a strong control environment, high ethical standards, and financial reporting integrity and transparency***.

181. In the 2017 Second Quarter Report, Akorn disclosed that:

Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, for the three month period ended June 30, 2017.

Based on this evaluation, ***our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective at a reasonable assurance level for the purpose of ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management including the CEO and CFO, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure***.

In prior filings, we identified and reported a material weakness in the Company's internal control over financial reporting related to

> our internal controls over the accounting for indefinite-lived IPR&D-related intangible assets. We have now executed our remediation plan and testing procedures.
>
> We believe that we have designed and implemented the appropriate controls to fully remediate the material weakness. These controls include additional procedures related to the review of assumptions and data inputs, as well as the review of the results and documentation of the IPR&D indefinite-lived intangible assets impairment analysis. We also believe the Company has now demonstrated the effectiveness of the new processes for a sufficient period of time to be considered remediated. Therefore, all remedial actions as described fully in our 2016 Form 10-K, as filed on March 1, 2017, including the efforts to test the necessary control activities we identified, are fully completed.

182. In the 2017 Third Quarter Report, Akorn made the exact same disclosure for the applicable quarter as is made in the 2017 Second Quarter Report for the second quarter of 2017.

183. In the 2017 Annual report, Defendants stated:

> Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.
>
> As of December 31, 2017, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). ***Based on this evaluation, such officers have concluded that our disclosure controls and procedures are effective as of December 31, 2017***.

184. Akorn repeated that disclosure for the applicable time period in the 2018 First Quarter Report and the 2018 Second Quarter Report.

185. Along with the 2016 Annual Report, Defendants Rai and Portwood provided a certification, pursuant to Section 302 of SOX, concerning Akorn's internal controls. Each of Rai and Portwood stated:

> 1. I have reviewed this annual report on Form 10-K of Akorn, 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;
>
> . . .
>
> 4. The registrant's other certifying officer 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;
>
> . . .
>
> 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; and
>
> 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 . . . .

186. Rai and Portwood provided substantially identical certifications pursuant to Section 302 of SOX for the relevant periods with the 2017 First Quarter Report, the 2017 Second Quarter Report, the 2017 Third Quarter Report, the 2017 Annual Report, the 2018 First Quarter Report, and the 2018 Second Quarter Report.

187. These statements, which caused Akorn securities to trade at artificially inflated prices, were materially false and misleading because Akorn did not have effective disclosure controls and procedures in place between 2016 and 2018, even taking into account the material weakness in financial reporting that Akorn disclosed. As of 2016, Akorn senior management and Akorn's Board were aware of widespread material FDA noncompliance at Akorn's facilities, as well as severe data-integrity problems throughout the Company. Akorn did not have sufficient disclosure controls and procedures to ensure that such material information was reported to investors. Indeed, senior management and the Board swept these problems under the rug to further their own personal financial interests – rather than publicly disclose these issues – because Akorn's disclosure controls and procedures were completely ineffective and inadequate. Far from being "committed to achieving and maintaining a strong control environment" and "high ethical standards," Defendants were (at best) indifferent to ensuring that Akorn had in place adequate internal controls to protect Akorn's investors and customers.

## ADDITIONAL ALLEGATIONS OF SCIENTER

188. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

189. Defendants Rai, Portwood, Weinstein, Johnson and Tambi acted with scienter with respect to the materially false and misleading statements of material fact set forth above

because they knew, or at the very least recklessly disregarded, that those statements were false when made. As the most senior executives of Akorn and/or members of the Board's Quality Oversight Committee during the relevant time period, their scienter is imputable to Akorn.

190. As a senior executive of the Company, Silverberg's scienter is also imputable to Akorn.

191. The evidence adduced at the trial of the Merger Litigation established that there was a toxic "tone at the top" of Akorn that encouraged employees to disregard quality assurance and compliance issues if they stood in the way of Akorn's production of pharmaceuticals. This was especially true of Silverberg, who frequently looked the other way when quality assurance issues were reported to him, even though he was the head of quality assurance. Minutes from one of the Board's Quality Oversight Committee's meetings in 2014 cited the need for a "change in culture" with respect to quality control.

192. The Individual Defendants were aware of Silverberg's antics. One employee (who was based at Akorn's corporate headquarters) shockingly reported in January 2016 that:

> Our current Executive Vice President of Quality Assurance [Silverberg] is not fostering a willingness to change the current Akorn culture. Instead of acknowledging and embracing our compliance gaps and working collaboratively with other groups to change and mature our quality systems, he actively works to prevent collaboration and transparency. ***He has actually counselled his staff to not speak to Global Quality Compliance staff and to not share information with GQC***. . . . ***He has also provided misleading information to regulatory bodies including the US FDA***.

193. This comment was made in a survey that was sent to Defendant Rai, Defendant Portwood, and other members of Akorn senior management. However, Rai, Portwood, and the other executives took no action in response to this report.

194. In point of fact, although Defendant Rai was the Chair of Akorn's Quality Oversight Committee and its executive steering committee on data-integrity remediation, Defendant Rai consciously disregarded Akorn's quality issues, including widespread data-integrity failures. Rai testified in the Merger Litigation that he received Akorn's internal audit reports, but did not actually read them. He also did not read the Cerulean reports.

195. Rai also testified in the Merger Litigation that he and other members of Akorn's Quality Oversight Committee (which included Defendants Weinstein, Johnson and Tambi) were "aware of ***significant and repeat problems*** that Akorn was having in its quality function" as of November 2016. Rai further testified that Akorn was experiencing such problems across all of its sites at that time.

196. In June 2016, Defendant Johnson wrote an email to Silverberg raising concerns:

> I continue to be concerned that our position always seems to be that FDA got it wrong and we are just fine. I do not think we are fine, I think there are signals that we are missing. As the leader of the quality function, I do not understand how you can tolerate the ***continued non-compliance by employees, supervisors and quality assurance staff***. . . . We have do[d]ged a bullet a number of times, but at some point, our number will be up unless we, once and for all, fix the underlying reasons why ***our people do not adhere to procedures***. Why do we not see an effort to do this?

197. Silverberg's response was to request that Johnson and he discuss these issues "on the phone." There is no evidence that any further action was taken.

198. In December 2016, during a meeting of the Board's Quality Oversight Committee, Defendant Johnson "expressed his concern around the repetitiveness of issues between sites and across sites identified during audits & external inspections." And Defendant Tambi recognized that "the implementation of corrective action is lacking or not timely."

199. Silverberg's scienter is beyond peradventure given his conduct in responding to the FDA's CRL for the azithromycin ANDA. Indeed, as Vice Chancellor Laster found in his

post-trial opinion, "Silverberg knew that the CRL would rely on fabricated data but authorized it anyway because he did not want to withdraw the ANDA and wave a red flag in front of Fresenius that would call attention to Akorn's data integrity problems while the Merger was pending." Silverberg reported directly to Defendant Rai. Silverberg was ultimately fired by Akorn. Defendant Rai suddenly "retired" following the conclusion of the Merger Litigation.

200. Akorn's improper conduct continued even after the trial of the Merger Litigation. In September 2018, Akorn was forced to inform the Delaware court that certain Company documents had been spoliated. On August 22, 2018, during the pendency of the FDA's investigation of Akorn, someone at Akorn's Somerset, New Jersey facility erased electronic data relevant to issues raised in a recent FDA Form 483.

201. In addition to their knowledge or, at the very least, severe recklessness, the Individual Defendants had a motive to commit fraud. The Individual Defendants had enormous financial incentives to have another company acquire Akorn. Defendant Rai stood to receive more than $14 million if the merger with Fresenius was consummated. Defendant Portwood was in line to receive $4 million from the consummation of the merger. Weinstein would receive $3.3 million, Johnson would receive over $5 million, and Tambi would receive $2.5 million.

## PRESUMPTION OF RELIANCE

202. Plaintiffs intend to rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations or failed to disclose material facts during the relevant time period; (b) the omissions and misrepresentations were material; (c) Akorn common stock traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Akorn common stock; and (e) Plaintiffs purchased Akorn common stock and Akorn common stock-based swaps between the time Defendants misrepresented or failed to

disclose material facts and the time when the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

203. The market for Akorn stock was open, well-developed and efficient at all relevant times. As a result of the aforementioned materially false and misleading statements, Akorn common stock traded at artificially inflated prices during the relevant period. The artificial inflation continued until the time the market fully came to realize the nature and extent of Defendants' misrepresentations and omissions concerning Akorn's compliance with FDA regulations, Akorn's manufacturing facilities, Akorn's ANDA pipeline, Akorn's operations during the pendency of the merger, Fresenius's investigation of Akorn's data integrity, and the effectiveness of Akorn's disclosure controls and procedures.

204. At all relevant times, the market for Akorn common stock was efficient for the following reasons, among others: (a) Akorn filed periodic reports with the SEC; (b) Akorn common stock was listed and actively traded on the Nasdaq; (c) numerous analysts followed Akorn; and (d) Akorn regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

205. Plaintiffs purchased Akorn common stock and Akorn common stock-based swaps in reliance on the market price of Akorn common stock, which reflected all the information in the market, including Defendants' misstatements.

## LOSS CAUSATION

206. As the truth about Akorn's widespread regulatory violations, pervasive compliance problems, and sham control environment gradually and slowly leaked into the market, the price of Akorn common stock dropped precipitously.

207. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs. During the time that Plaintiffs purchased Akorn common stock and Akorn common stock-based swaps, as set forth in Exhibits A through I, the market price of those securities was artificially inflated as a direct result of Defendants' materially false and misleading statements and omissions.

208. As a series of partial but inadequate disclosures was issued correcting the prior false and misleading statements and omissions with respect to Akorn's widespread regulatory violations, pervasive compliance problems, and sham control environment – and as the risks previously concealed by Defendants' material misstatements and omissions gradually materialized – the price of Akorn stock declined precipitously, and Plaintiffs were damaged.

209. On February 26, 2018, after the markets closed, Fresenius released a press release concerning its 2017 yearend result, which also included a statement revealing that it was conducting an independent investigation of Akorn based on "alleged breaches of FDA data integrity requirements relating to product development," and that the closing of the merger "may be affected" based on the results of the investigation. Fresenius's statement concerning Akorn read:

> Fresenius is conducting an independent investigation, using external experts, into alleged breaches of FDA data integrity requirements relating to product development at Akorn, Inc. The Management and Supervisory Boards of Fresenius will assess the findings of that investigation. The consummation of the transaction may be affected if the closing conditions under the merger agreement are not met. Fresenius does not intend to provide further updates as the investigation proceeds. Fresenius continues to seek FTC clearance.

210. This announcement caused the price of Akorn's stock to plummet. At the close of the market on February 27, 2018, Akorn's stock price fell to $18.65 per share, down 38.4% from the previous day's closing price of $30.28 per share.

211. Notwithstanding its knowledge of serious and widespread data-integrity flaws, Akorn responded to Fresenius's statement by stridently denying that there was any truth to Fresenius's allegations and informing market that the closing of the merger was not in jeopardy. Akorn's statement read as follows:

> Akorn and Fresenius Kabi AG, with the assistance of outside consultants, are investigating alleged breaches of FDA data integrity requirements relating to product development at the Company. To date, the Company's investigation has not found any facts that would result in a material impact on Akorn's operations and the Company does not believe this investigation should affect the closing of the transaction with Fresenius. The Company does not intend to provide further updates as the investigation proceeds. The Company is continuing to work to obtain regulatory clearance for the transaction.

212. After Fresenius's confidential investigation of Akorn revealed to Fresenius (but not to the public) widespread noncompliance and data-integrity issues at Akorn, on Sunday, April 22, 2018, Fresenius gave Akorn notice that it was terminating the Merger Agreement. Fresenius's press release announcing the termination stated in pertinent part:

> Fresenius has decided today to terminate the company's merger agreement with Akorn, due to Akorn's failure to fulfill several closing conditions.
>
> Fresenius' decision is based on, among other factors, material breaches of FDA data integrity requirements relating to Akorn's operations found during Fresenius' independent investigation. Fresenius offered to delay its decision in order to allow Akorn additional opportunity to complete its own investigation and present any information it wished Fresenius to consider, but Akorn has declined that offer.

213. Akorn's stock price again plummeted in response to this news. On April 23, 2018, Akorn's stock price closed at $13.05 per share, down 33.8% from the previous trading day's closing price of $19.70 per share.

214. Again, however, Akorn publicly responded to Fresenius's disclosure with a "categorical" denial of Fresenius's allegations, stating:

> We categorically disagree with Fresenius' accusations. ***The previously disclosed ongoing investigation***, which is not a condition to closing, ***has not found any facts that would result in a material adverse effect on Akorn's business and therefore there is no basis to terminate the transaction***. We intend to vigorously enforce our rights, and Fresenius' obligations, under our binding merger agreement.

215. During the course of the Merger Litigation, more negative information concerning Defendants' public misrepresentations was revealed to the market, and the foreseeable risks previously concealed by Defendants' material misstatements and omissions further materialized.

216. On May 2, 2018, during trading hours, Reuters released an article summarizing the contents of Fresenius's previously sealed court filings. The article revealed that Fresenius believed that it had "uncovered 'blatant fraud at the very top level'" of Akorn. Reuters reported that "Fresenius [had] alleged that an Akorn executive vice president for quality assurance . . . knowingly directed the submission of fraudulent testing data to the U.S. Food and Drug Administration." In response to this news, the price of Akorn's stock fell again. On May 1, 2018, Akorn common stock closed at a price of $14.76 per share. On May 2, 2018, it declined by 15%, closing at a price of $12.55 per share.

217. On August 23, 2018, Vice Chancellor Laster held post-trial oral argument. During the argument, the Vice Chancellor asked questions that led observers to believe and publicly report that things were not going well for Akorn. In response to this news, Akorn's common stock decreased in price $3.18 per share, or 17.56%, from the prior day's closing price.

218. On October 1, 2018, Vice Chancellor Laster issued his post-trial decision. The court found that Fresenius had validly terminated the Merger Agreement because Akorn violated its compliance representations and its covenant to continue to conduct its business in the ordinary

course during the pendency of the merger. The court determined that Akorn's breaches of its compliance representations were material because they amounted to approximately $900 million in economic harm. The price of Akorn's stock dropped precipitously – ***losing more than half of its value*** – in response to the release of the post-trial decision. Specifically, on the prior trading day, September 28, 2018, Akorn common stock closed at a price of $12.98. By the close of trading on October 1, 2018, the stock price closed at $5.36 per share (down 58.71%).

219. Yet the truth about Akorn's FDA noncompliance was still not completely revealed. On January 4, 2019, Akorn received a warning letter from the FDA related to an inspection of Decatur. When Akorn disclosed the existence of this letter on January 9, 2019, its stock price dropped even lower. The stock lost another 11.68% in value, closing at a price of $3.48 per share, down $0.46 from the prior day's closing price.

**NO SAFE HARBOR**

220. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not "forward-looking statements" nor were they identified as "forward-looking statements" when made. Nor was it stated with respect to any of the statements forming the basis of this Complaint that actual results "could differ materially from those projected." To the extent there were any forward-looking statements, 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. Alternatively, to the extent that the statutory safe harbor does 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 knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized

and/or approved by an executive officer or director of Akorn who knew that those statements were false when made.

## COUNT I

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

221. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

222. Count I is brought against Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j, and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

223. Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi, both directly and indirectly, used the means and instrumentalities of interstate commerce in the United States to make the materially false and misleading statements and omissions of material fact alleged herein to: (a) deceive the investing public, including Plaintiffs, as alleged herein; (b) artificially inflate and maintain the market price of Akorn common stock; and (c) cause Plaintiffs to purchase Akorn common stock and Akorn common stock-based swaps at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi took the actions set forth above.

224. Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi, both directly and indirectly: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Akorn common stock and Akorn common stock-based

swaps in an effort to artificially inflate and maintain the market prices for Akorn common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5.

225. By virtue of their high-level positions at the Company and on the Board, Rai, Portwood, Weinstein, Johnson, and Tambi were authorized to make public statements, and made public statements on Akorn's behalf. These senior executives and Board members were privy to and participated in the creation, development, and issuance of the materially false and misleading statements alleged herein, and/or were aware of the Company's and their own dissemination of information to the investing public that they knew or recklessly disregarded was materially false and misleading.

226. In addition, Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi had a duty to disclose (a) truthful information necessary to render their affirmative statements not materially misleading so that the market price of the Company's securities would be based on truthful, complete and accurate information; and (b) in Akorn's periodic filings with the SEC, under Item 303 of Regulation S-K, "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations."

227. Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi acted with knowledge or reckless disregard for the truth of the misrepresented and omitted facts alleged herein, in that they failed to ascertain and disclose the facts, even though such facts were known or readily available to them. Defendants Akorn's, Rai's, Portwood's, Weinstein's, Johnson's, and Tambi's material misrepresentations and omissions were done knowingly and/or recklessly, and had the effect of concealing the truth with respect to Akorn's operations, business, performance and prospects from the investing public, including misrepresenting the truth about

Akorn's compliance with FDA regulations, Akorn's manufacturing facilities, Akorn's ANDA pipeline, Akorn's operations during the pendency of the merger, Fresenius's investigation of Akorn's data integrity, and the effectiveness of Akorn's disclosure controls and procedures. By concealing these material facts from investors, Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi supported the artificially inflated price of Akorn's common stock.

228. The dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, artificially inflated the market price of Akorn's common stock. In ignorance of the fact that the market prices were artificially inflated, and relying indirectly upon the materially false and misleading statements made by Defendants and upon the integrity of the market in which the Company's securities trade, or upon the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants, Plaintiffs purchased Akorn common stock and Akorn common stock-based swaps at artificially inflated prices. As a series of partial but inadequate disclosures were issued, the price of Akorn's securities substantially declined.

229. At the time of the material misrepresentations alleged herein, Plaintiffs were ignorant of their falsity. Had Plaintiffs known the truth with respect to the business, operations, performance and prospects of Akorn, which was concealed by Defendants, Plaintiffs would not have purchased Akorn securities, or if they had purchased such securities, they would not have done so at the artificially inflated prices that they paid.

230. By virtue of the foregoing, Defendants Akorn, Rai, Portwood, Weinstein, Johnson, and Tambi have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

231. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages in connection with their transactions in the Company's securities.

232. Taking into account, *inter alia,* tolling of the limitations period by the filing of the class action complaint against Defendants in the Class Action, Plaintiffs have brought this claim within two years of discovery of the violations alleged herein, and within five years of the violations alleged herein. Consequently, this action is timely.

## COUNT II

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

233. Plaintiffs repeat and reallege each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

234. Count II is asserted against Defendants Rai, Portwood, Weinstein, Johnson, and Tambi and is based upon Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

235. Each of Defendants Rai, Portwood, Weinstein, Johnson, and Tambi was a controlling person of Akorn within the meaning of Section 20(a) of the Exchange Act.

236. By virtue of their high-level positions and Board membership, and their ownership and contractual rights, substantial participation in, and/or awareness of, the Company's operations and/or knowledge or reckless disregard of the materially false and misleading statements and material omissions disseminated to the investing public, Defendants Rai, Portwood, Weinstein, Johnson, and Tambi had the power to influence and control, and did in fact influence and control, directly or indirectly, the decision-making of the Company.

237. Defendants Rai, Portwood, Weinstein, Johnson, and Tambi were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged herein to be materially false and misleading prior to and/or shortly after these

statements were issued and had the ability to prevent the issuance of the statements of cause the statements to be corrected. In particular, Defendants Rai, Portwood, Weinstein, Johnson, and Tambi each had direct and/or supervisory involvement in the day-to-day operations of the Company, and therefore are presumed to have had the power to control or influence the particular false and misleading statements and omissions giving rise to the securities violations alleged herein.

238. Defendants Rai, Portwood, Weinstein, Johnson, and Tambi culpably participated in Akorn's violation of Section 10(b) and Rule 10b-5 with respect to Count I.

239. By reason of the conduct alleged in Count I, Akorn is liable for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and Defendants Rai, Portwood, Weinstein, Johnson, and Tambi are liable pursuant to Section 20(a) based on their control of Akorn.

240. Defendants Rai, Portwood, Weinstein, Johnson, and Tambi are liable for the aforesaid wrongful conduct, and are liable to Plaintiffs for the substantial damages suffered in connection with their purchases of Akorn common stock and Akorn common stock-based swaps.

241. Taking into account, *inter alia,* tolling of the limitations period by the filing of the class action complaint against Defendants in the Class Action, Plaintiffs have brought this claim within two years of discovery of the violations alleged herein, and within five years of the violations alleged herein. Consequently, this action is timely.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request relief and judgment, as follows:

(a) Awarding compensatory damages against Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

(b) Awarding Plaintiffs their reasonable costs and expenses incurred in this action; and

(c) Awarding such other and further relief as the Court may deem just and proper.

## JURY DEMAND

The Plaintiffs hereby demand a trial by jury as to all issues so triable.

Dated: December 24, 2019

Respectfully submitted,

MAGNETAR CONSTELLATION FUND II-PRA LP, MAGNETAR SYSTEMATIC MULTI-STRATEGY MASTER FUND LTD, MAGNETAR PRA MASTER FUND LTD, MAGNETAR MSW MASTER FUND LTD, MPROVED SYSTEMATIC MERGER ARBITRAGE FUND, MPROVED SYSTEMATIC MULTI-STRATEGY FUND, AMX MASTER – MAGNETAR – PASSIVE RISK ARBITRAGE, BLACKSTONE ALTERNATIVE MULTI-STRATEGY SUB FUND IV LLC, and BLACKSTONE DIVERSIFIED MULTI-STRATEGY FUND

By: /s/ *Andrew D. Campbell*

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