UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

KBC ASSET MANAGEMENT NV, SHEET METAL WORKERS' NATIONAL PENSION FUND, and CHESTER COUNTY EMPLOYEES RETIREMENT FUND, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. AEGERION PHARMACEUTICALS, INC., et al., Defendants.	No. 1:14-cv-10105-MLW CLASS ACTION **DEMAND FOR TRIAL BY JURY**

THIRD AMENDED CLASS ACTION COMPLAINT

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By and through their undersigned counsel, and pursuant to Federal Rule of Civil Procedure 15(a)(1)(B), KBC Asset Management NV, Sheet Metal Workers' National Pension Fund, and Chester County Employees' Retirement Fund (collectively, "Plaintiffs") allege the following against Aegerion Pharmaceuticals, Inc. ("Aegerion" or the "Company"), Marc D. Beer ("Beer"), Craig Fraser ("Fraser"), and Mark J. Fitzpatrick ("Fitzpatrick") (collectively, "Defendants"), upon personal knowledge as to those allegations concerning Plaintiffs and, as to all other matters, upon the investigation of counsel, which included, without limitation: (a) review and analysis of public filings made by Aegerion with the Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and other publications disseminated by certain of the Defendants and other related non-parties; (c) review of news articles, securities analyst reports, and shareholder communications; (d) review of other publicly available information concerning Defendants; (e) information readily obtainable on the Internet; (f) interviews with factual sources, including individuals formerly employed by Aegerion; and (g) consultation with experts. Many of the facts supporting the allegations contained herein are known only to Defendants named herein or are exclusively within their custody and control. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. This is a federal securities fraud class action against Aegerion and certain of its former officers and/or directors for violations of the federal securities laws. Plaintiffs bring this action on behalf of themselves and all other similarly situated persons or entities, other than Defendants and certain other excluded persons and entities as set forth below who purchased or otherwise acquired the publicly traded common stock of Aegerion between April 30, 2013 and May 11, 2016 ("Class Period") and who were damaged hereby ("Class"). This action seeks

remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act").

2. Aegerion is a biopharmaceutical company engaged in the development of novel therapeutics to treat debilitating and fatal rare diseases in the United States. The Company's exclusive product throughout the majority of the Class Period was JUXTAPID™ (lomitapide) capsules ("JUXTAPID"), an adjunct to a low-fat diet and other lipid-lowering treatments in patients with an extremely rare cholesterol condition known as Homozygous Familial Hypercholesterolemia ("HoFH").

3. At bottom, this case involves an illegal marketing campaign for JUXTAPID to target patients that fell outside of the drug's approved label (*i.e.*, non-HoFH patients), and in direct violation of various criminal and regulatory provisions. By taking advantage of ambiguous diagnostic criteria to distinguish between HoFH and another closely related, but not nearly as severe, condition known as Heterozygous Familial Hypercholesterolemia ("HeFH"), the Company targeted non-HoFH patients for whom the drug had not been approved by touting the supposed off-label benefits.

4. Defendants embarked on their deceptive and illegal marketing scheme to generate as much revenue as possible where the annual drug price was between $295,000-$377,000 per patient and knowing that a more tolerable, less-expensive competitor drug, PCSK9, was due to be available to patients beginning in late 2015. Defendants' scheme was highly successful, at least on the surface. Based on its illicit marketing practice, the Company went on to achieve brilliant results for fiscal year ("FY") 2013. Specifically, Aegerion initially expected to end the year with "approximately 250-300 patients on therapy on a global basis" and "global net revenues of $15 million to $25 million for FY 2013." However, as a direct result of Defendants'

off-label marketing practices, the Company raised its revenue guidance twice, ultimately ending 2013 with $48.5 million in net product sales and 467 active patients on therapy globally.

5. As would later be revealed, however, the Company's successful launch was predicated on its illicit marketing practices that were developed to reach non-HoFH patients. These marketing practices, once discovered, would lead to investigations by three federal agencies for violations of criminal and regulatory violations and would cause the Company to alter these marketing practices that would ultimately lead to its demise.

6. Questions began to be raised when the Company's then Chief Executive Officer ("CEO") appeared on two televised interviews wherein he made statements touting the "off-label" uses of JUXTAPID. These statements drew the attention of the U.S. Food and Drug Administration ("FDA") who, in November 2013, issued a Warning Letter, described more fully below, chastising the Company for its statements and requiring that it take corrective action ("Warning Letter"). Although the Company was able to assuage the FDA through a series of corrective actions outlined in the agency's close-out letter, privately issued in August 2014, the same illegal marketing practices also resulted in investigations by the U.S. Department of Justice ("DOJ") and SEC that remained pending throughout the course of the Class Period until it was finally revealed that Aegerion had agreed to a stunning $40 million settlement for criminal and civil violations. Aegerion also agreed to plead guilty to two misdemeanor charges in connection with the settlement.

7. The change to lawful marketing practices had a crippling effect on the Company's sales due to its inability to add adequate new patients, but Defendants shielded the market from understanding the true impact of its marketing scheme on the Company's financial condition and prospects, as well as the ongoing federal investigations, by continuously touting how it closely

monitored certain key metrics that informed its guidance and better positioned it to capitalize on the JUXTAPID market.

8. In monitoring these key metrics, such as the number of patients that would begin, but ultimately stop, treatment ("dropouts"), the number of patients that obtained prescriptions but never started on the therapy ("non-starts"), and the number of patients that began and continued treatment ("compliance"), however, Defendants knew, but the market did not understand at the time, that just as quickly as non-HoFH patients were starting JUXTAPID therapy, they almost as quickly stopped due to the associated significant side effects and dietary restrictions.

9. Therefore, to hide their fraudulent scheme from investors, Defendants stopped reporting such metrics to the market. Instead, they encouraged investors to simply "trust the guidance." By the end of the Class Period, however, investors would come to learn that the Company's drop-out rate had increased from 10% to a staggering 58%.

10. The result of the change in marketing practices, that reduced the number of patients to whom the drug was prescribed, combined with the increasing rate of patient discontinuations, caused Defendants to have to revise Aegerion's otherwise optimistic 2014 financial guidance down twice which, when revealed, resulted in a huge blow to the Company's stock price, falling nearly 41% in a single day on high trading volume.

11. The Company fared no better in the years that followed. While the Company was able to achieve its fiscal 2015 guidance, it did so only by raising the price of JUXTAPID because, behind the scenes, the availability of PCSK9 entering the market resulted in additional dropouts, the inability to target non-HoFH patients resulted fewer new patient adds (the Company ended the year with 142 fewer U.S. prescriptions than it had the prior year), and

virtually every executive, including its CEO, Chief Financial Officer ("CFO"), and Chief Operating Officer ("COO") had "resigned" by year-end.

12. In 2016, not only was the Company suffering financially as a result of its dismal JUXTAPID sales – the full-effect of its revised marketing plan resulted in a dearth of new patients and the discontinuation by those that were on the drug, despite the Company's best efforts to keep them on – but on May 12, 2016, the Company announced that it had reached preliminary agreements in principle with the DOJ and the SEC to settle the ongoing investigations by these agencies into the Company's sales activities and disclosures related to JUXTAPID.

13. The Company's stock price fell from a Class Period high of $97.24 per share to a close of $1.91 per share on the date the settlement was announced, resulting in devastating losses for investors. The Company has since entered into a definitive merger agreement under which Aegerion will be merged with a wholly owned indirect subsidiary of QLT Inc. ("QLT"), a biotechnology company dedicated to the development and commercialization of innovative ocular products that address the unmet medical needs of patients and clinicians worldwide.

II. JURISDICTION AND VENUE

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

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act.

16. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) because Defendants maintain an office in this District, and many of the acts and omissions complained of herein occurred in substantial part in this District.

17. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiffs

18. Plaintiffs, as set forth in the certifications on file [Dkt. Nos. 11-1, 18-2, and 46-1 through 46-3], and incorporated by reference, purchased Aegerion shares at artificially inflated prices during the Class Period and were damaged when the truth was revealed, as detailed herein.

B. Defendants

19. Defendant Aegerion is a Delaware corporation with its principal executive offices located at 101 Main Street, Suite 1850, Cambridge, Massachusetts. Aegerion common stock trades on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "AEGR."

20. Defendant Beer served as the CEO and director of Aegerion from August 19, 2010 to July 27, 2015. He has more than 20 years' experience in profit and loss management, sales and marketing management, and research and development program management in therapeutic, surgical, and in vitro diagnostic systems businesses. Defendant Beer received a Bachelor of Science in Business Administration from Miami University in Ohio.

21. Defendant Fraser joined the Company in 2011. From October 2011 to September 2012, Defendant Fraser served as Aegerion's President, U.S., until he transitioned to the position as the Company's President, U.S. Commercial & Global Manufacturing and Supply Chain. He served as Aegerion's COO from July 30, 2014 until July 27, 2015. Defendant Fraser holds a Bachelor of Science degree from Slippery Rock University.

22. Defendant Fitzpatrick served as the Company's CFO from May 9, 2011 until June 5, 2015 and its Chief Accounting Officer from February 29, 2012 until May 2015. Defendant Fitzpatrick has over 18 years of experience in the financial management of biotechnology and high technology companies. Defendant Fitzpatrick earned his Bachelor of Science in Accounting from Boston College's School of Management. He earned a Certified Public Accountant certificate in Massachusetts in 1987.

23. The Defendants referenced above in ¶¶20-22 are sometimes referred to herein as the "Individual Defendants." The Individual Defendants and Aegerion are collectively referred to herein as the "Defendants."

24. During and prior to the Class Period, the Individual Defendants, as senior executive officers of Aegerion, were privy to confidential and proprietary information concerning the Company, its operations, finances, financial condition, and present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Aegerion's sales trends, prescription count, and patient dropouts as discussed in detail below. Because of their positions with the Company, the Individual Defendants had access to non-public information about Aegerion's business, finances, and present and future business prospects via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and any committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

25. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause (and did cause) the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to, and did, directly or indirectly, control the conduct of Aegerion's business.

26. The Individual Defendants participated in the drafting and preparation of, and had ultimate authority over, various public, shareholder, and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom. Because of their executive and managerial positions with Aegerion, each of the Individual Defendants had access to the adverse undisclosed information about Aegerion's business prospects, financial condition, and sales trends as particularized herein, and knew, or recklessly disregarded, that these adverse facts rendered the positive representations made by or about Aegerion and its business issued or adopted by the Company materially false and misleading.

27. As senior executive officers and as controlling persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was, and is, traded on the NASDAQ and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Aegerion's financial condition and performance, growth, operations, financial statements, business, sales, management, earnings, and present and future business prospects, and to correct any previously issued statements that were materially misleading or untrue so that

the market price of Aegerion's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

28. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Aegerion's publicly traded common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public regarding the Company's business prospects and the intrinsic value of Aegerion common stock, causing Plaintiffs and other members of the Class to purchase Aegerion common stock at artificially inflated prices.

IV. SUBSTANTIVE ALLEGATIONS

A. Background of the Company

29. Aegerion is a biopharmaceutical company, engaged in the development and commercialization of novel therapeutics to treat debilitating and fatal rare diseases in the United States. The Company's first product, lomitapide, received marketing approval, under the brand JUXTAPID™, from the FDA in late December 2012, as an adjunct to a low-fat diet and other lipid lowering treatments, including low-density lipoprotein ("LDL") apheresis where available, to reduce low-density lipoprotein cholesterol ("LDL-C"), total cholesterol ("TC"), apolipoprotein B ("apo B") and non-high-density lipoprotein cholesterol ("non-HDL-C") in adult patients with HoFH. The drug was launched in the United States in late January 2013 and granted orphan drug status[1] for a period of seven years for the treatment of HoFH in the United States.

[1] "Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will

B. JUXTAPID: Its Purpose and the Road to FDA Approval

30. JUXTAPID is a small molecule microsomal triglyceride protein ("MTP") inhibitor developed by Aegerion as a treatment for HoFH. MTP exists in the liver and intestines where it contributes to the formation of cholesterol. Aegerion believes that the inhibition of MTP is a way to lower cholesterol.

31. HoFH is a serious and rare genetic disease that impairs the function of the receptor responsible for removing the bad cholesterol (LDL-C) from a person's blood. The loss of the low density lipoprotein receptor ("LDL-R") function results in an extreme elevation of blood cholesterol levels. Cholesterol, which is a naturally occurring molecule, is transported in the blood and packaged in the liver and intestines to release throughout the body. Excess levels of cholesterol in the blood, or HoFH, can cause serious diseases.

32. HoFH is usually the result of a genetic mutation in both alleles of the LDL-R gene, but can also be caused by other mutations. It is the most severe form of an inherited disease known as Familial Hypercholesterolemia "FH."

33. People with HoFH have a decreased ability to remove excess LDL cholesterol (so-called "bad" cholesterol) from their bloodstream. As a result, cholesterol in the blood builds up, resulting in very high LDL cholesterol levels.

34. According to the American Heart Association, optimal LDL cholesterol levels for the general population are less than 100 mg/dL. Millions of Americans have high cholesterol, which is often considered to be 160 mg/dL or higher. But most people with HoFH have LDL

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be recovered from sales in the U.S. for that drug." *See* Aegerion Pharm., Inc., Annual Report for FY ended December 31, 2012 ("2012 Form 10-K") at 19 (Mar. 18, 2013), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312513112185/d447885d10k.htm.

cholesterol levels many times higher than that. Optimal LDL cholesterol levels for most people with HoFH should be even lower than 100 mg/dL, and often lower than 70 mg/dL.

35. A patient with untreated HoFH may develop a premature and progressive narrowing or blocking of the arteries, or atherosclerosis, that may lead to cardiovascular events such as heart attack or stroke in the patients in their twenties. Additionally, if left untreated, a patient with HoFH will generally die before the age of 30.

36. Closely related to HoFH is HeFH, the second form of Familial Hypercholesterolemia (FH). Like HoFH, HeFH is an inherited genetic disorder that causes dangerously high cholesterol levels, which can lead to heart disease, heart attack, or stroke at an early age if left untreated. Those with one parent with FH have a 50 percent chance of inheriting HeFH.

37. However, the signs and symptoms of HoFH are the same as for HeFH. Although the clinical symptoms are not as pronounced as in cases of HeFH, both HoFH and HeFH patients still have an elevated risk of developing coronary heart disease at some time in their life. Early diagnosis and treatment for both HoFH and HeFH can significantly reduce the risk of coronary heart disease or delay its onset.

38. Although there is no universally accepted criterion for the diagnosis of HoFH, a diagnosis is usually made by: (1) an assessment of cholesterol levels; (2) a physical examination for the presence of xanthomas;[2] and (3) an assessment of the family history of the patient. Genetic testing detects roughly 80% of the cases.

[2] A xhanthoma is an irregular yellow patch or nodule on the skin, caused by deposition of lipids. http://medical-dictionary.thefreedictionary.com/xanthoma.

C. Prevalence of HoFH in the United States

39. A patient registry does not currently exist, nor does an alternative method of establishing the actual number of patients with HoFH in any geography. Although no formal studies or epidemiologic data have estimated the prevalence of HoFH, medical literature has reported a one in a million prevalence rate of genotypic HoFH.[3] This prevalence rate was determined based on a prevalence rate of 1:500 for the HeFH population. The U.S. population is approximately 314.8 million, which would result in approximately 315 people with HoFH in the United States.

40. Although the Company acknowledged the "true" HoFH patient population is only approximately one in 1,000,000 people (or approximately 315 people in the U.S.) in its New Drug Application ("NDA"), described below, the Company, notwithstanding, publicly stated that it believed that the prevalence rate of HoFH was higher because the historically reported definition of HoFH used a narrower genotypic definition of HoFH. Further, the Company acknowledged just prior to the start of the Class Period, that its "business . . . depends entirely on the successful commercialization of our first product, [JUXTAPID]" and that its ability to "meet expectations with respect to sales of lomitapide and revenues from such sales, and to attain profitability and positive cash flow from operations . . . , will depend on a number of factors, including . . . : the prevalence of HoFH being significantly higher than the historically reported rate of one person in one million, and more consistent with management's estimates . . . ."[4]

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[3] *See* Raghu Vishwanath & Linda C. Hemphill, Familial hypercholesterolemia and estimation of US patients eligible for low-density lipoprotein apheresis after maximally tolerated lipid-lowering therapy, J. CLINICAL LIPIDOLOGY 8, 18-28 (2014).

[4] Aegerion's 2012 Form 10-K at 35.

D. JUXTAPID Trials, FDA Approval and the Addressable Population

41. The FDA regulates drugs such as JUXTAPID under the Federal Food Drug and Cosmetic Act ("FDCA").

42. Before a company can market a drug in the United States, the FDA's process generally includes the following requirements:

- The completion of preclinical laboratory test, animal studies and the formulation of studies in accordance with the Good Laboratory Practices and other applicable regulations;
- The submission of an investigational drug application to the FDA which must become effective prior to the commencement of a human clinical trial;
- The performance of human clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- The submission of the NDA to the FDA;
- The completion of registration batches and validation of the Company's manufacturing process to show that the Company is capable of consistently producing quality batches of the drug;
- A satisfactory completion of an FDA inspection of the Company's manufacturing facility or facilities responsible for producing the drug to assess compliance with current good manufacturing practice; and
- An FDA review and approval of the NDA.

43. As part of the process of obtaining FDA approval, Aegerion was required to conduct human clinical studies with JUXTAPID. Clinical studies are conducted in a series of phases, with each phase designed to answer a specific research question. The four phases include:

- Phase I: a new drug or treatment is tested on a small group of people for the first time to evaluate its safety, determine the dosage range, and identify any side effects;
- Phase II: the drug or treatment is given to a larger group of people to determine if it is effective and to further evaluate its safety;

- Phase III: the drug or treatment is given to an even larger group of people to confirm its effectiveness, monitor side effects, compare the drug or treatment to commonly used treatments, and to collect information that will allow it to be used safely; and

- Phase IV: after the drug or treatment has been marketed, studies are conducted to gather information on its effect on various patient populations and any side effects associated with long-term use.

44. Aegerion has conducted a total of 24 clinical studies with lomitapide,[5] including Phase I, II, and III studies on healthy adults, adults with HoFH, adults with elevated LDL-C levels (without HoFH), adults with hepatic impairment, and adults with end-stage renal disease.[6]

45. Of most importance to obtaining FDA approval was the Company's Phase III clinical study. A total of 29 subjects with genetically confirmed HoFH were treated with lomitapide in the Phase III study. The purpose of the Phase III clinical study was to evaluate the safety and effectiveness of JUXTAPID in reducing LDL-C level in the 29 patients with HoFH who participated. The Phase III study was a multi-national, single-arm, open-label trial that lasted 78 weeks. Aegerion published its results on November 2, 2012.

46. During this Phase III study, JUXTAPID was initiated at 5 mg daily and was gradually increased to doses of 10 mg, 20 mg, 40 mg, and 60 mg, based on the tolerability and liver enzyme levels in each patient. The addition of JUXTAPID to an existing lipid-lowering therapy of HoFH patients significantly reduced the LDL-C from a baseline average of 336 mg/dL to 190 mg/dL, or a 40% reduction at Week 26 of the study. Twenty-three subjects completed treatment through the primary efficacy endpoint at Week 26, and six subjects discontinued prior to that time.

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[5] At the time Aegerion conducted its clinical studies, lomitapide had not received the brand name JUXTAPID by the FDA and was simply referred to as lomitapide.

[6] *See* Aegerion Pharmaceuticals Sponsor's Background Package, "Lomitapide, for the Treatment, etc." for the Endocrinologic and Metabolic, etc. (Oct. 17, 2012).

47. Among the 23 subjects who completed the Phase 3 study through Week 78, nineteen were enrolled in the extension study AEGR-733-012 for continued treatment with lomitapide. Among the nineteen subjects enrolled, sixteen remained on treatment as of the data cut-off date of December 31, 2011 for reporting in the four-month Safety Update Report, and three (17%) had discontinued.

48. Together with the FDA, Aegerion developed a Risk Evaluation and Mitigation Strategy ("REMS") strategy to manage known or potential serious risks associated with the drug. In fact, because of the risk of hepatotoxicity, JUXTAPID is available only through REMS. The JUXTAPID REMS program educates prescribers about the risk of hepatoxicity associated with the use of JUXTAPID and the need to monitor patients during treatment with JUXTAPID per product labeling. The REMS program also restricts access to therapy with JUXTAPID to patients with a clinical or laboratory diagnosis consistent with HoFH.[7] The program requires prescribers: (a) train on the risk of hepatoxicity associated with the use of JUXTAPID, appropriate patient selection and monitoring, and the REMS requirements; (b) certify completion of training and enrollment in the JUXTAPID REMS program; and (c) attest to the safe use of the drug for each new prescription by completing a Prescription Authorization Form (which includes an affirmation by the prescriber that the "patient has a clinical or laboratory diagnosis consistent with HoFH.").

49. Specifically, the REMS-authorized prescribers must attest on the JUXTAPID REMS Prescription Authorization Form[8] that: (a) they understand that JUXTAPID is indicated

[7] JUXTAPID REMS Program, http://www.juxtapidremsprogram.com (last visited June 22, 2016).

[8] JUXTAPID REMS Program Prescription Authorization Form, *available at* http://www.juxtapidremsprogram.com/_pdf/JUXTAPID%20REMS_Program_Prescription_Authorization%20Form.pdf (last visited June 22, 2016).

as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL-C, TC, apo B, and non-HDL-C in patients with HoFH; (b) they affirm that their patient has a clinical or laboratory diagnosis consistent with HoFH; (c) they understand that JUXTAPID has not been studied in patients less than 18 years of age; and (d) liver-related laboratory tests have been obtained as directed on the label (also referred to as the "Prescribing Information.").

50. According to the FDA-approved label, JUXTAPID was intended for use in patients with HoFH. Specifically, the limitations of use provide that "[t]he safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH."[9] The limitations of use further provide that "[t]he effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined."[10] The Prescribing Information further provides: "[i]t is not known if JUXTAPID can decrease problems from high cholesterol, such as heart attack, stroke, death or other health problems."[11]

51. In addition to marketing and selling JUXTAPID within the United States, Aegerion sought, and ultimately obtained, approval to market and sell the drug in global markets as well, including, among others, Canada, Mexico, South America, Europe, and Asia. As of February 2014, the Company emphasized that it expected a total global population of 4,000 to

[9] Highlights of Prescribing Information at 1, *available at* http://www.aegerion.com/Collateral/Documents/English-US/Prescribing_Information.pdf (last visited June 27, 2016).

[10] *Id*. at 2.

[11] *Id*. at 11.

5,000 patients, at $295,000 per patient annually.[12] The Company further expected that annual revenue from JUXTAPID would eventually exceed $1 billion.[13]

52. In 2010, Aegerion commissioned an independent consultant to prepare a commercial assessment of the HoFH market. In the report, it was estimated that the total number of patients likely to seek treatment with symptoms, signs or laboratory findings consistent with HoFH in each the United States and the European Union ("EU") was approximately 3,000 patients. This estimate, however, included a segment of severe HeFH patients whose levels of LDL-C are not controlled by current therapies and are not approved for JUXTAPID. According to the Company, rare diseases are often found to have a higher than expected prevalence rate once the first product available to treat the disease is introduced. The Company also stated that the actual size of the total addressable market in the United States was to be determined after a substantial commercial history of selling JUXTAPID and after Aegerion could assess how the drug was being used clinically.

53. That said, though the signs and symptoms of HoFH are the same as for HeFH, in HoFH cases they appear earlier, often in early childhood, and the disease progresses much more

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[12] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q4 2013 Aegerion Pharm. Inc., Earnings Conf. Call, Feb. 26, 2014, at 3 ("Q4 2013 Earnings Conf. Call"). JUXTAPID has undergone numerous price increases throughout the Class Period, the most recent being on May 15, 2015, where the Company raised the cost per patient to $377,000 annually. Cowen and Company, *Another Price Increase For Juxtapid*, May 19, 2015.

[13] *Id*. By March 2014, the Company reported that "there still may be at least 3,000 HoFH patients in the U.S. based on our belief that the base prevalence rate may be higher than our consultant estimated." Aegerion Pharm., Inc., Annual Report for FY ended December 31, 2013 ("2013 Form 10-K") at 11 (Mar. 3, 2014), *available at* http://ir.aegerion.com/secfiling.cfm?filingID=1193125-14-79791&CIK=1338042. The Company continued to report these expected patient populations throughout the Class Period. *See also* Aegerion Pharm., Inc., Quarterly Report (Form 10-Q), at 28 (May 9, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312514192076/d70792 9d10q.htm.

aggressively. Further, although the clinical symptoms are not as pronounced as in cases of HeFH, both HoFH and HeFH patients still have an elevated risk of developing coronary heart disease at some time in their life. Early diagnosis and treatment for both HoFH and HeFH can significantly reduce the risk of coronary heart disease or delay its onset. In the case of HeFH, patients tend to develop many of the noticeable warning signs associated with heart disease by the time they reach their 40s or 50s. If the disorder is left untreated, the condition could even be fatal by this stage of life.

E. JUXTAPID Launches in the United States to Great Success

54. JUXTAPID was launched within the United States in late January 2013 and granted orphan drug status for a period of seven years for the treatment of HoFH in the United States. That status is scheduled to expire on December 21, 2019.[14]

55. On January 7, 2013, the Company announced its business objectives for 2013 stating that it "expect[ed] 2013 to be a transformational year."[15] Aegerion expected to end the year with "approximately 250-300 patients on therapy on a global basis" and "global net revenues of $15 million to $25 million for FY 2013."[16]

56. Throughout 2013, the Company touted the interest it was experiencing from cardiologists and informed the market as to how it was altering its marketing practices to target

[14] In July 2013, the Company received marketing authorization for lomitapide in the EU, under the brand name LOJUXTA® (lomitapide) hard capsules as a treatment for HoFH in adults. Lomitapide is also approved for the treatment of HoFH in Norway, Iceland, Mexico, and Canada. The Company sells lomitapide, on a named patient basis, in Brazil and in a limited number of other countries outside the United States and the EU where such sales are authorized based on the U.S. or EU approval.

[15] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Jan. 7, 2013), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312513004424/d462863dex991.htm.

[16] *Id*.

this "higher-than-initially-anticipated interest and excitement from cardiologists who are eager to treat and who appear to have a meaningful number of patients within their practices."

57. As a result of this interest, and the number of patients that cardiologists were onboarding, by July 30, 2013, the Company had 215 patients taking JUXTAPID, and another 463 prescriptions had been written for the drug.[17] As a result of this success, the Company raised its sales forecast to a range of $30-35 million on the July 30, 2013 earnings conference call. At that time, the Company reported that with six months of launch experience under its belt, the dropout rate from JUXTAPID therapy was "less than 10%" and the compliance rate, *i.e.*, the percentage of patients who take their pill daily, was "80-90 percent."[18]

58. On October 30, 2013, the Company once again raised its full year 2013 revenue guidance for net product sales to $45 to $50 million, from the previous range of $30 to $35 million.

59. The Company ended 2013 with $48.5 million in net product sales and 467 active patients on therapy globally with 87% of its net product sales coming from its United States business, and 13% coming from other countries, primarily Brazil.

F. The Company Engaged In Deceptive Marketing Practices That Draw the Attention of Three Federal Agencies

60. The success of 2013, however, was predicated on what the market would eventually come to learn were deceptive marketing practices aimed at targeting patients for whom JUXTAPID was not approved.

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[17] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q2 2013 Aegerion Pharm. Inc., Earnings Conf. Call, July 30, 2013, at 4 ("Q2 2013 Earnings Conf. Call").

[18] *Id*. at 4.

61. The Company's statements and actions, detailed below, were contrary to REMS and the drug's Prescribing Information which, as stated above, specifically limited the intended use of JUXTAPID to patients with HoFH and provided that the safety and effectiveness of the drug was not approved, nor determined to be effective, for the treatment of non-HoFH patients or those with cardiovascular (or other) medical conditions.

62. To reach this larger category of patients, Defendants targeted cardiologists, rather than solely lipidologists. Throughout the Class Period, the Company touted its marketing strategies, the "interest and excitement" of cardiologists, and the larger population of patients that it was able to reach:

April 30, 2013

- "As I have communicated to you previously, we're seeing higher-than-initially-anticipated interest and excitement from cardiologists who are eager to treat and who appear to have a meaningful number of patients within their practices."[19]

- "[W]e were surprised at the number of cardiologists that had patients and that were onboarding. We continue to be surprised by that [because] the characterization of those cardiologists that we're learning a lot about and we're optimizing our marketing and sales plan real time. And I think that has something to do with the acceleration of scripts this last couple months. So I -- we are learning a lot. We've got lots of metrics and analytics around this launch and there's more patients with the community cardiologists than we had previously thought of, and the severity of those patients is very severe."[20]

July 30, 2013

- "[W]e're getting more prescriptions from cardiologists than we are from lipidologists. We do have a large percentage of our patients coming from lipidologists as well. But the larger percentage -- and again, it's probably

[19] Defendant Beer, Thomson Reuters Streetevents, Edited Transcript, AEGR-Q1 2013 Aegerion Pharm. Inc., Earnings Conf. Call, Apr. 30, 2013, at 3 ("Q1 2013 Earnings Conf. Call").

[20] *Id*. at 8.

just, it's consistent with just more cardiologists and just where the patients reside."[21]

October 30, 2013

- "We are beginning to see growing traction from our focused commercial activities specifically several commercial awareness and educational programs focused on the cardiologists that we began in Q2. These activities were data-driven actions and are beginning to show results. In the third quarter, we added a significant number of patients to our growing base of active patients on JUXTAPID. Prescription rates continue."[22]

- "Yes, we continue to see the cardiologist as a growing market and we are getting more prescriptions of patients on therapy there than in other specialties. So as we shared with you, there was a strong focus in putting some activities that focused -- educational activities focused on cardiologists in Q2. I will emphasize we are just at the beginning of that and the vast majority of cardiologists we still have not seen. So there is a good educational set of programs that Craig and his team are focused on the cardiologists and that will be important going forward. The severity of the patient hasn't changed. The HoFH patient obviously is a very severe patient to start off with but we haven't seen fluctuation in severity."[23]

- "I will also comment that I think this disease is underdiagnosed and we haven't called on the majority of the cardiologists."[24]

- "We get a lot of patients that come in from the lipidologists. I will say that they have fewer patients in their practice. They tend to study the patient longer and it takes them longer to put somebody on therapy because I think that they are trying a lot of different products at the same time. The cardiologists not that case. The cardiologists tell us that we are seeing 35 patients today, we are very busy, we've got to get the patient out of harm's way quickly. We can't make every patient a study and they tend to put the patient on therapy quicker than a lipidologist. But both are treating effectively and we are getting good support…. But there's more cardiologists out there so just by number of cardiologists and the fact that they haven't referred the HoFH patient unless the patient is being

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[21] Defendant Beer, Q2 2013 Earnings Conf. Call, at 18.

[22] Defendant Beer, Thomson Reuters Streetevents, Edited Transcript, AEGR-Q3 2013 Aegerion Pharm. Inc., Earnings Conf. Call, Oct. 30, 2013 at 3 ("Q3 2013 Earnings Conf. Call").

[23] *Id*. at 8.

[24] *Id*. at 9.

> apheresed. That's what they keep telling us. They say we feel very comfortable putting a patient on max dose statins and trying everything the medical community can try but if they don't go on apheresis, we don't feel a need to pass them onto lipidologists. That's when the cardiologist is holding on to the patient."[25]

- "We've talked a lot about our early launch learning that cardiologists were managing many more HoFH patients than we or they had initially expected. This remains true. We have worked quickly to prioritize and increase our activities to be able to effectively reach this market."[26]

63. These sorts of repeated representations were of significant interest to the market because they provided a huge financial upside to the Company and its revenue projections.

64. Additionally, this sort of illicit practice was material to the Company, as the benefits associated with such practices included, among other things, justifying a larger patient population, acceleration in prescriptions written, and an increase in the overall number of patients taking JUXTAPID. As Defendants noted throughout 2013:

April 30, 2013

- "Since launch, I have personally spent 8 days on the road with our LSMs visiting doctors, and doing so has given me greater comfort in our estimates for the total available market for Juxtapid. Based on our early experience and launch, we have increased confidence in our estimates that there are approximately 3,000 patients in the US who have clinical or laboratory diagnosis consistent with HoFH."[27]

July 30, 2013

- "We're seeing a good, steady acceleration of prescriptions and patients. I mean, you have week-to-week variation, you have month-to-month variation. But if you look at the first 6 months, it was a nice, steady climb.

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[25] *Id*. at 11.

[26] Defendant Fraser, *id*. at 4.

[27] Defendant Beer, Q1 2013 Earnings Conf. Call, at 3.

So I don't have anything internally that's telling me that it's extremely lumpy."[28]

October 30, 2013

- "[W]e added a significant number of patients to our growing base of active patients on JUXTAPID. Prescription rates continue to accelerate through Q3."[29]

- "[W]e see very few patients be genotyped. It is not common and the physicians have different ways of diagnosing these patients and we don't guide that. We market to the HoFH patient population and these physicians are very radical educated physician specialists. Even the cardiologists, they read the literature and they come up with their phenotypical definition of this disease. So they are not genotyping the patients. The baseline LDL, we don't have it on all patients so we wouldn't be able to give that to you. I would guide you to the fact that it was a large number of our patients that had an LDL below 250 that were genotyped HoFH patients. So LDL on a standalone isn't a -- it's an important serious metric but it's not the only thing that positions physicians look at. They look at patient history thus demonstrating that there is a genetic component to it and a number of other risk factors. But the baseline we don't have on all patients and the patients in the US and outside the US are not being genotyped typically."[30]

65. Defendants were motivated to target and sell JUXTAPID to as many patients as they could because they recognized that they had a very short window within which to do so. In this regard, a new class of drugs, known as a PCSK9 inhibitor, was on the horizon and expected to launch in late fiscal 2015.

66. Despite the Company's assurances to the contrary, PCSK9 inhibitors were a threat to the larger population of JUXTAPID patients. In order to meet the risk threshold for PCSK9 inhibitor eligibility, a patient will need to suffer from FH that does not respond to standard therapy; have multiple risk factors, such as diabetes and a previous cardiovascular disease event,

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[28] Defendant Beer, Q2 2013 Earnings Conf. Call, at 14.

[29] Defendant Beer, Q3 2013 Earnings Conf. Call, at 3.

[30] *Id*. at 13.

in addition to hypercholesterolemia; or be intolerant of statins. This category is a significant population[31] and, thus, necessarily overlapped significantly with the greater population of patients the Company was targeting to increase its sales of JUXTAPID.

67. Though the Company explained "[w]e don't believe that [the introduction of PSCK9] is going to have a material impact . . . because as an approach to a disease which is caused by a defect in the LDL receptor, a therapeutic which targets the LDL receptor isn't really a rational approach," the Company, in truth, knew that its opportunity to sell JUXTAPID and to reach as many patients as possible was closing, particularly those illegally targeted patients for whom JUXTAPID was not an approved therapy.

68. While Defendants' fraudulent scheme was underway and in full effect, Defendant Beer made statements regarding JUXTAPID marketing during broadcast interviews on CNBC's television show "Fast Money," on both June 5, 2013 and October 31, 2013. The following are the relevant statements made by Defendant Beer during those television appearances:

June 5, 2013

> "In these [HoFH] patients, they have a devastating disease. They have a lethal level of cholesterol, bad cholesterol, which we call LDL, going through their blood stream. And they're born with this disease and often not diagnosed until 8, 10 years of age when they have a heart attack. If you can imagine a child having a heart attack at 8, 10, 12 years of age. And then they have another event, usually about every 18 months, and die by the age of 30. And we've found out that we can lower it significantly with this drug . . . ."
>
> "It's a devastating disease that causes early death. And the drug is corrective against that disease and that's the most important thing. If you think about some oncology products that may lengthen life three months or six months, this product has the potential of taking a patient that would die at 30 and allow then to meet their grandkids."

[31] Nicole Gray, *9 Important things to know about PCSK9 cholesterol drugs*, BioPharma DIVE, Mar. 20, 2015, http://www.biopharmadive.com/news/9-important-things-to-know-about-pcsk9-cholesterol-drugs/377519.

October 31, 2013

> "These patients are going to die of a cardiac event, either a stroke or a heart attack, if we don't have them on therapy."

69. On November 8, 2013, news reports revealed that the Company had received an FDA Warning Letter, addressed to Defendant Beer, regarding the above-referenced statements.

70. Specifically, the FDA Office of Prescription Drug Promotion ("OPDP") challenged these statements as "misleadingly suggest[ing] that Juxtapid is safe and effective for use in decreasing the occurrence of cardiovascular events including heart attacks and strokes, and increasing the lifespan of patients with HoFH, and thus will have an effect on cardiovascular morbidity and mortality as well as overall mortality."

71. Further, "the statements made regarding Juxtapid misleadingly suggest that Juxtapid is safe and effective as a monotherapy." The OPDP noted that "[i]nformation sufficient to demonstrate that Juxtapid is safe and effective for any of these new intended uses has not been submitted to FDA in an application." The OPDP further demanded that Aegerion "immediately cease misbranding Juxtapid and introducing it to interstate commerce for unapproved uses for which it lacks adequate directions" and required that Aegerion submit a written response to confirm compliance and to include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the approved use of JUXTAPID.

72. Analysts understandably questioned the Company regarding the Warning Letter and based on those conversations recognized that "[w]e do not see any impact on our estimates since this warning letter is unrelated to the drug."[32] Notwithstanding, the Company

[32] Deutsche Bank Markets Research, *Management Color on FDA Warning Letter*, Nov. 8, 2013.

acknowledged that it would "change the wording" of the way it has been marketing JUXTAPID "going forward."[33]

73. The Company issued a statement to the market a few days later, assuring that:

> We take regulatory compliance very seriously and acknowledge that our messaging in any setting, including a media interview as in this particular instance, needs to be accurate and fair balanced. Our plan is to take quick action in response to the FDA's letter and immediately and effectively address any unsuitable language. We appreciate that the FDA's objective is to ensure that promotion is consistent with approved labeling, and in that respect we are aligned with the agency.[34]

74. What the market would later come to learn, however, is that the FDA Warning Letter was just the beginning of what was to become a three federal agency investigation into the Company's JUXTAPID marketing practices and public disclosures regarding the same, which would ultimately result in Aegerion pleading guilty to violations of both criminal and civil provisions of Federal law.

75. On January 9, 2014, almost two months to the day from the date the Company received the Warning Letter, the Company announced that it had received a subpoena from the DOJ requesting documents regarding its illegal marketing of JUXTAPID.[35]

76. During its presentation on January 13, 2014 at the JPMorgan Healthcare Conference, Defendant Beer addressed both the Warning Letter and the DOJ investigation. Specifically, he falsely stated:

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[33] *Id*.

[34] *See* Adam Feurstein, *FDA Slaps Aegerion CEO For 'Serious' Violations of Drug Promotion Law* (Nov. 11, 2013 6:00 AM EST), http://www.thestreet.com/story/12103490/1/fda-slaps-aegerion-ceo-for-serious-violations-of-drug-promotion-law.html.

[35] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 ("Jan. 9, 2014 Form 8-K"), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312514006791/d655771dex991.htm.

> [G]iven the strong focus on safe and appropriate use of JUXTAPID I want to take an opportunity to address two recent events that I'm sure you are aware of. In November we received a warning letter relating to the interviews I gave on CNBC Fast Money, in the on-air interviews I should have chosen words that would've been more balanced in nature. We're working with the FDA to resolve these concerns and plan to return -- run a corrective broadcast on CNBC in the near future which will correct any potential misimpressions or reinforce our label and safety information. **I should note that this does not impact any of our sales and marketing material** or what physicians are seeing day in and day out by our sales reps; **our promotional materials do not include the statements of any type that were cited in the warning letter**.[36]
>
> You're also I'm sure aware of a recent announcement we made last week that we received a subpoena for an investigation by the Department of Justice into our sales and marketing practices. While I can't talk about the specifics of the investigation, **I can tell you that Management is passionate about ensuring we are operating in the best-in-class way when it comes to compliance. We've been diligent in our efforts to ensure that all promotional material**, our training of our sales reps, messaging to physicians, **and our activities are consistent with on-label promotion and all applicable laws that are related to that compliance. We have a strong focus and discipline about compliance internally**.[37]

77. Notwithstanding the investigations, on the heels of a very successful launch year, and with its profitable, albeit illegal, marketing plan in place, Defendants projected that the Company's FY 2014 revenue guidance would be almost ***four times*** what it had projected for 2013.

78. On or about August 27, 2014, the FDA privately issued its close-out letter, confirming that in response to the Warning Letter, Aegerion had:

> Ceased dissemination of all materials such as those containing statements referenced in the Warning Letter
>
> Reviewed existing promotional materials for Juxtapid to determine if any of the materials contain statements such as those described in the Warning Letter and that Aegerion did not identify any such materials

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[36] Unless otherwise noted, all emphasis is added.

[37] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at JPMorgan Healthcare Conf., Jan. 13, 2014, at 3-4 ("JPMorgan Healthcare Conf., Jan. 13, 2014").

> Submitted the broadcast corrective under cover of Form FDA-2253
>
> Disseminated the broadcast corrective once on Fox Business Network's After the Bell (air date: July 16, 2014), once on Fox News' Your World with Neil Cavuto (air date: July 17, 2014), and for 30 days on Aegerion's corporate website (July 16 to August 15, 2014)
>
> Submitted written confirmation to OPDP on August 18, 2014, that the corrective dissemination plan has been completed

79. While the existence of the close-out letter was not made known and its specific contents not publically available other than through a Freedom of Information Act Request to the OPDP, Company officials did address the matter in a general fashion. In that regard, Martha Carter, the Company's Chief Regulatory Officer, said in a statement that "[w]e worked closely with OPDP to resolve the issues raised in the warning letter and are pleased that OPDP considers the matter closed."

80. Upon information and belief, as a result of the various investigations, Aegerion was forced to adjust its marketing plan from aggressively targeting cardiologists to a more tailored approach of issuing a uniform statement in its public disclosures. For example, the Company would thereafter repeatedly state: "We believe there are still more cardiologists and other physicians who have HoFH patients which we have yet to reach. However, with the expanded team, we are making meaningful gains to do so."[38]

81. What Aegerion knew, yet the market could not then appreciate, was that this change in marketing plan would have a tremendous negative impact on the Company's profitability and ability to add new JUXTAPID patients because the Company would no longer be able to target non-HoFH patients that it had been illegally targeting. This was a significant blow to the Company because the Company was also aware that, despite its assurances to the

[38] *See, e.g.*, Thomson Reuters Streetevents, Edited Transcript, AEGR-Q1 2014 Aegerion Pharm. Inc., Earnings Conf. Call, May 6, 2014, at 5 ("Q1 2014 Earnings Conf. Call").

contrary, the launch of a new drug, a PCSK9 inhibitor, described more fully below, was on the horizon and that, once launched, it would exacerbate the negative effect on the Company's existing and potential patient population.

82. On January 9, 2015, the Company disclosed, buried at the end of the filing, that it was now also the target of an SEC investigation "related to the Company's sales activities and disclosures" related to JUXTAPID.[39] Specifically, the filing stated:

> In late 2014, the Company received a request for information from the U.S. Securities and Exchange Commission ("SEC"). The SEC requested from the Company certain information related to the Company's sales activities and disclosures related to the Company's first product, JUXTAPID® (lomitapide) capsules. The SEC also is requesting documents and information on a number of other topics, including documents related to the subject matter of the previously disclosed investigations by government authorities in Brazil into whether the Company's activities in Brazil violated Brazilian anti-corruption laws. The Company is cooperating with the SEC. While the Company believes that it has the appropriate policies and procedures in place to ensure accurate financial reporting and compliance with SEC rules and regulations, the Company cannot predict when the SEC will conclude its investigation or the outcome of the investigation.

83. The full truth of Aegerion's deceptive marketing practices was ultimately revealed to the market on May 12, 2016, when Aegerion announced that it had entered into preliminary agreements with the DOJ and SEC to settle those agencies' ongoing investigations for a total of $40 million. As part of their settlement, the Company is to plead guilty to two misdemeanors. The press release[40] issued by the Company the same day stated:

> CAMBRIDGE, Mass., May 12, 2016 (GLOBE NEWSWIRE) -- Aegerion Pharmaceuticals, Inc. ("Aegerion" or the "Company") (NASDAQ:AEGR), a biopharmaceutical company dedicated to the development and commercialization

[39] Aegerion Pharm., Inc., Current Report (Form 8-K) (Jan. 12, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515007222/d850051d8k.htm.

[40] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex. 99.1 (May 12, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000110465916120275/a16-11074_3ex99d1.htm ("May 12, 2016 Form 8-K").

of innovative therapies for patients with debilitating rare diseases, announced today that it has reached preliminary agreements in principle with the Department of Justice ("DOJ") and the staff of the Securities and Exchange Commission ("SEC") regarding a settlement of the ongoing investigations by these agencies into the Company's sales activities and disclosures related to JUXTAPID® (lomitapide) capsules ("JUXTAPID").

"These preliminary agreements in principle with the DOJ and the SEC represent an important step forward towards addressing the immediate issues facing Aegerion and positioning the Company for near-term value creation and growth," said Chief Executive Officer Mary Szela. "As a company, we are deeply committed to legal and regulatory compliance, and we have made significant investments to ensure that these values resonate throughout our organization. We look forward to putting these matters behind us and to continuing our focused efforts on developing and commercializing innovative therapies for patients with debilitating rare diseases."

The preliminary agreements in principle provide for a consolidated monetary package that covers payments due to both the DOJ and the SEC. The consolidated monetary package includes payments to the DOJ and the SEC totaling approximately $40 million in the aggregate (the "Settlement Payments"), payable over five years as follows: approximately $3 million upon finalization of the settlement with the DOJ and the SEC, approximately $3.7 million per year, payable quarterly, for three years following finalization of the settlement, and approximately $13 million per year, payable quarterly, in years four and five following finalization of the settlement. Outstanding amounts would accrue interest from the date of the final agreements in principle at a rate of 1.75% per annum, compounded quarterly. The Settlement Payments are subject to acceleration in the event of certain change of control transactions or the sale of the Company's JUXTAPID or MYALEPT® (metreleptin) for injection assets. The Company has increased its existing reserve related to the investigations by approximately $28 million, bringing the aggregate reserve for these matters to approximately $40 million. The increased reserve of approximately $28 million was recorded in the first quarter of 2016.

Under the terms of the preliminary agreement in principle with the DOJ, the Company would plead guilty to two misdemeanor misbranding violations of the Food, Drug and Cosmetic Act. One count would be based on the Company's alleged marketing of JUXTAPID with inadequate directions for use (21 U.S.C. §§ 352(f)), and the second count would involve an alleged failure to comply with a requirement of the JUXTAPID Risk Evaluation and Mitigation Strategies ("REMS") program (21 U.S.C. §§ 352(y)). The Company would separately enter into a five-year deferred prosecution agreement with regard to charges that the Company violated the Health Insurance Portability and Accountability Act and engaged in obstruction of justice relating to the REMS program. The preliminary agreement in principle with the DOJ also requires the Company to enter into a civil settlement agreement with the DOJ to resolve alleged violations of the False

> Claims Act. Additionally, the Company would enter into a non-monetary consent decree with the Food and Drug Administration prohibiting future violations of law and may have to enter into a corporate integrity agreement with the Department of Health and Human Services as part of any final settlement with the DOJ. Under the preliminary agreement in principle, the Company would not be subject to mandatory exclusion from participation in federal health care programs under 42 U.S.C. § 1320a-7(a).
>
> Under the terms of the preliminary agreement in principle with the SEC staff, the SEC's Division of Enforcement will recommend that the SEC accept a settlement offer from the Company on a neither-admit-nor-deny basis that contains alleged negligent violations of Sections 17(a)(2) and (3) of the Securities Act of 1933, as amended (the "Securities Act"), related to certain statements made by the Company in 2013 regarding the conversion rate of patients receiving JUXTAPID prescriptions, with remedies that include censure, an order prohibiting future violations of the securities laws and payment of a civil penalty.
>
> The terms of the preliminary agreements in principle described above may change following further negotiations and other terms of the final settlement remain subject to further negotiation. The preliminary agreement in principle with the DOJ is subject to approval of supervisory personnel within the DOJ and relevant federal and state agencies and approval by a U.S. District Court judge of the criminal plea and sentence and the civil settlement agreement. The preliminary agreement in principle with the SEC is subject to review by other groups in the SEC and approval by the Commissioners of the SEC. The preliminary agreements in principle do not cover the DOJ and SEC's inquiries concerning the Company's operations in Brazil.

84. As a result of this news, the Company's stock price fell nearly 17% from a closing price of $2.30 per share on May 11, 2016, to a closing price of $1.91 per share on May 12, 2016.

G. Key Metrics and Initiatives within Aegerion

85. As detailed above, Defendants' illegal marketing campaign carried with it positive financial results in 2013 and caused Defendants to wildly forecast FY 2014 financial guidance to between $190 million and $210 million, almost four times the profitability it had achieved in fiscal 2013.

86. In reality, however, there were a number of negative impacts on key corporate metrics that the market would not come to learn about until later on, which caused Aegerion to revise its 2014 guidance down twice. Aegerion then further narrowed its guidance, and later

revealed the Company's ***lack*** of visibility concerning these key metrics, despite its repeated assurances to the contrary.

87. There are three key metrics the Company monitored that, individually and collectively, contributed directly to Aegerion's projected sales of JUXTAPID. In addition to tracking the number of prescriptions that were being written, the Company focused on: (1) the patient compliance rate (whether the patient was taking the drug as prescribed); (2) the dropout or discontinuation rate (the number of patients who start, but then stop taking the drug); and (3) what the Company termed "patient-elected non-starts," or those patients who received a prescription but who never started on the drug.

88. The Company recognized the critical nature of these metrics and acknowledged that "[m]anaging patient elected non-starts and dropouts [was] integral to the long-term success of [its] business."[41] At the JPMorgan Healthcare Conference held on January 13, 2014, following the announcement of the Company's successful launch of JUXTAPID, Defendant Beer touted "we have experienced success to date in managing the dropout and the compliance on this therapy. These are critical metrics as we have invested significantly to manage these metrics of dropout and compliance."[42]

89. This awareness and acknowledgement of the significance of these metrics is clearly evidenced by how closely the Company tracked the number of prescriptions written, how many patients failed to start treatment, and how many dropped out after starting therapy. *See, e.g.*, ¶¶90-116, *infra*.

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[41] Defendant Fraser, Q1 2014 Earnings Conf. Call, at 5.

[42] JPMorgan Healthcare Conf., Jan 13, 2014, at 5.

90. In addition to tracking and informing investors about the acceleration of prescriptions being written (as a result of their off-label marketing practices), throughout the Class Period, Defendants assured investors of their vigilance and commitment to monitor and adjust their internal systems where necessary:

July 30, 2013

- "[W]e diligently monitor and manage the systems and process. And we've learned a lot along the way and have applied those learnings."[43]

January 2014

- "We have strong analytics and dashboards in place, providing a visibility around this launch on a daily basis that allows us to learn in real time and course correct if there's certain markets that we have to course correct in. It allows us to rely on this information as we go forward with our guidance into 2014."[44]

- "I want to remind you how important it is that we are closely managing the relationship with our patients."[45]

February 2014

- "Now it's a matter of understanding those metrics, optimizing them, and that's what Craig [Fraser] and Mark Fitzpatrick have worked hard at understanding those metrics and optimizing them."[46]

- In response to Cowen and Company analyst questions concerning non-starts, Defendant Beer expressed how "frustrating" it was "when a physician makes a risk-benefit decision and diagnoses his patient as a an [sic] HoFH patient" and "then the patient . . . goes into denial and does not start." "[W]e are studying this more and more." "So it's frustrating to us, but we will optimize that metric."[47]

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[43] Defendant Fraser, Q2 2013 Earnings Conf. Call, at 11.

[44] Defendant Beer, JPMorgan Healthcare Conf., Jan. 13, 2014, at 5.

[45] *Id*. at 6.

[46] Defendant Beer, Q4 2013 Earnings Conf. Call, at 11.

[47] *Id*. at 12.

May 2014

- "[W]e are really religious about dashboards and measuring."[48]

July 2014

- "We're seeing the right trends in the key metrics that tell us that the resource allocation that we made at the beginning of this year was the right level."[49]

October 2014

- "We can look back now over 18 months and look at prescription rates per day and we measure them daily."[50]

91. Aegerion tracked and monitored dropouts and patient-elected non-starts with a platform called salesforce.com.

92. Salesforce.com had the capability to track the process from the time a patient case was opened (*i.e.*, when a prescription was written and faxed to Aegerion) until the prescription was filled.

93. The program also had the ability to track a patient's compliance (according to whether the patient renewed the prescription at the end of a particular month), as well as the dropouts (those patients that did not renew).

94. Defendants Beer, Fitzpatrick, and Fraser could access salesforce.com themselves or request reports that would detail the number of active patients, the number of prescriptions

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[48] Defendant Beer, Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at Deutsche Bank Healthcare Conf., May 7, 2014, at 8 ("Deutsche Bank Healthcare Conf., May 7, 2014").

[49] Defendant Beer, Thomson Reuters Streetevents, Edited Transcript, AEGR-Q2 2014 Aegerion Pharm. Inc., Earnings Conf. Call, July 29, 2014, at 16 ("Q2 2014 Earnings Conf. Call").

[50] Defendant Fitzpatrick, Thomson Reuters Streetevents, Edited Transcript, Q3 2014 AEGR-Aegerion Pharm. Inc., Earnings Conf. Call, Oct. 30, 2014, at 9 ("Q3 2014 Earnings Conf. Call").

broken down by region, patients ready for renewal and prescriptions with payer refusal, among other things.

95. In addition to tracking compliance, renewals and dropouts on salesforce.com, the Company also tracked the number of prescriptions needed to reach revenue projections. This tally was typically tracked daily and displayed on a whiteboard that indicated – by territory – the number of prescriptions for that quarter (as of a certain date) and the number of prescriptions and renewals still needed for the quarter to reach the forecasts.

96. In fact, it was evident from the "whiteboard" that Aegerion was going to be short on prescriptions during 1Q14. Indeed, by the end of the 1Q14, the whiteboard confirmed that the Company had not met the forecasted number of prescriptions and had only filled a certain percentage of what was needed to meet the revenue forecasts.

97. As a result of Defendants' monitoring and oversight of the status of these key metrics, they were well informed of the current state of affairs at any given time:

April 30, 2013

- "We're not seeing dropout as an issue and we're not seeing GI as an issue when I look at the feedback I'm getting from the field."[51]

July 30, 2013

- "6 months into launch, our experience with dropout and compliance with Juxtapid has been well within the expectations of the trends, and are encouraging."[52]

- "Moving forward, minimizing patient dropout and ensuring compliance with therapy will continue to be a primary focus of our team."[53]

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[51] Defendant Beer, Q1 2013 Earnings Conf. Call, at 11.

[52] Defendant Beer, Q2 2013 Earnings Conf. Call, at 4.

[53] *Id*.

- "[D]ropout and compliance trends have been well managed thus far, and we believe this to be a direct result of having clear insight into our business and patient status, and by providing the physicians, patients, and office staff with the education and support they need to optimize treatment."[54]

- "I don't see [the dropout] number changing drastically. We're doing everything we can do to make sure that it doesn't."[55]

October 30, 2013

- "Dropout and compliance with JUXTAPID continues to be on track with our expectations. As you know, we have placed a tremendous amount of investment towards managing these important factors in the launch and we are pleased with the results of these efforts thus far."[56]

- "Minimizing patient dropout and ensuring compliance with therapy will continue to be a primary focus of our team and we continue to invest in these services that we will be able to scale effectively as our patient base grows."[57]

- "I feel very confident in the fundamentals of our business. The JUXTAPID launch is tracking well in all important categories including prescriptions, reimbursements, and managing patients on therapy."[58]

February 2014

- "[A] dynamic that we began to understand in a more meaningful way, in the second half of the year, was that we had patient-elected non-starts in circumstances. These are patients from whom a prescription is written, possibly even with reimbursement approval achieved, but whom chose not to start therapy."[59]

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[54] Defendant Fraser, *id*. at 5.

[55] Defendant Beer, *id*. at 10.

[56] Defendant Beer, Q3 2013 Earnings Conf. Call, at 3.

[57] *Id*. at 4.

[58] *Id*. at 7.

[59] Defendant Beer, Q4 2013 Earnings Conf. Call, at 4.

- "We recognize that we will always have to maintain a strong focus on dropout, and we plan to do additional work in that area."[60]

- "As Marc [Fitzpatrick] referenced, one notable behavioral dynamic that emerged as a factor in our business is that of patient-elected non-starts. While we have been clear in the past that not every prescription leads to a patient going on to therapy, this dynamic is more meaningful than we had previously anticipated. And it became apparent to us that patient education and comprehensive healthcare provider engagement are critical to successful patient on boarding."[61]

May 2014

- "It was clear to us in 2013, JUXTAPID prescriptions both outpaced the capacity of our patient service infrastructure, as evidenced by patient non-starts and by increasing drop rates towards the end of the year. It became more apparent by year-end, that the meaningful changes -- that meaningful changes were necessary in order to fully meet the need for rapid prescription conversion and patient retention."[62]

- "[T]he non-patient starts were felt in our model and internally during Q4, coming out of Q4 and early in Q1 . . . . So, the big numbers of prescriptions were in that timeframe and it takes 4-6 months to feel, is the patient really not going to start. So, we had them in a pending bucket but the they started to really identify them self at the end of Q4 going into Q1. So, I think, when we had a big enough N of those patients and we understood the non-patient start, thoroughly, is when we sort of talked about that."[63]

98. Further, Defendants clearly understood the specific reasons for these non-starts and dropouts: they had conducted a study regarding these very motives affecting patient compliance in 2013. Specifically, the Company knew through this study and continued tracking that a patient may be a non-start for a number of reasons, including, an unwillingness to adhere to the strict diet which is a major lifestyle change and prevents the patient from eating any fatty

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60 *Id*.

61 Defendant Fraser, *id*.

62 Defendant Beer, Q1 2014 Earnings Conf. Call, at 3.

63 Defendant Beer, Deutsche Bank Healthcare Conf., May 7, 2014, at 6-7.

foods; the necessity of frequent blood testing for potential liver issues; and denials of insurance coverage. The same reasons could cause a patient to drop out.

99. Moreover, the illicit marketing plan resulted in a larger number of non-HoFH patients being prescribed the drug. These patients were less likely to adhere to the strict diet and lifestyle change, and were less tolerant of the side-effects associated with taking JUXTAPID because they were not "true" HoFH patients for whom the JUXTAPID treatment was medically essential.

100. Nevertheless, on May 6, 2014, Defendant Beer stated: "We believe the patient elected non-starts and dropouts are directly correlated to the thoroughness and the timeliness of comprehensive patient education of HoFH patients and the importance of the diet in taking JUXTAPID along with it, along with strong physician involvement in the patient education process."[64]

H. The Company Took Efforts to Deal with the Growing Number of Non-Starts and Dropouts Throughout 2014

101. To service the growing number of dropouts and patient-elected non-starts, the Company implemented a "robust" customer-facing support program in order to meet the expectations of the HoFH market. In fact, as of January 2014, the Company had already "invested meaningfully" in the program they called the COMPASS Support Program – a free, confidential and comprehensive set of services available to people taking JUXTAPID. As Defendant Beer described during the JPMorgan Healthcare Conference on January 13, 2014, the program "[i]s a very high-touch, high-service program for patients in the US . . . ."[65] Defendant Fraser reassured investors on the February 26, 2014 Q4 2013 Earnings Conference Call, that

[64] Q1 2014 Earnings Conf. Call, at 4.

[65] JPMorgan Healthcare Conf., Jan. 13, 2014, at 6.

Aegerion was confident these efforts would work: "We believe, based on the work that we've done, that the rate of patient-elected non-starts should decline with the full implementation of these initiatives."[66]

102. According to the Company's website, COMPASS provides patients with: (a) access to an experienced registered dietitian who can help personalize a low-fat eating plan designed to meet a patient's specific nutritional goals and lower the chance of having stomach problems while taking JUXTAPID; (b) ideas for commencing JUXTAPID treatment and tips for staying on track; (c) access to a knowledgeable pharmacist who could answer questions related to JUXTAPID; (d) reminders about topics that a patient could address with his/her doctor and nurse; (e) access to information regarding physicians and specialists with experience treating HoFH; (f) access to patient advocacy groups and updates on meetings and events; (g) suggestions for how to talk with family or friends about HoFH; and (h) ideas for how a patient could advocate for his/her own health and quality care.[67]

103. The program was conducted by COMPASS Care Managers ("CCM") who were responsible for contacting patients who were prescribed JUXTAPID and reading an eight-page script that provided information on HoFH, JUXTAPID side effects, the dietary requirements while taking JUXTAPID, and provided answers to frequently asked questions. The Company referred to this process as "onboarding." In addition to onboarding patients, CCMs were also responsible for contacting patients who stopped using JUXTAPID in attempt to get the patient to resume treatment.

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[66] Q4 2013 Earnings Conf. Call, at 6.

[67] *See* Juxtapid – Support Services: The COMPASS Program, https://web.archive.org/web/20150818153154/http://www.juxtapid.com/healthcare-professionals/support-services-compass-program (last visited June 27, 2016).

104. The CCM group had daily meetings (also referred to as a "daily huddle") to discuss all patients and when the patient was expected to begin the treatment. In addition to these daily meetings, CCMs also participated in conference calls with Sales Directors inquiring about various patients and the reasons why prescriptions were not filled.

105. The Company also employed Patient Education Managers who interacted directly with patients being prescribed JUXTAPID. Patient Education Managers typically had nursing backgrounds and were trained by the Company on the disease, which included learning the chemistry and biochemistry of HoFH. They received additional training at Aegerion headquarters approximately every three months, which primarily reinforced the information learned during the initial training.

106. At the JPMorgan Healthcare Conference held January 13, 2014, Defendant Beer stated that the COMPASS Team, among others, were "top priority hires in 2013."[68] On the February 26, 2014 earnings conference call, he explained: "[i]n the second half of [2013], we made the decision to increase the scale of our business for the start of 2014."[69] As a result, by February 2014, the Company touted that it had "assembled a sales team of the highest caliber"[70] and that the "expansion of our customer-facing organization [was] largely now complete."[71]

107. Throughout the Class Period, Defendants reinforced their commitment to identifying, educating and managing both doctors and patients about the JUXTAPID experience in an effort to stay on top of patient-elected non-starts and the dropout rate:

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[68] JPMorgan Healthcare Conf., Jan. 13, 2014, at 6.

[69] Q4 2013 Earnings Conf. Call, at 4.

[70] Defendant Beer, JPMorgan Healthcare Conf., Jan. 13, 2014, at 4, 6.

[71] Defendant Beer, Q4 2013 Earnings Conf. Call, at 4.

February 2014

- "[W]e are currently focused on identifying physicians who have potential adult HoFH patients, bringing them onto therapy and keeping those patients on therapy."[72]

- "We believe an important factor that will support our ability to achieve these objectives is to enhance physician and patient education and support programs we have further established at the outset of 2014."[73]

May 2014

- "[W]e feel confident that the increased commercial reach has the potential to result in meaningful growth. In our view, resource allocation and execution are the gating factors in JUXTAPID capturing maximum share of HoFH market on a global basis."[74]

- "In an effort to further enhance our patient focus commercialization strategy, we have established a new patient engagement team, which includes a new nurse educator group . . . . We expect nurse educators to have the potential for a positive impact on dropout rates with patients beginning therapy in an educated and committed way and nurses helping to support them."[75]

July 2014

- "The patient elected non-starts is an area that we have invested in and are implementing a whole host of programs designed around HoFH patient education, on boarding, patient and physician commitment to therapy."[76]

- "We understand the dynamics associated with patient commitment to therapy. Further, we recognize that education about adherence to a low-fat diet is a key driver of success with JUXTAPID therapy, and therefore, additional investments in dietitian directed patient support has also been made."[77]

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[72] Defendant Beer, Q4 2013 Earnings Conf. Call, at 4.

[73] *Id*.

[74] Defendant Beer, Q1 2014 Earnings Conf. Call, at 4.

[75] Defendant Fraser, *id*. at 4-5.

[76] Defendant Fraser, Q2 2014 Earnings Conf. Call, at 8.

[77] *Id*. at 4.

October 30, 2014

- We believe that working with physician practices to enhance patient education during on boarding combined with more robust dietary counseling will positively impact conversion and both short and long-term dropout rates . . . . We are monitoring and focused on these dynamics closely and look forward to providing greater detail when we have a large-enough number of patients who have been on boarded and educated according to our new patient engagement protocol over a meaningful time period.[78]

August 5, 2015

- Importantly, we believe we have improved our understanding of the JUXTAPID business and the adult HoFH patient dynamics, making what we believe are the right investments. Our goal is to optimize the adult HoFH patient experience with JUXTAPID.[79]

108. Despite repeated reassurances to the contrary, the Company's efforts to stem the turning tide attributable to non-starts and dropouts were wholly ineffective. Defendants knew this and the Company decided to no longer provide investors with specific metrics, such as new patient adds, patient-elected non-starts, dropout rates, etc. Despite repeated questions from analysts requesting more concrete information, the Company and the Individual Defendants encouraged the market, instead, to (a) consider Aegerion's 2013 results "so that you can come into 2014 with a more accurate view of our business;"[80] (b) "trust management;"[81] and (c) "trust the guidance."[82]

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[78] Defendant Fraser, 3Q14 Conf. Call, at 5.

[79] 2Q15 Conf. Call, at 4.

[80] Defendant Beer, Q4 2013 Earnings Conf. Call, at 4.

[81] *See id*. at 13.

[82] *See* Defendant Beer, Q1 2014 Earnings Conf. Call, at 9; Defendant Beer, Q3 2014 Earnings Conference Call, at 14.

- "As you know, our goal has been to move away from providing detailed lomitapide prescriptions and patient metrics and should focus to our top line revenue guidance, with revenue results serving the best barometer of our business."[83]

- "As stated before, I don't want to get into the practice of commenting on quarters."[84]

- "I want to stay away from quarterly comments, only because it's just not the right thing."[85]

- "[W]e don't plan to provide a specific metric, because you are asking about a metric question on this. But I want you to know that we made a lot of effort and a lot of investment to -- with the -- ideal optimizing in this area."[86]

109. In February 2014, without providing specifics to support their 2014 projections, Defendants reinforced their confidence that the 15% dropout they had experienced in 2013 "would maintain throughout the year" and that the Company would continue to focus on "understanding" and "optimizing" those metrics going forward.[87]

110. On May 6, 2014, the Company announced a reduction in its FY 2014 guidance "to between $180 and $200 million, from between $190 and $210 million,"[88] but despite multiple requests for more specifics, the Company reiterated its decision not to provide details surrounding the key metrics driving the business. In response to a question from an analyst from Bank of America regarding the continuing validity of the 15% discontinuation rate, Defendant Beer answered: "[W]e'd like to get away from quarterly quantification for qualitative statements

[83] Defendant Beer, Q4 2013 Earnings Conf. Call, at 4.

[84] *Id*. at 9.

[85] *Id*. at 10.

[86] Defendant Fraser, *id*. at 13.

[87] *See* Defendant Beer, *id.* at 11, 13.

[88] Q1 2014 Earnings Conf. Call, at 8.

around dropout compliance or non-patient starts. But really focus on the revenue guidance and growth and the predictors around that business."[89] Again, Defendant Beer simply stated that investors "trust the guidance."[90]

111. In July 2014, Aegerion narrowed its guidance "towards the lower end of the previously stated guidance range of between $180 and $200 million."[91] At the same time, however, Defendants declined to provide any details regarding key metrics:

- "We're trying not to give quarterly metric numbers either directionally or quantifying the individual metrics."[92]
- "One other thing, of course, is we've moved away from providing very specific quantitative metrics."[93]

112. However, Defendant Fraser did assure the market during the Q2 2014 Earnings Conference Call, that "I am confident that we are now operating at an adequate scale and are focused on ensuring consistency of execution across our teams."[94]

113. At the same time, Defendant Beer also confirmed the latest announcement regarding guidance:

> Mark [Fitzpatrick] and Craig [Fraser] and I point to a specific model and we're coming out of Q2 with the trends that really make us feel comfortable with the guidance we're giving at the lower end of that $180 million to $200 million. So I think we've got enough predictability around this business to feel comfortable at

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89 Q1 2014 Earnings Conf. Call, at 12.

90 *Id*. at 9.

91 Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (July 29, 2014), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312514284688/d765174dex991.htm ("July 29, 2014 Form 8-K").

92 Defendant Beer, Q2 2014 Earnings Conf. Call, at 15.

93 Defendant Fraser, *id.* at 9.

94 *Id*. at 4.

> this point and time of the year of pointing to that expectation, and I feel like we're going to hit that goal.[95]

114. Then, on October 30, 2014, when the Company announced its third quarter 2014 results, it again revised its guidance figure. Moreover, Aegerion reported, for the first time, that despite its repeated prior assurances that it was managing the dropout rate at 15%, that its "meaningful"[96] investment into the customer experience was "bear[ing] fruit,"[97] and that investors should "trust the guidance,"[98] "the cumulative dropout rate for all patients who have started therapy from the launch in January 2013 to the end of this September [was] 36%. This overall cumulative is substantially higher than our forecasted projection and is running at a rate that we have so far been unsuccessful in turning around."[99]

115. Defendants' October 30, 2014 revelations immediately caused the Company's stock price to plummet by **41%**, falling from a close of $34.21 per share on October 30, 2014 to a close of $20.19 per share on October 31, 2014.

116. Ultimately, after the Company pre-announced its FY 2014 results on January 12, 2015, it finally acknowledged it had a "much better understanding of the patient journey," explaining that throughout 2014, it "had a challenge with really understanding the dropout rate

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[95] *Id*. at 9.

[96] *See, e.g.*, Defendant Beer, Q1 2014 Earnings Conf. Call, at 4.

[97] *See, e.g.*, *id*.

[98] *See, e.g.*, *id*. at 9.

[99] Defendant Fraser, Q3 2014 Earnings Conf. Call, at 4. Aegerion defines its cumulative drop-out rate as the total number of patients who have definitively determined to discontinue therapy from the date of initial launch to the end of 2014 as a percentage of all patients who have received at least one shipment during that period. Jan. 12, 2015 Form 8-K, Ex. 99.2.

and impact on our business."[100] The Company's January 12, 2015 press release attached as an exhibit to a Form 8-K stated that there were approximately 745 active commercial patients on JUXTAPID globally, with approximately 632 located in the United States and that the cumulative drop-out rate was 41%.[101] Ultimately, the dropout rate would reach as high as 58% by March 3, 2015 which was a dramatic increase from the initial 10% that the Company reported mid-way through.

I. The Market Would Finally Come to Learn that JUXTAPID Would Not Be the Success It Was Lead to Believe It Would Be

117. Heading into 2015, the Company continued to tout its "key focus on continued growth of JUXTAPID as our cornerstone product" with "contributing support" from the sales of its second product, MYALEPT, which it acquired in January 2015.[102]

118. On January 13, 2015, the Company announced "$195 million to $215 million in sales from JUXTAPID," for FY 2015 and reiterated that it felt "comfortable that there's 3,000 plus adult HoFH patients in the US."[103]

119. But the PCSK9 inhibitors were scheduled to hit the market in late 2015. In that regard, the Company stated on February 26, 2015, that "[w]e expect disruption of new patient starts as a result of the introduction of PCSK-9 inhibitors, and have factored this disruption and

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[100] Defendant Beer, Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., JPMorgan Healthcare Conf., Jan. 13, 2015 ("JP Morgan Healthcare Conf., Jan. 13, 2015"), at 2.

[101] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex. 99.2 (Jan. 12, 2015), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312515007222/d850051dex992.htm.

[102] Defendant Beer, JP Morgan Healthcare Conf., Jan. 13, 2015, at 3.

[103] *Id*.

some attrition of our existing patients into our 2015 financial guidance,"[104] but that overall, the "introduction of PCSK-9 inhibitors may result in the possible identification of more HoFH patients who may be candidates for JUXTAPID."[105]

120. Aegerion continuously touted its expectations for fiscal 2015, gloating on March 3, 2015, for example, that the Company has "a spectacular 2015 lined up."[106] In its May 8, 2015 Form 10-Q, the Company stated that any negative impact of the introduction of the PCSK9 inhibitors would be "offset, in whole or in part, over the long term by the possible identification of more HoFH patients who may be candidates for JUXTAPID":[107]

- Looking first at the Juxtapid business, we believe there are opportunities for growth.[108]
- We believe Juxtapid addresses a significant need in the medical community for therapies to treat adult HoFH patients, and we remain confident in our estimates of the total addressable adult HoFH market in this rare disease.[109]

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[104] As the market would later learn, the Company expected and allegedly factored in a patient erosion in the range of roughly 10%, but on November 18, 2015, revealed that "[w]e actually saw more of a doubling of that, so we saw closer to 20%. We also anticipated that new patient additions would be lower and somewhat slower, so they would be delayed. I think that was roughly on plan. So I think the big impact we saw was just that we lost more patients, more quickly." Thomson Reuters Streetevents, Edited Transcript, AEGR - Aegerion Pharm. Inc., at Jefferies Autumn Global Healthcare Conf., Nov. 18, 2015 ("Jefferies Healthcare Conf., Nov. 18, 2015"), at 5-6.

[105] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Feb. 25, 2013), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515065678/d880381dex991.htm.

[106] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc. at Cowen Health Care Conf., Mar. 3, 2015, at 9.

[107] Aegerion Pharm., Inc., Current Report (Form 10-Q) (May 8, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515179359/d896578d10q.htm.

[108] Thomson Reuters Streetevents, Edited Transcript, AEGR – Q1 2015 Aegerion Pharm. Inc., Earnings Conf. Call, May 4, 2015 ("Q1 2015 Earnings Conf. Call"), at 3.

[109] *Id*.

- We think we've been very prudent and cautious in our guidance. . . . And we studied it very carefully.[110]

121. Analysts understood that the Company believed it had "learned from its experiences in 2014,"[111] but despite its continued assurances, analysts remained curious about Aegerion's expectations once the PCSK9 inhibitors actually launched. In November 2015, for example, at the Jefferies Autumn Global Healthcare Conference, one analyst asked the Company "what you think is going to happen over the next month or so," to which the Company responded acknowledging that there would be patient "erosion," but adding that "the PCSK9s have a very differentiated efficacy in the HO population. And so we do think that if docs really looking at the lipids and they are looking at the lipid level, that there could be an opportunity that they are not going to be satisfied with a number of their patients. And those patients would be candidates to come back to us."[112]

122. That same month the Company also reported its financial results, wherein it narrowed its guidance of net product sales of JUXTAPID for fiscal 2015 "to be between $205 million and $215 million, revised from the prior range of between $195 million and $215 million."[113] Aegerion also revealed that, as a consequence of the DOJ investigation, the

[110] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at Deutsche Bank Health Care Conf., May 6, 2015, at 4 ("Deutsche Bank Health Care Conf., May 6, 2015").

[111] Leerink Partners LLC ("Leerink"), *Aegerion Pharm. Inc., 4Q Recap: Focused on Execution With Juxtapid and Diversification With Myalept*, Feb. 26, 2015.

[112] Jefferies Healthcare Conf., Nov. 18, 2015, at 6.

[113] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Nov. 9, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837015002520/aegr-20151109ex9915af111.htm.

Company was in breach of certain debt covenants, which resulted in the default of a $25 million loan.[114]

123. On the conference call that followed the announcement, Defendants also discussed the dropout rate which, by then, had risen to a staggering 58%, but did not reveal the cause of this increase.[115] Only later would the market specifically learn of the Company's illegal marketing practices and finally appreciate that, as a result, the prior patients that had been added were, in fact, non-HoFH patients, and, therefore, the future financial picture for JUXTAPID was substantially diminished.

124. Ultimately, the Company concluded the year announcing that it met its FY 2015 guidance of $213.0 million in net product sales of JUXTAPID for the full year of 2015.

125. But the year was not without tumult. By the time the Company announced its 3Q15 financial results, Defendants Beer, Fitzpatrick, ***and*** Fraser had all left the Company. Defendant Fitzpatrick was the first to resign just days after the Company announced its 2Q15 earnings, on May 14, 2015. Defendants Beer and Fraser resigned days before 3Q15 earnings were announced, on July 30, 2015. It would not be until the end of the Class Period that the market would come to understand the background for these executives' sudden departure.

J. Aegerion Can No Longer Avoid Reality in Fiscal 2016

126. Defendants' reckless behavior with regard to its off-label marketing, and its complete disregard for the realities facing its patient population (in light of the intolerance to JUXTAPID's side effects and the PCSK9 drug class hitting the marketplace), finally came to bear in 2016.

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[114] *Id*.

[115] Thomson Reuters Streetevents, Edited Transcript, AEGR – Q3 2015 Aegerion Pharm. Inc Earnings Conf. Call, Nov. 09, 2015 at 4.

127. On January 14, 2016, Aegerion participated in the JPMorgan Healthcare Conference, during which it announced that it "expect[s] JUXTAPID sales to be $212 million," and explained that the introduction of PCSK9 inhibitors had an "obviously" caused an "erosion of the active patient base" of "more than half of those are associated with switches to PCSK9, half of those that have been lost."[116] What it failed to disclose, however, was that while PCSK9s may have had an impact on Aegerion's patient population, the real reason for that decline was that the Company's corrected marketing practices no longer provided access to the wide range of patients it had previously been targeting.

128. At this same time, the Company spoke positively about the status of the various government investigations. Specifically, it stated:

> [T]here have been a number of very productive discussions. Obviously, the Company has been for some time cooperating fully with the government agencies to try to move this to a very quick resolution.
>
> And so I would say that we are at a point where we continue in those productive discussions, and we understand the importance of trying to reach some type of understanding. But we're not at a point where we can boundary yet what those economic consequences might be. But we are hopeful that the Company has taken some very significant steps to ensure that we are doing business in a very compliant way, and that will be reflected in the negotiations as we go forward.[117]

129. By the time the Company made the official announcement of its fiscal 2016 guidance just over one month later, on February 25, 2016, the Company already slashed its

[116] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at JPMorgan Healthcare Conf., Jan. 14, 2016, at 3.

[117] *Id*. at 4.

expectations by nearly ***40%***, expecting its FY 2016 global net product sales of JUXTAPID to be between $120 million and $140 million, lower than any year since its launch.[118]

130. Aegerion also described its efforts to "realign" itself by conducting a "Company-wide resource analysis" and "enact[ing] a 25% reduction of the global workforce, to approximately 230 employees."[119]

131. That same day, on February 25, 2016, the Company announced that it recorded a $12 million charge "representing the current estimate of the minimum amount required to resolve the ongoing Department of Justice and Securities and Exchange Commission investigations."[120]

132. Despite the obvious effect that the PCSK9 inhibitors were having on JUXTAPID's patient population – and the Company's acknowledgement of the same – Aegerion nevertheless continued to assuage investors that "the global market opportunity for JUXTAPID is meaningful":

> As you are aware, the HoFH marketplace continues to evolve. With the introduction of PCSK9 inhibitors, HoFH patients now have another treatment option available to them, one that they and their physicians may determine to be the best therapy for them. We will continue to assess the competitive impact of the PCSK9 inhibitors, and we believe JUXTAPID has a role to play for adult HoFH patients who have little or no LDL receptor activity. The efficacy of a PCSK9 inhibitor requires some function of the LDL receptor, so it's possible that

[118] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Feb. 25, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837016003540/aegr-20160225ex991325c2d.htm.

[119] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q4 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Feb. 25, 2016, at 3.

[120] May 12, 2016 Form 8-K, Ex. 99.1.

> responses in patients with HoFH who have limited or absent functionality are inadequate.[121]

133. In reality, however, the number of patients were continuing to dwindle.

134. On May 16, 2016, after the close of trading, Aegerion reported dismal results for the first quarter of fiscal 2016, recording a total of $26.2 million in net product sales of JUXTAPID and reporting that, as of March 31, 2016, there were 498 active commercial patients on JUXTAPID therapy globally, approximately 373 of whom are U.S. patients. In addition to reporting the quarterly financial results, the Company reduced its JUXTAPID sales guidance to between "$90 million and $100 million," from between $120 million and $140 million.[122]

135. Analysts questioned the dramatic change in guidance and recognized that at its current sales levels "Aegerion is not profitable, and risks running out of capital to fund operations."[123]

136. On June 15, 2016, the Company announced that it entered into a definitive merger agreement under which Aegerion will be merged with a wholly owned indirect subsidiary of QLT. Additionally, Aegerion and QLT entered into a loan agreement under which QLT agreed to loan Aegerion up to $15 million for working capital. Pursuant to the agreement, Aegerion will borrow $3 million in connection with execution of the Merger Agreement and may borrow up to $3 million per month in subsequent months, subject to certain conditions, if and to the extent such amounts are necessary in order for Aegerion to maintain an unrestricted cash balance of $25

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[121] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q4 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Feb. 25, 2016 ("Q4 2015 Earnings Conf. Call"), at 4.

[122] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex. 99.1 (May 16, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837016006026/aegr-20160516ex991 13664a.htm.

[123] Cowen and Company, *Reports Q1; 2016 Juxtapid Guidance Lowered*, May 16, 2016.

million. Upon completion of the proposed merger, the combined companies would be known as Novelion Therapeutics Inc. ("Novelion") and its common shares will trade on the NASDAQ Global Select Market and the Toronto Stock Exchange.[124]

V. DEFENDANTS' FALSE AND MISLEADING CLASS PERIOD STATEMENTS

A. First Quarter 2013 Financial Results

137. On April 30, 2013, the Company issued a press release reporting its "First-Quarter 2013 Financial Results," which was also filed with the SEC as an exhibit to a Form 8-K the same day. The press release announced that "Aegerion has more than 185 U.S. commercial and global named patient prescriptions for JUXTAPID written, and 75 patients are currently on JUXTAPID therapy. Re-orders for patients are on track and dropouts to date have been minimal."[125]

138. On that same day, following the issuance of the press release, Aegerion held a conference call with analysts and investors to discuss the Company's earnings release and operations where it reiterated the Company's successes to date. At that time, Defendant Beer falsely indicated the following:

> Anecdotally, the enthusiasm we have seen from physicians -- who, for the first time, have a treatment option for their [HoFH] patients -- has been very encouraging to us. As I have communicated to you previously, we're seeing higher-than-initially-anticipated interest and excitement from cardiologists who are eager to treat and who appear to have a meaningful number of patients within their practices. Since launch, I have personally spent 8 days on the road with our LSMs visiting doctors, and doing so has given me greater comfort in our estimates for the total available market for Juxtapid. Based on our early experience and launch, we have increased confidence in our estimates that there are approximately 3,000 patients in the US who have clinical or laboratory diagnosis consistent with HoFH. Each day we gain greater clarity in this significant unmet medical need of this HoFH market.

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[124] *Id*. at 4.

[125] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex.99.1 (Apr. 30, 2013), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312513184458/d528865dex991.htm.

* * *

To address a question that arises frequently . . . I thought it would be helpful to briefly address our expectations regarding the class of PCSK9 candidates currently in various stages of development. We believe if the products are shown to be safe and effective that they will be an appropriate treatment option for the statin-intolerant in broader FH patient population. As you may know, inhibition of PCSK9 works by increasing hepatic cell surface levels of the LDL receptor, and while it would likely show drops in LDL comparable to the efficacy of statins in a general population, we wouldn't expect it to be adequately effective in HoFH patients with defect or absent LDL receptors, nor to bring these patients to goal. We're confident in the demonstrated efficacy of Juxtapid in reducing LDL-C levels in HoFH patients. We currently do not view PCSK9 as a threat to our market opportunity in the near or long term.[126]

139. During the call, Cory Kasimov, JPMorgan Analyst, asked:

Okay. That makes sense. And then lastly -- and I'll hop back in the queue -- but on the topic of the PCSK9s, I appreciate your comments and perspective there. However, do you think there's a risk to this class kind of slotting into the more moderate dyslipidemia market and then significantly slowing down -- or that trickle-down effect of patients into the more severe setting that Juxtapid currently addresses? So maybe it's not so much head-to-head competition, but they slow -- they kind of decrease the incidence of your market over time?[127]

140. Defendant Beer responded:

I don't, Cory, and I'll tell you why. I represented -- well, first off, the data came out yesterday exactly kind of where we expected it. Dr. Mark is sitting next to me. He sent me a message this morning saying, "I don't know what the reaction is. It's exactly kind of what we expected." Interestingly, we've talked to a lot of thought leaders and, obviously, we're not privy to the data other than what's public like you are, but in talking to the thought leaders and also looking at the mechanism of this drug, it's a very important platform. It's going to play a very important role in clinical practice. It's just not going to, I think, single-handedly get patients out of harm's way that are HoFH patients. So at the January JP Morgan conference, I had laid out a slide that said that we believe that it would have an effect on HoFH of 10% to 20%, and I still believe that it's going to, which means that it'll have no effect in some patients, it'll have a better effect than 20% in some patients, and I think the mean is going to be somewhere between 10% to 20%. That's not enough for these patients. And if you look at the patients that we're onboarding, they're very severe. They need more of a drop

[126] *Id*. at 5.

[127] *Id*. at 7.

> than what PCSK9 is going to give them. So when I go out 5 to 8 years, I can tell you that looking at the results that were published yesterday are completely consistent with what we had talked about in our long -- in what we call our LRP. And it will change -- it will not change any of the projections that I'm making internally to my board or that I'll make in the future to the outside world. Again, that's not a discouraging comment about PCSK9 as a platform. It's going to be a very useful platform. I just don't think that it's going to, in any way, put our franchise at risk.[128]

141. In response to analyst questions regarding the patient population, the characteristics of patients being prescribed the drug and the doctors who are prescribing, Defendant Beer further falsely stated:

> I messaged in the fourth-quarter call that we were surprised at the number of cardiologists that had patients and that were onboarding. We continue to be surprised by that [because] the characterization of those cardiologists that we're learning a lot about and we're optimizing our marketing and sales plan real time. And I think that has something to do with the acceleration of scripts this last couple months. So I -- we are learning a lot. We've got lots of metrics and analytics around this launch and there's more patients with the community cardiologists than we had previously thought of, and the severity of those patients is very severe.[129]

142. Analysts questioned the Company's experience with a patient's tolerance of the side effects from taking the drug, especially in the early stages where its efficacy may not be fully appreciated. In response, Defendant Beer falsely assured:

> [T]here's a couple things at every launch, you sit back and you go -- the team really did well on this and they missed this issue over here. I think we missed how many patients were in the cardiology practice. But on tolerance, the team did a spectacular job in putting the right program in place around the diet and nutritional counseling. I -- in the field, I had a number of physicians tell me that you turned an Achilles heel of a drug -- call it a potential Achilles heel -- into a benefit because these physicians commented to me that they couldn't get the patient to stay on diet, but we have. So they said it's actually a benefit of the drug. And it's a really nice compliment that physicians have made to me. So I think that the sales and marketing team has done a really nice job of putting the

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[128] *Id*.

[129] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q1 2013 Aegerion Pharm. Inc. Earnings Conf. Call, Apr. 30, 2013, at 8.

> right support around these patients. We're not seeing dropout as an issue and we're not seeing GI as an issue when I look at the feedback I'm getting from the field.[130]

143. Analysts also questioned the percentage of lipidologists versus cardiologists that were prescribing the drug. In response to this line of questioning, Defendant Beer falsely responded:

> Well, we believed a larger percentage of them were treated by lipidologists than what we're seeing in the marketplace now . . . . We haven't given a specific breakdown in the past of how many would be (inaudible) lipidologists and how many were (inaudible) cardiologists. What we had previously communicated is that we believed we were calling on about 80%-plus -- percent of those 3,000 in the 1,800 targets that we launched with and that we've expanded beyond those targets to pick up the additional patients that we're finding out there right now. But it makes us very comfortable that that 3,000 is real, looking at the numbers and the trends that we see with cardiologists.[131]

144. Bill Tanner, an analyst for Lazard Capital Markets, asked:

> Just to be clear on the PCSK9, there is really no role for that -- those drugs in terms of progression for the target population that you guys are looking at -- that this is something that -- it -- in theory, it shouldn't work -- shouldn't be predicted to work. So as you think about backfilling the patient population going forward, this isn't something that, even if the compound is approved and marketed, is going to have an impact on what you guys now at least think is your target population.[132]

145. The Company responded:

> We don't believe that it's going to have a material impact -- that's correct -- because as an approach to a disease which is caused by a defect in the LDL receptor, a therapeutic which targets the LDL receptor isn't really a rational approach. That doesn't mean to say that in some cases physicians wouldn't try PCSK9 in (inaudible) patients that aren't at goal (inaudible) the desire to achieve further efficacy. But generally speaking, you can see that, from some of the preliminary data, patients are very far away from the LDL cholesterol goals they need to achieve. So it's very difficult to envisage patients being managed

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[130] *Id*. at 11.

[131] *Id*. at 13.

[132] *Id*. at 17-18.

> effectively with an isolated PCSK9 inhibitor and getting anywhere close to where they need to be.[133]

146. Analysts reacted positively to Defendants' statements and maintained their ratings of "Buy," "Overweight," or "Outperform." For example, Cowen and Company stated:

> These results were also ahead of expectations: prescriptions written now total more than 185 (vs. 85 as of March 6), and patients on drug total 75. We think investors were likely looking for 170 or more prescriptions written, as we believe this number would approximate linear growth in scripts and assuage any fears of an early bolus. Therefore this scrip number should be well-received. In addition, we think the 75 patients on drug exceeded investor expectations substantially, likely indicating that prior authorization timelines are proceeding more efficiently than Aegerion had previously suggested. We believe current launch trends suggest that Aegerion is on pace to at least meet, and likely exceed, current year-end guidance of 250-300 patients on drug.[134]

147. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's earnings release dated April 30, 2013, and the earnings conference call held the same day, all of which touted strong growth and continued sales momentum, including Defendants' statements that they were "optimizing our marketing and sales plan" and downplaying the market risk associated with the existence of PCSK9 inhibitors, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) the wildly successful launch of JUXTAPID was predicated on an illicit marketing campaign that violated both criminal and civil regulatory provisions; (2) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (3) the Company was using the inability to clearly

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[133] *Id*. at 18.

[134] Cowen and Company, *Quick Take: Juxtapid Launch Update Strong; PCSK9 Results Lift Overhang*, Apr. 30, 2013.

diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (4) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (6) as the market would later learn, once Aegerion altered its marketing practices, it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

B. Second Quarter 2013 Financial Results

148. On July 30, 2013, the Company issued a press release reporting its "Second-Quarter 2013 Financial Results," which also was filed with the SEC as an exhibit to a Form 8-K the same day. The press release announced that the Company "has 463 U.S. commercial and global named patient prescriptions for JUXTAPID written, and 215 patients are currently on JUXTAPID therapy." The Company also "rais[ed] its full year 2013 revenue guidance from the previous range of $15 to $25 million, to the higher range of $30 to $35 million." The announcement reported, "[w]hile the company expects to exceed prior guidance of 250 to 300 patients on therapy by year-end, the company no longer plans to provide guidance for this specific metric."[135]

[135] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (July 30, 2013), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312513308675/d575008dex991.htm.

149. On that same day, following the issuance of the press release, Aegerion held a conference call with analysts and investors to discuss the Company's earnings release and operations where it reiterated the Company's successes to date. At this time, the Company provided the following false assurances:

> I believe one of the most important points that had been reinforced to date is that there may be a more significant population of homozygous FH patients in need of therapy than we had initially anticipated. As we might have predicted based on a number of new patients identified, we believe that the incidence of both homozygous and heterozygous FH is almost certainly greater than reported in the literature.
>
> Consistent with what we might expect, recognizing that homozygous FH is a disease that is [intracycly] diagnosed and has a very broad spectrum of severity, we've seen that the range of LDL cholesterol levels among HoFH patients is wide. However, anecdotally, the patients we're seeing prescribed Juxtapid in a commercial setting have a severe clinical phenotype that demonstrates aggressive and advanced cardiovascular disease. These are, without question, patients at high risk of cardiovascular events. They are also patients that, for the most part, we don't believe will be adequately treated by potential future therapies currently in development . . . .[136]

150. Defendant Fitzpatrick, Aegerion's CFO, stated during the call:

> Based up on the results we have seen to date and our current insights into launch, we are revising 2013 full-year- revenue guidance upwards. We now expect to achieve between $30 million and $35 million in net product sales in 2013.
>
> While we expect the number of patients on therapy at year end to exceed our prior estimate of 250 to 300 patients, consistent with our plan to discontinue offering specific launch metrics other than sales, we no longer plan to provide guidance for the number of patients on therapy at year end.[137]

151. Analyst questions surrounding the types of doctors prescribing the drug were met with repeated false assurances that each doctor was REMS-trained and that the training was taken very seriously. Defendant Beer falsely stated:

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[136] Q2 2013 Earnings Conf. Call, at 5.

[137] *Id*. at 7.

> We emphasize this organization that we want appropriate patients that meet the FDA label and REMS requirement. And it's critical that we do the proper education of both risk and benefit of what we studied in clinical development, with the physicians that have an intent to prescribe.
>
> So we have a high comfort that our organization, our sales organization has done that in a high-quality way. And so we're in front of every physician . . . prior to a script.[138]

152. In a follow-up response, Defendant Beer falsely explained the mix between lipidologists and cardiologists who were prescribing JUXTAPID:

> [W]e're getting more prescriptions from cardiologists than we are from lipidologists. We do have a large percentage of our patients coming from lipidologists as well. But the larger percentage -- and again, it's probably just, it's consistent with just more cardiologists and just where the patients reside.
>
> But we are getting a bunch from both lipidologists and cardiologists, but more from cardiologists than lipidologists.[139]

153. Analysts reacted positively to the continued acceleration of prescriptions and the Company's efforts to target cardiologists, and maintained their ratings of "Buy," "Overweight," or "Outperform." For example:

- "We continue to believe that the hoFH opportunity is larger than the Street is modeling and that based on AEGR's revised patient number guidance, estimate that new 2013 revenue guidance could be beatable."[140]

- "As of today, Aegerion reported 463 unique new scrips written (vs. "more than 185" on April 30, or about 90 adds/month), 215 patients on drug (vs. 75 on April 30, or about 45 adds/month). Moreover, the dropout rate has been less than 10%, a metric that Aegerion does not expect to increase appreciably over time, because patients who stop the drug, generally stop it early. We believe these metrics exceeded investor expectations."[141]

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[138] *Id*. at 15.

[139] *Id*. at 18.

[140] Leerink, *2Q13 EPS: Strong Juxtapid Launch, Execution on Track to Expand Globally*, July 30, 2013.

[141] Cowen and Company, *Juxtapid Launch Trends Strong; Raising Our Estimates*, July 30, 2013.

- "We are maintaining our OW rating as investors continue to gravitate to this name given the stellar execution and potential for significant earnings leverage in the model (that could be realized sooner rather than later)."[142]

154. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's earnings release dated July 30, 2013, and the earnings conference call held the same day, which touted its increasing patient prescriptions, increased full year 2013 guidance, and that "there may be a more significant population of homozygous FH patients in need of therapy than we had initially anticipated," were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) the wildly successful launch of JUXTAPID was predicated on an illicit marketing campaign that violated both criminal and civil regulatory provisions; (2) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (3) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (4) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (6) as the market would later learn, once Aegerion

[142] JPMorgan, *2Q Snapshot - Follow-Up Thought's on Juxtapid's Strong Launch and Still Conservative Guidance; Increasing Target to $99*, July 30, 2013.

altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

August 15, 2013 – Aegerion at Canaccord Genuity Growth Conference

155. On August 15, 2013, Aegerion participated in the Canaccord Genuity Growth Conference. During the conference, Defendant Fraser stated:

> In the past we have told you that in the US that we believe that there's upwards of 3,000 patients in the US that meet and fit the definition of clinical and/or laboratory diagnosis consistent with HoFH. And as we've been out in the marketplace we've also said that we have increasing confidence that there is at least that many patients in the US marketplace that fit that definition.
>
> * * *
>
> We've priced in the United States the product at $295,000 now across all of our strengths, and we also have a cap that we've put into place with the payers for the product to not exceed that level. And when you put this opportunity together, as well as in the marketplace and the market size, with this price and our commercial capabilities that we'll bring to bear, we can see the potential for lomitapide in the future to potentially reach $1 billion in terms of the opportunity that we're moving against.
>
> * * *
>
> We also revised our guidance upward for this year to be between $30 million and $35 million in net product sales. We continue to reiterate our guidance of moving to cash flow positive past breakeven in the second half of next year.[143]
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> * * *
>
> So when we think about our product in relationship to the PCSK9s in the future, I think a couple of things are important to note.
>
> First of all, these patients need this type of mechanism of action to be able to have such a huge reduction and move towards goal. We are adjunct therapy. We're

[143] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc. at Canaccord Genuity Growth Conf., Aug. 15, 2013, at 4-5.

> adjunct therapy today to things such as apheresis, and we'll remain adjunct therapy. In a future role in a future state, you can see combinations; perhaps see combinations of therapies being brought to bear to fully pull somebody to goal. And we think we're always going to have a place, but in particularly this patient population, we really have a defendable franchise for the long term.[144]

156. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made during the Canaccord Genuity Growth Conference held August 15, 2013, that "we can see the potential for lomitapide in the future to potentially reach $1 billion in terms of the opportunity that we're moving against," and that "we really have a defendable franchise for the long term" despite the future availability of PCSK9, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) the wildly successful launch of JUXTAPID was predicated on an illicit marketing campaign that violated both criminal and civil regulatory provisions; (2) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (3) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (4) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were

[144] *Id*. at 6.

illegally marketing; and (6) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

C. Third Quarter 2013 Financial Results

157. On October 30, 2013, the Company issued a press release reporting its "Third-Quarter 2013 Financial Results," which also was filed with the SEC as an exhibit to a Form 8-K the same day. The press release announced that "[a] significant number of patients were added to the Company's growing base of active patients on JUXTAPID, and new prescription rates continued to accelerate."[145]

158. On that same day, following the issuance of the press release, Aegerion held a conference call with analysts and investors to discuss the Company's earnings release and operations where it reiterated the Company's successes to date. Analysts continued to question Defendants about patient compliance and dropouts, as well as the Company's views on the acceleration in prescriptions being written.

159. In response to questions regarding the acceleration in prescriptions, Defendant Beer falsely assured:

> [W]e continue to see the cardiologist as a growing market and we are getting more prescriptions of patients on therapy there than in other specialties. So as we shared with you, there was a strong focus in putting some activities that focused -- educational activities focused on cardiologists in Q2. I will emphasize we are just at the beginning of that and the vast majority of cardiologists we still have not seen.
>
> So there is a good educational set of programs that Craig and his team are focused on the cardiologists and that will be important going forward.

[145] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Oct. 30, 2013), *available at* http://www.sec.gov/Archives/edgar/data/1338042/000119312513417085/d620399dex991.htm.

* * *

I think this disease is underdiagnosed and we haven't called on the majority of the cardiologists. Craig [Fraser] will comment more on the seventh about how we will look at the cardiology field and the amount of business and number of patients that are important to get on therapy that are out there with the cardiologists.

* * *

I'll continue to emphasize that we've called on a small percentage of the cardiologists out there in the US but the majority of our patients are coming from the cardiologists . . . .

At the beginning of the year, we had targeted 400 lipidologists and over 800 cardiologists and it was -- as we looked at the prescriptions coming in and the proactive cardiologists frankly, that were becoming aware of the availability of JUXTAPID, we had redirected quite a bit of educational activity to cardiologists which is yielding a lot of patients that were not in the tracker. And more are not in the tracker than are that we are getting right now.

We get a lot of patients that come in from the lipidologists. I will say that they have fewer patients in their practice. They tend to study the patient longer and it takes them longer to put somebody on therapy because I think that they are trying a lot of different products at the same time.

The cardiologists not that case. The cardiologists tell us that we are seeing 35 patients today, we are very busy, we've got to get the patient out of harm's way quickly. We can't make every patient a study and they tend to put the patient on therapy quicker than a lipidologist. But both are treating effectively and we are getting good support. When I look at it city by city, we look very carefully at the KOLs. We've got good support KOL by KOL.

But there's more cardiologists out there so just by number of cardiologists and the fact that they haven't referred the HoFH patient unless the patient is being apheresed. That's what they keep telling us. They say we feel very comfortable putting a patient on max dose statins and trying everything the medical community can try but if they don't go on apheresis, we don't feel a need to pass them onto lipidologists. That's when the cardiologist is holding on to the patient."

* * *

These patients are very severe and the cardiologists combat that. This really is the first thing that they've been able to use effectively with these patients.

> I will emphasize something else that cardiologists said to me that was very powerful. He said, Marc, this is the first therapy for this HoFH patient that my goal has changed from just do everything I can do so I can sleep at night to the goal is to get the patient to goal. That's a really important nuance, a really important nuance.
>
> And when you are looking at the size of the market and the number of physicians you call on and you are looking at is the therapy working for a physician to say that and we are hearing that over and over now, that I used to just try to throw everything I can throw at them so I can sleep at night knowing that I'm doing everything that I can do.
>
> That's not how they position JUXTAPID. JUXTAPID is the first thing that has given them the medical goal to get these patients to goal. So it's exciting; we've got a lot of patients getting to goal.
>
> But I would emphasize that what we are seeing in the marketplace is just reconfirming that 3,000 plus US number, approximately 15,000 patients globally and we feel comfortable committing that we can get 4000 to 5000 patients on therapy globally and have this exceed $1 billion in revenue per year.[146]

160. Finally, in response to an analyst inquiry concerning the addressable population and, specifically, the correlation between HeFH and HoFH, Defendant Fraser falsely assured investors that:

> The only thing I would say in conclusion . . . is to remind everybody that the physicians who are prescribing JUXTAPID are attesting to the fact that the patient has a clinical or a laboratory diagnosis consistent with HoFH and as such, as you know, it's actually a very thoughtful process is what we are seeing. And beyond that, the payers themselves are helping to ensure it's a thoughtful process as well.
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> * * *
>
> [I]t appears as if HoFH is significantly underdiagnosed.
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> * * *
>
> We've talked a lot about our early launch learning that cardiologists were managing many more HoFH patients than we or they had initially expected. This remains true. We have worked quickly to prioritize and increase our activities to be able to effectively reach this market.

[146] Q3 2013 Earnings Conf. Call, at 8-9, 11-13.

We believe that there is significant room for growth based on our continued optimization and substantial investment in reaching into the cardiology segment.[147]

161. Defendant Beer stated during the call:

Finally, we are looking very carefully at the impact the PCSK9 class of products will have when they reach the market which is anticipated to occur around 2016.

As we have discussed during previous calls, because of the mechanism of action of PCSK9 class of drugs which like statins is LDL receptor dependent, we believe the vast majority of HoFH patients will not be effectively treated to go with PCSK9 inhibition alone. A PCSK9 commercial launch could shine an even larger spotlight on the HoFH market and increase not only the HoFH diagnosis rates but also the number of HoFH patients we identify in all markets.[148]

162. Defendant Fitzpatrick added:

Turning to a review of our financials on slide 7, net product sales of JUXTAPID were $16.3 million in the third quarter compared to $6.5 million in the second quarter of 2013. This brings total JUXTAPID net product sales in the first nine months of commercial availability to $24.1 million.

* * *

Based upon the results we have seen to date and our current insights into launch, we are revising 2013 full-year revenue guidance upwards. We now expect to achieve between $45 million and $50 million in net product sales in 2013.[149]

163. Responding to an analyst's question about market size, Defendant Beer stated:

We started to see the real evidence and enough prescriptions and identified patients around the late April timeframe which caused me to be comfortable saying that we would get 4000 to 5000 patients globally on therapy on this product and it's a $1 billion product in May. We're we are seeing reconfirmation of that every day as our field is calling on cardiologists and we are investing significantly in our customer-facing organization exiting this year going into 2014 because we see the patient need. It is an underdiagnosed market.[150]

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[147] *Id*. at 4, 17.

[148] *Id*. at 6.

[149] *Id*. at 6-7.

[150] *Id*. at 12.

164. Analysts reacted positively to the Company's statements both about the dropout rates and the continued interest by cardiologists and acceleration in prescriptions, causing them to maintain their ratings of "Buy," "Overweight," or "Outperform." For example:

- "While management, as expected, stayed away from providing quantitative information on the launch (number of pts on drug and Rx written), all the qualitative information was encouraging, in our view."[151]

- "We believe the 2013 exit trajectory implied in guidance and the growing pipeline of yet-to-be filled new prescriptions (we estimate AEGR has 350+ unfilled scrips in the queue today) suggest a strong 2014, and expect Street revenue and EPS estimates to rise."[152]

165. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's earnings release dated October 30, 2013, and the earnings conference call held the same day, touting a "significant" number of patient adds, that "HoFH is significantly underdiagnosed," and that PCSK9s could increase the HoFH diagnosis rates, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) the wildly successful launch of JUXTAPID was predicated on an illicit marketing campaign that violated both criminal and civil regulatory provisions; (2) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (3) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as

[151] JPMorgan, *3Q Snapshot – Another Beat and Raise; Fundamentals Intact Despite Market Weakness*, Oct. 30, 2013:

[152] Cowen and Company, *Juxtapid Gaining Global Traction*, Oct. 30, 2013.

supported by medical literature; (4) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (6) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

D. Preliminary Fiscal 2013 Net Product Sales and Fiscal 2014 Financial Guidance

166. On January 9, 2014, the Company issued a press release reporting its "Preliminary 2013 Net Product Sales, its Outlook for 2014 and Other Business Updates," which also was filed with the SEC as an exhibit to a Form 8-K the same day. The press release announced that the Company expected to achieve "global net product sales of between $190 million and $210 million" for FY 2014, thereby falsely and misleadingly informing the market that FY 2014 would be almost *four times* more profitable than was 2013.[153]

167. At the JPMorgan Healthcare Conference held on January 13, 2014, Defendant Beer reiterated the Company's fiscal 2014 revenue guidance and continued to falsely and misleadingly express his confidence in the Company's ability to manage the dropout and compliance rates of patients on therapy and the strength of the systems Aegerion had in place to actively track these critical metrics and adjust when (and if) necessary, stating:

[153] Jan. 9, 2014 Form 8-k.

> So taking it back into 2014, based on the continued progress, we expect net sales of the organization to go from the $48 million to $49 million ending Q4 of 2013 to grow to $190 million to $210 million in 2014.
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> * * *
>
> Now let me mention PCSK-9 because I get asked often about PCSK-9 as a platform. PCSK-9 inhibitors are also dependent on LDL receptor activity, and they function on the LDL receptor, so it is not our belief that HoFH patients and the population of patients that we market to for mechanistic reasons similar to the statins will PCSK-9 be an effective therapy.
>
> * * *
>
> We have strong analytics and dashboards in place, providing a visibility around this launch on a daily basis that allows us to learn in real time and course correct if there's certain markets that we have to course correct in. It allows us to rely on this information as we go forward with our guidance into 2014.[154]

168. Defendant Beer also spoke about the Company's efforts in response to the FDA Warning Letter it received in November 2013, and also briefly touched upon the recently issued DOJ subpoena. Specifically, Defendant Beer falsely stated:

> [G]iven the strong focus on safe and appropriate use of JUXTAPID I want to take an opportunity to address two recent events that I'm sure you are aware of. In November we received a warning letter relating to the interviews I gave on CNBC Fast Money, in the on-air interviews I should have chosen words that would've been more balanced in nature. We're working with the FDA to resolve these concerns and plan to return -- run a corrective broadcast on CNBC in the near future which will correct any potential misimpressions or reinforce our label and safety information. I should note that this does not impact any of our sales and marketing material or what physicians are seeing day in and day out by our sales reps; our promotional materials do not include the statements of any type that were cited in the warning letter.
>
> You're also I'm sure aware of a recent announcement we made last week that we received a subpoena for an investigation by the Department of Justice into our sales and marketing practices. While I can't talk about the specifics of the investigation, I can tell you that Management is passionate about ensuring we are operating in the best-in-class way when it comes to compliance. We've been diligent in our efforts to ensure that all promotional material, our training of our sales reps, messaging to physicians, and our activities are consistent with on-label

[154] JPMorgan Healthcare Conf., Jan. 13, 2014, at 3-5.

> promotion and all applicable laws that are related to that compliance. We have a strong focus and discipline about compliance internally.[155]

169. Analysts reacted positively to the Company's fiscal 2014 guidance announcement, and maintained their ratings of "Buy," "Overweight," or "Outperform." For example:

- "We believe AEGR is providing reasonable and achievable guidance with potential upside and recommend purchase of the stock at these levels now that expectations have decreased significantly."[156]

- "AEGR also provided FY14 Juxtapid revenue guidance of $190M-$210M, bracketing consensus of $204M, which we view as achievable and allows for upside given the patient bolus and significant increase in the sales force as of Jan. 1."[157]

170. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's earnings release dated January 9, 2014, and the presentation it made at the JPMorgan Healthcare Conference on January 13, 2014, all of which touted strong growth and continued sales momentum, as well as Defendants' statements that the Company had "strong analytics and dashboards in place, providing . . . visibility," were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) the wildly successful launch and the resulting full year 2014 preliminary fiscal guidance were predicated on sales derived from an illicit marketing campaign that violated both criminal and civil regulatory provisions; (2) as first revealed by the three federal agency investigations that would ultimately result in a settlement,

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[155] JPMorgan Healthcare Conf., Jan. 13, 2014, at 3-4.

[156] Leerink, *4Q Juxtapid Revenue Consistent With Expectations, 2014 Guidance Solid*, Jan. 9, 2014:

[157] Canaccord Genuity, *AEGR PRIMED FOR 2014 REBOUND; NICE FY14 GUIDANCE*, Jan. 10, 2014:

the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (3) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (4) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (6) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

E. Fourth Quarter 2013 and Fiscal Year 2013 Financial Results

171. On February 26, 2014, the Company issued a press release announcing its "Fourth Quarter 2013 and Fiscal Year 2013 Results," which also was filed with the SEC as an exhibit to a Form 8-K the same day. The Company falsely and misleadingly confirmed its previously announced 2014 guidance: "Aegerion expects global net product sales of between $190 million and $210 million for FY 2014."[158]

172. On that same day, following the issuance of the press release, Aegerion held a conference call with analysts and investors to discuss the Company's earnings release and

[158] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Feb. 26, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312514068394/d683222dex991.htm.

operations where it reiterated the Company's 2014 guidance. Defendant Beer falsely indicated the following: "Our 2014 guidance is based on a forecast model that is continually refined to reflect a deep understanding of the business, and which captures these variables that we've discussed."[159]

173. Defendant Fraser explained to the market:

> We believe, based on the work that we've done, that the rate of patient-elected non-starts should decline with the full implementation of these initiatives. We also believe that many of these non-starts may consider JUXTAPID in the future, and we plan to maintain ongoing interaction with physicians and patients to support a potential on boarding of previously scripted patients in the future.
>
> Increasing patient education and commitment is necessary, and we expect it to have a positive effect on adherence as well, mirroring what we saw in our phase III study, we see dropouts happen most frequently during the first one to two months of treatment.[160]

174. During the question and answer session that followed, analysts questioned Defendants about the Company's expected sales trends, patient growth in the United States, and the impact of the Company's investments in its sales force and patient education program on patient conversion and retention, in light of its confirmed FY 2014 guidance. Analysts consistently probed Defendants for specifics on the key metrics driving its business. While they acknowledged "investor desire to have more visibility into the business," Defendants did not comment on 2014 trends. Instead, Defendant Beer falsely stated:

> Guidance: "Coming out of 2013 and the understanding of this business, and the, I would say, diligent process that Craig [Fraser] and Mark Fitzpatrick have done to understand the variables of our model. It makes me feel very comfortable coming into 2014 that our guidance for the year of $190 million to $210 million, I feel good about."[161]

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[159] Q4 2013 Earnings Conf. Call, at 5.

[160] *Id*. at 6.

[161] *Id*. at 10.

Dropouts: "I'm clearly communicating to you that we're at 15% [dropout rate], and that would maintain throughout the year . . . . We just want to be as accurate as we can. And I want to see that improve. But I think I trust that metric right now, because it's off a bigger end than midyear [10% or less at that time on smaller numbers]. So we are just trying to give clarity."[162]

* * *

[T]he dropout rate from midyear to now, I would just say, it's a smaller number at midyear. So less than 10% midyear. It's 15% over the course of the year. I trust that 15% more than the 10%, because it's just off a bigger number. And I just want everybody to be comfortable how we are calculating that. [163]

175. Defendant Fitzpatrick stated:

With just one year of commercial experience now in hand, we have experienced confidence in our estimate of the total addressable adult HoFH market, and continue to foresee long-term potential for 4,000 to 5,000 patients on therapy globally, and $1 billion in annual net product sales in the future. Assuming pricing and market acceptance consistent with our expectations.

We continue to believe HoFH is an under-diagnosed disease, and that a significant number of HoFH patients are in need of therapy. This belief is also shared by more experts in the medical community and in peer reviewed publications. Having now completed the first year of launch, we believe we have only just begun to penetrate the total addressable adult HoFH patient population.[164]

176. Defendant Beer stated:

The other thing that I will mention that Craig and I both tried to mention is two things. One, we see the patients out there. This market is under-diagnosed. And there's an educational and awareness that is needed. But we think we're sized right to do that over the next couple years, so the patient potential is out there.

* * *

I will emphasize that we are religious about compliance, and who we can market to, and marketing on-label.[165]

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[162] *Id*. at 13.

[163] *Id*. at 14.

[164] *Id*. at 3.

[165] *Id*. at 18.

177. With regard to the "surprise" in patient-elected non-starts, Defendant Beer responded to a Cowen and Company analyst:

> So we are studying this more and more. We look at the patients that have had a prescription, and we've achieved authorization for insurance. We look at that as a HoFH patient pool that we need to study more and educate the patient and the physician through the physician better.
>
> It's a great pool of future patients, if we effectively educate the patient through the physician. And that's where the focus has been. So I think there's a lot of potential in those numbers. I could tell you this, still, the majority of patients, we haven't scraped the surface of this market yet, because we did not have the reach to do it.
>
> We launched with 25 reps. We significantly increase the sales force in the back half of the year. We did that because we did not have the reach to get to all the cardiologists that we need to get to.
>
> So I do believe that the majority of this market is out in front of us, and we are now sized appropriately to get to those patients. And I have a lot of confidence in Craig optimizing this non-start metric. That's clearly more frustrating to me than the patients we haven't educated yet. Because these are patients that -- a physician has made the decision.
>
> So it's frustrating to us, but we will optimize that metric.[166]

178. Defendant Fraser supplemented Defendant Beer's comments as follows:

> For us, we have specifically looked at our patients; we understand how the patients do have varied understandings of this. We've seen where it works really well, with regard to education. And as Marc mentioned, it is truly a partnership of making sure that the health care provider has all the education and support and tools that they need to be able to pause and successfully educate their patients about their disease, and the therapies, and so forth. And we've put together a whole engagement team to be part of that effort.
>
> * * *
>
> Now, Marc mentioned earlier as well, we don't plan to provide a specific metric, because you are asking about a metric question on this. But I want you to know that we made a lot of effort and a lot of investment to -- with the -- ideal optimizing in this area. I also mentioned in my part of the script, a side benefit, an important benefit is, when you do this the right way, right up front, you not

[166] *Id*. at 12.

> only have positive effect on conversion rates in patients going onto drugs. But you've educated them in a manner that sets up better support of optimizing adherence, once they are on therapy, both compliance and drop. So we see that as a key area and a key focus for us that we've done heading into this year.[167]

179. Yet another analyst asked for additional comment on the patient-elected non-start metric and, specifically, when the Company had discovered it and whether it was something that was seen throughout the year. Defendant Beer responded:

> Obviously, you are, in the first half of the year, dealing again with smaller numbers. And you can't decipher whether a patient non-start is just the fear of the diet, and eventually you are going to eventually will get them on therapy.
>
> So, as the numbers got larger, as the scrip numbers got larger in the back half of the year, and we started to study those more carefully, we really deciphered out, this person doesn't today have the intent to go on therapy, and this person is. And they've got an appointment scheduled. So this definitely emerged, and we understood it much better in the back half of the year.
>
> And it was never something that we looked at as the dropout, because the patient wasn't shipped, and we did not count the revenue. So it's not a dropout component. It is just a patient that, we never realized the revenue. And it is pushing the shipment off and pushing the shipment off. So we got a better understanding when we went and spoke to these patients and got more clarity, but it was definitely a back half of the year kind of emerging metric.[168]

180. Analysts were encouraged by the fact that the Company provided more "concrete disclosures allowing increased clarity on Juxtapid's uptake and addressing a few investor concerns that had not been previously explained,"[169] and reiterated their confidence in the Company's revenue estimate. As such, they maintained ratings of "Buy," "Overweight," or "Outperform." As noted in one such analyst report: "The business continues to grow & the co

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[167] *Id*. at 13.

[168] *Id*. at 14.

[169] Cowen and Company, *A Return to Transparency in Q4 Report*, Feb. 26, 2014.

ended '13 with net 467 pts on drug (>2x vs. July '13). If the co could double this in '14, we see '14 revs at $210M w/ 15% drop-out & 10% gross to net."[170]

181. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's fourth quarter and FY 2013 earnings release dated February 26, 2014, and the earnings conference call held the same day, all of which touted strong growth and continued sales momentum, "religious[ness] about compliance," an "understanding of the business" that incorporates a "diligent process" employed to "understand the variables of the model" so as to make the Company "very comfortable" with its projected guidance, and the 15% dropout rate that the Company stated it would maintain "throughout the year" were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (2) as would later be revealed, while Defendants announced its FY 2014 guidance of "between $190 million and $210 million," that announcement was false and misleading because the Company failed to disclose that it was "ceas[ing] dissemination of promotional materials such as those containing statements referenced in the Warning Letter" which was material information to the market in order to evaluate the Company's ability to meet its guidance; (3) as Defendant Beer would later reveal in October 2014, the Company lacked a sufficient understanding of the patient journey related specifically

[170] Deutsche Bank Markets Research, *DB thoughts on AEGR weakness post 4Q call*, Feb. 26, 2014.

to the key metrics discussed herein; (4) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (5) Defendants failed to disclose that despite attempts at increasing Aegerion's customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (6) the Company failed to disclose that it was actually experiencing higher patient-elected non-starts and dropouts/discontinuations than the 15% it was currently reporting and "that would maintain throughout the year"; (7) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (8) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (9) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (10) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; (11) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients

discontinuing treatment; and (12) the Company was not "religious" about compliance – in point of fact, Aegerion had embarked on an illegal marketing campaign involving JUXTAPID.

F. First Quarter 2014 Financial Results

182. On May 6, 2014, Aegerion issued a press release detailing its first-quarter 2014 financial results, which also was filed with the SEC as an exhibit to a Form 8-K the same day. The press release reported that the Company was lowering its FY 2014 guidance, falsely and misleadingly announcing that the Company "now expects global net product sales of between $180 million and $200 million for FY 2014, revised from the prior range of between $190 million and $210 million."[171] Defendant Beer further falsely and misleadingly assured investors that Aegerion would hit these numbers, stating "we expect 2014 net product sales growth from the U.S. business to be more weighted towards the second half of the year."[172]

183. Aegerion hosted an earnings conference call with analysts that same afternoon, wherein Defendant Fitzpatrick falsely and misleadingly confirmed: "As we noted in today's press release, we have revised our expectations for global lomitapide net product sales in 2014 to between $180 million and $200 million from the prior range of $190 million to $210 million."[173]

184. In discussing the greater-than-expected headwinds associated with patient-elected non-starts and dropouts, Defendant Beer falsely stated:

> It was clear to us in 2013, JUXTAPID prescriptions both outpaced the capacity of our patient service infrastructure, as evidenced by patient non-starts and by increasing drop rates towards the end of the year. It became more apparent by year-end, that the meaningful changes -- that meaningful changes were necessary

[171] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (May 6, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312514184972/d723227dex991.htm.

[172] *Id*.

[173] Q1 2014 Earnings Conf. Call, at 8.

in order to fully meet the need for rapid prescription conversion and patient retention.

We believe the patient elected non-starts and dropouts are directly correlated to the thoroughness and the timeliness of comprehensive patient education of HoFH patients and the importance of the diet in taking JUXTAPID along with it, along with strong physician involvement in the patient education process. Q1 represented an important period of optimization and investment as illustrated by the magnitude of our increase in operating expenses in Q1 versus Q1 of last year.

* * *

Second, we continue to have confidence in our estimate of the total addressable adult HoFH market. We believe HoFH, while still rare, is underdiagnosed. And the significant number of HoFH patients globally are in need of therapy. This belief is shared by an increasing number of experts in the medical community and in peer and youth publications. We believe the global HoFH represents a significant commercial opportunity.

Finally, our efforts to optimize the scale of our business which will continue during the start of 2014, are just beginning to bear fruit. Although we do not expect to see topline impact until the second half of 2014, we feel confident that the increased commercial reach has the potential to result in meaningful growth. In our view, resource allocation and execution are the gating factors in JUXTAPID capturing maximum share of HoFH market on a global basis.[174]

185. Defendant Fraser added his thoughts regarding the addressable population:

The first quarter represents a pivotal period for the US sales force expansion and for the continuing to strengthen our commercial strategy and execution. We remain confident in JUXTAPID's addressable global market opportunity as a treatment for HoFH. And are taking operational steps to maximize long-term fundamentals.

In mid to late January, we trained and then deployed our expanded US sales team into new territories. As with any sales force realignment, there is a period of downtime for redeployment and training.

Also, a particularly long harsh winter resulted in delays and outbound physician calls and has slowed down for patient onboarding. These factors contributed to the year beginning with a flatter scrip trend, and thus we had fewer new patient starts in the first quarter than expected. However, we see early positive traction behind the sales force expansion.

[174] *Id*. at 3-4.

> We saw a meaningful uptick in scripts and new patient starts in the later [sic] half of the first quarter. And observed these recent trends continue into the early part of the second quarter. We continue to stress how important it is that patients gain a full understanding of HoFH and education about the optimal diet for success with JUXTAPID.
>
> In an effort to further enhance our patient focus commercialization strategy, we have established a new patient engagement team, which includes a new nurse educator group. These nurse educators have begun to assist with patient and nurse education about HoFH and JUXTAPID use with strong emphasis during the crucial onboarding phase. We believe the nurse educators will assist with HoFH patients in their efforts to successfully manage their transition to JUXTAPID therapy.
>
> Also important, as a result of the nurse educators in the field, sales representatives previously responsible for onboarding patients can now focus primarily on identifying new physicians with HoFH patients needing JUXTAPID therapy. We are receiving early encouraging feedback that nurse educators are having a positive impact in the field. However, we are still scaling this team and it's too early to meaningfully quantify the potential impact on reducing patient elected non-starts.
>
> We expect nurse educators to have the potential for a positive impact on dropout rates with patients beginning therapy in an educated and committed way and nurses helping to support them. Managing patient elected non-starts and dropouts remain integral to the long-term success of our business.
>
> We believe the recent enhancements in our commercial team were the right investments given the insights we learned from both the field and patients. And we expect these investments to both impact those metrics in a positive way. As Marc previously indicated, we believe the management of appropriate resource allocation and execution remain critical factors to our growth within the HoFH market opportunity.[175]

186. During the question-and-answer session that followed, Defendants Beer, Fraser, and Fitzpatrick fielded questions concerning first quarter and projected 2014 sales trends, the dropout rate, the apparent plateau in total new patient growth in the United States and the impact of investments in the Company's sales force and patient education program on patient

[175] *Id*. at 4-5.

conversion and retention, and the Company's plans for meeting the newly revised FY 2014 guidance.

187. In response to specific questions regarding the Company's confidence in the newly revised guidance, Defendant Beer falsely and misleadingly stated:

> We have a very defined model in the US. The majority of our revenue this year, even with the growth of international, is going to be the US. Obviously, we have to get the US right. And we feel good about what that's going to produce the next three quarters . . . . I feel good about the guidance. I believe we'll see the growth that we're forecasting in our model and we have a good understanding of the trend and different metrics. So the $180 million to $200 million, I feel good about that guidance.
>
> My comfort [that revenue will accelerate in the second half of that year] is around early trends of the expansion. So we look very closely. Craig [Fraser] has how many scripts and patients on therapy, did we have with the previous size of our sales force? How does that production per rep look coming out of the first quarter with an expanded sales force? How do we take those trends to the business the rest of the year? We have a very defined model in the US. The majority of our revenue this year, even with the growth of international, is going to be the US. Obviously, we have to get the US right. And we feel good about what that's going to produce the next three quarters.
>
> * * *
>
> I feel good about the guidance. I believe we'll see the growth that we're forecasting in our model and we have a good understanding of the trend and different metrics. So the $180 million to $200 million, I feel good about that guidance.[176]

188. In response to analyst questions regarding specifics on the patient-elected non-start and dropout metrics, Defendants falsely and misleading stated:

> Defendant Beer: "We believe the patient elected non-starts and dropouts are directly correlated to the thoroughness and the timeliness of comprehensive patient education of HoFH patients and the importance of the diet in taking JUXTAPID along with it, along with strong physician involvement in the patient education process."[177]

[176] *Id*. at 16-17.

[177] *Id*. at 4.

> Defendant Fraser: "We are receiving early encouraging feedback that nurse educators are having a positive impact in the field. However, we are still scaling this team and it's too early to meaningfully quantify the potential impact on reducing patient elected non-starts."[178]
>
> Defendant Beer: "The majority of our calls were on new physicians and we had a large percentage of our scripts come from previous non-writers that we weren't calling on. So all of that optimization was happening in the quarter. Now let me characterize the quarter. The first half of the quarter was lighter on scripts than we expected . . . . We're not going to comment on net patients by quarter. We'd like to get away from that and trust the guidance."[179]
>
> Defendant Beer: "[W]e'd like to get away from quarterly quantification for qualitative statements around dropout compliance or non-patient starts. But really focus on the revenue guidance and growth and the predictors around that business."[180]
>
> Defendant Beer: "We're really excited about the full course of 2014 on the script trends in the US combined with the nurse educating group to affect – positively affect the non-starts and the dropouts."[181]

189. On May 7, 2014, the day following Aegerion's earnings release and conference call, Defendant Beer attended the Deutsche Bank Healthcare Conference. There, Defendant Beer reinforced the Company's strong fundamentals and the success of the Company's personnel investments and resource allocations, falsely and misleadingly reporting:

> We believe 2014 is going to be an important year to continue to drive these fundamentals forward and we look forward to delivering a successful year in the second year of launch, learning what we've learned in the first year, and the first quarter.
>
> * * *
>
> I think if you talk to a cardiologist, or lipidologist, they'll confirm that they've tried everything on these patients and they still have a dangerously high LDL. Even the platform coming out is a critical platform, PCS K9. It is a platform that

[178] *Id*. at 5.

[179] *Id*. at 9.

[180] *Id*. at 12.

[181] *Id*. at 11.

> we believe will offer tremendous clinical benefit to patients. But, in this patient population, because of the level of defects in the receptor, and the mechanism of PCS K9 operating on the receptor, it generally will not be effective enough for model therapy in HoFH patients. So we do believe that we've got a patient population that will be of need even after that platform comes out.
>
> Further, when PCS K9 comes out, we believe that it will surface through education of some major companies, more HoFH patients that we can potentially treat around the world.
>
> * * *
>
> [I]f we were physically at the onboarding, and we had an active role in the education and the importance of the diet, usually the patient does very well. If not, they drop quickly. So, it's really important. The investment we've made in nurse educators, I think, are going to really impact our ability to improve non-patient starts and drop outs.
>
> * * *
>
> When you're launching a product in the first year, and they have scale issues, they identify themselves with real metrics, and we are really religious about dashboards and measuring. So, that happened in real time, when you think about this dynamic, and I think the scale of the business has happened between December and January. We trained them the last two weeks in January, that expansion hit the field in February, and we're starting to see the early traction of that. The proof is in us delivering the numbers, now. And, trust me, management understands the next three quarters have to show the proof of that expansion.[182]

190. In response to an analyst's question about how the Company is calculating its expected growth in light of the newly revised guidance, Defendant Beer revealed:

> [I]f we maintain the prescription production in the legacy territories and the new territories, that will deliver the revenue. As long as we maintain the conversion, which we are, the conversion from prescription to revenue. And I actually think that we're going to see improvement in some key metrics which will be non-patient starts because we have invested heavily in these nurse educators.
>
> That's why I got back to, you know, I wish I had better scale in 2013 going into '14. But until I saw the script production in '13 I didn't feel comfortable making the investment in more sales reps. And until we could get our arms around the non-patient starts in the December/January time frame, we didn't have the vision of putting the nurse educators in place. So, it's a combination of real clarity

[182] Deutsche Bank Healthcare Conf., May 7, 2014, at 2-3, 7-8.

> around the non-patient starts in that back half of Q4 and early in Q1, that said these nurse educators would be the right asset to put in place to make that non-existent, or less.[183]

191. Analyst responses following the earnings release, the earnings conference call, and/or the Deutsche Bank conference noted that the Company's guidance was not in line with its current growth rates. However, absent concrete metrics, analysts accepted Defendants' positive reassurances that the sales force and patient education expansion efforts would positively affect retention and conversion rates, sales would increase in the back half of 2014, and the Company would meet its revised guidance. As such, these analysts maintained their prior ratings of "Buy," "Overweight," or "Outperform." For example:

- "[W]e still value AEGR above where it is currently trading. As such, we are maintaining our OW rating although we acknowledge that sales will need to pick up substantially in 2H to meet new 2014 guidance of $180-200M."[184]

192. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's first quarter 2014 earnings release dated May 6, 2014, the earnings conference call held the same day, and the Deutsche Bank Healthcare Conference held on May 7, 2014, all of which touted continued sales momentum and/or that the Company had "properly weighted" the revenue for the remainder of the year and had a "good understanding of the trend and different metrics" thus leading Defendant Beer to conclude, again, "I feel good about that guidance," were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because, for example: (1) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing

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[183] *Id*. at 9.

[184] JPMorgan, *1Q Snapshot-Juxtapid Disappoints and Guidance Lowered*, May 7, 2014.

scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) as would later be revealed, while Defendants announced revised FY 2014 guidance of "between $180 million and $200 million," that announcement was false and misleading because the Company failed to disclose that it was "ceas[ing] dissemination of promotional materials such as those containing statements referenced in the Warning Letter" which was material information to the market in order to evaluate the Company's ability to meet its guidance; (4) as Defendant Beer would later reveal in October 2014, the Company lacked a "greater understanding" of the patient journey related specifically to the key metrics discussed herein, to properly prognosticate FY 2014 revenue guidance; (5) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (6) Defendants failed to disclose that despite attempts at increasing Aegerion's customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (7) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (8) Defendants failed to disclose that it was actually experiencing higher patient-elected non-starts

and dropouts/discontinuations than what it disclosed to the market; (9) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (10) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (11) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (12) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

G. Second Quarter 2014 Financial Results

193. On July 29, 2014, Aegerion issued a press release detailing its second quarter 2014 financial results, which also was filed with the SEC as an exhibit to a Form 8-K the same day.[185] Among other things, the Company falsely and misleadingly announced that while it still expected to reach its newly revised 2014 guidance, that "[b]ased upon six months of results, and expectations for the balance of the year, the Company now expects full year JUXTAPID net sales to be towards the lower end of the previously stated guidance range of between $180 and $200 million."[186]

[185] July 29, 2014 Form 8-K.

[186] *Id*.

194. Following the issuance of the press release, Aegerion held a conference call with analysts and investors that same day to discuss the Company's earnings release and business updates. Defendant Beer reiterated the Company's financial results, falsely and misleadingly assuring investors that "[w]e believe this is a strong Q2 performance in the second year of launch and we are encouraged by these results and trends."[187]

195. Defendant Fitzpatrick explained the Company's narrowing of its revised guidance, falsely and misleadingly reiterating: "Given the first six months of JUXTAPID sales in 2014, plus increasing experience of our sales dynamics, we are able to refine our 2014 sales forecast. Based on our results to-date and our current plans and expectations for the balance of the year, we believe full-year JUXTAPID net product sales are most likely to come in towards the lower end of our previous guidance range of $180 million to $200 million."[188]

196. During the question-and-answer session that followed, Defendants Beer, Fraser, and Fitzpatrick fielded questions concerning second quarter sales trends and the new patient growth in the United States and the impact of investments in the Company's sales force and patient education program on patient conversion and retention. Defendants falsely and misleadingly stated:

- "Importantly, we see early positive traction behind the sales force expansion, with prescriptions and new patient starts in the US in line with our plan."[189]
- "We understand the dynamics associated with patient commitment to therapy."[190]

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[187] Q2 2014 Earnings Conf. Call, at 3.

[188] *Id*. at 7.

[189] Defendant Fraser, *id*. at 4.

[190] *Id*.

- "We believe that recent investments in our commercial team were correctly targeted given the insights we gained from market research and our experience in the field. And we expect these investments to impact those factors in a positive way. We look forward to having several quarters of data for true clarity on the precise impact of these strategies and investments."[191]

- "Based upon our current forecasts, we believe the up front investments we've made have optimized our US commercial operations to a scale that we expect will support our US growth for the next three years. But we will continually assess our size and investments related to the US HoFH market opportunity."[192]

- "On our guidance, we try to at all times just give the absolute most clear transparent look at what our forecast and model was telling us," but as a result of the Company's increased global reach, explained that the despite 93% of its second quarter revenue being attributed to U.S. sales, the "business is going to become increasingly dynamic and hopefully is going to mitigate the risk of revenue guidance as we open up new markets and we don't rely just on two markets."[193]

- "Yes, we do [have enough wiggle room in the guidance given the amount of uncertainty] because again Mark [Fitzpatrick] and Craig [Fraser] and I point to a specific model and we're coming out of Q2 with the trends that really make us feel comfortable with the guidance we're giving at the lower end of that $180 million to $200 million. So I think we've got enough predictability around this business to feel comfortable at this point and time of the year of pointing to that expectation, and I feel like we're going to hit that goal."[194]

197. Defendants continued to rebuke the persistent questions from analysts requesting specifics on the key metrics, explaining that "we've moved away from providing very specific quantitative metrics."[195] Instead, in an effort to assuage the market of its related concerns,

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[191] *Id*. at 5.

[192] Defendant Fitzpatrick, *id*. at 7.

[193] Defendant Beer, *id*. at 8.

[194] *Id*. at 9.

[195] *Id*. at 9.

Defendants made the following false and misleading representations focused primarily on the Company's investment in its customer-facing organization:

- "The patient elected non-starts is an area that we have invested in and are implementing a whole host of programs designed around HoFH patient education, on boarding, patient and physician commitment to therapy. There's many programs, and these investments have included the addition of the fill based nurse educators that we have been talking about, as well as peer to peer patient ambassadors and an even greater focus on patient on boarding and education. Really Q2 was the first quarter that we had these types of programs and these assets really coming online. With everybody fully hired, fully trained, and the supporting materials and initiatives into place. But as I indicated during the call, we have some early encouraging signs."[196]

- "I would just say that we're seeing the early signs that we need to see that investment was the right investment. It is just off of an end that the management team starts to quantify trends. We really want it off of the large end. So we want to see a couple more quarters of that trend, but the early signs are that the trends going the right way."[197]

- "We're seeing the right trends in the key metrics that tell us that the resource allocation that we made at the beginning of this year was the right level. And that's probably the most important thing I think for investors to get the sense of is did you make the right resource allocation at the right level? And will it carry you for a couple years?"[198]

- "I think it should be encouraging to all that we saw the new patient starts and prescriptions in line with what we expected given the significant investment we made in the field. So I'm going to leave it at that and have you follow our annual guidance, but on an annual basis we'll guide a little bit deeper into key metrics."[199]

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[196] Defendant Fraser, *id*. at 8.

[197] Defendant Beer, *id*. at 15.

[198] *Id*. at 16.

[199] *Id*.

198. Analyst responses following the earnings release and the earnings conference call noted Defendants' confident tone. Accepting Defendants' assurances, analysts reacted favorably to the quarterly update. For example:

- "Recovery in 2Q Juxtapid sales of $36M (+34% q/q vs. 1Q14) is somewhat reassuring."[200]
- "We believe AEGR shares are due for a significant positive bounce due to widespread fear on the Street heading into this quarter."[201]
- "We view this guidance as very positive."[202]
- "The co needs another q to get out of the penalty box, but we would be buyers as this q was a good start; We see 2Q as encouraging."[203]
- "While management would not quantify patient numbers, it did note several favorable trends that contributed to Q2 strength and which bode well for continued growth in H2."[204]
- "As many investors were expecting a 2Q sales miss and lowered 2014 guidance, we view the slight beat-and-maintain as a win. Sales still need to show substantial growth in 2H14 to meet ~$180M for the year, but we thought management sounded a confident tone on this goal. The bottom line is that we anticipate a favorable reaction to this quarterly update and are maintaining our OW rating."[205]

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[200] Jefferies & Company, Inc. ("Jefferies"), *Encouraging ~ in-line 2Q14 Juxtapid Sales Impart Cautious Optimism*, July 29, 2014.

[201] Leerink, *2Q Recap: Major Positive Surprise for Quarter and Guidance*, July 29, 2014.

[202] *Id*.

[203] Deutsche Bank Markets Research, *Inline revs of $36M for 2Q, emerging from the penalty box*, July 29, 2014.

[204] Cowen and Company, *A Good Quarter for Juxtapid, But Guidance Still Looks Aggressive*, July 30, 2014.

[205] JPMorgan, *2Q Snapshot . . . Slight Beat-and-Maintain Is Much Better than Expected*, July 30, 2014.

- "Overall, we see 2014 sales guidance as achievable, but acknowledge that a substantial uptick in sales will still be needed in 2H14."[206]

199. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the Company's second quarter 2014 earnings release dated July 29, 2014, and the earnings call held that same day were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) as would later be revealed, while Defendants announced its FY 2014 guidance of "between $180 million and $200 million," that announcement was false and misleading because the Company failed to disclose that it was "ceas[ing] dissemination of promotional materials such as those containing statements referenced in the Warning Letter" which was material information to the market in order to evaluate the Company's ability to meet its guidance; (4) as Defendant Beer would later reveal in October 2014, the Company lacked a sufficient understanding of the patient journey related specifically to the key metrics discussed herein; (5) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (6) Defendants failed to disclose that despite attempts at increasing Aegerion's

[206] *Id*.

customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (7) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (8) the Company failed to disclose that it was actually experiencing higher patient-elected non-starts and dropouts/discontinuations than the 15% it was currently reporting and "that would maintain throughout the year"; (9) the Company was using the inability to clearly diagnose HoFH patients to justify its own calculations of a 3,000 person addressable population in the U.S., as opposed to the approximately 315 people it submitted to the FDA and as supported by medical literature; (10) Defendants were employing an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (11) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (12) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

H. Third Quarter 2014 Financial Results

200. On October 30, 2014, Aegerion issued a press release detailing its financial results and business highlights for the third-quarter of 2014, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[207] The press release stated:

> Based upon results to date, the Company now expects to achieve between $150 million and $160 million of net product sales in 2014, revised from the previous expectation of the lower end of the $180 to $200 million range.
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> "We continue to believe in the overall market potential of JUXTAPID. However, we are reducing our full year's sales estimates at this time to reflect both higher patient dropout rates and lower U.S. prescription growth rates than previously anticipated following the commercial investments we made earlier this year," said Marc D. Beer, Chief Executive Officer.
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> * * *
>
> Aegerion expects 2015 revenue growth of between 30% and 40% over 2014 projected revenue, taking into account forecasted prescription rates, drop-out rates, conversion trends, and the potential slowing impact on new patients starts following the anticipated launch of the PCSK-9 class of drugs in mid-2015, an impact Aegerion believes will ultimately be offset, in whole or part, through the identification of more HoFH patients as a result of the greater disease awareness likely to follow introduction of PCSK-9 inhibitors.[208]

201. On October 30, 2014, Aegerion hosted a third-quarter earnings conference call with analysts. During that call Defendant Beer stated:

> We are now providing a revised full-year guidance for net product sales of between $150 million and $160 million. Additionally, our current budget for 2015 estimate a 30% to 40% net product sales growth over 2014, which accounts for these factors as well as the potential slowing impact of new patients starts following the anticipated launch of the PCSK-9 class of drugs in mid-2015, an impact we believe will ultimately be offset, either in whole or part, through the

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[207] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Oct. 30, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312514389675/d811202dex991.htm ("Oct. 30, 2014 Form 8-K").

[208] *Id*.

> identification of more HoFH patients as a result of the greater disease awareness likely to follow the introduction of PCSK-9 inhibitors.
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> * * *
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> With respect to previous financial guidance, we haven't until recently experienced adequate time with a sufficient number of chronic patients on therapy to understand how a dropout will play out over the long term. While we were optimistic that investments in patient educators and dieticians made earlier this year would have more rapid positive impact on patient engagement, their positive impact has been slower to evolve and is more recently been observed in a measurable way.
>
> We now have a greater understanding of both the short-term and the long-term patient journey and the challenges along that journey. These additional insights and experiences we believe, we are at a better position to more accurately forecast the impact of our patient engagement efforts and the effects of long-term dropouts in our models.
>
> Despite September US prescriptions produced being strong, we experienced lower prescription rates during Q3 than we had forecasted in our model, which was the second factor impacting our US revenue during the quarter.[209]

202. Defendant Fraser added to Defendant Beer's comments regarding the Company's insights into the key metrics, including compliance and new patient adds, by stating:

> Another variable that we focus on is the conversion rate, which represents the percentage of patients prescribed JUXTAPID that actually start on therapy. This rate is reflective of all potential factors for a prescription not converting including reimbursement denials and duration of appeals, patient-elected non-starts and scripts initiated and subsequently canceled by a physician and is generally in line with our recent internal models running in the range of approximately 50% to 60%. In Q3, we saw the first signs of our patient educators' ability to partner with physician practices in patient education and to begin to positively impact conversion rates.
>
> * * *
>
> Compliance rates continue to be in the range of 80% to 90% and we continue to devote significant resources to appropriately support long and short-term adherence to therapy. Year-to-date prescriptions are up 32% versus the same period last year and September represented a strong month. With the expanded reach of our sales force, we continue to grow our prescriber base. In the third

[209] Q3 2014 Earnings Conf. Call, at 3.

> quarter 44% of prescriptions came from new writers and we added nearly 400 new prescribers thus far this year, more than we had in the whole of 2013.
>
> * * *
>
> With the better understanding of long-term dropout, we can now focus our investments on appropriately improving adherence. Armed with substantial data from our launch experience, we are making informed metric-driven calibrations that we believe will support continued growth.[210]

203. During the same third-quarter earnings call, Defendant Fraser, Aegerion's President of U.S. Commercial & Global Manufacturing and Supply Chain, stated:

> We believe that working with physician practices to enhance patient education during on boarding combined with more robust dietary counseling will positively impact conversion and both short and long-term dropout rates . . . . We are monitoring and focused on these dynamics closely and look forward to providing greater detail when we have a large-enough number of patients who have been on boarded and educated according to our new patient engagement protocol over a meaningful time period. Despite challenges, our solid execution in several important areas of the launch continues and is contributing to the growth in JUXTAPID that Marc described earlier.
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> * * *
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> Compliance rates continue to be in the range of 80% to 90% and we continue to devote significant resources to appropriately support long and short-term adherence to therapy. Year-to-date prescriptions are up 32% versus the same period last year and September represented a strong month. With the expanded reach of our sales force, we continue to grow our prescriber base. In the third quarter 44% of prescriptions came from new writers and we added nearly 400 new prescribers thus far this year, more than we had in the whole of 2013.
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> * * *
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> Management is fully focused on bringing JUXTAPID and LOJUXTA to as many possible adult HoFH patients who are appropriate for this therapy worldwide. The commercial investments made in the US early in 2014 are beginning to show impact. We have solid prescription growth, strong compliance for a daily oral therapy, an evidence of our ability working with physicians to use education and engagement to impact patients' transition on to therapy.[211]

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[210] *Id*. at 5-6.

[211] *Id*.

204. Defendant Fitzpatrick added:

> [W]e now believe full year JUXTAPID net product sales are likely to come in between $150 million and $160 million.
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> * * *
>
> Net product sales of JUXTAPID were $43.7 million in the third quarter of 2014, compared to $16.3 million in the third quarter of 2013.[212]

205. Defendant Beer continued:

> [I]t's important to note that the launch of JUXTAPID is still relatively early in its overall sales trajectory. And we believe the trajectory is in growth mode on an absolute basis despite the challenges we face.[213]

206. Defendant Fraser stated:

> And prescription rates, the US is up 32% this year and while that is solid growth and we had a good September, the trajectory of that growth isn't on the rates that we had initially expected. So we've carried forward a different trajectory in rate in Q4; and as we look to 2015, we're accounting for all possibilities, including PCSK-9 launches mid-year and so forth, and making sure that we have good, prudent, conservative projections on what we're going to expect out of scripts in the US.
>
> * * *
>
> [W]e've had 32% more prescriptions in this year versus the same period of last year.[214]

207. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the October 30, 2014 press release and on the earnings call that same day, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) as first revealed by the three federal agency investigations that would ultimately result in settlement, the Company was

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[212] *Id*. at 6.

[213] *Id*. at 7.

[214] *Id*. at 10, 13.

engaged in an illicit marketing scheme to target cardiologists and non-HoFH patients that was inconsistent with JUXTAPID's FDA approval and the established REMS program protocols; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) as would later be revealed, while Defendants announced its FY 2014 guidance of "between $150 million and $160 million," that announcement was false and misleading because the Company failed to disclose that it was "ceas[ing] dissemination of promotional materials such as those containing statements referenced in the Warning Letter" which was material information to the market in order to evaluate the Company's ability to meet its guidance; (4) as Defendant Beer revealed, the Company lacked a sufficient understanding of the patient journey related specifically to the key metrics discussed herein; (5) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (6) Defendants failed to disclose that despite attempts at increasing Aegerion's customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (7) Defendants had employed an illicit marketing practice to target non-HoFH patients thereby inflating its sales figures and revenue guidance; (8) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (9) when

Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (10) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

I. Fourth Quarter 2014 and Fiscal 2014 Financial Results

208. On February 26, 2015, Aegerion issued a press release detailing its financial results and business highlights for the fourth quarter of 2014, which also was filed with the SEC as an Exhibit to a Form 8-K the same day:[215]

> Aegerion recorded $51.7 million in net product sales of JUXTAPID® (lomitapide) capsules in the fourth quarter of 2014 . . . . 86% of net product sales in the fourth quarter were from prescriptions written in the United States.
>
> For the full-year of 2014, Aegerion recorded $158.4 million in net product sales of JUXTAPID . . . . 91% of net product sales in 2014 were from prescriptions written in the United States.
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> * * *
>
> "We believe 2015 will begin to provide clarity on the impact that PCSK-9 inhibitors will have on the growth trajectory of JUXTAPID. We expect disruption of new patient starts as a result of the introduction of PCSK-9 inhibitors, and have factored this disruption and some attrition of our existing patients into our 2015 financial guidance. We believe, over the long term, the greater disease awareness likely to follow introduction of PCSK-9 inhibitors may result in the possible identification of more HoFH patients who may be candidates for JUXTAPID.
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> * * *

[215] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex. 99.1 (Feb. 26, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515065678/d880381dex991.htm.

> Aegerion expects full-year 2015 global net product sales of JUXTAPID to be between $195 million and $215 million.[216]

209. Following the issuance of the press release, Aegerion hosted an earnings conference call with analysts that same afternoon, during which Defendant Beer stated:

> We continue to believe there's an opportunity for growth in the JUXTAPID business. We have calibrated our operations with calculated investments and data-driven focus, and shown the ability to impact patient-elected non-starts. We believe we now have a more accurate understanding of the HoFH patient journey and that we have made the right investments to optimize our patient services and to support the HoFH experience on therapy.[217]

210. During the call, Defendant Fraser, stated:

> [B]eginning with JUXTAPID. Despite the challenges of 2014 we are encouraged by a 226% net sales growth in 2014 over 2013 for the full year. Supported by our sales force expansion and increased reach, we continue to experienced solid demand and script growth in 2014, with success in our primary targets for HoFH treaters of lipidology and cardiology, and now with the additional focus in endocrinology.[218]

211. Defendant Fitzpatrick stated:

> Net product sales of JUXTAPID were $51.7 million in the fourth quarter of 2014 compared to $24.5 million in the fourth quarter of 2013. 86% of net product sales in the fourth quarter came from prescriptions written for JUXTAPID in the US
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> * * *
>
> For the full year of 2014 net product sales of JUXTAPID were $158.4 million compared to $48.5 million for the full year full year of 2013. 91% of net product sales for the full year came from prescriptions written for JUXTAPID in the US.[219]

212. Defendant Beer added:

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[216] *Id*.

[217] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q4 2014 Aegerion Pharm. Inc., Earnings Conf. Call, Feb. 26, 2015, at 3 ("Q4 2014 Earnings Conf. Call").

[218] *Id.* at 5.

[219] *Id*. at 7.

> So we [sic] exiting 2014 and entering 2015, we have really focused on the philosophy of forecast and how we set guidance. And we've got a lot of year in front of us. So we feel good about the guidance. We look forward to succeeding on that guidance this year. And we are not trying to message any decline quarter over quarter. And really focusing everybody on that annual guidance of $205 million to $235 million.[220]

213. On the same date, February 26, 2015, Leerink's analyst report stated:

> AEGR believes it has learned from its experiences in 2014, made adjustments to its operations and guidance philosophy, and diversified with the acquisition of Myalept.[221]

214. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the February 26, 2015 press release and on the earnings call that same day, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's year-end revenue guidance was overstated; (2) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (3) Defendants failed to disclose that despite attempts at increasing Aegerion's customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (4) Defendants' statement that it had "a more accurate understanding of the HoFH patient journey and that we have made the right investments to optimize our patient services and to support the HoFH experience on therapy," were false and misleading because, as

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[220] *Id*. at 14.

[221] Leerink, *4Q Recap: Focused on Execution With Juxtapid and Diversification With Myalept*, Feb. 26, 2015.

would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (5) in light of their illegal marketing scheme, Defendants knew that PCSK9 was a very real threat to Aegerion's business; (6) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (7) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

March 2, 2015 – 2014 Form 10-K

215. On March 2, 2015, Aegerion filed its 2014 Form 10-K with the SEC.[222] The filing stated the following:

> During the year ended December 31, 2014, we generated approximately $158.4 million of revenues from net product sales of lomitapide, of which $143.4 million was derived from prescriptions for lomitapide written in the U.S. . . . .
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> * * *
>
> We are not permitted to promote lomitapide for HeFH or any other indication other than HoFH. As part of the prescriber authorization form under the JUXTAPID REMS Program in the U.S., the prescriber must affirm that the

[222] Aegerion Pharm., Inc., Annual Report for FY ended December 31, 2014 ("2014 Form 10-K") (Mar. 2, 2015), *available at* http://ir.aegerion.com/secfiling.cfm?filingID=1193125-15-73654&CIK=1338042.

> patient has a clinical or laboratory diagnosis consistent with HoFH. This language is not, however, intended to expand the approved indication of HoFH.
>
> * * *
>
> We generated revenues from net product sales of lomitapide of $158.4 million for the year ended December 31, 2014, as compared to $48.5 million for the year ended December 31, 2013. The significant increase in net product sales in the year ended December 31, 2014 is primarily attributable to an increase in the number of shipments to patients on therapy in the U.S., an increase in named patient sales to patients in Brazil, and a higher average sales price of lomitapide as compared to the year ended December 31, 2013.
>
> We expect revenues from net product sales to continue to increase in 2015 due to an increase in the number of new patients starting lomitapide and in the number of existing patients maintained on lomitapide.[223]

March 3, 2015 Healthcare Conference

216. On March 3, 2015, Aegerion participated at the Cowen Health Care Conference, during which Defendant Beer stated:

> You know, Phil, we have got, I think, a spectacular 2015 lined up. We are intensely focused on launching MYALEPT right now and succeeding on a third year of launch with JUXTAPID. JUXTAPID has gone from $48.5 million in its first year to a second year of a little over $150 million, with a run rate coming out of the year that I think is very healthy. We really finished the year strong on JUXTAPID. We're coming out of Q4 with a lot of momentum on JUXTAPID.[224]

217. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made in the 2014 Form 10-K and the March 3, 2015 Healthcare Conference, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) while Defendants stated that it had "a spectacular 2015 lined up" and that it was "coming out of Q4 with a lot of momentum on JUXTAPID," those announcements were false and misleading because Aegerion

[223] *Id*. at 4, 10, 101.

[224] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at Cowen Health Care Conf., Mar. 3, 2015, at 9.

had "ceased dissemination of promotional materials such as those containing statements referenced in the Warning Letter such that it was no longer illegally marketing to non-HoFH patients which would, in turn, affect the Company's sales of JUXTAPID; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (4) Defendants failed to disclose that despite attempts at increasing its customer-facing organization, including Aegerion's sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (5) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (6) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (7) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

J. First Quarter 2015 Financial Results

218. On May 4, 2015, Aegerion issued a press release detailing its financial results and business highlights for the first-quarter of 2015, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[225] The press release reiterated its financial guidance for 2015, expecting full-year 2015 global net product sales of JUXTAPID to be between $195 million and $215 million, of which it expected "product sales of MYALEPT to be between $195 million and $215 million." The press release also stated, in part::

> Aegerion recorded $57.3 million in net product sales of JUXTAPID® (lomitapide) capsules in the first quarter of 2015 . . . . 84% of JUXTAPID net product sales in the first quarter of 2015 were from prescriptions written in the United States.

219. That same day, Aegerion hosted a first-quarter earnings conference call with analysts, during which Defendant Beer stated:

> We've made good progress early in 2015, and we continue to have confidence in the potential for Aegerion's growth.
>
> * * *
>
> Looking first at the Juxtapid business, we believe there are opportunities for growth, based upon the evolving knowledge we have about the adult HoFH patient journey, and the potential for geographic expansion. As you know, in 2014 we took action to form matrix teams, which in addition to our rare disease managers, who are our sales reps, include patient education managers, who typically have a nursing background, as well as registered dietitians and customer care reimbursement specialists, to help support a better patient experience for Juxtapid from the outset of therapy.
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> * * *
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> We believe Juxtapid addresses a significant need in the medical community for therapies to treat adult HoFH patients, and we remain confident in our estimates of the total addressable adult HoFH market in this rare disease. We continue to

[225] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (May 4, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515169044/d920159dex991.htm ("May 4, 2015 Form 8-K").

> add new Juxtapid prescribers, dispersed among lipidologists, cardiologists, and endocrinologists. We also believe that there are likely adult HoFH patients in some places that we do not have the reach to call on.[226]

220. Defendant Fraser added commentary regarding the Company's other key metrics:

> With respect to conversion and drop-out rates, I'd like to provide an update on those trends. Turning to an overview of metrics for Juxtapid on Slide 5. Our conversion rate from prescription to patient on therapy in the first quarter was steady, in the 50% to 60%, range, reflecting consistent payer approval rates, and patient choice to initiate therapy from our experience at the end of 2014. While we always strive for improving this rate, this range remains consistent with our forecast.
>
> Managing the drop-out rate, including both short-term drop and longer-term attrition, remains a primary area of focus. As of April 24, we had a cumulative drop-out rate of 46%, compared with 41% at the end of 2014, and we see that the long-term attrition is the primary contributor to this trend.[227]

221. On the same day, Leerink's analyst report stated:

> Overall, the first six months of Matrix teams have been encouraging in improving onboarding of pts and reducing patient non-starts. AEGR is currently employing 20 teams in US, and while some are more effective than others, mgmt. believes the teams are now experienced and knowledgeable enough to also focus on retaining existing patients and decreasing dropouts . . . .[228]

May 6, 2015 Healthcare Conference

222. Two days later, on May 6, 2015, Aegerion participated in the Deutsche Bank Health Care Conference, during which Defendant Beer stated:

> There was some concern on the call for -- asking questions around the sequential growth of our largest market, obviously the US, on Juxtapid. We saw in the first quarter very solid production of prescriptions, which is our leading indicator.

* * *

[226] Q1 2015 Earnings Conf. Call, at 3.

[227] *Id*. at 5.

[228] Leerink, *1Q15 Recap: Topline Beat Driven By Juxtapid Order in Brazil & Myalept Relaunch*, May 4, 2015.

> We think we've been very prudent and cautious in our guidance. We were challenged in our call Monday night that you just reported a $60 million quarter and you're not moving guidance from $205 million to $235 million. We think that's prudent and cautious given the year we just came out of. And we studied it very carefully.[229]

May 13, 2015 Healthcare Conference

223. On May 13, 2015, Aegerion participated in the Bank of America Merrill Lynch Health Care Conference. During the conference, Defendant Beer stated:

> We're proud of the fact that our ninth quarter into this, we've approached the $60 million quarter at the 112% growth over Q1 of 2014. It's important for me to demonstrate leverage in the business and when I go to operating expenses, we're demonstrating that leverage.
>
> * * *
>
> Again as a reminder, we ended the quarter with $67.4 million in cash at the end of the quarter and our financial guidance for full year going forward is for JUXTAPID to be between $195 million and $215 million in annualized sales . . . .[230]

224. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made on May 4, 6, and 13, 2015, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's quarterly financial results were, in part, attributable to sales to non-HoFH patients that, over the course of the year, as Defendants would later admit, would discontinue treatment; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the

[229] Deutsche Bank Healthcare Conf., May 6, 2015, at 2, 4.

[230] Thomson Reuters Streetevents, Edited Transcript, AEGR-Aegerion Pharm. Inc., at Bank of America Merrill Lynch Health Care Conf., May 13, 2015, at 4.

FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (4) Defendants failed to disclose that despite attempts at increasing Aegerion's customer-facing organization, including its sales force, the addition of nurse educators, dieticians, and CCMs, for example, the number of new patients that were signing up for the drug were inadequate to meet projected sales revenues; (5) Defendants' statement that it "believe[d] there are opportunities for growth, based upon the evolving knowledge we have about the adult HoFH patient journey" was false and misleading because, as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (6) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (7) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

K. Second Quarter 2015 Financial Results

225. On August 5, 2015, Aegerion issued a press release detailing its financial results and business highlights for the second-quarter of 2015, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[231] The press release stated, in part:

> Aegerion recorded $57.1 million in net product sales of JUXTAPID® (lomitapide) capsules in the second quarter of 2015 . . . . 96% of JUXTAPID net product sales in the second quarter of 2015 were from prescriptions written in the United States.
>
> [The Company] commented, "Aegerion continued to show good progress during the second quarter in key areas of the business, including growth in number of patients on therapy for both of our products. We believe we are on track to deliver strong results; however, as we navigate through the early days of the PCSK9 inhibitor launches, we are maintaining our prior guidance for the year."
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> * * *
>
> Net product sales for JUXTAPID for the second quarter ended June 30, 2015 were $57.1 million . . . . 96% of net product sales in the second quarter of 2015 were from prescriptions written in the U.S. . . . . The increase in JUXTAPID net products sales was attributable to an increase in the number of patients on therapy and the higher average sales price of JUXTAPID in the U.S. in the second quarter of 2015 compared to the same period in 2014.
>
> * * *
>
> Aegerion expects full-year 2015 global net product sales of JUXTAPID to be between $195 million and $215 million.

226. That same day, Aegerion hosted a second-quarter earnings conference call[232] with analysts, during which the Company stated:

> With respect to JUXTAPID, in the second quarter of 2015, we executed well, recording 15% growth in the US business over the first quarter. JUXTAPID was supported by its strong prescription growth, and by net patient adds. **We're**

[231] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Aug. 5, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515278720/d93154dex991.htm ("Aug. 5, 2015 Form 8-K").

[232] Thomson Reuters Streetevents, Edited Transcript, AEGR - Q2 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Aug. 5, 2015, at 4 ("2015 Conf. Call").

> encouraged that we're seeing the increase in the rate of short-term-drop slow. Let me say that again. We're encouraged that we are seeing the increase in the rate of short-term-drop slow, as a result of the work of our matrix support system. These focused efforts began last year.
>
> Importantly, we continue to give attention to stemming the attrition of adult HoFH patients who have been on longer term therapy. We have also focused our efforts on working with healthcare professionals to reengage with adult HoFH patients who have discontinued therapy, or who were prescribed JUXTAPID, but ultimately never initiated therapy. Many of these adult HoFH patients may continue to be appropriate candidates for therapy, and may also be able to benefit from expanded resources we have today, including additional dietary consulting.[233]

227. It was further stated that:

> Net products sales of JUXTAPID were $57.1 million in the second quarter of 2015, compared to $36 million in the second quarter of 2014. The increase in JUXTAPID net product sales was attributed to more patients on therapy, and also to the higher average sales price of JUXTAPID in the US in the second quarter of this year compared to the same last year.[234]

* * *

> We believe, based on the performance of the business in the first half of the year, that we're in a strong position to achieve our full year guidance. This includes total net product sales of between . . . . $195 million and $215 million for lomitapide . . . .[235]

228. In addition to the statements regarding its confidence in the trajectory of the business, the Company added:

> We're pleased by the performance of the US commercial organization thus far in 2015. In the second quarter, we continued to observe strong prescription numbers in the US, coming from lipidologists, cardiologists, and endocrinologists. Importantly, we believe we have improved our understanding of the JUXTAPID business and the adult HoFH patient dynamics, making what we believe are the

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[233] *Id*.

[234] *Id*. at 7.

[235] *Id*. at 8.

> right investments. Our goal is to optimize the adult HoFH patient experience with JUXTAPID.[236]
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> * * *
>
> We've done significant trend analysis on an ongoing basis, and our data now consistently show that patients on boarded according to our protocol with the matrix team are more likely to stay on therapy within the first 90 days. These data are very encouraging.[237]

229. During question and answer session of that followed, analysts requested "color on the challenges of reducing the cumulative dropout rate." The Company assured:

> We have a lot of plans in place, as we disclosed to you in our planned remarks, that we'll be reaching out with the right people, our [physician] education managers and our registered dieticians, to be able to offer services to those patients who are on JUXTAPID therapy.
>
> Those HoFH patients who we have the proper authorizations in order to reach and to discuss and support of the health care professionals who look after them to be able to offer more of these services to them. To help them potentially understand HoFH as a disease better, to understand how to be able to manage their diet properly to reduce the potential for gastrointestinal side effects. So the plan that we have in place, as we indicated earlier, is really continue to move that focus of the matrix team not just on the short-term elements of things to be able to try to improve short-term drop, but also to reach back into our patient base through the appropriate ways to try to help in the ways that I just mentioned.[238]

230. Defendants' statements had their intended effect. On August 5, 2015, Deutsche Bank's analyst report stated:

> We were encouraged by the top line performance in 2Q. 1) Juxtapid appeared to be growing by volume & price Q/Q at $57.1M in sales . . . .
>
> * * *
>
> The co is currently exploring new versions of Juxtapid that have less GI tolerability issues (potentially subQ, pro-drug, or patch). While this would likely

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[236] *Id*. at 4.

[237] *Id*. at 5.

[238] *Id*. at 11.

> not significantly augment the market, it might make pts more apt to start therapy.[239]

231. And, on the same date, Jefferies' analyst report stated:

> Given widely known concerns, risks seem limited if PCSK9i impact turns out less than feared.... AEGR is testing prodrug, SC injection and transcutaneous patch approaches for reformulating lomitapide, in order to avoid MTP binding in the gut (which causes GI SEs).[240]

232. Furthermore, Leerink's August 5, 2015 analyst report stated:

> Meanwhile, mgmt. was hopeful that PCSK9 inhibitors could assist pt. and physician education and perhaps identify new HoFH pts.[241]

233. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made on August 5, 2015 in the press release and earnings call, were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's quarterly financial results were, in part, attributable to sales to non-HoFH patients that, over the course of the year, as Defendants would later admit, would discontinue treatment; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer

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[239] Deutsche Bank Markets Research, *New team, new dream? Is this AEGR 2.0*, Aug. 5, 2015.

[240] Jefferies, *Narrower 2Q Net Income; Focus is on Level of PCSK9i Impact on Juxtapid Use*, Aug. 5, 2015.

[241] Leerink, *2Q Recap: Strong Juxtapid and Myalept Sales Drive Another Beat*, Aug. 5, 2015.

promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (4) Defendants' statement that, through its COMPASS program, it spoke to "HoFH patients who we have the proper authorizations in order to reach and to discuss and support of the health care professionals," was false and misleading because the Company, in fact, utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; and (6) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

L. Third Quarter 2015 Financial Results

234. On November 9, 2015, Aegerion issued a press release detailing its financial results and business highlights for the third-quarter of 2015, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[242]

[242] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Nov. 9, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837015002520/aegr-20151109ex9915af111.htm ("Nov. 9, 2015 Form 8-K").

235. In that press release, the Company reported "$58.8 million in net product sales of JUXTAPID (lomitapide) capsules in the third quarter of 2015, $49.6 million of which was from prescriptions written in the United States."[243]

236. In addition to publishing its quarterly results, the Company also narrowed its guidance of net product sales of JUXTAPID for fiscal 2015 "to be between $205 million and $215 million, revised from the prior range of between $195 million and $215 million."[244]

237. The press release also announced that the Company was now in default of certain of its loans:

> As a result of a breach of certain covenants under the loan agreement with Silicon Valley Bank (SVB), the Company is currently in default on its outstanding $25 million term loan. SVB has granted a temporary forbearance on the defaulted loan, and the Company has reclassified $25.5 million of cash as restricted cash, and reclassified $25 million from long-term debt to current.[245]

238. The Company hosted an earnings conference call for investors that same day.[246] During opening remarks, the Company announced its anticipated settlement with the U.S. government and the resulting breach of certain covenants which caused them to default on outstanding loans:

> Despite the solid progress . . . , we did have a disappointing development, which resulted from the Company's ongoing government investigations. I emphasize that we are continuing to cooperate fully with government authorities. We recently determined that it is probably that the Company will incur a settlement with the U.S. government or face an enforcement action as a result of the ongoing investigations.

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[243] *Id*.

[244] *Id*.

[245] *Id*.

[246] Thomson Reuters Streetevents, Edited Transcript, AEGR – Q3 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Nov. 9, 2015.

> We are not yet able to predict the timing or nature of the outcomes of these investigations. However, as a consequence of this potential enforcement, we are now in breach of certain covenants within our loan agreement with Silicon Valley Bank. This makes us in default of the outstanding $25 million loan. The bank has granted a 30-day forbearance on the loan and we'll use this time to our best advantage in continuing discussions.[247]

239. The conversion and dropout rates, as well as the effects of the PCSK9 inhibitors on sales of JUXTAPID, were also discussed. First, with regard to the conversion rate, the Company explained:

> The conversion rate from prescription to patient on therapy was 41% in the third quarter, down from 48% in the second quarter, with a cumulative launch-to-date conversion rate of 52%.
>
> This rate was impacted by widespread PCSK9 sampling programs. These sampling programs led to instances where patients who were in the queue waiting for JUXTAPID reimbursement approval were moved to a PCSK9 treatment by their healthcare provider. We continue to believe that over the long term, the availability of PCSK9 coupled with market awareness initiatives by the PCSK9 companies will serve to increase the identification of adult HoFH patients and that this will also result in potential opportunity for JUXTAPID over time.[248]

240. With regard to the dropout rate, the Company announced that it had increased to a whopping 58%:

> Regarding our existing base of JUXTAPID patients, cumulative dropout from the outset of launch through October 30th was 58%, an increase of approximately 9 percentage points from our last report. Of that 9%, we believe at least half can be attributed to patients switching to a PCSK9, with the remainder being patients who discontinued as a result of GI tolerability, diet, or other issues. These details regarding the rationale behind patient discontinuations rely on information that is self-reported by patients and/or their physicians so they are directional in nature only.
>
> We believe that the switching of current JUXTAPID patients to PCSK9 is the result of three primary reasons; GI tolerability issues, and/or low-fat diet fatigue,

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[247] *Id*. at 3.

[248] *Id*. at 4.

> and patients for whom the physician had concern about potential for liver toxicity. Observed switches are mainly physician-directed rather than patient choice.[249]

241. Following Aegerion's earnings call, on November 10, 2015, Jefferies' analyst report stated:

> It's surprising to see greater early impact from PCSK9 on Juxtapid;
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> * * *
>
> On FY15 guidance, est ~20% q/q decline in Juxtapid U.S. sales in 4Q would be far steeper than we had assumed; thus, lowering est's for >2016 by ~22-29%. If future sales are ~10%/20% higher/lower vs. our est's, we see a fair value of ~$19/$9. AEGR working towards DOJ/SEC settlement could be a positive step . . . . Patients switching to PCSK9i largely physician-driven per AEGR, due to reasons such as GI issues, low-fat diet fatigue, and/or concerns on liver toxicity. AEGR also saw slower new pt starts on Juxtapid in 3Q vs. prior quarters, noting some pts waiting for Juxtapid reimbursement approval from insurers were switched to PCSK9i by their physicians . . . .[250]

242. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, Defendants' statements made on the November 9, 2015 earnings call were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's quarterly financial results were, in part, attributable to sales to non-HoFH patients that, over the course of the year, as Defendants would later admit, would discontinue treatment; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ

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[249] *Id*.

[250] Jefferies, *Juxtapid 3Q Sales Beat, but Reduce PT on Steeper Decline from Competition*, Nov. 10, 2015.

investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (4) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; (5) when Defendants spoke of the potential effect that PCSK9 would have on JUXTAPID sales, they knew that, in reality, the less-expensive, more tolerable PCSK9 inhibitors on the horizon were a threat to JUXTAPID sales because they were more suitable for the non-HoFH patients to whom Defendants were illegally marketing; (6) Defendants failed to disclose that its illegal marketing practices would result in breaches of certain of its debt covenants, such that it would default on its outstanding loans; and (7) as the market would later learn, once Aegerion altered its marketing practices it could no longer target the broader population of non-HoFH patients that was offsetting the negative financial impact attributable to the patient erosion caused by the PCSK9 inhibitors and/or the increasing number of patients discontinuing treatment.

M. Fourth Quarter 2015 Financial Results

243. On February 25, 2016, the Company announced its financial results for the three months and year ended December 31, 2015. In the Form 8-K filed with the SEC that same day,[251] the Company reported:

[251] Aegerion Pharm., Inc., Current Report (Form 8-K) Ex. 99.1 (Feb. 25, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837016003540/aegr-20160225ex991325c2d.htm.

- Aegerion recorded $39.7 million in net product sales of JUXTAPID™ (lomitapide) capsules in the fourth quarter of 2015, $36.0 million, or 91%, of which was from prescriptions written in the United States (U.S.).

- Aegerion recorded $213.0 million in net product sales of JUXTAPID for the full year of 2015, $188.4 million, or 89%, of which was from prescriptions written in the U.S.

- As of December 31, 2015, there were 615 active commercial patients on JUXTAPID therapy globally, approximately 490 of whom are U.S. patients. The number of U.S. patients on JUXTAPID has continued to significantly decline since December 31, 2015, but at a lower rate than in the fourth quarter of 2015.

244. The press release also announced that the Company "recorded a charge of $12 million, representing the current estimate of the minimum amount required to resolve the ongoing Department of Justice and Securities and Exchange Commission investigations."[252]

245. Aegerion hosted a conference call with investors later that day.[253] The Company provided opening remarks and stressed its delight to speak on Aegerion's "financial performance, and the transformation underway at the Company."[254] The Company described "four distinct efforts" that it developed to "swiftly tackle" the challenges it faced, the first step being to "repair the immediate issues facing the Company,"[255] including a focus on "legal and regulatory compliance."[256] The Company stated:

> Compliance metrics are now part of our processes, and educational efforts are underway to ensure employees live and breathe these core values. A new Board-level compliance committee has been established and is chaired by Donald Stern, former US attorney for the district of Massachusetts. Roger Lewis, who has 20

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[252] *Id*.

[253] *Id*.

[254] *Id*. at 3.

[255] *Id*.

[256] *Id*.

> years of experience overseeing compliance in the life science and pharmaceutical space, was appointed Chief Compliance Officer in November of 2015.[257]

246. With regard to the DOJ and SEC investigations, the Company explained:

> We are in discussions with the DOJ and SEC in order to resolve potential claims arising from their investigations. As noted in our fourth-quarter press release, we recorded a charge of $12 million, representing our current estimate of the minimum amount required to resolve these investigations. Discussions relating to the investigations are ongoing and we are encouraged by the productive dialogue. At this point, however, there can be no assurance that we will reach a negotiated settlement of these matters, when such a settlement would occur, or what the final terms of any such settlement would be, including the dollar value of any such settlement.
>
> These legal and regulatory issues, and the costs associated with them, as well as the future uncertainty regarding the resolution of these matters have hurt the value of our Company. We are determined to enhance our commitment to compliance and reduce our legal expenses so that the strength and the quality of the underlying business and the commitment of our people can once again shine through.[258]

247. During the question and answer session that followed the prepared remarks, analysts inquired about the DOJ investigation and expected settlement, specifically questioning whether the $12 million charge "reflect[s] your expectations for a civil penalty? Or does it also include potential criminal penalty because that is something that has been levered in the past?" The Company responded:

> I think the way I would characterize it is that it's really a current estimate of the minimum required amount to resolve the litigation matters, both criminal and civil, in amongst kind of a global settlement if you will between DOJ and SEC.
>
> Again I just want to caution that, really, the final amount, the timing is really uncertain and this is not something that has been agreed to by the government. And this certainly isn't an estimate. In fact, I would not want to give any assurances that we can reach a settlement. But certainly we are making progress and the conversations we're having are very productive, but it's really the accounting guidance based on the fact that we've made an offer to the

[257] *Id*.

[258] *Id*.

> government that leads us to this $12 million charge that we have recorded in the fourth quarter.[259]

248. On February 26, 2016, Cowan and Company's analyst report stated:

> Management suggested that it is still relatively early in the launch of the PCSK9's, and therefore Juxtapid's long-term opportunity remains uncertain . . .[260]

249. Also on February 26, 2016, Leerink's analyst report stated:

> New mgmt. is continuing to engage w/ a third party firm to assist in analyzing AEGR's in-house Juxtapid use data to understand tx. discontinuation patterns w/ the goal of returning to growth in the near future.[261]

250. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, the statements on the February 25, 2016 earnings call were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's sales projections were overstated; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) as would later be revealed, while Defendants projected JUXTAPID sales to

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[259] *Id*. at 12.

[260] Cowen and Company, *Q4 In-Line, Guidance Includes Big Cuts To Revenue And Expenses*, Feb. 26, 2016.

[261] Leerink, *4Q Recap: 2016 a Turnaround Year; Guidance Lower, PT to $15*, Feb. 26, 2016.

be "between $120 million and $140 million," they failed to disclose that Aegerion was "ceas[ing] dissemination of promotional materials such as those containing statements referenced in the Warning Letter" which was material information to the market in order to evaluate the Company's ability to meet its guidance; (4) the Company was experiencing adverse trends with regard to the key metrics discussed herein; and (5) In light of their illegal marketing scheme, Defendants knew that PCSK9 was a very real threat to Aegerion's business.

March 9, 2016 – Aegerion at Cowen Health Care Conference

251. On March 9, 2016, Aegerion participated in the Cowen Health Care Conference, during which Mary Szela, Aegerion's CEO, stated:

> Now, looking at the JUXTAPID business, we ended 2015 with 615 patients on therapy globally. 490 were US patients. While we believe we saw the most significant impact of the entrance of the PCSK9 inhibitors in the fourth quarter, as noted on our earnings call, we continue to see the volume of active JUXTAPID patients declining significantly, albeit at a lower rate as compared to the fourth quarter.[262]

252. For the reasons stated above in the Substantive Allegations section, and as further detailed herein, the statements on the March 9, 2016 conference were materially false and misleading when made or omitted material facts to make such statements not false and misleading, because: (1) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the FDA-approved label and the demands of the FDA Warning Letter, Defendants knew and/or recklessly disregarded that Aegerion's quarterly financial results were, in part, attributable to sales to non-HoFH patients that, over the course of the year, as Defendants would later admit, would discontinue treatment; (2) Defendants failed to disclose that as a result of having to tailor the Company's marketing efforts to comply with the

[262] Thomson Reuters Streetevents, Edited Transcript, AEGR – Aegerion Pharm. Inc., at Cowen Health Care Conference, Mar. 9, 2016 ("Cowen Health Care Conf., Mar. 9, 2016"), at 3.

FDA-approved label and the demands of the FDA Warning Letter and pending DOJ investigation, Defendants knew and/or recklessly disregarded that Aegerion's FY 2014 revenue and patient projections were overstated because the Company was no longer promoting the drug as a means for preventing "a cardiac event" and "lengthen life"; (3) as would later be revealed, while Defendants projected JUXTAPID sales to be of "$120 million to $140 million" that announcement was false and misleading because the Company had "ceased dissemination of promotional materials such as those containing statements referenced in the Warning Letter" such that it was no longer illegally marketing to non-HoFH patients which would, in turn, affect the Company's ability to meet its guidance; (4) the Company was experiencing adverse trends with regard to the key metrics discussed herein; (5) as would later be revealed, Defendants utilized its COMPASS program illegally in order to, without proper authorization, contact and encourage non-HoFH patients to begin and/or remain on JUXTAPID therapy, and would later result in the Company pleading guilty to violation of the Health Insurance Portability and Accountability Act; and (6) in light of their illegal marketing scheme, Defendants knew that PCSK9 was a very real threat to Aegerion's business.

VI. THE TRUTH SLOWLY EMERGES

253. On November 8, 2013, news reports revealed that the Company received an FDA Warning Letter addressed to Defendant Beer, in connection with statements the Company's CEO made regarding the market for its JUXTAPID capsules, during broadcast interviews on CNBC's television show, "Fast Money," that aired on June 5, 2013 and October 31, 2013. The Warning Letter stated that Defendant Beer made public statements which "provide evidence that Juxtapid is intended for new uses, for which it lacks approval and for which its labeling does not provide

adequate directions for use, which renders Juxtapid misbranded within the meaning of the [FDCA] and makes its distribution violative of the FDCA."[263]

254. Specifically, Defendant Beer had previously stated:

June 5, 2013

- "In these [HoFH] patients, they have a devastating disease. They have a lethal level of cholesterol, bad cholesterol, which we call LDL, going through their blood stream. And they're born with this disease and often not diagnosed until 8, 10 years of age when they have a heart attack. If you can imagine a child having a heart attack at 8, 10, 12 years of age. And then they have another event, usually about every 18 months, and die by the age of 30. And we've found out that we can lower it significantly with this drug . . . ."

- "It's a devastating disease that causes early death. And the drug is corrective against that disease and that's the most important thing. If you think about some oncology products that may lengthen life three months or six months, this product has the potential of taking a patient that would die at 30 and allow then to meet their grandkids."

October 31, 2013

- "These patients are going to die of a cardiac event, either a stroke or a heart attack, if we don't have them on therapy."

255. The Warning Letter criticized Defendant Beer's statements regarding the safety and effectiveness of JUXTAPID, stating in relevant part:

> These statements misleadingly suggest that Juxtapid is safe and effective for use in decreasing the occurrence of cardiovascular events including heart attacks and strokes, and increasing the lifespan of patients with HoFH, and thus will have an effect on cardiovascular morbidity and mortality as well as overall mortality. However, Juxtapid is approved only for use as an adjunct to a low- fat diet and other lipid lowering treatments, to reduce specific lipids . . . in patients with HoFH; its PI specifically includes a limitation of use stating that the effect of the drug on cardiovascular morbidity and mortality has not been determined. Furthermore, the statements made regarding Juxtapid misleadingly suggest that Juxtapid is safe and effective as a monotherapy. Juxtapid's labeling limits its use

[263] FDA Warning Letter, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM374338.pdf.

> to use as an adjunct to other therapies, and use as a monotherapy is an unapproved use. The approved labeling for Juxtapid does not provide instructions for, or otherwise indicate that Juxtapid will be safe and effective if used, either to reduce the occurrence of cardiovascular events in HoFH patients and to increase their lifespans, or as a stand-alone therapy for reducing lipids in these patients. Information sufficient to demonstrate that Juxtapid is safe and effective for any of these new intended uses has not been submitted to FDA in an application. In sum, the statements cited above provide evidence that Juxtapid is intended for new uses for which it lacks approval, and for which its labeling does not provide adequate directions for use.
>
> Additionally, while the statements cited above include substantial and repeated efficacy claims for Juxtapid, the presentation fails to communicate any of the risks associated with these new intended uses or its approved use. As previously noted, Juxtapid's PI in fact includes a Boxed Warning regarding potential liver toxicity, and the product is subject to an associated REMS. The repeated statements regarding Juxtapid, including the claims that patients taking the drug will "meet their grandchildren," misleadingly suggest that Juxtapid lacks significant risks.
>
> Conclusion and Requested Action
>
> For the reasons discussed above, your statements provide evidence that Juxtapid is intended for new uses, for which it lacks approval and for which its labeling does not provide adequate directions for use, which renders Juxtapid misbranded within the meaning of the FD&C Act and makes its distribution violative of the FD&C Act. *See* 21 U.S.C. 352(f)(1), 331(a); 21 CFR 201.5, 201.100, 201.115, 201.128. OPDP requests that Aegerion immediately cease misbranding Juxtapid and introducing it into interstate commerce for unapproved uses for which it lacks adequate directions. Please submit a written response to this letter on or before November 22, 2013, stating whether you intend to comply with this request, listing any promotional materials (with the 2253 submission date) for Juxtapid that contain statements such as those described above, and explaining your plan for discontinuing use of such materials or, in the alternative, your plan to cease distribution of Juxtapid. Because the violations described above are serious, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to correct any misimpressions about the approved use of Juxtapid.[264]

256. Deutsche Bank Markets Research reported that it spoke to management regarding the FDA Warning Letter on November 8, 2013. Among the key points it noted, was the

[264] *Id*.

Company's acknowledgment that it would "change the wording" of the way it has been marketing JUXTAPID "going forward."[265] Specifically, this analyst report states:

> We spoke to AEGR management regarding the FDA warning letter and below are the key points:
>
> - The warning letter was related to comments made during TV interview.
> - In particular the FDA did not like the comment which suggested that Juxtapid extends lives of HoFH patients.
> - The company will change the wording going forward.
> - The warning letter does not affect Juxtapid.
>
> We do not see any impact on our estimates since this warning letter is unrelated to the drug.

257. In response to the FDA's Warning Letter, Aegerion issued the following statement:

> We take regulatory compliance very seriously and acknowledge that our messaging in any setting, including a media interview as in this particular instance, needs to be accurate and fair balanced. Our plan is to take quick action in response to the FDA's letter and immediately and effectively address any unsuitable language. We appreciate that the FDA's objective is to ensure that promotion is consistent with approved labeling, and in that respect we are aligned with the agency.[266]

258. On November 11, 2013, *MarketWatch* reported that Aegerion "issu[ed] a statement vowing to comply with the FDA and reassuring analysts that it would change the wording on Juxtapid's abilities in the future."[267]

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[265] Deutsche Bank Markets Research, *Management Color on FDA Warning Letter*, Nov. 8, 2013.

[266] *See* Feurstein, *supra* n. 34.

[267] Russ Britt, *Investors forgive Aegerion for brush with regulators, shares jump 16%*, MARKETWATCH (Nov. 11, 2013, 4:38 PM EST), http://blogs.marketwatch.com/health-exchange/2013/11/11/investors-forgive-aegerion-for-brush-with-regulators-shares-jump-16/.

259. The Company's stock price remained artificially inflated despite this negative news as a result of the Investor Event Aegerion held in New York City just the day before the issuance of the Warning Letter, on November 7, 2013. Following that conference, analysts reported that "management sounded a very confident tone on Juxtapid's sales potential, commercial and financial leverage, and competitive outlook and also used the forum to provide some constructive physician feedback."[268] Defendant Beer opened his remarks by sounding a very optimistic tone, stating that the Company was "on track to have the most successful launch in the orphan industry" and further noting that "the best is truly yet to come."[269]

260. Analysts reported that the Company touted the growing patient population and its continued efforts to call on cardiologists where they were finding more patients than it had originally anticipated:

> HoFH appears far more common than the 1 in a million once thought. A physician presenter [Dr. Seth Baum of Preventive Cardiology] highlighted recent scientific literature supporting >2,000 genetically HoFH patients in the U.S., with a diagnosis rate of <1%. The higher prevalence is seemingly due in part to HoFH patients now sometimes surviving into old age with aggressive interventions. Commercial experience corroborates the literature: AEGR is finding far more HoFH patients in cardiologist practices than initially expected. In fact, AEGR says that most cardiologist group practices are found to have one or more candidate patients when visited. Despite a salesforce expansion, with more than 25,000 cardiologists in the U.S. (vs. 1,300 targeted in the initial launch in Q1:13), AEGR is still barely scratching the surface of this opportunity.[270]

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[268] JPMorgan, *Aegerion Pharmaceuticals: Takeaways from AEGR Investor Event*, Nov. 7, 2013.

[269] *Id*.; *see also* Jefferies, Update from AEGR Analyst and Investor Day, Nov. 8, 2013 ("AEGR noted that the "best is yet to come" with explosive cash flow and revenue generation, particularly in 2014-2016.").

[270] Cowen and Company, *Highlights from Analyst Day*, Nov. 8, 2013; *see also* Canaccord Genuity, *All Systems Are Go*, Nov. 8, 2013 ("AEGR hosted an analyst day where management reiterated its conviction on the ~15K WW (3K U.S., 3K E.U.) HoFH patient opportunity, given an underdiagnosis, of which they expect to capture 4-5K with Juxtapid, which we believe may prove conservative.").

261. One analyst from Canaccord Genuity reported "We expect the increasing focus on cardiologists (AEGR has not called on the vast majority of them) coupled with script growth from both new and established writers in U.S. and ex-U.S. markets will set up Juxtapid's launch trajectory well for FY14+." That same analyst described that Aegerion presented a "physician expert" who "endorse[d]." Specifically, "Dr. Seth Baum of Preventive Cardiology spoke on his experience as a cardiologist treating HoFH, stating that the prevalence is higher than 1/1M (old literature) and these patients have a wide range of presentations (*e.g.*, older patients)."[271]

262. Cowen and Company added:

> A physician presenter highlighted recent scientific literature supporting >2,000 genetically HoFH patients in the U.S., with a diagnosis rate of <1%. The higher prevalence is seemingly due in part to HoFH patients now sometimes surviving into old age with aggressive interventions. Commercial experience corroborates the literature: AEGR is finding far more HoFH patients in cardiologist practices than initially expected. In fact, AEGR says that most cardiologist group practices are found to have one or more candidate patients when visited. Despite a salesforce expansion, with more than 25,000 cardiologists in the U.S. (vs. 1,300 targeted in the initial launch in Q1:13), AEGR is still barely scratching the surface of this opportunity.[272]

263. Then, on January 9, 2014, the Company announced it had received a subpoena from the DOJ requesting documents regarding its marketing and sale of JUXTAPID.[273]

264. Defendant Beer assured the market that "Management is passionate about ensuring we are operating in the best-in-class way when it comes to compliance. We've been diligent in our efforts to ensure that all promotional material, our training of our sales reps, messaging to physicians, and our activities are consistent with on-label promotion and all

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[271] Canaccord Genuity, *All Systems Are Go*, Nov. 8, 2013.

[272] Cowen and Company, *Highlights from Analyst Day*, Nov. 8, 2013.

[273] Jan. 9, 2014 Form 8-K.

applicable laws that are related to that compliance. We have a strong focus and discipline about compliance internally."[274]

265. On this news, Aegerion shares declined $7.98 per share, or nearly 11%, to close at $65.77 per share on January 10, 2014.

266. On February 26, 2014, in addition to reiterating its FY 2014 guidance, Defendant Beer also informed the market during the earnings conference call held later that day, that "[a]t the outset of the launch, we assumed an average dropout rate of 15%, and we were successful in maintaining a dropout rate at the end of 2013 that was consistent with this estimate that we began the year with."[275] Understanding the potential for market concern, Defendant Beer assured investors, "We recognize that we will always have to maintain a strong focus on dropout, and we plan to do additional work in that area."[276]

267. Though couched in a positive tone, analysts focused upon this revelation, noting that the disclosed rate was "a little higher then [sic] you indicated in the past."[277] Specifically, an analyst from Cowen and Company asked:

> [I]n your prepared remarks, you indicated that you're seeing a discontinuation rate consistent with your initial expectation of about 15%. Which is a little higher then you indicated in the past. Is that an accurate perception? Are you seeing an uptick? And I guess once patients are on the drug, can you comment at all on what the discontinuation rate is after the first couple months?[278]

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[274] JPMorgan Healthcare Conf., Jan. 13, 2014, at 4.

[275] Q4 2013 Earnings Conf. Call, at 4.

[276] *Id*.

[277] *Id*. at 13.

[278] *Id.*

268. In response, Defendant Beer assured the market that, although the number was bigger than it had previously reported, the Company was confident it would maintain this newly revealed rate of 15% throughout 2014:

> [T]he number the [sic] I gave midyear, I think . . . . was 10% or less at that time on smaller numbers. I think what you can trust now is a bigger end. So I'm clearly communicating to you that we're at 15%, and that would maintain throughout the year.
>
> * * *
>
> [T]he dropout rate from midyear to now, I would just say, it's a smaller number at midyear. So less than 10% midyear. It's 15% over the course of the year. I trust that 15% more than the 10%, because it's just off a bigger number. And I just want everybody to be comfortable how we are calculating that."[279]

269. But the higher than expected dropout/discontinuation rate was not the only revelation Defendants made during the February 26, 2014 earnings conference call. Defendant Beer further revealed that the Company was, for the first time, appreciating the impact of patient-elected non-starts. Specifically, Defendant Beer revealed: "[A] dynamic that we began to understand in a more meaningful way, in the second half of the year, was that we had patient-elected non-starts in circumstances."[280]

270. Defendant Fraser expanded on this revelation, explaining to the market:

> [O]ne notable behavioral dynamic that emerged as a factor in our business is that of patient-elected non-starts. While we have been clear in the past that not every prescription leads to a patient going on to therapy, this dynamic is more meaningful than we had previously anticipated. And it became apparent to us that patient education and comprehensive healthcare provider engagement are critical to successful patient on boarding. Some form of this dynamic is present in nearly every disease area.
>
> For HoFH patients, a reluctance to start JUXTAPID can often stem from a lack of understanding about the nature and severity of their disease. We believe we have

[279] *Id*. at 13-14.

[280] *Id*. at 4.

> a solid understanding of best practices for increasing patient commitment and affecting higher prescription conversion rates.
>
> * * *
>
> We believe, based on the work that we've done, that the rate of patient-elected non-starts should decline with the full implementation of these initiatives. We also believe that many of these non-starts may consider JUXTAPID in the future, and we plan to maintain ongoing interaction with physicians and patients to support a potential on boarding of previously scripted patients in the future.
>
> Increasing patient education and commitment is necessary, and we expect it to have a positive effect on adherence as well, mirroring what we saw in our phase III study, we see dropouts happen most frequently during the first one to two months of treatment.[281]

271. An analyst from Cowen and Company asked Defendants to expand on the "surprise" in patient-elected non-starts. Specifically, he asked about:

> the mention that you made of the surprise and patient elected non-starts. Just curious if you can comment on the fraction of the market you think that you have touched at this point in the terms of getting a physician to prescribe for them, and then either starting the drug or not?[282]

272. Defendant Beer responded:

> So we are studying this more and more. We look at the patients that have had a prescription, and we've achieved authorization for insurance. We look at that as a HoFH patient pool that we need to study more and educate the patient and the physician through the physician better.
>
> It's a great pool of future patients, if we effectively educate the patient through the physician. And that's where the focus has been. So I think there's a lot of potential in those numbers. I could tell you this, still, the majority of patients, we haven't scraped the surface of this market yet, because we did not have the reach to do it.
>
> We launched with 25 reps. We significantly increase the sales force in the back half of the year. We did that because we did not have the reach to get to all the cardiologists that we need to get to.

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[281] *Id*. at 5-6.

[282] *Id*. at 12.

> So I do believe that the majority of this market is out in front of us, and we are now sized appropriately to get to those patients. And I have a lot of confidence in Craig optimizing this non-start metric. That's clearly more frustrating to me than the patients we haven't educated yet. Because these are patients that -- a physician has made the decision.
>
> So it's frustrating to us, but we will optimize that metric.[283]

273. Defendant Fraser added to Defendant Beer's comments, again assuring the market that it was specifically looking at its patients with an eye toward gaining an insight and understanding of the patient experience:

> We have an understanding, as we look at this, that patients do have a varied understanding about the nature and the severity of their disease in in [sic] relationship to the potential benefits and risks associated with going onto therapy.
>
> * * *
>
> For us, we have specifically looked at our patients; we understand how the patients do have varied understandings of this. We've seen where it works really well, with regard to education. And as Marc mentioned, it is truly a partnership of making sure that the health care provider has all the education and support and tools that they need to be able to pause and successfully educate their patients about their disease, and the therapies, and so forth. And we've put together a whole engagement team to be part of that effort.
>
> * * *
>
> Now, Marc mentioned earlier as well, we don't plan to provide a specific metric, because you are asking about a metric question on this. But I want you to know that we made a lot of effort and a lot of investment to -- with the -- ideal optimizing in this area. I also mentioned in my part of the script, a side benefit, an important benefit is, when you do this the right way, right up front, you not only have positive effect on conversion rates in patients going onto drugs. But you've educated them in a manner that sets up better support of optimizing adherence, once they are on therapy, both compliance and drop. So we see that as a key area and a key focus for us that we've done heading into this year.[284]

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[283] *Id*.

[284] *Id*. 13.

274. Defendant Beer continued to assuage the market of any potential concerns surrounding the effect patient-elected non-starts would have on the business. Specifically, he espoused: "[W]e'll get our arms around this non-patient start. We're studying it carefully. We look at every one of those patients as a potential future patient, and we're working it hard."[285]

275. An analyst from JPMorgan asked when the Company had first discovered this patient-elected non-start dynamic. Specifically, he asked: "My first question is on this patient elected non-start issue. Is this something you saw throughout the year? Or is this dynamic relatively new and really just emerged around the holidays?"[286]

276. Defendant Beer responded:

> Obviously, you are, in the first half of the year, dealing again with smaller numbers. And you can't decipher whether a patient non-start is just the fear of the diet, and eventually you are going to eventually will get them on therapy.
>
> So, as the numbers got larger, as the scrip numbers got larger in the back half of the year, and we started to study those more carefully, we really deciphered out, this person doesn't today have the intent to go on therapy, and this person is. And they've got an appointment scheduled. So this definitely emerged, and we understood it much better in the back half of the year.
>
> And it was never something that we looked at as the dropout, because the patient wasn't shipped, and we did not count the revenue. So it's not a dropout component. It is just a patient that, we never realized the revenue. And it is pushing the shipment off and pushing the shipment off. So we got a better understanding when we went and spoke to these patients and got more clarity, but it was definitely a back half of the year kind of emerging metric.[287]

277. Analysts reacted positively to the Company's revelations, apparently persuaded by Defendants' attempts at assuaging any potential concerns, especially in light of the "increased clarity" as a result of Defendants' "transparency" into the Company's key metrics:

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[285] *Id*. at 14.

[286] *Id*.

[287] *Id*.

- "While shares traded off in reaction to the report due to concerns on patient-elected non-starts, dropout rate, and Q1 revenue expectations, we expect the recent hires (sales reps and COMPASS patient-support) and patient ambassadors to stabilize/improve dropouts and non-starts through education . . . . [W]e model for a stable 15% dropout in Q1+ and expect improvement in non-starts given new hires."[288]

- "There has been investor discomfort with management's (pre-planned) limitation of transparency on specific metrics in regarding the launch. Therefore we were pleased to see management give several concrete disclosures allowing increased clarity on Juxtapid's uptake and addressing a few investor concerns that had not been previously explained . . . higher than the ~ 10% quoted around mid-year. Both of these dynamics had been suspected by some investors over the past few months as Aegerion expanded its reach into less specialized physician practices, so we are pleased with management's forthrightness."[289]

- "The co recently observed 'patient elected non-starts' (patients who receive a prescription but opt not to begin therapy). The company is trying to counteract this w/ new education and support programs. While this is a negative for the co at present, we believe some of these pts could be future opp'y if they decide to start drug later on."[290]

- "Investors are concerned about increasing drop-out rates at 15% at end of 2013 vs. less than 10% seen at and of July. While this is higher than previously disclosed, this is in-line with the company expectations. The company is putting efforts to keep it stable. Looking at the clinical trial, we note that patients did not dropout once they were past first 26 week."[291]

- "We do not think that the street was expecting a guidance revision. While this guidance does not imply accelerated growth, it does point to steady growth in our view."[292]

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[288] Canaccord Genuity, *FOCUS ON DROPOUTS/NON-STARTS SHOULD DRIVE FY14 REVENUE*, Feb. 26, 2014.

[289] Cowen and Company, *A Return to Transparency in Q4 Report*, Feb. 26, 2014.

[290] Deutsche Bank Markets Research, *DB thoughts on AEGR weakness post 4Q call*, Feb. 26, 2014.

[291] *Id*.

[292] *Id*.

278. Defendants' February 26, 2014 revelations caused the Company's stock price to decline over a three-day period. The stock price fell from $66.35 per share on February 25, 2014 to $61.54 per share on February 26, 2014, then again on February 27, 2014 to $60.85 per share, and finally to $54.76 per share on February 28, 2014, for a three-day combined loss of $11.59 per share, or ***over 17.4%***.

279. Subsequently, on May 6, 2014, the Company announced its first quarter 2014 financial results and revised its guidance from between $190 million and $210 million to "between $180 million and $200 million of net product sales in 2014."[293]

280. During the Q1 2014 earnings conference call held that same day, the Company revealed that while it had experienced quarter-over-quarter growth, it was still experiencing greater-than-expected headwinds associated with patient-elected non-starts and dropouts. Specifically, Defendant Beer revealed:

> It was clear to us in 2013, JUXTAPID prescriptions both outpaced the capacity of our patient service infrastructure, as evidenced by patient non-starts and by increasing drop rates towards the end of the year. It became more apparent by year-end, that the meaningful changes -- that meaningful changes were necessary in order to fully meet the need for rapid prescription conversion and patient retention.
>
> We believe the patient elected non-starts and dropouts are directly correlated to the thoroughness and the timeliness of comprehensive patient education of HoFH patients and the importance of the diet in taking JUXTAPID along with it, along with strong physician involvement in the patient education process. Q1 represented an important period of optimization and investment as illustrated by the magnitude of our increase in operating expenses in Q1 versus Q1 of last year.
>
> * * *
>
> Second, we continue to have confidence in our estimate of the total addressable adult HoFH market. We believe HoFH, while still rare, is underdiagnosed. And the significant number of HoFH patients globally are in need of therapy. This belief is shared by an increasing number of experts in the medical community and

[293] Q1 2014 Earnings Conf. Call, at 8.

> in peer and youth publications. We believe the global HoFH represents a significant commercial opportunity.
>
> Finally, our efforts to optimize the scale of our business which will continue during the start of 2014, are just beginning to bear fruit. Although we do not expect to see topline impact until the second half of 2014, we feel confident that the increased commercial reach has the potential to result in meaningful growth. In our view, resource allocation and execution are the gating factors in JUXTAPID capturing maximum share of HoFH market on a global basis.[294]

281. Defendant Fraser also provided some positive reinforcement, expressing his confidence in the "early positive traction" the Company was experiencing as a result of its investment in its customer-facing organization:

> The first quarter represents a pivotal period for the US sales force expansion and for the continuing to strengthen our commercial strategy and execution. We remain confident in JUXTAPID's addressable global market opportunity as a treatment for HoFH. And are taking operational steps to maximize long-term fundamentals.
>
> In mid to late January, we trained and then deployed our expanded US sales team into new territories. As with any sales force realignment, there is a period of downtime for redeployment and training.
>
> Also, a particularly long harsh winter resulted in delays and outbound physician calls and has slowed down for patient onboarding. These factors contributed to the year beginning with a flatter scrip trend, and thus we had fewer new patient starts in the first quarter than expected. However, we see early positive traction behind the sales force expansion.
>
> We saw a meaningful uptick in scripts and new patient starts in the later [sic] half of the first quarter. And observed these recent trends continue into the early part of the second quarter. We continue to stress how important it is that patients gain a full understanding of HoFH and education about the optimal diet for success with JUXTAPID.
>
> In an effort to further enhance our patient focus commercialization strategy, we have established a new patient engagement team, which includes a new nurse educator group. These nurse educators have begun to assist with patient and nurse education about HoFH and JUXTAPID use with strong emphasis during the crucial onboarding phase. We believe the nurse educators will assist with HoFH

[294] *Id*. at 3-4.

> patients in their efforts to successfully manage their transition to JUXTAPID therapy.
>
> Also important, as a result of the nurse educators in the field, sales representatives previously responsible for onboarding patients can now focus primarily on identifying new physicians with HoFH patients needing JUXTAPID therapy. We are receiving early encouraging feedback that nurse educators are having a positive impact in the field. However, we are still scaling this team and it's too early to meaningfully quantify the potential impact on reducing patient elected non-starts.
>
> We expect nurse educators to have the potential for a positive impact on dropout rates with patients beginning therapy in an educated and committed way and nurses helping to support them. Managing patient elected non-starts and dropouts remain integral to the long-term success of our business.
>
> We believe the recent enhancements in our commercial team were the right investments given the insights we learned from both the field and patients. And we expect these investments to both impact those metrics in a positive way. As Marc previously indicated, we believe the management of appropriate resource allocation and execution remain critical factors to our growth within the HoFH market opportunity.[295]

282. In response to an analyst's question concerning the Company's confidence that it would meet this newly revised guidance, Defendant Beer explained: "We significantly invested in a couple of areas that we believe are paying off. We're seeing early signs of that. Both in field and salespeople."[296] He continued:

> The majority of our calls were on new physicians and we had a large percentage of our scripts come from previous non-writers that we weren't calling on. So all of that optimization was happening in the quarter. Now let me characterize the quarter. The first half of the quarter was lighter on scripts than we expected.
>
> And the back half, called the last six weeks of that quarter, we saw a really nice uptick in scripts. And we've seen that early. We have one month into the quarter in Q2. So we're seeing that trend continue. So the expansion caused lighter scripts over the whole quarter because of the first half versus the second half of

[295] *Id*. at 4-5.

[296] *Id*. at 9.

> the quarter. We're not going to comment on net patients by quarter. We'd like to get away from that and trust the guidance.[297]

283. Another analyst questioned the results the Company was experiencing with patient-elected non-starts and dropouts as result of its increased sales force and Defendants' commentary that it was "having some good impact." Defendant Beer responded:

> Starting with the non-starts, and I think we will see a direct correlation in the future of our performance on non-starts and dropouts. Because from our studying of why we had non-starts and dropouts, it comes down to education of the disease, by both us and by the physician. We recently conducted a large market research study. Craig did this study with his staff -- of patients in 2013, to better understand why we had non-patients and dropouts. That's why we put the medical educational organization in these nurse educators. As Craig talked about in our prepared comments, we've seen early signs of success there.
>
> We're really excited about the full course of 2014 on the script trends in the US combined with the nurse educating group to affect – positively affect the non-starts and the dropouts.[298]

284. Notwithstanding Defendants' continued positive reassurances, they refused to provide any specifics related to the key metrics when questioned by analysts. Defendant Beer, instead, explained, "we'd like to get away from quarterly quantification for qualitative statements around dropout compliance or non-patient starts. But really focus on the revenue guidance and growth and the predictors around that business."[299]

285. Defendant Beer subsequently made a presentation at the Deutsche Bank Healthcare Conference on May 7, 2014. Analysts took the opportunity to question Defendant Beer further regarding some of the responses Defendants provided during the previous day's earnings conference call. Specifically, one analyst questioned:

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[297] *Id*.

[298] *Id*. at 11.

[299] *Id*. at 12.

So, I was reading the transcript last night, again, and I noticed that you said, it was clear to us in 2013 JUXTAPID scripts were outpaced by the capacity of our patient service infrastructure as evidenced by the patient non-starts and by increasing drop out rates toward the end of the year. And it became more apparent by the end of the year that (inaudible). And I was just thinking back to the end of the year. I feel like we didn't hear about you taking non-patient starts until the fourth quarter call and you had an analyst day where none of this came out. So, I'm just trying to understand. Seemed like at the analyst day the message was scripts are accelerating, and we didn't hear about non-patient starts, and we didn't hear about some of the issues where you may need to add sales to support the current region. So, help me understand the mindset from analyst day and why that wasn't communicated more clearly.[300]

286. Defendant Beer then revealed:

[N]on-patient starts were felt in our model and internally during Q4, coming out of Q4 and early in Q1. We were probably diagnosing patients as still pending because it takes sometimes up to six months to gain reimbursement, and then go back to the patient and say you've gotten reimbursement, and then start them. And if you think about the real [N] of prescriptions started to really kick in at the end of Q2, and in Q3.

So, the big numbers of prescriptions were in that timeframe and it takes 4-6 months to feel, is the patient really not going to start. So, we had them in a pending bucket but the they started to really identify them self at the end of Q4 going into Q1. So, I think, when we had a big enough N of those patients and we understood the non-patient start, thoroughly, is when we sort of talked about that.

* * *

[I]t was really kind of the December time frame, December/January time frame when we really started to feel the non-patient starts and testing these patients that we could get reimbursement approval when we went back to try to ship product, too much time went by and the patient was away from the education of the disease and they decided not to go on therapy. So, that was felt in the December/January time frame at an order of magnitude, we felt this is real, and we've really got to talk about it.

But prior to that, there were pending patients, there were drop out patients, and there was compliance. Those were the metrics that we were verbalizing, and the metrics we were watching internally. In every launch, it takes at least 12-months, sometimes 24-months, to reveal every metric. That's why we have to be careful with those metrics. But, the metrics we were managing to the best of our ability through Q1, through Q3, really were compliance, which we're still proud of, it's

[300] Deutsche Bank Healthcare Conf., May 7, 2014, at 6.

> very high, atypically high for a small molecule, there was drop outs, and there was pending patients, which we were very focused on reimbursement.
>
> And then that number got larger, in the December/January time frame where we got approval, in many cases we got approval of reimbursement, and we go back to ship the product and the patient decides not to go on it. I think all those patients are possible patients for us to go back in, work with the caregiver, to educate them of the severity of the disease, and I hope they'll be patients in the future.[301]

287. Finally, in response to an analyst's question about how the Company is calculating its expected growth in light of the newly revised guidance, Defendant Beer revealed:

> [I]f we maintain the prescription production in the legacy territories and the new territories, that will deliver the revenue. As long as we maintain the conversion, which we are, the conversion from prescription to revenue. And I actually think that we're going to see improvement in some key metrics which will be non-patient starts because we have invested heavily in these nurse educators.
>
> That's why I got back to, you know, I wish I had better scale in 2013 going into '14. But until I saw the script production in '13 I didn't feel comfortable making the investment in more sales reps. And until we could get our arms around the non-patient starts in the December/January time frame, we didn't have the vision of putting the nurse educators in place. So, it's a combination of real clarity around the non-patient starts in that back half of Q4 and early in Q1, that said these nurse educators would be the right asset to put in place to make that non-existent, or less.[302]

288. Defendants' revelations on May 6 and 7, 2014, caused the Company's stock price to decline by **over 25%** in the two days following the foregoing May 2014 revelations, dropping a total of $11.17 per share, from $44.16 per share at close on May 6, 2014 to $32.99 per share on May 8, 2014.

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[301] *Id*. at 6-7.

[302] *Id*. at 9.

289. Then, on October 30, 2014, Aegerion issued a press release detailing its financial results and business highlights for the third-quarter of 2014, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[303]

290. At that time, the Company again revised its FY 2014 net product sales guidance downward:

> Based upon results to date, the Company now expects to achieve between $150 million and $160 million of net product sales in 2014, revised from the previous expectation of the lower end of the $180 to $200 million range.
>
> * * *
>
> 'We continue to believe in the overall market potential of JUXTAPID. However, we are reducing our full year's sales estimates at this time to reflect both higher patient dropout rates and lower U.S. prescription growth rates than previously anticipated following the commercial investments we made earlier this year,' said Marc D. Beer, Chief Executive Officer.[304]

291. Aegerion then hosted an earnings conference call with analysts the afternoon of October 30, 2014. Defendant Beer opened the call by providing the revised full-year guidance for net product sales of between $150 million and $160 million, but stating that he "remain[s] proud of the execution in the JUXTAPID commercial launch in the US."[305] He explained that "[t]here are many lessons learned in a new product launch that crystallized for us this past quarter," and described the two main "drivers" of the guidance revision.[306] Specifically, he stated:

> I would like to directly address the drivers of this latest revision in guidance. There are two key areas where our near-term forecast anticipated either more

[303] Oct. 30, 2014 Form 8-K.

[304] *Id*.

[305] Q3 2014 Earnings Conf. Call, at 3.

[306] *Id*.

> rapid growth or more rapid improvement following our substantial investment in the US infrastructure earlier this year, prescription rates in the US and long-term patient drop-out rates.
>
> * * *
>
> With respect to previous financial guidance, we haven't until recently experienced adequate time with a sufficient number of chronic patients on therapy to understand how a dropout will play out over the long term. While we were optimistic that investments in patient educators and dieticians made earlier this year would have more rapid positive impact on patient engagement, their positive impact has been slower to evolve and is more recently been observed in a measurable way.
>
> We now have a greater understanding of both the short-term and the long-term patient journey and the challenges along that journey. These additional insights and experiences we believe, we are at a better position to more accurately forecast the impact of our patient engagement efforts and the effects of long-term dropouts in our models.
>
> Despite September US prescriptions produced being strong, we experienced lower prescription rates during Q3 than we had forecasted in our model, which was the second factor impacting our US revenue during the quarter.
>
> * * *
>
> To be clear, although our most recent quarter did not meet expectations, we believe we now have a more accurate forecasting assumption as we approach the end of the second year of launch, which we expect will enable more predictable forecasting going forward. We are committed to this improvement in forecasting.[307]

292. Defendant Fraser then supplemented Defendant Beer's comments regarding dropout rates:

> I would like to update you on the most sensitive forecast variables. In the evolution of our launch metrics dropout has presented as the slowest to evolve and the most challenging to manage. HoFH patients have a disease that generally has silent symptoms which often makes it more challenging for them when faced with a therapy that may cause unpleasant GI symptoms and elevations in liver enzymes and which also requires a significant commitment to a low fat diet.
>
> * * *

[307] Q3 2014 Earnings Conf. Call, at 3-4.

. . . Recall that when we ended 2013 with a cumulative dropout rate for all patients that had started therapy in 2013 of approximately 15%. Cumulative dropout is defined as all patients who have been definitively determined to a discontinued therapy as a percentage of all patients who have received at least one shipment. As such it is a blended rate of both the oldest to the newest patients on therapy over that period of time.

With the passage of additional time, we now understand that while the majority of dropouts happened during the first 60 days of treatment, dropouts continue to accumulate at a lower rate over time. Currently the cumulative dropout rate for all patients who have started therapy from the launch in January 2013 to the end of this September is 36%. This overall cumulative is substantially higher than our forecasted projection and is running at a rate that we have so far been unsuccessful in turning around as we had anticipated despite our expanded patient engagement efforts.

* * *

Another variable that we focus on is the conversion rate, which represents the percentage of patients prescribed JUXTAPID that actually start on therapy. This rate is reflective of all potential factors for a prescription not converting including reimbursement denials and duration of appeals, patient-elected non-starts and scripts initiated and subsequently canceled by a physician and is generally in line with our recent internal models running in the range of approximately 50% to 60%. In Q3, we saw the first signs of our patient educators' ability to partner with physician practices in patient education and to begin to positively impact conversion rates.

* * *

. . . Compliance rates continue to be in the range of 80% to 90% and we continue to devote significant resources to appropriately support long and short-term adherence to therapy. Year-to-date prescriptions are up 32% versus the same period last year and September represented a strong month. With the expanded reach of our sales force, we continue to grow our prescriber base. In the third quarter 44% of prescriptions came from new writers and we added nearly 400 new prescribers thus far this year, more than we had in the whole of 2013.

* * *

With the better understanding of long-term dropout, we can now focus our investments on appropriately improving adherence. Armed with substantial data from our launch experience, we are making informed metric-driven calibrations that we believe will support continued growth.[308]

[308] *Id*. at 4-6.

293. Despite several quarters of assuring the market of the Company's careful oversight and encouraging investors to "trust the guidance" provided in lieu of real time metrics of prescription and patient counts, Defendant Beer now remarked:

> As I mentioned at the outset of this call, we are acutely aware that of inaccurate forecasting of year two of the lomitapide launch, including an expectation of more rapid positive impact on prescription rates and dropout rates this year has had a negative impact on the overall impression of this launch.
>
> * * *
>
> Our understanding of the factors that are required for future growth by [sic] increasing with time and we believe that we have implemented the changes necessary to help optimize our sales efforts and operating results.[309]

294. During the question-and-answer session that followed, Defendants Beer, Fraser, and Fitzpatrick fielded questions concerning third quarter results, including questions regarding the revised 2014 guidance, the confusion surrounding the dropout rate, and the Company's plans for meeting the newly revised FY 2014 guidance. Specifically, an analyst from Leerink questioned the Company's revelation regarding a 36% discontinuation rate, recalling a prior representation from the Company that "if they ever exceeded 20%, Craig Fraser would be taking [sic] out to Springfield and shot."[310] In response to that question, and several others that requested the same type of information, the Company explained its "philosophical" view on forecasting and guidance, generally.[311] Ultimately, however, Defendant Beer took full responsibility for the guidance miss the Company reported:

> I just want for everybody to hear a very clear ownership for this forecast and guidance challenge. It is a miss, this is our third revision of guidance in 2014 and

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[309] *Id*. at 11.

[310] *Id*. at 8.

[311] *Id*.

> I do not plan on that continuing going forward. I take full ownership for that miss and us being able to get this forecast right prior to this.[312]

295. Despite their prior support and cautious optimism quarter-after-quarter, analysts had finally heard enough from Aegerion, and concluded that they could not trust management to accurately forecast sales. For example:

(a) On October 30, 2014, Cowen and Company issued its report, *Juxtapid Misses, Guidance Cut*, reiterating the Company's true dropout rate and other financial results, including the Company's revenue guidance miss. As a result, the Cowen and Company reported that it had increased the annualized dropout rate assumed in its model from a modest 6-8% to a whopping 20%.

(b) Deutsche Bank Markets Research downgraded Aegerion stock on October 31, 2014, questioning whether management could "execute," and providing a list of reasons why it answered the question as a negative, including:

- "We do not trust the ability of management to accurately forecast sales; given the quarterly changes in guidance."
- "We question the ability of [management] to reverse course and slow the increasing dropout rates."
- "During the call, management provided no updates as to what will be done differently aside from revising forecasts."
- "We question how they plan on turning around these negative trends (especially the higher than projected pt discontinuation rates)."
- "We do not see the investment in the commercial team paying off (*e.g.*, nurse educators, dieticians, etc.)."[313]

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[312] *Id*. at 11.

[313] Deutsche Bank Markets Research, *Can mgmt execute? Downgrade to HOLD, new TP $26*, Oct. 31, 2014.

(c) Jefferies similarly downgraded Aegerion to a "Hold" position on October 31, 2014, surrendering to the fact that "2x miss in sales/2x downward revisions in FY14 guidance (by ~5%/18%) leave little room for optimism."[314]

296. Defendants' October 30, 2014 revelations, and the resulting analyst commentary, immediately caused the Company's stock price to plummet. In just one trading day, the Company's stock price dropped by ***41%***, falling from a close of $34.21 per share on October 30, 2014 to a close of $20.19 per share on October 31, 2014, on abnormally high trading volume.

297. On May 4, 2015, Aegerion issued a press release detailing its financial results and business highlights for the first-quarter of 2015, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[315]

298. At that time, the Company reiterated its financial guidance for 2015, expecting "full-year 2015 global net product sales of JUXTAPID to be between $195 million and $215 million."[316]

299. Aegerion then hosted an earnings conference call with analysts the afternoon of May 4, 2015.[317] Defendant Beer opened the call by providing a summary of the Company's progress in early 2015. Specifically, he stated:

> we continue to have confidence in the potential for Aegerion's growth. We are focused on growing revenues in our existing approved indications, while carefully managing our expenses, and investing in our business, including our commercial activities, clinical development, geographic expansion, life cycle management,

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[314] Jefferies, *Aegerion Pharmaceuticals (AEGR) 2nd-time for Juxtapid Sales Miss & Lowering FY14 Guidance: Moving to Hold*, Oct. 31, 2014.

[315] May 4, 2015 Form 8-K, Ex. 99.1.

[316] *Id*.

[317] Q1 2015 Earnings Conf. Call, at 3.

> and business development. We feel optimistic about the potential value creation opportunities in the year ahead.
>
> Looking first at the Juxtapid business, we believe there are opportunities for growth, based upon the evolving knowledge we have about the adult HoFH patient journey, and the potential for geographic expansion. As you know, in 2014 we took action to form matrix teams, which in addition to our rare disease managers, who are our sales reps, include patient education managers, who typically have a nursing background, as well as registered dietitians and customer care reimbursement specialists, to help support a better patient experience for Juxtapid from the outset of therapy.
>
> The matrix team as a whole has been focused on on-boarding new patients, and staying close to the patients during the early days of therapy. We look forward to expanding their HoFH educational efforts towards the entire adult HoFH patient base, working closely with their health care professionals.
>
> We have seen evidence that optimized matrix teams can have a positive impact on patients starting and staying on therapy in the short term. Our data tracking these trends show some inconsistency on a month-to-month basis, however, and require further continued evaluation. Importantly, we've turned significant attention to stemming the attrition of adult HoFH patients who have been on therapy long term, with focused patient-engagement efforts with these patients and their health care professionals. As you know, both short-term and long-term attrition impact our re-order revenue in a meaningful way. Craig will speak to this further and deeper in his remarks further in the discussion.
>
> We see opportunities to continue to improve our adult HoFH patients' experience with Juxtapid therapy.[318]

300. Defendant Fraser addressed investors next. He echoed some of Defendant Beer's thoughts and then provided an update with respect to conversion and drop-out rates. He stated:

> Our conversion rate from prescription to patient on therapy in the first quarter was steady, in the 50% to 60%, range, reflecting consistent payer approval rates, and patient choice to initiate therapy from our experience at the end of 2014. While we always strive for improving this rate, this range remains consistent with our forecast.
>
> Managing the drop-out rate, including both short-term drop and longer-term attrition, remains a primary area of focus. As of April 24, we had a cumulative drop-out rate of 46%, compared with 41% at the end of 2014, and we see that the long-term attrition is the primary contributor to this trend.

[318] *Id*.

> We continue to define cumulative drop-out as the total number of patients who have definitively determined to discontinue therapy from the date of initial launch in January 2013 as a percentage of all patients who have received at least one shipment, and thus the cumulative drop-out percentage may continue to increase with time. Again, we are focused on managing the dynamics associated with drop-out to improve upon this rate, and have focused investments and approaches on this objective across the entire patient base, with the goal of having positive impact on drop-out over the long-term.[319]

301. The Company also discussed the upcoming launch of the PCSK9 inhibitors, assuring that their fiscal 2015 guidance took their existence into account:

> With respect to PCSK-9 inhibitors, we are watching carefully for warehousing of prescriptions ahead of their launch anticipated in the third quarter, but haven't yet seen this dynamic with any significance. We do believe there is potential to see it, to some greater degree, in the coming quarter.
>
> As you know, we have factored into our forecasting guidance for 2015 a slowing of new patient starts on Juxtapid in the US, and some attrition of our chronic base patients in the second half of 2015, as a result of the anticipated launch of PCSK-9 inhibitors.[320]

302. During the question and answer session, analysts requested more clarity on the Company's outlook and how it modeled its revenue guidance for the new fiscal year. In addition to speaking on the revenue attributable to JUXTAPID, and the impact from delayed insurance authorizations and other supportive requirements, Defendant Fraser spoke regarding the impact of PCSK9 inhibitors on new patients:

> We do project a slowing of new patient starts following the anticipated launch of PCSK-9, as we mentioned a little bit earlier, and for the purposes of revenue guidance have modeled for a percentage of existing Juxtapid patients to be switched to a PCSK-9 inhibitor once they're available.
>
> We continue to believe ultimately, and to close out the point on PCSK-9s, that in whole or part, identification of more HoFH patients from these being on the

[319] *Id*.

[320] *Id*.

> market will help offset that in the long term, in whole or part. But we did have some of those effects early on in the year from Q1 coming out of Q4.[321]

303. In response to another analyst's question regarding what, if anything, the Company was "paying particular attention to . . . or anything you expect to learn coming out of [the PCSK9 advisory committee meetings]", Defendant Beer assured:

> The only other thing, Morgan, that I would emphasize is that there's a strong belief across this Management team that PCSK-9 as a class is going to be great for patient care and good for physicians. They're going to spend tremendous amounts on proper education and awareness, which I think is good for all therapies. But most importantly, it's going to be good for patient care and good for physicians. If a patient can be effectively -- if an HoFH patient can be effectively treated with PCSK-9 they should.[322]

304. Another analyst honed in on the 5% increase in the cumulative dropout rate that occurred between December 31, 2014 and April 24, 2015 and whether the dropout rate "could potentially continue to up-tick with the introduction of PCSK-9 inhibitors later in the year?" Defendant Fraser stated:

> Well, I think there's another dynamic that I was mentioning a few moments ago that comes into play. You have the drop-off that actually occurs both short term and longer term related to the therapy and the disease and so forth. Things from GI upset and/or liver enzyme elevations that are not resolved with following the PI dosage adjustments and so forth. That will always be there as a part of the on-growing chronic maintenance with -- of these patients with this therapy.
>
> We also have another dynamic post-PCSK-9 that is any patients -- and we factored into our forecast and guidance a percentage of patients switching from the base over to PCSK-9 therapy. That is part of what set the guidance for us, which is a factor unique to the time frame after PCSK-9s.[323]

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[321] *Id*. at 12.

[322] *Id*. at 13-14.

[323] *Id*. at 16.

305. Despite the Company's assurances, analysts remained optimistic, but were nevertheless concerned with dropout rates and the potential impact of the PCSK9 launches. For example:

- On the surface, the topline revenue number for Juxtapid ($57.3M +112% y-o-y) looks like a resounding positive and a clear beat (~16% over consensus). However, several contributing factors are masking true growth rates. We're incrementally concerned with the lull in patient adds as we already anticipated patient base and new starts would decline with the launch of PCSK-9s later this year, in line with management guidance. Additionally, cumulative discontinuation rates continued to increase and are now at 46% vs. 41% at the end of 2014.[324]

- Aegerion's Juxtapid has been FDA and EMA approved for the orphan condition homozygous familial hypercholesterolemia (HoFH). While Juxtapid's launch began strongly in 2013, it faced several headwinds in 2014, leading Aegerion to cut guidance several times. These headwinds to Juxtapid's launch are problematic, given that we expect anti-PCSK9 availability (likely by Q3:15) to limit future growth. In Q4:14, acquired Myalept is FDA-approved for the treatment of generalized lipodystrophy. We project that Myalept could have $200MM in peak sales potential. We remain on the sidelines pending more visibility on demand trends for Juxtapid and Myalept. Our DCF-derived valuation suggests that AEGR shares are fairly valued.[325]

306. On July 6, 2015, Guggenheim Securities, LLC ("Guggenheim") downgraded Aegerion in a report titled *AEGR-Downgrading to SELL-Juxtapid on the Road to Nowhere* with a price target of $9 per share. According to the report, the analysts believed the drug had passed its prime and that the Company would have a difficult time enrolling new patients and controlling the dropout rate moving forward, among other things. Specifically, the report stated:

> Downgrading to SELL on bleak Juxtapid outlook. We believe Juxtapid has passed its prime. The drug's intrinsic shortcoming, poor tolerability, and the advent of PCSK9 inhibitors could conspire, in our opinion, to erode the existing business and significantly curtail future growth opportunities. Opex would likely need to

[324] JPMorgan, *1Q15 Snapshot – True Growth Is Cause for Concern*, May 4, 2015.

[325] Cowen & Company, *Juxtapid Beats on U.S. Pricing, Brazilian Order, But 2015 Guidance Unchanged*, May 4, 2015.

be cut substantially to achieve even modest profitability, and we believe the emerging competitive market dynamic disfavors such a tactic.

Recent commercial metrics create an unattractive mosaic. Some investors groused about discontinuation of commercial metrics shortly after Juxtapid was launched. Data provided on the 1Q15 results conference call (e.g., number of patients on treatment, cumulative dropouts and conversion rate) were useful, we believe, to support the outlook that a meaningful percentage of the patient population has already been treated with the drug. Our negative outlook on AEGR stock is predicated, in part, by the belief that patients, once touched, will be unlikely revisit Juxtapid.

Keeping our eyes/ears peeled for genetic testing. Physician consultants view PCSK9 inhibitors as viable alternatives and their significantly lower cost may make them attractive to payers. Potentially dousing hopes that new market entrant activity could uncover patient opportunities for Juxtapid may be the requirement by payers, noted by one consultant, for genetic testing prior to initiation of treatment. At a minimum, we believe payers would require step editing with PCSK9 inhibitors before authorizing use of Juxtapid.

Setting Price Target at $9 on expected increase in dropout rate and lower patient enrollments. Without providing any detail, Aegerion guided to 2015 Juxtapid sales of $195-215M, including a potential PCSK9 market entry in the August/September time frame. While the approval recommendation may have been unsurprising, we suspect the contemplated use profile was.

307. With regard to the Company's remarks on the co-existence of JUXTAPID and the PCSK9 inhibitors, the analyst opined:

The working hypothesis espoused by Aegerion management has been that it is unlikely any overlap would be significant given the presumed need for functional LDL receptors (LDL-R) to be present if PCSK9 inhibitors are to be effective. (As known now by most investors, the PCSK9 enzyme is involved in LDL-R recycling and its activity may reduce the ability to clear LDL-C. Inhibiting the PCSK9 enzyme has been shown to reduce LDL-C in humans.) Setting aside whether the hypothesis is even valid, prescribing of Juxtapid has largely been done based on phenotype (e.g., LDL-C level), and not a genetic analysis of potential LDL-R defects. So, in our view, we are challenged in believing that Aegerion can make even a semi-qualitative assessment as to the potential overlap. More likely may be the evolution of a hypothesis driven by results from empirical testing.

* * *

Instead of PCSK9 inhibitors and Juxtapid occupying non-overlapping (or at least limited overlapping) segments of the hypercholesterolemia spectrum, advisory

> panel recommendations that the PCSK9 inhibitors should initially be used to treat patients with severe hypercholesterolemia, heterozygous familial hypercholesterolemia (HeFH), and/or homozygous familial hypercholesterolemia (HoFH) appear to put the drugs on a direct collision course with Juxtapid.[326]

308. On July 27, 2015, Aegerion issued a press release announcing the resignations of Defendants Beer and Fraser, effective July 26, 2015.[327] The press release, which also was filed with the SEC as an Exhibit to a Form 8-K that same day, also announced the appointment of the interim CEO, who would also assume the COO responsibilities.

309. The Company did not host a conference call following the announcement, but several analysts issued reports providing their views and commentary on the day's events. For the most part, analysts viewed these management changes as positive news, opining that the news was "an incremental positive in turning the tide for AEGR"[328] that "may encourage investors to revisit the stock."[329]

310. Though the Company did not provide any reasons for the departures of Defendants Beer and Fraser, an analyst for Cowen and Company summarized the matter as follows:

> Juxapid's launch struggled in 2014 and the company had to revise its full year guidance several times. The slower-than-expected uptake resulted from a number of factors, including a higher than expected cumulative dropout rate, and difficulties obtaining reimbursement outside of the United States. The repeated misses, combined with other issues, severely damaged the credibility of senior AEGR management. Therefore, we think a management transition is wise. AEGR is facing a rough patch over the next several quarters as the PCSK9s launch.

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[326] *Id*.

[327] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (July 30, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000119312515268692/d30495dex991.htm.

[328] Deutsche Bank Markets Research, *CEO & COO resign; prelimin 2Q net sales of $63-64M v. cons. of $57M*, July 27, 2015.

[329] Leerink, *Management Changes May Encourage Investors to Revisit the Stock*, July 27, 2015.

> These will almost certainly reduce the number of patients who start Juxtapid, and could increase the number of patients who drop off therapy. A new management team will not change the fact that the PCSK9s will be disruptive. However, a management team who has the trust of investors will be better able to take the company through these competitive launches and maintain investor faith that a viable and profitable Juxtapid franchise will emerge on the other side.[330]

311. On August 5, 2015, Aegerion issued a press release detailing its financial results and business highlights for the second-quarter of 2015, which also was filed with the SEC as an Exhibit to a Form 8-K the same day.[331]

312. In the press release, the Company reported positive results for the second quarter and reiterated its financial guidance for 2015, expecting full-year 2015 global net product sales of JUXTAPID to be between $195 million and $215 million.[332] The press release also stated:

> Aegerion continued to show good progress during the second quarter in key areas of the business, including growth in number of patients on therapy for both of our products. We believe we are on track to deliver strong results; however, as we navigate through the early days of the PCSK9 inhibitor launches, we are maintaining our prior guidance for the year. We remain focused on building a fully integrated, leverageable and risk-diversified company to deliver therapies to patients with rare diseases.[333]

313. Aegerion then hosted an earnings conference call with analysts the afternoon of August 5, 2015.[334] An agent for the Company opened the call by providing a summary of the Aegerion's progress. The Company stated:

> With respect to JUXTAPID, in the second quarter of 2015, we executed well, recording 15% growth in the US business over the first quarter. JUXTAPID was

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[330] Cowen and Company, *Management Reshuffled, Q2 Sales Solid, But Future Still Uncertain*, July 27, 2015.

[331] Aug. 5, 2015 Form 8-K.

[332] *Id*.

[333] *Id*.

[334] Q2 2015 Earnings Conf. Call.

> supported by its' strong prescription growth, and by net patient adds. We're encouraged that we're seeing the increase in the rate of short-term-drop slow. Let me say that again. We're encouraged that we are seeing the increase in the rate of short-term-drop slow, as a result of the work of our matrix support system. These focused efforts began last year.
>
> Importantly, we continue to give attention to stemming the attrition of adult HoFH patients who have been on longer term therapy. We have also focused our efforts on working with healthcare professionals to reengage with adult HoFH patients who have discontinued therapy, or who were prescribed JUXTAPID, but ultimately never initiated therapy. Many of these adult HoFH patients may continue to be appropriate candidates for therapy, and may also be able to benefit from expanded resources we have today, including additional dietary consulting.
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> * * *
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> Despite the confidence that we have in the trajectory of the business this year, and the positive trends that are supporting our growth, after considerable Management debate, we have elected not to increase our guidance at this time. We feel it's prudent to maintain our current guidance as we navigate through the early days of the PCSK9 inhibitor launches. However, if sales trends continue, we will reevaluate guidance for the third quarter call.[335]

314. In addition, the Company continued to tout its "improved . . . . understanding of the JUXTAPID business and the adult HoFH patient dynamics" and the "encouraging" trends regarding patient onboarding when done through the matrix teams (*i.e.*, sales representatives, patient education managers who typically had nursing backgrounds, registered dieticians, and reimbursement specialists) that were launched in 2014.[336] The Company also stated:

> Through these initiatives, our goal is to impact long term attrition in a similar way as we've begun to affect short-term drop out. We foresee opportunities to support better patient adherence to therapy through these established resources and working with healthcare professionals. There have been significant learnings along the way. We feel we have a better handle on where we can have meaningful impact to support growth in the adult HoFH market.[337]

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[335] *Id*. at 4.

[336] *Id*.

[337] *Id*. at 5.

315. With regard to the increasing slope of cumulative dropouts, the Company reported "[w]e believe our data show that we have begun to flatten that slope. And we believe that this improvement is a direct result of our impact on the short-term drop rate."[338]

316. Finally, even though the Company acknowledged the potential negative impact the PCSK9 inhibitors would have on JUXTAPID prescriptions, the Company spoke positively about its efforts "watch[ing] carefully" and "monitor[ing]" their commercial metrics, and assured the market that they were "keenly attuned to any trend changes we might begin to experience as a result of the now on-going launch of the first approved PCSK9 inhibitor."[339]

317. With regard to PCSK9's impact on its financial guidance, the Company reiterated:

> As you know, we factored into our forecast and guidance for 2015 a slowing of new patient starts on JUXTAPID in the US, and some attrition of our chronic-base patients in the second half of 2015 as a result of the launch of the PCSK9 inhibitors We feel confident that we're well prepared to manage through the evolving market for the treatment of adult HoFH. Despite the potential disruption to new patient starts, and possible attrition of our base in the early days of the PCSK9 inhibitor launches, we believe JUXTAPID will remain a cornerstone therapy and have a clear role within the adult HoFH patient population.
>
> In our preparation for the introduction of PCSK9 inhibitors, we have executed various campaigns to educate physicians and their adult HoFH patients about the important role of JUXTAPID in treating adult HoFH and the importance of healthcare professionals and HoFH patients discussing LDL-C levels in order to reinforce efficacy. Over time, additional HoFH patients may be properly diagnosed with the increased promotional investment by the PCSK9 manufacturers. We plan to invest in marketing programs to extend our reach to adult HoFH patients whom we believe will be uncovered by the much larger PCSK9 inhibitor sales forces.[340]

318. During the question and answer session that followed, analysts probed the Company for more specific details regarding new patient starts, the challenges the Company was

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[338] *Id*.

[339] *Id*.

[340] *Id*. at 5-6.

facing with reducing the cumulative dropout rate, and potential changes in how JUXTAPID is prescribed in the presence of PCSK9 inhibitors.

319. An analyst from BofA Merrill Lynch asked for some further insight on new patient starts, and while the Company refused to provide "specific numbers on that element," it did say "we were very pleased with our overall performance in the second quarter. Certainly, we have a very healthy business . . . and we're continuing to – we're looking forward to continuing that momentum."[341]

320. A Leerink analyst inquired regarding the "challenges of reducing the cumulative dropout rate" for JUXTAPID. The Company asserted:

> We have a lot of plans in place, as we disclosed to you in our planned remarks, that we'll be reaching out with the right people, our [physician] education managers and our registered dieticians, to be able to offer services to those patients who are on JUXTAPID therapy.
>
> Those HoFH patients who we have the proper authorizations in order to reach and to discuss and support of the health care professionals who look after them to be able to offer more of these services to them. To help them potentially understand HoFH as a disease better, to understand how to be able to manage their diet properly to reduce the potential for gastrointestinal side effects. So the plan that we have in place, as we indicated earlier, is really continue to move that focus of the matrix team not just on the short-term elements of things to be able to try to improve short-term drop, but also to reach back into our patient base through the appropriate ways to try to help in the ways that I just mentioned.[342]

321. An analyst from Deutsche Bank questioned the potential of a "combo treatment" of JUXTAPID and a PCSK9 inhibitor, and the rationale behind the Company's interest in pursuing such a study. The Company explained:

> [T]here are several reasons why we would be interested in doing that. I think it starts with what is actually the foundation approach to the management of patients with hypercholesterolemia, in the general sense, which is that all patients, in fact,

[341] *Id*. at 10.

[342] *Id*. at 11.

> should be managed, particularly patients with homozygous FH with multiple lipid layering treatments because these patients have very high LDL cholesterol levels and they are difficult to treat.
>
> And so, it's frequently the case that the clinical pathway involves adding multiple medications. [patents] should really be the foundation, but there are multiple other drugs that are frequently tried. Apheresis is sometimes added, and PCSK-9 inhibitor certainly might be used in a patient that may be diagnosed as homozygous FH. I think it's certainly a logical approach to consider, because not -- for the majority of patients with homozygous have some degree of LDL receptive function. So we know that would expect some elements of LDL cholesterol reduction, although that's difficult to predict.
>
> Of course the other parts of clinical practice is that the reason that these drugs are all added together in combination is to get the LDL down below a target level or a goal. Our expectation is that many patients who may be on multiple lipid layering treatments, including a PCSK-9 inhibitor, may not be at goal. So there will be a desire in diagnosed patients with HoFH for a physician to add another product. So it's an expectation that we believe physicians will want to do that.
>
> We think it's a very relevant clinical and also a very relevant scientific question to establish both from an efficacy point of view, as well as a safety point of view, how these drugs and these different classes would behave. We would like to establish some data in that respect in the context of a clinical trial.[343]

322. Following the conference call, analysts noted dropouts as a continued concern for the Company moving forward, and predicted that JUXTAPID was moving closer to its peak revenue. But, they remained positive based on, among other things, the "new interim management team,"[344] and "better than expected results during 2Q15 and the expectation that a portion of those inferred additional patients will remain on therapy for at least parts of the remaining year."[345]

323. On November 9, 2015, Aegerion announced its third quarter 2015 financial results for the three months ended September 30, 2015, in a press release filed with the SEC as

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[343] *Id*. at 14.

[344] Deutsche Bank Markets Research, *New team, new dream? Is this AEGR 2.0?*, Aug. 5, 2015.

[345] Guggenheim, *AEGR-SELL- Recasting the Story, Complete with New Holes*, Aug. 6, 2015.

an Exhibit to a Form 8-K that same day.[346] In that document, the Company reported "$58.8 million in net product sales of JUXTAPID® (lomitapide) capsules in the third quarter of 2015, $49.6 million of which was from prescriptions written in the United States."[347]

324. In addition to announcing a narrowed guidance of "between $205 million and $215 million, revised from the prior range of between $195 million and $215 million," the Company also announced that it was in default of certain covenants under a loan agreement and, thus, had defaulted on an outstanding $25 million term loan.[348]

325. Aegerion then hosted an earnings conference call to discuss the anticipated government settlement as well as the resulting breach of covenants and default on outstanding loans, calling the development "disappointing," and notifying investors that it was "probable [sic] that the Company will incur a settlement with the U.S. government or face an enforcement action as a result of the ongoing investigations."[349]

326. The Company also discussed conversion and dropout rates, as well as the effects of the PCSK9 inhibitors on sales of JUXTAPID. The Company explained that the conversion rate had been impacted by "widespread PCSK9 sampling programs," thus falling 7% in only one quarter. Notwithstanding, the Company assured that PCSK9 inhibitors, "over the long term," "coupled with market awareness initiatives by the PCSK9 companies will serve to increase the

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[346] Nov. 9, 2015 Form 8-K.

[347] *Id*.

[348] *Id*.

[349] Thomsom Reuters Streetevents, Edited Transcript, AEGR-Q3 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Nov. 9, 2015, at 3.

identification of adult HoFH patients and that this will also result in potential opportunity for JUXTAPID over time."[350]

327. Just as the conversion rate decreased, the dropout rate increased to a staggering 58%, which it attributed to "patients switching to a PCSK9, with the remainder being patients who discontinued as a result of GI tolerability, diet, or other issues."[351]

328. The Company also provided more insight into the impact of the PCSK9 inhibitors now entering the market place:

> As expected, in the third quarter we began to see the impact of the PCSK9 inhibitors on our JUXTAPID business in the U.S. We have experienced a slowing of new patient starts. A meaningful number of patients have switched off JUXTAPID to try the new therapy, particularly given the significant number of free samples being provided in the market by nearly 1,000 reps.
>
> I'm sure you'll agree that it's still too early in the PCSK9 launch to predict the full impact on JUXTAPID sales. At the present time, we've really not been able to establish any specific trends. What is clear, I think, is that JUXTAPID will continue to have an important role in the treatment of adult HoFH patients going forward. This is because of its unique mechanism of action, which is not receptor-based.[352]

329. The Company tried to temper the foregoing negative news by announcing, on a positive note, that it had made significant progress on its latest initiatives to JUXTAPID. For example, the Company reported:

- We remain on track for a Japanese MDA filing in early 2016.[353]
- We're currently finalizing the pediatric study protocol for lomitapide.[354]

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[350] *Id*. at 4.

[351] *Id*.

[352] *Id*. at 3.

[353] *Id*. at 5.

[354] *Id*.

- [W]e have plans underway towards development of a second-generation version of lomitapide, exploring ways to improve tolerability by reducing or eliminating the gastrointestinal side effects. As we have discussed, we've selected three potential pathways for evaluation and proof of concept; a pro drug, a subcutaneous injection, and a patch. We now expect to have data to decide which path forward we select towards the end of the first quarter of 2016.[355]

330. During the question and answer session that followed, analysts asked several questions regarding the Company's views on the challenges posed to JUXTAPID sales by PCSK9 inhibitors, and the effects of PCSK9 inhibitors on the Company's revenue guidance in general, to which the Company responded by essentially repeating the summary provided in its opening remarks.

331. Further, one analyst from Cowen and Company, however, asked pointed questions regarding the DOJ and SEC investigations that caused the Company to default on its loans. Specifically, he asked, "Can you give us some sense of the scope of those investigations? What, in particular, are they looking at? And which covenants were therefore violated to result in the loan default?"[356]

332. In response, the Company stated:

> What I'd do is I'd point you to our 10-Q, which we filed just after the market closed. And, really, the disclosures in the 10-Q really reflect our current assessment of the investigation and, certainly, our understanding of the nature of the investigation as well as potential outcomes. And that has evolved over time and I think you'll see that in the disclosure that we've provided.[357]

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[355] *Id*.

[356] *Id*. at 12.

[357] *Id*.

333. Following the conference call, analysts were concerned with the lack of information that had been provided regarding the DOJ investigation, the increase in dropout rates, and the early impact from PCSK9 inhibitors:

- AEGR beat on both top and bottom lines for 3Q15 (slides here) as another sizeable ex-US order pushed revenues higher. Despite the beat, AEGR has already begun to feel the heat from PCSK9 inhibitors as discontinuation rates spiked and US Juxtapid sales declined ~10% Q/Q. We expect this dynamic to continue as the newly launched products are added to more formularies over the next few quarters. Additionally, AEGR disclosed that ongoing government investigations could soon materially impact the business. On the bright side, Myalept continued its solid performance after its relaunch, resulting in a bump in 2015 revenue guidance. We're maintaining our Neutral rating following 3Q15 with the magnitude and duration of the impact from the PCSK9s still unknown on AEGR.[358]

- It's surprising to see greater early impact from PCSK9 on Juxtapid; lack of AEGR's assuring comments add further uncertainty (albeit too early to tell).[359]

- **Government investigations render AEGR shares uninvestable, in our view.** Aegerion disclosed that it is "probable that the company will incur a settlement with the U.S. government or face an enforcement action" stemming from DOJ and SEC investigations "regarding disclosure statements related to the prevalence of HoFH, and its U.S. marketing and promotional practices." AEGR has also disclosed that investigations are ongoing in Brazil to determine whether anti-corruption laws have been violated. One consequence of the activities is that certain covenants under a loan agreement with Silicon Valley Bank have been breached and Aegerion is currently in default on an outstanding $25M term loan.[360]

- **Evidence that Juxtapid is a flawed molecule just keeps coming.** Management heralded the 300bp increase in the cumulative dropout rate for 2Q15 as an improvement over the three prior quarters in which the dropout rate increased by 500bps in each. For 3Q15, management disclosed that the cumulative dropout rate increased by 900bps to 58%. In

[358] JPMorgan, *3Q Snapshot & Model Update*, Nov. 9, 2015.

[359] Jefferies, *Juxtapid 3Q Sales Beat, but Reduce PT on Steeper Decline from Competition*, Nov. 10, 2015.

[360] Guggenheim, *AEGR-SELL-Juxtapid High-Water Mark May Have Been Reached – Government Investigations Cause a Breach; Lowering PT*, Nov. 10, 2015.

> our minds, the 2Q15 dropout performance was an aberration creating the mirage that, somehow, the franchise was being better managed or that the drug's intolerability had abated. Advent of the PCSK9 inhibitors will only accelerate the dropout rate, we believe. We have reduced our price target to $7 from $9, primarily on changes to our Juxtapid dropout rate.[361]

334. As a result of the news, Aegerion stock price by plummeted 21% on November 10, 2015, closing at $10.64 per share that day, down from a close the previous day of $13.12 per share on extremely high volume.

335. On February 25, 2016, the Company announced its financial results for the three months and year ended December 31, 2015 which, among other things, announced that the total number of patients on JUXTAPID had declined since the prior year, totaling, as of December 31, 2015, 615 active commercial patients on JUXTAPID therapy globally, of which approximately 490 were U.S. patients.[362] The Company admitted "the number of U.S. patients on JUXTAPID has continued to significantly decline since December 31, 2015," but assured that it had done so "at a lower rate than in the fourth quarter of 2015." *Id*.

336. The press release also announced that the Company "recorded a charge of $12 million, representing the current estimate of the minimum amount required to resolve the ongoing Department of Justice and Securities and Exchange Commission investigations." *Id*.

337. During the conference call with investors that followed, the Company described "four distinct efforts" it developed to "swiftly tackle" the various challenges the Company faced.[363] There, the Company admitted to a need for "legal and regulatory compliance," assuring

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[361] *Id*.

[362] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (Feb. 25, 2016), *available at* https://sec.gov/Archives/edgar/data/1338042/000155837016003540/aegr-20160225ex99135cd2.htm.

[363] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q4 2015 Aegerion Pharm. Inc., Earnings Conf. Call, Feb. 25, 2016, at 3.

that "[c]ompliance metrics are now part of our processes, and educational efforts are underway to ensure employees live and breathe these core values."[364]

338. The Company also discussed the DOJ and SEC investigations, informing investors that it was "in discussions" with the two agencies "in order to resolve potential claims arising from their investigations" and reiterating that it had recorded a $12 million charge, "representing our current estimate of the minimum amount required to resolve these investigations." The Company stressed, "[w]e are determined to enhance our commitment to compliance and reduce our legal expenses so that the strength and the quality of the underlying business and the commitment of our people can once again shine through."[365]

339. The Company then described its intent to "realign":

> Recognizing that the company was oversized in certain areas for the current state of the JUXTAPID business, we conducted a Company-wide resource analysis. Based on our findings, we enacted a 25% reduction of the global workforce, to approximately 230 employees. The reduction preserved resources that were adding value, that we believe will be integral to the successful completion of our lifecycle expansion efforts, including the global infrastructure and the unique capabilities of the Company.[366]

340. Finally, with regard to the challenges facing the Company regarding the competition it faced with the existence of the PCSK9 inhibitors, the Company remarked:

> [W]e will continue to maximize the value of JUXTAPID. As you are aware, the HoFH marketplace continues to evolve. With the introduction of PCSK9 inhibitors, HoFH patients now have another treatment option available to them, one that they and their physicians may determine to be the best therapy for them. We will continue to assess the competitive impact of the PCSK9 inhibitors, and we believe JUXTAPID has a role to play for adult HoFH patients who have little or no LDL receptor activity. The efficacy of a PCSK9 inhibitor requires some

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[364] *Id*.

[365] *Id*.

[366] *Id*.

> unction of the LDL receptor, so it's possible that responses in patients with HoFH who have limited or absent functionality are inadequate.
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> As JUXTAPID efficacy is not dependent on LDL receptor activity, it represents a treatment option for those patients. Unfortunately, there is no reliable biologic test to determine the level of LDL receptor activity present in HoFH patients, unless you see and will continue to see for some time physicians switching their HoFH patients to a PCSK9 inhibitor. We expect that those patients who have little or no LDL receptor activity will have an inadequate response to PCSK9 inhibition and may be considered for JUXTAPID.
>
> As physicians and payers work to understand which patients benefit most from which product, we expect to continue to experience a lower base of JUXTAPID patients. During this time, we will continue to focus on educating healthcare providers on JUXTAPID's indication, so that they can identify those adult HoFH patients who are most appropriate candidates for JUXTAPID in this country and in the global marketplace. We continue to believe that the global market opportunity for JUXTAPID is meaningful. For example, in Japan we expect approval in the fourth quarter of this year, and our pre-launch disease awareness activities are ongoing in this important market.[367]

341. During the question and answer session that followed the prepared remarks, analysts asked about the Company's guidance, the patient starts on JUXTAPID, the effects of the existence of PCSK9 inhibitors, and the ongoing DOJ investigation.

342. With regard to its guidance, the Company informed investors that:

> [W]e brought in a firm who Mary had experience with and who is an analytical house and spent a lot of time looking at pharmaceutical forecasts and preparing estimates. So we brought them in and shared some of the marketing information we had. Some of our data, but not our own forecasting methodology. And so we used their input to also triangulate around the number that we included in our forecast.
>
> There are no guarantees here. This is still a dynamic situation, but it certainly gave us a bit more measure of confidence that this third party weighed in on the forecast.[368]

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[367] *Id*. at 4.

[368] *Id*. at 9.

343. Recognizing the dramatic decrease in patient adds as a result of the introduction of PCSK9 inhibitors, the Company no longer attempted to hide from the debilitating effect of the competition posed by those drugs. Specifically, the Company stated:

> What I would say is that, when you look at the shape of our new starts, they have been significantly impacted by PCSK9s, both in the fourth quarter and in the first quarter. And it's going to take time for these physicians to continue to think about how PCSK9's efficacy is going to help their patients or not help their patients get an LDL-C response, in which time they would decide whether to start JUXTAPID.
>
> The point I know that you are asking about is, that it has been a steady decline in our new start patients. As we ended the fourth quarter and enter the first quarter we continue to see significant reductions in our new start patients for JUXTAPID.[369]

344. Finally, with regard to the DOJ investigation and expected settlement, analysts specifically asked whether the $12 million charge "reflect[s] your expectations for a civil penalty? Or does it also include potential criminal penalty because that is something that has been levered in the past?"[370] The Company responded:

> I think the way I would characterize it is that it's really a current estimate of the minimum required amount to resolve the litigation matters, both criminal and civil, in amongst kind of a global settlement if you will between DOJ and SEC.
>
> Again I just want to caution that, really, the final amount, the timing is really uncertain and this is not something that has been agreed to by the government. And this certainly isn't an estimate. In fact, I would not want to give any assurances that we can reach a settlement. But certainly we are making progress and the conversations we're having are very productive, but it's really the accounting guidance based on the fact that we've made an offer to the government that leads us to this $12 million charge that we have recorded in the fourth quarter.[371]

345. Following the call, analysts remained uncertain how to view Aegerion's future:

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[369] *Id*. at 9.

[370] *Id*. at 12.

[371] *Id*.

- We view 2016 as a "show me" year for Aegerion following a cautious 4Q15 commentary/guidance suggesting a continued substantial impact to the Juxtapid franchise from the PCSK9s and we believe the Street will need to see something encouraging in the topline to become more positive. We believe the shares are reflecting a challenging year. Along these lines, to the extent Juxtapid can meet our forecast, we could see modest upside in the stock from current levels. That said, given the substantial uncertainty around the trajectory of this asset, we are keeping the rating at Neutral and remain on the sidelines pending more clarity on the PCSK9 impact to sales/earnings.[372]

- 2016 guidance calls for total revenue and operating expenses significantly below our prior estimates, as management restructures AEGR for the size of Juxtapid's opportunity following the launch of the PCSK9's. Our price target has been cut from $15 to $7.[373]

- Disappointing 2016 Juxtapid guidance of $120-140MM (~60% decline y/y) factors in an aggressive increase in drop-out rates & slowing new pt. starts resulting from a growing use of anti-PCSK9s in adult HofH pts. AEGR ended 2015 w/ 615 active pts on drug globally, incl. 490 US pts (down from >700 since YE14). A very steep volume decline in on-drug pts was observed in 4Q, which is beginning to stabilize in 1Q. New mgmt. is continuing to engage w/ a third party firm to assist in analyzing AEGR's in-house Juxtapid use data to understand tx. discontinuation patterns w/ the goal of returning to growth in the near future. Mgmt. believes payors still value magnitude of Juxtapid's LDL-C lowering effect, which should translate into increased uptake going forward in anti-PCSK9-refractory pts.[374]

346. On February 29, 2016, the Company issued a press release, which was also filed with the SEC as an Exhibit to a Form 8-K that same day,[375] announcing that it had entered into a third amendment to the forbearance agreement dated November 9, 2015, as amended on

[372] JPMorgan, *Thoughts Post 4Q; Reasons for Optimism, But Not Out of the Woods Yet*, Feb. 25, 2016.

[373] Cowen and Company, *Q4 In-line, Guidance Includes Big Cuts To Revenue And Expenses*, Feb. 26, 2016.

[374] Leerink, *4Q Recap: 2016 a Turnaround Year; Guidance Lower, PT to $15*, Feb. 26, 2016.

[375] Aegerion Pharm., Inc., Current Report (Form 8-K) (Feb. 29, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000110465916101002/a16-5475_18k.htm.

December 7, 2015 and January 7, 2016, between the Company and Silicon Valley Bank, wherein Silicon Valley Bank agreed to forbear exercising its rights under the Loan and Security Agreement through June 30, 2016.

347. On March 9, 2016, the Company revealed that it had determined it was "oversized in certain areas for the current state of the JUXTAPID business," and had reiterated that it "conducted a Company-wide resource analysis, and based on that finding, we enacted a 25% global reduction to the workforce to approximately 230 employees."[376]

348. Finally, the true extent of the Company's problems were fully revealed on May 12, 2016, when it announced that it had entered into preliminary agreements with the DOJ and SEC to settle those agencies' ongoing investigations for a total of $40 million. These preliminary agreements also called for two guilty pleas by Aegerion and also included a five-year deferred prosecution agreement with regard to charges that the Company violated the Health Insurance Portability and Accountability Act and engaged in obstruction of justice relating to the REMS program. *See* ¶83, *supra*.

349. As a result of this news, the Company's stock suffered a severe blow. It fell from a closing price of $2.30 per share on May 11, 2016 to a closing price of $1.91 per share on May 12, 2016, a drop of nearly 17%.

350. On May 16, 2016, the Company issued a press release wherein it announced that it expected full-year revenues for JUXTAPID to be between "$90 million and $100 million."[377]

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[376] Cowen Health Care Conf., Mar. 9, 2016, at 2.

[377] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (May 16, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837016006026/aegr-20160516ex99113664a.htm.

The Company also reported that, as of March 31, 2016, there were 498 active commercial patients on JUXTAPID therapy globally, approximately 373 of whom were U.S. patients.[378]

351. During the conference call with investors that followed, the Company reported total net product sales for the first quarter ended March 31, 2016 of $35.7 million, compared with "$59.4 million in the first quarter of 2015," and "net product sales for JUXTAPID for the first quarter ended March 31, 2016 were $26.2 million, compared with $57.3 million in the first quarter ended March 31, 2015."[379]

352. The Company further stated:

> First, with regard to repair, we are extremely pleased to have announced preliminary agreements in principle with the DOJ and the SEC related to ongoing investigations of our marketing and sales practices for JUXTAPID and related public disclosures. This represents a significant step forward for Aegerion.
>
> These legal and regulatory investigations, as well as the legal and other costs and uncertainties associated with them pose roadblocks to our execution of the strategy we outlined. And we're pleased to have these agreements in principle in place and to turn our attention to maximizing JUXTAPID and MYALEPT, developing a broad and sustainable pipeline and building an organization of the right size and structure to support these activities.
>
> As we disclosed last week, under the terms of the preliminary agreements in principle, we will make payments equal to $40 million over a period of five years beginning with a $3 million upfront payment paid upon settlement and quarterly payments thereafter. We worked closely with the DOJ and SEC to develop the terms of these agreements in principle and believe that they're in the best interest of shareholders, one that helps minimize the time and expense devoted to the investigation, allows us to satisfy the DOJ and SEC without placing undue burden on our stakeholders; and, most importantly, permits us to operate appropriately moving forward without placing overly significant constraints on our business.

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[378] Aegerion Pharm., Inc., Current Report (Form 8-K), Ex. 99.1 (May 16, 2015), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000155837016006026/aegr-20160516ex99113664a.htm.

[379] Thomson Reuters Streetevents, Edited Transcript, AEGR-Q1 2016, Aegerion Pharm. Inc., Earnings Conf. Call, May 16, 2016.

More specifically, under the terms of the preliminary agreements, we anticipate that we will not be precluded from doing business with government agencies, nor will our products be excluded from Medicare or Medicaid coverage, which of course is key to commercializing our products in the U.S.

Finally, the preliminary agreements are structured such that our payments to the government are back end weighted. This enables us to pay smaller sums up front and larger sums in the future, after we've had an opportunity to realign our business and when cash flows are more readily available.

* * *

In the first quarter, we deepened this resource analysis and also conducted a careful review of our JUXTAPID business and market opportunity. And as a result of this review, which I'll detail in a moment, we now have a new understanding of the JUXTAPID franchise and believe JUXTAPID should be able to generate approximately $65 million to $75 million in the U.S. revenue annually and $90 million to $100 million globally.

* * *

As was discussed in the past, the introduction of PCSK9 inhibitors has dramatically changed the landscape of the HoFH marketplace. After careful review, we believe that JUXTAPID offers the strongest value proposition to adult HoFH patients, who cannot be served by a PCSK9 inhibitor; for example, those patients who have little to no LDL receptor activity. This is a significantly smaller group of adult HoFH patients than previously envisioned for JUXTAPID.

We now expect JUXTAPID to bring in about $100 million globally in 2016 and approximately $65 million to $75 million annually in the U.S. moving forward. This conclusion is reflected in our quarterly results.

And as of March 31, there were 498 active patients on JUXTAPID globally, 373 of whom are U.S. patients. Based on our recent review of the JUXTAPID franchise, we believe that the most of the impact of PCSK9's launch on core JUXTAPID adult HoFH patients is behind us, as evidenced by the fact that the rate of patient erosion due to PCSK9 inhibitors flattened in the quarter, indicating a slower rate of patient switches. This is also true from a percentage standpoint. The proportion of patients dropping off therapy has continued to decrease and appears to be stabilizing in the low-single digits.

* * *

Total net product sales for the first quarter of 2016 were $35.7 million, compared to total net product sales of $59.4 million in the first quarter of 2015.

> Looking at JUXTAPID, net product sales were $26.2 million in the first quarter, compared to $57.3 million in the first quarter of 2015. About 90% of total JUXTAPID net product sales in the first quarter of 2016 came from prescriptions written in the U.S., while 10% were from prescriptions written outside the U.S.
>
> * * *
>
> And with regard to our 2016 financial guidance, we're revising our previously stated full year net sales guidance. We now expect total net product sales to be between $130 million and $150 million for full year 2016, including between $90 million and $100 million for JUXTAPID and between $40 million and $50 million for MYALEPT.[380]

353. Following the call, Cowen and Company issued an analyst report on May 16, 2016 that expressed significant concerns: "At the current sales levels of Juxtapid and Myalept, Aegerion is not profitable, and risks running out of capital to fund operations."[381] The report added: "Our model suggests that AEGR will need to continue to cut costs, and secure financing, in order to fund operations through 2017 and to achieve cash flow breakeven. AEGR did not provide cash flow or cash guidance on tonight's call." Cowen and Company laid the blame on the Company's inability to compete with PCSK9 inhibitors, stating that "[u]nfortunately, AEGR has struggled to maintain Juxtapid sales in face of competition from the PCSK9's, and to find lipodystrophy patients to grow Myalept revenue."[382]

354. Other analysts were similarly disappointed. On May 17, 2016, JPMorgan issued an analyst report in which it stated: "Bigger picture, however, the disappointing 1Q Juxtapid sales and substantial downward revision to Juxtapid guidance leave the sales trajectory for the

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[380] *Id*. at 4-6.

[381] Cowen and Company, *Reports Q1; 2016 Juxtapid Guidance Lowered*, May 16, 2016.

[382] *Id*.

product, and ultimate profitability of the company, in question. Along these lines, barring an improvement in sales trends we see a difficult path to recovery for the stock."[383]

355. On May 20, 2016, Jeffries issued an analyst report in which it stated that it was dropping coverage of Aegerion due to a "reallocation of resources" and noted that "[r]isks include continued declining sales of Juxtapid."[384]

356. Then, on June 15, 2016, the Company announced that it entered into a definitive merger agreement under which it would merge with a biotechnology company dedicated to the development and commercialization of innovative ocular products and that, upon completion, the combined companies would be known as Novelion.[385]

VII. LOSS CAUSATION

357. As detailed throughout and further herein, Defendants' fraudulent scheme artificially inflated Aegerion's stock price by misrepresenting and concealing: (1) that the Company was marketing JUXTAPID to cardiologists for off-label uses not authorized by the FDA; (2) the true weakness in Aegerion's prescription count and inability to accurately and effectively monitor and manage patient dropout and discontinuation rates; (3) the ongoing nature of the investigations by the DOJ and the SEC; and (4) the true impact of the PCSK9 inhibitors on JUXTAPID sales. While each of Defendants' misrepresentations and omissions was independently fraudulent, they all were motivated by Defendants' desire to artificially inflate Aegerion's stock price and misrepresent its future business prospects by giving the market the

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[383] JPMorgan, *Disappointing Juxtapid Sales & Guidance Cut*, May 17, 2016.

[384] Jefferies, *Dropping Coverage*, May 20, 2016.

[385] Aegerion Pharm., Inc., Current Report (form 8-K), Ex. 99.1 (June 15, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000110465916127353/a16-13380_1ex99d1.htm

false impression that Aegerion was engaging in lawful marketing practices and was actively and accurately monitoring prescription and patient counts. These false and misleading statements and omissions, among others, had the intended effect of preventing the market from learning the full truth and keeping the Company's stock price artificially inflated throughout the Class Period. Indeed, Defendants' false and misleading statements and omissions had the intended effect and caused, or were a substantial contributing cause of, Aegerion's stock trading at artificially inflated levels, reaching as high as $97.24 per share during the Class Period.

358. The true picture about Aegerion's marketing practices, dropout and discontinuation rates, and the impact of PCSK9 inhibitor competition emerged after the markets closed (a) on January 9, 2014, when it was reported that the Company had received a subpoena from the DOJ; (b) on February 26, 2014, when it was first reported that patient non-starts were higher than expected and that the Company's dropout rate was 15% versus the last reported amount of 10%; (c) on May 6, 2014, when the Company lowered its 2014 annual guidance for the first time; (d) on October 30, 2014, when the Company announced its financial results and business updates for the third fiscal quarter of 2014, wherein Defendants revealed that the Company was lowering FY 2014 revenue guidance for the second time since the beginning of the year and projecting a reduction of nearly 24% from its original announcement in January 2014; (e) on July 6, 2015 when Guggenheim downgraded Aegerion to "sell" with a price target of $9 reasoning that it believed JUXTAPID had passed its prime and the Company would have a difficult time enrolling new patients and controlling the dropout rate moving forward; (f) on November 9, 2015, when the Company reported its financial results for 3Q15, disclosed it was likely the Company would face some type of enforcement as a result of the DOJ investigation into its improper marketing practices, reported that as a consequence of the DOJ investigation,

the Company had defaulted on a $25 million loan, and disclosed that the cumulative patient dropout rates had increased 900 bps, to 58%; and (g) May 12, 2016 when the Company finally announced that it had plead guilty to two misdemeanor charges regarding the misbranding investigations by the DOJ and SEC and that it had agreed to pay $40 million to the DOJ and SEC over the course of the next five years.

359. The foregoing revelations on January 9, 2014, February 26, 2014, May 6, 2014, October 30, 2014, July 6, 2015, November 9, 2015, and May 12, 2016, indicated to the market that Defendants' prior Class Period statements were false and misleading. As a result, Aegerion's stock immediately dropped ***over 10%*** following the January 9, 2014 announcement, another ***17%*** following the February 26, 2014 announcement, an additional ***25%*** after the May 6, 2014 revelation, another ***41%*** following the October 30, 2014 revelation, ***over 6%*** following the July 6, 2015 announcement, an additional ***21%*** following the November 9, 2015 announcement, and ***nearly 19%*** following the May 12, 2016 revelation, each on abnormally high trading volume, as the market reacted to revelations in the Company's various announcements.

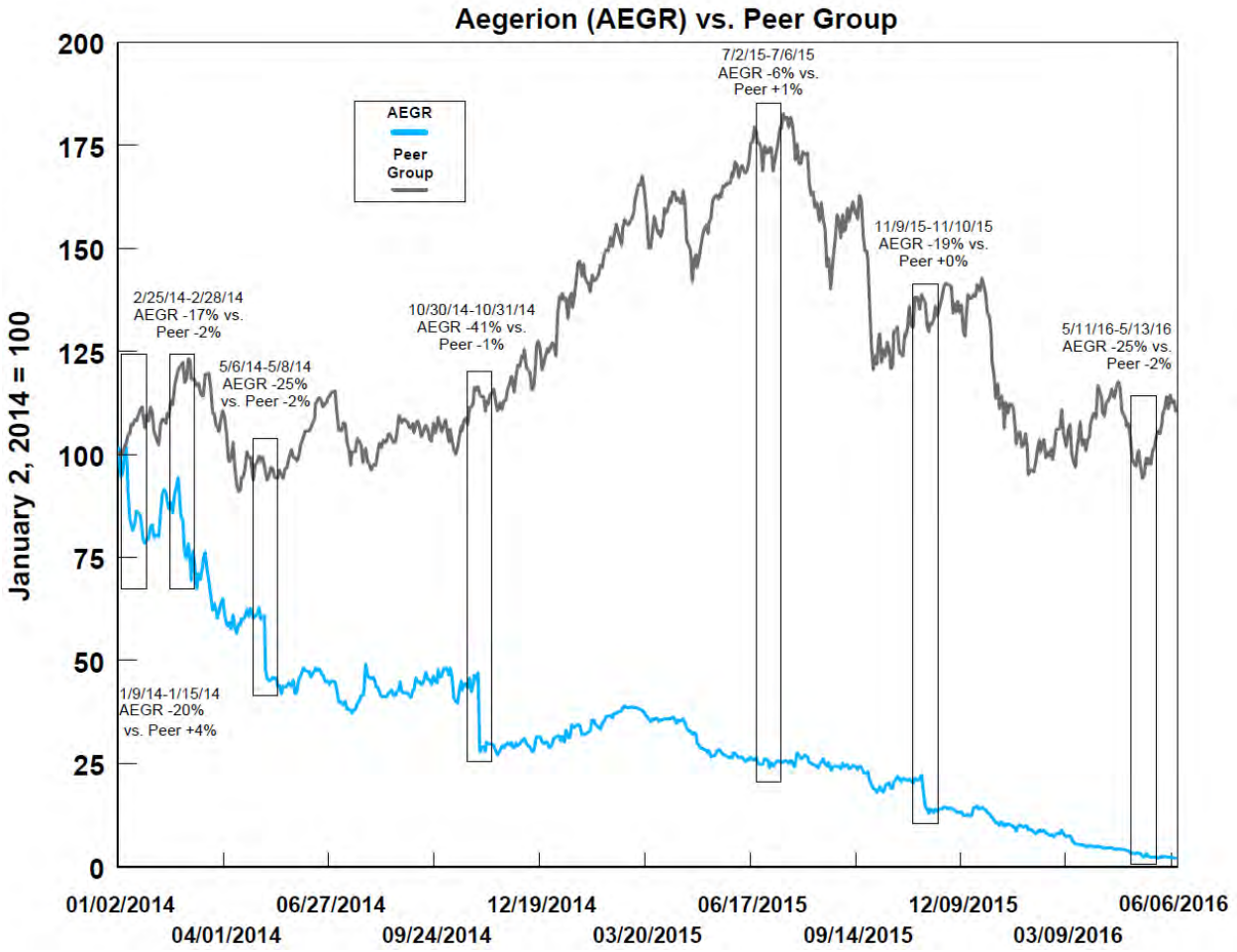
360. The rapid decline in Aegerion's stock price was the direct result of the nature and extent of the revelations made to investors and the market regarding the Company's true marketing initiatives, lackluster net sales, higher than expected dropout and/or discontinuation rates and low patient add-ons, and the true impact of PCSK9 inhibitor competition, which had been concealed or misrepresented by Defendants' fraudulent scheme and misstatements.

361. These revelations of the truth, as well as the resulting clear market reaction, support a reasonable inference that the market understood that Defendants' prior statements were false and misleading.

362. As the truth about Defendants' prior misrepresentations and concealments was revealed, the Company's stock price declined rapidly and dramatically, the artificial inflation was removed from the stock price, and Plaintiffs and other members of the Class were damaged.

363. The timing and magnitude of Aegerion's stock price declines during the Class Period negates any inference that the losses suffered by Plaintiffs were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. This point is evidenced by the chart below, which demonstrates the clear divergence of Aegerion's stock price from the aggregate stock price of its 2016 Peer Group[386] as the revelation of the truth became known to the market:

[386] Aegerion's Proxy Statement filed pursuant to Section 14(a) of the Securities Exchange Act filed on April 29, 2016 identifies 19 companies that comprised the Company's "2016 Peer Group," which were "selected on the basis of similarity to the Company at the time of selection based on the following criteria: business comparability, stage of product development, number of employees, market capitalization, financial profile and, to some degree, similarity of product or therapeutic focus." *See* Aegerion Pharm., Inc., Proxy Statement (DEF 14A) at 33 (Apr. 29, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1338042/000104746916012755/a2228493zdef14a.htm.



364. Damages suffered by Plaintiffs in the form of economic loss was a direct and proximate result of Defendants' fraudulent scheme and misrepresentations and omissions that artificially inflated Aegerion's stock price and the subsequent significant decline in the value of Aegerion's stock when the truth concerning Defendants' prior misrepresentations and fraudulent conduct entered the marketplace.

VIII. ADDITIONAL ALLEGATIONS REGARDING SCIENTER

365. The Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading, and knowingly or recklessly substantially

participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

366. The Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Aegerion, its operations, and its business practices, their control over and/or receipt of Aegerion's materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning, among other things, Aegerion's marketing practices and sales trends, were active and culpable participants in the fraudulent scheme alleged herein. The Individual Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information, which they caused to be disseminated to the investing public. The ongoing fraud as described herein could not have been perpetrated without the knowledge and/or recklessness and complicity of personnel at the highest level of the Company, including the Individual Defendants.

367. Defendants Beer and Fitzpatrick also undertook the affirmative obligation to obtain knowledge to ensure the Company's disclosures to the market were truthful when they executed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX Certifications"). The SOX Certifications stated that Defendants Beer and Fitzpatrick reviewed the Company's Form 10-Ks and Form 10-Qs throughout the Class Period and that they did "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[s] covered by" those reports. The SOX Certifications signed by Defendants Beer and Fitzpatrick were materially false and misleading because, at the time they were executed, these individuals were aware of, or recklessly disregarded, the severe deficiencies in the Company's financial and operational controls.

368. Moreover, as further detailed above (*see, e.g.*, ¶¶2, 29, 40, 117), during a significant part of the Class Period, JUXTAPID was Aegerion's only commercial product, and the commercialization of JUXTAPID was therefore ***the*** core operation of Aegerion. With a total global population of 4,000 to 5,000 patients (according to Defendants), at $295,000 per patient annually, the Company stated that it expected it would eventually exceed $1 billion in revenue annually. Therefore, patient-elected non-starts and dropouts/discontinuation of JUXTAPID, as well as the potential effects of competition from PCSK9 inhibitors, were of critical importance to the Company's core business product and function. Indeed, the Company's SEC filings (such as the 2013 Form 10-K) have conceded that "[o]ur business currently depends ***entirely***" on the success of JUXTAPID.

369. Even after Aegerion purchased a second commercial product, MYALEPT, JUXTAPID remained the Company's primary commercial product. For example, on May 4, 2015, Aegerion provided 2015 financial guidance stating it expected between $205 million and $235 million in global net product sales, of which between $195 million and $215 million related to JUXTAPID and between $10 million and $20 million related to MYALEPT. *E.g.*, ¶¶ 218, 298.

370. During the Class Period, the Individual Defendants were high-ranking officers (*i.e.*, CEO, COO, and CFO) who were intimately involved with, and had day-to-day responsibilities concerning, the Company's commercialization of JUXTAPID. Accordingly, through their receipt of internal reports and their involvement with the daily operations of Aegerion, the Individual Defendants were intimately aware of the true nature and prospects of the Company's commercialization of JUXTAPID and repeatedly touted the successful launch and performance of this product. As a result, as Aegerion's most senior executives, the

Individual Defendants knew or, at a minimum, were severely reckless in not knowing, about JUXTAPID's patient-elected non-starts and dropout/discontinuation rates, particularly among the Company's core population of severely ill patients, and the significant impact of PCSK9 inhibitors would have on the Company's core operation. Moreover, throughout the Class Period, the Individual Defendants made a number of specific statements about JUXTAPID, its prospects and related competition from other products. *See, e.g.*, ¶¶ 138, 140-43, 145, 149-52, 155, 159-63, 167-68, 173-79, 184-90, 195-97, 200-06, 208-12, 215-16, 218-20, 222-23, 225-29, 238-40. By choosing to speak about the patient-elected non-starts and dropout/discontinuation rates, guidance, and the potential impact of PCSK9 inhibitors, the Individual Defendants led investors to believe that they had specific knowledge, and/or had acquired specific knowledge, of these matters and were speaking truthfully.

371. During the Class Period, Aegerion had fewer than 300 full-time employees. *See* ¶¶230, 339, 347. When, as here, a company is small, it can be readily inferred that top executives are more likely to be aware of any alleged facts which strengthens the inference of scienter. Moreover, it would be absurd to suggest that senior management in such a small operation were without knowledge of matters directly affecting the marketability and profitability of its flagship (and for most of the Class Period, only commercially viable) product.

372. Apart from the foregoing, under applicable law, the cumulative knowledge of Aegerion's employees is imputed to the Company and supports a finding of corporate scienter.

373. As detailed above, the Individual Defendants had intimate knowledge of JUXTAPID's patient usage, patient-elected non-starts and dropout/discontinuation rates, financial projections, and impact of competing products such as PCSK9 inhibitors. *See, e.g.*, ¶¶ 120, 132, 174, 201, 251, 269-70. In fact, the Company monitored the successes of its illegal

marketing campaign and factored those successes into its global revenue forecast model for the U.S., which took into account both label use and "spontaneous use," defined as the non-label use of JUXTAPID. At times, the "spontaneous use" revenues were actually higher than the revenue forecasts for label use.

374. Further Defendant Fraser stated that "[w]e diligently monitor and manage the systems and process." ¶90. Reports were available to the Individual Defendants, and the Company regularly tracked patient-elected non-starts and dropouts/discontinuations. *See, e.g.*, ¶¶89-91. Moreover, Defendants themselves admitted to conducting extensive market research prior to the launch of JUXTAPID, and tracking JUXTAPID on a frequent basis through the Company's customer-facing program after the launch. *See, e.g.*, ¶¶101, 106, 163. This further demonstrates that, throughout the Class Period, Defendants closely monitored and possessed actual knowledge of, JUXTAPID's patient-elected non-starts, dropouts/discontinuation rates, and potential impact of PCSK9 inhibitors.

375. On January 9, 2014, the Company announced it had received a subpoena from the DOJ requesting documents concerning the illegal marketing of JUXTAPID. ¶¶75-76, 263. On May 12, 2016, Aegerion announced it had reached preliminary agreements in principle with the DOJ and SEC regarding a settlement of the ongoing investigations by those agencies into the Company's sales activities and disclosures related to JUXTAPID. The consolidated monetary package includes payments to the DOJ and the SEC totaling approximately $40 million.

376. Under the terms of the preliminary settlement agreement, the Company will plead guilty to two misdemeanor misbranding violations of the FDCA. One count is based on Aegerion's alleged marketing of JUXTAPID with inadequate directions for use, and the second count involves an alleged failure to comply with a requirement of the JUXTAPID REMS

program. The Company will also enter into a five-year deferred prosecution agreement with regard to charges that it violated the Health Insurance Portability and Accountability Act ("HIPPA") and engaged in obstruction of justice relating to the REMS program. Those guilty pleas described above are highly significant. It would constitute unconditional admissions of guilt, as well as an admission of all of the elements of a formal criminal charge. Indeed, as to those elements, such a plea is as conclusive as a jury verdict.

377. Defendants' HIPPA violations are further illustrated by the changes the Company made to its website with regard to the COMPASS program. Specifically, the Company altered the language outlining the various services provided by its patient outreach program (as detailed in ¶102, *supra*), to a very simple description of services mainly promoting the program's ability in "helping you navigate insurance coverage to making sure you receive your medication, to providing educational information."[387]

378. The preliminary agreement in principle with the DOJ also requires the Company to enter into a civil settlement agreement with the DOJ to resolve alleged violations of the False Claims Act. Additionally, Aegerion will enter into a non-monetary consent decree with the FDA prohibiting future violations of law and may have to enter into a corporate integrity agreement with the Department of Health and Human Services as part of any final settlement with the DOJ.

379. On July 27, 2015, while Aegerion was under investigation by the SEC and DOJ, Aegerion announced that Defendants Beer and Fraser had resigned, effective immediately. These purported resignations evidence that knowledge of the violations alleged herein reached the very highest levels of the Company.

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[387] *See* Juxtapid – Support Services: The COMPASS Program, http://juxtapid.cbstage.com.php53-12.dfw1-2.websitetestlink.com/healthcare-professionals/patients/compass-support-program (last visited June 27, 2016).

380. These facts, in conjunction with the additional indicia of scienter detailed in the Substantive Allegations above, particularly Defendants' specific and repeated assurances that they were tracking, measuring, focusing on and knowledgeable regarding patient-elected non-starts and dropout/discontinuations, collectively support a strong inference of each Individual Defendant's scienter.

381. In addition, while in possession of non-public adverse information regarding the Company's true marketing efforts and true patient-elected non-starts and dropouts/discontinuation rates of JUXTAPID – the Company's core product – the Individual Defendants took full advantage of the artificial inflation of Aegerion's stock price caused by their misrepresentations and omissions. In fact, during the Class Period, the Individual Defendants disposed of a combined 156,000 shares of common stock for proceeds greater than ***$13 million***.

382. Indeed, on October 30, 2014, just days before receipt of the FDA Warning Letter, Defendant Beer sold 40,000 shares of Aegerion common stock at an artificially inflated prices of between $84.15 and $99.18 per share, for total proceeds of over $3.5 million. In addition to the more than $5 million he sold on August 15, 2014, Defendant Beer liquidated over ***$8,824,150***, or nearly 8% of his ownership in the Company, during the Class Period.

383. Defendant Fitzpatrick's stock sale was unusual and suspicious in amount in that he liquidated more than 7.6% of his common stock holdings, or ***$1,763,168***, during the Class Period.

384. Additionally, between October 7, 2013 and April 30, 2014, Defendant Fraser sold 33,500 shares of Aegerion common stock at an artificially inflated prices of between $43.18 and

$96.25 per share for total proceeds of ***$2,721,506***. Defendant Fraser's stock sale was unusual and suspicious in amount in that he liquidated more than 18.13% of his common stock holdings.

Filer Name	Title	Date	Shares	Price	Proceeds
Marc D. Beer	CEO	15-Aug-2013	21,160	$89.95	$1,903,342
		15-Aug-2013	12,301	$88.21	$1,085,071
		15-Aug-2013	100	$90.72	$9,072
		15-Aug-2013	6,275	$89.09	$559,040
		15-Aug-2013	20,164	$87.08	$1,755,881
		30-Oct-2013	300	$95.90	$28,770
		30-Oct-2013	10,000	$87.08	$870,800
		30-Oct-2013	2,800	$84.15	$235,620
		30-Oct-2013	6,019	$87.83	$528,649
		30-Oct-2013	200	$94.25	$18,850
		30-Oct-2013	1,200	$99.18	$119,016
		30-Oct-2013	2,314	$85.94	$198,865
		30-Oct-2013	3,800	$89.01	$338,238
		30-Oct-2013	2,700	$89.85	$242,595
		30-Oct-2013	7,067	$85.00	$600,695
		30-Oct-2013	2,500	$91.21	$228,025
		30-Oct-2013	700	$92.03	$64,421
		30-Oct-2013	400	$93.00	$37,200
Mark J. Fitzpatrick	CFO	14-Aug-2013	2,512	$92.74	$232,963
		14-Aug-2013	4,400	$93.71	$412,324
		14-Aug-2013	588	$94.44	$55,531
		11-Nov-2013	200	$76.14	$15,228
		11-Nov-2013	200	$73.01	$14,602
		11-Nov-2013	200	$74.43	$14,886
		11-Nov-2013	622	$78.38	$48,752
		11-Nov-2013	1,800	$80.03	$144,054
		11-Nov-2013	4,478	$79.34	$355,285
		10-Feb-2014	486	$64.69	$31,439
		10-Feb-2014	900	$63.72	$57,348
		10-Feb-2014	2,814	$62.94	$177,113
		10-Feb-2014	3,300	$61.71	$203,643
Craig Fraser	COO	07-Oct-2013	3,800	$94.82	$360,316
		07-Oct-2013	7,092	$93.18	$660,833
		07-Oct-2013	9,008	$92.40	$832,339
		07-Oct-2013	100	$96.25	$9,625
		01-Nov-2013	1,550	$83.22	$128,991
		01-Nov-2013	300	$82.28	$24,684
		01-Nov-2013	400	$83.99	$33,596

		02-Dec-2013	1,550	$70.10	$108,655
		02-Dec-2013	700	$71.10	$49,770
		02-Jan-2014	900	$70.65	$63,585
		02-Jan-2014	1,350	$71.42	$96,417
		11-Feb-2014	2,250	$67.00	$150,750
		31-Mar-2014	1,149	$45.84	$52,670
		31-Mar-2014	1,001	$46.51	$46,557
		31-Mar-2014	100	$47.20	$4,720
		30-Apr-2014	1,171	$43.90	$51,407
		30-Apr-2014	1,079	$43.18	$46,591
Total					***$13,308,824***

IX. PRESUMPTION OF RELIANCE

385. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein are primarily predicated upon omissions of material fact which Defendants had a duty to disclose. Specifically, Plaintiffs are entitled to a presumption of reliance throughout the Class Period because, as more fully alleged above, Defendants failed to disclose material information regarding, *inter alia*, Aegerion's marketing practices, as well as its new patient add-ons, and higher-than-reported dropout and/or discontinuation rates.

386. Plaintiffs also are entitled to a presumption of reliance under the fraud-on-the-market doctrine for Defendants' material misrepresentations, because the market for Aegerion's publicly traded common stock was open, well-developed, and efficient at all times. As a result of Defendants' materially false and misleading statements, Aegerion's publicly traded common stock traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Aegerion's publicly traded common stock relying upon the integrity of the market price of those securities and the market information relating to Aegerion, and have been damaged thereby.

387. At all relevant times, the market for Aegerion's securities was an efficient market for the following reasons, among others:

(a) Aegerion's stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Aegerion regularly made public filings with the SEC, including its Form 10-Ks, Form 10-Qs, and related press releases;

(c) Aegerion regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press, and other similar reporting services; and

(d) Aegerion was followed by several securities analysts employed by major brokerage firms, such as JPMorgan Securities LLC, Cowen and Company, Jefferies, Leerink, and Canaccord Genuity, among others, who wrote research reports that were distributed to each brokerage firms' sales force and the public at large. Each of these reports was publicly available and entered the public marketplace.

388. As a result of the foregoing, the market for Aegerion's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of Aegerion's common stock.

389. Under these circumstances, all purchasers of Aegerion's publicly-traded common stock during the Class Period suffered similar injury through their purchase of such at artificially inflated prices. As a result, a presumption of reliance applies.

390. At the times they purchased or otherwise acquired Aegerion's publicly-traded common stock, Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not reasonably have discovered those facts. As a result, the presumption of reliance applies.

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

(a) Defendants made public misrepresentations during the Class Period;

(b) the misrepresentations were material;

(c) the Company's common stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's publicly traded common stock; and

(e) Plaintiffs and other members of the Class purchased the Company's securities between the time Defendants misrepresented material facts and the time the true facts were disclosed, without knowledge that such facts were misrepresented.

X. NO SAFE HARBOR

392. The federal statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the allegedly false and misleading statements pled in this complaint. Many of the specific statements pled herein were not identified as "forward-looking statements" when made. 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.

393. Indeed, the risk warnings that were provided by Defendants in their Class Period statements (and before), include boilerplate statements, such as:

- Our business depends primarily on the success of lomitapide. We may not be able to meet expectations with respect to sales of lomitapide and revenues from such sales, and if we are not able to meet such expectations, we may not be able to attain or maintain positive cash flow and profitability in the time periods we anticipate, or at all.

- We may not be able to gain market acceptance for lomitapide.

- The number of patients suffering from HoFH is small, and has not been established with precision. We believe that the patient population is significantly larger than the reported prevalence indicates, but our assumptions and estimates may be wrong. If the actual number of patients is smaller than we estimate or if any approval outside the U.S. and EU is based on a narrower definition of these patient populations, our revenue and ability to achieve profitability and to become cash-flow positive will be adversely affected, possibly materially.

- As a result of the side effects observed in the Phase 3 clinical study and other clinical and preclinical studies of lomitapide, the prescribing information for lomitapide in the U.S. and the EU and in the other countries in which lomitapide is approved contains significant limitations on use and other important warnings and precautions, including a boxed warning in the JUXTAPID labeling, and warnings in the LOJUXTA prescribing information, citing concerns over liver toxicity. Lomitapide may continue to cause such side effects or have other properties that could impact market acceptance, result in adverse limitations in any approved labeling or other adverse regulatory consequences, including delaying or preventing additional marketing approval in territories outside the U.S. and EU.

- If we are unable to execute effectively our sales and marketing activities, we may be unable to generate sufficient product revenue.

- We may face resistance from certain private, government and other third-party payers given the price we charge for JUXTAPID in the U.S., and expect to charge for lomitapide in the EU and in other countries in which lomitapide is or may be approved. It will be difficult for us to profitably sell lomitapide if reimbursement for the product is limited or delayed.

- The amount of reimbursement for JUXTAPID and the manner in which government and private payers in the U.S. may reimburse for our potential products is uncertain.

- The FDA, the EU Member States and other regulatory agencies outside the U.S. actively enforce laws and regulations prohibiting the promotion of off-label uses. If we are found to have promoted off-label uses, we may be subject to significant liability.

394. These or other materially identical risks were disseminated well before the Class Period and did not serve to adequately inform the market of the true risks and actual operational experience of the Company.[388] Indeed, that these stated warnings were inadequate and provided no new, meaningful, information, is evident from the market's reaction to the revelation of Defendants' prior untrue and/or misleading statements. *See, e.g.*, ¶¶357-364, *supra*.

395. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pled herein, Defendants are liable for those false and misleading forward-looking statements because, at the time each of those forward-looking statements were made, as detailed above in the Substantive Allegations, the particular speaker had actual knowledge that the particular forward-looking statement was false or misleading and/or the forward-looking statement was authorized and/or approved by an executive officer of Aegerion who had actual knowledge that those statements were false or misleading when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading since they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

XI. PLAINTIFFS' CLASS ACTION ALLEGATIONS

396. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all those who purchased or otherwise acquired the publicly traded common stock of Aegerion between April 30, 2013 and

[388] *Compare* FY 2010 Aegerion Pharm., Inc., Annual Report (Form 10-K), at 27-41 (Mar. 31, 2011), *with* FY 2011 Aegerion Pharm., Inc., Annual Report (Form 10-K), at 31-49 (Mar. 15, 2012), *with* 2012 Form 10-K, at 27-46, *with* 2013 Form 10-K, at 35-47, *with* 2014 Form 10-K, at 44-74, *available at* https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001338042&type=10-k&dateb=&owner=exclude&count=40.

May 11, 2016, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

397. Because Aegerion has millions of shares of common stock outstanding and because the Company's shares were actively traded on the NASDAQ, members of the Class are so numerous that joinder of all members is impracticable. According to Aegerion's SEC filings, as of March 31, 2016, Aegerion had approximately 29.5 million shares of common stock outstanding.[389] While the exact number of Class members can only be determined by appropriate discovery, Plaintiffs believe that Class members number at least in the thousands and that they are geographically dispersed.

398. Plaintiffs' claims are typical of the claims of the members of the Class because Plaintiffs and all of the Class members sustained damages arising out of Defendants' wrongful conduct complained of herein.

399. Plaintiffs will fairly and adequately protect the interests of the Class members and have retained counsel experienced and competent in class actions and securities litigation. Plaintiffs have no interests that are contrary to, or in conflict with, the members of the Class they seek to represent.

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

[389] Aegerion Pharm., Inc., Quarterly Report (Form 10-Q) (May 16, 2016), available at https://www.sec.gov/Archives/edgar/data/1338042/000155837016006027/aegr-20160331x10q.htm.

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

401. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members in that Defendants have acted on grounds generally applicable to the entire Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants violated the federal securities laws as alleged herein;

(b) whether Defendants' publicly disseminated press releases and statements during the Class Period omitted and/or misrepresented material facts;

(c) whether Defendants failed to convey material facts or to correct material facts previously disseminated;

(d) whether Defendants participated in and pursued the fraudulent scheme or course of business complained of herein;

(e) whether Defendants acted knowingly or with severe recklessness, in omitting and/or misrepresenting material facts;

(f) whether the market prices of Aegerion's securities during the Class Period were artificially inflated due to the material nondisclosures and/or misrepresentations complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the appropriate measure of damages.

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

402. Plaintiffs repeat and reallege the allegations set forth above as though fully set forth herein. This claim is asserted against all Defendants.

403. During the Class Period, Aegerion and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, Plaintiffs, and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Aegerion's publicly traded common stock; and (iii) cause Plaintiffs and other members of the Class to purchase Aegerion's publicly traded common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Aegerion and the Individual Defendants, and each of them, took the actions set forth herein.

404. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Company's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued as primary participants in the wrongful and illegal conduct charged herein. The Individual Defendants are also sued as controlling persons of Aegerion, as alleged below.

405. In addition to the duties of full disclosure imposed on Defendants as a result of their making affirmative statements and reports, or participating in the making of affirmative statements and reports to the investing public, they each had a duty to promptly disseminate

truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. §210.01, *et seq*.) and S-K (17 C.F.R. §229.10, *et seq*.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, sales, product marketing and promotion, financial condition, and operational performance so that the market price of the Company's publicly traded common stock would be based on truthful, complete, and accurate information.

406. Aegerion and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information regarding, among other things, the Company's illicit marketing practices, and Aegerion's patient elected non-starts, dropout rate, and associated revenue guidance as specified herein.

407. Defendants each employed devices, schemes, and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Aegerion's value, performance and continued substantial sales and financial growth, which included, among other things, the making of, or the participation in the making of, untrue statements of material facts about the Company's marketing practices and Aegerion's patient elected non-starts, dropout rates and associated revenue guidance and omitting to state material facts necessary to make the statements made about revenue not misleading in light of the circumstances under which they were made, as set forth more particularly herein, and engaged in transactions, practices, and a

course of business which operated as a fraud and deceit upon the purchasers of Aegerion's common stock during the Class Period.

408. The Individual Defendants' primary liability arises from the following facts, among others: (i) the Individual Defendants were high-level executives at the Company during the Class Period; (ii) the Individual Defendants, by virtue of their responsibilities and activities as senior executive officers, were privy to, and participated in, the creation, development, and reporting of the Company's sales, marketing, projections, and/or reports; (iii) the Individual Defendants enjoyed significant personal contact and familiarity with, were advised of, and had access to other members of the Company's management team, internal reports, and other data and information about the Company's marketing practices, prescriptions, and patient count at all relevant times; and (iv) the Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

409. Each of the Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with severely reckless disregard for the truth, in that each failed to ascertain and disclose such facts, even though such facts were available to each of them. Defendants' material misrepresentations and/or omissions were made knowingly or with deliberate recklessness and for the purpose and effect of concealing adverse information regarding the Company from the investing public and supporting the artificially inflated price of its securities. As demonstrated by the Individual Defendants' misstatements and omissions throughout the Class Period, the Individual Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain

such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

410. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Aegerion common stock was artificially inflated during the Class Period. In ignorance of the fact that the market price of Aegerion's publicly traded common stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the stock traded, and/or on the absence of material adverse information that was known to, or disregarded with deliberate recklessness by, Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and other members of the Class acquired Aegerion's publicly traded common stock during the Class Period at artificially high prices and were damaged thereby, as evidenced by, among others, the stock price declines referenced above.

411. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known of the true nature and prospects of Aegerion's revenue figures, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Aegerion publicly traded common stock during the Class Period; or, if they had purchased or otherwise acquired such during the Class Period, they would not have done so at the artificially inflated prices which they paid.

412. By virtue of the foregoing, Aegerion and the Individual Defendants have each violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

413. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their respective purchases and sales of the Company's publicly traded common stock during the Class Period, as evidenced by the stock price declines discussed above, when the artificial inflation was removed from the price of Aegerion's stock.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

414. Plaintiffs repeat and reallege the allegations set forth above as though fully set forth herein. This claim is asserted against the Individual Defendants.

415. The Individual Defendants acted as controlling persons of Aegerion within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in, and/or awareness of, the Company's operations, and/or intimate knowledge of the Company's fraudulent practices and the Company's actual results and future prospects, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

416. In addition, the Individual Defendants had direct 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 transactions giving rise to the securities violations as alleged herein and exercised the same.

417. As set forth above, Aegerion and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their controlling positions, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's publicly traded common stock during the Class Period, as evidenced by the stock price declines discussed above, when the artificial inflation was removed from the price of Aegerion's stock.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the Class, pray for relief and judgment, as follows:

(a) Declaring that this action is a proper class action and certifying Plaintiffs as Class representatives pursuant to Rule 23 of the Federal Rules of Civil Procedure and Lead Counsel as Class Counsel for the proposed Class;

(b) Awarding compensatory damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Such other and further relief as the Court deems appropriate.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

DATED: June 27, 2016

ROBBINS GELLER RUDMAN
& DOWD LLP

/s/ Jack Reise
JACK REISE

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CERTIFICATE OF SERVICE

I, Jack Reise, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and papers copies will be sent to those indicated as non-registered participants on June 27, 2016.

/s/ Jack Reise