UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. AMARIN CORPORATION PLC, JOHN F. THERO, and MICHAEL W. KALB, Defendants.	Civil Action No.: CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, brings this complaint against Amarin Corporation plc ("Amarin" or the "Company"), John F. Thero ("Thero"), and Michael W. Kalb ("Kalb"), (collectively, "Defendants") based upon personal knowledge as to his own acts and on information and belief as to all other matters. Plaintiff based this information and belief on, among other things, the investigation conducted by counsel, which included, among other things, a review of the U.S. Securities and Exchange Commission ("SEC") filings of Amarin, Company press releases and other public statements, and analysts' reports, media reports and other publicly disclosed reports and information about the Company. Counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to Defendants or are exclusively within their custody or control. Plaintiff's investigation indicates substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a Class consisting of all persons and entities who purchased or otherwise acquired Amarin securities between December 5, 2018 and June 21, 2021, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder by the SEC.

2. Amarin is a biopharmaceutical company whose lead product since 2008 is Vascepa® (AMR-101) ("Vascepa"), a prescription grade ultra-pure omega-3 fatty acid derived from fish oil. In July 2012, the U.S. Food and Drug Administration ("FDA") first approved Vascepa to treat patients with very high levels of triglycerides ("TG"), a type of fat found in blood,

and in December 2019, expanded the label to include the reduction of cardiovascular disease events, including heart attack, stroke and cardiovascular death, in high-risk patients.

3. In order to protect its market share, Amarin sought and obtained dozens of U.S. patents in connection with Vascepa, including for its formulation and method of use. Indeed, going into the Class Period, Vascepa stood to have patent protection until 2030, when the last patent was set to expire. At the same time, Amarin was engaged in patent litigation against applicants who submitted Abbreviated New Drug Applications ("ANDA") for generic drug products of Vascepa – exposing the Company to real risks related to the validity and scope of coverage in its patent portfolio.

4. Patent litigation can be fairly common in the pharmaceutical industry, and throughout the Class Period, Defendants gave the impression that such litigation was simply a cost of doing business and did not pose a material threat to the Company's business or future prospects. As Defendant Thero, Amarin's President and Chief Executive Officer ("CEO"), stated on the first day of the Class Period:

> There were four [ANDA filers]. One of them dropped out fairly early. Another was Teva. They settled. They could come into the market in August 2029, so about 11 years from now. The other two, Hikma and Dr. Reddy's continue in the litigation process. There's been no court date set yet. There have been Markman hearings.
>
> I think the results coming out of that claims construction was very favorable to us. At least one of the claimant says acknowledge that if they were to launch, they would be infringing upon our patents. I think it's sort of impossible not to. ***Our patents cover key elements of the label for the product, and you can't have a generic without having that label***. We intend to defend our patents vigorously.
>
> I think they'd have to – if they're acknowledging that they infringe, they'd have to invalidate these patents. And ***these patents were heavily prosecuted through the US Patent Office***.[1]

[1] Unless otherwise noted, internal citations are omitted and emphasis is added throughout.

5. What Defendants failed to disclose, however, was that as the litigation progressed, there was an increasingly high risk that some of Amarin's key patents would be invalidated because the asserted claims were obvious based on earlier printed publications. As a result, the Company was not as strong of a merger and acquisition ("M&A") target as investors believed.

6. From the start of the Class Period, industry analysts touted Amarin as "represent[ing] one of the few wholly owned, global, multi-billion-dollar pot'l products that fits easily with DTC ads and M&A pharma tuck-in." This was because Vascepa was "already FDA approved and ramping now, and the pot'l new big label expansion coming by early 2020 takes it perfectly for big pharma from current niche drug (high TG) to broad primary care opportunity (CV risk reduction for wide population). Big pharma needs 'big' drugs in 'big' markets and there aren't that many around that are de-risked."

7. Specifically, throughout the Class Period, Defendants made false and misleading statements and/or failed to disclose that: (i) there was an increasingly high risk that certain of Amarin's patents would be invalidated; (ii) once the District Court invalidated certain of Amarin's patents, there was little to no chance of reversing that ruling; (iii) the Company's litigation was preventing it from effectuating a successful takeover; (iv) Defendants were downplaying the true threat the ongoing ANDA litigation posed to the Company's business and future prospects; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

8. After markets closed on March 30, 2020, Defendants partially revealed the truth about the strength of Amarin's patent portfolio. That day, the Company announced that "the United States District Court for the District of Nevada's rul[ed] in favor of the generic companies in the

company's patent litigation against two filers of abbreviated new drug applications, or ANDAs, for Amarin's VASCEPA® (icosapent ethyl) capsule franchise."

9. On this news, Amarin's share price plummeted over ***70.5%*** to close at $4.00 on March 31, 2020, on heavy trading volume.

10. Analysts recognized that investors were beginning to learn about weaknesses in the patent protection the Company had touted. As Seeking Alpha ("SA") news editor Stephen Alpher noted in an article titled "Amarin plunges after court decision on Vascepa" on March 30, 2020, the Company "has lost its patent battle against generics."

11. To allay investor concerns, Defendant Thero provided reassurance that "[w]e believe ***we are favorably situated to obtain an injunction against generic launch pending appeal***, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal." Thus, despite Amarin's loss in the District Court, Defendants expressed confidence in the appeal, and in the strength of its patent portfolio and business prospects, boasting that the Company was continuing to pursue additional regulatory approval in other countries. Consequently, investors saw the potential for a revival of Amarin's key patents and still believed the Company was a viable M&A target.

12. Then, starting at 10:00 AM ET on September 2, 2020, the U.S. Court of Appeals for the Federal Circuit held an oral argument for the Company's patent litigation. The very next day, the Federal Circuit affirmed the District Court's ruling.

13. As the oral argument had progressed and the Federal Circuit's ruling had become known to investors, Amarin's share price fell over 34.5% to close at $4.30 on September 4, 2020, on heavy trading volume, as the truth about the Company's patent portfolio continued to emerge.

14. As SA news editor Douglas W. House noted on September 2, 2020, "arguments by attorneys representing the company are not going that well. Shares are down 27% on almost 7x higher volume 2 1/2 hours into session." Another SA analyst similarly noted on September 6, 2020, "Amarin shares have taken a beating this week during the appellate hearing and especially after the adverse ruling came down on September 3."

15. Despite the appellate loss, the Company continued to assure investors about the strength of its patent portfolio. On September 3, 2020, the Company issued a press release stating that it would be filing a petition with the U.S. Supreme Court for an *en banc* review of the Federal Circuit's decision and "continuing to pursue additional regulatory approvals for VASCEPA in China, Europe and the additional countries in the Middle East." The Company further stated that "[g]eographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this litigation and judgment. No generic litigation is pending outside the United States." As a result, the market still believed that the Company was a desirable target and well positioned to effectuate a successful takeover.

16. Then, on April 12, 2021, Amarin announced the retirement of Defendant Thero as President and CEO and the appointment of the Company's Senior Vice President ("SVP") and Head of Commercial for Europe, Karim Mikhail, as his successor, effective August 1, 2021. In announcing the "CEO Succession Plan," the Company highlighted that previously, Mr. Mikhail had been "responsible for reversing [Merck's] decline in the U.S. market and globally, accelerating revenue by an additional $380 million through the launch of ATOZET and driving EBITDA growth through international expansion. Prior to that, Mr. Mikhail led the successful commercial launch of dozens of products, including ezetimibe and various molecules in diabetes, hypertension,

immunology, and oncology, and served as Merck's chief marketing officer for Europe, Middle East and Africa and chief operating officer for emerging markets."

17. On this news, the Company's share price fell over 14.3% to close at $5.08 on April 13, 2021, on heavy trading volume.

18. As one analyst explained it on April 12, 2021, Amarin "[i]nvestors may be disappointed in the transition and that it may signal no near-term M&A on the table (which is the clear and primary bull case to the stock)." However, the "strategic move could finally unlock the [C]ompany's value" because as noted on April 13, 2021, by another analyst, while Defendant Thero "deserves some credit for overseeing the completion of the landmark REDUCE-IT trial, he also must take responsibility for their legal failures, their underwhelming sales performance, and the share price." For the "new era", Mr. Mikhail "brings with him substantial connections in Europe from his time with Merck."

19. Despite Defendants' consistent reassurances in the strength of Amarin's patent portfolio and its abilities to vigorously defend this critical asset, on June 21, 2021, investors learned "that the Supreme Court rejected the [C]ompany's bid to revive Vascepa patents."

20. On this news, Amarin's share price fell 8.3% to close at $4.54 on June 23, 2021, on heavy trading volume.

21. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Amarin's securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

22. The claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. § 240.10b-5.

23. This Court has jurisdiction over the subject matter of this action under § 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States of America.

24. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa(c), and 28 U.S.C. § 1391(b). Amarin maintains its executive office in this District, Defendants conduct business in this District, and a significant portion of Defendants' actions took place within this District.

25. In connection with the acts and conduct alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, without limitation, the U.S. mail, interstate telephone and other electronic communications and the facilities of the NASDAQ Global Select Market ("NASDAQ"), a national securities exchange.

III. PARTIES

26. Plaintiff purchased Amarin securities at artificially inflated prices during the Class Period, as set forth in the accompanying Certification incorporated by reference herein and was damaged upon the revelation of the alleged corrective disclosures.

27. Defendant Amarin is a biopharmaceutical company with its headquarters located in Dublin, Ireland and its U.S. office located at 440 Route 22, Bridgewater, New Jersey, 08807. Amarin shares traded on the NASDAQ under the symbol "AMRN" during the Class Period.

28. Defendant Thero was, at all relevant times, President and Chief Executive Officer ("CEO") and a director of Amarin.

29. Defendant Kalb was, at all relevant times, SVP and Chief Financial Officer ("CFO") of Amarin.

30. Defendants Thero and Kalb are collectively referred to herein as the "Individual Defendants." During the Class Period, the Individual Defendants ran the Company as hands-on managers overseeing Amarin's operations and made the materially false and misleading statements described herein. The Individual Defendants were privy to confidential and proprietary information concerning the Company, its operations, product, finances, financial condition, and present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Amarin, its singular product, Vascepa, its extensive intellectual property, and the pending litigation. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts contradicting their misrepresentations and omissions that had not been disclosed to, and were being concealed from, the investing public. The Individual Defendants are liable for the false statements and omissions pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

A. Relevant U.S. Regulatory Background

31. Prior to marketing or selling a new drug (*i.e.*, a "brand-name drug") in the U.S., a potential drug manufacturer or sponsor must obtain a grant of approval from the FDA. To do so, an applicant must file a New Drug Application ("NDA"), which contains, *inter alia*, information about safety and efficacy of the drug, the components of the drug, and any patents issued on the composition of the drug or methods for its use. Upon approval of an NDA, the FDA publishes the drug and patent information in the "Orange Book," formerly known as *Approved Drug Products with Therapeutic Equivalence Evaluations*.

32. New Drug Product Exclusivity is available for new chemical entities ("NCE")[2], which, by definition, are innovative, and for significant changes in already approved drug products, such as a new use. Exclusivity provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug product. This limited protection precludes submission or approval of certain ANDA for prescribed periods of time.

33. A 5-year period of exclusivity is granted to NDAs for products containing NCEs never previously approved by the FDA either alone or in combination. During the 5-year exclusivity period, no ANDA may be submitted, with the exception that such applications may be submitted after 4 years if they contain a certification of patent invalidity or noninfringement.

34. A 3-year period of exclusivity is granted for a drug product that contains an active moiety that has been previously approved, when the NDA contains reports of new clinical investigations[3] conducted, that were essential to approval of the NDA. For example, the changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of

[2] NCE means a drug that contains no active moiety that has been approved by the FDA in any other application submitted. An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

[3] FDA interprets "new clinical investigation" as an investigation in humans, the results of which: (1) have not been relied upon by the FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety in a new patient population; and (2) do not duplicate the results of another investigation relied upon by FDA to demonstrate a previously approved drug's effectiveness or safety in a new patient population. A clinical investigation that provides a "new" basis for approval of an application can qualify for exclusivity. In this context, "new" is intended to convey a lack of prior use of a clinical investigation rather than any temporal requirement.

administration or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the NDA containing those changes.

35. Generic drugs, as required by regulation of the FDA, are exact copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

36. To promote the development of more generic drugs and to speed up the approval process, Congress passed the Hatch-Waxman Act in 1984. Under the Hatch-Waxman Act, a potential generic manufacturer only needs to file an ANDA if it can establish that its generic is the bioequivalent of an FDA-approved brand-name drug.

37. An ANDA applicant must, *inter alia*, make one of four "paragraph certifications": (1) no patent information for the brand-name drug has been filed with the FDA ("paragraph I"); (2) the patent has expired ("paragraph II"); (3) the patent will expire on a specifically identified date ("paragraph III"); or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted ("paragraph IV").

38. An applicant that certifies under paragraph IV must send prompt notice to the patent holder of its position that the patent is invalid or will not be infringed by the applicant's generic drug. This notification triggers a 45-day period during which the patent holder may file an infringement lawsuit against the ANDA applicant to prevent the FDA from proceeding with the ANDA application process. The ANDA thus gives the brand-name manufacturer a jurisdictional basis on which it may bring an infringement suit without the generic having yet come to market. If the patentee files an infringement suit, the FDA stays the ANDA approval process for either 30-months or until the generic manufacturer has obtained a final judgment of non-infringement or invalidity, whichever occurs first.

B. Amarin and its Patent Litigation

39. Amarin is a biopharmaceutical company focused on the commercialization and development of Vascepa, a brand-name prescription drug, primarily used to treat heart disease. Vascepa is made up of a single ultra-purified omega-3 fatty acid: Eicosapentaenoic acid ("EPA"), derived from fish oil. EPA has purportedly been associated with cardiovascular benefits including reducing TG levels, inhibiting platelet aggregation, stabilizing plaque, causing anti-inflammatory effects, and improving blood flow.

40. The FDA first approved Vascepa on July 26, 2012, as "an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG greater than or equal to 500 mg/dL) hypertriglyceridemia." The approved daily dose of Vascepa was 4 grams per day, taken as two 1-gram (or four 500 mg) capsules twice daily with food.

41. Amarin has long claimed that its success depended, in part, on the Company's ability to obtain and maintain intellectual property protection. As of February 2014, Amarin had 40 patent applications in the U.S. that had been either issued or allowed and more than 30 additional patent applications are pending. Of the 40 issued or allowed, Amarin had two directed to a pharmaceutical composition of Vascepa in a capsule, one covering a composition containing highly pure EPA, and several others covering the method of use of Vascepa, as implemented in two clinical trials (ANCHOR and MARINE) conducted by the Company.

42. By the first half of 2014 generic manufacturers saw Vascepa as an open brand-name target. Amarin received six paragraph IV notices notifying the Company of accepted ANDAs based on the FDA's determination that Amarin was entitled to 3-year exclusivity. As a result, Amarin sued the ANDA applicants for patent infringement, and filed a lawsuit against the FDA seeking an order requiring the FDA to recognize a 5-year, NCE exclusivity for Vascepa.

43. On May 28, 2015, the Company announced that Judge Randolph D. Moss of the U.S. District Court for the District of Columbia had granted Amarin's motion for summary judgment in the Company's lawsuit against the FDA. Following this order, the FDA notified the ANDA filers that the status of their applications had been updated and were no longer considered accepted. In rescinding acceptance of the ANDAs, the statutory basis for Amarin's patent litigation no longer existed and the Company moved to dismiss the pending lawsuits.

44. On January 22, 2016, in the U.S. District Court for the District of New Jersey, the judge granted Amarin's motion to dismiss all patent litigation. One of the ANDA applicants filed an appeal, but later withdrew following the FDA's May 2016 grant of Vascepa's 5-year, NCE exclusivity.

45. As a result, NCE exclusivity for Vascepa would extend from its date of FDA approval on July 26, 2012, through July 25, 2017, subject to any statutory exceptions.

46. By September and October 2016, four years into the NCE exclusivity period, Amarin received paragraph IV certification notices from four generic manufacturers seeking FDA approval to market generic versions of Vascepa, contending to varying degrees that certain patents held by the Company were invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in the applicants' ANDA.

47. Shortly thereafter, Amarin filed patent infringement lawsuits against three of the four ANDA applicants[4], seeking, among other remedies, an order enjoining each defendant from

[4] The fourth ANDA applicant, Apotex Inc., which sent Amarin a paragraph IV certification notice in September 2016, only made notice as to some, but not all, of the patents listed in the Orange Book for Vascepa. Because the ANDA applicant did not make a paragraph IV certification as to all listed patents, it could not market a generic version of Vascepa before the last to expire of the excluded patents, which is in 2030. The applicant was free to amend its ANDA to make a paragraph IV certification as to all listed patents, and if it chose to do so,

marketing generic versions of Vascepa before the last of the asserted patents (the "Asserted Patents") was set to expire in 2030.[5] The three lawsuits were consolidated, and because of the statutory stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA could not grant final approval to the ANDA applicants before January 26, 2020, unless there was an earlier court decision holding that the Asserted Patents were not infringed and/or invalid.

48. While litigation was ongoing and just before Vascepa's 5-year NCE exclusivity was set to expire, in June 2017, the Company listed in the Orange Book of patents associated with the drug product, a 0.5-gram dose strength of Vascepa, and subsequently introduced the new dosage to the market in October 2016. As a result, in August 2017, one of the previous ANDA applicants, Teva Pharmaceuticals USA, Inc. ("Teva"), sent Amarin a paragraph IV certification notice contending that certain of the Company's patents were invalid, unenforceable and/or would not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of Vascepa, as described in the Teva ANDA. This ANDA was filed as an amendment to the 1-gram ANDA previously filed by Teva and was related to the Asserted Patents at issue in the ongoing patent litigation. Since the Company's June 2017 listing was within the 5-year NCE exclusivity period, in October 2017, Amarin filed a patent infringement lawsuit against Teva[6], which was later consolidated with the prior patent lawsuits.[7]

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would be required to send notice to Amarin. Amarin would then have the right to file a lawsuit against the ANDA applicant.

[5] *Amarin Pharma, Inc. et al. v. Hikma Pharms. USA Inc. et al.*, No. 2:16-cv-02525 (D. Nev.) (filed in Oct. 2016); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 2:16-cv-02562 (D. Nev.) (filed in Nov. 2016); *Amarin Pharma, Inc. et al. v. Teva Pharms. USA, Inc. et al*., No. 2:16-cv-02658 (D. Nev.) (filed in Nov. 2016).

[6] *Amarin Pharma, Inc. et al. v. Teva Pharms. USA, Inc. et al.,* No. 2:17-cv-2641 (D. Nev.).

[7] *Amarin Pharma, Inc., et al. v. Hikma Pharms. USA Inc., et al.*, No. 2:16-cv-02525 (D. Nev.).

49. As is the case with any issued U.S. patent, whether the patents are valid could be challenged in court or in the United States Patent and Trademark Office ("USPTO"), and whether such patents actually cover the approved product, and potentially even whether the expiration date of the patents is correctly listed in the Orange Book, could be challenged in court. As such, the ANDA applicants asserted counterclaims of noninfringement and invalidity against Amarin.

50. As of the filing date of the first three patent lawsuits, the Company had 47 patent applications issued or allowed in the U.S. and more than 30 additional applications pending. By October 2017, Amarin had 60 patent applications approved or issued in the U.S. and more than 30 additional patent applications pending. The 60 U.S. patents included:

- two directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively;
- one covering a composition containing highly pure EPA that expires in 2021;
- 44 covering or related to the use of Vascepa in either the MARINE or ANCHOR populations that have terms that expire in 2030 or later;
- three related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030;
- two related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- one related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- one related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- one related to the use of Vascepa to treat obesity with a term that expires in 2030;
- two covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- three covering a new combination therapy comprised of EPA and another drug.

51. Specifically, when Amarin first filed the patent lawsuits, the Asserted Patents included 14 of the Company's U.S. patents: 8,293,728 (the '728 patent); 8,318,715 (the '715 patent); 8,357,677 (the '677 patent); 8,367,652 (the '652 patent); 8,377,920 (the '920 patent);

8,399,446 (the '446 patent); 8,415,335 (the '335 patent); 8,426,399 (the '399 patent); 8,440,650 (the '650 patent); 8,501,225 (the '225 patent); 8,518,929 (the '929 patent); 8,524,698 (the '698 patent); and 8,431,560 (the '560 patent).[8]

52. On May 24, 2018, Amarin announced that it had successfully negotiated a settlement of the patent litigation with Teva. As part of this settlement agreement, Teva was permitted to begin selling its generic version of Vascepa in the U.S. on August 9, 2029, or earlier under certain customary circumstances, including commercial launch by another generic manufacturer under certain circumstances, in which event Teva would pay Amarin royalties on its generic version of Vascepa. The agreement also provided that Amarin would pay Teva $2.0 million in recognition of the savings to Amarin in the avoidance of costs, expenditure of time and resources, disruption and burden associated with continued litigation with Teva.

53. While the patent litigation would continue against the remaining two ANDA applicants, and their affiliated parties, Defendant Thero is quoted in the Company's press release stating, "[w]e are delighted to announce this settlement with Teva as it reinforces our confidence in Amarin's patent portfolio and allows us to avoid the incremental litigation expense and distraction associated with Teva's participation."

54. An analyst report issued by Cantor Fitzgerald on May 24, 2018, echoed the Company stating, "[w]e think these terms are favorable to A[marin], reflecting its strong IP position and saving it litigation dollars down the line."[9] The report also noted that "[a]lthough A[marin] did not comment on its interactions with the remaining two parties under litigation, West-

[8] *Amarin's U.S. Patent Protection for Vascepa*, SEEKING ALPHA (November 30, 2018), https://seekingalpha.com/article/4225644-amarins-u-s-patent-protection-for-vascepa (last visited Oct. 13, 2021).

[9] Louise Chen, Brandon Folkes, CFA, Jennifer Kim, *Teva Settlement Trims a Little Fat Off the Vascepa Patents*, CANTOR FITZGERALD (May 24, 2018).

Ward Pharmaceuticals (subsidiary of Hikma []) and Dr. Reddy's [], we think Teva was the most experienced manufacturer of the three in this area.… This bodes well for other settlements, in our view."

55. Then, in July 2018, Amarin received another paragraph IV certification notice from one of the remaining ANDA applicants in the patent litigation, contending that certain patents held by the Company were invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of Vascepa, as described in the applicant's ANDA—submitted as an amendment to its 1-gram ANDA and was related to the patents already at issue in the patent litigation. This certification also came as a follow up to Amarin's June 2017 listing of patents associated with the 0.5-gram product in the Orange Book.

56. Accordingly, in August 2018, Amarin filed a patent infringement lawsuit against the ANDA applicant in the U.S. District Court for the District of Nevada.[10] Similar to the ongoing litigation, Amarin was seeking, among other remedies, an order enjoining the ANDA applicant from marketing generic versions of the 0.5-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030. Because of the overlap between the cases, both parties stipulated that the final judgment on the merits of the parties' contentions in the consolidated 1-gram patent litigation would also be binding in the 0.5-gram case.

57. In January 2020, the District Court held a bench trial in the consolidated patent infringement case. As of the time of the bench trial, the remaining Asserted Patents at issue were the '728 patent, the '715 patent, the '677 patent, the '652 patent, the '560 patent, and the '929 patent. Amarin, more specifically, asserted that the ANDA applicants infringed the following ten

[10] *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 2:18-cv-01596 (D. Nev.)

claims of the Asserted Patents (the "Asserted Claims"): Claims 1 and 16 of the '728 patent, Claim 14 of the '715 patent, Claims 1 and 8 of the '677 patent, Claim 1 of the '652 patent, Claims 4 and 17 of the '560 patent, and Claims 1 and 5 of the '929 patent. Chief Judge Miranda M. Du noted in her bench order issued on March 30, 2020, that, "[b]ecause the Asserted Patents are related, their disclosures—the information contained within their respective specifications—are essentially the same."

C. Amarin's Viability as an M&A Target

58. Based on Defendants' representations about the strength of its patent portfolio, from the start of the Class Period, the market saw Amarin as a top M&A target for big pharmaceutical companies like Johnson & Johnson, Novartis AG, Pfizer Inc., Merck & Co. Inc., GlaxoSmithKline plc, and Eli Lilly and Company.

59. Industry analysts touted Amarin as "represent[ing] one of the few wholly-owned, global, multi-billion-dollar pot'l products that fits easily with DTC ads and M&A pharma tuck-in." This was because Vascepa was "already FDA approved and ramping now, and the pot'l new big label expansion coming by early 2020 takes it perfectly for big pharma from current niche drug (high TG) to broad primary care opportunity (CV risk reduction for wide population). Big pharma needs 'big' drugs in 'big' markets and there aren't that many around that are de-risked."

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS[11]

60. The Class Period begins on December 5, 2018, when Defendant Thero presented at Citi's 2018 Global Healthcare Conference ("Citi Conference") on behalf of the Company. During the Citi Conference, he stated in relevant part:

[11] The particular portions of the statements alleged to be false and/or misleading are bolded and italicized in this Section.

> ***So, the protection of Vascepa is really at three levels these days***. . .. And the last [level] is our patents. We now have over 60 patents on the product. There are ANDA filers. Any good product gets ANDA filers. It would be almost insulting if there weren't, I guess.
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> There were four. One of them dropped out fairly early. Another was Teva. They settled. They could come into the market in August 2029, so about 11 years from now. The other two, Hikma and Dr. Reddy's continue in the litigation process. There's been no court date set yet. There have been Markman hearings.
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> I think the results coming out of that claims construction was very favorable to us. At least one of the claimant says acknowledge that if they were to launch, they would be infringing upon our patents. I think it's sort of impossible not to. ***Our patents cover key elements of the label for the product and you can't have a generic without having that label***. We intend to defend our patents vigorously.
>
> I think they'd have to – if they're acknowledging that they infringe, they'd have to invalidate these patents. And ***these patents were heavily prosecuted through the US Patent Office***.

61. On February 27, 2019, Amarin filed a Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2018 (the "2018 Form 10-K"), which was signed and certified by Defendants Thero and Kalb. While the 2018 Form 10-K discussed several "Risks Related to Our Intellectual Property," Defendants failed to adequately warn investors that certain "Risks" had already materialized at the time of this annual report.

62. First, the 2018 Form 10-K warned that "[g]eneric company competitors are seeking FDA approval of generic versions of Vascepa. We are now engaged in related patent litigation and could face other challenges to our exclusivity." Specifically, the 2018 Form 10-K provided, in relevant part, that:

> ***Any generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations.*** In addition, ***even if a competitor's effort*** to introduce a generic product ***is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company*** and our stock price.

63. The 2018 Form 10-K also warned that "[w]e are dependent on patents, proprietary rights and confidentiality to protect the commercial potential of Vascepa," stating, in relevant part:

> ***Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates***, technology and know-how, and to operate without infringing the proprietary rights of others. ***Our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to***:
>
> - ***obtain, defend and maintain patent protection and market exclusivity for our current and future products***;
> - preserve any trade secrets relating to our current and future products;
> - acquire patented or patentable products and technologies; and
> - operate without infringing the proprietary rights of third parties.

64. Next, the 2018 Form 10-K warned that "[o]ur issued patents may not prevent competitors from competing with Vascepa, even if we seek to enforce our patent rights," stating, in relevant part:

> Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of Vascepa or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. ***Any such competition could undermine sales, marketing and collaboration efforts for Vascepa, and thus reduce, perhaps materially, the revenue potential for Vascepa.***
>
> ***Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us.*** Patent litigation is costly and time consuming, and we may not have sufficient resources to bring these actions to a successful conclusion.

65. In addition, the 2018 Form 10-K warned that "[p]otential business combinations or other strategic transactions may disrupt our business or divert management's attention," stating, in relevant part:

> ***On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party***, exclusive licenses of Vascepa or other strategic transactions or collaborations with third parties. For example, in March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa in the United States. ***The consummation and performance of any such future transactions or collaborations will involve risks, such as****:*
>
> - diversion of managerial resources from day-to-day operations;
> - exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;
> - misjudgment with respect to the value;
> - higher than expected transaction costs; or
> - ***an inability to successfully consummate any such transaction or collaboration***.
>
> ***As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders***. If we are unsuccessful in consummating any such transaction or collaboration, we may be required to reevaluate our business only after we have incurred substantial expenses and devoted significant management time and resources.

66. On May 1, 2019, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the first quarter of 2019 ("1Q19 Call"). During the 1Q19 Call, Defendant Thero stated, in relevant part that:

> ***Our patents expire in 2030***, the public record for the ANDA litigation is available for all to view and many have. As a reminder, there are two ANDA filers that remain in the litigation from the original four. Apotex determined to not litigate in the case early on in the proceeding. Rather than continue to litigate, Teva settled with us, to enter in August of 2029. There is no IPR proceeding, that is inter parties review in that case. The statutory one-year window for IPRs from the end of filers on the relevant patent has expired.
>
> While court schedules can change, ***current timing suggest that this matter, assuming it is not settled, would go to trial in early 2020***. We continue to defend our patents vigorously.

67. On June 25, 2019, Defendant Thero presented at the 2019 BMO Prescription For Success Healthcare Conference ("BMO Conference") on behalf of the Company. He had the following exchange with an analyst there:

> *Analyst*: [Y]ou touched briefly on the patents that you have on the product, but maybe just spend another minute or so, just how comfortable you are? I forget if there are ANDA filers already on a product and you're in the middle of litigation. So just give us an update there, and is there actually any potential lifecycle extension beyond the REDUCE-IT data, which I'm sure you could try and file for patents around that I would imagine, but is there anything else in terms of the ingredient itself or things that you're working on to try and extend the lifecycle of the franchise even further?
>
> *Thero*: So, regarding patents, ***the majority of our patents go to 2030***, and some potentially beyond. Regarding the tail-end of your question about lifecycle management, we've got plenty of time to think about that. In terms of the here and now, there are ANDA filers, ironically sort of insulting if there wouldn't be ANDA filers around a good drug. There were four; Apotex sort of removed themselves from the process relatively early. Teva settled. They could come into the market with a generic in the second half of 2029, so a little over 10 years from now. There are two remaining ANDA filers, Dr. Reddy's and Hikma. Claims, construction, the Markman hearings are done. ***We did very well in those, more recently procedurally***. The court has allowed us to introduce the results of the REDUCE-IT study, which we think supports the uniqueness of Vascepa.

68. On November 5, 2019, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the third quarter of 2019 ("3Q19 Call"). During the 3Q19 Call, Defendant Thero stated, in relevant part:

> Seeking summary judgment at this stage in ANDA patent litigation is a common approach for generics to seek an early end to litigation and for both parties to seek to limit the scope of issues at trial. The Judge ruled against the ANDA filer's summary judgment motion that sought to end the case at this early stage in their favor, enrolled more in Amarin's favor to limit the scope of issues that remain for trial.
>
> We see this ruling as strengthening our position in the litigation by eliminating from the case several potential lines of generic argument. ***As such, the ruling strengthens Amarin's position should it be determined that case settlement is in the Company's best interest***.

69. On January 15, 2020, Defendant Thero presented at the 38th Annual J.P Morgan Healthcare Conference on behalf of the Company. He stated, in relevant part, during the conference:

> ***From a data exclusivity perspective, in the United States, we've protected, via patents, 2 different indications.*** Our initial indication, which is for the trigs greater than 500 is currently subject to ANDA litigation. We did settle with Teva, and Teva could come into the market in August of 2029. Litigation continues and is active currently with Dr. Reddy's and Hikma. We believe we'll hear the results of that case somewhere near the end of March of this year. Obviously, we're confident in the results, which is why we're expanding our commercial infrastructure.
>
> ***The new indication of cardiovascular risk reduction is supported by numerous patents, of which over 20 are now listed in the Orange Book***.

70. On February 25, 2020, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the fourth quarter of 2019 ("4Q19 Call"). During the 4Q19 Call, Defendant Thero stated, in relevant part:

> ***Amarin's commercial plans assume that the courts uphold our patents and otherwise ensure that Amarin retains the exclusivity***, which we believe we deserve under law. Such exclusivity will support Amarin's further promotion and education leading to expanded use for the benefit of millions of at-risk patients. In my view, it would be a considerable setback to pharmaceutical development and patient care if we do not prevail in this litigation. As we've described before the litigation began, while there is risk in any litigation, we believe that our legal arguments are persuasive and should prevail. ***The U.S. patent office was convinced of the appropriateness of our patents,*** and we believe that the courts should conclude similarly.
>
> Amarin has made considerable progress in the past year. ***In many respects, we're just getting started***. A year ago, there were four primary areas of concern expressed to us by investors; one, FDA approval of an expanded VASCEPA label [sic]; two, competition from Epanova; three, accuracy of our financial resources; and four, results of end of litigation [sic]. Three of these four have been successfully addressed with the court, the results of the end of litigation scheduled to be addressed soon.

71. On February 25, 2020, Amarin filed a Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2019 (the "2019 Form 10-K"), which was signed and certified by Defendants Thero and Kalb. While the

2019 Form 10-K discussed several "Risks Related to the Commercialization and Development of Vascepa," Defendants failed to adequately warn investors that certain "Risks" had already materialized at the time of this annual report.

72. First, the 2019 Form 10-K warned that "[g]eneric company competitors are seeking FDA approval of generic versions of Vascepa in the United States. We are now engaged in related patent litigation based on our MARINE trial-based indication, expect appeals of any judgment, and expect additional patent litigation given FDA approval of a REDUCE-IT-based indication." Specifically, the 2019 Form 10-K provided, in relevant part that:

> The statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016, expired on January 26, 2020, seven-and-a-half years from our initial FDA approval of Vascepa. However, based on court proceedings, we do not expect an at-risk launch from either generic filer before the court issues a decision on the merits in the pending MARINE-related patent litigation, which decision, based on statements by the Court, is expected by the end of March 2020. ***Based on historical practice in the field, we expect the final decision by the Court on the merits of this MARINE-related patent litigation to be appealed by the losing parties.*** The timing of such appeal proceedings and an outcome on the merits is difficult to predict. It is not uncommon for such an appeal to take from several months to approximately one year until judgment. ***Based on our current understanding of the strength of our position in the litigation, if the Court were to rule against us, we expect we would file an expedited motion for an injunction to prevent any generic launch while the appeal is pending. We believe we would be favorably situated to obtain an injunction against generic launch pending appeal, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal.*** There can be no guarantee we would be successful in any of such efforts.
>
> If final approval of a generic ANDA is granted, an ANDA filer is able to supply the product in significant commercial quantities and circumstances described in the preceding paragraph do not maintain the status quo as it existed prior to any adverse Court ruling, generic companies could introduce generic versions of Vascepa in the market. ***Any such introduction of a generic version of Vascepa would also be subject to current patent infringement claims that may then be subject to an appeal.***
>
> A***ny generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations.*** In addition, ***even if a competitor's effort*** to introduce a generic product ***is ultimately***

unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price.

73. Next, the 2019 Form 10-K warned that "[w]e are dependent on patents, proprietary rights and confidentiality to protect the commercial potential of Vascepa." Specifically, the 2019 Form 10-K provided, in relevant part, that:

> ***Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates***, technology and know-how, and to operate without infringing the proprietary rights of others. ***Our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to:***
>
> - ***obtain, defend and maintain patent protection and market exclusivity for our current and future products***;
> - preserve any trade secrets relating to our current and future products;
> - acquire patented or patentable products and technologies; and
> - operate without infringing the proprietary rights of third parties.
>
> We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa development program.

74. The 2019 Form 10-K also warned that "[o]ur issued patents may not prevent competitors from competing with Vascepa, even if we seek to enforce our patent rights," stating, in relevant part:

> Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of Vascepa or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. ***Any such competition could undermine sales, marketing and collaboration efforts for Vascepa, and thus reduce, perhaps materially, the revenue potential for Vascepa***.
>
> ***Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us.*** Patent litigation is

costly and time consuming, and we may not have sufficient resources to bring these actions to a successful conclusion.

75. In addition, the 2019 Form 10-K wanted that "[p]otential business combinations or other strategic transactions may disrupt our business or divert management's attention." Specifically, the 2019 Form 10-K stated, in relevant part, that:

> ***On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party***, exclusive licenses of Vascepa or other strategic transactions or collaborations with third parties. ***The consummation and performance of any such future transactions or collaborations will involve risks, such as***:
>
> - diversion of managerial resources from day-to-day operations;
> - exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;
> - misjudgment with respect to the value;
> - higher than expected transaction costs; or
> - ***an inability to successfully consummate any such transaction or collaboration***.
>
> ***As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders.*** If we are unsuccessful in consummating any such transaction or collaboration, we may be required to reevaluate our business only after we have incurred substantial expenses and devoted significant management time and resources.

76. The statements referenced in ¶¶ 60-75 were materially false and misleading and/or failed to disclose material adverse facts about the Company's business and patent portfolio. Specifically, Defendants made false and misleading statements and/or failed to disclose that: (i) there was an increasingly high risk that certain of Amarin's patents would be invalidated; (ii) the Company's litigation was preventing it from effectuating a successful takeover; (iii) Defendants were downplaying the true threat the ongoing ANDA litigation posed to the Company's business

and future prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

77. On April 13, 2020, the Company hosted a conference call with investors and analysts to provide, among other things, an update on the ANDA litigation and the Company's plans for reversal of the District Court decision ("1Q20 Update Call"). During the 1Q20 Update Call, Defendant Thero stated, in relevant part:

> ***All experienced independent commentators took a serious look at the record agree the trial should have resulted in a judgment for Amarin***.
>
> * * *
>
> ***The uniqueness and inventive nature of VASCEPA has been well recognized for years, as was well documented in the U.S. Patent Office.***
>
> ***There was the unanimous view of those lawyers and analysts reporting on the matter that Amarin had made a winning case at trial***.

78. On April 30, 2020, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the first quarter of 2020 ("1Q20 Results Call"). During the 1Q20 Results Call, Defendant Thero stated, in relevant part:

> Because of the importance of the appeal and because the Federal Circuit appeals are specialized, we have appointed a new lead counsel to augment our existing legal team.
>
> * * *
>
> For reasons described on our April 13th call, ***it remains stunning that the invention of VASCEPA can now be viewed by anyone as obvious***.

79. On August 4, 2020, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the second quarter of 2020 ("2Q20 Call"). During the 2Q20 Call, Defendant Thero stated, in relevant part:

> We will start with this last topic first, as patent litigation is typically the first topic of enquiry from investors.
>
> * * *

> Our ongoing appeal to the Federal Circuit in U.S. patent litigation is in response to the decision in March of this year from the Federal District Court in Nevada, which ruled that the discoveries underlying VASCEPA's patents that protected our initial FDA approved indication for VASCEPA were obvious.
>
> Thus, in effect, the court ruled that the patents upon which Amarin has relied should not have been granted by the U.S. patent office. ***This decision was unexpected by everyone, including we understand the generic companies involved in the litigation***.
>
> * * *
>
> The next significant step in our Federal Circuit appeal is expected to be the oral hearing. The oral hearing is scheduled for September 2 at 10:00 AM Eastern Time. Additional information regarding the logistics for this hearing, such as listening instructions are provided in the FAQ section of Amarin's website.
>
> * * *
>
> The Federal Circuit at our request will quickly to schedule the oral hearing and hopefully that quick pace continues to reaching a decision on this important appeal.

80. On November 5, 2020, the Company hosted a conference call with investors and analysts to discuss, among other things, financial results for the third quarter of 2020 ("3Q20 Call"). During the 3Q20 Call, Defendant Thero stated, in relevant part:

> You know that we have been tracking the GSK versus Teva case for some time. ***The legal team representing GSK at trial and on appeals substantially overlaps with the legal team that represented Amarin before the Federal Circuit. And the attorneys that submitted a brief for pharma on appeal in GSK versus Teva represented us at trial and on appeal.***

81. On November 16, 2020, Defendant Thero presented at the 2020 Stifel Virtual Healthcare Conference on behalf of the Company. He stated, in relevant part, during the conference in response to a question about the "read through to the VASCEPA kind of IP litigation in the [GSK, Teva] case":

> We are certainly aware of -- I mean, ***our counsel was involved in representing GSK in the litigation that you've just referenced***. I think that there is -- ***that bears continuing to watch***.

82. On February 25, 2021, Amarin filed a Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 Form 10-K"), which was signed and certified by Defendants Thero and Kalb. While the 2020 Form 10-K discussed several "Risks Related to the Commercialization and Development of VASCEPA," Defendants failed to adequately warn investors that certain "Risks" had already materialized at the time of this annual report.

83. First, the 2020 Form 10-K warned that "[a]s generic company competitors seek to compete with copies of VASCEPA in the United States and elsewhere we could face additional challenges to our patents and additional patent litigation." Specifically, the 2020 Form 10-K stated, in relevant part, that:

> ***Any significant degree of generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations.*** In addition, ***even if a competitor's effort*** to introduce a generic product ***is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the reputation of VASCEPA or the perceived value of our company*** and our stock price. For example, our stock price suffered a significant decline following our announcement of the Nevada Court's ruling in favor of the Defendants and the Federal Circuit ruling upholding the Nevada Court's ruling.

84. The 2020 Form 10-K also warned that "[w]e are dependent on patents, proprietary rights and confidentiality to protect the commercial potential of VASCEPA," stating, in relevant part:

> ***Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates,*** technology and know-how, and to operate without infringing the proprietary rights of others. ***While certain key patents related to our product based on the MARINE clinical study were determined to be invalid as obvious by a district court in the United States, and we are pursuing an appeal process, it remains the case that our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to***:
>
> - ***obtain, defend and maintain patent protection and market exclusivity for our current and future products***;

- preserve any trade secrets relating to our current and future products;
- acquire patented or patentable products and technologies; and
- operate without infringing the proprietary rights of third parties.

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the VASCEPA development program.

85. The 2020 Form 10-K further warned that "[o]ur issued patents may not prevent competitors from competing with VASCEPA, even if we seek to enforce our patent rights," stating, in relevant part:

> Patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion. Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of VASCEPA or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. ***Any such competition could undermine sales, marketing and collaboration efforts for VASCEPA, and thus reduce, perhaps materially, the revenue potential for VASCEPA.***
>
> ***Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us.*** Patent litigation is costly and time consuming, and we may not have sufficient resources to bring these actions to a successful conclusion.

86. In addition, the 2020 Form 10-K warned that "[t]he loss of key personnel could have an adverse effect on our business," stating, in relevant part:

> We are highly dependent upon the efforts of our senior management. ***The loss of the services of one or more members of senior management could have a material adverse effect on us.*** Given our rapidly expanding enterprise coupled with a streamlined management structure, ***the departure of any key person could have a significant impact and would be potentially disruptive to our business*** until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, ***as our business plan progresses, we will be highly dependent upon our ability to attract and retain qualified scientific, technical and***

key management personnel. As we continue to evolve from a development stage company to a commercial stage company, we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. As we prepare for commercialization in Europe, we need to rapidly hire employees and ensure that they are well trained and working cohesively with core values which are consistent with our existing operations and which, we believe, help improve our position for success. In the United States, employees are increasingly being recruited by other companies. ***While our business priorities emphasize continued promotion of VASCEPA in the United States, the current and potential threat of generic competition can create employee uncertainty which could lead to increased employee turnover. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.***

87. In addition, the 2020 Form 10-K warned that "Potential business combinations or other strategic transactions may disrupt our business or divert management's attention." Specifically, the 2020 Form 10-K provided that:

> ***On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party***, exclusive licenses of VASCEPA or other strategic transactions or collaborations with third parties. ***The consummation and performance of any such future transactions or collaborations will involve risks, such as:***
>
> - diversion of managerial resources from day-to-day operations;
> - exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;
> - misjudgment with respect to the value;
> - higher than expected transaction costs; or
> - ***an inability to successfully consummate any such transaction or collaboration.***
>
> ***As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders***. If we are unsuccessful in consummating any such transaction or collaboration, we may be required to reevaluate our business only after we have

> incurred substantial expenses and devoted significant management time and resources.

88. On March 1, 2021, Defendant Thero presented at the Cowen 41st Annual Health Care Conference on behalf of the Company. He stated, in relevant part, during the conference in response to a question "to just highlight GSK versus Teva versus -- and as opposed to your litigation":

> Again, all legal matters are separate, but that is a precedent case that shows that a generic product isn't allowed to just market for any potential purpose. It does need to limit itself to where it has authority to act. And in that case, it was trampling on GSK's patents elsewhere.
>
> * * *
>
> So, it's early. That product just launched four months ago. Our court case is in the formative stages. But we think ***it's appropriate for us to – and common for us to enforce our intellectual property rights***, and what we're attempting to do.

89. The statements referenced in ¶¶ 77-88 were materially false and misleading and/or failed to disclose material adverse facts about the Company's business and patent portfolio. Specifically, Defendants made false and misleading statements and/or failed to disclose that: (i) once the District Court invalidated certain of Amarin's patents, there was little to no chance of reversing that ruling; (ii) the Company's litigation was preventing it from effectuating a successful takeover; (iii) Defendants were downplaying the true threat the ongoing ANDA litigation posed to the Company's business and future prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

VI. THE TRUTH SLOWLY EMERGES

90. After markets closed on March 30, 2020, Defendants partially revealed the truth about the strength of Amarin's patent portfolio. That day, the Company announced that "the United States District Court for the District of Nevada's rul[ed] in favor of the generic companies in the

company's patent litigation against two filers of abbreviated new drug applications, or ANDAs, for Amarin's VASCEPA® (icosapent ethyl) capsule franchise."[12]

91. Specifically, Chief Judge Miranda M. Du found that defendants' proposed ANDA Products would induce infringement of the Asserted Claims, but all the Asserted Claims were invalid as obvious under 35 U.S.C. § 103.[13] Thus, the court found in favor of the defendants on Amarin's remaining infringement claim, and in defendants favor on their counterclaims asserting the invalidity of the Asserted Claims under 35 U.S.C. § 103. Ultimately, the court ruled that defendants had provided clear and convincing evidence of obviousness, and that Amarin did not proffer evidence of secondary considerations sufficient to save the Asserted Claims.

92. The heart of defendants' argument was that the Physician's Desk Reference (PDR) published in 2007 in connection with Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, was prior art to the Asserted Patents. Lovaza was approved by the FDA in 2004 and has been on the market in the U.S. since 2005. The Lovaza PDR disclosed a commercially available preparation of EPA and DHA administered at 4 grams/day and provided that "Lovaza is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with very high (> 500 mg/dl) triglyceride levels." The court found that "the Lovaza PDR covers many of the limitations of the Asserted Claims and making the obvious substitution of only EPA instead of a mixture of EPA and DHA renders most limitations of the Asserted Claims obvious."

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[12] *Amarin Comments on Ruling in VASCEPA® ANDA Litigation*, AMARIN CORPORATION (Mar. 30, 2020, 06:25 PM EDT), https://investor.amarincorp.com/news-releases/news-release-details/amarin-comments-ruling-vascepar-anda-litigation (last visited Oct. 5, 2021).

[13] Bench Order, *Amarin Pharma, Inc., et al., v. Hikma Pharms. USA Inc., et al.*, No. 2:16-cv-02525-MMD-NJK (Dist. of Nev.), ECF No. 381.

93. On this news, Amarin's share price plummeted over ***70.5%*** to close at $4.00 on March 31, 2020, on heavy trading volume.

94. As SA news editor Stephen Alpher noted in an article titled "Amarin plunges after court decision on Vascepa" on March 30, 2020, the Company "has lost its patent battle against generics."[14]

95. At the same time, Defendant Thero assured investors that "[w]e believe ***we are favorably situated to obtain an injunction against generic launch pending appeal***, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal."[15]

96. Then, starting at 10:00 AM ET on September 2, 2020, the U.S. Court of Appeals for the Federal Circuit held an oral argument for the Vascepa patent ANDA litigation.[16] The very next day, the Federal Circuit affirmed the District Court's ruling.[17]

97. As the oral argument had progressed and the Federal Circuit's ruling had become known to investors, Amarin's share price fell over 34.5% to close at $4.30 on September 4, 2020, on heavy trading volume as the truth about the Company's patent portfolio continued to emerge.

98. As SA news editor Douglas W. House noted on September 2, 2020, "arguments by attorneys representing the company are not going that well. Shares are down 27% on almost 7x

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[14] Stephen Alpher, *Amarin plunges after court decision on Vascepa*, SEEKING ALPHA (Mar. 30, 2020, 04:59 PM ET), https://seekingalpha.com/news/3556531-amarin-plunges-after-court-decision-on-vascepa (last visited Oct. 5, 2021).

[15] *Amarin Comments on Ruling in VASCEPA® ANDA Litigation*, AMARIN CORPORATION (Mar. 30, 2020, 06:25 PM EDT), https://investor.amarincorp.com/news-releases/news-release-details/amarin-comments-ruling-vascepar-anda-litigation (last visited Oct. 5, 2021).

[16] Case Information for MARINE Patent ANDA Litigation Appeal, AMARIN CORPORATION (July 21, 2020), https://investor.amarincorp.com/static-files/84996559-1594-458d-b4bc-f55a116e674a (last visited Oct. 5, 2021).

[17] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.,* 819 F. App'x 932 (Fed. Cir. 2020), *cert. denied*, No. 20-1119, 2021 WL 2519113 (U.S. June 21, 2021).

higher volume 2 1/2 hours into session."[18] Another SA analyst similarly noted on September 6, 2020, "Amarin shares have taken a beating this week during the appellate hearing and especially after the adverse ruling came down on September 3."[19]

99. Then, on April 12, 2021, Amarin announced the retirement of Defendant Thero as President and CEO and the appointment of the Company's SVP and Head of Commercial for Europe, Karim Mikhail ("Mikhail"), as his successor, effective August 1, 2021.[20] In announcing the "CEO Succession Plan," the Company highlighted that previously, Mr. Mikhail had been "responsible for reversing [Merck's] decline in the U.S. market and globally, accelerating revenue by an additional $380 million through the launch of ATOZET and driving EBITDA growth through international expansion. Prior to that, Mr. Mikhail led the successful commercial launch of dozens of products, including ezetimibe and various molecules in diabetes, hypertension, immunology, and oncology, and served as Merck's chief marketing officer for Europe, Middle East and Africa and chief operating officer for emerging markets." *Id*.

100. On this news, the Company's share price fell over 14.3% to close at $5.08 on April 13, 2021, on heavy trading volume.

101. As Jefferies analyst Michael Yee explained on April 12, 2021, Amarin "[i]nvestors may be disappointed in the transition and that it may signal no near term M&A on the table (which

[18] Douglas W. House, *Amarin Under Pressure on Advancement of Vascepa Patent Case*, SEEKING ALPHA (Sept. 2, 2020, 09:29 AM ET), https://seekingalpha.com/news/3610942-amarin-under-pressure-on-advancement-of-vascepa-patent-case (last visited Oct. 5, 2021).

[19] Andy Jones, *Amarin Is A Good Contrarian Pick To Consider After Post-Appeal Sell-Off*, SEEKING ALPHA (Sept. 6, 2020, 08:27 PM ET), https://seekingalpha.com/article/4372840-amarin-is-good-contrarian-pick-to-consider-after-post-appeal-sell-off (last visited Oct. 5, 2021).

[20] *Amarin Announces CEO Succession Plan*, AMARIN CORPORATION (Apr. 12, 2021, 04:30 PM EDT), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-ceo-succession-plan (last visited Oct. 5, 2021).

is the clear and primary bull case to the stock)."[21] However, the "strategic move could finally unlock the [C]ompany's value" because as a SA analyst noted on April 13, 2021, while Defendant Thero "deserves some credit for overseeing the completion of the landmark REDUCE-IT trial, he also must take responsibility for their legal failures, their underwhelming sales performance, and the share price."[22] That analyst further noted that Mr. Mikhail "brings with him substantial connections in Europe from his time with Merck." *Id*.

102. On June 21, 2021, however, Amarin investors learned "that the Supreme Court has rejected the [C]ompany's bid to revive Vascepa patents."[23]

103. On this news, Amarin's share price fell 8.3% to close at $4.54 on June 23, 2021, on heavy trading volume.

VII. NO SAFE HARBOR

104. Defendants' "Safe Harbor" warnings accompanying Amarin's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. Most, if not all, of the statements alleged to be false and misleading herein relate to then-existing facts or conditions, thus the Safe Harbor has no applicability.

105. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was

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[21] SA News Team, *Amarin falls as new CEO may mean M&A less likely in the near term*, SEEKING ALPHA (Apr. 13, 2021, 08:08 AM ET), https://seekingalpha.com/news/3681280-amarin-falls-as-new-ceo-may-mean-ma-less-likely-in-the-near-term (last visited Oct. 5, 2021).

[22] *With Their European Approval In Hand, Amarin Signals A Strategic Shift With A New CEO*, SEEKING ALPHA (Apr. 13, 2021, 05:45 PM ET), https://seekingalpha.com/article/4418943-european-approval-in-hand-amarin-stock-signals-strategic-shift-new-ceo (last visited Oct. 5, 2021).

[23] Dulan Lokuwithana, *Amarin falls after Supreme Court rejection on Vascepa (updated)*, SEEKING ALPHA (June 21, 2021, 09:41 AM ET), https://seekingalpha.com/news/3708168-amarin-falls-unfavorable-court-ruling-attributed-to-the-weakness (last visited Oct. 5, 2021).

authorized and/or approved by an executive officer and/or director of Amarin who knew that the FLS was false. In addition, the FLS were contradicted by existing, undisclosed material facts that were required to be disclosed so that the FLS would not be misleading. Finally, most of the purported "Safe Harbor" warnings were themselves misleading because they warned of "risks" that had already materialized or failed to provide any meaningful disclosures of the relevant risks.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

106. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents and actions intended to manipulate the market price of Amarin securities in violation of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Amarin, their control over, and/or receipt or modification of Amarin's allegedly materially misleading misstatements and/or their associations with the Company, which made them privy to confidential proprietary information concerning Amarin, participated in the fraudulent scheme alleged herein.

107. Notably, the adverse developments at issue impacted Amarin's sole drug product, Vascepa. Governments, media, and the general public around the world were closely watching Defendants' progress in the development and commercialization of Vascepa, and the Individual Defendants repeatedly held themselves out to investors as the employees most knowledgeable on the subject. As such, the Individual Defendants knew or were reckless in not knowing of the undisclosed facts detailed herein.

IX. LOSS CAUSATION

108. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Amarin securities and operated as a fraud or deceit on purchasers of Amarin securities. As detailed above, when the truth about Amarin's misconduct was revealed over time, the value of the Company's securities declined precipitously as the prior artificial inflation no longer propped up the price of the securities. The declines in the price of Amarin securities were the direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the share price declines negate any inference that the losses suffered by Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic or industry factors or Company specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members, was a direct result of Defendants' fraudulent scheme to artificially inflate the price of the Company's securities and the subsequent significant decline in the value of the Company's securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

109. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by Plaintiff and the other members of the Class. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Amarin's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing the price of Amarin's securities to be artificially inflated. Plaintiff and other Class members purchased Amarin securities at artificially inflated prices, causing them to suffer damages as complained of herein.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

110. At all relevant times, the market for Amarin's securities was an efficient market for the following reasons, among others:

a. Amarin securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. During the Class Period, Amarin's shares were actively traded, supporting a strong presumption of a broad and efficient market;

c. As a regulated issuer, Amarin filed periodic public reports with the SEC;

d. Amarin regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services, the Internet and other wide-ranging public disclosures;

e. Amarin was followed by at least nine securities analysts employed by major brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms, and entered the public marketplace;

f. Multiple market makers made a market in Amarin's securities during the Class Period; and

g. Unexpected material news about Amarin was rapidly reflected in and incorporated into the Company's share price during the Class Period.

111. As a result of the foregoing, the market for Amarin's securities promptly digested current information regarding Amarin from all publicly available sources and reflected such information in Amarin's share price. Under these circumstances, all purchasers of Amarin's

securities during the Class Period suffered similar injury through their purchase of Amarin's securities at artificially inflated prices and a presumption of reliance applies.

112. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XI. CLASS ALLEGATIONS

113. This is a class action on behalf of all purchasers of Amarin securities during the Class Period who were damaged thereby (the "Class"). Excluded from the Class are Defendants and their families, 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.

114. Common questions of law and fact predominate and include: (a) whether Defendants violated the Exchange Act; (b) whether Defendants omitted and/or misrepresented material facts; (c) whether Defendants knew or recklessly disregarded that their statements were false; (d) whether the price of Amarin securities was artificially inflated during the Class Period; and (e) the extent of and appropriate measure of damages.

115. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Amarin securities were actively traded on the NASDAQ. Upon information and belief, these shares are held by hundreds, if not thousands, of individuals located geographically throughout the country.

116. Plaintiff's claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiff will adequately protect the interests of the Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

XII. CAUSES OF ACTION

COUNT I
For Violations of § 10(b) of the Exchange Act and Rule 10b-5
(*Against All Defendants*)

117. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

118. During the Class Period, Defendants disseminated or approved the false or misleading statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

119. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they, directly and indirectly, by the use of the means or instrumentality of interstate commerce, or the mails or facility of a national securities exchange:

(a) Employed devices, schemes and artifices to defraud;

(b) Made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Amarin securities during the Class Period.

120. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Amarin securities. Plaintiff and the Class would not have purchased Amarin securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

121. By virtue of the foregoing, Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

122. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Amarin securities during the Class Period.

COUNT II
For Violations of § 20(a) of the Exchange Act
(*Against the Individual Defendants*)

123. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

124. During the Class Period, the Individual Defendants acted as controlling persons of Amarin within the meaning of § 20(a) of the Exchange Act. By virtue of their share ownership, high-level positions and contractual rights, and their culpable participation, as alleged above, the Individual Defendants had the power to influence and control and did, directly or indirectly, influence and control the decision-making of the Company, including the content and

dissemination of the various statements which Plaintiff contends are false and misleading as detailed herein.

125. The Individual Defendants were provided with or had unlimited access to the Company's internal reports, releases, public filings, and other statements alleged by Plaintiff to be misleading prior to 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. In particular, the Individual Defendants had direct involvement in and responsibility over the day-to-day operations of Amarin 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.

126. By virtue of such wrongful conduct, the Individual Defendants are liable pursuant to § 20(a) of the Exchange Act.

127. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

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

a) Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as Class representative pursuant to Rule 23 of Federal Rules of Civil Procedure, and appointing Lead Counsel;

b) Awarding compensatory damages in favor of Plaintiff and the 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 Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

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

JURY DEMAND

Plaintiff respectfully demands a trial by jury.