

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RAFIK TADROS, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

v.

KADMON HOLDINGS, INC., HARLAN
W. WAKSAL, and STEVEN MEEHAN,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Rafik Tadros (“Plaintiff”), individually and on behalf of all others similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Kadmon Holdings, Inc. (“Kadmon” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Kadmon securities between October 1, 2020 and March 10, 2021, both dates 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, against the Company and certain of its top officials.

2. Kadmon is a biopharmaceutical company that discovers, develops, and commercializes small molecules and biologics primarily for the treatment of inflammatory and fibrotic diseases. The Company's lead product candidates include, among others, belumosudil (KD025), an orally administered selective inhibitor of the rho-associated coiled-coil kinase 2 ("ROCK2"), which is in Phase II clinical development for the treatment of chronic graft-versus-host disease ("cGVHD").

3. On September 30, 2020, post-market, Kadmon announced the submission of a New Drug Application ("NDA") for belumosudil for the treatment of cGVHD (the "Belumosudil NDA") with the U.S. Food and Drug Administration ("FDA").

4. Then, on November 30, 2020, Kadmon announced the FDA's acceptance of the Belumosudil NDA, and that the FDA had assigned the NDA a Prescription Drug User Fee Act ("PDUFA") target action date of May 30, 2021.

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Belumosudil NDA was incomplete and/or deficient; (ii) the additional new data that the Company submitted in support of the Belumosudil NDA in response to an information request from the FDA materially altered the NDA submission; (iii) accordingly, the initial Belumosudil NDA submission lacked the degree of support that the Company had led investors to believe; (iv) accordingly, the FDA was likely to extend the PDUFA target action date to review the Belumosudil NDA; and (v)

as a result, the Company's public statements were materially false and misleading at all relevant times.

6. On March 10, 2021, Kadmon issued a press release "announc[ing] that the [FDA] has extended the review period" for the Belumosudil NDA and that, "[i]n a notice received from the FDA on March 9, 2021, the Company was informed that the [PDUFA] goal date for its Priority Review of belumosudil has been extended to August 30, 2021." Kadmon advised investors that "[t]he FDA extended the PDUFA date to allow time to review additional information submitted by Kadmon in response to a recent FDA information request," and that "[t]he submission of the additional information has been determined by the FDA to constitute a major amendment to the NDA, resulting in an extension of the PDUFA date by three months."

7. On this news, Kadmon's stock price fell \$0.52 per share, or 10.57%, to close at \$4.40 per share on March 11, 2021.

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

JURISDICTION AND VENUE

9. 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).

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

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), as the alleged misstatements entered and the

subsequent damages took place in this Judicial District. Pursuant to Kadmon's most recent annual report on Form 10-K, as of March 1, 2021, there were 171,816,945 shares of the Company's common stock outstanding. Kadmon's common stock traded on the New York Stock Exchange ("NYSE") and Nasdaq Global Select Market ("NASDAQ") during the Class Period. Accordingly, there are presumably hundreds, if not thousands, of investors in Kadmon's common stock located within the U.S., some of whom undoubtedly reside in this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Kadmon securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Kadmon is a Delaware corporation with principal executive offices located at 450 East 29th Street, New York, New York 10016. The Company's common stock traded in an efficient market on the NYSE under the ticker symbol "KDMN" until on or about October 26, 2020, when the Company voluntarily transferred its stock exchange listing to the NASDAQ under the retained ticker symbol "KDMN."

15. Defendant Harlan W. Waksal ("Waksal") has served as Kadmon's President and Chief Executive Officer at all relevant times.

16. Defendant Steven Meehan ("Meehan") has served as Kadmon's Executive Vice President and Chief Financial Officer at all relevant times.

17. Defendants Waksal and Meehan are sometimes referred to herein as the “Individual Defendants.”

18. The Individual Defendants possessed the power and authority to control the contents of Kadmon’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Kadmon’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Kadmon, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

19. Kadmon and the Individual Defendants are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

20. Kadmon is a biopharmaceutical company that discovers, develops, and commercializes small molecules and biologics primarily for the treatment of inflammatory and fibrotic diseases. The Company’s lead product candidates include, among others, belumosudil (KD025), an orally administered selective inhibitor of ROCK2, which is in Phase II clinical development for the treatment of cGVHD.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on October 1, 2020. On September 30, 2020, post-market, Kadmon issued a press release announcing the submission of the Belumosudil NDA. That press release stated, in relevant part:

Kadmon . . . today announced the submission of a[n] [NDA] to the [FDA] for belumosudil (KD025), the Company’s [ROCK2] inhibitor, for the treatment of patients with [cGVHD].

“Today’s NDA submission under the FDA’s Real-Time Oncology Review pilot program marks an exciting milestone for Kadmon and for patients living with cGVHD,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “We believe the robust and durable clinical trial results achieved with belumosudil demonstrate its potential to offer meaningful clinical benefit to cGVHD patients. We look forward to our continued dialogue with the FDA as we continue to make preparations for potential launch, if approved.”

As previously reported, the NDA is being reviewed under the Real-Time Oncology Review (RTOR) pilot program, an initiative of the FDA’s Oncology Center of Excellence. The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

The NDA submission is supported by positive data from ROCKstar (KD025-213), the Company’s pivotal clinical trial evaluating belumosudil in 132 patients with cGVHD who have received two or more prior lines of systemic therapy. As previously reported, belumosudil achieved clinically meaningful and statistically significant Overall Response Rates (ORR) of 73% with 200 mg once daily and 74% with 200 mg twice daily. Responses were achieved across key patient subgroups and complete responses were observed in all organ systems. Belumosudil has been well tolerated and adverse events have been consistent with those expected in the patient population. Data from ROCKstar are expected to be presented at an upcoming medical meeting.

22. On November 5, 2020, Kadmon filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2020 (the “Q3 2020 10-Q”). In providing an overview of the Company, the Q3 2020 10-Q stated, in relevant part:

We are a clinical-stage biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address significant unmet medical needs. Our pipeline includes developmental treatments for immune and fibrotic diseases as well as immuno-oncology therapy candidates. We leverage our multi-disciplinary research and development team members to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing our small molecule and biologics platforms. We believe that we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. We expect to continue to progress our clinical candidates and have further clinical trial and regulatory events to report in the remainder of 2020 and in 2021.

The Company's most advanced product candidate, belumosudil (KD025) is an orally administered, selective small molecule inhibitor of Rho-associated coiled-coil kinase 2 ("ROCK2"), a signaling pathway that modulates inflammatory response. The Company is initially developing belumosudil for the treatment of chronic graft-versus-host disease ("cGVHD"), an immune-mediated inflammatory and fibrotic disorder. On September 30, 2020, the Company submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for belumosudil for the treatment of patients with cGVHD. The NDA is subject to acceptance by the FDA. The NDA is being reviewed under the Real-Time Oncology Review ("RTOR") pilot program, an initiative of the FDA's Oncology Center of Excellence ("OCE"). The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

The NDA submission is supported by positive data observed in ROCKstar (KD025-213), the Company's pivotal clinical trial evaluating belumosudil in 132 patients with cGVHD who have received two or more prior lines of systemic therapy. As previously reported, belumosudil achieved clinically meaningful and statistically significant Overall Response Rates of 73% with 200 mg once daily and 74% with 200 mg twice daily. Responses were achieved across key patient subgroups and complete responses were observed in all organ systems. Belumosudil has been well tolerated and adverse events have been consistent with those expected in the patient population.

The FDA has granted Orphan Drug Designation to belumosudil for the treatment of cGVHD, and the FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy.

23. Appended to the Q3 2020 10-Q as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "the

information contained in [the Q3 2020 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

24. Corresponding with the Q3 2020 10-Q, Kadmon issued a press release providing a business update and announcing the Company’s Q3 2020 financial results. The press release stated, in relevant part:

“The submission of our belumosudil New Drug Application to the FDA represents a significant achievement for Kadmon and advances our efforts to make this therapy available to patients living with chronic GVHD,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “We look forward to presenting 12-month safety, efficacy and durability data from our ongoing ROCKstar pivotal trial of belumosudil at the ASH Annual Meeting in December 2020.”

* * *

Upcoming Milestones:

Belumosudil (KD025)

- Present 12-month data from ROCKstar pivotal trial at the American Society of Hematology (ASH) Annual Meeting on December 6, 2020; the presentation will include updated efficacy and safety data and key secondary endpoints including duration of response, Failure-Free Survival, steroid dose reductions and quality-of-life improvements
- Continue ongoing dialogue with the U.S. Food and Drug Administration (FDA) as they review the New Drug Application (NDA) under their Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible
- Continue progressing belumosudil commercial launch readiness activities in anticipation of potential FDA approval in 2021
- The Company expects to share an update on the path forward for belumosudil in Europe in 1H 2021
- Continue enrollment in ongoing placebo-controlled Phase 2 clinical trial in diffuse cutaneous systemic sclerosis (KD025-209); the Company continues to work with sites and trial coordinators to facilitate patient enrollment amid the COVID-19 pandemic
- Initiate small (12-15 patient), open-label Phase 2 clinical trial of belumosudil in patients with diffuse cutaneous systemic sclerosis in Q1 2021

25. On November 30, 2020, Kadmon issued a press release announcing the FDA's acceptance of the Belumosudil NDA, and that the FDA had assigned the NDA a PDUFA target action date of May 30, 2021. That press release stated, in relevant part:

Kadmon . . . today announced that the [FDA] has accepted the Company's [NDA] for belumosudil (KD025), the Company's [ROCK2] inhibitor, for the treatment of patients with [cGVHD]. The FDA granted Priority Review for the NDA for belumosudil, which provides for a six-month review, and assigned a [PDUFA] target action date of May 30, 2021.

"The FDA's acceptance of our NDA for belumosudil represents an important milestone for Kadmon and further highlights the efforts of the Agency to bring meaningful new therapies to cGVHD patients as quickly as possible," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We look forward to the opportunity to bring belumosudil to market as we continue preparations for a launch, if approved."

Kadmon submitted the NDA for belumosudil under the FDA's Real-Time Oncology Review (RTOR) pilot program. This pilot program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality.

The review of the belumosudil NDA is also being conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among participating international partners.

* * *

The NDA submission is supported by positive data from ROCKstar (KD025-213), the Company's pivotal clinical trial evaluating belumosudil in patients with cGVHD who have received two or more prior lines of systemic therapy. Twelve-month data from ROCKstar will be presented in an oral session at the 62nd American Society of Hematology (ASH) Annual Meeting on December 6th, 2020.

26. On December 6, 2020, Kadmon issued a press release "Announc[ing] 12 Month Data from Pivotal Trial of Belumosudil for cGVHD at the 62nd ASH Annual Meeting." The press release quoted Defendant Waksal, stating, in relevant part:

"We are extremely pleased with the 12-month results from this trial, as the Overall Response Rates have consistently strengthened, the durability has proven to be

robust, the drug continues to perform across a number of key secondary endpoints and has been well tolerated,” said Harlan W. Waksal, M.D., President and CEO at Kadmon. “With the FDA’s recent acceptance of our NDA filing and a PDUFA date of May 30, 2021, we are moving forward with our commercial preparation efforts, having hired two-thirds of our planned field force. We look forward to continuing to work closely with the FDA as they complete their review of belumosudil in cGVHD.”

27. On March 4, 2021, Kadmon filed an annual report on 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 10-K”). The 2020 10-K also made positive statements regarding the Belumosudil NDA, stating, in relevant part:

In November 2020, the [FDA] accepted the [NDA] for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a [PDUFA] target action date of May 30, 2021. The NDA is being reviewed under the FDA’s Real-Time Oncology Review (“RTOR”) and Project Orbis pilot programs.

According to the FDA, the RTOR pilot program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. In addition, the FDA has granted Breakthrough Therapy Designation (BTD) for belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD. BTD is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

28. Further, in providing an overview of the Company’s strategy, the 2020 10-K stated, in relevant part:

Our goal is to develop innovative therapies for significant unmet medical needs. Our key strategies to achieve this goal are listed below:

- ***Advance belumosudil for the treatment of immune diseases.*** Our NDA has been accepted by the FDA for belumosudil for the treatment of cGVHD. As further discussed below, we recently announced positive results from the 12-month follow-up analysis of the trial. We are also conducting a placebo-controlled Phase 2 clinical trial of belumosudil in systemic sclerosis and

plan to initiate an open-label Phase 2 clinical trial of belumosudil in systemic sclerosis in 2021.

29. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by the Individual Defendants, attesting that “the information contained in [the 2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

30. Corresponding with the 2020 10-K, Kadmon issued a press release providing a business update and announcing the Company’s Q4 2020 financial results. The press release stated, in relevant part:

“With the acceptance of Kadmon's new drug application for belumosudil in cGVHD in hand, we are preparing for our potential commercial launch in light of our May 30th PDUFA date,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “We are leveraging our existing commercial infrastructure and have thus nearly completed the scale-up required to launch belumosudil, if approved. We continue to seek to understand the needs of cGVHD patients in key transplant centers throughout the United States and look forward to working closely with FDA to bring this much-needed therapy to cGVHD patients in the coming months.”

* * *

2021 Anticipated Key Clinical Milestones:

Belumosudil

- Continue ongoing dialogue with the U.S. Food and Drug Administration (FDA) as they review the New Drug Application (NDA) of belumosudil, the Company's (ROCK2) inhibitor, for the treatment of patients with chronic graft-versus-host disease (cGVHD).
 - The FDA set a Prescription Drug User Fee Act (PDUFA) date for belumosudil of May 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible.
 - The review of the belumosudil NDA is also being conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among participating international countries.
- Continue belumosudil commercial launch readiness activities in anticipation of potential FDA approval in 1H 2021. The Company has the

majority of its planned field sales and medical science liaison teams. The Company believes these focused teams can adequately address the concentrated cGVHD market, where approximately 80% of patients are treated at 70 U.S. transplant centers.

- Initiate small (12-15 patient), open-label Phase 2 clinical trial of belumosudil in patients with dcSSc (Study KD025-215) in 2021. The Company plans to present initial data from this study by year-end 2021.
- Continue enrollment in ongoing placebo-controlled Phase 2 clinical trial in dcSSc (KD025-209); the Company continues to work with sites and trial coordinators to facilitate patient enrollment amid the COVID-19 pandemic

31. The statements referenced in ¶¶ 21-30 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Belumosudil NDA was incomplete and/or deficient; (ii) the additional new data that the Company submitted in support of the Belumosudil NDA in response to an information request from the FDA materially altered the NDA submission; (iii) accordingly, the initial Belumosudil NDA submission lacked the degree of support that the Company had led investors to believe; (iv) accordingly, the FDA was likely to extend the PDUFA target action date to review the Belumosudil NDA; and (v) as a result, the Company’s public statements were materially false and misleading at all relevant times.

The Truth Emerges

32. On March 10, 2021, Kadmon issued a press release “announc[ing] that the [FDA] has extended the review period for the [Belumosudil NDA][.]” The press release advised investors, in relevant part:

[i]n a notice received from the FDA on March 9, 2021, the Company was informed that the Prescription Drug User Fee Act (PDUFA) goal date for its Priority Review of belumosudil has been extended to August 30, 2021.

The FDA extended the PDUFA date to allow time to review additional information submitted by Kadmon in response to a recent FDA information request. The submission of the additional information has been determined by the FDA to constitute a major amendment to the NDA, resulting in an extension of the PDUFA date by three months.

“We remain confident in the data supporting our application for belumosudil in cGVHD and look forward to continuing to work closely with the FDA during the remainder of the review process,” said Harlan W. Waksal, M.D., President and CEO of Kadmon. “We are committed to bringing belumosudil to market, once approved, to help meet the needs of patients living with cGVHD.”

33. On this news, Kadmon’s stock price fell \$0.52 per share, or 10.57%, to close at \$4.40 per share on March 11, 2021.

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

PLAINTIFF’S CLASS ACTION ALLEGATIONS

35. Plaintiff brings 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 Kadmon securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, 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.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Kadmon securities were actively traded on the NYSE and NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds

or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Kadmon or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

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

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Kadmon;
- whether the Individual Defendants caused Kadmon to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Kadmon securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

40. 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 Class members may be relatively small, the expense and burden of individual litigation make it impossible for 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.

41. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Kadmon securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE and NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Kadmon securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

42. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

43. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

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

44. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

45. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

46. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Kadmon securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Kadmon securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

47. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Kadmon securities. Such reports, filings, releases and statements were

materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Kadmon's finances and business prospects.

48. By virtue of their positions at Kadmon, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

49. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Kadmon, the Individual Defendants had knowledge of the details of Kadmon's internal affairs.

50. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Kadmon. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Kadmon's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Kadmon securities was artificially inflated throughout the Class Period. In

ignorance of the adverse facts concerning Kadmon's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Kadmon securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

51. During the Class Period, Kadmon securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Kadmon securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Kadmon securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Kadmon securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

52. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

53. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

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

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

55. During the Class Period, the Individual Defendants participated in the operation and management of Kadmon, and conducted and participated, directly and indirectly, in the conduct of Kadmon's business affairs. Because of their senior positions, they knew the adverse non-public information about Kadmon's misstatement of income and expenses and false financial statements.

56. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Kadmon's financial condition and results of operations, and to correct promptly any public statements issued by Kadmon which had become materially false or misleading.

57. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Kadmon disseminated in the marketplace during the Class Period concerning Kadmon's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Kadmon to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Kadmon within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Kadmon securities.

58. Each of the Individual Defendants, therefore, acted as a controlling person of Kadmon. By reason of their senior management positions and/or being directors of Kadmon, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Kadmon to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Kadmon and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

59. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Kadmon.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: