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**UNITED STATES DISTRICT COURT**

**SOUTHERN DISTRICT OF CALIFORNIA**

ERVIN DERR, and PETER SHOEMAKER, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

RA MEDICAL SYSTEMS, INC., DEAN IRWIN, ANDREW JACKSON, MELISSA BURSTEIN, MARTIN BURSTEIN, RICHARD HEYMANN, MAURICE BUCHBINDER, MARTIN COLOMBATTO, RICHARD MEJIA, JR., MARK E. SAAD, and WILLIAM ENQUIST, JR.,

Defendants.

Case No. 3:19-cv-01079-LAB-AHG

**SECOND AMENDED COMPLAINT**

The Hon. Larry Alan Burns

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Lead Plaintiffs Ervin Derr and Peter Shoemaker ("Plaintiffs"), individually and on behalf of all others similarly situated, by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Ra Medical Systems, Inc. ("Ra Medical" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Ra Medical; and (c) review of other publicly available information concerning Ra Medical.

## I. INTRODUCTION

1. This is a federal securities class action on behalf of persons and entities that purchased or otherwise acquired Ra Medical securities: (a) pursuant and/or traceable to the registration statement and prospectus (collectively, the "Registration Statement") issued in connection with the Company's September 2018 initial public offering ("IPO" or the "Offering"); and/or (b) between September 27, 2018 and November 27, 2019, inclusive (the "Class Period"). Plaintiffs pursue claims against the Defendants under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

2. Ra Medical is a medical device manufacturer. In September 2018, the Company completed its IPO and sold 4,485,000 shares of common stock for $17.00 per share, raising $67.6 million in proceeds. When the Company completed its IPO, its DABRA laser system and catheter, which dissolve plaque in vascular blockages, positioned Ra Medical for a steady stream of recurring revenue. Specifically, the DABRA system is offered to physicians for a nominal fee, and the Company recognizes revenue from sales of its single-use disposable DABRA catheter. Though the Company is limited to marketing the DABRA system and catheter (collectively called DABRA) for the intended use approved by the U.S. Food and Drug

Administration ("FDA") in ablating a channel in occlusive peripheral vascular disease, a form of peripheral artery disease ("PAD"), Ra Medical planned to seek expanded indications, including for atherectomy, which presented a total addressable market of over $1 billion. Thus, DABRA presented a unique growth opportunity for Ra Medical, with some analysts predicting DABRA would quadruple the Company's revenue in the first year after the IPO.

3. Initially, Ra Medical seemed to be executing its strategy in expanding its salesforce and increasing its sales. And when a competitor accused Ra Medical of off-label marketing, the Company denied the allegations and claimed that it "compl[ied] with these restrictions," which "allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products." In particular, though the medical community refers to the breakdown of plaque as atherectomy, DABRA's FDA label is limited to use in certain forms of PAD. Unbeknownst to investors, the FDA had already warned the Company that it improperly marketed DABRA as an atherectomy device, but Ra Medical continued to instruct its sales representatives to promote DABRA for atherectomy and to encourage physicians to bill using atherectomy reimbursement codes.

4. In March 2019, Ra Medical began to disclose manufacturing problems with DABRA catheters, but falsely claimed that these problems were resolved and omitted other material information. On March 14, 2019, in connection with its fourth quarter 2018 financial results, Ra Medical disclosed that "production limitations" as the Company "scaled up catheter production" to meet increased demand negatively impacted fourth quarter 2018 revenue, but that it had "solved" those issues and would "begin to see the positive impact on revenue beginning in the second quarter of 2019." On this news, the Company's share price fell $2.14 per share, or approximately 32.57%, to close at $4.43 per share on March 15, 2019, on unusually heavy trading volume.

5. But this masked the real manufacturing issue: in reality, the manufacturing problem had existed since February 2018, seven months before the IPO, and resulted in DABRA catheters that failed to calibrate, leading to inconsistent performance. As early as February 2018, Ra Medical had been engaged in a covert product recall, as technicians serviced affected lasers and replaced catheters for physicians, while the Company attempted to fix the manufacturing problem without disclosing the DABRA catheters' failure to calibrate.

6. In May 2019, Ra Medical suggested that it had overcome problems with DABRA catheters and was on track to increase sales. In connection with its first quarter 2019 financial results, on May 13, 2019, defendant Jackson stated that the production limitations were "***a one-off***," and defendant Irwin stated that the Company had "completed the validation of [its] upgraded manufacturing process to accommodate catheter production at scale."

7. However, just three months later, Ra Medical was forced to disclose the real manufacturing issues and to acknowledge that they had not been resolved. On August 12, 2019, Ra Medical admitted that it had "experienced inconsistencies in its DABRA catheter manufacturing process" and that "[t]he percentage of catheters that fail to calibrate at customer sites . . . began to increase." In addition, Ra Medical surprised investors by disclosing that its Audit Committee had launched an investigation into an anonymous complaint and that Irwin had been terminated from his positions as Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors. On this news, Ra Medical's share price tanked—it fell $1.61, or nearly 57.09%, to close at $1.21 per share on August 13, 2019, on unusually heavy trading volume.

8. Still, Ra Medical continued to mislead investors about the extent of the manufacturing issue because it failed to disclose the covert product recall that Ra Medical had undertaken to save its relationships with physicians. It also failed to disclose that the Company had engaged in off-label marketing by promoting

DABRA for atherectomy, even though DABRA is only approved by the FDA to treat certain forms of PAD.

9. Then, on September 27, 2019, Ra Medical finally disclosed that it had initiated a "voluntary recall of its DABRA laser system single-use catheters due to a change in product labeling." The recall purportedly reflected a recent "relabeling [of] the catheters with two-month expiration, replacing its previous twelve-month shelf life expiration." On this news, the Company's stock price fell $0.18, or nearly 11.38%, to close at $1.40 per share on September 30, 2019, on unusually heavy trading volume.

10. However, the Company did not disclose that it had undertaken the covert product recall, or efforts leading to the recall, nearly a year and a half earlier in February 2018 when Ra Medical's technicians started visiting customer facilities to service affected lasers.

11. On October 31, 2019, after the market closed, Ra Medical disclosed the Audit Committee investigation's findings, admitting: (1) that DABRA catheters frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (2) that this inconsistent performance with DABRA catheters had adversely affected the Company's fourth quarter 2018 and first quarter 2019, rather than "production limitations" due to increased demand; and (3) that, due to the DABRA catheters' failure to calibrate, Ra Medical began systematically replacing product for customers, without disclosing the covert product recall to investors or to the FDA.

12. In addition, the Company admitted the same day that it engaged in off-label marketing—a reversal from prior denials—by directing physicians to use DABRA for atherectomy, and that it used other tactics, including bribery, to increase its sales in the midst of the product performance issues. Specifically, Ra Medical admitted: (1) that it had directed its sales representatives to market and promote DABRA as an atherectomy device and to encourage doctors seeking

reimbursement using atherectomy codes; (2) that it had made over $300,000 in payments to physicians without adequate documentation, suggesting that the payments were an improper attempt to obtain business; and (3) that it had directed benefits and opportunities to certain doctors based on sales prospects.

13. Ra Medical's off-label marketing increased regulatory scrutiny on the Company, as the U.S. Department of Justice ("DOJ") sent a civil investigative demand concerning whether Ra Medical fraudulently obtained marketing clearance for DABRA from the FDA, and the SEC investigated the findings of the Audit Committee. Not only does Ra Medical's off-label marketing of DABRA jeopardize the FDA approval for the device, the Company also admitted that it failed to timely make at least two medical device reports to the FDA, which are used as post-market surveillance to monitor the device's performance and safety.

14. Furthermore, the Company acknowledged on October 31, 2019 that internal complaints had drawn attention to these and other ethical concerns, but these issues were not promptly investigated. Specifically, Ra Medical admitted that it had "received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not." On this news, the Company's stock price fell $0.11, or nearly 7.28%, to close at $1.40 on November 1, 2019, on unusually heavy trading volume.

15. Finally, on November 29, 2019, before the market opened, Ra Medical disclosed that the DOJ inquiry had escalated to a criminal investigation. The Company also disclosed that deficiencies in its internal controls existed as of December 31, 2018 and March 31, 2019, which aggregated to a material weakness. On this news, the Company's stock price fell $0.16, or nearly 11.19%, to close at $1.27 per share on November 29, 2019, on unusually heavy trading volume.

16. On November 29, 2019, the Company' stock price closed at $1.27 per share, a decline of approximately 92.53% from the IPO price of $17.00. As a result,

investors who bought pursuant and/or traceable to the IPO suffered substantial losses.

## II. JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o) and 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).

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

19. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged securities law violations, and/or the effects of the violations, occurred in this Judicial District. Many of the acts charged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this Judicial District.

20. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

## III. PARTIES

### Plaintiffs

21. Lead Plaintiff Ervin Derr, as set forth in his previously-filed certification (*See* Dkt. No. 1), incorporated by reference herein, purchased Ra Medical common stock pursuant or traceable to the Registration Statement issued in connection with the Company's IPO and during the Class Period, and suffered

damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

22. Lead Plaintiff Peter Shoemaker, as set forth in his previously-filed certification (Dkt. No. 22), incorporated by reference herein, purchased Ra Medical common stock pursuant or traceable to the Registration Statement issued in connection with the Company's IPO and during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

**Defendants**

23. Defendant Ra Medical is incorporated under the laws of Delaware with its principal executive offices located in Carlsbad, California. Ra Medical's common stock trades on the New York Stock Exchange ("NYSE") under the symbol "RMED."

24. Defendant Dean Irwin ("Irwin") co-founded Ra Medical in 2002 and served as the Company's Chief Executive Officer ("CEO"), Chief Technology Officer, Co-President, and Chairman of the Board of Directors from September 2002 to August 12, 2019. Prior to founding Ra Medical, Irwin was Vice President of Research, Development, and Engineering of PhotoMedex, Inc., a manufacturer of excimer lasers, from February 1998 to August 2002. Irwin signed or authorized the signing of the Company's Registration Statement filed with the SEC.

25. Defendant Andrew Jackson ("Jackson") has served as the Company's Chief Financial Officer ("CFO") since April 2018 and as Interim CEO since August 12, 2019. Jackson signed or authorized the signing of the Company's Registration Statement filed with the SEC.

26. Defendants Irwin and Jackson, collectively referred to hereinafter as the "Exchange Act Individual Defendants," because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities

analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Exchange Act Individual Defendants were provided with copies of the Company's reports 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 cause them to be corrected. Because of their positions and access to material non-public information available to them, the Exchange Act 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 which were being made were then materially false and/or misleading. The Exchange Act Individual Defendants are liable for the false statements pleaded herein.

27. Defendant Melissa Burstein ("Burstein") co-founded Ra Medical in 2002 and served as Executive Vice President and a director of the Company from September 2002 to March 2019, and as Vice President from April 2019 to November 1, 2019. She is Irwin's wife. Burstein signed or authorized the signing of the Company's Registration Statement filed with the SEC.

28. Defendant Martin Burstein ("Martin Burstein") has served as a director of the Company since October 2003, and signed or authorized the signing of the Company's Registration Statement filed with the SEC. Martin Burstein is Irwin's father-in-law.

29. Defendant Richard Heymann ("Heymann") has served as a director of the Company since July 2008 and as an employee in Corporate Strategy and Business Development since January 2016. Heymann signed or authorized the signing of the Company's Registration Statement filed with the SEC.

30. Defendant Maurice Buchbinder ("Buchbinder") has served as a director of the Company since January 1, 2017 and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

31. Defendant Martin Colombatto ("Colombatto") has served as a director of the Company since January 2017 and signed or authorized the signing of the

Company's Registration Statement filed with the SEC. Colombatto is a member of Ra Medical's Audit Committee.

32. Defendant Richard Mejia, Jr. ("Mejia") has served as a director of the Company since July 2018 and signed or authorized the signing of the Company's Registration Statement filed with the SEC. Mejia is a member of Ra Medical's Audit Committee.

33. Defendant Mark E. Saad ("Saad") has served as a director of the Company since July 2018 and signed or authorized the signing of the Company's Registration Statement filed with the SEC. Saad is a member of Ra Medical's Audit Committee.

34. Defendant William Enquist Jr. ("Enquist") has served as a director of the Company since July 2018 and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

35. Defendants Irwin, Jackson, Burstein, Martin Burstein, Heymann, Buchbinder, Colombatto, Mejia, Saad, and Enquist are collectively referred to hereinafter as the "Securities Act Individual Defendants."

36. Unless otherwise noted, "Defendants" refers to Defendants Ra Medical, Irwin, Jackson, Burstein, Martin Burstein, Heymann, Buchbinder, Colombatto, Mejia, Saad, and Enquist.

**Relevant Non-Parties**

37. Piper Sandler & Co. f/k/a Piper Jaffray & Co. ("Piper Sandler") served as an underwriter for the Company's IPO. In the IPO, Piper Sandler sold 1,560,000 shares of Ra Medical, exclusive of the underwriter's overallotment option. Piper Sandler served as a joint book-running manager of the Offering. Piper Sandler changed its name from Piper Jaffray & Co., effective January 3, 2020. *See* Dkt. No. 20.

38. Cantor Fitzgerald & Co. ("Cantor") served as an underwriter for the Company's IPO. In the IPO, Cantor sold 1,365,000 shares of Ra Medical, exclusive

of the underwriter's overallotment option. Cantor served as a joint book-running manager of the Offering.

39. SunTrust Robinson Humphrey, Inc. ("SunTrust") served as an underwriter for the Company's IPO. In the IPO, SunTrust sold 585,000 shares of Ra Medical, exclusive of the underwriter's overallotment option.

40. Nomura Securities International, Inc. ("Nomura") served as an underwriter for the Company's IPO. In the IPO, Nomura sold 292,500 shares of Ra Medical, exclusive of the underwriter's overallotment option.

41. Maxim Group LLC ("Maxim") served as an underwriter for the Company's IPO. In the IPO, Maxim sold 97,500 shares of Ra Medical, exclusive of the underwriter's overallotment option.

42. Thomas Fogarty ("Fogarty") has been the Company's Chief Commercial Officer ("CCO") since December 17, 2018.

43. Confidential Witness ("CW") 1 was a senior Ra Medical employee who self-identified him/herself as the whistleblower whose letters launched the Audit Committee investigation. CW 1 was employed by Ra Medical from before the IPO until fall 2019.

44. CW 2 was a Marketing Coordinator and Executive Assistant to defendant Burstein from several months before the IPO until October 2019. As Marketing Coordinator, CW 2 attended all sales training sessions to coordinate logistics of the sessions. CW 2 was also responsible for planning and setting up at national and international tradeshows, including shipping materials and supplies for the events. CW 2 reported to defendant Burstein, who was responsible for the marketing for dermatology and cardiovascular products and approved all brochures and marketing materials until January 2019, when Fogarty was hired. Defendant Burstein was also the sole sales trainer for all sales representatives until January 2019. According to CW 2, defendant Burstein reported to defendant Irwin until January 2019, when she began reporting to Fogarty. As Executive Assistant, CW 2

was responsible for submitting defendant Burstein's expense reports, among other things.

45. CW 3 was a sales representative for DABRA catheters in the Midwest region from the IPO until the second quarter 2019. CW 3 reported to Manager Scott Creecy and later to Manager David Hampton. Prior to joining Ra Medical, CW 3 had over 10 years of experience in medical device sales.

## IV. PLAINTIFFS PURCHASED RA MEDICAL SHARES PURSUANT OR TRACEABLE TO THE REGISTRATION STATEMENT

46. Plaintiff Ervin Derr first purchased shares of Ra Medical common stock on February 6, 2019, *see* Dkt. No. 1, and Plaintiff Peter Shoemaker first purchased shares of Ra Medical common stock on February 8, 2019, *see* Dkt. No. 22. Plaintiffs are informed and believe that the only shares in the public market at the time of these purchases were the common shares issued in connection with the Registration Statement, so Plaintiffs purchased shares pursuant or traceable to the Registration Statement.

47. When the IPO closed, there were 12,689,251 shares of common stock outstanding. Of these, 4.485 million shares had been issued in connection with the Registration Statement. According to the Registration Statement, the remaining 8,204,251 shares of common stock were "restricted securities," as defined under Rule 144 of the Securities Act ("Rule 144"). According to the Registration Statement, these restricted securities became available for sale in the public market as follows: (a) beginning 181 days after the date of the Prospectus, 7,887,820 restricted shares were eligible for sale, subject in some cases to the volume and other restrictions of Rule 144 (the "Lock-Up"); and (b) 316,431 restricted shares were eligible for sale pursuant to Rule 144.

48. Shares subject to the Lock-Up were not eligible for sale until 181 days after the date of the prospectus, *i.e.* March 27, 2019, so the 7,887,820 non-IPO

shares could not have entered the market before Plaintiffs purchased their shares in February 2019.

49. The remaining 316,431 restricted shares became eligible for sale subject to Rule 144, which "allows public resale of restricted and control securities if a number of conditions are met."[1] Even when a holder meets the conditions of Rule 144, the restricted shares cannot be sold unless the restrictive legend is removed from the certificate. *Id.* Only a transfer agent can remove a restrictive legend, and the transfer agent will do so only with the consent of the issuer, which is usually in the form of an opinion letter from the issuer's counsel. *Id.* Therefore, in order for any of the 316,431 shares to enter the market, Ra Medical must have provided consent to remove the restrictive legend and permit the sale.

50. For example, counsel for Ra Medical provided a copy of a letter dated January 3, 2019 regarding a single shareholder's request to remove the restrictive legends from 151,071 shares of Ra Medical stock and instructions to the transfer agent to reissue the shares with no restrictive legends.[2] Plaintiffs are informed and believe, based on a conversation between Plaintiffs' counsel and the shareholder identified in the letter, that the shareholder did not sell any of the 151,071 shares prior to February 8, 2019.

51. Moreover, a review of Form 4s (reflecting insider sales) and Form 144s filed with the SEC suggests that the earliest instance where unregistered shares could have entered the market is on April 11, 2019, *i.e.* after Plaintiffs purchased shares in February 2019.

[1] https://www.sec.gov/reportspubs/investor-publications/investorpubsrule144htm.html

[2] Counsel for Ra Medical provided a copy of the letter dated January 3, 2019 to Plaintiffs' counsel as an attachment to a letter dated June 23, 2020.

52. Due to the foregoing, Plaintiffs are informed and believe that no non-IPO shares of Ra Medical entered the market prior to Plaintiffs' purchases, which will be confirmed during discovery.

## V. CLASS ACTION ALLEGATIONS

53. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class (the "Class"), consisting of all persons and entities that purchased or otherwise acquired Ra Medical securities: (a) pursuant and/or traceable to the Company's IPO; and/or (b) between September 27, 2018 and November 27, 2019, inclusive, and were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

54. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Ra Medical's common shares actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Ra Medical common stock were traded publicly during the Class Period on the NYSE. As of November 20, 2019, Ra Medical had approximately 13,407,995 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Ra Medical 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.

55. Plaintiffs' 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.

56. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

57. 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:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public in the Registration Statement and/or during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Ra Medical; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

58. 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 makes 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.

## VI. BACKGROUND

### A. Company Overview

59. Ra Medical is a commercial-stage medical device manufacturer that offers two products: DABRA and Pharos.

60. The DABRA laser system and disposable catheter, together referred to as DABRA, is used in the endovascular treatment of vascular blockages by dissolving plaque without generating harmful particulates. DABRA can cross and

debulk, reduce, or remove a broad range of blockage types without the use of a guidewire.

61. The Company offers DABRA on a razor/razorblade model: the laser system is given away for a nominal monthly fee, and Ra Medical derives revenue principally from sales of the single-use disposable catheter. The Company's main competitive advantage is its lower average selling price: the DABRA catheter is sold for approximately $1,200 apiece, while competitors offer similar products for at least $2,500. Thus, DABRA catheter sales is the primary driver of revenue growth.

62. Ra Medical received 510(k) clearance in May 2017 to market DABRA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use in ablating a channel in occlusive peripheral vascular disease, a form of peripheral artery disease ("PAD").

63. Pharos is also an excimer laser device and is used to treat dermatological skin disorders using highly concentrated ultraviolent light.

64. In September 2018, the Company completed its IPO.

**B. Ra Medical Must Comply With Strict FDA Regulations**

65. As a medical device manufacturer, Ra Medical must adhere to FDA requirements, including: registration with the FDA; listing commercially distributed products with the FDA; complying with current good manufacturing practices ("cGMPs") under the Quality System Regulations, or QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing.

66. Since DABRA is a medical laser, Ra Medical must also ensure that it complies with FDA requirements to ensure the radiological safety of the product,

including filing certain reports with the FDA about DABRA and defects/safety issues, as well as complying with radiological performance standards.

### 1. FDA Limits The Intended Use Of DABRA To Treat Certain Forms Of PAD

67. Prior to selling a medical device, manufacturers must seek premarket clearance from the FDA pursuant to Section 510(k) of the Food, Drug and Cosmetic Act by demonstrating that the device is substantially equivalent to, *i.e.* at least as safe and effective as, a legally marketed device that is not subject to premarket approval.

68. Ra Medical received 510(k) clearance in May 2017 to market DABRA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use in ablating a channel in occlusive peripheral vascular disease, a form of peripheral artery disease ("PAD"). In June 2018, the Company completed its 12-month commercial launch period, including training, production, and staffing for marketing DABRA in the United States.

69. In May 2019, Ra Medical submitted an investigational device exemption ("IDE") to the FDA for expansion of the DABRA label to specifically include atherectomy. An IDE allows the device to be used in a clinical study to collect safety and effectiveness data. When it announced the IDE submission, the Company expected to enroll up to 100 patients at up to 10 clinical sites with a six-month follow-up for each patient and to receive trial results in first quarter 2020. At all relevant times herein, DABRA did not have an FDA-approved indication for atherectomy.

### 2. Ra Medical Can Only Market DABRA For Its Intended Use

70. The FDA regulates the advertising and promotion of medical devices. Physicians may determine that a device is appropriate for a treatment that is not yet approved by the FDA. However, manufacturers can only market and promote their

products for the intended use approved by the FDA; promoting the device for other, unapproved uses is called "off-label marketing."

71. For example, though the medical community refers to the breakdown of plaque as atherectomy, DABRA's FDA label is limited to treat certain forms of PAD. The FDA definition of atherectomy includes a predetermined increase in the openness of the artery at a pre-defined time point. To market DABRA for atherectomy, the Company must seek an expanded indication demonstrating an acceptable level of openness of the artery at a pre-defined time point using a consistent assessment tool.

### 3. If Ra Medical Initiates Any Correction Or Recall Of DABRA, It Must Notify The FDA

72. Medical device manufacturers must undertake a product recall to protect the public from products that present a risk of injury or gross deception or are otherwise defective.

73. If any correction or removal of a medical device was initiated to reduce a risk to public health posed by the device or to remedy a violation of the Food, Drug and Cosmetic Act, the manufacturer is required to make a report to the FDA pursuant to 21 C.F.R. § 806. A correction includes any repair, modification, or relabeling of a product without its physical removal to some other location.

### 4. Ra Medical Must Notify The FDA If DABRA Malfunctions

74. The FDA uses medical device reports ("MDRs") to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

75. Manufacturers are mandatory reporters pursuant to 21 C.F.R. § 803. Device manufacturers must timely report to the FDA any instances, among others, where the device malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur.

### C. Unbeknownst To Investors, The FDA Warned Ra Medical Prior To The IPO That The Company Was Improperly Engaging In Off-Label Marketing

76. Multiple sources report that in September 2018, the FDA contacted Ra Medical and warned that its marketing materials improperly promoted DABRA as an atherectomy device. They further recount that the Company continued to promote DABRA as an atherectomy device despite the FDA's warnings.

77. ***The FDA Told Ra Medical not to Mention Atherectomy.*** According to CW 2, Ra Medical participated in the Transcatheter Cardiovascular Therapeutics tradeshow in San Diego held September 21 – 25, 2018 and used marketing materials that mentioned atherectomy. Defendant Burstein told CW 2 that the FDA contacted the Company about these marketing materials and instructed Ra Medical not to mention atherectomy in marketing materials any longer. CW 3 was also aware of a verbal warning from the FDA to remove any mention of atherectomy from marketing literature prior to the IPO. Similarly, David Oliveri, a former employee of Ra Medical, recalls the FDA's warning to the Company. Mr. Oliveri was employed by Ra Medical from September 12, 2018 to January 10, 2019.[3] According to Mr. Oliveri, he attended a training session on September 17, 2018 during which Defendant Burstein "alerted the team that RA Medical had just received a 'gentle reminder' from the FDA not to market DABRA as an 'atherectomy system' because that was not the approved indication for the product." *Id.*

78. ***Ra Medical Removed Written References to Atherectomy, but Continued to Market DABRA for Atherectomy.*** Despite the warning, Mr. Oliveri recalls that Defendant Burstein "still ordered the sales representatives to 'stay on message' and advise their accounts to bill the DABRA product as an atherectomy

[3] *See* Complaint, *Oliveri v. Ra Medical Systems, Inc.*, Case No. 37-2019-00043227-CU-WT-NC (San Diego Super. Ct. Aug. 15, 2019), attached hereto as Exhibit ("Ex.") 1; *see also* Complaint, *Oliveri v. Ra Medical Systems, Inc.*, Case No. A-20-81349-C (8th Judicial Dist. Ct. of Nev. Apr. 10, 2020), attached hereto as Ex. 2.

system." *Id.* CW 2 was instructed to destroy the marketing materials that the FDA had referenced, but CW 3 stated that the Company continued to direct sales representatives to market DABRA for atherectomy. Indicating that Defendant Burstein knew such practices contravened FDA guidance, Defendant Burstein "asked the sales representative to ***be careful with the information they put in writing*** but to continue to market the DABRA product as an atherectomy device." *Id.*

79. ***Ra Medical Settles Claims with the DOJ Regarding Off-Label Marketing.*** On January 4, 2021, Ra Medical announced that it had entered into a settlement agreement to resolve a pending DOJ investigation and related action regarding the Company's marketing of the DABRA laser system, improper payments to certain physicians, and undisclosed product defects.[4] According to the settlement agreement, the United States "contends that it has certain civil claims against [Ra Medical] for engaging in the following conduct during the period from May 1, 2017 through October 31, 2019 . . . (2) [Ra Medical] knowingly marketed the DABRA Laser for use in atherectomy procedures [even though] [t]he DABRA Laser was not approved or cleared by the FDA for use in atherectomy procedures."[5] The settlement also encompasses an action by a former employee brought on behalf of the federal government alleging, among other things "that the Company violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by . . . promoting off-label use of the DABRA system . . . ." *See* Ex. 3.

[4] *See* Ra Medical Form 8-K dated January 4, 2021, attached as Ex. 3.

[5] *See* Exhibit 10.19 to Ra Medical's fiscal 2020 Form 10-K filed with the SEC on March 17, 2021, attached hereto as Ex. 4.

**D. Before The IPO, Ra Medical Denied Allegations Of Off-Label Marketing In Connection With A Dispute With Strata Skin Sciences, Inc.**

80. Prior to the IPO, Ra Medical had a dispute with a competitor, Strata Skin Sciences, Inc. ("Strata"), a medical device company that sells products for the treatment of dermatologic conditions. The dispute centered around statements by Uri Geiger ("Geiger"), Chairman of the Board of Directors of Strata, to John Hagens ("Hagens") of UBS Investment Bank, which had agreed to act as the lead bookrunning manager for Ra Medical's IPO. Geiger had accused Ra Medical of off-label marketing, among other things, and the Company denied the claims in connection with litigation resulting from the dispute. *See* Complaint, *Strata Skin Scis., Inc. v. Ra Med. Sys., Inc.*, C.A. 2018-21421 (Pa. Ct. Com. Pl. Aug. 30, 2018) (the "Strata Complaint").

81. According to the Strata Complaint, on May 22, 2018, Geiger sent an email to Hagens to "alert [him] to some concerning issues regarding the IPO of RA Medical which may result in underwrite[r] liability and [a]ffect your brand." The email alleged that Ra Medical engaged in potential off-label marketing and infringed certain patents, stating in relevant part:

> ***Potential Off-Label Marketing***
>
> ***I heard that RA may*** be promoting the DEBRA [sic] laser as atherectomy device (and physicians are collecting reimbursement from payer as such) while the FDA clearance is limited to CTO (which presents only 10% of the antrectomy [sic] cases). I am confident you don't want to associate your brand with inaccurate description in a prospectus, potential off-label marketing and improper collection of CMS reimbursement, ***if such indeed exist (and assume you will have your own independent investigation into the same).***

Strata Complaint, ¶ 33 (emphasis in original).

82. The Strata Complaint also alleged that, on June 4, 2018, Irwin sent a message to Geiger on LinkedIn stating:

> Hi Uri, I pegged you as a very smart guy. I suppose you're just educated. ***It will be exciting for both of us, perhaps I can school you, as I did your predecessors,*** perhaps I'm wrong. I hope you studied well at law. Too bad. We could have helped people together. I guess you're

> interested in ripping off the consumer, and everyone else as well. I'm sorry you're part of the "Dark Side." ***Let's go! Get ready for a ride, I never give up!*** I suspect you have so much more to lose than me! Dean

Strata Complaint, ¶ 58 (emphasis in original).

83. In response to Geiger's statements, the Strata Complaint alleged that Ra Medical sent a cease and desist letter to Strata dated August 22, 2018 threatening litigation if Strata did not affirmatively retract its allegations regarding patent infringement, arguing that Strata was a successor to a 2011 settlement agreement between PhotoMedex and Ra Medical.

84. On August 30, 2018, Strata and Geiger filed the Strata Complaint, seeking a declaration that, among other things, they are not liable for any reason as a result of statements made in Geiger's email. In the Strata Complaint, Geiger alleged that he "had a reasonable basis for suggesting that UBS investigate possible off-label marketing by Ra" because he was "aware that Ra was promoting the product as a device broadly and generally for atherectomy procedures, notwithstanding that the FDA had cleared the product only for chronic total occlusions ('CTO'), which constitute a small portion of atherectomy procedures." Strata Complaint, ¶¶ 43-54.

85. Then, on May 16, 2019, Ra Medical commenced an action in this District against Geiger and Strata alleging, among other things, intentional interference with contractual relations, intentional interference with prospective economic relations, and trade libel. *See* Complaint, *Ra Med. Sys., Inc. v. Geiger et al.*, Case No. 3:19-cv-00920 (S.D. Cal. May 24, 2019, ECF No. 5) (the "Ra Medical Complaint"). In the Ra Medical Complaint, the Company explicitly rejected claims about off-label marketing, suggesting that physicians had determined on their own accord that DABRA was appropriate for indications other than that approved by the FDA:[6]

> In addition, Mr. Geiger made several false statements regarding Ra Medical's DABRA laser and potential off-label marketing. ***First, Mr.***

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

> ***Geiger falsely implied that Ra Medical was encouraging physicians to improperly seek and receive reimbursements for procedures using the DABRA device from government payors like the Centers for Medicare and Medicaid Services ("CMS").*** *See* Exhibit B. This is a serious accusation, suggesting Ra Medical and physicians could face liability for inducing improper government payments. But Mr. Geiger's insinuation is entirely false. First, physicians are not strictly limited to use of medical devices consistent with FDA indications, if they determine that the device and procedure are medically appropriate for a particular patient. ***Many physicians have determined that the DABRA laser system is appropriate to treat a variety of artery blockages.*** Moreover, third party health payers can reimburse a procedure performed by a device that is not cleared or approved for a specific indication ***if, again, the physician determines that the device and procedure are medically appropriate for a particular patient.*** Indeed, CMS payments are predicated on the underlying treatment, *e.g.*, atherectomy for a blocked artery, not the device used to perform the treatment. Second, Mr. Geiger falsely implied that Ra Medical's device works in only 10% of the population, stating "the FDA clearance is limited to CTO (which represents only at 10% of a[]trectomy cases)." Id. In fact, Ra Medical's FDA clearance describes DABRA's "Intended Use" as "[f]or use in ablating a channel in occlusive peripheral vascular disease." This broader description of DABRA's FDA clearance, beyond chronic total occlusions, is omitted from Mr. Geiger's email altogether. Physicians use DABRA on all types of plaque, not just chronic total occlusions, which are some of the most serious artery blockages. Mr. Geiger, as the managing partner of Accelmed, is well acquainted with these issues as a result of ownership of the Eximo company and its B-laser products and, on information and belief, is aware that these statements are false or misleading.

Ra Medical Complaint, ¶ 31.

86. Moreover, Ra Medical claimed in its complaint that Geiger had alerted other underwriters to possible off-label marketing before the IPO, including Piper Sandler:

> This is not the case of a single email. Ra Medical has been informed, and on that basis alleges on information and belief, that Mr. Geiger sent communications like the one he sent to Mr. Hagens to many other banking partners involved in Ra Medical's IPO, including Oppenheimer Funds, as well as other banks who considered participation in the IPO. For example, Ra Medical understands that Piper Jaffray, the bank that ultimately led Ra Medical's IPO, received similar communications from Mr. Geiger.

Ra Medical Complaint, ¶ 33.

87. However, as alleged herein, the Company's denials were admittedly false. Ra Medical's Audit Committee's subsequent investigation found that the Company's sales representatives had indeed marketed DABRA as an atherectomy

device and encouraged physicians to seek reimbursement for atherectomy. *See* Section VIII.A, *infra.*

## VII. SUMMARY OF DEFENDANTS' VIOLATIONS OF THE SECURITIES ACT

### A. The Company Completed The IPO

88. On July 16, 2018, Ra Medical filed its Registration Statement on Form S-1 with the SEC.

89. On September 24, 2018, the Company filed its final amendment to the Registration Statement with the SEC on Form S-1/A, which forms part of the Registration Statement. The Registration Statement was declared effective on September 26, 2018.

90. On September 27, 2018, the Company filed its prospectus on Form 424B4 with the SEC, which forms part of the Registration Statement. In the IPO, the Company sold 4,485,000 shares of common stock at a price of $17.00 per share. The Company received proceeds of approximately $67.6 million from the Offering. The proceeds from the IPO were purportedly to be used for expansion of its direct sales force and marketing of its products; clinical studies for new products and product enhancements; and other research and development activities, working capital, and general corporate purposes.

91. The Company's stock began trading on the NYSE on September 27, 2018.

### B. The Registration Statement Contained Untrue Statements Of Material Facts And/Or Omitted To State Material Facts Required To Be Stated Therein Or Necessary To Make The Statements Therein Not Misleading

92. The Registration Statement was signed by the Securities Act Individual Defendants, and the IPO was underwritten by the Underwriters.

93. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts and/or omitted to state facts necessary to make the statements made therein not misleading, and the Registration Statement

was not prepared in accordance with the rules and regulations governing their preparation.

94. The statements made in the Registration Statement were materially misleading and/or omitted to state the following facts necessary to make the statements made therein not misleading: (1) that Ra Medical was experiencing manufacturing problems that caused DABRA catheters to fail to calibrate; (2) that, as a result of these performance issues, Ra Medical was engaged, or was reasonably likely to engage, in a product recall of DABRA catheters; (3) that the Company instructed its sales representatives to characterize DABRA as performing atherectomy and to seek reimbursement using atherectomy codes, despite the FDA's warning indicating that such practices constituted off-label marketing in violation of FDA regulations; and (4) that Ra Medical lacked a system to ensure adequate documentation of expenses, including payments to physicians.

95. The failure to disclose the above facts also rendered the Registration Statement materially misleading because those facts were required to be stated therein pursuant to Item 303 of SEC Regulation S-K ("Item 303"), 17 C.F.R. § 229.303(a)(3)(ii), which mandates that registration statements disclose "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Similarly, the regulation requires that the registration statement disclose events that the registrant knows would "cause a material change in the relationship between costs and revenues" and "any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected." 17 C.F.R. § 229.303(a)(3)(ii).

96. The Registration Statement was materially false and/or misleading because it failed to disclose, among others, the following known adverse trends and/or uncertainties that Ra Medical was required to disclose under Item 303,

including: (1) that Ra Medical was experiencing manufacturing problems that caused DABRA catheters to fail to calibrate; (2) that, as a result of these performance issues, Ra Medical was engaged, or was reasonably likely to engage, in a product recall of DABRA catheters; (3) that the Company instructed its sales representatives to characterize DABRA as performing atherectomy and to seek reimbursement using atherectomy codes, despite the FDA's warning indicating that such practices constituted off-label marketing in violation of FDA regulations; and (4) that Ra Medical lacked a system to ensure adequate documentation of expenses, including payments to physicians.

97. For example, among others, the Registration Statement failed to disclose problems that Ra Medical was experiencing at the time of the IPO. For example, the Registration Statement claimed that Ra Medical ***could*** encounter manufacturing problems that would limit its revenue, stating that the Company "***may*** encounter unforeseen situations in the manufacture and assembly of [its] products that would result in delays or shortfalls in [its] production." The Registration Statement purported to warn that, in such circumstances, Ra Medical's "revenue ***could*** be impaired[ and] market acceptance of [its] products could be adversely affected." However, the Registration Statement omitted that, at the time of the IPO, Ra Medical ***was already experiencing*** manufacturing problems causing its DABRA catheters to fail to calibrate, leading to inconsistent performance.

98. Similarly, the Registration Statement purported to warn that Ra Medical hypothetically ***could*** need to recall its products in the future if the Company encountered quality-related issues, stating that a "voluntary product recall by us could occur because of, for example, component failures, device malfunction, or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects." However, the Registration Statement omitted that Ra Medical had in fact already engaged in a

covert product recall, or efforts leading to the product recall, since as early as February 2018 due to DABRA catheters' failure to calibrate.

99. Additionally, the Registration Statement omitted that the Company instructed its sales representatives to market DABRA for atherectomy, *i.e.* an off-label use, despite the fact that the FDA label was limited to use in certain forms of PAD and that the FDA definition of atherectomy was narrower than the colloquial one. Instead, the Registration Statement falsely and/or misleadingly asserted: "We market and sell DABRA for use in the treatment of vascular blockages resulting from lower extremity vascular disease . . . . [M]anufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label."

100. Though the Registration Statement acknowledged that the "failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians . . . could have a material adverse effect on our business, financial condition, and results of operations," the Registration Statement failed to disclose that Ra Medical lacked a system to ensure proper documentation of expenses and payments to physicians.

### C. Defendants Admit That Statements In The Registration Statement Were Untrue And/Or Omitted Material Information

101. On October 31, 2019, Defendants admitted, among other things, that: (1) "the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients;" and (2) for fourth quarter 2018 and first quarter 2019, Ra Medical's sales were negatively impacted by the inconsistent DABRA catheter performance and catheter failures.

102. Since the calibration issue affected Ra Medical's sales for the first two quarters following the IPO, it is reasonable to infer that the DABRA catheters' failure to calibrate was an issue that existed at the time of the IPO.

103. Indeed, the Company's recall notice, published on the FDA's website on or about August 8, 2019, reflects that Ra Medical had engaged in a covert product recall in response to the calibration issue since February 2018—***seven months before the IPO***—when technicians started visiting customer facilities to service affected lasers. As the Audit Committee reported, due to the calibration issue, the Company had "engaged in systematic efforts to replace the product held by customers, which constituted product recalls, but were not documented as such."

104. Moreover, Defendants have also admitted that the Company engaged in off-label marketing. On October 31, 2019, Defendants also admitted that "while the indication for use in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes."

105. Confidential witnesses corroborate that Ra Medical engaged in off-label marketing before and after the IPO. According to CW 2, Ra Medical participated in the Transcatheter Cardiovascular Therapeutics tradeshow in San Diego held September 21 – 25, 2018 and used marketing materials that mentioned atherectomy. Defendant Burstein told CW 2 that the FDA contacted the Company about these marketing materials and instructed Ra Medical not to mention atherectomy in marketing materials any longer. CW 2 was instructed to destroy the marketing materials. CW 3 was also aware of a verbal warning from the FDA to remove any mention of atherectomy from marketing literature prior to the IPO. Though Ra Medical removed mention of atherectomy from marketing materials, CW 3 stated that the Company continued to direct sales representatives to market DABRA for atherectomy.

106. Similarly, Defendants have admitted that Ra Medical lacked adequate documentation for expenses and payments to physicians. Specifically, Defendants admitted on October 31, 2019 that "the Company lacks documentation of sufficient

detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments."

107. CW 2 corroborated that the Company lacked a system for adequately documenting expenses. As Executive Assistant, CW 2 submitted expense reports for Defendant Burstein, including business lunches with physicians. According to CW 2, until May or June 2019 (*i.e.*, months after the IPO), there was little oversight for expenses: expenses were tracked on spreadsheets and were typically not reviewed until six months later, when not much could be done to confirm expenses or obtain additional documentation. There were not many rules about expense reports, and CW 2 found that expenses could be "excessive."

### D. Investors Who Bought Ra Medical Stock Pursuant And/Or Traceable To The IPO Suffered Substantial Losses

108. Since the IPO, and as a result of the disclosures of material adverse facts omitted from the Registration Statement, Ra Medical's stock price has fallen below its IPO price, thereby damaging investors, including Plaintiffs, who bought Ra Medical stock pursuant and/or traceable to the IPO.

109. On November 29, 2019, the Company' stock price closed at $1.27 per share, a decline of approximately 92.53% from the IPO price of $17.00. As a result, investors who bought pursuant and/or traceable to the IPO suffered substantial losses.

## VIII. SUMMARY OF DEFENDANTS'[7] VIOLATIONS OF THE EXCHANGE ACT

### A. When Ra Medical Went Public, Its DABRA Catheter Presented Strong Prospects For Future Sales Growth

110. When Ra Medical became a public company, it was viewed as "disruptive" to the medical device industry with its innovative DABRA laser and catheter system.

111. Key to the Company's success would be its cost-effective single use DABRA catheter, as many analysts recognized:

(a) On October 22, 2018, SunTrust issued a report entitled "Initiating at Buy; $16 Price Target" in which it predicted "***sales growth of 113% driven principally by the peripheral vascular catheter*** sales of the DABRA laser." The report also stated: "Our ***share assumptions depend heavily upon the low price point of DABRA catheters*** (~$1200) which appears to be at a pronounced discount to more proven competitive single use offerings (~$3000 per case)."

(b) The same day, Piper Sandler issued a report entitled "Initiating Coverage of Compelling Technology Provider with OW Rating and $23 PT" ***modeling Ra Medical's revenue to quadruple*** over the next year because its "***DABRA system is a differentiated offering*** with procedural . . . 2-5 times faster than competitive systems and offers considerable economic incentives for end-users."

(c) Similarly, the same day, Cantor issued a report entitled "DABRA is a Step Forward in PAD Treatment; Initiating at Overweight with $21 PT," stating that "DABRA recurring revenue business model is positioned to capitalize on PAD atherectomy market trends and drive strong top-line growth."

[7] Throughout this section, "Defendants" refers to Defendants Ra Medical, Irwin, and Jackson.

112. The Company's razor/razorblade model, and in particular, its DABRA catheter, was a source of recurring revenue and the primary driver of future revenue growth. Thus, the safety and effectiveness of the DABRA catheter was central to investors' expectations of Ra Medical's prospects.

### B. After The IPO, Ra Medical Touts Positive Progress In Expanding Its Salesforce And Denies Claims Of Off-Label Marketing

113. The Registration Statement and statements by Ra Medical and defendants Irwin and Jackson during the Class Period were materially false and/or misleading because they failed to disclose: (1) that DABRA catheters frequently failed to calibrate; (2) that, as a result, Ra Medical had engaged in a covert product recall; (3) that Ra Medical's disappointing fourth quarter 2018 and first quarter 2019 financial results were attributable to DABRA catheter calibration issue, rather than "production limitations" resulting from increased scale; (4) that Ra Medical had instructed its sales representatives to market DABRA for atherectomy and to seek reimbursement using atherectomy codes, even though the 510(k) clearance was limited to use in certain forms of PAD; (5) that Ra Medical had made certain payments to physicians without adequate documentation and directed certain benefits to physicians due to sales prospects, which could be perceived as bribery attempts; (6) that the Company failed to timely file at least two MDRs; and (7) that the Company lacked an adequate system of controls to ensure that complaints regarding regulatory or ethical compliance were properly redirected for further investigation.

114. After the IPO, on November 14, 2018, Ra Medical continued to deny allegations that the Company engaged in off-label marketing, stating: "We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, and ***we believe that we comply with these restrictions."*** However, Ra Medical failed to disclose that the

FDA had already notified the Company that its existing marketing materials improperly promoted DABRA for atherectomy and that Ra Medical risked regulatory action by continuing to market DABRA as an atherectomy device despite the FDA's warnings.

115. Regarding the undisclosed covert product recall, the third quarter 2018 report falsely stated that a "voluntary product recall by us ***could occur*** because of, for example, . . . quality-related issues such as manufacturing errors or design or labeling defects." In reality, Ra Medical was experiencing calibration issues with the DABRA catheter that led, or was reasonably likely to lead, to a product recall.

### C. The Truth Begins To Emerge As Ra Medical Discloses Manufacturing Problems, While Defendants Falsely Claim That The Problems Have Been Fixed And Omit Other Material Information

#### 1. Ra Medical Falsely Claims That "Production Limitations" Stemming From Increased Demand Negatively Impacted Fourth Quarter 2018 Sales

116. Ra Medical began to disclose certain manufacturing problems that had apparently impacted the Company's fourth quarter 2018 sales, but misrepresented the nature and extent of these manufacturing problems.

117. On March 14, 2019, Ra Medical issued a press release which reported fourth quarter 2018 financial results that fell below investors' expectations, but assured that the Company had addressed the issues with "production limitations" that had purportedly caused the disappointing results. Specifically, in the Company's press release, defendant Irwin disclosed that "***production limitations*** in our manufacturing process ***as we scaled up catheter production***" had negatively impacted fourth quarter 2018 revenue, but that those issues were "addressed" and Ra Medical "***will begin to see the positive impact on revenue beginning in the second quarter of 2019.***"

118. On this news, the Company's share price fell $2.14 per share, or approximately 32.57%, to close at $4.43 per share on March 15, 2019, on unusually heavy trading volume.

119. The same day, during a conference call to discuss the results, defendant Irwin continued to represent that the manufacturing issues were related to increased production targets and that these issues were "solved." Specifically, he stated that the Company "experienced production limitations on [its] manufacturing process as [it] scaled up catheter production" but that "***we have solved those*** and we are now back into full production."

120. Also during the conference call, defendant Irwin repeatedly claimed that the production issues were related to "the ***scale up of that [manufacturing] process to meet demand***." He explained that: "The issues were related to a very specific piece of equipment that we have now upgraded and we've completed the validation on that process."

121. During the call, defendant Jackson dismissed concerns that there were further undisclosed problems, stating: "We don't expect any additional disclosure controls coming out of the manufacturing issues other than just disclosing exactly what we just mentioned on this call."

122. Similarly, on March 15, 2019, Ra Medical filed its 2018 annual report with the SEC, stating "***we have only recently begun manufacturing at scale*** and may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production."

123. But this explanation was false. Rather than problems related to the "scale up" of production, Ra Medical was battling a manufacturing issue that affected the calibration of its DABRA catheters, and the Company had experienced these issues since as early as February 2018.

124. Though analysts acknowledged the disruptive issues that had impacted the quarter, analysts remained optimistic about the Company's future prospects, given that the issues had apparently been resolved. For example:

a) On March 15, 2019, Maxim issued a report entitled "Lowering Estimates and PT to $15, from $23, on 4Q18 Miss and Weak 1Q19 Guidance; New CCO to Drive Sales Growth in 2019," stating: "We would continue to be buyers of RMED despite reporting lower-than-expected 4Q18 results, given DABRA's significant growth opportunities in the peripheral artery disease (PAD) and atherectomy markets."

b) The same day, Cantor issued a report entitled "Commercial Strategy Overhaul and Mfg Hiccup Push Out Sales Ramp; Lower PT to $11" and repeated the explanation offered by the Company regarding production:

> We expect RMED shares to be under pressure following 4Q results (-9% pre-market), but think shares could rebound with a couple of quarters of strong execution.
>
> **Manufacturing disruption appears to be in the rear-view mirror.** While scaling for higher catheter demand, one of RMED's production machines was unable to keep up with capacity and required an upgrade. The upgrade forced RMED to re-validate its machinery and slowed down the company's ability to ramp production. RMED was able to ship products to select customers. Management said that manufacturing is back in full production

125. Defendant Melissa Burstein resigned as a director in March 2019, purportedly due to "time constraints," according to the 2018 10-K, but remained Ra Medical's Executive Vice President. However, she had transitioned to Vice President and was no longer an executive officer as of the filing of the Company's proxy statement filed April 16, 2019.

**2. Ra Medical Falsely And/Or Misleadingly Assures Investors That Problems With Catheter Production Have Been Resolved**

126. When Ra Medical announced its first quarter 2019 results, the Company claimed that the manufacturing issues were "solved" when, in reality, Ra Medical continued to face calibration problems with its DABRA catheters.

127. On May 13, 2019, in the Company's press release issued in connection with the first quarter 2019 financial results, defendant Irwin claimed that "in the first quarter, [Ra Medical] completed the validation of [its] upgraded manufacturing process to accommodate catheter production at scale and commenced [a] new commercial strategy." Still, he did not admit that the catheters failed to calibrate.

128. Defendants also omitted to disclose that the manufacturing issue was related to catheter calibration and had existed since as early as February 2018. During a conference call held on May 13, 2019 in connection with the first quarter 2019 financial results, defendant Irwin maintained that the "limitations we experienced related to the scale up in catheter production," and defendant Jackson claimed that "the scale of issues we experienced in the vascular segment" was "***a one-off***."

129. Analysts tempered expectations for future revenue, but were pleased that the manufacturing issues had been resolved. For example:

a) On May 13, 2019, Piper Sandler issued a report entitled "Good Q1 Results, Corporate Repositioning Continues; Reiterate OW," stating: "Importantly, the company has fixed its manufacturing problems and can now make as much product as demand it can generate."

b) The same day, Cantor issued a report entitled "A Step in the Right Direction; Reiterate Overweight, but Move PT to $10," stating in relevant part:

> RMED's 1Q revenue of $1.7MM, which was $500k above FactSet consensus and above the upper end of company guidance, was a step in the right direction following the manufacturing issue and commercial organization changes the company announced on its 4Q call. Vascular revenue of $500k came in above the company's guidance of $300-400k. RMED completed the validation of its manufacturing process and is seeing progress on its new commercial strategy.

c) On May 14, 2019, Maxim issued a report entitled "Better-than-Expected 1Q19 Revenue, but Vascular Ramp Will Take Some Time; Reducing Estimates and PT to $12," stating in relevant part:

> During the quarter, production limitations of the DABRA catheters had been largely resolved with the validation of its upgraded manufacturing process, and we expect revenue growth and positive gross margin for the vascular segment beginning in 2Q19. As RMED shifts its focus to long-term customer relationships, it is hiring new, highly qualified sales representatives and providing more comprehensive clinical training.

**D. The Truth Further Emerges As Defendants Admit That DABRA Catheters Failed To Calibrate, Resulting In A Product Recall, And That Ra Medical Engaged In Off-Label Marketing**

**1. Ra Medical Admits To The Product Issues And Its Audit Committee Launches An Investigation Into An Anonymous Complaint**

130. Then, on August 12, 2019, the Company admitted that it had experienced manufacturing issues that caused the DABRA catheter to fail to calibrate during fourth quarter 2018 and first quarter 2019. Ra Medical's previous explanation given in March 2019 had suggested that the manufacturing issue related to an inability to produce sufficient catheters at an increased scale, rather than the truth, which is that problems impacted calibration of catheters, an integral function of the product. Though the manufacturing issue had purportedly been corrected, Ra Medical acknowledged that the catheters still failed to calibrate at customer sites prior to procedures. In a press release, the Company stated, in relevant part:

> **Manufacturing Update**
>
> In the fourth quarter of 2018 and first quarter of 2019, ***Ra Medical experienced inconsistencies in its DABRA catheter manufacturing process, due to issues controlling the temperature of the oven used in that process, which had an adverse impact on revenue during the fourth quarter of 2018 and the first half of 2019.*** In response, Ra Medical upgraded its temperature control regulator and made certain changes in its production flow and validated the changes that Ra Medical believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, Ra Medical is again experiencing inconsistent performance. ***The percentage of catheters that fail to calibrate at customer sites prior to a procedure being performed began to increase after decreasing during April and May 2019.*** Ra Medical is fully committed to resolving the inconsistencies in performance, but until these are fully resolved, our DABRA sales may continue to be adversely impacted.

131. Also in the August 12, 2019 press release, Ra Medical further disclosed that its Audit Committee was investigating allegations made in an anonymous

complaint and that its co-founder Irwin was terminated from his positions as CEO, Co-President, Chief Technology Officer, and Chairman of the Board of Directors. The August 12, 2019 press release stated, in relevant part:

> **Leadership Transition**
>
> Ra Medical today announced that ***Dean Irwin was terminated without cause*** from his position as Ra Medical's Chief Executive Officer, Co-President, and Chief Technology Officer, and as Chairman of Ra Medical's Board of Directors. Andrew Jackson, currently serving as Chief Financial Officer, has been appointed to serve as Interim Chief Executive Officer while the Company continues its search for a permanent Chief Executive Officer.
>
> "On behalf of the entire Ra Medical Board, I want to thank Dean for his contributions and for his years of service to Ra Medical. The Board is focused on finding a CEO who can guide us through the next phase of commercialization and growth," said newly-appointed Chairman Martin Colombatto.
>
> * * *
>
> **Audit Committee Investigation**
>
> ***The Audit Committee of Ra Medical's Board of Directors has commenced an independent investigation in connection with an anonymous complaint.*** The Audit Committee of the Board of Directors is responsible for investigating the allegations and has retained independent counsel to assist it in the process. The investigation is not yet completed and no conclusions with respect thereto have been reached. Ra Medical cannot predict the duration or outcome of the investigation, and the Company will not be in a position to file the Form 10-Q until the Audit Committee completes its work.

132. On this news, Ra Medical's share price tanked—it fell $1.61, or nearly 57.09%, to close at $1.21 per share on August 13, 2019, on unusually heavy trading volume.

133. Analysts still found DABRA to be promising technology but concluded that the host of issues injected uncertainty to the future of Ra Medical, leading them to slash price targets. For example:

a) On August 12, 2019, Piper Sandler issued a report entitled "Downgrading to Neutral; Uncertainty Outweighs our Enthusiasm for Technology," stating in relevant part:

> Despite the dermatology business coming in ahead of expectations, the key vascular franchise was again soft at $0.4-0.5M, which fell well short of our $0.9M estimate. The cause of the vascular shortfall was a resurfacing of manufacturing issues that began in the latter half of 2018, which affected the company's ability to sell product. . . . We lower our price target to $1.50.
>
> **Reasons for the Downgrade.** This is utterly painful for us as we have long covered the peripheral vascular space and believe RMED has a compelling technology to treat a variety of lesions in this part of the anatomy. However, these repeated manufacturing issues speak to significant operational problems across the company that will likely take time to resolve. Further, it will likely cause significant levels of skepticism among clinicians even when the company attempts to fully re-address the market. . . .

b) On August 13, 2019, Cantor issued a report entitled "Developments Create Too Much Uncertainty; Downgrading to Neutral – PT to $2 from $10," stating in relevant part:

> These announcements, notably the manufacturing issues and reduced salesforce size, raise concerns about the company's ability to grow the vascular business in the near-term.
>
> **Return of manufacturing issue clouds ability to ramp production.** RMED again experienced issues with the manufacturing of its DABRA catheters starting in June, after previously stating that the disruptions experienced during 4Q were behind them. The issue seems to be related to scale and RMED is working to identify and correct this issue. The company has stated that it has units on hand to meet demand and that it is not supply constrained at the moment.

c) On August 14, 2019, Maxim issued a report entitled "CEO Terminated and 10-Q Delayed; Damage to Stock Overdone; Reducing PT, but Maintain Buy on Untapped Market Opportunity," stating in relevant part:

> **We believe the removal of the CEO is related to the ongoing DABRA catheter manufacturing issues. In terms of the investigation, we believe it may be the result of a 'whistleblower' lawsuit, which is leading to a delayed 10-Q filing. 2Q19 earnings and the Form 10-Q filing will be delayed until completion of the Audit Committee investigation, which creates additional uncertainty.**
>
> **Based on the lack of revenue visibility associated with DABRA, and the abovementioned items, we are slashing our DABRA projections.**
>
> . . . Continued manufacturing issues with the DABRA catheter and announced sales and marketing downsizing indicate that near-term DABRA sales may be negatively impacted. Based on the lack of

> revenue visibility associated with DABRA, and the above-mentioned items, we are slashing our DABRA projections and lowering our price target to $3.00, from $12.00.

134. On August 15, 2019, Ra Medical filed a Notification of Late Filing on Form 12b-25 with the SEC, stating that, due to the Audit Committee's investigation, it was unable to timely file its second quarter 2019 quarterly report with the SEC.

135. On this news, the Company's share price fell $0.16, or approximately 8.16%, to close at $1.80 per share on August 16, 2019, on unusually heavy trading volume.

136. On August 23, 2019, Ra Medical issued a press release disclosing that it received a notice from the NYSE that the Company's stock was at risk of being delisted for failure to timely file its second quarter 2019 quarterly report. Ra Medical had conducted the IPO less than one year prior to receiving the notice.

137. On this news, the Company's share price fell $0.08, or nearly 4.28%, to close at $1.79 per share on August 26, 2019, the next trading session, on unusually heavy trading volume.

**2. Obscuring That It Had Been Engaged In A Covert Recall For Months, Ra Medical Announces A Voluntary Recall**

138. Ra Medical finally admitted that the DABRA catheters' failure to calibrate was so pervasive that the Company was forced to recall products. On September 27, 2019, Ra Medical filed a Form 8-K with the SEC to report that it initiated a "voluntary recall of its DABRA laser system single-use catheters due to a change in product labeling." The recall purportedly reflected a recent "relabeling [of] the catheters with two-month expiration, replacing its previous twelve-month shelf life expiration."

139. On this news, the Company's stock price fell $0.18, or nearly 11.38%, to close at $1.40 per share on September 30, 2019, on unusually heavy trading volume.

140. However, the Company omitted to disclose that the covert product recall, or efforts leading to the recall, had begun nearly a year and a half earlier in February 2018 when Ra Medical's technicians started visiting customer facilities to service affected lasers.

### 3. The Audit Committee Investigation Reports Its Findings

141. The findings of the Audit Committee investigation reflected wide-ranging issues plaguing Ra Medical's operations, from problems with the DABRA catheter (its primary revenue driver) to a shocking lack of compliance with regulatory requirements. On October 31, 2019, after the market closed, Ra Medical issued a press release that admitted, in relevant part:

> The Audit Committee's primary investigative findings are: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) the Company's explanations regarding the Company's fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) the Company failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) the Company, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) the Company lacks documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) Company determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) the Company received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not.
>
> The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies involving certain current and former executive officers and employees of the Company. With respect to current Company executives and employees, the Audit Committee referred these matters to the Board or the Company for appropriate action and discipline.

142. The October 31, 2019 press release also disclosed that these findings sparked scrutiny from the SEC and the DOJ. The press release stated, in relevant part:

> As also previously announced, the Company voluntarily contacted the SEC regarding the Audit Committee's investigation. In October 2019, the Department of Justice provided the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning ***whether the Company fraudulently obtained 510(k) marketing clearance for its ablation devices marketed under the trade name DABRA (which is not an item that has been investigated by the Audit Committee),*** whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. The Company intends to cooperate with the SEC and the Department of Justice's inquiries or investigations.

143. Furthermore, according to the October 31, 2019 press release, the DABRA catheter recall delayed the process to secure FDA approval for an atherectomy indication. The press release stated, in relevant part:

> In addition, in order to more effectively market DABRA, the Company currently is pursuing expanded indications for use of DABRA to include an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or a prespecified increase in the openness of the artery at a predefined time point. To satisfy the FDA's data requirements to support an atherectomy indication, the Company submitted an investigational device exemption, or IDE, designed to gather the clinical data necessary to determine substantial equivalence in support of the atherectomy indication. ***This IDE was approved in July 2019. However, as a result of the DABRA catheter recall to change the shelf life, the Company plans to submit updates to the IDE and enroll the first patient in the first quarter of 2020.***

144. Ra Medical also terminated Defendant Melissa Burstein as Vice President and as an employee, as disclosed in a Form 8-K filed with the SEC on November 1, 2019.

145. On this news, the Company's stock price fell $0.11, or nearly 7.28%, to close at $1.40 on November 1, 2019, on unusually heavy trading volume.

146. On November 15, 2019, Ra Medical filed a Notification of Late Filing on Form 12b-25 with the SEC, disclosing that it was unable to timely file its third

quarter 2019 quarterly report because it was reviewing the facts and circumstances surrounding its 510(k) marketing clearance in response to the DOJ's Civil Investigative Demand.

**4. Ra Medical Discloses A Criminal Investigation And Deficiencies In Its Internal Controls**

147. After the Audit Committee investigation was completed, Ra Medical finally filed the quarterly reports that had been delayed for months. On November 29, 2019, before the market opened, Ra Medical filed its quarterly reports for the periods ended June 30, 2019 and September 30, 2019, revealing that the DOJ inquiry had escalated to a criminal investigation. The reports stated:

> On November 21, 2019, we became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to the Company. At this time, it is unclear if the Company is a target in this investigation. The Company intends to cooperate with the DOJ criminal investigation.

148. The same day, the Company filed amendments to its 2018 10-K and its 1Q19 10-Q to disclose that deficiencies in its internal controls had existed as of December 31, 2018 and March 31, 2019, respectively, which aggregated to a material weakness. Specifically, the reports were amended to state, in relevant part:

> ***Control environment***
>
> We identified certain deficiencies in our internal controls, which aggregated to a material weakness in the control environment component of the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (the "COSO Framework). The material weakness results from the aggregation of control deficiencies in the Company's control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, including a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization. The ineffective control environment resulted in the following:
>
> - behavior that was inconsistent with our Code of Ethics and Conduct and related policies ***involving certain former executive officers*** and employees of the Company;
> - explanations regarding the issues that had an impact on our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because the explanations did not explicitly reference

the effect of inconsistent catheter performance and catheter failures;

- failure to timely make at least two Medical Device Reports, or MDRs, to the FDA;
- engagement in systematic efforts to replace product held by customers, which constituted product recalls, were not documented as such;
- lack of documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage;
- while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes;
- determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects.

The ineffective control environment contributed significantly to the material weakness described below.

149. On this news, the Company's stock price fell $0.16, or nearly 11.19%, to close at $1.27 per share on November 29, 2019, on unusually heavy trading volume.

## IX. RA MEDICAL ADMITS THAT THE REGISTRATION STATEMENT AND STATEMENTS MADE DURING THE CLASS PERIOD WERE MATERIALLY FALSE AND/OR MISLEADING AND/OR OMITTED MATERIAL FACTS

150. Ra Medical's Audit Committee's investigation concedes that statements made in connection with the IPO and during the Class Period were false and/or misleading and/or omitted material facts.

### A. The Audit Committee Investigation Findings

151. On October 31, 2019, Ra Medical issued a press release to announce the findings of the Audit Committee's internal investigation of "allegations raised by an employee, as well as additional matters discovered throughout the investigation."

152. Ra Medical admitted that calibration problems with the DABRA catheter, rather than "production limitations", caused the disappointing financial results for fourth quarter 2018 and first quarter 2019. Specifically, the Company admitted in the October 31, 2019 press release:

a) that "the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients;"

b) that its explanations regarding "fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference DABRA catheter performance and catheter failures;" and

c) that it "failed to timely make at least two Medical Device Reports, or MDRs, to the FDA."

153. Regarding the covert product recall, the Company admitted in the October 31, 2019 press release that it, "out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such."

154. Ra Medical also admitted that it engaged in off-label marketing of DABRA for atherectomy, which is not the indication approved by the FDA, and that it had engaged in other tactics to boost sales. Specifically, the Company admitted in the October 31, 2019 press release:

a) that, "while the indication for us in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes;"

b) that it "lacks documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose or nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or gain special advantage;" and

c) that its "determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects."

155. In addition, the Company admitted that it failed to timely investigate ethical complaints raised by employee(s) in connection with these issues. Specifically, the Company admitted in the October 31, 2019 press release that it had "received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not."

### B. Former Ra Medical Employees Corroborate The Audit Committee's Findings

156. Former Ra Medical employees provide valuable knowledge, confirming that: (1) at the time of the IPO, the Company was already experiencing calibration problems with the DABRA catheters; (2) that the resulting inconsistent performance of DABRA catheters caused Ra Medical to replace product for physicians, without disclosing the covert product recall to investors or the FDA; (3) that Ra Medical directed its sales representatives to promote DABRA as an atherectomy device, despite receiving warnings from the FDA that such promotion is improper; (4) that the Company lacked a sufficient system to ensure that expenses were properly documented; and (5) that Ra Medical did not report to the FDA an injury a patient experienced during the 2017 pivotal study for DABRA.

#### 1. Ra Medical Was Experiencing Calibration Issues With The DABRA Catheter At The Time Of The IPO

157. According to CW 1, Ra Medical's executive officers and directors knew of the calibration issues with the DABRA catheter as early as 2017, *i.e.* before the IPO.

158. The calibration issue was the "number one" issue experienced with DABRA, and it was consistently discussed during sales training from the time CW 2 began attending training sessions (approximately three months after CW 2 began working for Ra Medical).

159. CW 3 stated that physicians expressed concerns about the difficulty calibrating and overheating when using DABRA. Due to the product inconsistencies, CW 3 stated that a physician could go through several catheters with a patient on the operating table before s/he could get one to work. CW 3 had even heard of the catheter burning physicians' fingers. One sales representative expressed concerns to CW 2 that the calibration issues could injure patients.

160. CW 3 stated that some sales representatives were told not to report injuries or issues with the product. CW 3 always reported to Ra Medical any issues or injuries that s/he had been made aware of by physicians, but did not know what, if anything, was done.

161. CW 3 confirmed that the DABRA calibration issue was already well known at the Company when CW 3 joined at the time of the IPO. CW 3 stated that sales representatives were blamed for the calibration issue because the Company's position was that they were not properly trained to provide calibration instructions.

162. When Ra Medical conducted its national sales meeting in January/February 2019, CW 3 stated that the product issues, overheating and calibration issues were brought up by sales representatives but that they were told the device is "perfect" and that the issues were caused by sales representatives not knowing how to use the product.

163. According to CW 3, Ra Medical had poor quality assurance, explaining that if three different catheters were placed next to each other, they could vary greatly in size with some being as much as ten inches longer than others. When sales representatives raised concerns about the inconsistencies with the product, they were told that the difference in lengths was within the product specifications.

**2. Ra Medical Engaged In A Covert Product Recall**

164. CW 2 knew from communicating with sales representatives that they were oftentimes replacing the product for physicians as a remedy for the calibration

issues. According to CW 2, Ra Medical wanted to keep this quiet, so the covert product recall was not discussed during sales training.

165. According to CW 2, Fogarty was tasked with "fixing the product" and hired Al Memmolo approximately March 2019 to work with engineers to fix calibration issues with the DABRA catheter.

### 3. Sales Representatives Were Directed To Market DABRA For Off-Label Uses

166. According to CW 2, Ra Medical participated in the Transcatheter Cardiovascular Therapeutics tradeshow in San Diego held September 21 – 25, 2018 and used marketing materials that mentioned atherectomy. Burstein told CW 2 that the FDA contacted the Company about these marketing materials and instructed Ra Medical not to mention atherectomy in marketing materials any longer. CW 2 was instructed to destroy the marketing materials.

167. CW 3 was also aware of a verbal warning from the FDA to remove any mention of atherectomy from marketing literature prior to the IPO. Though Ra Medical removed mention of atherectomy from marketing materials, CW 3 stated that the Company continued to direct sales representatives to market DABRA for atherectomy.

168. CW 2 recalls a PowerPoint that Burstein used during sales training to teach sales representatives how to mention atherectomies to doctors. The presentation was supposed to explain the difference between "indication" and "intended use" specific to atherectomy, but CW 2 could not convey the difference because Burstein's explanation was very "confusing."

169. CW 3 also recalled that Ra Medical attempted to distinguish between "indication" and "intended use" during training but could not further explain or recall what the distinction was. According to CW 3, this distinction was to justify or explain to sales representatives how to "walk around" the fact that the device did not have an atherectomy indication.

170. CW 3 stated that sales representatives were instructed to market DABRA for atherectomy even though the device did not have an indication for such use. CW 3 stated that sales training was held in California at the corporate headquarters for approximately four days and conducted by Burstein. CW 3 recalled that significant time was spent discussing atherectomy during sales training. CW 3 stated that other executives, including Irwin, discussed marketing for atherectomy.

171. Though physicians can use devices off-label or for indications not yet approved by the FDA, CW 3 knew that sales representatives are not supposed to market off-label. Nonetheless, according to CW 3, sales representatives were told to tell doctors to use atherectomy reimbursement codes for the DABRA laser. Based on experience in medical device sales, CW 3 felt that sales representatives should not be advising doctors or hospitals about how to seek reimbursement.

172. Furthermore, CW 3 was concerned that the Company instructed sales representatives to focus more on outpatient instead of hospital surgeons, which signaled an effort to have the product used off-label unchecked. According to CW 3, outpatient facilities have less oversight than hospitals, and hospital billing and coding personnel would not take instructions from sales representatives. CW 3 believed this was an effort to keep the off-label marketing from becoming known.

173. According to CW 2, Fogarty changed Burstein's responsibilities soon after he joined Ra Medical such that she no longer conducted sales training by January or February 2019. Burstein's training sessions were a "disaster" because she was not organized and "jumped around" when presenting information to sales representatives. Often, Burstein could not answer questions from sales representatives and would stop the training to ask Irwin to find the answer.

174. Fogarty then appointed two individuals to conduct sales training sessions, and CW 2 continued to attend the sessions. New training materials were created for the new sales training program, which was held at a building previously occupied by Ra Medical and down the street from the corporate headquarters. The

building included a conference room for up to 50 people and a room for simulated surgeries. Fogarty combined sales representatives and clinical specialists into what was called the DABRA team.

#### 4. Ra Medical Lacked An Adequate System to Document Expenses

175. According to CW 2, until May or June 2019, there was little oversight for expenses. Expenses were tracked on spreadsheets and were typically not reviewed until six months later, when not much could be done to confirm expenses or obtain additional documentation. There were not many rules about expense reports, and CW 2 found that expenses could be "excessive."

176. Then, in May or June 2019, Ra Medical began using a new accounting system called Certify. This provided a clearer approval process for expenses, and Fogarty approved Burstein's expenses.

177. CW 2 stated that physicians who performed consulting services for Ra Medical were called key opinion leaders (or "KOLs"). These physicians used Ra Medical's products, and approximately five to ten doctors would consistently discuss DABRA at conferences and sometimes perform "live cases" at conferences.

178. As Burstein's Executive Assistant, CW 2 was responsible for submitting her expense reports, including business lunches with physicians. After Ra Medical began using Certify, CW 2 would break down receipts to allocate the portion of a meal which was for Burstein and which was for a KOL. This practice was intended to more accurately track the total dollar amount spent on KOLs throughout the year.

#### 5. An Injury During The 2017 Pivotal Study Was Not Reported To The FDA

179. According to CW 1, defendant Irwin was informed of an injury caused to a patient in the pivotal study for DABRA that was not reported to the FDA.

### C. Recall Notice Suggests That Ra Medical Initiated The Recall Seven Months Before The IPO

180. On or about August 8, 2019, a Class 2 Device recall notice was published on the FDA website, suggesting that Ra Medical initiated the covert recall of DABRA seven months before the IPO. The notice states that the recall was "initiated by the firm," *i.e.* Ra Medical, on February 15, 2018 when "service technicians started visiting customer facilities to service affected lasers." The reported reason for the recall was that "lasers/catheters did not calibrate during set-up prior to use."

### D. Ra Medical Failed To Timely File Three MDRs

181. The FDA maintains a database called Manufacturer and User Facility Device Experience (MAUDE), which stores MDRs of suspected device-associated deaths, serious injuries, and malfunctions that are submitted by mandatory reports (including manufacturers, importers, and device user facilities) and voluntary reporters (including health care professionals, patients, and consumers).

182. According to MAUDE, Ra Medical filed three reports months after the incident was reported to the Company:

(a) On June 4, 2019, a physician was treating a patient with a 15 mm calcified lesion in the left sfa. "A femoral antegrade approach was used with the DABRA catheter. The catheter was introduced into the lsfa, and after about 5cm of travel, the patient complained of pain. The laser was stopped and subsequent angio showed a perforation in the lsfa." Ra Medical received a report of the incident on June 10, 2019, and it was reported to the FDA ***four months later*** on October 3, 2019.

(b) On June 24, 2019, a physician observed a perforation in a calcified lesion of a patient. Ra Medical received a report of the incident on June 28, 2019, and it was reported to the FDA ***four months later*** on October 25, 2019.

(c) On August 5, 2019, a physician was treating a patient with a 40 mm atheromatous lesion in the sfa. "A popliteal retrograde approach was used with the dabra catheter. The physician experienced access issues; the vessel was wired, the sheath inserted, and intravascular ultrasound was used. While using ivus, the physician pulled the sheath back to see more of the popliteal. When he tried to insert the dabra catheter it would not advance because the sheath had been pulled back too far. Access was gained a second time; when the physician started using the dabra with a buddy wire technique, just as it exited the sheath, it went behind of piece of plaque and perforated the sfa. The perforation was treated with balloon angioplasty without further complication. The physician stated that the perforation was due to the vessel access and the presentation of disease." Ra Medical received a report of the incident on August 7, 2019, and it was reported to the FDA ***two months later*** on October 3, 2019.

### E. Ra Medical Settles DOJ Investigation Into Off-Label Marketing and Kickbacks to Physicians

183. On January 4, 2021, Ra Medical announced that it had entered into a settlement agreement to resolve a pending DOJ investigation and related action regarding the Company's marketing of the DABRA laser system, improper payments to certain physicians, and undisclosed product defects. *See* Ex. 3. Specifically, the settlement relates to claims by a former employee brought on behalf of the federal government and certain states, alleging:

> that the Company violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the [FDA], marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices.

*Id.*

184. The settlement also relates to claims brought by the United States and certain states, alleging:

> that from May 1, 2017 through October 31, 2019, the Company (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk of physicians and patients (the "Covered Conduct").

Ex. 3.

185. As to the claims of illegal remuneration (i.e., kickbacks), the federal government alleges that Ra Medical "tracked utilization of its high-volume physician customers using an internal document titled 'Who Deserve[] Love,' which was used to identify physicians that [Ra Medical] should target with offers of improper remuneration," which "consisted of cash payments and fees paid in connection with purported training events and consulting services." Ex. 4. In connection with these claims, Ra Medical also entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.[8]

186. As to the claims of off-label marketing, the federal government contends that Ra Medical "knowingly marketed the DABRA Laser for use in atherectomy procedures [even though] [t]he DABRA Laser was not approved or cleared by the FDA for use in atherectomy procedures." Ex. 4.

## X. DEFENDANTS' FALSE AND/OR MISLEADING STATEMENTS AND/OR OMISSIONS

### A. False And/Or Misleading Statements And/Or Omissions Made In Connection With The IPO

#### 1. The Registration Statement And Roadshow Materials Touted Ra Medical's Manufacturing Facility

187. On September 24, 2018, Ra Medical filed its final amendment to the Registration Statement with the SEC on Form S-1/A, which forms part of the Registration Statement. The Registration Statement stated that the Company's

[8] *See* Exhibit 10.20 to Ra Medical's fiscal 2020 Form 10-K filed with the SEC on March 17, 2021, attached hereto as Ex. 5.

manufacturing capability is a key element of its strategy "to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases." Under "Our Strategy," the Registration Statement claimed, in relevant part:

> Optimizing existing manufacturing capabilities to generate operating leverage. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. ***We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner.*** We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and expand our margins.

188. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; and (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale.

189. The Registration Statement claimed that Ra Medical ***could*** encounter manufacturing problems that would limit its revenue, stating in relevant part:

> *We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*
>
> ***We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production.*** For example, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.
>
> * * *

> ***If our manufacturing activities are adversely impacted, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected*** and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

190. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; and (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale.

191. Ra Medical also used a presentation during IPO roadshows in September 2018 entitled "Initial Public Offering" (the "Roadshow Presentation"). Slide 18 of the Roadshow Presentation entitled "Fully Operational Manufacturing Facility" stated "Sizeable capacity for laser and catheter production" and "We believe our existing facility is capable of manufacturing over 400 lasers/year and 140,000 catheters/year."

192. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; and (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale.

193. Slide 23 of the Roadshow Presentation entitled "Business Model" described "DABRA Catheter Consumable" as a source of "recurring revenue" and

as "practical, easy to use equipment, anticipated recurring revenue single-use catheter solution."

194. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; and (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue.

**2. The Registration Statement Warned Of A Hypothetical Product Recall But Omitted Quality-Related Issues It Was Already Experiencing**

195. The Registration Statement stated that Ra Medical ***may*** recall its products due to quality-related issues, stating in relevant part:

> A government mandated or ***voluntary product recall by us could occur because of, for example, component failures, device malfunctions,*** or other adverse events, such as serious injuries or deaths***, or quality-related issues such as manufacturing errors or design or labeling defects***. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

196. This statement was materially false and/or misleading because it failed to disclose: (1) that, at the time of the IPO, service technicians had been deployed because DABRA catheters failed to calibrate; and (2) that, as a result of the calibration issue, Ra Medical had engaged, or was reasonably likely to engage, in a covert product recall.

**3. The Registration Statement And Roadshow Materials Omitted To Disclose That Ra Medical Engaged In Off-Label Marketing To Increase DABRA Sales**

197. The Registration Statement asserted:

> ***We market and sell DABRA for use in the treatment of vascular blockages resulting from lower extremity vascular disease*** and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, ***manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label.***

198. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical promoted DABRA as an atherectomy device, which is not the approved use and thus the Company engaged in off-label marketing; and (2) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

199. The Registration Statement claimed that ***if*** Ra Medical did not market its products consistently with the approved labeling, it could face penalties, stating in relevant part:

> Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As ***such, we may not promote our products for indications or uses for which they do not have clearance or approval.*** However, many physicians use our products for off-label purposes and are allowed to do so. . . .
>
> ***If a regulatory agency*** discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or ***disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market.*** If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:
>
> - subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
> - issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
> - impose civil or criminal penalties;
> - suspend or withdraw regulatory clearances or approvals;
> - refuse to clear or approve pending applications or supplements to approved applications submitted by us;
> - impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
> - seize or detain products; or
> - require a product recall.

200. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical promoted DABRA as an atherectomy device, which is not the approved use and thus the Company engaged in off-label marketing; (2) that the FDA had already warned Ra Medical that its promotional materials should not market DABRA as an atherectomy device; and (3) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

**4. The Registration Statement And Roadshow Materials Omitted To Disclose That Ra Medical Engaged In Potential Bribery To Increase DABRA Sales**

201. The Registration Statement recognized that the Company's relationships with physicians would be closely scrutinized by regulatory authorities, stating in relevant part:

> *The continuing development of our products depends upon our maintaining strong working relationships with physicians.*
>
> The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ. ***Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations***. . . .

202. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage;

and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

203. According to the Registration Statement, Ra Medical was subject to laws and regulations regarding bribery, stating in relevant part:

> *We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.*
>
> In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations.
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> * * *
>
> Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

204. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage;

and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

205. Similarly, the Registration Statement stated that Ra Medical could face penalties for improper contributions to physicians, stating in relevant part:

> *Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.*
>
> Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our cleared devices.
>
> Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:
>
> - the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
>
> - ***federal false claims laws***, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims ***by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label***;
>
> * * *

- the ***U.S. Physician Payments Sunshine Act, which requires certain manufacturers*** of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) ***to report annually to the government information related to payments or other "transfers of value" made to physicians*** (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

206. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

**5. The Registration Statement And Roadshow Materials Omitted A Patient's Injury Experienced During The 2017 Pivotal Study For DABRA**

207. The Registration Statement touted the safety of DABRA, claiming that "[n]o serious adverse events were reported in [its] 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA."

208. This statement was materially false and/or misleading because it failed to disclose: (1) that a patient had been injured during the pivotal study for DABRA; (2) that this safety incident had not been reported to the FDA; and (3) that, as a result, Ra Medical and 510(k) clearance for DABRA were reasonably likely to be scrutinized by regulatory authorities, including FDA, DOJ, and SEC, and likely to face penalties.

209. Slide 11 of the Roadshow Presentation titled "Clinically Demonstrated Solutions" describes the pivotal study for DABRA and states that "0% reported serious adverse events (SAE), observed in our 2017 pivotal study and post-market surveillance of DABRA."

210. This statement was materially false and/or misleading because it failed to disclose: (1) that a patient had been injured during the pivotal study for DABRA; (2) that this safety incident had not been reported to the FDA; and (3) that, as a result, Ra Medical and 510(k) clearance for DABRA were reasonably likely to be scrutinized by regulatory authorities, including FDA, DOJ, and SEC, and likely to face penalties.

**B. False And/Or Misleading Statements And/Or Omissions In Ra Medical's Code of Ethics and Conduct**

211. Ra Medical adopted a Code of Ethics and Conduct (the "Code of Ethics"), which was available on the Company's website throughout the Class Period. The Code of Ethics was adopted purportedly "to deter wrongdoing" and promote full and fair disclosure, compliance with applicable rules, and ethical conduct. Specifically, the Code of Ethics provided the following non-exclusive examples of violations of the code:

- Improper or excessive payments for "miscellaneous expenses" not properly categorized;
- Payroll-related expenditures, bonuses, awards, and gifts given to or by Ra Medical employees without proper approval and adequate documentation;

* * *

- Payments or billings made, or fees collected or paid, that are greater or less than normal payments, billings, or fees for the services provided or received and made at the request of a supplier or customer; or any payment made or received in an amount greater or less than, or for purposes other than, as described in supporting documentation;

212. This statement was materially false and/or misleading because it failed to disclose that the Company lacked an adequate system of controls to document, oversee, and regulate expenses made by/to Ra Medical employees.

213. Similarly, the Code of Ethics stated:

> **XIX. GIFTS AND ENTERTAINMENT**
>
> Business gifts and entertainment are designed to build goodwill and sound working relationships among business partners. A problem may arise if:
>
> - The receipt by one of our employees of a gift or entertainment would compromise, or could reasonably be viewed as compromising, that person's ability to make objective and fair business decisions on behalf of Ra Medical; or
> - The offering by one of our employees of a gift or entertainment would appear to be an attempt to obtain business through improper means or to gain any special advantage in our business relationships, or could reasonably be viewed as such an attempt.
>
> Employees must use good judgment and ensure there is no violation of these principles. Any questions about whether any gifts or proposed gifts are appropriate should be directed to Ra Medical's Chief Ethics Officer.

214. This statement was materially false and/or misleading because it failed to disclose: (1) that the Company lacked an adequate system of controls to document, oversee, and regulate expenses made by/to Ra Medical employees; and (2) that, as Ra Medical admitted on November 29, 2019, the Company's executive officers violated the Code of Ethics.

215. Regarding recordkeeping, the Code of Ethics stated:

> **XI. RECORDKEEPING**
>
> All of Ra Medical's books, records, accounts, and financial statements must be maintained in reasonable detail, must appropriately reflect the transactions and matters to which they relate and must conform both to applicable legal requirements and to Ra Medical's system of internal controls. All assets of Ra Medical must be carefully and properly accounted for. The making of false or misleading records or documentation is strictly prohibited. Unrecorded funds or assets should not be maintained. Please refer also to the more detailed requirements under Section VI (Financial Records and Public Disclosure).

216. This statement was materially false and/or misleading because it failed to disclose that the Company lacked an adequate system of controls to document, oversee, and regulate expenses made by/to Ra Medical employees; (2) that, as Ra Medical admitted on November 29, 2019, the Company's executive officers violated the Code of Ethics.

217. Moreover, regarding ethics complaints, the Code of Ethics stated:

> **E. Investigations**
>
> Reported violations will be promptly investigated. The applicable Board of Directors or its designated committee will be responsible for investigating violations and determining appropriate action for matters involving members of such Board of Directors, executive officers, or managing directors. The Board of Directors or its designated committee may designate others to conduct or manage investigations on its behalf and recommend appropriate action. Subject to the general authority of the Board of Directors to administer this Code, the Ethics Officer and the Chief Executive Officer will be jointly responsible for investigating violations and determining appropriate action for other U.S.-based employees and directors, and, typically, the local managing director will be responsible for investigating non-financial violations and determining appropriate action for non-U.S. based employees and directors. Ra Medical's General Counsel, the Chief Executive Officer, Chief Financial Officer, and local managing directors may designate others to conduct or manage investigations on their behalf and recommend appropriate action. ***For reports of suspected violations lawfully reaching the Board of Directors,*** the Board of Directors reserves the right to investigate violations and determine appropriate action on its own or to designate others to do so in place of, or in addition to, the Ethics Officer. Employees and directors are expected to cooperate fully with any investigation made by Ra Medical into reported violations.

218. This statement was materially false and/or misleading because it failed to disclose: (1) that the Company lacked a system to ensure that complaints concerning executive officers were timely addressed by the Board of Directors; (2) that, as Ra Medical admitted on November 29, 2019, the Company's executive officers violated the Code of Ethics.

### C. False And/Or Misleading Statements And/Or Omissions Made In Connection With The Announcement Of Ra Medical's Third Quarter 2018 Financial Results

219. On November 13, 2018, the Company issued a press release entitled "Ra Medical Systems Reports Third Quarter 2018 Results." The same day, Ra

Medical held a conference call with investors, analysts, and the public to discuss the Company's Q3'18 financial results. During the call, when an analyst asked about reimbursements for atherectomy during the call, defendant Irwin suggested that atherectomy is the same as the approved indication for DABRA and that physicians who perform atherectomy using DABRA are granted reimbursements. Specifically, the exchange occurred as follows:

> **Analyst:** just turning back to the label again, you noted in the S-1 that some competitor ha[s] written you . . . saying you're encouraging off label use. Just comment generally on, is that an impediment where people are afraid they may not get reimbursed for atherectomy? And just as a footnote to that question, it just sounds like the FDA is actually working collaboratively with you regarding this new study, basically to help you put the label in place or am I misreading that?
>
> **Irwin:** No. I think, I tell the story, I was at the VIVA conference not too long ago, not this year but previously and one of the Office of Device Evaluation people from the FDA came to me and we were talking about additional indications and I mentioned atherectomy and she told me, but that's all you do and you do that now. ***Atherectomy is a medical term used to denote the removal of plaque and that's really all our system does. We essentially dissolve plaque into its fundamental chemistry.***
>
> ***As far as the reimbursement, the FDA doesn't control reimbursement. That's largely the payers and Medicare. So, if the physicians are actually performing the procedure, they should get reimbursed for it and in our case, they submit through reimbursement and they are getting paid and we don't have a single report of any instance where that's not true.***

220. This statement was materially false and/or misleading because it failed to disclose: (1) that physicians used DABRA for atherectomy at least in part because Ra Medical instructed its sales representatives to promote the product for such use; (2) that such sales practices constituted off-label marketing because DABRA was only approved for use in certain forms of PAD; (3) that, as a result, the Company was reasonably likely to face regulatory scrutiny, including from the FDA, SEC, and DOJ, which could lead to increased costs and penalties; and (4) that the foregoing could jeopardize reimbursement for DABRA.

221. When describing the 2017 pivotal study for DABRA, defendant Irwin stated during the call that the study "demonstrated 94% effectiveness at the time of the procedure with no reported serious adverse events."

222. This statement was materially false and/or misleading because it failed to disclose: (1) that a patient had been injured during the pivotal study for DABRA; (2) that this safety incident had not been reported to the FDA; and (3) that, as a result, Ra Medical and 510(k) clearance for DABRA were reasonably likely to be scrutinized by regulatory authorities, including FDA, DOJ, and SEC, and likely to face penalties.

223. On November 14, 2018, Ra Medical filed its Quarterly Report on Form 10-Q for third quarter 2018 (the "3Q18 10-Q"), which was signed by defendants Irwin and Jackson. The 3Q18 10-Q asserted:

> We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label.

224. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical promoted DABRA as an atherectomy device, which is not the approved use and thus the Company engaged in off-label marketing; and (2) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

225. Moreover, Ra Medical claimed that it complied with applicable regulations concerning off-label marketing. The 3Q18 10-Q stated, in relevant part:

> *We may be subject to enforcement actions, competitor lawsuits, or other claims if we engage in the off-label promotion of our products.*
>
> Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of

medicine. ***Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion.*** For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication. While our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool, ***we believe that we can promote the device using the truthful and not misleading information from this study that is not inconsistent with our cleared indication.***

We recently received correspondence from a competitor claiming our promotion for DABRA as an atherectomy tool used by surgeons to treat peripheral vascular disease is off-label promotion for the product. ***We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, and we believe that we comply with these restrictions.*** . . . If we are found to have improperly promoted off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct. ***Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations, guidance and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products***, for example FDA's June 2018 guidance document, "Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers." Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we are not in compliance with such requirements, and if such non-compliance is proven, it could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations. Moreover, any threatened or actual government enforcement actions or lawsuits by third parties could also generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

226. This statement was materially false and/or misleading because it failed to disclose: (1) that the Company's promotion and marketing of DABRA for atherectomy was reasonably likely to be misleading to physicians because the FDA definition of atherectomy is narrower than that used colloquially by the medical community; (2) that such sales practices constituted, or could be perceived as, off-label marketing; (3) that the FDA had already warned Ra Medical that its promotional materials should not market DABRA as an atherectomy device; (4) that, as such, any belief that Ra Medical's marketing practices complied with FDA guidance was unreasonable; (5) that the Company's interactions were beyond non-promotional speech because sales representatives actively encouraged physicians to bill DABRA as an atherectomy device; and (6) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

227. Regarding manufacturing capability, the 3Q18 10-Q stated, in relevant part:

> *We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*
>
> ***We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production.*** For example, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.
>
> * * *
>
> ***If our manufacturing activities are adversely impacted, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected*** and our customers might instead purchase our competitors' products, which

> would have a material adverse effect on our business, financial condition, and results of operations.

228. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; and (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale.

229. Regarding the covert product recall, the 3Q18 10-Q stated, in relevant part:

> A government mandated or ***voluntary product recall by us could occur because of, for example, component failures, device malfunctions,*** or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

230. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; (2) that the lack of calibration caused inconsistent catheter performance and even catheter failures; and (3) that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018 to maintain positive relationships with physicians.

231. Regarding relationships with physicians, the 3Q18 10-Q stated, in relevant part:

> *The continuing development of our products depends upon our maintaining strong working relationships with physicians.*
>
> The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and

> product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ. ***Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations.***

232. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

233. Regarding payments to physicians, the 3Q18 10-Q stated, in relevant part:

> *We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.*
>
> In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material

> adverse effect on our business, financial condition, and results of operations.
>
> * * *
>
> Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

234. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

235. Similarly, the 3Q18 10-Q also stated, in relevant part:

> *Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.*
>
> Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our cleared devices.
>
> Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:
>
> - the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent

to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

* * *

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

236. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

### D. False And/Or Misleading Statements And/Or Omissions Made At Biotech Showcase On January 8, 2019

237. On January 8, 2019, defendants Irwin and Jackson participated in the Biotech Showcase on behalf of Ra Medical. During the presentation, defendant

Irwin touted that the 2017 pivotal study for DABRA had "not a single complication, not a single adverse event reported."

238. This statement was materially false and/or misleading because it failed to disclose: (1) that a patient had been injured during the pivotal study for DABRA; (2) that this safety incident had not been reported to the FDA; and (3) that, as a result, Ra Medical and 510(k) clearance for DABRA was likely to be scrutinized by regulatory authorities, including FDA, DOJ, and SEC, and likely to face penalties.

### E. False And/Or Misleading Statements And/Or Omissions Made In Connection With The Announcement Of Ra Medical's Fourth Quarter 2018 Financial Results

239. On March 14, 2019, Ra Medical issued a press release entitled "Ra Medical Systems Reports 2018 Fourth Quarter and Full Year Financial Results." Therein, defendant Irwin further stated: "In addition, we experienced production limitations in our manufacturing process as we scaled up catheter production. We believe we addressed those issues and will begin to see the positive impact on revenue beginning in the second quarter of 2019."

240. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale; and (4) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

241. During the call, defendant Irwin also stated: "***In addition, we experienced production limitations on our manufacturing process as we scaled up catheter production.*** We made changes in our production flow and we're now in the final stages of validating our manufacturing process. As of today, we're back, up and running in full production."

242. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; (3) that, as a result of the foregoing, Ra Medical could not produce quality DABRA catheters at scale; and (4) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

243. When analysts sought to confirm that Ra Medical had resolved the issues impacting the lower-than-expected DABRA sales, defendant Irwin reassured during the call:

> So ***we did have some manufacturing issues as we scaled up and we have solved those and we are now back into full production.*** And our top accounts are performing at model. So we believe that each rep would be able to handle as few as four accounts producing up to $1 million a year in catheter sales. And that's at a rate of about 240 catheters per year per account. ***We're very confident that that's holding true and that we'll be able to supply those customers now through the remainder of Q1 and through Q2.***

244. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; and (2) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

245. An analyst sought additional detail regarding the manufacturing issues, but defendant Irwin simply reiterated that the problems were related to meeting increased demand. Specifically, he stated in relevant part during the call:

> **Analyst:** Okay. And then just the last question on the manufacturing/production issues in the fourth quarter 2018, was it the ramp up in that or was there an issue at the plant itself?
>
> **Irwin:** Yeah, as you know our product is simple, but the process is very complicated. ***And during the scale up of that process to meet demand we had production issues. The issues were related to a very specific piece of equipment that we have now upgraded and we've completed the validation on that process. So again, we're back in production today.***

> **Vendetti:** And that, you said you're up and running on that. When did you officially come back up and running at full capacity?
>
> **Irwin**: It was very recently.

246. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical was experiencing manufacturing problems that prevented DABRA catheters from properly calibrating; (2) that, since catheters were a source of recurring revenue, the Company would experience limited revenue growth and incur additional expenses until it resolved the calibration issue; (3) that Ra Medical could not produce quality DABRA catheters at scale; and (4) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

247. When an analyst questioned whether the Company would disclose anything related to internal controls in the upcoming annual report, defendant Jackson dismissed concerns, stating: "We don't expect any additional disclosure controls coming out of the manufacturing issues other than just disclosing exactly what we just mentioned on this call."

248. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; and (2) that the Company's disclosures did not adequately describe the nature and extent of the manufacturing problems.

249. During the call, defendant Irwin suggested that physicians determined on their own accord to use DABRA for atherectomy, stating:

> Although the DABRA is not currently cleared by the FDA for that indication [*i.e.* atherectomy], nevertheless, we believe third-party health payors reimburse for photo ablation performed with the DABRA procedure ***if the physician determines the device and the procedure are medically appropriate for that particular patient***.

250. This statement was materially false and/or misleading because it failed to disclose: (1) that physicians used DABRA for atherectomy at least in part because Ra Medical instructed its sales representatives to promote the product for such use;

(2) that such sales practices constituted off-label marketing because DABRA was only approved for use in certain forms of PAD; and (3) that, as a result, the Company was reasonably likely to face regulatory scrutiny, including from the FDA, SEC, and DOJ, which could lead to increased costs and penalties.

251. Finally, when an analyst asked about the timeline for Ra Medical's submission to the FDA seeking an expanded indication for atherectomy for DABRA, defendant Irwin volunteered that physicians were reimbursed for atherectomy even though the DABRA label was limited to use in certain forms of PAD:

> **Irwin**: We've not had a single customer be denied a claim or have any response relative to any sort of clawbacks or refund. So our physicians are using the device, they're getting paid and we're having no issues there whatsoever.
>
> **Analyst**: Okay. So reimbursement hasn't been an issue, whether they're using it for atherectomy or PAD.
>
> **Irwin**: That's correct. It has not been an issue.

252. This statement was materially false and/or misleading because it failed to disclose: (1) that physicians used DABRA for atherectomy at least in part because Ra Medical instructed its sales representatives to promote the product for such use; (2) that such sales practices constituted off-label marketing because DABRA was only approved for use in certain forms of PAD; (3) that, as a result, the Company was reasonably likely to face regulatory scrutiny, including from the FDA, SEC, and DOJ, which could lead to increased costs and penalties; and (4) that the foregoing could jeopardize reimbursement for DABRA.

253. On March 15, 2019, Ra Medical filed its Annual Report on Form 10-K with the SEC for the period ended December 31, 2018 (the "2018 10-K"), which was signed by defendants Irwin and Jackson. Regarding marketing of DABRA, the 2018 10-K stated, in relevant part:

> We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis

> and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label.

254. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical promoted DABRA as an atherectomy device, which is not the approved use and thus the Company engaged in off-label marketing; and (2) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

255. Moreover, Ra Medical claimed that it complied with applicable regulations concerning off-label marketing. The 2018 10-K stated, in relevant part:

> *We may be subject to enforcement actions, competitor lawsuits, or other claims if we engage in the off-label promotion of our products.*
>
> Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. ***Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion.*** For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication. ***While our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use,*** which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool, ***we believe that we can promote the device using the truthful and not misleading information from this study that is not inconsistent with our cleared indication.***
>
> ***During our initial public offering process, we received correspondence from a competitor claiming our promotion for DABRA as an atherectomy tool used by surgeons to treat peripheral vascular disease is off-label promotion for the product. We are also aware of similar claims being made to physicians by our competitors. We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional***

> ***speech concerning the off-label use of products, and we believe that we comply with these restrictions. We cannot predict the extent to which our competitors may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement.*** . . . If we are found to have improperly promoted off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct. Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations, guidance and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, for example FDA's June 2018 guidance document, "Medical Product Communications That Are Consistent With the FDA-Required Labeling - Questions and Answers." Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we are not in compliance with such requirements, and if such non-compliance is proven, it could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations. Moreover, any threatened or actual government enforcement actions or lawsuits by third parties could also generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

256. This statement was materially false and/or misleading because it failed to disclose: (1) that the Company's promotion and marketing of DABRA for atherectomy was reasonably likely to be misleading to physicians because the FDA definition of atherectomy is narrower than that used colloquially by the medical community; (2) that such sales practices constituted, or could be perceived as, off-label marketing; (3) that the FDA had already warned Ra Medical that its promotional materials should not market DABRA as an atherectomy device; (4) that, as such, any belief that Ra Medical's marketing practices complied with FDA guidance was unreasonable; (5) that the Company's interactions were beyond non-promotional speech because sales representatives actively encouraged physicians to bill DABRA as an atherectomy device; and (6) that by continuing to promote

DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

257. Regarding manufacturing capability, the 2018 10-K stated, in relevant part:

> *We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*
>
> ***We have only recently begun manufacturing at scale, and may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, in the fourth quarter of 2018, we experienced production limitations as we were scaling up our catheter production, which had an adverse impact on our revenue. In response, we made changes in our production flow and we are now in the final stages of validating our manufacturing process.*** In addition, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

258. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; (2) that the lack of calibration caused inconsistent catheter performance and even catheter failures; (3) that such inconsistent catheter performance led to lower-than-expected sales in fourth quarter 2018; (4) that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018 to maintain positive relationships with physicians; and (5) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

259. Regarding relationships with physicians, the 2018 10-K stated, in relevant part:

> *The continuing development of our products depends upon our maintaining strong working relationships with physicians.*

> The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ for improper relationships with physicians. ***Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations.***

260. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

261. Regarding payments to physicians, the 2018 10-K stated, in relevant part:

> *We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.*
>
> In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false

> statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations.
>
> * * *
>
> Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

262. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

263. Attached as Exhibit 31.1 to the 2018 10-K was a certification by defendant Irwin pursuant to Sarbanes-Oxley Act of 2002 ("SOX") stating:

> I, Dean Irwin, certify that:
>
> 1. I have reviewed this Annual Report on Form 10-K of Ra Medical Systems, Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

264. These statements were materially false and/or misleading because it failed to disclose that there were material weaknesses in the Company's internal controls, as Ra Medical admitted on November 29, 2019 in an amended 2018 10-K. Additionally, though the certification attests that defendant Irwin was not aware of any undisclosed material facts, he was aware of the calibration issues, rendering the statements in the 2018 10-K false and misleading. Defendant Irwin was also aware

of the Company's off-label marketing because he attended the sales training sessions, which were conducted by his wife defendant Burstein, instructing the representatives to market DABRA as an atherectomy device and to encourage physicians to bill DABRA for atherectomy.

265. Attached as Exhibit 31.2 to the 2018 10-K was a certification by defendant Jackson making substantially similar statements to those identified in ¶ 263.

266. These statements were materially false and/or misleading because it failed to disclose that there were material weaknesses in the Company's internal controls, as Ra Medical admitted on November 29, 2019 in an amended 2018 10-K. Additionally, though the certification attests that defendant Jackson was not aware of any undisclosed material facts, he was aware of—at a minimum—the calibration issues, rendering the statements in the 2018 10-K false and misleading.

**F. False And/Or Misleading Statements And/Or Omissions Made In Connection With The Announcement Of Ra Medical's First Quarter 2019 Financial Results**

267. On May 13, 2019, the Company issued a press release entitled "Ra Medical Systems Reports First Quarter 2019 Financial Results." Therein, defendant Irwin stated, in relevant part: "I'm pleased to report that in the ***first quarter we completed the validation of our upgraded manufacturing process to accommodate catheter production at scale and commenced our new commercial strategy***."

268. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; (2) that the lack of calibration caused inconsistent catheter performance and even catheter failures; (3) that such inconsistent catheter performance led to lower-than-expected sales in first quarter 2019; (4) that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018 to maintain positive relationships with

physicians; and (5) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

269. The same day, the Company held a conference call with investors, analysts, and the public to discuss the financial results. During the call, defendant Irwin emphasized that the manufacturing issues were related to production limitations in response to increased demand, stating in relevant part:

> I'm also pleased to report that in March, we completed the validation of our upgraded manufacturing process. ***The limitations we experienced related to the scale up in catheter production*** impacted the number of evaluation cases we performed during the fourth quarter and into the first quarter.

270. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; (2) that the lack of calibration caused inconsistent catheter performance and even catheter failures; (3) that such inconsistent catheter performance led to lower-than-expected sales in first quarter 2019; (4) that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018 to maintain positive relationships with physicians; and (5) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

271. Similarly, during the call, defendant Jackson assured that the problems were "a one-off" and were resolved:

> **Analyst:** Was there a onetime hit that you saw from the changes that you're making on the manufacturing process that affected that metrics specifically and how do we think about that metric going forward?
>
> **Jackson:** Yes, that's exactly right, Matt. So our dermatology gross margin was 40%, which is very consistent with the prior quarters. ***So it really came from the scale of issues we experienced in the vascular segments and that was kind of a one-off***.
>
> **Analyst:** And do you think that metric will start to improve here in Q2 and really turned the quarter?
>
> **Jackson:** I do. I think we've got a pretty much everything out in Q1. They may have been a little trail into Q2. The Q2 will definitely be trending on.

272. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; and (2) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

273. On May 14, 2019, Ra Medical filed its Quarterly Report on Form 10-Q with the SEC for the period ended March 31, 2019 (the "1Q19 10-Q"), which was signed by defendants Irwin and Jackson. Regarding marketing of DABRA, the 1Q19 10-Q stated, in relevant part:

> We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label.

274. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical promoted DABRA as an atherectomy device, which is not the approved use and thus the Company engaged in off-label marketing; and (2) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

275. Moreover, Ra Medical claimed that it complied with applicable regulations concerning off-label marketing. The 1Q19 10-Q stated, in relevant part:

> *We may be subject to enforcement actions, competitor lawsuits, or other claims if we engage in the off-label promotion of our products.*
>
> Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. ***Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion.*** For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received

> FDA clearance or approval to market DABRA for an atherectomy indication. ***While our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use,*** which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool, ***we believe that we can promote the device using the truthful and not misleading information from this study that is not inconsistent with our cleared indication.***
>
> ***During our initial public offering process, we received correspondence from a competitor claiming our promotion for DABRA as an atherectomy tool used by surgeons to treat peripheral vascular disease is off-label promotion for the product. We are also aware of similar claims being made to physicians by our competitors. We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, and we believe that we comply with these restrictions.*** We cannot predict the extent to which our competitors may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement. In addition, we operate in an industry characterized by extensive litigation. However, the scope of potential liability with respect to any such claims, enforcement actions, or lawsuits is uncertain, and we cannot assure you that we will not receive claims from competitors or other third parties or be subject to enforcement actions in the future from regulatory agencies. . . . Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations, guidance and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, for example FDA's June 2018 guidance document, "Medical Product Communications That Are Consistent With the FDA-Required Labeling - Questions and Answers." Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we are not in compliance with such requirements, and if such non-compliance is proven, it could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations. Moreover, any threatened or actual government enforcement actions or lawsuits by third parties could also generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

276. This statement was materially false and/or misleading because it failed to disclose: (1) that the Company's promotion and marketing of DABRA for atherectomy was reasonably likely to be misleading to physicians because the FDA definition of atherectomy is narrower than that used colloquially by the medical

community; (2) that such sales practices constituted, or could be perceived as, off-label marketing; (3) that the FDA had already warned Ra Medical that its promotional materials should not market DABRA as an atherectomy device; (4) that, as such, any belief that Ra Medical's marketing practices complied with FDA guidance was unreasonable; (5) that the Company's interactions were beyond non-promotional speech because sales representatives actively encouraged physicians to bill DABRA as an atherectomy device; and (6) that by continuing to promote DABRA as an atherectomy device, Ra Medical risked regulatory scrutiny and penalties.

277. Regarding manufacturing capability, the 1Q19 10-Q stated, in relevant part:

> *We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*
>
> ***We have only recently begun manufacturing at scale and may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, in the fourth quarter of 2018, we experienced production limitations as we were scaling up our catheter production, which had an adverse impact on our revenue during the fourth quarter of 2018 and the first quarter of 2019. In response, we made changes in our production flow and validated our manufacturing process.*** In addition, our production processes and assembly methods may require additional changes to accommodate any significant expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

278. This statement was materially false and/or misleading because it failed to disclose: (1) that manufacturing problems prevented DABRA catheters from properly calibrating; (2) that the lack of calibration caused inconsistent catheter performance and even catheter failures; (3) that such inconsistent catheter performance led to lower-than-expected sales in fourth quarter 2018 and first quarter

2019; (4) that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018 to maintain positive relationships with physicians; and (5) ) that Ra Medical lacked adequate assurance that such manufacturing problems were resolved.

279. Regarding relationships with physicians, the 1Q19 10-Q stated, in relevant part:

> *The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians.*
>
> The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ for improper relationships with physicians. ***Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations.***

280. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

281. Regarding payments to physicians, the 1Q19 10-Q stated, in relevant part:

> *We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws,*

> *such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.*
>
> In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations.
>
> * * *
>
> Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

282. This statement was materially false and/or misleading because it failed to disclose: (1) that Ra Medical paid and/or directed benefits to certain physicians to gain, or which could be perceived as being to gain, an improper business advantage; and (2) that such practices were reasonably likely to draw scrutiny to the Company and to the physicians from regulatory authorities, including the FDA and DOJ.

283. Attached as Exhibits 31.1 and 31.2 of the 1Q19 10-Q were certifications by defendants Irwin and Jackson, respectively, pursuant to SOX, substantially similar to the statements identified in ¶ 263.

284. These statements were materially false and/or misleading because it failed to disclose that there were material weaknesses in the Company's internal controls, as Ra Medical admitted on November 29, 2019 in an amended 1Q19 10-Q. Additionally, though the certification attests that defendants Irwin and Jackson were not aware of any undisclosed material facts, they were aware of the calibration issues, rendering the statements in the 1Q19 10-Q false and misleading. Defendant Irwin was also aware of the Company's off-label marketing because he attended the sales training sessions, which were conducted by his wife Defendant Burstein, instructing the representatives to market DABRA as an atherectomy device and to encourage physicians to bill DABRA for atherectomy.

**G. False And/Or Misleading Statements And/Or Omissions Regarding The Product Recall**

285. In a Form 8-K filed with the SEC on September 27, 2019, the Company stated, in relevant part:

> ***Ra Medical Systems, Inc. ("Ra Medical") has initiated a voluntary recall of its DABRA laser system single-use catheters due to a change in product labeling.*** As previously announced, Ra Medical's DABRA laser system is experiencing inconsistent performance due to catheters that fail to calibrate prior to a procedure being performed, resulting in a temporary delay in the procedure. The Company has been continually reviewing its production processes to improve the product's quality and consistency in performance. After collecting field data and performing internal testing, Ra Medical observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization had a significantly higher rate of non-calibration than catheters that were within than two months from sterilization. ***Ra Medical is relabeling the catheters with two-month expiration, replacing its previous twelve-month shelf life expiration.*** Ra Medical believes that this change in product labeling will significantly reduce the number of catheters that fail to calibrate and thereby improve customer satisfaction with the product. ***As a result of the relabeling, Ra Medical will recall its catheters at customer sites to replace them with catheters displaying the new label.*** The product-related costs that are expected to be associated with the recall are estimated to be between $0.2 and $0.4 million.
>
> Ra Medical is continuing to review and upgrade its manufacturing process extending the period that the catheters will calibrate reliably and thereby extending the shelf life beyond two months.
>
> Ra Medical is in the process of notifying its physician customers of this recall and is arranging for the replacement of the recalled products. Ra

> Medical will be sending a notification letter to each customer detailing steps for return of affected products

286. This statement was materially false and/or misleading because it failed to disclose that Ra Medical implemented a covert product recall, or engaged in efforts leading to a product recall, as early as February 2018.

## XI. LOSS CAUSATION

287. During the Class Period, as detailed herein, Defendant Ra Medical and the Exchange Act Individual Defendants made materially false and/or misleading statements and/or omissions. This course of wrongful conduct caused the price of Ra Medical securities to be artificially inflated. But for Defendant Ra Medical's and the Exchange Act Individual Defendants' misrepresentations and/or omissions, Plaintiffs and the other members of the Class would not have purchased Ra Medical securities or would not have purchased such securities at artificially inflated prices. Later, when Defendant Ra Medical's and the Exchange Act Individual Defendants' prior misrepresentations and/or omissions were disclosed to the market, the price of Ra Medical shares fell significantly as the prior artificial price inflation was dissipated. As a result of their purchases and/or acquisition of Ra Medical securities during the Class Period, Plaintiffs and other members of the Class suffered economic loss, *i.e.* damages, under the Exchange Act. The timing and magnitude of the decline in the prices of the Company's shares negates any inference that the economic losses and damages suffered by Plaintiffs and the other members of the Class were caused by changed market conditions, macroeconomic factors, or Company-specific facts unrelated to defendants' wrongful conduct.

288. The truth about the material misrepresentations and/or omissions was partially revealed to the public on or around: (i) March 14, 2019; (ii) August 12, 2019; (iii) August 15, 2019; (iv) August 23, 2019; (v) September 27, 2019; (vi) October 31, 2019; and (vii) November 29, 2019.

289. On March 14, 2019, after the market closed, the Company announced, among others, that its fourth quarter 2018 financial results were negatively impacted by "production limitations" in its manufacturing process and issues related to the hiring and training of qualified sales personnel.

290. On this news, the Company's share price fell $2.14 per share, or approximately 32.57%, to close at $4.43 per share on March 15, 2019, on unusually heavy trading volume.

291. The price decline on March 15, 2019 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on March 14, 2019 was a partial disclosure because, among others, contrary to the Company's prior positive statements, its manufacturing facility was not capable of producing catheters at increased scale and the hiring of experienced sales representatives was insufficient to drive sales. Nevertheless, Ra Medical failed to disclose that the manufacturing problems actually concerned the calibration of catheters, which is integral to their function, and that sales representatives were improperly instructed to promote DABRA for atherectomy, which is not encompassed by the product's 510(k) clearance.

292. On August 12, 2019, minutes before the market closed, trading in Ra Medical's stock was halted and the Company issued a press release disclosing, among others, the nature and extent of the manufacturing issues that impacted DABRA product performance and partially disclosing that additional problems impacted the Company's operations. Specifically, Ra Medical disclosed, among others: (1) that improper temperature control of the oven used in the manufacturing process caused inconsistencies in DABRA catheters, which failed to calibrate at customer sites, and that these production inconsistencies (rather than an inability to scale up production for increased demand) had had an adverse impact on revenue during the fourth quarter of 2018 and first quarter of 2019; (2) that the Audit

Committee had launched an investigation into allegations raised by an anonymous complaint; and (3) that defendant Irwin had been terminated without cause.

293. On this news, Ra Medical's share price tanked—it fell $1.61, or nearly 57.09%, to close at $1.21 per share on August 13, 2019, on unusually heavy trading volume.

294. The price decline on August 13, 2019 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on August 12, 2019 was a partial disclosure because, contrary to the Company's prior positive statements, the previously-identified manufacturing problems had not been resolved. Nevertheless, Ra Medical failed to disclose that the Company instructed its sales representatives to promote DABRA for atherectomy, which is not encompassed by the product's 510(k) clearance.

295. On August 15, 2019, after the market closed, Ra Medical disclosed that, due to the Audit Committee's investigation, the Company was unable to timely file its quarterly report on Form 10-Q for the period ended June 30, 2019 with the SEC.

296. On this news, the Company's share price fell $0.16, or approximately 8.16%, to close at $1.80 per share on August 16, 2019, on unusually heavy trading volume.

297. The price decline on August 16, 2019 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market.

298. On August 23, 2019, after the market closed, Ra Medical disclosed that it received a notice from the NYSE that the Company's stock was at risk of being delisted for failure to timely file its second quarter 2019 quarterly report. Ra Medical had conducted the IPO less than one year prior to receiving the notice.

299. On this news, the Company's share price fell $0.08, or nearly 4.28%, to close at $1.79 per share on August 26, 2019, the next trading session, on unusually heavy trading volume.

300. The price decline on August 26, 2019 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market.

301. On September 27, 2019, before the market opened, Ra Medical partially disclosed the covert product recall, stating that the Company had initiated a "voluntary recall of its DABRA laser system single-use catheters due to a change in product labeling."

302. On this news, the Company's stock price fell $0.18, or nearly 11.38%, to close at $1.40 per share on September 30, 2019, on unusually heavy trading volume.

303. The price decline on September 27, 2019 and September 30, 2019 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market.

304. On October 31, 2019, after the market closed, Ra Medical revealed the wide-ranging issues plaguing the Company's operations, from problems with the DABRA catheter (its primary revenue driver) to lack of compliance with regulatory requirements. Specifically, Ra Medical admitted, among others: (1) that DABRA catheters frequently failed to calibrate; (2) that Ra Medical's disappointing fourth quarter 2018 and first quarter 2019 financial results were attributable to DABRA catheter calibration issue, rather than a production issue caused by increased scale; (3) that Ra Medical had engaged in a covert product recall; (4) that Ra Medical had instructed its sales representatives to market DABRA for atherectomy and to seek reimbursement using atherectomy codes, even though the 510(k) clearance was limited to use in certain forms of PAD; (5) that Ra Medical had made certain payments to physicians without adequate documentation and directed certain

benefits to physicians due to sales prospects, which could be perceived as bribery attempts; (6) that the Company failed to timely file at least two MDRs; (7) that the Company lacked an adequate system of controls to ensure that complaints regarding regulatory or ethical compliance were properly redirected for further investigation; and (8) that Melissa Burstein had been terminated as Ra Medical's Vice President.

305. On this news, the Company's stock price fell $0.11, or nearly 7.28%, to close at $1.40 on November 1, 2019, on unusually heavy trading volume.

306. The price decline on November 1, 2019 was the result of the nature and extent of defendants' wrongful conduct being revealed to investors and the market.

307. On November 29, 2019, Ra Medical revealed that the DOJ inquiry had escalated to a criminal investigation related to the Company. Ra Medical also disclosed that deficiencies in its internal controls existed as of the year ended December 31, 2018, that these deficiencies aggregated to a material weakness, and that this ineffective control environment led to the previously-disclosed problems involving the manufacturing problems, product recall, off-label marketing, and ethical violations.

308. On this news, the Company's stock price fell $0.16, or nearly 11.19%, to close at $1.27 per share on November 29, 2019, on unusually heavy trading volume.

309. The price decline on November 29, 2019 was the result of the nature and extent of defendants' wrongful conduct being revealed to investors and the market. *Inter alia*, the disclosure on November 29, 2019 was a partial disclosure because it emphasized the severity of the October 31 disclosure—the misconduct led to a criminal investigation.

## XII. POST-CLASS PERIOD EVENTS

310. On November 29, 2019, Ra Medical filed amendments to its 2018 annual report on Form 10-K/A with the SEC, amendments to its first quarter 2019

report on Form 10-Q/A, its second quarter 2019 report on Form 10-Q, and its third quarter 2019 report on Form 10-Q.

311. On December 6, 2019, Ra Medical disclosed that it had received a notice from the NYSE "that it is not in compliance with a NYSE continued listing requirement for maintaining an average total market capitalization of not less than $50 million over a period of 30 consecutive trading days and having stockholders' equity of not less than $50 million." Though the Company planned to submit a plan within 45 days advising how Ra Medical plans to regain compliance, "NYSE may initiate delisting procedures" if it does not accept the plan or if Ra Medical is not in compliance with listing standards within 18 months of receipt of the notice.

## XIII. ADDITIONAL SCIENTER ALLEGATIONS

312. As alleged herein, Ra Medical and the Exchange Act Individual Defendants acted with scienter since they knew that the public documents and statements issued or disseminated by Ra Medical and the Exchange Act Individual Defendants, including in the name of the Company, were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly or substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants Irwin and Jackson by virtue of their receipt of information reflecting the true facts regarding Ra Medical, their control over, and/or receipt and/or modification of Ra Medical's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Ra Medical, participated in the fraudulent scheme alleged herein.

313. Defendants Irwin and Jackson knew or recklessly disregarded the false and/or misleading nature of the information they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been

perpetuated during the Class Period without the knowledge and complicit or, at least, the reckless disregard of the personnel at the highest level of the Company, including defendants Irwin and Jackson.

314. The following additional facts give rise to a strong inference that the Exchange Act Individual Defendants acted with scienter.

315. The wrongful conduct alleged herein, relating to the failure to disclose the calibration problems with the DABRA catheters and the resulting inconsistent performance and impact on Ra Medical's financial results, involved Ra Medical's core operations, and knowledge of the wrongful conduct may therefore be imputed to defendants Irwin and Jackson. Specifically, DABRA catheter sales was crucial to the Company's viability and success because it was a source of recurring revenue, so defendants Irwin and Jackson closely monitored, or should have closely monitored, the manufacture and/or performance of DABRA catheters. Therefore, defendants Irwin and Jackson knew or should have known that DABRA catheters failed to calibrate, resulting in inconsistent performance, reduced sales, and increased costs.

316. Moreover, Ra Medical is a small company such that defendants Irwin and Jackson had access to information about the Company's manufacturing operations, which are located in the same building as the Company's corporate headquarters in Carlsbad, California. The manufacturing facility is relatively small, occupying only about 2,000 square feet of the corporate headquarters, which is approximately 32,000 square feet. Furthermore, Ra Medical only had 118 full-time employees as of December 31, 2018.

317. Similarly, defendants Irwin and Jackson had access to information about Ra Medical's training programs for its sales representatives. According to CW 3, sales training was held at the corporate headquarters and conducted by defendant Burstein, Irwin's wife. Defendant Irwin attended sales trainings; according to CW 2, defendant Burstein would stop training sessions to ask defendant Irwin questions.

CW 3 also stated that defendant Irwin discussed marketing for atherectomy. Even after Fogarty changed the sales training program starting around January 2019, the sessions were conducted at a building previously occupied by Ra Medical and down the street from the corporate headquarters, according to CW 2.

318. Defendants Irwin and Jackson also knew, or should have known, that complaints received about DABRA should be properly reviewed and timely reported to the FDA because the Company had recently modified its complaint review procedures. After a May 2018 inspection, the FDA had notified the Company that it failed to properly evaluate whether certain complaints rose to a level required to be reported to the FDA. According to the Registration Statement, the Company modified its complaint review procedures in response to this notification to ensure that MDRs are timely filed. Therefore, defendants Irwin and Jackson knew or should have known that certain complaints should have been reported to the FDA timely.

319. Defendants Irwin and Jackson knew, or should have known, that they must comply with the Code of Ethics. As Ra Medical admitted, executive officers violated the Code of Ethics.

320. Defendants Irwin and Jackson took advantage of the artificially inflated price of Ra Medical stock resulting from the false and/or misleading statements by selling a significant amount of their directly and indirectly owned shares in the weeks following the March 14, 2019 and May 13, 2019 disclosures that the "production limitations" were resolved.

321. Defendant Irwin made the following stock sales during the Class Period:

| Transaction Date | Number of Shares | Price Sold | Proceeds Received |
|---|---|---|---|
| 4/11/2019 | 13,152 | $3.49 | $45,900 |
| 4/11/2019 | 7,776* | $3.49 | $27,138 |

| | | | |
|---|---|---|---|
| 5/13/2019 | 13,736 | $3.82 | $52,472 |
| 5/13/2019 | 8,246* | $3.82 | $31,500 |
| 7/12/2019 | 7,400 | $3.2665 | $24,172 |
| 7/12/2019 | 4,400* | $3.2756 | $14,412 |
| 7/18/2019 | 14,302 | $2.9314 | $41,924 |
| 7/18/2019 | 8,584* | $2.9314 | $25,163 |

* Shares are indirectly owned by Irwin and directly owned by Burstein.

322. Defendant Jackson made the following stock sales during the Class Period:

| Transaction Date | Number of Shares | Price Sold | Proceeds Received |
|---|---|---|---|
| 6/13/2019 | 5,134 | $3.0763 | $15,793 |

## XIV. UNDISCLOSED ADVERSE FACTS

323. The market for Ra Medical's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements, Ra Medical's shares traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Ra Medical's shares relying upon the integrity of the market price of the Company's shares and market information relating to Ra Medical, and have been damaged thereby.

324. During the Class Period, Ra Medical and the Exchange Act Individual Defendants materially misled the investing public, thereby inflating the price of Ra Medical's shares, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Ra Medical's and the Exchange Act Individual Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading in that they failed to disclose material adverse information and/or

misrepresented the truth about Ra Medical's business, operations, and prospects as alleged herein.

325. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Ra Medical and the Exchange Act Individual Defendants made or caused to be made a series of materially false and/or misleading statements about Ra Medical's business and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its business and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Ra Medical's and the Exchange Act Individual Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

## XV. APPLICABILITY OF PRESUMPTION OF RELIANCE

326. The market for Ra Medical's shares was open, well-developed, and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Ra Medical's securities traded at artificially inflated prices during the Class Period. On September 27, 2018, the Company's shares closed at a Class Period high of $20.00 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's shares relying upon the integrity of the market price of Ra Medical's shares and market information relating to Ra Medical, and have been damaged thereby.

327. During the Class Period, the artificial inflation of Ra Medical's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, which in turn caused the damages sustained by Plaintiffs and other

members of the Class. As described herein, during the Class Period, Ra Medical and the Exchange Act Individual Defendants made or caused to be made a series of materially false and/or misleading statements about Ra Medical's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Ra Medical and its business, operations, and prospects, thus causing the price of the Company's shares to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company's shares. Ra Medical's and the Exchange Act Individual Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's shares at such artificially inflated prices, and each of them has been damaged as a result.

328. At all relevant times, the market for Ra Medical's shares was an efficient market for the following reasons, among others:

(a) Ra Medical shares met the requirements for listing, and were listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Ra Medical filed periodic public reports with the SEC and/or the NYSE;

(c) Ra Medical 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 and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Ra Medical was followed by securities analysts employed by 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. Each of these reports were publicly available and entered the public marketplace.

329. As a result of the foregoing, the market for Ra Medical's shares promptly digested current information regarding Ra Medical from all publicly

available sources and reflected such information in Ra Medical's share price. Under these circumstances, all purchasers of Ra Medical's shares during the Class Period suffered similar injury through their purchase of Ra Medical's securities at artificially inflated prices and a presumption of reliance applies.

330. 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 Ra Medical's and the Exchange Act Individual Defendants' material misrepresentations and/or omissions. Because this action involves Ra Medical's and the Exchange Act Individual Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Ra Medical and the Exchange Act Individual 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.

## XVI. NO SAFE HARBOR

331. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and/or misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and/or there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Ra

Medical and the Exchange Act Individual Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Ra Medical who knew that the statement was false or misleading when made.

**FIRST CLAIM**

**(Violations of Section 11 of the Securities Act)**

**Against All Defendants**

332. Plaintiffs repeat and re-allege each and every allegation contained above in ¶¶ 17-109, 187-210 as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

333. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against the Defendants.

334. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

335. Ra Medical is the registrant for the IPO. The Defendants named herein were responsible for the contents and dissemination of the Registration Statement.

336. As issuer of the shares, Ra Medical is strictly liable to Plaintiffs and the Class for the misstatements and omissions.

337. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

338. By reasons of the conduct herein alleged, each Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

339. Plaintiffs acquired Ra Medical shares pursuant or traceable to the Registration Statement for the IPO.

340. Plaintiffs and the Class have sustained damages. The value of Ra Medical common stock has declined substantially subsequent to and due to the Defendants' violations.

## SECOND CLAIM

**(Violations of Section 15 of the Securities Act)**

**Against the Securities Act Individual Defendants**

341. Plaintiffs repeat and re-allege each and every allegation contained above in ¶¶ 17-109, 187-210 as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

342. This count is asserted against the Securities Act Individual Defendants and is based upon Section 15 of the Securities Act.

343. The Securities Act Individual Defendants, by virtue of their offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Ra Medical within the meaning of Section 15 of the Securities Act. The Securities Act Individual Defendants had the power and influence and exercised the same to cause Ra Medical to engage in the acts described herein.

344. The Securities Act Individual Defendants were culpable participants in the violations of Section 11 of the Securities Act as alleged above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

345. By virtue of the conduct alleged herein, the Securities Act Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiffs and the Class for damages suffered.

**THIRD CLAIM**

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

**Against Ra Medical and the Exchange Act Individual Defendants**

346. Plaintiffs repeat and re-allege each allegation contained above as if fully set forth herein.

347. This claim is asserted against Ra Medical and the Exchange Act Individual Defendants and is based on Section 10(b) of the Exchange Act.

348. During the Class Period, Ra Medical and the Exchange Act Individual Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Ra Medical's shares at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Ra Medical and the Exchange Act Individual Defendants took the actions set forth herein.

349. Ra Medical and the Exchange Act Individual Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares in an effort to maintain artificially high market prices for Ra Medical's shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Ra Medical and the Exchange Act Individual Defendants were either primary participants in the wrongful and illegal conduct charged herein or were controlling persons as alleged below.

350. Ra Medical and the Exchange Act Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous

course of conduct to conceal adverse material information about Ra Medical's financial well-being and prospects, as specified herein.

351. Ra Medical and the Exchange Act Individual Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Ra Medical's value and performance and continued growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Ra Medical and its business operations and prospects, in light of the circumstances under which they were made, not misleading, and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares during the Class Period.

352. Each of the Exchange Act Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Exchange Act Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of the Exchange Act Individual Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of the Exchange Act Individual Defendants enjoyed significant personal contact and familiarity with the other Exchange Act Individual Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, and operations at all relevant times; and (iv) each of the Exchange Act Individual Defendants was aware of the Company's dissemination of information to the

investing public which they knew and/or recklessly disregarded was materially false and/or misleading.

353. Ra Medical and the Exchange Act Individual Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Ra Medical's and the Exchange Act Individual Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Ra Medical's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Ra Medical's and the Exchange Act Individual Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Ra Medical and the Exchange Act Individual Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

354. Because of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Ra Medical's shares was artificially inflated during the Class Period. In ignorance of the fact that the market price of the Company's shares was artificially inflated, and relying directly or indirectly on the false and/or misleading statements made by Ra Medical and the Exchange Act Individual Defendants, or upon the integrity of the market in which the shares traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by Ra Medical and the Exchange Act Individual Defendants, and not disclosed in public during the Class Period, Plaintiffs and the other members of the Class acquired Ra Medical's shares during the Class Period at artificially high prices, and were damaged thereby.

355. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the Company's misrepresentations, which were not disclosed by Ra Medical and the Exchange Act Individual Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Ra Medical shares, or, if they had acquired such shares during the Class Period, they would not have done so at the artificially inflated prices which they paid.

356. Because of the foregoing, Ra Medical and the Exchange Act Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

357. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's shares during the Class Period.

## FOURTH CLAIM

**(Violations of Section 20(a) of the Exchange Act)**

**Against the Exchange Act Individual Defendants**

358. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

359. This claim is asserted against the Exchange Act Individual Defendants and is based on Section 20(a) of the Exchange Act.

360. The allegations alleged above, and incorporated into this claim, demonstrate a primary violation of Section 10(b) of the Exchange Act.

361. The Exchange Act Individual Defendants acted as controlling persons of Ra Medical within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or

intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Exchange Act Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and/or misleading. The Exchange Act Individual Defendants were provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

362. In particular, each of the Exchange Act Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular statements giving rise to the securities law violations as alleged herein and exercised the same.

363. Because of their positions as controlling persons, the Exchange Act Individual Defendants are thus liable pursuant to Section 20(a) of the Exchange Act for Ra Medical's primary Exchange Act Section 10(b) violations. As a direct and proximate result of the Exchange Act Individual Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's shares during the Class Period.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

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

(d) Such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiffs hereby demand a trial by jury.

DATED: April 19, 2021

**GLANCY PRONGAY & MURRAY LLP**

By: */s/ Robert V. Prongay*
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**PROOF OF SERVICE BY ELECTRONIC POSTING**

I, the undersigned say:

I am not a party to the above case, and am over eighteen years old. On April 19, 2021, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Southern District of California, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on April 19, 2021, at Los Angeles, California.

*s/ Robert V. Prongay*
Robert V. Prongay