UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: ISOLAGEN, INC.	:	
SECURITIES & DERIVATIVE LITIGATION	:	**MDL NO. 1741**
	:	
THIS DOCUMENT RELATES TO:	:	
No. 2:05-cv-04983-RB and	:	
Consolidated Class Actions	:	**JURY TRIAL DEMANDED**
	:	
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CONSOLIDATED CLASS ACTION COMPLAINT

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Court-appointed Lead Plaintiffs, Context Capital Management, LLC, Silverback Asset Management, LLC, Silverback Master Ltd., Silverback Life Sciences Master Fund, Ltd. and Michael McNulty, bring this federal securities law class action on behalf of themselves and all other persons and entities, other than Defendants and their affiliates as specified in ¶¶ 25 to 69 below, who purchased or acquired publicly traded securities of Isolagen, Inc. (together with all subsidiaries and affiliates, "Isolagen" or the "Company") during the period March 3, 2004 through and including August 9, 2005 (the "Class Period").

I. NATURE OF THE ACTION

1. Isolagen is a biotechnology company that throughout the Class Period sold the market on an intriguing idea: that a patient's own skin cells could be extracted, reproduced, and then re-injected back into the patient's treatment area to, among other things, counter the effects of aging. The so-called "Isolagen Process" (referred to herein as the "Isolagen Process" or the "Process") was presented to patients – and investors – as an attractive alternative to other "anti-aging" cosmetic treatments such as Botox or collagen implants, which involve the injection of a foreign substance into a patient. Defendants represented that Isolagen would have a competitive advantage in the multi-billion dollar cosmetics procedure market because its product would produce a more "natural" outcome, and because the Isolagen Process would have longer-lasting effects than chemical toxins and fillers that typically last less than six months. Moreover, according to defendants, the market for Isolagen would grow exponentially, because of the aging of the "baby boomer" generation (*i.e.*, roughly ages 39-59), which accounted for nearly half of the non-surgical cosmetic procedures in 2003. As the Process was Isolagen's sole product, the Company's representations regarding the Process, especially those concerning its efficacy and marketability, materially affected the prices of the Company's securities.

2. In order to tap into the potentially abundant United States cosmetics procedure market, however, Isolagen had to obtain approval of its Process from the United States Food & Drug Administration (the "FDA"), and in order to gain that approval and market its product, the Company had to prove that the Process was effective and could be utilized and distributed in a consistently effective and safe manner. Thus, throughout the Class Period, defendants informed the market that the Company's only product was advancing smoothly through the necessary phases of the FDA regulatory approval process and achieving the positive results the Company anticipated and promised. According to defendants, Isolagen was close to successfully completing its "pivotal Phase III clinical trials" and would soon be submitting to the FDA its "Biologics License Application" (BLA) – the last regulatory step for approval and marketing of the Process.

3. In communications with the investing public, defendants repeatedly touted the fact that the Company had been successfully marketing the Process in the United Kingdom since 2002, and the results there had been uniformly positive. Thus, defendants suggested, based on Isolagen's experience marketing its product in the United Kingdom, the Process was effective and could soon be mass-produced and marketed in the United States.

4. With respect to the mass-production and marketing of the Isolagen Process, defendants also repeatedly touted the development status of the Company's so-called "Automated Cellular Expansion" (ACE) system. The ACE system was to be an automated cell growth and harvesting technology that would permit the Company to grow cells in large numbers and distribute them to tens of thousands of patients globally. According to Isolagen, the effective and timely development of the ACE system was central to the successful marketing of the Isolagen Process because the use of its existing system – the "flask growth" system – could

not be used to produce Isolagen Process injections in commercial quantities at costs that would allow the Company to maximize its profits. During the Class Period, the Company assured the public that it was in the "final stages" of developing the ACE system.

5. The truth was, however, that defendants knew from the Company's experience in the United Kingdom that the product was *far* from uniformly effective, and, significantly, knew that the Process was demonstrably *ineffective* for the Company's claimed target market – *i.e.*, patients within the "baby boomer" generation. What is more, contrary to the Company's public statements, defendants knew or should have known throughout the Class Period that there was no chance of Isolagen's "pivotal Phase III" clinical trials succeeding – and thus regulatory approval was in fact years, rather than months, away – because there was no controlled, uniform method established and implemented for the subject injections. Defendants were informed of this fact repeatedly by physicians in the United Kingdom throughout the Class Period. Indeed, one of the confidential informants located by counsel during their investigation (referred to herein as "Confidential Witness #1" or "CW#1") – a physician who not only treated approximately 20 patients per month with the Isolagen Process but who was also authorized by Isolagen to train or re-train in excess of 100 physicians, surgeons and nurses with respect to the Process – explicitly informed Isolagen's senior management that the Company would be "in trouble" with respect to its Phase III trials in the United States if the Company's practitioners were not properly trained in a proper and standardized injection technique.

6. As the Company became aware of increasing numbers of non-responders in early to mid-2004, its desperation became evident as it abruptly changed the protocol in the United Kingdom so that there were only two injections administered to each patient, but more cells

being injected. When this technique also failed to work, Isolagen changed the protocol again to three injections – vastly increasing the cost of treatment.

7. Later, when Isolagen officials – including Defendant Michael Avignon – visited the United Kingdom and witnessed CW#1's technique in injecting patients, they realized that practitioners in the United States were not injecting patients in the same manner. As a result, those officials asked CW#1 to come to the United States to train doctors on there proper technique. This, they said, was essential because the Company was beginning its pivotal Phase III trials. Subsequently, however, the Company – in particular, Defendant Robert J. Bitterman, Isolagen's CEO and President from September 2004 to April 21, 2005 -- informed CW#1 that the Company would no longer need CW#1's services. Accordingly, because, among other things, there was no uniform methodology in injection technique, defendants knew or should have known that the pivotal Phase III clinical trials would not be successful.

8. On August 1, 2005, the market first learned what defendants had known for more than a year: that the Isolagen Process was not sufficiently or consistently effective enough to gain FDA approval, and that the filing of the Company's BLA application was far off in the future, as it required, among other things, a demonstration of consistent results. On that day, before the market opened, Isolagen revealed that the preliminary results from its Phase III clinical trial evaluating the safety and efficacy of the Isolagen Process for the treatment of facial wrinkles had failed to meet all of its primary "end points." Moreover, the Company revealed that the results from one of the studies had failed to demonstrate any statistical significance at all, and a wide variance in response rates ranging from 73.3% to just 7.6% was reported from site to site across the studies. This disparity evidenced the complete absence of a uniform method of administering the Process, which was a flaw that ensured failure of the Phase III trials. The

Company now made clear that when it would begin the clinical trials anew, "only physicians trained in the proper Isolagen injection technique will participate as investigators in this trial."

9. In reaction to this news, the price of Isolagen stock fell $2.75 from a closing price of $5.59 on July 31, 2005 to below $2.84 on August 1, 2005, on unusually high volume – a 45% drop. An analyst from UBS Securities LLC following the Company expressed "concern" in his August 1, 2005 report regarding the "wide variance in response rates among the study sites." He further noted: "We are curious about the injection technique issue, as it seems like the company should have ensured that the physicians in the trial were already properly trained before allowing them to participate." Another analyst's report of the same day similarly expressed "surprise" over the results, and CIBC World Market Corp. downgraded Isolagen's stock in reaction to this news.

10. A little more than a week later, on August 9, 2005, Isolagen held a conference call in which two additional misrepresentations were revealed to the public: that (i) contrary to the Company's representations regarding its high success rates in treating patients, substantial numbers of patients were returning to physicians for re-treatment; and (ii) the ACE system was not in the "final stages" of development, as defendants had represented during the Class Period, but, in fact, was far from implementation.

11. In reaction to the news concerning the Company's misrepresented success rates and development status of the ACE system, the price of Isolagen stock fell a further 10% from its closing price on August 8, 2005, to $2.66 on August 9, 2005 on unusually high volume.

12. As set forth below, defendants' scheme to mislead the investing public concerning Isolagen's chances of obtaining FDA approval of the Process and mass-produce its sole product pumped up the price of Isolagen securities and allowed Isolagen to sell millions of dollars of new

securities to investors – even while the Company's executives were dumping their own Isolagen stock at artificially inflated prices. Indeed, during the Class Period, Individual Defendants DeLape, Macaluso, Avignon, Tomz, Boss, and Marko collectively sold 2,450,000 shares of Company stock for proceeds totaling $17,353,000.

13. In this complaint, Lead Plaintiffs assert two different sets of claims. In the first set (Count One through Count Three), Lead Plaintiffs assert fraud-based claims under the Securities Exchange Act of 1934 (the "Exchange Act") against those defendants, including the Company and its principals, who directly and knowingly participated in a fraudulent scheme to deceive the investing public by artificially inflating the price of Isolagen's securities for their own ill-gotten gain. In that regard, Lead Plaintiffs assert liability under section 10(b) of the Exchange Act against these defendants for using deceptive and manipulative devices in connection with the sale of securities, and also for insider-trading in violation of section 20A of the Exchange Act. In this first set of claims, Lead Plaintiffs also assert control person liability under section 20 of the Exchange Act against various principals of Isolagen, including Isolagen's directors and officers.

14. In the second set of claims (Count Four through Count Nine), Lead Plaintiffs assert a series of strict liability and negligence claims based on the Securities Act of 1933 (the "Securities Act"). The Securities Act claims are asserted against those defendants who are statutorily responsible under sections 11 and 12(a)(2) of the Securities Act for the material untrue statements and misleading omissions in the registration statements and prospectuses pursuant to which Isolagen issued securities to the public. These defendants include the Company, its directors and officers, who are signatories to Isolagen's registration statements and prospectuses, and the underwriters – who, in acting as professional gatekeepers for the investing public, are

statutorily liable for materially inaccurate statements contained in Isolagen's registration statements and prospectuses. In this second set of claims, Lead Plaintiffs also assert control person liability under section 15 of the Securities Act against various principals of Isolagen, including directors and officers of Isolagen. Lead Plaintiffs' Securities Act claims are not based on any knowing or reckless misconduct on behalf of the defendants – *i.e.*, they do not allege, and do not sound in, fraud. Lead Plaintiffs specifically disclaim any allegations of fraud in these non-fraud claims under the Securities Act.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Securities Exchange Act of 1934, 15 U.S.C. § 78aa and Section 22 of the Securities Act, 15 U.S.C. § 77v. This Court also has jurisdiction over the subject matter of this action pursuant to 28 U.S.C §§ 1331 and 1337. The claims asserted herein arise under Sections 10(b), 20(a) and 20A of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a); Sections 11, 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§ 77k, 77*l*(a)(2) and 77o; and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. 240.10b-5.

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act, Section 22 of the Securities Act, and 28 U.S.C. § 1391(b) and (c). In addition, many of the acts and transactions giving rise to the violations of law complained of herein, including the preparation and dissemination to the public of materially false and misleading public filings, occurred in this District. Isolagen maintains its principal executive offices in this District at 405 Eagleview Boulevard, Exton, Pennsylvania 19341.

17. In connection with the wrongful acts and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mail and the facilities of a national securities market.

III. PARTIES

A. Lead Plaintiffs

18. Lead Plaintiff, Context Capital Management, LLC ("Context") is a private investment firm based in Greenwich, Connecticut and San Diego, California that manages funds in excess of $400 million. Context manages a number of investment funds including AHFP Context; Context Convertible Arbitrage Fund, LP; Lyxor/Context Fund Ltd,; National Bank of Canada; Context Convertible Arbitrage Offshore, Ltd; Royal Bank of Canada (Norshield); and Univest Convertible Arbitrage Fund II LTD (Norshield). Context acts as attorney-in-fact for these funds and has full and complete authority to purchase and sell securities for each of these funds and to initiate legal action on their behalf. During the Class Period, Context purchased the securities of Isolagen on behalf of each of these funds, and suffered damages as a result.

19. Lead Plaintiff, Silverback Asset Management, LLC ("Silverback Management") is a private investment fund that, during the Class Period, managed funds in excess of $100 million. Silverback Management is located in Chapel Hill, North Carolina.

20. Lead Plaintiff, Silverback Master, Ltd. ("Silverback Master") is an investment fund managed by Silverback Management. During the Class Period, Silverback Master purchased the securities of Isolagen, and suffered damages as a result.

21. Lead Plaintiff, Silverback Life Sciences Master Fund, Ltd. ("Silverback Life Sciences") is an investment fund managed by Silverback Management. During the Class Period Silverback Life Sciences purchased the securities of Isolagen, and suffered damages as a result.

22. Lead Plaintiff, Michael F. McNulty ("McNulty") is an individual who resides in Greenwich, Connecticut. During the Class Period, McNulty purchased the securities of Isolagen, and suffered damages as a result.

23. By Order of the Court dated April 4, 2006, Context, Silverback, and McNulty were appointed Lead Plaintiffs in this action in accordance with Section 21D(a)(3)(B) of the Exchange Act, as amended by Section 101(a) of the Private Securities Litigation Reform Act of 1995. Accordingly, Silverback Asset Management, Silverback Master, Silverback Life Sciences (collectively "Silverback"), Context, and McNulty are collectively referred to herein as "Lead Plaintiffs."

24. Lead Plaintiffs each purchased or acquired the securities of Isolagen as set forth in the certifications previously filed with the Court. Lead Plaintiffs each suffered damages as a result of violations of the federal securities laws as alleged herein.

B. Defendants

1. Isolagen Inc.

25. Defendant Isolagen, Inc. is a Delaware corporation with its corporate headquarters in Exton, Pennsylvania. Isolagen conducts operations exclusively through its wholly-owned subsidiary, Isolagen Technologies, Inc., a Delaware corporation ("Isolagen Technologies"). In turn, Isolagen Technologies wholly-owns and controls three subsidiaries: (1) Isolagen Europe Limited, a company organized under the laws of the United Kingdom (herein referred to as "Isolagen UK"); (2) Isolagen Australia Pty Limited, a company organized under the laws of the Australia ("Isolagen Australia"); and Isolagen International, a company organized under the laws of Switzerland ("Isolagen Switzerland").

26. According to its public filings during the Class Period, Isolagen's operations consisted of the development and commercialization of "autologous" (i.e., from the patient's own body) cellular therapies for soft tissue regeneration. As described above, Isolagen's sole product is the Isolagen Process – a cosmetic treatment based on the use of injections of a patient's own collagen-producing cells to mitigate the normal effects of aging on the skin.

27. During the Class Period, the Company's common stock was traded on the American Stock Exchange ("AMEX") under the symbol "ILE" and the Company filed annual reports on Form 10-K ("Forms 10-K") and quarterly reports on Form 10-Q ("Forms 10-Q") with the United States Securities and Exchange Commission (the "SEC"). In April 2004, the Company announced a proposed public offering of 7,000,000 shares of common stock, which was conducted pursuant to a Form S-3 registration statement dated April 28, 2004, a Form S-3/A registration statement dated May 17, 2004, a Form S-3/A registration statement dated June 9, 2004 and a Form 424B4 prospectus dated June 10, 2004 (the "Secondary Offering Prospectus") (collectively, the "Secondary Registration Statement"). On February 1, 2005, Isolagen filed with the SEC a Registration Statement on Form S-3 in connection with its sale of Convertible Notes, and, on May 2, 2005, Isolagen filed with the SEC an amended registration statement on Form S-3/A (collectively the "Convertible Notes Registration Statement"). The Convertible Notes Registration Statement registered the Company's $90,000,000 face value convertible notes and the common stock issuable upon their conversion. Following registration, the Company's Convertible Notes were publicly traded. As of August 4, 2005, there were 30,260,289 shares of Isolagen common stock outstanding. Isolagen operates on a fiscal year that ends on December 31.

2. The Officer Defendants

28. **Frank L. DeLape.** Defendant Frank M. DeLape ("DeLape") is a member of a group of investors, including defendants Michael Macaluso and Michael Avignon, who took control of and recapitalized Isolagen in 2001. Mr. DeLape was elected to Isolagen's Board of Directors in June 2001, and in August 2001, became Chairman of the Board and served in this capacity throughout the Class Period. DeLape also served as the Company's Interim Chief Executive Officer for approximately five months between April 2005 and October 2005.

29. Defendant DeLape signed both the Secondary Registration Statement and the Convertible Notes Registration Statement, as well as many of the Company's periodic filings with the SEC, including its Forms 10-K and 10-K/A for the fiscal years ending December 31, 2003 and December 31, 2004. He also further signed Sarbanes-Oxley Certifications filed with the SEC in connection with Isolagen's Form 10-K/A for the fiscal year ending December 31, 2004 and Forms 10-Q for the fiscal quarters ended March 31, 2005 and June 30, 2005. In direct communications with investors, DeLape was also one of the Company's principal spokepersons, and was frequently quoted in the press releases challenged herein.

30. As of April 26, 2004, DeLape was Isolagen's largest shareholder. On April 26, 2004, prior to the Secondary Offering, DeLape held a beneficial interest in 2,941,666 shares of Isolagen common stock or 10.9% of all shares then outstanding. During the Class Period, Defendant DeLape sold a total of 51% of directly held Isolagen holdings in two tranches for total proceeds of $5,024,795. On or about June 15, 2004, DeLape sold 293,270 Isolagen shares for $2,492,795, representing 21% of his direct holdings at the time. Then, on or about November 3, 2004, Defendant DeLape sold an additional 400,000 shares of Isolagen for $3,532,000, representing 37% of his direct holdings at that time.

31. **Michael Macaluso**. Defendant Michael Macaluso ("Macaluso") served as Chief Executive Officer ("CEO") and Director of the Company from 2001 until his resignation as CEO in September 2004, and his subsequent resignation as a director in April 2005. Macaluso also served as President of the Company between January 2003 and September 2004.

32. Macaluso signed the Secondary Registration Statement, as well as many of the Company's periodic filings with the SEC including its Forms 10-K and 10-K/A for the fiscal years ending December 31, 2003 and December 31, 2004. Macaluso also signed Sarbanes-Oxley

Certifications in connection with Isolagen's Forms 10-K and 10-K/A for the fiscal year ending December 31, 2003; Forms 10-Q for the fiscal quarters ended March 31, 2003, June 30, 2003, September 30, 2003, March 31, 2004, and June 30, 2004; Forms 10-Q/A for the fiscal quarters ending March 31, 2003 and June 30, 2003. Macaluso was also one of the company's principal spokespersons and was frequently quoted in its press releases.

33. During the Class Period, Macaluso was one of Isolagen's largest shareholders. On April 26, 2004, prior to the Secondary Offering, Macaluso held a beneficial interest in 2,875,734 shares of Isolagen common stock or 10.3% of all shares then outstanding. On or about November 3, 2004, Macaluso sold 400,000 Isolagen shares, representing 29% of his direct holdings in the Company at the time, garnering proceeds of $2,532,000.

34. **Michael Avignon**. Defendant Michael Avignon ("Avignon") is another member of the group of investors who took control of Isolagen in 2001. He served at various times as Director, President, and Manager of International Operations for the Company. Mr. Avignon was Director of Isolagen from 2001 until March 18, 2004. After resigning as Director, Mr. Avignon continued to serve in a representative capacity for the Company, often traveling to the United Kingdom to meet with practitioners there and monitor the implementation of the Isolagen Process in Europe.

35. During the Class Period, Avignon was one of Isolagen's largest shareholders. On April 26, 2004, prior to the secondary offering, Avignon held a beneficial interest in 2,875,734 shares of Isolagen common stock or 10.3% of all shares then outstanding. On or about November 3, 2004, Defendant Avignon sold 400,000 Isolagen shares, which represented 29% of his direct holdings in the Company at the time and from which he gained profits of $2,532,000.

36. **Jeffrey W. Tomz**. Defendant Jeffrey W. Tomz ("Tomz") served as Isolagen's Chief Financial Officer and Secretary from August 2001 to April 2005. On or about April 19, 2005, Tomz resigned as the Company's CFO and was appointed Principal Financial and Accounting Officer of Isolagen. In addition, Tomz is a "Principal" at Benchmark Equity Group, Inc, a firm wholly owned by Defendant DeLape.

37. Defendant Tomz signed the Secondary Registration Statement and the Convertible Notes Registration Statement. Tomz also signed many of the Company's filings with the SEC, including its Forms 10-K and 10-K/A for the fiscal years ending December 31, 2004 and December 31, 2005 and the Sarbanes-Oxley Certifications in connection with Isolagen's the Forms 10-K and 10-K/A for the fiscal year ending December 31, 2003. Tomz also signed Forms 10-Q for the fiscal quarters ended March 31, 2003, June 30, 2003, September 30, 2003, March 31, 2004, June 30, 2004, and September 30, 2004 as well as Sarbanes-Oxley Certifications in connection with each of those Forms 10-Q. He also signed Forms 10-Q/A for the fiscal quarters ending March 31, 2003 and June 30, 2003, as well as the Sarbanes-Oxley Certifications in connection with those Forms 10-Q/A.

38. On April 26, 2004, prior to the secondary offering, Tomz held a beneficial interest in 323,600 shares of Isolagen common stock or 1.2% of all shares then outstanding. On or about June 15, 2004, Defendant Tomz sold 24,587 Isolagen shares, 22% of his direct holdings, for proceeds of $208,989.

39. **Robert J. Bitterman**. Defendant Robert J. Bitterman ("Bitterman") served as the Company's President and CEO from September 2004 until his resignation on or about April 21, 2005.

40. Bitterman signed many of the Company's filings with the SEC, including its Form 10-K for the fiscal year ending December 31, 2004, as well as Sarbanes-Oxley Certifications in connection with that Form 10-K as and the Form 10-Q filed September 30, 2004. Mr. Bitterman was also quoted in certain of the press releases challenged herein.

41. **Olga Marko**. Defendant Olga Marko ("Marko") is a founder of Isolagen. She served as Senior Vice President and Director of Research of the Company from August 2001 until at least June 10, 2004.

42. During the Class Period, Marko sold a total of 60% of her Isolagen holdings in two tranches for total proceeds of $4,463,693. On or about June 15, 2004, Marko sold 227,258 of her Isolagen shares, which represented 21% of her holdings in the Company at the time, for proceeds totaling $1,931,693. On or about November 3, 2004, Marko sold 400,000 more Isolagen shares, which then represented 49% of her remaining holdings, providing her with an additional gain of $2,532,000.

43. **Martin E. Schmieg.** Defendant Martin E. Schmieg ("Schmieg") served as Chief Financial Officer and Senior Vice President of Isolagen between April 2005 and March 2006.

44. Schmieg signed the Convertible Notes Registration Statement, as well as periodic Company filings with the SEC, including the Form 10-K/A for the fiscal year ended December 31, 2004 and Forms 10-Q for the fiscal quarters ended March 31, 2005 and June 30, 2005. In addition, Schmieg signed Sarbanes-Oxley Certifications in connection with the Form 10-K/A filed for the fiscal year ended December 31, 2004 and in connection with the Forms 10-Q dated March 31, 2005 and June 30, 2005.

45. Defendants DeLape, Macaluso, Avignon, Tomz, Bitterman, Marko, and Schmieg are collectively referred to herein as the "Officer Defendants."

3. The Director Defendants

46. **Williams K. Boss, Jr.** Defendant William K. Boss, Jr. ("Boss") was a founder of Isolagen and, along with Defendant Marko, invented the Isolagen Process. After the Company's recapitalization in 2001, he served as Isolagen's Vice Chairman of the Board of Directors until April 19, 2004, at which time he resigned and became a consultant to the Company. On or about June 15, 2004, Boss collected $2,591,522 from the sale of 304,885 of his Isolagen shares, representing 19% of his holdings in the Company at the time.

47. Boss signed the Secondary Registration Statement and the Convertible Notes Registration Statement. In addition, he signed the company's Forms 10-K and 10-K/A for the fiscal year ended December 31, 2003.

48. **Steven Morrell**. Defendant Steven Morrell has served as a director of the Company since May 2002. Morrell signed both the Secondary Registration Statement and the Convertible Notes Registration Statement. In addition, Morrell signed Isolagen's Forms 10-K and 10-K/A for the fiscal years ending December 31, 2003 and December 31, 2004.

49. **Henry Y.L. Toh**. Defendant Henry Y.L. Toh ("Toh") has served as a director of the Company since January 2004. Toh signed both the Secondary Registration Statement and the Convertible Notes Registration Statement. In addition, Toh signed Isolagen's Forms 10-K and 10-K/A for the fiscal years ending December 31, 2003 and December 31, 2004.

50. **Ralph V. De Martino**. Defendant Ralph V. De Martino ("De Martino") has served as a director of the Company since December 2002. De Martino signed both the Secondary Registration Statement and the Convertible Notes Registration Statement. In addition, De Martino signed Isolagen's Forms 10-K and 10-K/A for the fiscal years ending December 31, 2003 and December 31, 2004.

51. **Marshall G. Webb**. Defendant Marshall G. Webb ("Webb") has served as a director of the Company since April 2004. Webb signed both the Secondary Registration Statement and the Convertible Notes Registration Statement. In addition, Webb signed Isolagen's Form 10-K/A for the fiscal year ending December 31, 2003 and Isolagen's Forms 10-K and 10-K/A for the fiscal year ending December 31, 2004.

52. Together, Defendants Boss, Morrell, Toh, De Martino, and Webb are referred to herein as the "Director Defendants."

53. The Officer Defendants and the Director Defendants are herein collectively referred to as the "Individual Defendants."

4. The Underwriter Defendants

54. **CIBC World Markets Corp.** Defendant CIBC World Markets Corp. ("CIBC") is global investment bank with headquarters in Toronto, Canada. CIBC has at least 16 offices in the United States and provides services that include securities underwriting, brokerage, investment advisory services, and equity research services.

55. CIBC was sole bookrunner and co-lead manager of Isolagen's Secondary Offering and sold and distributed 4,025,000 shares of Isolagen common stock, including 525,000 shares allocated in an over-allotment option, to the investing public pursuant to the Registration Statement and Prospectus filed with the SEC in connection with the Secondary Offering (the "Secondary Registration Statement" and "Secondary Prospectus").

56. As part of its duties as an underwriter, CIBC was required to conduct, prior to the Secondary Offering, a due diligence investigation of the Company. CIBC was paid approximately $2.1 million in fees for its underwriting services in connection with the Secondary Offering. During the Class Period, CIBC also provided equity research coverage of Isolagen

shares in which it recommended the shares as "Sector Outperformer" and advised that they should reach a price target of $13 per share within 12 – 18 months.

57. CIBC was also underwriter of $4,490,000 face value Isolagen Convertible Notes or 490,308 shares of Isolagen common stock issuable upon their conversion. The stock or notes were registered pursuant to the Convertible Notes Registration Statement (defined below), which was declared effective May 2, 2005. The Convertible Notes Registration Statement explicitly stated: "[CIBC] is a broker-dealer, and is deemed to be an underwriter within the meaning of Section 2(11) of the Securities Act."

58. **Legg Mason Wood Walker, Inc.** Defendant Legg Mason Wood Walker, Inc. ("Legg Mason") was an investment bank with headquarters in Baltimore, Maryland. At the time the Secondary Registration Statement became effective, Legg Mason provided services that included securities underwriting, brokerage, investment advisory services, and equity research services. Legg Mason was co-lead manager of Isolagen's Secondary Offering and it sold and distributed 2,817,500 shares of Isolagen common stock, including 367,500 shares allocated in an over-allotment option, to the investing public pursuant to the Registration Statement and Prospectus filed with the SEC in connection with the Secondary Offering.

59. As part of its duties as an underwriter, Legg Mason was required to conduct, prior to the Secondary Offering, a due diligence investigation of the Company. Legg Mason was paid approximately $1.4 million in fees for its underwriting services in connection with the Secondary Offering. During the Class Period, Legg Mason provided equity research coverage of Isolagen shares in which it gave Isolagen a "Buy" rating, and advised that they should reach a price of $13 per share within 12 – 18 months.

60. **Legg Mason, Inc.** Defendant Legg Mason, Inc. (also "Legg Mason") is a financial services holding corporation with headquarters in Baltimore, Maryland. Legg Mason, Inc. owned Legg Mason Wood Walker, Inc. at the time of the Secondary Offering.

61. **Citigroup Inc.** Defendant Citigroup Inc. (also "Legg Mason") is a global financial services corporation with headquarters in New York City, New York. Citigroup Inc. acquired Legg Mason Wood Walker, Inc. from Legg Mason, Inc. on December 1, 2005.

62. **Stifel Financial Corp.** Defendant Stifel Financial Corp. (also "Legg Mason") is a financial services holding corporation with headquarters in St. Louis, Missouri. Stifel Financial Corp. acquired Legg Mason Capital Markets, the Investment Banking, Equity and Fixed Income Research, Equity Sales and Trading, and Taxable Fixed Income Sales and Trading Departments of Legg Mason Wood Walker, Inc. from Citigroup Inc. on December 1, 2005.

63. As noted in ¶¶ 58 to 62, defendants Legg Mason Wood Walker, Inc., Legg Mason, Inc., Citigroup Inc, and Stifel Financial Corp. are collectively referred to herein as "Legg Mason."

64. **Canaccord, Adams, Inc.** Defendant Canaccord Adams, Inc. (formerly known as and referred to herein as "Adams Harkness") is an international investment bank with headquarters in Vancouver, British Columbia and offices in Boston, Massachusetts. Adams Harkness formerly conducted business under the names Adams Harkness, Inc., and Adams, Harkness & Hill, Inc., at which time it maintained its headquarters in Boston, Massachusetts. At the time the Secondary Registration Statement became effective, Adams Harkness provided services that included securities underwriting, brokerage, investment advisory services, and equity research services. Adams Harkness was co-manager of Isolagen's Secondary Offering and it sold and distributed 1,207,500 shares of Isolagen common stock, including 157,500 shares

allocated in an over-allotment option, to the investing public pursuant to the Secondary Registration Statement.

65. As part of its duties as an underwriter, Adams Harkness was required to conduct, prior to the Secondary Offering, a due diligence investigation of the Company. Adams Harkness was paid approximately $616,000 in fees for its underwriting services in connection with the Secondary Offering. During the Class Period, Adams Harkness also provided equity research coverage of Isolagen shares in which it recommended the shares as "Strong Buy" and "Best Pick" and advised that they should reach a price of $14 per share within 12 months.

66. **UBS Securities LLC.** Defendant UBS Securities LLC. ("UBS") is the United States affiliate of UBS AG, a Swiss Corporation with headquarters in London and New York offering investment banking services. UBS has United States headquarters in Stamford, Connecticut.

67. UBS was underwriter of $1,930,000 face value Isolagen Convertible Notes or 210,756 shares of Isolagen common stock issuable upon their conversion. The stock or notes were registered pursuant to the Convertible Notes Registration Statement which was declared effective May 2, 2005. Concerning UBS, the Convertible Notes Registration Statement explicitly stated: "[UBS] is a broker-dealer, and is deemed to be an underwriter within the meaning of Section 2(11) of the Securities Act."

68. Defendants CIBC, Legg Mason, and Adams Harkness are collectively referred to herein as the "Secondary Offering Underwriter Defendants."

69. Defendants CIBC and UBS are collectively referred to herein as the "Convertible Notes Underwriter Defendants"

IV. CLASS ACTION ALLEGATIONS

70. Lead Plaintiffs bring this action on behalf of themselves and as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities (the "Class") who purchased or otherwise acquired Isolagen common stock or convertible debt securities during the period from March 3, 2004 to August 9, 2005, inclusive, including but not limited to purchasers of Isolagen common stock on the open market and/or in the Company's Secondary Offering pursuant to the Secondary Registration Statement, and/or the sale of Isolagen common stock or convertible debt securities pursuant to the Convertible Notes Registration Statement and who sustained a loss as result of said acquisition(s).

71. Excluded from the Class are (i) the Defendants; (ii) members of the family of each individual Defendant; (iii) any person who was an officer or director of Isolagen during the Class Period; (iv) any person who was an employee of any Underwriter Defendant during the Class Period; (v) any firm, trust, corporation, officer, or other entity in which any Defendant has or had a controlling interest; and (vi) the legal representatives, agents, affiliates, heirs, successors-in-interest of assigns of any such excluded party.

72. The Class is so numerous that joinder of all Class members is impracticable. Isolagen common stock was actively traded on the AMEX, an efficient market, throughout the Class Period. While the exact number of Class members can only be determined by appropriate discovery, Lead Plaintiffs believe that Class members number in the thousands. Throughout the Class Period, there were over 30.2 million shares of Isolagen common stock issued and outstanding. Approximately 8.05 million shares of Isolagen common stock were issued pursuant to the Company's Secondary Offering. Approximately $90 million face value of convertible debt securities were, pursuant to the Convertible Notes Registration Statement, issued and outstanding during the Class Period and were convertible into shares of common stock. Based

on the volume of trading of Isolagen securities during the Class Period, it is believed that hundreds, if not thousands, of investors purchased Isolagen common stock on the open market and in the Secondary Offering, as well as its convertible debt securities during the Class Period, rendering joinder of all such purchasers impracticable.

73. Lead Plaintiffs' claims are typical of the claims of the members of the Class. Lead Plaintiffs and all Class members sustained damages as a result of the wrongful conduct complained of herein.

74. Lead Plaintiffs will fairly and adequately protect the interests of the Class members and has retained counsel competent and experienced in class action and securities litigation. Lead Plaintiffs have no interests that are contrary to or in conflict with those of the Class members that Lead Plaintiffs represent.

75. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for the Class members individually to seek redress for the wrongful conduct alleged herein.

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

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

(ii) whether documents including the registration statements, prospectuses, SEC filings, press releases and public statements

made by defendants during the Class Period contained misstatements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(iii) whether defendants acted with the requisite state of mind in omitting and/or misrepresenting material facts in the documents filed with the SEC, press releases and public statements during the Class Period;

(iv) whether the market price of Isolagen's common stock and convertible debt securities during the Class Period were artificially inflated due to the material misrepresentations and omissions complained of herein; and

(v) whether the Class members have sustained damages and, if so, the appropriate measure thereof.

77. Lead Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

78. The names and addresses of the record owners of Isolagen common stock or convertible debt securities purchased during the Class Period in the Secondary Offering, Private Placement, and in the open market are obtainable from information in the possession of the Company's transfer agent(s) and the Underwriter Defendants. Notice can be provided to the record owners of Isolagen common stock and convertible debt securities via first class mail using techniques and form of notice similar to those customarily used in securities class actions.

V. FACTUAL ALLEGATIONS PERTINENT TO CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

A. BACKGROUND

1. The Early Marketing of the "Isolagen Process"

79. In the early 1990's, Defendant Olga Marko began investigating the possibility of using a patient's own cells to produce collagen, the protein responsible for skin strength and elasticity. Marko's research eventually developed into the Isolagen Process.

80. The Isolagen Process is a cosmetic treatment in which a patient's own collagen-producing cells (known as "dermal fibroblasts") are, according to the Company, used to reduce the normal effects of aging on the skin, such as wrinkles. The Isolagen Process involves the following steps. A biopsy is used to obtain a small piece of skin tissue – usually taken from behind a patient's ear. The skin sample is then packed in a container and sent to a laboratory where the collagen-producing cells are cultured using what Isolagen refers to as its generic "Autologous Cellular System" or, more commonly, its "ACS" process. The ACS process separates the collagen-producing fibroblast cells from the rest of the skin tissue and then stimulates these cells to multiply into tens of millions of new cells. After approximately six weeks, the cultured fibroblasts are sent back to the doctor for injection into the patient's wrinkles, lines, and/or scars. According to the Company's public filings at the beginning of the Class Period and its website throughout the Class Period, three sets of injections should be performed, about two weeks apart, with tens of millions of collagen-producing cells being injected during each visit.

81. In 1995, Defendant Marko, with the support of Defendant Boss, founded Isolagen Technologies and began marketing the Isolagen Process in the United States. Initially, Isolagen marketed its product without approval from the FDA, taking the position that such approval was

not necessary because the Process involved the implantation of a patient's own skin cells, and the FDA had not determined the Process to be unsafe.

82. In 1999, however, the FDA demanded that Isolagen provide clinical evidence of the safety and efficacy of the Isolagen Process, and prohibited the Company from marketing it in the United States without FDA approval. Isolagen's response to the FDA's prohibition was to begin marketing the Process in the United Kingdom – a market known to have lower regulatory hurdles. Throughout the Class Period, defendants publicly touted the fact that the Company had been successfully marketing the Process in the United Kingdom since 2002, and the results there had been uniformly positive. These statements conveyed to the investing public the notion that they could and should rely on Isolagen's positive experience in the United Kingdom in evaluating the Company's ability to succeed with FDA approval, and commercialization in the United States.

2. The FDA Regulatory Process for Biotechnology Products

83. In 2003, Isolagen began the process of seeking FDA approval to resume marketing the Process in the United States. Generally, a company must establish that its product is safe and effective in order to gain FDA approval. This is accomplished through pre-clinical testing, followed by a series of human clinical trials, which are rolled out in three general "phases." In "Phase I," the product is tested in a small number of people (under 100) to see how well the product is tolerated and determine the correct dosage to be administered.

84. Once a product is found to be well-tolerated, it is tested in "Phase II" for effectiveness in a small number of patients. During Phase II, between 100 and 300 people are tested to see if the product actually works, and to determine its short-term effects.

85. Finally, "Phase III" trials involve a large-scale study of the effectiveness of the product, involving between 1000-3000 patients. Aside from testing the product's viability, a

company must also determine during this third phase whether the product can be manufactured and distributed on a large scale.

86. If, after the pivotal Phase III trials, the product proves to be both safe and effective, a company seeking approval of a biotechnology-derived product (such as the Isolagen Process) must file what is known as a "Biological License Application" or "BLA." BLA's are typically at least 100,000 pages long and require a great deal of organization and structure. The FDA reviews the BLA and determines whether to approve the product for marketing and sale in the United States.

87. The FDA's review of a BLA is characteristically quite rigorous. The reviewers evaluate not only the clinical trial results, but also whether the studies were "adequate and well-controlled," 21 C.F.R. § 314.126, and whether the data are complete, accurate and unbiased. Without solid clinical data developed under carefully controlled conditions, the data gathered in clinical trials will not meet the FDA's "adequate and well-controlled" criteria for acceptable clinical trials.

88. Thus, in its effort to gain FDA approval, Isolagen faced two significant hurdles in demonstrating the efficacy of the Isolagen Process: (i) the development of an effective and efficient method of manufacturing, transporting, storing and distributing patients' cellular material on a wide-scale basis; and (ii) instructing and training physicians in the proper method for injecting the treated cellular material back into the patients so that there would be uniformity in the administration and results of the Process.

3. Isolagen Reports Steady Progress and Positive Results Through Its Clinical Trials and In the United Kingdom

89. In early 2003, Isolagen commenced clinical trials of the Isolagen Process for the treatment of wrinkles and scars, and for the treatment of periodontal disease in the United States.

In a pre-Class Period press release dated April 15, 2003, the Company reported that it had met with representatives of the FDA and "defined the regulatory FDA roadmap to license approval." The Company also announced that it would begin the "pivotal" Phase III trial to prepare for its BLA filing. Dr. Vaughn Clift, Isolagen's Vice-President of Operations, explained clearly the importance of regulatory approval in the United States and set the tone for what the United States market could expect based on the Company's purportedly positive experience in the United Kingdom:

> We anticipate starting our pivotal trial on or before May 15, 2003. We are very pleased with our progress to date with not only the scientific improvements in our process, but, as important, the clinical results we are experiencing with our commercial patients in the United Kingdom. Clearly, the United States market is a critical market for Isolagen, and once approved, we look forward to achieving success and market acceptance domestically, adding to our growing acceptance overseas.

The Company's Phase III trial actually began on or around July 29, 2003.

90. In a press release dated November 20, 2003, the Company again touted its allegedly positive results in the United Kingdom as an indicator of future approval in the United States. According to Isolagen, data collected from 59 of the 400 patients treated in the United Kingdom demonstrated a 73% positive response rate just two months after treatment with the Isolagen Process and a 100% positive response rate six months after treatment with the Isolagen Process. The Company reported in this press release that "[t]his data will be part of a submission package that will be presented to the … [FDA] for a trial design discussion in December of this year."

91. Beyond pointing to its commercial results in the United Kingdom with respect to the efficacy of the Isolagen Process, Isolagen also made clear that based on the technology it had developed in the United Kingdom, the Company would be able to mass produce the Process in

the United States. In a press release dated June 10, 2003, the Company announced the "full commercialization phase" of its European production facility, and on December 16, 2003, reported that it had developed a new cell culturing system that would "result in significant cost reduction and allow the Company to move toward a platform that enables mass production." The development of these facilities would allow the Company to "scale production efficiently as [it] complete[d] the transition from a research and development entity to an earnings-focused company."

4. As More Clients Receive Isolagen Treatments, Results in the United Kingdom Fail To Live Up to the Company's Early Promises

92. While the Company reported in mid-2003 that patients treated in an important independent study in the United Kingdom had obtained 100% positive results, Lead Plaintiffs' investigation has revealed that, as time went on and more patients underwent the Isolagen Process, beginning in early 2004, physicians in the United Kingdom increasingly reported to Isolagen's management that the results obtained were far from uniformly positive. Most significantly, it became clear that the results for patients aged 45 and older were "appalling," according to one prominent London physician who was among the first doctors to start treating patients using the Isolagen Process and who had, by 2004, treated more than 50 patients (herein referred to as "Confidential Witness #2" or "CW#2"). Indeed, according to CW#2, for patients aged 45 and older, approximately 80% showed no improvement at all -- even after taking multiple injections over the course of a year or more. When this physician would convey these complaints to Company officials, Isolagen would attempt to placate the patients by offering them a free treatment.

93. As 2004 wore on, this problem was exacerbated, as the Company desperately changed treatment protocols in an attempt to obtain positive results. Whereas the Company

represented in public filings that its standard Process called for a total of three injections over the course of four to six weeks, in mid-2004, it abruptly announced to its practitioners in the United Kingdom that the Process should now include two injections, but with more cells injected. Ultimately, that new protocol also did not work, and the Company changed tack again, instructing its practitioners to return to three injections.

94. Lead Plaintiffs' investigation has further revealed that, in mid-2004, two Isolagen officials – Individual Defendant Avignon and a public relations officer from the Company's United States operations – visited Confidential Witness #1 to discuss training issues. CW#1 treated 20 new patients a month in his office in London and had been asked to re-inject numerous patients of other practitioners who had reported poor results. When Avignon and the other official observed CW#1's technique, they realized that it was radically different from the techniques they had observed in the United States. CW#1 asked whether, in light of the upcoming FDA trials, the Company had in place a standardized injection technique that it was teaching the practitioners who would be conducting the trials. Without such a standardized technique, CW#1 said, the Company's trials would not be successful. As a result of this meeting, Isolagen asked CW#1 to come to New York in September 2004 to train doctors in the United States on the technique prior to the commencement of the FDA trials. Subsequently, however, at Defendant's Bitterman's instruction, that training was cancelled.

95. Beyond CW#1's and CW#2's many communications with Isolagen representatives regarding the lack of response among many patients, scientists who worked for Isolagen in the United States -- including at least one very senior executive -- reported that they, too, were aware during the Class Period of inconsistencies between what the Company was reporting concerning its clinical experience in the United Kingdom and the reality. Among other things, those

scientists were aware that in the United Kingdom, there were patients receiving more than the usual number of injections -- *i.e.*, "more than our normal schedule would be and more than we were testing for in the clinical trials"; and that throughout the Class Period, demand for treatment was slackening in the United Kingdom, not growing as reported by the Company.

96. In addition, confidential informants who worked for Isolagen on the compilation and submission of the BLA have also reported that "in preparing for the BLA, there were certain things that needed to be done, that weren't done," and that the Company had no confidence internally that given the amount of paperwork to "push through to get to the FDA," that it would get the BLA submission ready in time to be filed according to the schedule. According to these informants, the Company was skipping steps and not properly documenting items so as to comply with the strict FDA guidelines for submission.

5. Defendants Tout the Company's Phase III Results As a Precursor to the 2004 Secondary Offering

97. On March 3, 2004, the start of the Class Period, the Company officially ushered in the final step to FDA approval, and eventual marketing of the Isolagen Process in the United States, when it announced positive results from its Initial Phase III study. According to a press release published at the time, the Company stated "the results indicate statistically that the therapy is both safe and effective." Again, Medical Director Vaughn Clift pointed to results from the United Kingdom as evidence that the results would get better with time:

> We have already published some of our international experience showing improvements with the Isolagen Process are better at six (6) months and even greater at twelve (12) months, leading us to believe that the strong results in this clinical trial represent early results which are likely to continue to improve over the next six months.

Defendant Macaluso added: "The results from the trial position us well to move into the final phase of our clinical development process." The press release concluded that the Company

anticipated that the Isolagen Process could be available in the United States as early as 2005.

98. As a result of this positive news, the price of Isolagen stock rose steadily from $8.60 per share on March 2, 2004, to a Class Period high of $12.04 per share on April 2, 2004.

6. The Secondary Offering

99. In April 2004, bolstered by its reported success in the March 2004 Phase III clinical trials, the Company announced a proposed public offering of 7,000,000 shares of common stock (the "Secondary Offering"). The Secondary Offering was conducted pursuant to the Secondary Registration Statement.

100. The Secondary Registration Statement was signed by Officer Defendants Tomz, Macaluso, and DeLape, and Director Defendants Toh, De Martino, Morrell, and Webb.

101. The Secondary Offering was underwritten by Defendants CIBC, Legg Mason and Adams Harkness. Beginning on June 10, 2004, Defendants CIBC, Legg Mason and Adams Harkness sold stock in this offering pursuant to the Secondary Registration Statement. The offering was priced on June 10, 2004, at $8.50 per share. The Company and Individual Defendants DeLape, Marko, Tomz and Boss also granted Defendants CIBC, Legg Mason and Adams Harkness an over-allotment option to purchase an additional 200,000 and 850,000 shares of common stock, respectively, at the same price per share as the public offering price, less an underwriting discount of $0.51 per share.

102. As detailed below in ¶¶ 131 to 141, the Secondary Registration Statement represented, among other things, that (i) the Isolagen Process could successfully reduce the appearance of facial wrinkles across all age groups; (ii) the Isolagen Process could be profitably marketed to a target group consisting of baby boomers aged 39 to 58; and (iii) the Company would imminently introduce technology it had developed to automate its costly manufacturing operations and thereby make the Isolagen Process commercially viable. Further, the Secondary

Registration Statement explicitly incorporated by reference, among other things, the Company's Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 10-K/A"), filed on April 27, 2004, which contained similar material misstatements and/or omissions as set forth below at ¶¶ 142-50.

103. The Secondary Offering was completed on June 10, 2004. The Company sold 7.2 million shares of common stock, including 200,000 shares in an over-allotment option, for gross proceeds of $61,200,000. In addition, on June 15, 2004, Defendants DeLape, Boss, Marko and Tomz personally sold stock in the over-allotment as follows:

Selling Shareholder	**Shares Sold**	**Gross Proceeds**
DeLape	293,270	$2,492,795
Boss	304,885	$2,591,523
Marko	227,258	$1,931,693
Tomz	24,587	$208,990

104. Within weeks of the Secondary Offering, each of the Underwriter Defendants initiated coverage on Isolagen common stock with a "buy" or "strong buy" rating: Adams, Harkness & Hill with a report dated June 21, 2004 ("Strong Buy: Underfollowed story in attractive growth market"); Legg Mason with a report dated June 21, 2004 ("Buy" rating); and CIBC World Markets with a report dated June 21, 2004 ("'Sector Outperformer' Rating: The Face You Save May Be Your Own -- Initiating With SO Rating").

105. In their June 2004 reports, the analysts highlighted the success the Company had reported in Europe and in its earlier trials, as well as its belief that utilizing an automated process, it would soon break even with $16-20 million in annual sales. For instance, CIBC reported that "[t]he company has already published the results of a successful Phase III trial in treating wrinkles and acne scars that showed that 77% of patients saw a two plus point improvement in their photoguide score at four-month follow-up versus baseline." Adams

Harkness similarly noted that "[e]arly clinical data appears compelling" and that "Isolagen should implement its ACE manufacturing system in the UK later this summer...with which the company believes it will bring costs down to $500 per patient." Finally, Legg Mason also identified Isolagen as a potentially "significant market opportunity" in view of the "encouraging initial response" in the United Kingdom, and noted that the Company was developing its ACE system, which it described as "necessary" to meet consumer demand.

7. The Company Continues to Report Positive Results in Its Early Clinical Trials

106. In the months after the Secondary Offering, defendants continued to report positive developments on the FDA regulatory front. In press releases dated May 23, 2004 and July 21, 2004, the Company touted its receipt of what is called a "Special Protocol Assessment" or "SPA," pursuant to which, according to the Company, the FDA had agreed to the design of the Phase III trials. The release stated that the SPA "significantly lowers the risk to the [C]ompany" in the approval process and "the successful completion of clinical studies covered by an SPA typically results in a license/approval being granted." In the July 21 release, Defendant Macaluso concluded: "The start of the Phase III Pivotal Trials in July 2004 should allow Isolagen to file for our Biological License Application ("BLA") as early as the first quarter of 2005."

107. Similarly, on July 28, 2004, the Company issued a press release stating that the six month marker data from Isolagen's initial Phase III study indicated a positive response of 82% of the Isolagen treated patients.

108. Again, the analysts following the Company were impressed by both the pace and results of Isolagen's trials. Legg Mason reported that Isolagen's announcement on July 21 that it had commenced its Phase III trials was "in line with expectations and should allow for filing of

the [BLA] in 1Q05 as planned" and that "capacity expansion" also "appears on track." Adams Harkness pointed to the Company's entry into its pivotal Phase III trial as the "first of many positive announcements over the next few months" Finally, based on conversations with Isolagen management, CIBC pointed to Isolagen as its "favorite small-cap pick" in its July 7, 2004 report.

109. On August 5, 2004, the Company announced its results for the Second Quarter of 2004, which came in ahead of analysts' expectations, and on August 12, 2004, Isolagen filed its Form 10-Q for the quarter ending June 30, 2004 ("Second Quarter 2004 10-Q"), which, as set forth below, reiterated the positive results the Company had obtained to date in connection with its Phase III trials, and confirmed that Isolagen still expected to file its BLA in the first quarter of 2005. According to Adams Harkness' August 13 report, "U.S. pivotal Phase III trials for dermal indication are near completely enrolled and are on track for a 1Q '05 BLA filing." In its August 13 report, Legg Mason stated that the "U.K. experience remains encouraging" and that "capacity expansion appears on track."

110. After a September 10, 2004 conference call with investors to introduce Isolagen's new Chief Executive Officer, Defendant Robert Bitterman, Adams Harkness reported that "the ACE system is currently being tested in London and should be fully implemented in early '05" which will "lead to significant productivity gains." The report concluded: "Given the strong demand and positive feedback in London, the expected BLA filing in the U.S. in 1Q05, and the product's large market potential, we reiterate our Strong Buy rating."

111. On October 20, 2004, another Company press release announced "further developments" in its "global strategy to commercialize the Isolagen Process." According to the October release, the Company's BLA submission would include "regulatory documentation to

support the implementation of its Automated Cellular Expansion ("ACE") system" as well as "additional data to demonstrate comparability of the ACE process to the existing manual system used in the clinical studies."

8. The Convertible Notes Offering

112. On October 25, 2004, the Company announced that it had entered into an agreement to sell to initial purchasers CIBC, UBS Securities LLC ("UBS"), and Adams Harkness, $75 million in principal amount of 3.5% Convertible Subordinated Notes due November 1, 2024 ("Convertible Notes") and the option to purchase $15 million in additional notes carrying the same terms (the "Notes Offering"). The Company said it intended to use: (i) $39 million of the net proceeds for working capital, capital expenditures and general corporate purposes; and (ii) $32 million of the proceeds to purchase up to two million shares of common stock in "privately negotiated transactions" concurrent with the offering, and up to two million shares of its common stock from "certain insiders, affiliates and founders of Isolagen."

113. In connection with the Notes Offering, the Company filed with the SEC an Offering Memorandum, dated October 28, 2004. As detailed below, the Offering Memorandum represented, among other things, that (i) the Isolagen Process could successfully reduce the appearance of facial wrinkles across all age groups; (ii) the Isolagen Process could be profitably marketed to a target group consisting of "baby boomers" aged 40 to 58; and (iii) the Company would, prior to the filing of the BLA, implement technology to reduce its variable costs and increase capacity in order to make the Isolagen Process commercially viable.

114. On November 3, 2004, the Company completed the private placement of $75 million aggregate principal amount of Convertible Notes. Isolagen received net proceeds of approximately $71.7 million, and granted purchasers of the Notes the option to purchase up to $15 million of additional Notes through December 2, 2004.

115. On November 5, 2004, the Company completed the private placement of the additional $15 million aggregate principal amount of Convertible Notes. Isolagen received net proceeds of approximately $14.5 million. Thus, the total net proceeds to the Company were approximately $86.2 million.

116. Isolagen used approximately $26 million of the net proceeds from the Notes Offering to repurchase four million shares of Isolagen stock, two million shares of which were sold by Individual Defendants DeLape, Macaluso, Marko and Avignon and shareholder Timothy J. Till (*i.e.*, at 400,000 shares each). The remaining two million shares were repurchased in "privately negotiated transactions" with unnamed sellers. The repurchase price from the named sellers was $6.33 per share, meaning that the Individual Defendants DeLape, Macaluso, Marko, Avignon, received more than $2.5 million each. The price paid in the "privately negotiated transactions" was $6.66 per share, the closing market price on October 28, 2005.

117. As noted by the Legg Mason analyst following the Company, while the convertible note offering was potentially dilutive, "the company was in a tough position," as it "appear[ed] as if certain insiders, affiliates, and founders of Isolagen, who have grown the company and have a significant amount of their wealth tied up in Isolagen stock, wanted to realize some of their gains."

9. The Company Moves Back Its Filing of the BLA

118. In its Form 10-Q for the third quarter of 2004, filed on November 8, 2004, Isolagen announced that it would now be filing its BLA for dermal application in the second half of 2005. The Company held a conference call that day and Defendant Bitterman spoke at a CIBC conference the next day to discuss current development and commercialization of the Isolagen Process. Based on those discussions, Legg Mason attributed the delay in the BLA filing to the Company's reported decision to include documentation from implementation of its ACE

system into its BLA to be filed with the FDA. Legg Mason reported that the Company was nearing completion of the injection phase of its Phase III trials and that the ACE system should be on-line in the United Kingdom by mid-2005. The report further noted that in the United States, the timing of the implementation of the ACE system was "also critical" because the "process needs to be online in order for the bridging studies to be completed in time for the BLA filing." According to the Adams Harkness analyst, the Company was making "a few adjustments to the [ACE] process but remains confident in the potential efficiencies."

10. The Convertible Notes Offering

119. On February 1, 2005, Isolagen filed with the SEC the Convertible Notes Registration Statement, which, as set out more fully below, contained numerous material misstatements and omissions.

120. In a press release issued on February 18, 2005 entitled "Isolagen Process Exploratory Phase III 12-Month Data Positive," Isolagen presented six-month data and new twelve-month follow-up data from the Company's "exploratory" clinical trial. Defendant Bitterman stated, "These findings, showing continued effect over 12 months, are consistent with our ongoing European experience that indicates a sustained response."

11. Isolagen "Unveils" the ACE System to the Public

121. On April 25, 2005, the Company announced that Defendant Bitterman was resigning as Chief Executive Officer. In that same press release, Isolagen said that it would report on the status of ACE at the 2005 UBS Global Health Pharmaceuticals Conference in May. In its April 26, 2005 report, Adams Harkness stated while it was disappointed with Defendant Bitterman's departure, it looked forward to the unveiling of the ACE process in May and had "heard that this progress has been significant." According to Defendant DeLape, Defendant Bitterman resigned because of "philosophical differences about the way that the company should

be run." The Company's Board apparently felt that Mr. Bitterman "did not embrace the automated cell expansion (ACE) system because key elements of it were developed by outside consultants Fairway Medical and IBC." Adams Harkness later reported that while its patience was "wearing thin," Isolagen's management had promised that the Company's new Swiss facility should be implementing the ACE system in 2006, and have capacity for "40-60k patients a year."

122. On May 23, 2005, the Company publicly "unveiled" its ACE system at the UBS Global Pharmaceuticals Conference in New York. Defendant DeLape first introduced the Company's design for the system and, in a "special session" following Mr. DeLape's presentation, Isolagen "unveiled" its ACE system with an on-site presentation and demonstration of the technology. In a press release issued the same day, beyond announcing the "unveiling" of the system, the Company also reiterated that it would be introducing ACE technology in the United Kingdom in 2006.

12. <u>The Truth Is Finally Revealed</u>

123. On August 1, 2005, before the market opened, Isolagen revealed in a press release that the preliminary results from its Phase III clinical trial evaluating the safety and efficacy of the Isolagen Process for the treatment of facial wrinkles showed that the trial had failed to meet its primary end points. Moreover, the results from one of the two studies failed to demonstrate any statistical significance at all, and "wide variance in results was reported from site to site," with response rates ranging to as low as 7.6%. The Company conceded that the inconsistent results from the trials would prevent the Company from filing its BLA -- thus delaying FDA approval of the Isolagen Process by at least a year. Dr. Marie Lindner, the recently hired Senior Vice President of Medical and Business Affairs of Isolagen, explained that when the Company

resumed its clinical trials, "only physicians trained in the proper Isolagen injection technique will participate as investigators in this trial."

124. In reaction to this news, the price of Isolagen stock fell $2.75 from its closing price of $5.59 per share on July 31, 205, to below $2.84 on August 1, 2005, on unusually high volume – a single-day drop of 45%. The price of Isolagen convertible notes similarly fell from $75 per 1,000 face value notes to $60 – a 25% decline.

125. On August 9, 2005, the Company conducted a conference call to discuss its second quarter 2005 results and the results from the pivotal Phase III clinical trials. During the call, Martin E. Schmieg, Isolagen's then-recently appointed Chief Financial Officer and Senior Vice President, explained that:

> [T]he Phase III trial protocol is under development as we speak and may include a certification process for all the participating clinicians, tighter criteria for study participants, an expanded measurement scale, improved photography for documentation and measurement purposes, implementation of a quality control system throughout the trial with the ability to alter or augment the trial during the study.

126. On that same conference call, Isolagen also revealed that in addition to revamping its clinical trial protocol, it would also be undergoing a substantial "transition period" with respect to upgrading its manufacturing capabilities. The Company lowered its calendar-year revenue guidance to $10-15 million from $15 million due, in large part, to the "limited capacity" of its United Kingdom facility "(moving from a flask system to a cell factoring process)," and because of "discounting efforts" in England. Isolagen also announced a further delay in the delivery of the ACE prototypes until sometime in the first half of 2006.

127. In reaction to this news, the price of Isolagen stock fell a further 10% from its closing price on August 8, 2005, to $2.66 on August 9, 2005 on unusually high volume. Similarly, the price of Isolagen convertible notes fell from $60 per $1,000 face value notes to

$57.50. As articulated by a UBS analyst: [W]e view the conflicting messages about the current market trends in the UK as confusing. With the discussion surrounding both the discounting efforts and potential capacity issues in the UK, it remains unclear to us whether the issue is a demand one or a supply one."

128. A lawsuit recently filed in state court in Texas reveals just how far away from being operational ACE really was throughout the Class Period. In *International Biophysics Corporation v. Isolagen Technologies, Inc.*, Civ. No. 1:06-cv-00371-SS (Travis County Court), International Biophysics Corporation ("IBC"), one of the two companies contracted by Isolagen to design the ACE system, sued the Company for non-payment under their contract. According to IBC, Isolagen "fraudulently misrepresented its success in growing adequate clinical yields of human fibroblast cells," and thereby fraudulently induced IBC into entering into a contract to "design, at the direction of Isolagen, a growth apparatus for the automation of Isolagen's Process based on its assurances that it would be able to grow cells in adequate clinical yields...under laboratory conditions." Remarkably, it turned out, Isolagen did not even enter into the contract with IBC to design the ACE system until July 20, 2005 -- nearly three months after the ACE system was publicly "unveiled" at the UBS Conference in May. In its Answer and Counterclaims, Isolagen alleged that IBC had breached its contract with the Company by failing to ever "deliver a functional design of [the] automated cell growth technology called for under [the] contract with Isolagen."

B. FALSE AND MISLEADING STATEMENTS

1. The March 2004 Press Release

129. On March 3, 2004, the Company issued a press release entitled "Isolagen Announces Positive Results in Phase III Study; Emerging Science Utilizes Patient's Own Cells

to Treat Facial Wrinkles/Scars" (the "March 2004 Press Release"). The March 2004 Press Release stated, in relevant part:

> Isolagen, Inc. (AMEX: ILE), a specialty pharmaceutical company specializing in the development and commercialization of autologous (a patient's own) cellular therapy for hard and soft tissue regeneration ("the Isolagen Process"), today announced that the initial portion of its Phase III study is complete and the results indicate statistically that the therapy is both safe and effective. Early results show an efficacy of 77% with the Isolagen treated group as compared to a 36% response with the placebo-controlled group at this early time point. The Fisher's Exact Test p-value < 0.0001 confirms the statistical significance.
>
> * * *
>
> "For this trial, we elected to examine the results at four (4) months for comparison to other injectable treatments used for wrinkles and scars and we are very pleased with the data," said Vaughan Clift, MD., Medical Director. "We have already published some of our international experience showing improvements with the Isolagen Process are better at six (6) months and even greater at twelve (12) months, leading us to believe that the strong results in this clinical trial represent early results which are likely to continue to improve over the next six months."
>
> We are very pleased with these results since we believe they strongly support the efficacy of the Isolagen Process," said Michael Macaluso, CEO and President. "The results from the trial position us well to move into the final phase of our clinical development process."

130. The statements in ¶ 129 concerning a statistical significance demonstrated by the "initial portion" of the Company's Phase III study were false and misleading because they misrepresented to investors that the Isolagen Process could be used to successfully and uniformly treat patients, and that the Company's "international experience" showed increasing improvement over time. Lead Plaintiffs' investigation has revealed that at the time these statements were made, physicians treating literally hundreds of patients had informed senior executives and persons in control of the Company that the Process failed to produce an

objectively measurable and uniform improvement in the appearance of facial wrinkles in patients.

2. The Secondary Registration Statement

131. The Secondary Registration Statement (including the Prospectus dated June 10, 2004) included numerous untrue statements and omissions of material fact.

132. Concerning the Company's clinical experience and ability to submit an application for FDA approval, the Secondary Registration Statement stated that:

> ... Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition...
>
> * * *
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. We are planning to initiate two pivotal Phase III clinical trials for this product candidate during the third quarter of 2004. We expect to file a Biologics License Application for this product candidate during the first quarter of 2005.... [Emphasis added].

(Reg. St at 1; Prospectus at 1).

133. The statements in ¶ 132 concerning the efficacy of the Isolagen Process were false and misleading because they omitted mention of material facts, including that, as revealed by Lead Plaintiffs' investigation, the Company's prior studies of the Process and anecdotal evidence presented to the Company and its controlling principals by physicians who actually treated patients with the Isolagen Process demonstrated that: (i) the Process frequently failed to demonstrate any objectively measurable improvement in facial wrinkles, scars, or other facial deformities; and (ii) that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

134. In addition, the statement in ¶ 132 concerning the Company's plan to file a BLA in the first quarter of 2005 was false and misleading because the Company and its controlling principals knew that the Company lacked a protocol for a consistent and proper injection technique, and because the Isolagen Process was resulting in highly inconsistent results in clinics in the United Kingdom.

135. Furthermore, the statement in ¶ 132 concerning the Company's plan to file a BLA in the first quarter of 2005 was false and misleading because, even if the Company was able to demonstrate statistically significant results from its Pivotal Phase III clinical trials, members of the Company's administrative staff had reported to senior executives that (i) the administrative staff was incapable of completing the paperwork within this timeline and (ii) the research staff had not begun to perform certain analyses required by the FDA to characterize the injectable cells to be injected that would be required for the filing.

136. Concerning the Company's target market, the Secondary Registration Statement also stated:

> ***Our Target Market Opportunity***
>
> Our first two product candidates are directed at the aesthetic and dental markets.
>
> * * *
>
> *Aesthetic Market.* According to the American Society for Aesthetic Plastic Surgery, more than 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:

> • aging of the "baby boomer" population, currently ages 39 to 57, representing over 27% of the U.S. population...

(Reg. St. at 1; Prospectus at 1).

137. The statements in ¶ 136 concerning the Company's target market were false and misleading when made because they omitted mention of material facts, including that, as revealed by Lead Plaintiffs' investigation, numerous physician reports to senior executives and controlling persons of the Company had indicated that most or all of the targeted "baby boomer" market had not consistently obtained any objectively measurable improvement in facial wrinkles, scars, or other facial deformities through use of the Isolagen Process.

138. Concerning the Company's planned automated manufacturing (ACE) system, the Secondary Registration Statement stated, in relevant part:

> We are in the final stages of developing our new Automated Cell Expansion, or ACE, System. We believe our ACE System will yield significant improvements in the manufacturing process and reduce costs... We currently expect to introduce the ACE System for new patients in our United Kingdom facility in the fourth quarter of 2004.
>
> We have been collaborating with Applikon Biotechnology to patent the manufacturing system improvements beyond Applikon Biotechnology's existing patents. Our ACE System has been successful in the research setting, and we are now undertaking the design fabrication and qualification of the mass-produced single-use, disposable component...

(Reg. St. at 25; Prospectus at 25).

139. The statements in ¶ 138 concerning the 2004 introduction of the ACE system for patients in the United Kingdom were false and misleading because the Company's system to grow and separate cells was in fact not in the final stages of development. It was not until May 2005 that Isolagen exhibited even a cosmetic mock-up of the proposed ACE system, at which time Isolagen claimed it would install prototypes in its Switzerland facilities in December 2005.

As set forth above, on April 6, 2006, one of the two companies contracted by Isolagen to design the ACE system sued the Company in County Court at Law No. 2 of Travis County, Texas for non-payment under their contract. *International Biophysics Corporation v. Isolagen Technologies*, Inc., File Number 1:06-cv-00371-SS. In that lawsuit, IBC claimed that Isolagen had fraudulently induced it to enter into a design contract by making fraudulent misrepresentations that the Company could grow human fibroblast cells in adequate clinical yields. Significantly, in its counterclaim, Isolagen stated that IBC had failed to produce, pursuant to their July 2005 contract, a functional design of the ACE system. Thus, contrary to defendants' representations, not only was the ACE system not in its "final stages" – it was not even yet designed.

140. Concerning the Company's studies of the clinical effects of the Isolagen Process in the United Kingdom, the Secondary Registration Statement stated, in relevant part:

> UK International Registry. We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of treatment as of November 2003 rather than a summary of patients at some fixed time point.
>
> The results indicate that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results at six months and one year after first injection....

(Reg. St. at 26; Prospectus at 28).

141. The statements in ¶ 140 concerning the Company's clinical results in the United Kingdom were false and misleading when made because they omitted mention of the fact that the clinical results in the United Kingdom, as explained above, were in fact wildly inconsistent,

and the Company was engaged in a massive and desperate effort to both change its protocols and re-inject those patients who complained that the Process did not work.

3. The 2003 Form 10-K/A

142. The Secondary Registration Statement incorporated by reference the Company's Annual Report on Form 10-K/A for the year ended December 31, 2003 (the "2003 10-K/A"). The 2003 10-K/A was filed April 28, 2004 (amending the Company's Form 10-K filed previously on March 26, 2004) and was signed by Defendants Macaluso, DeLape and Tomz.

143. Concerning the Company's target market, the 2003 10-K/A stated:

> ***Our Target Market Opportunity***
>
> Our first two product candidates are directed at the aesthetic and dental markets. For the aesthetic market, we will target primarily dermatologists, plastic surgeons and cosmetic surgeons, of which there are approximately 23,000 in the United States. For the dental market, we will target dentists, of which there are approximately 155,000 in the United States. We believe that both of these markets are influenced by consumer awareness of the available therapies and their benefits that drive patients to practitioners to seek out treatment.
>
> Aesthetic Market. According to the American Society for Aesthetic Plastic Surgery, more than 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 39 to 57, representing over 27% of the U.S. population; [Emphasis added]

144. The statements in ¶ 143 concerning the Company's target market were false and misleading because they omitted mention of material facts, including that, as stated above, physician reports to senior executives of the Company indicated that most or all of the targeted

"baby boomer" market had not consistently obtained any objectively measurable improvement in facial wrinkles, scars, or other facial deformities through use of the Isolagen Process.

145. Concerning the duration of the effect of the Process, the 2003 10-K/A stated, in relevant part:

> We have designed our proprietary Isolagen Process to address many of the drawbacks of existing treatment alternatives while providing an effective treatment outcome for patients. Some of the advantages of our Isolagen Process are as follows:
>
> • Longer duration of effect. Fibroblast cells remain viable for many years and, therefore, the effects are likely to last longer. Some patients treated with our Isolagen Process have exhibited positive results for longer than one year. We believe our Isolagen Process will produce longer-lasting effects, and a permanency claim based on 12-month efficacy data is the subject of the extended portion of our clinical trials.

146. The statements in ¶ 145 concerning the duration of the effects of the Isolagen Process were false and misleading because, as revealed by Lead Plaintiffs' investigation, they omitted mention of material facts, including that those patients who purportedly derived benefits from the Isolagen Process lasting longer than one year had received other treatments in addition to the Isolagen Process. Furthermore, as described in ¶¶ 92 to 95, Lead Plaintiffs' investigation has revealed that physicians experienced in treating patients with the Process had received results that contradicted the above statement. Moreover, these physicians had reported these contradictory results to Isolagen's senior executives, including Defendant Avignon.

147. Concerning the Company's clinical experience with the Process, the 2003 10-K/A also stated in relevant part:

> UK International Registry. We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of

> treatment as of November 2003 rather than a summary of patients at some fixed time point.
>
> The results indicate that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results at six months and one year after first injection. Very few adverse events, consisting of mild edema and bruising at the injection site, were reported, which resolved spontaneously.

148. The statements in ¶ 147 concerning the efficacy of the Isolagen Process were false and misleading because they omitted mention of material facts, including that the Company's prior studies of the Process, and anecdotal evidence presented to the Company by physicians who treated patients with the Isolagen Process demonstrated that the Process frequently failed to produce any objectively measurable improvement in facial wrinkles, scars, or other facial deformities, and that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

149. Defendants Macaluso and Tomz also signed Certifications required by the Sarbanes-Oxley Act of 2002 in Connection with the 2003 10-K/A for the year ended, which stated in relevant part:

> (a) I have reviewed this Annual Report on Form 10-K/A for the year ended December 31, 2003 of the registrant; and
>
> (b) 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; (ex. 31.1, 31.2)

150. As explained in ¶¶ 142 to 148 above, the statements in ¶ 149 were false and misleading because the 2003 10 K/A did contain untrue statements and omissions of material facts – of which Defendants Macaluso and Tomz knew or ought to have known.

4. May 23, 2004 and July 21, 2004 Press Releases

151. On May 23, 2004 and July 21, 2004, Isolagen issued press releases touting the Company's receipt of a "Special Protocol Assessment" or "SPA" from the FDA. The July 21 press release also announced, "Isolagen Begins Phase III Pivotal Trials." That release stated in relevant part:

> Isolagen will be conducting two identical trials for the treatment of facial wrinkles. The trials are randomized, double blind and placebo controlled and will be conducted at various sites in the United States. The trials, which will run simultaneously, each have 100 patients split evenly between treatment group and placebo controlled group. Efficacy will be measured by a two (2) point improvement on a six (6) point scale, as evaluated by an independent assessor after four (4) months of treatment.
>
> "We are encouraged by the Special Protocol Assessment ("SPA") and the very manageable size of the trials," said Michael Macaluso, CEO. "The start of the Phase III Pivotal Trials in July 2004 should allow Isolagen to file for our Biological License Application ("BLA") as early as the first quarter of 2005."

152. The statements in ¶ 151 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process were false and misleading because Isolagen was incapable of carrying out two identical trials for the treatment of facial wrinkles. Specifically, despite the Company's knowledge that clinical results varied based upon physician injection technique – as confirmed by CW#1 – the Company did not provide adequate training for or develop adequate controls over the critical process of patient injection. The lack of a standardized injection technique was known to the Company before the trials commenced and was repeatedly mentioned to the Company and its controlling persons such as DeLape and Avignon as they proceeded with the trials. Further, the Company and its controlling persons also knew that doctors were not injecting patients in a uniform manner because the Company remained in close

communication with physicians responsible performing the clinical trials throughout their duration.

153. The statement in ¶ 152 concerning the Company's plan to file a BLA in the first quarter of 2005 was false and misleading because the Company and its controlling persons knew that they lacked a protocol for a consistent and proper injection technique, and because the Process was giving rise to highly inconsistent results in clinics in the United Kingdom, as explained above. Further, as discussed more fully above, the Company lacked the ability to file a BLA within that time-frame – of which fact Isolagen and its controlling persons were aware.

5. July 28, 2004 Press Release and 8-K

154. On July 28, 2004, Isolagen issued a press release, also filed on Form 8-K, entitled "Isolagen Process Initial Phase III Six Month Marker Data Positive." The press release stated in relevant part:

> Isolagen released six-month marker data of the first Isolagen Process Phase III study that indicates a positive response in 82% of the Isolagen treated patients who were evaluated.
>
> This initial and ongoing study was designed to assess improvement for facial contour deformities. On July 21, 2004 the Company announced the commencement of two additional Phase III trials under a Special Protocol Assessment ("SPA") with the U.S. Food and Drug Administration ("FDA") for treatment of facial wrinkles only. These simultaneous pivotal Phase III trials are designed to further assess the safety and effectiveness of the Isolagen Process and provide the type of data necessary to support FDA approval of the process. The timing of these additional trials should allow Isolagen to file for its Biological License Application ("BLA") as early as the first quarter of 2005.
>
> In the initial Phase III study, 82% of the Isolagen treated group who were evaluated were responders at six (6) months, as compared to 77% at four (4) months.
>
> * * *

> "This preliminary Phase III trial was designed to assess facial contour deformities through objective measurements. To be considered responsive to the treatment process, a patient would have to move two (2) points on a seven (7) point scale. The six month results indicate that 82% of the patients evaluated had at least a two (2) point move on the scale which is very encouraging," said Michael Macaluso, CEO. "We remain optimistic that the study results at the one year mark will be even better."

155. The statements in ¶ 154 concerning the statistical significance of the results of the "initial" Phase III trial were false and misleading because they omitted mention of material facts, including, as more fully described above in ¶¶ 92 and 133, the fact that the Process was not uniformly effective at treating facial wrinkles, scars or other facial deformities.

156. The statements in ¶ 153 concerning the Company's plan to file a BLA in the first quarter of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

6. August 12, 2004 10-Q

157. On August 12, 2004, Isolagen filed its Form 10-Q for the quarter ending June 30, 2004 ("Second Quarter 2004 10-Q"). In relevant part, the Second Quarter 2004 10-Q stated:

> In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. We initiated two additional pivotal Phase III clinical trials for this product candidate in July 2004. We currently expect to file a Biologics License Application, or BLA, for this product candidate during the first quarter of 2005.

158. The statements in ¶ 157 concerning the Company's plan to file a BLA in the first quarter of 2005 were false and misleading because, as discussed more fully above in ¶¶ 87-88, 94, 96 and 135, the Company utterly lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

7. October 20, 2004 Press Release and 8-K

159. On October 20, 2004, Isolagen issued a press release, also filed on Form 8-K, entitled "Isolagen Announces Further Developments in its Global Strategy to Commercialize the Isolagen Process." The press release stated, in relevant part:

> Isolagen is currently in the injection phase of two pivotal phase III studies being conducted under the protocol agreement between Isolagen and the FDA in the Special Protocol Assessment (SPA). The BLA submission will include regulatory documentation to support the implementation of its Automated Cellular Expansion (ACE) system and will include additional data to demonstrate comparability of the ACE process to the existing manual system used in the clinical studies. "Once a facility is established, it will be incorporated into the BLA in order to mitigate the anticipated time between filing and commercialization," added Bitterman. Accordingly, the BLA would be expected to be filed in the second half of 2005.

160. The statements in ¶ 159 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known. In addition, defendants knew that given the state of development for the ACE system, the Company could not conceivably include the requisite information concerning ACE with its BLA by the second half of 2005.

8. 2004 Offering Memorandum

161. In October 2004, Isolagen offered $75,000,000 aggregate principal amount of its 3.5% Convertible Subordinated Notes due 2024 (the "Notes") to certain institutional investors in an offering exempt from the registration requirements of the Securities Act. The initial conversion rate was approximately $9.16 per share (*i.e.*, 109.2001 shares per $1,000 principal amount of notes). Isolagen sold the Notes pursuant to an offering memorandum dated October 28, 2004 (the "Offering Memorandum").

162. The Offering Memorandum stated, among other things:

> ... Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition...
>
> * * *
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials…. We expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005.....

(Offering Memorandum at 1).

163. The statements in ¶ 162 concerning the efficacy of the Isolagen Process were false and misleading because they omitted mention of material facts, including that, as revealed by Lead Plaintiffs' investigation, the Company's prior studies of the Process and anecdotal evidence presented to the Company and its controlling principals by physicians who actually treated patients with the Isolagen Process demonstrated that: (i) the Process frequently failed to demonstrate any objectively measurable improvement in facial wrinkles, scars, or other facial deformities; and (ii) that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

164. In addition, the statement in ¶ 162 concerning the Company's plan to file a BLA in the second half of 2005 was false and misleading because the Company and its controlling principals knew that the Company lacked a protocol for a consistent and proper injection technique, and because the Isolagen Process was resulting in highly inconsistent results in clinics in the United Kingdom.

165. Furthermore, the statement in ¶ 162 concerning the Company's plan to file a BLA in the second half of 2005 was false and misleading because, even if the Company were able to demonstrate statistically significant results from its Pivotal Phase III clinical trials, members of the Company's administrative staff had reported to senior executives that the administrative staff was incapable of completing the paperwork within this timeline, and the research staff had not begun to perform certain analyses required by the FDA to characterize the injectable cells to be injected that would be required for the filing.

166. Concerning the Company's target market, the Offering Memorandum also stated:

> ***Our Target Market Opportunity***
>
> Our first two product candidates are directed at the aesthetic and dental markets.
>
> * * *
>
> *Aesthetic Market.* According to the American Society for Aesthetic Plastic Surgery, more than 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population...

(Offering Memorandum at 1)

167. The statements in ¶ 166 concerning the Company's target market were false and misleading when made because they omitted mention of material facts, including that, as revealed by Lead Plaintiffs' investigation, numerous physician reports to the Company and its various senior executives and controlling persons had indicated that most or all of the targeted

"baby boomer" market had not consistently obtained any objectively measurable improvement in facial wrinkles, scars, or other facial deformities through use of the Isolagen Process.

168. Concerning the Company's planned automated manufacturing (ACE) system, the Offering Memorandum stated, in relevant part:

> Recent refinements in our Automated Cell Expansion, or ACE System and additional experience from U.K. operations and our clinical trials have allowed us to consider a number of different alternative technologies to wash and concentrate the cells that we harvest. We are presently evaluating the technological advantages and commercial viability of several options from other industry partners, in addition to a system we have been developing in conjunction with Applikon Biotechnology. We expect the implementation and commercial validation of our ACE system to be completed prior to the filing of the BLA….

(Offering Memorandum at 3).

169. The statements in ¶ 168 concerning the introduction and implementation of the ACE System were false and misleading because they omitted mention of the material fact that the Company's system to grow and separate cells had not reached a stage at which its development could possibly be described as "refinement." In fact, at the time, the system was non-existent. Indeed, as set forth above, it was not until May 2005 that Isolagen exhibited even a cosmetic mock-up of the proposed ACE System.

9. <u>November 8, 2004 10-Q</u>

170. On November 8, 2004, Isolagen filed its Form 10-Q for the period ending September 30, 2004 ("Third Quarter 2004 10-Q"). In relevant part, the Third Quarter 2004 10-Q stated:

> In July 2004, the Company announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which

> are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvements on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The Company expects to file a BLA for this product candidate during the second half of 2005.

171. The statements in ¶ 170 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process were false and misleading when made because, as set forth more fully above in ¶ 94, Isolagen was incapable of carrying out two identical clinical trials for the treatment of facial wrinkles.

172. The statements in ¶ 170 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

10. <u>January 2005 Prospectus</u>

173. On January 25, 2005, Isolagen filed a prospectus related to the sale of 5,311,563 common shares and warrants acquired by investors in various private placements in 2002 and 2003 ("January 2005 Prospectus").

174. Concerning the Company's clinical experience and ability to submit an application for FDA approval, the January 2005 Prospectus stated, in relevant part:

> We specialize in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Our first two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition.

* * *

> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. We expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005.

175. The statements in ¶ 174 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process are false and misleading because, as set forth more fully above in ¶ 134, Isolagen was incapable of carrying out two identical trials for the treatment of facial wrinkles.

176. The statements in ¶ 174 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully above in ¶ 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known. In addition, the statements touting the Company's "accumulated clinical experience" were false and misleading because the Company's accumulated clinical experience showed a lack of uniformly positive results.

177. Concerning the Company's target market, the January 2005 Prospectus stated:

> ***Our Target Market Opportunity***
>
> For the aesthetic market, we will target primarily dermatologists, plastic surgeons and cosmetic surgeons, and for the dental market, we will target dentists. We believe that both of these markets are influenced by consumer awareness of the available therapies and

> their benefits that drive patients to practitioners to seek out treatment.
>
> ***Aesthetic Market.*** According to the American Society for Aesthetic Plastic Surgery, nearly 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population.

178. The statements in ¶ 177 concerning the Company's target market of "baby boomers" are false and misleading because they omitted mention of material facts, including, as more fully described above in ¶¶ 92, 93 and 167, the fact that the Process was generally ineffective at treating facial wrinkles, scars or other facial deformities in patients over 45 years old.

179. Concerning the Company's planned automated manufacturing system, the January 2005 Prospectus stated:

> Automated Cell Expansion System. Recent refinements in our Automated Cell Expansion, or ACE, System and additional experience from our U.K. operations and our clinical trials have allowed us to consider a number of different alternative technologies to wash and concentrate the cells that we harvest. We are presently evaluating the technological advantages and commercial viability of several options from other industry partners, in addition to a system we have been developing in conjunction with Applikon Biotechnology. We expect the implementation and commercial validation of our ACE System to be completed prior to the filing of the BLA. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. We anticipate that the integration of either the Applikon or one of the alternative washing and collection technologies into

> our ACE System will allow us to reduce our variable costs and to increase our capacity.

180. The statements in ¶ 179 concerning the 2005 implementation and commercial validation of Isolagen's ACE System prior to the filing of the BLA were false and misleading because, as set forth more fully above in ¶¶ 128 and 169, the Company lacked the ability to implement and validate the ACE system within the time given for the filing of the BLA.

11. Convertible Notes Registration Statement

181. On February 1, 2005, Isolagen filed the Convertible Notes Registration Statement. Concerning the Company's clinical experience and ability to submit an application for FDA approval, the Convertible Notes Registration Statement stated:

> We specialize in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Our first two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition.
>
> * * *
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. We expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005.

182. The statements in ¶ 181 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process were false and misleading because, as set forth more fully above in ¶¶ 94, 96 and 134, Isolagen was incapable of carrying out two identical trials for the treatment of facial wrinkles. In addition, the statements touting the Company's "accumulated clinical experience" were false and misleading because the Company's accumulated clinical experience showed a lack of uniformly positive results.

183. The statements in ¶ 181 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully above in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

184. Concerning the Company's target market, the Convertible Notes Registration Statement stated:

> ***Our Target Market Opportunity***
>
> ***Aesthetic Market.*** According to the American Society for Aesthetic Plastic Surgery, nearly 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population.

185. The statements in ¶ 184 concerning the Company's target market of "baby boomers" were false and misleading when made because they omitted mention of material facts, including, as more fully described above in ¶¶ 92-95, the fact that the Process was generally

ineffective at treating facial wrinkles, scars or other facial deformities in patients over 45 years old.

186. Concerning the Company's proposed ACE System, the Convertible Notes Registration Statement further stated:

> **Automated Cell Expansion System**. Recent refinements in our Automated Cell Expansion, or ACE, System and additional experience from U.K. operations and our clinical trials have allowed us to consider a number of different alternative technologies to wash and concentrate the cells that we harvest. We are presently evaluating the technological advantages and commercial viability of several options from other industry partners, in addition to a system we have been developing in conjunction with Applikon Biotechnology. We expect the implementation and commercial validation of our ACE System to be completed prior to the filing of the BLA. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. We anticipate that the integration of either the Applikon or one of the alternative washing and collection technologies into our ACE System will allow us to reduce our variable costs and to increase our capacity.

187. The statements in ¶ 186 concerning the 2005 implementation and commercial validation of Isolagen's ACE System prior to the filing of the BLA were false and misleading because, as set forth more fully above in ¶¶ 87-88, 94, 96, 135, 139 and 169, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known. In addition, the statements touting the Company's "accumulated clinical experience" were false and misleading because the Company's accumulated clinical experience showed a lack of uniformly positive results.

12. February 2005 Press Release and 8-K

188. On February 18, 2005, Isolagen issued a press release, also filed on Form 8-K, entitled "Isolagen Process Exploratory Phase III 12 Month Data Positive." The press release stated, in relevant part:

> The percentage of responders of those evaluated for all treatment areas at one, two, four, and six months post-injection was 57.0%, 79.6%, 77.1%, and 82.2%, respectively. The therapeutic effect of the Isolagen Process compared to placebo was demonstrated at six months (82.2% vs. 38.2%, Fisher's exact, p-value <0.0001). Results of a twelve-month follow-up assessment on only the Isolagen-treated group demonstrated the therapeutic effect was maintained with a response rate of 82.4% in those patients who were evaluated at 12 months.
>
> "We're very pleased with the results to date and the observed long-term effects of the Isolagen Process," said Robert J. Bitterman, President and CEO, Isolagen, Inc. "These findings, showing continued effect over 12 months, are consistent with our ongoing European experience that indicate a sustained response."
>
> According to Mr. Bitterman, Isolagen has completed the injection (treatment) phase of the two pivotal Phase III Clinical Trials being conducted in the U.S. under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) for treatment of facial wrinkles only. These simultaneous pivotal phase III trials are designed to demonstrate the safety and effectiveness of the Isolagen Process and will provide the type of data necessary to support FDA approval of the process. The timing of these additional trials should allow Isolagen to file its Biological License Application (BLA) in the second half of 2005.

189. The statements in ¶ 188 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability and the results to file a BLA within that time-frame, which Defendants knew or ought to have known.

190. The statements in ¶ 188 concerning the "continued effect" of the Process and the Company's "ongoing European experience" were false and misleading because defendants knew that if anything, Isolagen's "European experience" was not demonstrating a uniformly positive or sustained effect.

13. 2004 Form 10-K

191. On March 15, 2005, Isolagen filed its From 10-K for the period ending December 31, 2004 ("2004 10-K"). Concerning the Company's clinical experience and ability to file an application for FDA approval, the 2004 10-K stated:

> We specialize in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Our two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition.
>
> * * *
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III exploratory clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The injection phase of both Phase III studies was completed in December 2004 and we expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005.

192. The statements in ¶ 191 concerning Isolagen's "accumulated clinical experience" and the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known, and because

the Company's clinical experience had, in fact, revealed an utter lack of uniformly positive results.

193. Concerning the Company's target market, the 2005 10-K stated:

> ***Our Target Market Opportunity***
>
> ***Aesthetic Market Opportunity***
>
> Aesthetic procedures have traditionally been performed by dermatologists, plastic surgeons and other cosmetic surgeons, of which there are approximately 23,000 in the United States, according to the American Society for Aesthetic Plastic Surgery, or ASAPS. According to the ASAPS, the total market for non-surgical cosmetic procedures was approximately $4.7 billion in 2004. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 41 to 59, representing over 27% of the U.S. population;
>
> Our lead product candidate is directed primarily at the aesthetic market. …
>
> Procedures among the 35 to 50 year old age group made up 45% of all non-surgical cosmetic procedures in 2004. The 51 to 64 year old age group made up 25% of all non-surgical cosmetic procedures in 2004**,** while the 19 to 34 year old age group made up 22% of the non-surgical cosmetic procedures. (at 2-3).

194. The statements in ¶ 193 concerning the Company's target market of "baby boomers" were false and misleading when made because they omitted mention of material facts, including, as more fully described above in ¶¶ 92-95, the fact that the Process was generally ineffective at treating facial wrinkles, scars or other facial deformities in patients over 45 years old – a fact that was reported to the company and its controlling persons.

195. Concerning the clinical effects of the Isolagen Process, the 2004 10-K stated:

> ***Long duration of effect.*** Fibroblast cells remain viable for many years and, therefore, the effects are likely to last longer. Some patients treated with our Isolagen Process have exhibited positive

> results for longer than one year. We believe our Isolagen Process will produce long-lasting effects. (at 4).

196. The statements in ¶ 195 concerning the duration of the effects of the Isolagen Process were false and misleading because, as more fully described above in ¶ 146, they omitted mention of material facts, including that those patients who purportedly derived benefits from the Isolagen Process lasting longer than one year had received other treatments in addition to the Isolagen Process. Furthermore, Lead Plaintiffs' investigation has revealed that physicians experienced in treating patients with the Process had received results that contradicted the above statement. Moreover, these physicians had reported these contradictory results to Isolagen's senior executives, including to Defendants DeLape and Avignon.

197. Concerning the Company's existing manufacturing practices and planned automated manufacturing system (ACE), the 2004 10-K stated in relevant part:

> We are currently developing an Automated Cell Expansion, or ACE, System. Our ACE System will eliminate several of the steps and materials involved in our current system, which we expect will lead to significant cost reductions in both skilled labor and materials and will enable scalable mass production. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. We expect the implementation and commercial validation of our ACE System to be completed prior to the filing of our BLA.

198. The statements in ¶ 197 concerning the 2005 implementation and commercial validation of Isolagen's ACE System prior to the filing of the BLA were false and misleading because, as set forth more fully above in ¶¶ 87-88, 94, 96, 139 and 169, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

199. Concerning the Company's studies of the clinical effects of the Isolagen Process, the 2004 10-K stated:

> UK International Registry. We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of treatment as of November 2003 rather than a summary of patients at some fixed time point.
>
> The results indicate that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results both at six months and one year after first injection.

200. The statements in ¶ 199 concerning the efficacy of the Isolagen Process were false and misleading because, as set forth above in ¶¶ 92 to 95, they omitted mention of material facts, including that the Company's prior studies of the Process, and anecdotal evidence presented to the Company by physicians who treated patients with the Isolagen Process: (i) demonstrated that the Process frequently failed to produce any objectively measurable improvement in facial wrinkles, scars, or other facial deformities; and (ii) that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

201. Defendants Bitterman and Tomz also signed Certifications required by the Sarbanes-Oxley Act of 2002 in Connection with the 2004 10-K for the year ended, which stated in relevant part:

> I have reviewed this Annual Report on Form 10-K/A for the year ended December 31, 2004 of the registrant;
>
> 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. (ex. 31.1, 31.2)

202. As explained in ¶¶ 191 to 200 above, the statements in ¶ 201 were false and misleading because the 2004 10-K did contain untrue statements and omissions of material facts – of which Defendants Bitterman and Tomz knew or ought to have known.

14. First Quarter 2005 10-Q

203. On May 10, 2005, Isolagen filed its Form 10-Q for the quarter ended March 31, 2005 ("First Quarter 2005 10-Q").

204. Concerning the Company's ability to file an application for FDA approval, the Second Quarter 2005 10-Q stated:

> In July 2004, the Company announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. The Company expects to file a BLA for this product candidate during the second half of 2005. [Emphasis added].

205. The statements in ¶ 204 concerning the Company's plan to file a BLA in the second half of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

206. The statements in ¶ 204 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process are false and misleading because, as set forth more fully in ¶¶ 94, 96 and 134, Isolagen was incapable of carrying out two identical trials for the treatment of facial wrinkles.

15. 2005 First Quarter Results Conference Call

207. On May 10, 2005, Isolagen conducted a conference call to discuss the results of its quarter ended March 31, 2005 ("First Quarter Results Conference Call"). In the First Quarter Results Conference Call, Defendant DeLape made the following statements concerning the Company's U.K. operations,:

> [Concerning the reduction in sales guidance for the United Kingdom] So the guidance has been amended, not due to a lack of interest in the market or a lack of scalability, but a deliberate choice by Management to utilize the U.K. facility for what it is, really a pilot factory… "So it's important when we talk about the change in guidance that we all understand that the change is deliberate, it's focused, and it's disciplined. We've chosen to use that pilot plant to the Company and eventually to shareholders' advantage, and that is to validate a lot of the things that we're out there doing….

208. The statements in ¶ 207 regarding customer demand and scalability of the Isolagen Process in the United Kingdom were false and misleading because defendants knew that the Process and the automated ACE system were not being validated in the United Kingdom.

209. In the First Quarter Results conference call Chief Technology Officer Dr. Forbes-McKean stated:

> We are putting together the data from the two Phase III double blind placebo controlled pivotal trials**.** The data from those studies will be unblended in July, which puts us on track for submission of our BLA in late third quarter, early fourth quarter, of this year. [Emphasis added].

210. The statements in ¶ 209 concerning the Company's plan to file a BLA in late third quarter or early fourth quarter of 2005 were false and misleading because, as discussed more fully in ¶¶ 87-88, 94, 96 and 135, the Company lacked the ability to file a BLA within that time-frame, which Defendants knew or ought to have known.

211. In the First Quarter Results conference call, in response to an analyst question concerning the decline in gross-margins generated by United Kingdom sales, Defendant DeLape stated:

> ***The gross margin's impacted because there's a lot of scientific discovery work. We've not optimized – that's what I was trying to explain earlier to everybody, we've not optimized the facility for profit and scalability.*** What we're doing is a lot of parallel science work, working in the flask system, working in the nunc [sic?] cell factory, and also looking at some alternative media solutions. So there's a lot of science that's in the building. And we're really standardizing our SOPs and really preparing the Company for the scaled version. So there's incremental head count in there that you would not have in a normal operation. [Emphasis added].

212. The statements in ¶ 211 concerning the decline in gross margin from United Kingdom sales are false and misleading because gross margin was impacted not only by scientific discovery costs but also because, according to physicians who treated patients with Isolagen, the Company was providing free or discounted treatments to between 500 and 1000 angry customers who had obtained no objectively measurable benefit from treatment with the Isolagen Process.

213. In the First Quarter Results conference call, in response to a further question from the same analyst concerning fixing a proposed timeline for implementing ACE system at "market capacity" in the United States and Switzerland because the Company's date "seems to be moving around," Defendant DeLape stated:

> We plan, to deliver ACS [sic] commercial units in December '05 to Switzerland. I believe it will be scalable and in place in both the U.S. and Switzerland in a full production capacity by mid-'06 for Switzerland, and maybe chiefly '06 for the U.S.

214. The statement in ¶ 213 concerning the introduction of ACS commercial units in December 2005 is false and misleading because at the time it was made, despite more than two

years of development efforts, the technology to build ACE had not yet been devised nor had a prototype been built. In the Company's Second Quarter Results conference call on August 9, the Company would again postpone the introduction date for ACE, promising delivery of "prototype" units to Switzerland and the U.K. in the "first half of 2006."

215. Also, in the First Quarter Results conference call, in response to an analyst question concerning the efficacy of the Isolagen Process and whether there existed any issues concerning efficacy based on data the Company had seen, Dr. Forbes-McKean stated:

> I haven't seen the data. As we've said, it's a blinded study and it will be un-blinded in July so, you know, I can't speculate on that data in the pivotal studies until we see it, because as I said, it's – we won't have it un-blinded until July.

216. The statement in ¶ 215 concerning the efficacy of the Isolagen Process is false and misleading because it fails to disclose that considerable data provided to the Company by physicians treating patients in the U.K. with the Isolagen Process demonstrated that the Isolagen Process was generally not effective for patients over the age of 45.

217. Later, in response to an analyst question concerning leveling or declining demand in the United Kingdom market, Defendant DeLape stated:

> We're just – I think really what impacted in the U.K. was again – you know, the biggest challenge the U.K. has always had is this ability to meet demand. We've never, as you know, been able to meet demand, due to the fact that we create sometimes, as you saw when you were in London, four to six months of backlog.

218. The statement in ¶ 217 concerning the leveling of demand in the U.K. market is false and misleading because in fact the number of new patients treated had leveled because, according to physicians who treated patients with the Isolagen Process, they were providing additional, discounted treatments to between 500 and 1000 angry customers who had obtained no objectively measurable benefit from treatment with the Isolagen Process.

16. August 2005 Press Release and 8-K

219. On August 1, 2005, Isolagen issued a press release, also filed on Form 8-K, entitled "Isolagen Announces Preliminary Results of Phase III Dermal Trial." This press release was the first disclosure in which Isolagen finally owned up to the truth about the Isolagen Process, which was that it had never been consistently effective in the target market of patients, that the Company's trials were not well designed or controlled, and that the Company was a long way from being able to file a BLA. The press release stated, in relevant part:

> Study B of the trial proved to be statistically significant with both patient and physician assessment achieving positive results. Study A results were mixed with a positive assessment from the patients only. Significantly, a wide variance in results was reported from site to site across both studies with response rates ranging from 73.3% to 7.6%. Comparison of the statistics from site to site suggests that results are dependent on injection technique. No major safety issues or serious adverse events were reported in either study.
>
> Dr. Robert Weiss of Johns Hopkins University, a principal investigator for the study, commented, "The patients that I have treated with the Isolagen Process are very pleased with the results. My experience with the Isolagen Process, commencing with the Phase II Study, is that proper injection technique is vital to a positive outcome. The technique requires an injection in the superficial dermis which varies in thickness based on skin type and age. The art of injecting fibroblast cells is simple, but exact."
>
> Dr. Marie Lindner, Senior Vice President of Medical and Business Affairs, stated, "We believe that the results from the trial demonstrate that the Isolagen Process can be used successfully to treat contour deformities. However, we think the wide variance in results precludes a BLA filing at this time. Therefore, in November 2005, Isolagen plans to initiate a 100-patient, clinical trial with a six-month endpoint the results of which could be combined with the successful results from Study B to support a BLA filing in 2006. In this new trial, only physicians trained in the proper Isolagen injection technique will participate as investigators in this trial."

220. The statements in ¶ 219 concerning the statistical significance demonstrated by the Company's Phase III Pivotal Trials are false and misleading because, among other things, investors would not learn the whole truth until August 9, 2005, as described in ¶¶ 139 and169, when it would emerge that the ACE System – a necessary component of the Company's plans for commercial profitability – was not nearly as far along in its development as the Company had previously represented and that the Company's success in treating patients in the U.K. had been materially misrepresented.

17. August 4, 2005 Presentation

221. On August 4, 2005, Isolagen participated in the Adams-Harkness Summer Seminar investor conference. The remarks made by Isolagen were circulated publicly by the Company on the Internet. In its presentation, Isolagen stated:

> This is a 62 year old woman [referring to slide] here we see the Isolagen treatment over multiple treatment sites. First we have treatment view of the naso-labial, vermillion borders, and the [inaudible], and a four month post-treatment with Isolagen. You can easily see the impressive results after four months and continuing results after 8 years. These photos illustrate the broad application of technology, overall youthful appearance, and duration of effect achieved with the Isolagen process.
>
> According to ASAPS, consumer demand increased 51% in 2004 for non-surgical cosmetic procedure, exceeding more than 9.7 million procedures. The statistics demonstrate that non-surgical cosmetic procedures involving injectable material has become more mainstream and accepted. We believe this growth in the aesthetic procedure market is driven by aging in the baby boomer population currently ages 41-59, representing over 27% of the U.S. population….
>
> In the accumulated experience of the company, through its retrospective study, clinical trials and treatments of over 8,000 patients in the United Kingdom, Isolagen has been found to be well tolerated and has produced expected efficacy responses.

222. The statements in ¶ 221 concerning the efficacy of the Isolagen Process were false and misleading because they omitted mention of material facts, including that the Company's prior studies of the Process, and anecdotal evidence presented to the Company by physicians who treated patients with the Isolagen Process: (i) demonstrated that the Process frequently failed to produce any objectively measurable improvement in facial wrinkles, scars, or other facial deformities; (ii) was generally ineffective at treating facial wrinkles, scars, or other deformities in patients over 45 years of age; and (iii) that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

VI. DEFENDANTS' SCIENTER

A. The Fraudulent Scheme and Insider Sales

223. Despite gathering evidence that showed the public statements regarding the clinical efficacy and marketability of the Isolagen Process to be false, as described above, defendants continued to knowingly and deliberately make false and misleading statements designed to artificially inflate the price of Isolagen securities, while selling sizable personal holdings for millions of dollars of profit.

224. Defendants were motivated to conceal the Company's failures concerning the Isolagen Process in order to allow the Company to complete an offering of over eight million shares in June 2004 for proceeds of over $61 million. In addition, company insiders, including certain Individual Defendants, were able to sell their personally-held shares of Isolagen stock for proceeds of more than $33 million; and the Company was able to complete a private placement of convertible debentures for proceeds of $90 million.

225. During the relevant period, and with the Company's stock trading at artificially inflated prices, Defendants DeLape, Macaluso, Avignon, Boss, Marko and Tomz collectively

sold at least 2.4 million shares of their personally held Isolagen stock for gross proceeds of over $15 million, as set forth in the following chart:

NAME	DATE	SHARES	PRICE	PROCEEDS RECEIVED
Frank DeLape	6/15/2004	293,270	$8.50	$2,492,795
	11/3/2004	400,000	$6.33	$2,532,000
Total		693,270		$5,024,795
Michael Macaluso	11/3/2004	400,000	$6.33	$2,532,000
Michael Avignon	11/3/2004	400,000	$6.33	$2,532,000
William K. Boss	6/15/2004	304,885	$8.50	$2,591,522
Olga Marko	6/15/2004	227,258	$8.50	$1,931,693
	11/3/2004	400,000	$6.33	$2,532,000
Total		627,258		$4,463,693
Jeffy W. Tomz	6/15/2004	24,587	$8.50	$208,989

226. DeLape's stock sales in June 2004 represented 28% of his Isolagen holdings at the time, and his sales in November 2004 represented 37% of his holdings at the time. The two stock sales together represented 51% of his Isolagen stock holdings. DeLape has not sold Isolagen stock on any other occasion.

227. Defendant Macaluso's November 2004 stock sales represented 29% of his Isolagen common stock holdings.

228. Defendant Boss' June 2004 stock sales constituted 19% of his Isolagen holdings, and he has not sold Isolagen stock on any other occasion.

229. Defendant Marko's June 2004 stock sales represented 28% of her holdings. She has not reported selling Isolagen stock on any other occasion. Marko's November 2004 stock sales represented 65% of her holdings at the time.

230. Tomz's June 2004 stock sales constituted 22% of his reported Isolagen holdings.

B. Additional Allegations of Defendants' Scienter

231. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and

misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth above in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Isolagen, their control over, and/or receipt and/or modification of Isolagen's materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Isolagen, participated in the fraudulent scheme alleged herein.

232. In particular, Defendants had actual knowledge that the Company's clinical trials would not be successful because, as set forth in greater detail above, Isolagen officers learned in 2004 that no standardized injection technique existed to ensure that the patients' cells were injected in the correct skin layer to ensure that the Process would be effective – *e.g.*, by actually filling in wrinkles. Defendants were aware of this fact because in early 2004, Isolagen representatives, including Defendant Avignon, visited one of the Company's lead trainers in the United Kingdom and when they observed his technique, realized that the injection technique was radically different from the injection techniques they had observed in the U.S. Isolagen contracted with the trainer to train doctors in the U.S. prior to commencement of the Phase III trials. However, Isolagen canceled the training sessions.

233. Defendants also were aware of the very large percentage of "non-responders" in the United Kingdom, which they sought to rectify by inviting patients to be re-injected by a properly-trained practitioner or by reinjecting patients with more fibroblasts. Then, in mid-2004, as the Isolagen Process repeatedly failed to produce observable results, Defendants changed the

protocol for the Process by adding additional vials of cells and/or additional injections (at greatly increased cost per treatment) to the standard treatment.

234. In addition, as the Isolagen Process repeatedly failed to produce observable results in older patients, beginning in summer 2004, Isolagen lowered the recommended age cutoff to 60, which they again lowered in 2005 to 55. In fact, seasoned practitioners informed Isolagen that they were not obtaining visible results in patients in the 45 to 50 years age group.

235. Finally, defendants knew that contrary to the Company's public statements during the Class Period, the ACE system was not in its "final stages," but, in fact, had barely begun even to be designed.

VII. ADDITIONAL ALLEGATIONS RELEVANT TO CONTROL PERSON LIABILITY UNDER THE EXCHANGE ACT

236. Because of their positions with Isolagen, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman had access to non-public information about Isolagen's business, finances, products, markets and present and future business prospects via access to internal corporate documents, conversation and connections with other corporate officers, employees and the physicians having hands-on practical experience with the Isolagen Process, attendance at management and board of directors' meetings and committees thereof and via reports and other information provided to them in connection therewith. Because of their possession of such information, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman knew or recklessly disregarded the fact that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

237. Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman are liable as direct participants in, and as co-conspirators, with respect to the wrongs complained of herein. In addition, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman by reason of their

status as senior executive officers and/or directors of Isolagen, were "controlling persons" and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman were able to and did, directly or indirectly, control the conduct of Isolagen's business.

238. Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman 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. Thus, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman had the opportunity to commit the acts complained of herein.

239. As senior executive officers and/or directors and as controlling persons of a public-traded company whose securities were, and are, registered with the SEC, pursuant to the Exchange Act, and was traded on the AMEX and governed by the federal securities laws, Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman had a duty to disseminate promptly accurate and truthful information with respect to Isolagen's financial condition and performance, growth, operations, financial statements business, products markets, management, earnings and present and future business prospects, to correct any previously issued statements had become materially misleading or untrue, so that the market price of Isolagen's securities would be based upon truthful and accurate information. Defendants DeLape, Macaluso,

Avignon, Tomz, and Bitterman's misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

240. Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman are liable as participants in the course of conduct that disseminated materially false and misleading statements and/or concealed material adverse facts. The course of conduct (i) deceived the investing public regarding Isolagen's business, operations and management and the intrinsic value of Isolagen securities; and (ii) caused Lead Plaintiffs and the members of the Class to purchase Isolagen securities at artificially-inflated prices.

VIII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT ONE

For Violations Of
Section 10(b) Of The Exchange Act
And Rule 10b-5 Promulgated Thereunder
Against Defendant Isolagen and the Individual Defendants

241. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

242. During the Class Period, Defendant Isolagen and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; (b) artificially inflate and maintain the market price of Isolagen's securities; and (c) cause Lead Plaintiffs and other members of the Class to purchase Isolagen's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

243. Defendant Isolagen and the Individual Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts,

practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Isolagen's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

244. In addition to the duties of full disclosure imposed on defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. Sections 210.01 et seq.) and Regulation S-K (17 C.F.R. Sections 229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and financial condition so that the market price of the Company's securities would be based on truthful, complete and accurate information.

245. Isolagen and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Isolagen as specified herein.

246. These 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 Isolagen's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material

facts necessary in order to make the statements made about Isolagen and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Isolagen's securities during the Class Period.

247. The Individual Defendants' primary liability arises from the following facts: (a) the Individual Defendants were high-level executives and directors at the Company during the Class Period; (b) the Individual Defendants were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; and (c) the Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

248. As alleged more fully above in ¶¶ 79 to 240, Defendants had actual knowledge of the misrepresentations and 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. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Isolagen's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' misstatements regarding the Company's business and operations, including, as alleged more fully above in ¶¶ 79 to 240, the efficacy and safety of the Isolagen Process and the development status of Isolagen's ACE system throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain

such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

249. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Isolagen's securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Isolagen's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, Lead Plaintiffs and the other members of the Class acquired Isolagen securities during the Class Period at artificially high prices and were damaged when the prices declined in reaction to corrective disclosures about the Company's business and the Isolagen Process.

250. At the time of said misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Lead Plaintiffs and the other members of the Class and the marketplace known of the true financial condition and business prospects of Isolagen, which were not disclosed by defendants, Lead Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Isolagen securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

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

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

COUNT TWO

For Violations Of Section 20(a) of The Exchange Act Against Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman

253. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

254. Defendants DeLape, Macaluso, Avignon, Tomz, and Bitterman (the "Section 20(a) Defendants") each acted as a controlling person of Isolagen 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 statements filed by the Company with the SEC and disseminated to the investing public, the Section 20(a) 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 that Lead Plaintiff contends are false and misleading. The Section 20(a) Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead 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.

255. Further, the Section 20(a) Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to

control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

256. In particular, the following facts evidence the Section 20(a) Defendants' control over Isolagen:

DeLape

(a) Throughout the Class Period, DeLape was Isolagen's Chairman of the Board of Directors. He became a member of the board of directors in June 2001, and Chairman of the Board of Directors in August 2001. DeLape also served as the Company's Interim Chief Executive Officer for approximately 5 months between April 2005 and October 2005. DeLape was one of three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) DeLape signed the Secondary Registration Statement, the Convertible Notes Registration Statement and the Company's annual and quarterly reports filed with the SEC. In addition, DeLape was one of Isolagen's primary spokespersons throughout the Class Period touted the ability of the Company to successfully treat patients who were members of the target market to secure FDA approval for the Isolagen Process, and to develop an automated manufacturing system that would be sufficiently efficient to make the Process commercially viable.

(c) DeLape's status as a controlling person of Isolagen is also reflected in his

employment agreement with Isolagen that was in effect throughout the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, DeLape was the beneficial owner of 8.6% of Isolagen common stock. Throughout the Class Period, DeLape was one of Isolagen's largest shareholders and thus had control by virtue of his substantial equity position.

Macaluso

(a) During the Class Period, Macaluso was Isolagen's President and CEO. He became President and CEO in August 2001, and continued in that position until September 2004. Mr. Macaluso was also a Director of Isolagen between June 2001 and April 2005. Macaluso was also one of the three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) Macaluso signed the Secondary Registration Statement and the Company's annual and quarterly reports filed with the SEC. In addition, Macaluso was one of Isolagen's primary spokespersons who, during the Class Period touted the ability of the Company to successfully treat patients who were members of the target market, to secure FDA approval for the Isolagen Process, and to develop an automated manufacturing system that would be sufficiently efficient to make the Process

commercially viable.

(c) That Macaluso was a control person of Isolagen is also reflected in his employment agreement with Isolagen that was in effect during the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, Macaluso was the beneficial owner of 10.3% of Isolagen common stock. Macaluso was one of Isolagen's largest shareholders during the Class Period and thus had control by virtue of his substantial equity position.

Avignon

(a) Avignon was a founder of Isolagen who served as both Isolagen's President and Manager of International Operations. Avignon was one of three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) As of April 26, 2004, Avignon was the beneficial owner of 10.3% of Isolagen common stock. Avignon was one of Isolagen's largest shareholders during the Class Period and thus had control by virtue of his substantial equity position.

Tomz

(a) Tomz was appointed Secretary and Treasurer of Isolagen in June 2001. He resigned as Treasurer in August 2001, at which time he

became CFO. Tomz resigned as Treasurer and CFO in April, 2005 when he was appointed Principal Financial and Accounting Officer of Isolagen.

(b) Tomz signed the Secondary Registration Statement, the Convertible Notes Registration Statement, and the Company's annual and quarterly reports filed with the SEC. In addition, Tomz was one of Isolagen's primary spokespersons who, during the Class Period participated in conference calls and represented to investors that the Company had sufficient assets to complete its BLA with the FDA.

(c) That Tomz was a control person of Isolagen is also reflected in his employment agreement with Isolagen that was in effect during the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, Tomz was the beneficial owner of 1.2% of Isolagen common stock. Tomz was one of Isolagen's largest shareholders during the Class Period and thus had control by virtue of his substantial equity position.

257. As alleged more fully above in ¶¶ 79 to 240, Section 20(a) Defendants had actual knowledge of the misrepresentations and 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. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing

Isolagen's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' misstatements regarding the Company's business and operations, including, as alleged more fully above in ¶¶ 79 to 240, the efficacy and safety of the Isolagen Process and the development status of Isolagen's ACE system throughout the Class Period, Section 20(a) Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

258. As set forth above in ¶¶ 241 to 252, Isolagen and the Section 20(a) Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Isolagen, the Section 20(a) Defendants are liable pursuant to Section 20(a) of the Exchange Act.

259. As a direct and proximate result of the Section 20(a) Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

COUNT THREE

Pursuant to Section 20A of the Exchange Act,
On Behalf of Purchasers of Isolagen Stock,
Against Defendants DeLape, Macaluso, Avignon, Boss, Marko and Tomz

260. Lead Plaintiffs repeat and reallege each of the allegations set forth above as if fully set forth herein.

261. This Claim is brought pursuant to Section 20A of the Exchange Act against Defendants DeLape, Macaluso, Avignon, Boss, Marko and Tomz (collectively, the "Section 20A Defendants") on behalf of all purchasers of Isolagen common stock pursuant to or traceable to the sale of Isolagen common stock sold by the Section 20A Defendants.

262. Section 20A Defendants, by virtue of their positions as insiders of Isolagen, had access to, and were in possession of, material non-public information about the Company at the time they each sold their Isolagen common stock, respectively. As alleged above, the Section 20A Defendants violated Sections 10(b) and 20(a) of the Exchange Act. In particular, as alleged more fully above in ¶¶ 79 to 240, Section 20A Defendants had actual knowledge of the misrepresentations and 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. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Isolagen's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' misstatements regarding the Company's business and operations, including, as alleged more fully above in ¶¶ 79 to 240, the efficacy and safety of the Isolagen Process and the development status of Isolagen's ACE system throughout the Class Period, Section 20A Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

263. During the Class Period, and with the Company's stock trading at artificially inflated prices, Defendants DeLape, Macaluso, Boss, Marko and Tomz collectively sold at least 1.6 million shares of their personally held Isolagen stock for gross proceeds of over $12 million, as set forth in the following chart:

NAME	**DATE**	**SHARES**	**PRICE**	**PROCEEDS RECEIVED**
Frank DeLape	6/15/2004 11/3/2004	293,270 400,000	$8.50 $6.33	$2,492,795 $2,532,000

Total		693,270		$5,024,795
Michael Macaluso	11/3/2004	400,000	$6.33	$2,532,000
Michael Avignon	11/3/2004	400,000	$6.33	$2,532,000
William K. Boss	6/15/2004	304,885	$8.50	$2,591,522
Olga Marko	6/15/2004	227,258	$8.50	$1,931,693
	11/3/2004	400,000	$6.33	$2,532,000
Total		627,258		$4,463,693
Jeffy W. Tomz	6/15/2004	24,587	$8.50	$208,989

264. These sales were made contemporaneously with Class members' purchases of Isolagen common stock in the Secondary Offering. In particular, among other contemporaneous purchases by Class Members, Silverback Master purchased 20,000 shares of Isolagen common stock on November 3, 2004, a purchase made contemporaneously with the Section 20A November 2004 Selling Defendants' sales of 1.6 million shares of Isolagen common stock on November 3, 2004.

265. All members of the Class who purchased shares of Isolagen common stock contemporaneously with sales of Isolagen common stock by the Section 20A Defendants (i) have suffered damages because, in reliance on the integrity of the market, they paid artificially inflated prices for Isolagen common stock as a result of the violations of Section 10(b) and 20(a) of the Exchange Act as alleged herein; and (ii) would not have purchased Isolagen common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the Section 20A Defendants' material false and misleading statements, omissions and concealment. At the time of the purchases of Isolagen stock by members of the Class who purchased in the Secondary Offering, the fair and true market value of Isolagen common stock was substantially less than the price paid by these Class members.

IX. LOSS CAUSATION

266. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Lead Plaintiffs and the Class.

267. During the Class Period, Lead Plaintiff and the Class purchased securities of Isolagen at artificially inflated prices and were damaged thereby. The prices of Isolagen securities declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, in whole or in part, causing investors' losses.

X. INAPPLICABILITY OF STAUTORY SAFE HARBOR

268. 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. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Isolagen who knew that those statements were false when made.

XI. FACTUAL ALLEGATIONS PERTINENT TO CLAIMS FOR RELIEF UNDER THE SECURITIES ACT

269. Lead Plaintiffs repeat and reallege each the allegations contained in ¶¶ 15 to 78 above, as if fully set forth herein.

270. The facts relevant to claims under the Securities Act are, as explained in greater detail below, that Isolagen's registration statements and prospectuses filed with the SEC

contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading.

271. As stated above in ¶ 14, in the allegations and claims set out in this part of the Complaint (Count Four through Count Nine), Lead Plaintiffs assert a series of strict liability and negligence claims based on the Securities Act. The Securities Act claims are asserted against those defendants who are statutorily responsible under sections 11 and 12(a)(2) of the Securities Act for the material untrue statements and misleading omissions in the registration statements and prospectuses pursuant to which Isolagen issued securities to the public, as described below. These defendants include the Company itself, its directors and officers, all signatories to Isolagen's registration statements and prospectuses, and the underwriters – who, in acting as professional gatekeepers for the investing public, are statutorily liable for materially inaccurate statements contained in Isolagen's registration statements and prospectuses. In this second set of claims, Lead Plaintiffs also assert control person liability under section 15 of the Securities Act against various principals of Isolagen, including directors and officers of Isolagen. Lead Plaintiffs' Securities Act claims are not based on any knowing or reckless misconduct on behalf of the defendants – *i.e.*, they do not allege, and do not sound in, fraud. Lead Plaintiffs specifically disclaim any allegations of fraud in these non-fraud claims under the Securities Act.

A. Untrue Statements and Omissions of Material Fact Contained in the Secondary Registration Statement

272. The Secondary Registration Statement (including the Prospectus) contained numerous untrue statements and omissions of material fact.

273. Concerning the Company's clinical experience and ability to submit an application for FDA approval, the Secondary Registration Statement stated that:

> ... Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create

> safe and effective therapies to treat the underlying cause of the patient's condition...
>
> * * *
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. We are planning to initiate two pivotal Phase III clinical trials for this product candidate during the third quarter of 2004. We expect to file a Biologics License Application for this product candidate during the first quarter of 2005.... [Emphasis added].

(Reg. St at 1; Prospectus at 1).

274. The statements in ¶ 273 concerning the efficacy of the Isolagen Process were untrue because the Company omitted to mention the material facts that (i) the Process frequently failed to demonstrate any objectively measurable improvement in facial wrinkles, scars, or other facial deformities; and (ii) that any objectively measurable improvement in facial wrinkles, scars, or other facial deformities was short-lived.

275. The statement in ¶ 273 concerning the Company's plan to file a BLA in the first quarter of 2005 was untrue because the Company lacked a protocol for a consistent and proper injection technique, and because the Process was resulting in highly inconsistent results in clinics in the United Kingdom.

276. Concerning the Company's target market, the Secondary Registration Statement also stated:

> ***Our Target Market Opportunity***
>
> * * *
>
> Aesthetic Market. According to the American Society for Aesthetic Plastic Surgery, more than 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than

> 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 39 to 57, representing over 27% of the U.S. population...

(Reg. St. at 1; Prospectus at 1).

277. The statements in ¶ 276 concerning the Company's target market were untrue because they omitted mention of the material fact that half or more of the targeted "baby boomer" market could not obtain any objectively measurable improvement in facial wrinkles, scars, or other facial deformities through use of the Isolagen Process.

278. Concerning the Company's planned automated manufacturing system, the Secondary Registration Statement stated, in relevant part:

> We are in the final stages of developing our new Automated Cell Expansion, or ACE, System. We believe our ACE System will yield significant improvements in the manufacturing process and reduce costs... We currently expect to introduce the ACE System for new patients in our United Kingdom facility in the fourth quarter of 2004.
>
> We have been collaborating with Applikon Biotechnology to patent the manufacturing system improvements beyond Applikon Biotechnology's existing patents. Our ACE System has been successful in the research setting, and we are now undertaking the design fabrication and qualification of the massed-produced single-use, disposable component...

(Reg. St. at 25; Prospectus at 25).

279. The statements in ¶ 278 concerning the 2004 introduction of the ACE system for patients in the United Kingdom were untrue because the ACE system had not been validated in a research or production setting and could not be implemented in a manner that would lead to

"significant cost reductions in both skilled labor and materials." Contrary to the statements in ¶ 278, the ACE system would not exist even in a demonstration form until much later.

280. Concerning the Company's studies of the clinical effects of the Isolagen Process in the United Kingdom, the Secondary Registration Statement stated, in relevant part:

> UK International Registry. We collected patient response data from 59 patients randomly chosen from a total of the approximately 400 patients treated as of November 2003 in the United Kingdom with our dermal product. This data was analyzed by an independent clinical research organization. The sampling reflects a cross section of all treated patients at all stages of treatment as of November 2003 rather than a summary of patients at some fixed time point.
>
> The results indicate that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results at six months and one year after first injection....

(Reg. St. at 26; Prospectus at 28).

281. The statements in ¶ 280 concerning the Company's clinical results in the United Kingdom were untrue because they omitted mention of the fact that the clinical results in the United Kingdom were, in fact, wildly inconsistent, and the Company had been changing its protocols and re-injecting patients who complained that the Process did not work.

B. Untrue Statements and Omissions of Material Fact Contained in the Convertible Notes Registration Statement

282. On February 1, 2005, Isolagen filed with the SEC a Registration Statement on Form S-3 in connection with its sale of the Convertible Notes and on May 2, 2005, Isolagen filed with the SEC an amended registration statement on Form S-3/A (collectively the "Convertible Notes Registration Statement").

283. Defendants CIBC and UBS were explicitly stated to be underwriters in the Convertible Notes Registration Statement.

284. Concerning the Company's clinical experience and ability to submit an application for FDA approval, the Convertible Notes Registration Statement stated:

> We specialize in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. Our first two product candidates, which are directed at the aesthetic and dental markets, utilize our proprietary Isolagen Process. Based on our accumulated clinical experience, we believe that our Isolagen Process can utilize the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition. Autologous cellular therapy is the process whereby a patient's own cells are extracted, allowed to multiply and then injected into the patient. Our product candidates are designed to be minimally invasive and non-surgical.
>
> We are developing our lead product candidate for the correction and reduction of the normal effects of aging, such as wrinkles and nasolabial folds. In March 2004, we announced positive results of our first Phase III clinical trial for our lead product candidate. In July 2004, we announced the commencement of two pivotal Phase III trials, which are being conducted in two different geographic and demographic populations in the United States as two identical trials for the treatment of facial wrinkles. These trials are randomized, double blind and placebo-controlled and are being conducted at various sites in the United States. The trials, which are being conducted simultaneously, each have in excess of 100 patients split evenly between the treatment group and the placebo group. Efficacy will be measured by a two-point improvement on a six-point scale, as evaluated by an independent assessor at four, six, nine and twelve months. We expect to file a Biologics License Application, or BLA, for this product candidate during the second half of 2005.

285. The statements in ¶ 284 concerning the Company's clinical trials to measure the efficacy of the Isolagen Process were untrue because Isolagen did not in fact design two identical trials for the treatment of facial wrinkles.

286. The statements in ¶ 284 concerning the Company's plan to file a BLA in the second half of 2005 were untrue because, in fact, the Company lacked the ability to file a BLA within that time-frame.

287. Concerning the Company's target market, the Convertible Notes Registration Statement stated:

> ***Our Target Market Opportunity***
>
> For the aesthetic market, we will target primarily dermatologists, plastic surgeons and cosmetic surgeons, and for the dental market, we will target dentists. We believe that both of these markets are influenced by consumer awareness of the available therapies and their benefits that drive patients to practitioners to seek out treatment.
>
> ***Aesthetic Market.*** According to the American Society for Aesthetic Plastic Surgery, nearly 8.3 million surgical and non-surgical cosmetic procedures were performed in 2003, up 20% from nearly 6.9 million in 2002. Consumer demand increased 22% in 2003 for non-surgical cosmetic procedures, exceeding more than 6.4 million procedures. Non-surgical procedures include injectable materials that are used to correct or reduce wrinkles and nasolabial folds. We believe growth in the aesthetic procedure market is driven by:
>
> • aging of the "baby boomer" population, currently ages 40 to 58, representing over 27% of the U.S. population; [Emphasis added].

288. The statements in ¶ 287 concerning the Company's target market of "baby boomers" were untrue when made because they omitted mention of material facts, including the fact that the Process was generally ineffective at treating facial wrinkles, scars or other facial deformities in patients over 45 years old.

289. Concerning the company's proposed automated manufacturing system, the Convertible Notes Registration Statement further stated:

> Automated Cell Expansion System. Recent refinements in our Automated Cell Expansion, or ACE, System and additional experience from U.K. operations and our clinical trials have allowed us to consider a number of different alternative technologies to wash and concentrate the cells that we harvest. We are presently evaluating the technological advantages and commercial viability of several options from other industry

> partners, in addition to a system we have been developing in conjunction with Applikon Biotechnology. We expect the implementation and commercial validation of our ACE System to be completed prior to the filing of the BLA. These technologies are based on low cost, commercially available cell concentration and washing devices, such as those used in the blood banking industry. We anticipate that the integration of either the Applikon or one of the alternative washing and collection technologies into our ACE System will allow us to reduce our variable costs and to increase our capacity.

290. The statements in ¶ 289 concerning the 2005 implementation and commercial validation of Isolagen's ACE System prior to the filing of the BLA were untrue because the Company could not in fact meet that time-frame.

XII. CLAIMS FOR RELIEF UNDER THE SECURITIES ACT

COUNT FOUR

Against Defendant Isolagen, Defendants Tomz, Macaluso, DeLape, Toh, De Martino, Morrell, and Webb and Defendants CIBC, Legg Mason and Adams Harkness For Violations of Section 11 of the Securities Act With Respect to the Secondary Offering

291. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if set forth fully herein, except any allegations that the Defendants made the untrue statements of material facts and omissions intentionally or recklessly. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all Class members who purchased or otherwise acquired Isolagen common stock pursuant and/or traceable to the Secondary Registration Statement and Prospectus and were damaged by acts alleged herein. For the purposes of this Count, Lead Plaintiffs assert only strict liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

292. This claim is asserted against (i) Defendant Isolagen; (ii) Individual Defendants Tomz, Macaluso, and DeLape, and Director Defendants Toh, De Martino, Morrell, and Webb, all of whom signed the Secondary Registration Statement and were directors at the time of the

filing of the Secondary Registration Statement with the SEC; and (iii) Defendants CIBC, Legg Mason and Adams Harkness who, pursuant to their underwriting agreements, were the underwriters and sellers of the common stock sold in the Secondary Offering within the meaning of the Securities Act. Defendants CIBC, Legg Mason and Adams Harkness participated in the preparation of the Secondary Registration Statement, and were responsible for its contents and dissemination.

293. As set forth more fully in ¶¶ 272 to 281 above, the Secondary Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading.

294. As a result of the material misrepresentations in and omissions from the Secondary Registration Statement, Defendant Isolagen, as the issuer of the registered securities is strictly liable to investors who purchased securities in or traceable to the Secondary Registration Statement.

295. None of Individual Defendants Tomz, Macaluso, and DeLape, and Director Defendants Toh, De Martino, Morrell, and Webb and Defendants CIBC, Legg Mason and Adams Harkness made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Secondary Registration Statement as set out above were accurate and complete in all material respects. Had they exercised reasonable care, these defendants could have known of the material misstatements and omissions alleged herein.

296. Certain plaintiffs and other members of the Class purchased Isolagen securities issued in, or traceable to, the Secondary Offering, which was conducted pursuant to the Secondary Registration Statement.

297. At the time they purchased shares in the Secondary Offering, neither Lead Plaintiffs nor any member of the Class knew, or by the reasonable exercise of care could have known of the material misstatements and omissions contained in the Secondary Registration Statement.

298. Class members who purchased Isolagen securities in or traceable to the Secondary Registration Statement have sustained damages for which they are entitled to compensation.

299. Lead Plaintiffs brought this action within one year after the discovery of the misstatements and omissions contained in the Secondary Registration Statement, and within three years after the Secondary Offering.

COUNT FIVE

Against Defendant Isolagen, Defendants DeLape, Schmieg, Tomz, Toh, De Martino, Morrell and Webb and Defendants CIBC and UBS For Violations of Section 11 of the Securities Act in respect of the Convertible Notes Registration Statement

300. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if set forth fully herein, except allegations that defendants made the untrue statements of material facts and omissions intentionally or recklessly. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all Class members who purchased or otherwise acquired Isolagen securities traceable to the Convertible Notes Registration Statement and were damaged by acts alleged herein. For the purposes of this Count, Lead Plaintiffs assert only strict liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

301. This claim is asserted against (i) Defendant Isolagen; (ii) Individual Defendants DeLape, Schmieg, Tomz, Toh, De Martino, Morrell and Webb, all of whom signed the Convertible Notes Registration Statement and/or were directors at the time of the filing of the

Convertible Notes Registration Statement with the SEC; and (iii) Defendants CIBC and UBS who were the underwriters and sellers of the securities sold pursuant to the Convertible Notes Registration Statement within the meaning of the Securities Act. Defendants CIBC and UBS were responsible for the contents and dissemination of the Convertible Notes Registration Statement.

302. As set forth more fully in ¶¶ 282 to 290 above, the Convertible Notes Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading.

303. As a result of the material misrepresentations in and omissions from the Convertible Notes Registration Statement, Defendant Isolagen, as the issuer of the registered securities is strictly liable to investors who purchased securities in or traceable to the Convertible Notes Registration Statement.

304. None of Individual Defendants DeLape, Schmieg, Tomz, Toh, De Martino, Morrell and Webb and Defendants CIBC and UBS made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Convertible Notes Registration Statement as set out above were accurate and complete in all material respects. Had they exercised reasonable care, these defendants could have known of the material misstatements and omissions alleged herein.

305. Certain plaintiffs and other members of the Class purchased Isolagen securities issued in, or traceable to, the offering of Isolagen securities that was conducted pursuant to the Convertible Notes Registration Statement.

306. At the time they purchased Isolagen securities pursuant to the Convertible Notes Registration Statement, neither Lead Plaintiffs nor any member of the Class knew, or by the

reasonable exercise of care could have known of the material misstatements and omissions contained in the Convertible Notes Registration Statement.

307. Class members who purchased Isolagen securities in or traceable to the Convertible Notes Registration Statement have sustained damages for which they are entitled to compensation.

308. Lead Plaintiffs brought this action within one year after the discovery of the misstatements and omissions contained in the Convertible Notes Registration Statement, and within three years after the offering of Isolagen securities conducted pursuant to the Convertible Notes Registration Statement.

COUNT SIX

Against Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness For Violations of Section 12(a)(2) of the Securities Act With Respect to the Secondary Offering

309. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if set forth fully herein, except any allegations that the Defendants made the untrue statements of material facts and omissions intentionally or recklessly. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77k, on behalf of all Class members who purchased or otherwise acquired Isolagen common stock pursuant to the Secondary Registration Statement and Prospectus and were damaged by acts alleged herein. For the purposes of this Count, Lead Plaintiffs assert only strict liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

310. This claim is asserted against Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness who, pursuant to their underwriting agreements, were the underwriters and sellers of the common stock sold in the Secondary Offering within the meaning

of the Securities Act. As such, Defendants CIBC, Legg Mason and Adams Harkness participated in the preparation of the Secondary Registration Statement, and were responsible for its contents and dissemination.

311. By means of the Secondary Registration Statement, and by using means and instruments of transportation and communication in interstate commerce and of the mails, Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness, through public offerings, offered and sold Isolagen common stock to members of the Class.

312. As set forth more fully in ¶¶ 272 to 281 above, the Secondary Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading.

313. Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness owed to the purchasers of Isolagen common stock, including Class members, the duty to make a reasonable and diligent investigation of the statements contained in the Secondary Registration Statement to ensure that it was true and that there was no omission to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

314. Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness did not make a reasonable and diligent investigation and did not possess reasonable grounds for the belief that the statements contained in the Secondary Registration Statement, as set out above, were accurate and complete in all material respects. Had they exercised reasonable care, these defendants could have known of the material misstatements and omissions alleged herein.

315. Members of the Class purchased Isolagen securities based on the Secondary Registration Statement.

316. At the time they purchased shares in the Secondary Offering, no member of the Class knew, or by the reasonable exercise of care could have known, of the material misstatements and omissions contained in the Secondary Offering Statement.

317. Class members have sustained damages as a result of the misstatements and omissions in the Secondary Offering Statement, for which they are entitled to compensation.

318. Lead Plaintiffs brought this action within one year after the discovery of the untrue statements and omissions, and within three years of the Secondary Offering.

319. By reason of the foregoing, Defendant Isolagen and Defendants CIBC, Legg Mason and Adams Harkness are liable to the members of the Class who purchased or otherwise acquired Isolagen common stock in the Secondary Offering pursuant to the Secondary Registration Statement for violations of section 12(a)(2) of the Securities Act, each of whom has been damaged by reason of such violations.

COUNT SEVEN

Against Defendant Isolagen and Defendants CIBC and UBS For Violations of Section 12(a)(2) of the Securities Act With Respect to the Convertible Notes Registration Statement

320. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if set forth fully herein, except any allegations that the Defendants made the untrue statements of material facts and omissions intentionally or recklessly. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77k, on behalf of all Class members who purchased or otherwise acquired Isolagen securities pursuant to the Convertible Notes Registration Statement and were damaged by acts alleged herein. For the purposes of this Count, Lead Plaintiffs assert only strict liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

321. This claim is asserted against Defendant Isolagen and Defendants CIBC and UBS who were underwriters and sellers of the securities sold pursuant to the Convertible Notes Registration Statement within the meaning of the Securities Act. As such, Defendants CIBC and UBS were responsible for the contents and dissemination of the Convertible Notes Registration Statement.

322. By means of the Convertible Notes Registration Statement, and by using means and instruments of transportation and communication in interstate commerce and of the mails, Defendant Isolagen and Defendants CIBC and UBS, through public offerings, offered and sold Isolagen common stock to members of the Class.

323. As set forth more fully in ¶¶ 282 to 290 above, the Convertible Notes Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading.

324. Defendant Isolagen and Defendants CIBC and UBS owed to the purchasers of Isolagen securities, including Class members, the duty to make a reasonable and diligent investigation of the statements contained in the Convertible Notes Registration Statement to ensure that it was true and that there was no omission to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

325. Defendant Isolagen and Defendants CIBC and UBS did not make a reasonable and diligent investigation and did not possess reasonable grounds for the belief that the statements contained in the Convertible Notes Registration Statement, as set out above, were accurate and complete in all material respects. Had they exercised reasonable care, these defendants could have known of the material misstatements and omissions alleged herein.

326. Members of the Class purchased Isolagen securities based on the Convertible Notes Registration Statement.

327. At the time they purchased shares pursuant to the Convertible Notes Registration Statement, no member of the Class knew, or by the reasonable exercise of care could have known, of the material misstatements and omissions contained in the Convertible Notes Registration Statement.

328. Class members have sustained damages as a result of the misstatements and omissions in the Convertible Notes Registration Statement, for which they are entitled to compensation.

329. Lead Plaintiffs brought this action within one year after the discovery of the untrue statements and omissions, and within three years of the offering of Isolagen securities conducted pursuant to the Convertible Notes Registration Statement. By reason of the foregoing, Defendant Isolagen and Defendants CIBC and UBS are liable to the members of the Class who purchased or otherwise acquired Isolagen securities pursuant to the Convertible Notes Registration Statement for violations of section 12(a)(2) of the Securities Act, each of whom has been damaged by reason of such violations.

COUNT EIGHT

Control Person Liability Pursuant to Section 15 of the Securities Act Against Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman (Based on Violations of Section 11 of the Securities Act by Isolagen)

330. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if fully set forth herein, except allegations that Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman made the untrue statements of material facts and omissions intentionally or recklessly. For the purposes of this Claim, Lead Plaintiffs assert only strict

liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

331. Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman each acted as a controlling person of Isolagen within the meaning of Section 15 of the Securities 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 statements filed by the Company with the SEC and disseminated to the investing public, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman 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 false and misleading statements of material facts and omissions. Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead 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.

332. Further, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

333. In particular, the following facts evidence Defendants DeLape's, Macaluso's, Avignon's, Tomz' and Bitterman's control over Isolagen:

DeLape

(a) Throughout the Class Period, DeLape was Isolagen's Chairman of the Board of Directors. He became a member of the board of directors in June 2001, and Chairman of the Board of Directors in August 2001. DeLape also served as the Company's Interim Chief Executive Officer for approximately five months between April 2005 and October 2005. DeLape was one of three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) DeLape signed the Registration Statement, the Convertible Notes Registration Statement and the Company's annual and quarterly reports filed with the SEC. In addition, DeLape was one of Isolagen's primary spokespersons throughout the Class Period and touted the ability of the Company to successfully treat patients who were members of the target market to secure FDA approval for the Isolagen Process, and to develop an automated manufacturing system that would be sufficiently efficient to make the Process commercially viable.

(c) DeLape's status as a controlling person of Isolagen is also reflected in his employment agreement with Isolagen that was in effect throughout the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, DeLape was the beneficial owner of 8.6% of

Isolagen common stock. During the Class Period, DeLape was one of Isolagen's largest shareholders and thus had control by virtue of his substantial equity position.

Macaluso

(a) During the Class Period, Macaluso was Isolagen's President and CEO. He became a President and CEO in August 2001 and continued in that position until September 2004. Macaluso was also a Director of Isolagen between June 2001 and April 2005. Macaluso was one of three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) Macaluso signed the Registration Statement and the Company's annual and quarterly reports filed with the SEC. In addition, Macaluso was one of Isolagen's primary spokespersons who, during the Class Period and touted the ability of the Company to successfully treat patients who were members of the target market, to secure FDA approval for the Isolagen Process, and to develop an automated manufacturing system that would be sufficiently efficient to make the Process commercially viable.

(c) That Macaluso was a control person of Isolagen is also reflected in his employment agreement with Isolagen that was in effect during the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, Macaluso was the beneficial owner of 10.3% of Isolagen common stock, one of Isolagen's largest shareholders and thus had control by virtue of his substantial equity position.

Avignon

(a) Avignon was a founder of Isolagen who served as both Isolagen's President and Manager of International Operations. Avignon was one of three investors who recapitalized the Company, then known as American Financial Holdings, before the Company purchased its subsidiary, Isolagen Technologies, commenced its present line of operations, and renamed itself Isolagen, Inc.

(b) As of April 26, 2004, Avignon was the beneficial owner of 10.3% of Isolagen common stock. Avignon was one of Isolagen's largest shareholders during the Class Period and thus had control by virtue of his substantial equity position.

Tomz

(a) Tomz was appointed Secretary and Treasurer of Isolagen in June 2001. He resigned as Treasurer in August 2001, at which time he was appointed CFO. Tomz resigned as Treasurer and CFO in April, 2005, when he became Principal Financial and Accounting Officer of Isolagen.

(b) Tomz signed the Registration Statement, the Convertible Notes Registration Statement and the Company's annual and quarterly reports filed with the SEC. In addition, Tomz was one of Isolagen's primary spokespersons who, during the Class Period, participated in conference

calls and represented to investors that the Company had sufficient evidence to submit its BLA with the FDA.

(c) That Tomz was a control person of Isolagen is also reflected in his employment agreement with Isolagen that was in effect during the Class Period. The employment agreement included provisions for bonuses, confidentiality, and non-competition.

(d) As of April 26, 2004, Tomz was the beneficial owner of 1.2% of Isolagen common stock. Tomz was one of Isolagen's largest shareholders during the Class Period and thus had control by virtue of his substantial equity position.

334. As set forth above in ¶¶ 291 to 308, Defendant Isolagen violated Section 11 of the Securities Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Defendant Isolagen, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman are therefore liable pursuant to Section 15 of the Securities Act. As a direct and proximate result of Isolagen's and Defendants DeLape's, Macaluso's, Avignon's, Tomz' and Bitterman's conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

COUNT NINE

Control Person Liability Pursuant to Section 15 of the Securities Act Against Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman (Based on Violations of Section 12(a)(2) of the Securities Act by Isolagen)

335. Lead Plaintiffs repeat and reallege each and every allegation made in ¶¶ 269 to 290 above as if fully set forth herein, except allegations that Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman made the untrue statements of material facts and omissions

intentionally or recklessly. For the purposes of this Claim, Lead Plaintiffs assert only strict liability and negligence claims and expressly disclaim any allegation of fraud or intentional misconduct.

336. Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman each acted as a controlling person of Isolagen within the meaning of Section 15 of the Securities 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 statements filed by the Company with the SEC and disseminated to the investing public, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman 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 false and misleading statements of material facts and omissions. Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead 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.

337. Further, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

338. In particular, the facts set out more fully in ¶ 333 above evidence Defendants DeLape's, Macaluso's, Avignon's, Tomz' and Bitterman's control over Isolagen.

339. As set forth above in ¶¶ 309 to 329, Defendant Isolagen violated Section 12(a)(2) of the Securities Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Defendant Isolagen, Defendants DeLape, Macaluso, Avignon, Tomz and Bitterman are therefore liable pursuant to Section 15 of the Securities Act. As a direct and proximate result of Isolagen's and Defendants DeLape's, Macaluso's, Avignon's, Tomz' and Bitterman's conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XIII. PRESUMPTION OF RELIANCE

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

a. Isolagen's common stock met the requirements for listing, and was listed and actively traded on the AMEX, a highly efficient market;

b. During the Relevant Period, an average of 1.26 million Isolagen shares were traded every week on the AMEX;

c. As a regulated issuer, Isolagen filed periodic public reports with the SEC and the AMEX;

d. Isolagen regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

e. Isolagen was followed by at least three securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

f. As a result of the foregoing, the market for Isolagen's securities promptly digested current information regarding Isolagen from all publicly available sources and reflected such information in Isolagen's stock price. Under these circumstances, all purchasers of Isolagen's securities during the Class Period suffered similar injury through their purchase of Isolagen's securities at artificially inflated prices and a presumption of reliance applies.

341. The Convertible Notes were convertible into Isolagen common stock. As a result, their prices were linked in part to the price of Isolagen in part in reaction to fluctuations in the price of Isolagen common stock.

JURY TRIAL DEMAND

342. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Lead Plaintiffs, on behalf of themselves and the Class, hereby demand a trial by jury in this action of all issues so triable.

PRAYER FOR RELIEF

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

1. Awarding Lead Plaintiffs and the Class compensatory damages and/or rescission.

2. Awarding Lead Plaintiffs and the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs;

3. Awarding extraordinary, equitable and/or injunctive relief as permitted by law or equity to attach, impound, or otherwise restrict the Defendants' assets to assure Lead Plaintiffs and the Class have an effective remedy, and any appropriate state law remedies; and

4. Awarding such other relief as this Court may deem just and proper.

Dated: July 14, 2006

Respectfully Submitted,

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