UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

[redacted] individually and on behalf of all others similarly situated,

Plaintiffs,

v.

Accentia Biopharmaceuticals, Inc., Samuel S. Duffey, Francis E. O'Donnell, Jr., Brian D. Bottjer, Carlos F. Santos, Ronald E. Osman, and Steven R. Arikian,

Defendants.

DEMAND FOR JURY TRIAL

Civil Action No. _____

COMPLAINT

Plaintiffs ("Plaintiffs"), by and through their attorneys, individually and on behalf of all others similarly situated, file this complaint against defendants Accentia Biopharmaceuticals, Inc. ("Accentia"), Samuel S. Duffey, Francis E. O'Donnell, Jr., Brian D. Bottjer, Carlos F. Santos and Steven Arikian (collectively, "Defendants"), and allege as follows.

PRELIMINARY STATEMENT

This is a federal securities class action on behalf of two classes (defined further below) consisting of (1) all persons and entities who purchased the common stock of Biovest International, Inc., a Delaware corporation ("Biovest"), and (2) all persons and entities who purchased the common stock of Accentia Biopharmaceuticals, Inc., a Florida corporation, each Class commencing five years prior to the filing of this complaint through August 14, 2012, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of federal securities laws.

PARTIES

1. Plaintiff [redacted] purchased shares of Biovest common stock and Accentia common stock during the Class Period, as set forth in his certification attached hereto, and was damaged thereby.

2. Plaintiff [redacted] purchased shares of Biovest common stock and Accentia common stock during the Class Period, as set forth in his certification attached hereto, and was damaged thereby.

3. Plaintiff [redacted] purchased shares of Biovest common stock and Accentia common stock during the Class Period, as set forth in his certification attached hereto, and was damaged thereby.

4. Defendant Accentia Biopharmaceuticals, Inc. is a Florida corporation with its principal place of business in Tampa, Florida.

5. Defendant Samuel S. Duffey ("Duffey") was Chief Executive Officer and Principal Executive Officer of Biovest from December 11, 2011 until on or about July 2013, as well as President and General Counsel of Biovest from February 2009 until on or about July 2013. Duffey has also been Chief Executive Officer and Principal Executive Officer of Accentia since December 11, 2011, as well as President and General Counsel of Accentia since at least February 2009.[1]

6. Defendant Francis E. O'Donnell, Jr. ("O'Donnell") was Vice-Chairman of Biovest from 2003 to 2009, Chief Executive Officer and Chairman of the Board of Biovest from February 2009 to December 2011, and Executive Chairman of the Board of Directors since

[1] The website of Hopkins Capital Group (see par. 11 below) states that Duffey has served as General Counsel to Accentia since 2003 and President of Accentia since 2008.

December 2011. O'Donnell has also served as Chief Executive Officer of Accentia from 2003 to December 2011, and as Chairman of the Board of Directors of Accentia from May 2002 to December 2011.

7. Defendant Brian D. Bottjer ("Bottjer") was the Senior Accountant at Biovest from September 2006 to May 2007. He has served as Controller of Biovest since June 2007, and Principal Financial Officer and Principal Accounting Officer of Biovest since January 2011.

8. Defendant Carlos F. Santos ("Santos") served as Senior Vice President, Product Development & Regulatory Affairs of Biovest beginning in March 2009, and became Chief Executive Officer on or about July 2013. He has served as Chief Science Officer for Accentia sinced March 2009.

9. Defendant Ronald E. Osman ("Osman") has been a director of Biovest since November 2006.

10. Defendant Dr. Steven R. Arikian ("Arikian") was a director of Biovest beginning in June 2003, Chairman of the Board of Directors beginning in March 2004, and Chief Executive Officer and President beginning in September 2004. Arikian has also been a director of Accentia.

11. Biovest is not named as defendant herein as it has filed for bankruptcy protection.

12. Biovest and Accentia are both portfolio companies of Hopkins Capital Group. The management team of The Hopkins Capital Group includes defendants O'Donnell (Chairman, CEO and Manager), Duffey (general counsel) and Santos (Chief Science Officer).

JURISDICTION AND VENUE

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

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

15. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a substantial part of the conduct complained of herein occurred in this District.

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

CLASS ACTION ALLEGATIONS

17. Plaintiffs bring this action on their own behalf and on behalf of a class pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) consisting of all persons or entities who purchased the common stock of Biovest during the Class Period and who were damaged thereby (the "Biovest Class"). Excluded from the Biovest Class are Biovest, Accentia, Defendants, the current and former officers and directors of Biovest and Accentia, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which any Defendant has or had a controlling interest.

18. Plaintiffs also bring this action on their own behalf and on behalf of a class pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) consisting of all persons or entities

who purchased the common stock of Accentia during the Class Period and who were damaged thereby (the "Accentia Class"). Excluded from the Accentia Class are Biovest, Accentia, Defendants, the current and former officers and directors of Biovest and Accentia, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which any Defendant has or had a controlling interest.

19. This action is properly maintainable as a class action under Federal Rule of Civil Procedure 23.

20. Each Class is so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, on information and belief there are at least hundreds, and likely thousands, of members in each class.

21. Biovest's Form 10-K filed on December 26, 2012 states that there were approximately 400 shareholders of record (other than Accentia) as of November 30, 2012 and approximately 147 million shares outstanding. Beneficial owners of Biovest shares are believed to number in the thousands. The average daily volume of Biovest shares traded during the last three months was approximately 130,000 shares.

22. Accentia's Form 10-K filed on December 26, 2012 states that there were approximately 150 shareholders of record as of November 30, 2012 and approximately 90 million shares outstanding. Beneficial owners of Accentia shares are believed to number in the thousands. The average daily volume of Accentia shares traded during the last three months was approximately 186,000 shares.

23. Members of each Class may be identified from records maintained by Biovest and Accentia or their transfer agents and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

24. There are questions of law and fact which are common to each Class and which predominate over questions affecting any individual member of each Class. The common questions include, *inter alia*, the following:

(a) whether Defendants violated the federal securities laws as alleged herein;

(b) whether the misstatements and omissions alleged herein were made with scienter;

(c) whether statements made by Defendants to the investing public during the Class Period misrepresented and/or omitted material facts; and

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

25. Plaintiffs' claims are typical of the claims of the other members of both Classes, and Plaintiffs do not have any interests adverse to the Classes.

26. Plaintiffs are adequate representatives of the Classes, have retained competent counsel experienced in litigation of this nature, and will fairly and adequately protect the interests of the Classes.

27. The prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications with respect to individual members of the Classes which would establish incompatible standards of conduct for the parties opposing the Classes.

28. Defendants have acted on grounds generally applicable to the Classes with respect to the matters complained of herein, thereby making appropriate the relief sought herein with respect to the Classes as a whole.

29. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of each Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FACTUAL ALLEGATIONS

30. Biovest is a biotechnology company in the business of developing therapeutic cancer vaccines. Its primary business activity involves the development of BiovaxID, a potential vaccine for the treatment of non-Hodgkin's lymphoma. Biovest conducted two Phase II clinical trials, and one Phase III clinical trial of BiovaxID which was completed in 2008.

31. Accentia acquired an 81% interest in Biovest in June 2003. As of September 30, 2012, Accentia owned approximately 59% of Biovest's outstanding common stock. The BiovaxID vaccine being developed by Biovest is and has been the most material element in Accentia's business and financial prospects.

32. Biovest and Accentia have common management. Defendant Duffey has been Chief Executive Officer and Principal Executive Officer of both Biovest and Accentia since December 11, 2011. Defendant O'Donnell was Chief Executive Officer of both companies prior to Duffey, and he served as Chairman of the Board of both companies. Defendant Santos is both Senior Vice President, Product Development & Regulatory Affairs of Biovest and Chief Science

Officer for Accentia. Defendant Arikian has served as a director of both Biovest and Accentia. Douglas W. Calder ("Calder") is the head of investor relations and Vice President, Strategic Planning & Capital Markets, for both Accentia and Biovest. Calder is also listed as the head of Investor Relations on The Hopkins Capital Group website (http://www.hopkinscap.com/contact.php).

33. The BiovaxID vaccine was originally developed by the National Cancer Institute (NCI). On June 21, 2001, NCI filed a Phase III clinical trial protocol (the "BV301 protocol") with the United States Food and Drug Administration (FDA).

34. The BV301 protocol stated that the primary endpoint of the study was "[t]o determine the impact of Id immunization on clinical disease-free survival (DFS) of FL [follicular lymphoma] patients achieving a CR [complete remission] with standard dose chemotherapy."

35. The BV301 protocol also detailed how the data would be analyzed.

> Disease free survival will be calculated from date of randomization until date of relapse or last follow-up of patients, and will include all randomized patients . . . . Any subgroup analysis. . . will be considered exploratory and reported as such.

36. The provision in the protocol that the primary endpoint of disease-free survival would be "calculated from the date of randomization" was consistent with the intention-to-treat principle ("ITT") for clinical studies. ITT requires that all participants that are randomized must be included in the final analysis and analyzed according to the treatment group to which they were originally assigned.

37. Clinical trials often have difficulties with things such as missing data or failure to adhere to protocol. To address these difficulties, many clinical trials exclude participants after the initial random assignment of participants. Analysis of trial results that does not include excluded participants is known as the modified intent-to-treat methodology ("mITT").

38. The protocol for the trial also specified a projected p-value of 0.01 or better as a standard for determining statistical significance in the results.[2]

39. In 2004, NCI transferred the development of the BiovaxID vaccine to Biovest.

40. There was a teleconference meeting between Biovest and the FDA on May 10, 2005 concerning the BiovaxID Phase III clinical trial.[3] During the teleconference meeting, the FDA informed Biovest that primary efficacy of the vaccine "must be based on all patients randomized (not . . .mITT . . . .)". Department of Health & Human Services, Meeting Summary re BiovestID, July 31, 2012, at 7 (attached hereto as Exhibit A). In other words, Biovest was informed that the statistical analysis of the trial would have to be on the ITT basis, not mITT.[4]

41. The Phase III clinical trial closed on April 15, 2008, and the clinical data from the trial was locked on June 30, 2008. Exh. A at 2.

42. On June 9, 2008, Biovest submitted a draft Statistical Analysis Plan (SAP to the FDA. Exh. A at 2.

43. The FDA never responded to or finalized Biovest's SAP.

44. Biovest and the FDA held a teleconference on September 24, 2008. In that teleconference, the FDA "remind[ed] [Biovest] that the primary ITT analysis will need to include **all patients randomized.**" Exh. A at 7. (emphasis added)

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[2] In statistical significance testing, the ***p*-value** is the probability of obtaining a test statistic at least as extreme as the one that was actually observed, assuming that the null hypothesis is true. The null hypothesis asserts that there is no difference between a group receiving an intervention and a control group, *i.e.*, that the intervention produces no effect. The lower the p-value, the more statistically significant are the test results, and the less likely are the test results to be due to chance.

[3] There are three phases of clinical trials for potential new drugs: Phase I, Phase II, and Phase III. Phase III is the usually the last stage of clinical trials leading up to approval or disapproval of the drug.

[4] There were 177 patients initially randomized in the trial, and only 117 patients entered the treatment phase of the trial and were randomized as to whether they received the vaccine or a placebo. Exh. A at 4.

45. The FDA further informed Biovest:

> that **the overall efficacy and safety datasets** submitted in the meeting package **do not appear to be sufficient** to support a BLA [Biologics License Application]. **FDA recommends that the sponsor** lay out their next developmental plan in their next submission and **consider designing a new study**.

Exh. A at 7 (emphasis added).

46. Biovest representatives attended an in person meeting with the FDA on September 8, 2010. According to the official minutes of that meeting, the FDA advised Biovest that during the September 24, 2008 teleconference:

> we identified and advised you of a number of major deficiencies with regard to the sample size, design, conduct, and statistical analysis of Study Protocol BV301 [*i.e.*, the Phase III clinical trial]. . . .These deficiencies render Study BV301 on its face scientifically incomplete to establish clinical evidence of effectiveness. . . .
>
> Exh. A at 7.

47. The September 8, 2010 meeting minutes further reflect that the FDA informed Biovest that "if an application is filed based primarily on the evidence from Study BV301 . . . [w]e would refuse to file such an application." Exh. A at 7.

48. The FDA recommended at the September 8, 2010 meeting "that [Biovest] submit a proposal for a new study that would constitute an adequate and well-controlled study." Exh. A at 7.

49. Since the closure of the BV301 Phase 3 clinical trial in April 2008, Biovest did not propose or conduct further clinical studies of BiovaxID. Exh. A at 7.

50. An in person meeting between Biovest and the FDA was held on July 31, 2012. Defendants Duffey and Santos attended the meeting along with other Biovest representatives.

The official minutes of the meeting were transmitted to Biovest by facsimile dated August 29, 2012 addressed to Santos.

51. According to the official minutes of the July 31, 2012 meeting, Biovest's objective for the meeting "was to find an alternative solution to FDA's recommendation to conduct a new Phase III clinical trial for BiovaxID in light of their current financial realities." Exh. A at 4.

52. The Executive Summary contained in the July 31, 2012 meeting minutes includes the following statements by the FDA:

a) the BV301 clinical trial results did not reach statistical significance, by either the intent-to-treat (ITT) or modified intent-to-treat (mITT) analysis. Thus, BV301 failed to show effectiveness of BiovaxID;

b) FDA reiterated that if Biovest were to submit an application based on BV301 results, such a submission would be scientifically incomplete;

c) FDA pointed out that the path forward was for Biovest to conduct new trial(s) as the available information was not sufficient to support a submission.

Exh. A at 3-4.

DEFENDANTS' FALSE STATEMENTS

53. Contrary to the repeated advice of the FDA that the results of BV301 (the Phase III clinical trial) did not support an application for approval of BiovaxID, Defendants repeatedly made statements touting the success of the Phase III clinical trial, and representing that Biovest was on the path to FDA approval of the BiovaxID vaccine.

54. On July 17, 2008, Biovest issued a press release with the headline: "Biovest Reports Results...Demonstrates Clinically and Statistically Significant Improvement of Disease-Free Survival in Non-Hodgkin's Lymphoma in Pivotal Phase 3 Clinical Trial".

55. The July 17, 2008 press release identified Biovest as a majority-owned subsidiary of Accentia with Accentia's trading symbol.

56. The July 17, 2008 press release made the following false and misleading statements:

> --the "overall median disease-free survival increased by more than one year (p-value = 0.047)," and that BiovaxID had the "potential to be the first ever anti-cancer vaccine approved in US and/or Europe."
>
> --"Biovest intends to move forward with plans to seek accelerated and/or conditional regulatory approvals in the US and European Union, respectively."
>
> --there was "clinically and statistically significant unblinded data from [Biovest's] randomized controlled pivotal Phase III... clinical trial...."

57. The July 17, 2008 press release was false and misleading, and omitted to state material facts in that: (a) the protocol for the clinical trial called for analysis of disease-free survival (DFS) based on data for **all** randomized patients (i.e., 177 patients) (ITT) but the reported "statistically significant" trial data and the reported increase in disease-free survival were based on a smaller subset of 117 patients (i.e., mITT); (b) the mITT analysis of the data was contrary to the FDA's position that primary efficacy of the vaccine "must be based on all patients randomized (not . . . mITT)" that was communicated to Biovest on May 10, 2005 as alleged above;[5] (c) the patient cohort of the 177 randomized patients did **not** demonstrate

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[5] Moreover, the Phase 3 clinical trial had incomplete trial enrollment, in that the trial was terminated after less than half of the planned number of subjects were randomized.

statistically significant difference in median disease-free survival (DFS); (d) the draft Statistical Analysis Plan submitted to the FDA on June 9, 2008 had not been approved; (e) the trial protocol specified a projected p-value of 0.01 or better as a standard for determining the statistical significance of the results, while the "statistically significant" data touted in the press release was based on the substantially higher p-value of 0.045; (f) there was no basis for the statement that "Biovest intends to move forward with plans to seek accelerated and/or conditional regulatory approvals in the US" because the trial data was not consistent with the FDA's requirement that primary efficacy of the vaccine "must be based on all patients randomized (not . . . mITT);" and (g) the press release failed to disclose what the FDA told Biovest on May 10, 2005.

58. On October 7, 2008, only two weeks after the September 24, 2008 teleconference with the FDA alleged above, Biovest issued a press release with the false and misleading headline that the BiovaxID vaccine "Prolongs Cancer-Free Survival by 44%" and that Biovest "Intends to Seek Approval in the U.S. and Internationally." The headline was false and misleading for the same reasons set forth in paragraph 56 above and for the additional reason that the FDA had informed Biovest in the September 24, 2008 conference that (i) the analysis had to include all patients randomized, (ii) that the data submitted at the conference did not appear sufficient to support a license application, and (iii) that the FDA recommended that Biovest "**lay out their next development plan** in their next submission and **consider designing a new study**," as alleged above.

Exh. A at 7 (emphasis added).

59. The October 7, 2008 press release identified Biovest as a majority-owned subsidiary of Accentia with Accentia's trading symbol. Accentia filed a form 8-K with the SEC on October 7, 2008, with the Biovest October 7, 2008 press release as an exhibit.

60. The October 7, 2008 press release contained the following false and misleading representation.

> The intent-to-treat (ITT) analysis from the point of randomization **for all patients in the trial who received at least one dose of BiovaxID** or control vaccination (n=117...) showed...clinically and statistically significant [results] compared to the control arm . . . ."
>
> (Emphasis added).

61. This statement was false and misleading because an analysis from the point of randomization for patients who received a dose of either the vaccine or control was an mITT analysis, not ITT, and it was contrary to the FDA's advice at the May 10, 2005 conference, reiterated by the FDA at the September 24, 2008 conference, that primary efficacy of the vaccine "must be based on all patients randomized," not the more limited number of patients who were still in the trial at the point of randomization when patients were given either the vaccine or the control.

62. The October 7, 2008 press release also gave the misleading impression that there was reason to believe the results of the trial put Biovest on track to obtain FDA approval. The press release stated as follows:

> After a recent meeting with the FDA, the Company closed the clinical trial, [and] unblinded the patients . . . . The Company has committed to provide the FDA with a detailed clinical report based on this end-of-study data, including statistical analysis . . . . [T]he Company now believes that it would be unethical to withhold BiovaxID from control patients, and that the study, therefore, is closed.

63. The October 7, 2008 press release again falsely represented that the analysis of 117 patients "is clinically and statistically significant," notwithstanding that Biovest had been told by the FDA that efficacy "must be based on all patients randomized (not...mITT....)."

64. Dr. Steven Arikian, the then-Chairman and CEO of Biovest and a director of Accentia, "commented on the Company's plans to seek U.S. and international approvals for BiovaxID." Dr. Arikian was quoted in the October 7, 2008 press release as stating:

> We believe that these strongly positive clinical results make it unethical to continue the trial as originally designed....Accordingly, we will be seeking... to file for Accelerated Approval in the U.S.

65. Defendant Arikian's statement was false and misleading in that the "strongly positive clinical results" were based on an mITT analysis of only the patients in the trial at the point of randomization in administering either the vaccine or a control, and not an analysis of all patients originally enrolled in the trial, as required by the FDA, and it failed to disclose the FDA's position that was communicated to Biovest at the May 10, 2005 and September 24, 2008 conferences. The statement that "we will be seeking... to file for Accelerated Approval in the U.S." was false and misleading for the same reasons, and for the additional reason that it flew in the face of, and omitted to disclose, the FDA's recommendation that Biovest "**lay out their next development plan** in their next submission and **consider designing a new study**."
Exh. A at 7 (emphasis added).

66. The false and misleading representation that the results of the Phase III clinical trial were "clinically and statistically significant" was repeated in a press release issued by Biovest on May 31, 2009. The press release bore the headline "Positive, Clinically Significant Phase III Results for Personalized Anti-Cancer Vaccine, BiovaxID, Presented at ASCO Plenary Session."

67. The May 31, 2009 press release identified Biovest as a majority-owned subsidiary of Accentia with Accentia's trading symbol. Accentia filed a form 8-K with the SEC on May 31, 2009, with the Biovest May 31, 2009 press release as an exhibit.

68. Defendant O'Donnell, who was then Chairman of the Board of Directors and Chief Executive Officer of both Biovest and Accentia, was quoted in the May 31, 2009 press release as follows:

> Despite the failures of other lymphoma vaccines...our unprecedented results presented today are a tribute to the more than 37 years of dedicated vision and labor by researchers....We congratulate and thank all that have been involved at every level in developing this ultimate targeted therapy....

69. The May 31, 2009 press release also contained a quotation from Duffey, who was then President and General Counsel of both Biovest and Accentia, as follows:

> In addressing regulatory and commercial plans for BiovaxID, Biovest's President and General Counsel, Samuel Duffey, commented, "We have already initiated discussions with the FDA...and are preparing for further meetings ...in order to share our significant results and determine the most appropriate approval regulatory pathways."

70. The May 31, 2009 press release was false and misleading, and omitted material facts, for the same reasons set forth in paragraphs 56, 57, 60 and 64 above.

71. Biovest issued yet another false and misleading press release on December 20, 2010. The press release contained at least the following false and misleading representations:

a) "BiovaxID represents the only lymphoma vaccine . . . to demonstrate positive clinical benefit and a completed, randomized Phase III clinical trial;"

b) "these data...clearly and unambiguously demonstrate that BiovaxID provides substantial benefits to patients diagnosed with follicular lymphoma;"

c) "accordingly, under our regulatory strategy, we plan to pursue marketing approval for BiovaxID...without conducting additional lengthy pre-approval clinical trials;" and

d) "this outcome [of the Phase III clinical trial] was statistically significant ($p = 0.045$)."

72. Defendant Santos was quoted in the December 20, 2010 press release as follows:

> Dr. Santos clarified Biovest's regulatory strategy. "It is important to note that our Phase III study achieved statistical significance for disease-free survival (p = 0.045) in the prospectively-identified, modified intent-to-treat population which analyzed all patients who were treated with BiovaxID or control. . . . Those previously announced results . . . form the foundation for our regulatory strategy. . . . Accordingly, we believe that the findings reported today will further cement the efficacy of BiovaxID and will play a significant role in our planned regulatory discussions."

73. The December 20, 2010 press release identified Biovest as a majority-owned subsidiary of Accentia and had a link to Accentia's trading symbol.

74. The December 20, 2010 press release was false and misleading, and omitted material facts, for the same reasons set forth in paragraphs 56, 57, 60 and 64 above. The press release also failed to disclose that the FDA had expressly told Biovest at the September 24, 2008 meeting alleged above that an application based on the BV301 clinical trial would be rejected.

75. Santos, Biovest's Senior Vice President, Scientific and Regulatory Affairs for Biovest, and Chief Science Officer for Accentia, made a presentation on March 14, 2011 at a Roth OC Growth Stock Conference. In his presentation, Santos falsely represented that: "The important question with regards to the regulatory strategy is there's no question that the vaccine works. The formal randomized trial has demonstrated that it provides benefit."

76. In response to a question at the Roth conference as to when Biovest would be filing its application for approval of BiovaxID, Santos stated: "this year, we will be, we will be filing for, yes." He further stated that "we are very confident going in that we are going to have a very high quality packet [i.e., application]. It will be this year."

77. The statements made at the Roth conference were false and misleading, and omitted material facts, in that the FDA had informed Biovest that the "formal randomized trial" would not support an application and that any application would be rejected. Santos knew, or recklessly disregarded, that "with regards to the regulatory strategy," the FDA did not accept the

results of the trial and would reject an application based on the trial. Santos's statement that "we are very confident going in that we are going to have a very high quality packet [i.e., application]" was totally false and misleading in light of the FDA's position.

78. On October 6, 2011, Biovest issued a press release announcing that "it has started the process to conduct clinical pre-filing discussions with various regulatory agencies including . . . the [FDA]." This statement was false and misleading for the reasons set forth in paragraphs 56, 57, 60, 64 and 72 above, and in particular because the FDA had told Biovest in September 2010 that an application based on the clinical trial would be rejected and that Biovest needed to conduct another clinical trial.

79. The October 6, 2011 press release identified Biovest as a majority-owned subsidiary of Accentia with Accentia's trading symbol.

80. Biovest filed an annual report on Form 10-K for the fiscal year ended September 30, 2011 on December 19, 2011 (the "Biovest 2011 10-K"). Biovest falsely represented in the Business/Overview section of the Form 10-K that

> BiovaxID has demonstrated statistically significant Phase 3 clinical benefit. . . .We believe that these clinical trials have demonstrated that BiovaxID . . . is effective in the treatment of these life-threatening diseases.

81. The Biovest 2011 10-K was signed by Defendants O'Donnell, Bottjer and Osman, as Chief Executive Officer, Acting Chief Financial Officer, and Director, respectively.

82. The statement in the Biovest 2011 10-K quoted above was false and misleading, and omitted material facts, for the reasons set forth in paragraphs 56, 57, 60, 64 and 72 above, and in particular because the FDA had informed Biovest that the Phase 3 clinical trial would not support an application and that a new clinical trial would have to be conducted.

83. Accentia filed an annual report on Form 10-K for the fiscal year ended September 30, 2011 on December 19, 2011 (the "Accentia 2011 10-K"), which was signed by O'Donnell as Chairman of the Board and Chief Executive Officer.

84. The Accentia 2011 10-K, in a section entitled "Results of Phase 3 Clinical Trial," represented that of the 117 patients that represented a mITT population who received either the BiovaxID vaccine or the control, "a statistically significant improvement of 13.6 months was observed in DFS [disease-free survival] of patients who received the vaccine." This statement was false and misleading in failing to disclose that the FDA would not accept a mITT analysis, and that statistical significance was based on a p-value of 0.045, which was materially higher than the protocol specification of a p-value of less than 0.01 to demonstrate statistical significance.

85. The Accentia 2011 10-K in a section entitled "BiovaxID Regulatory Status" made the following false and misleading statement concerning the regulatory status of BiovaxID.

> Biovest is in the process of conducting clinical pre-filing discussions with domestic and international regulatory agencies to discuss the potential regulatory approval pathway for BiovaxID. Biovest is focusing on its plan to see regulatory approval for BiovaxID . . . and these clinical pre-filing regulatory agency meetings are anticipated to confirm the next steps and requirements in the regulatory process.

86. This statement was false and misleading in failing to disclose that the FDA had informed Biovest that the Phase 3 clinical trial would not support an application, that any application based on the results of the trial would be rejected, and that a new clinical trial was recommended.

87. Biovest filed an S-1 registration statement with the SEC on March 30, 2012, which repeated some of the false and misleading statements concerning BiovaxID alleged above.

The registration statement was false and misleading in representing that the Phase 3 clinical trial demonstrated statistically significant benefits and the efficacy of BiovaxID.

> BiovaxID has demonstrated statistically significant Phase 3 clinical benefit by prolonging disease-free survival in FL patients treated with BiovaxID. We believe that these clinical trials demonstrate the safety and efficacy of BiovaxID.

88. In a section of the March 30, 2012 registration statement entitled "BiovaxID Regulatory Status", the following false and misleading statement was made:

> We are in the process of conducting clinical pre-filing discussions with domestic and international regulatory agencies to discuss the potential regulatory approval pathway for BiovaxID. We are focusing on our plans to seek regulatory approval for BiovaxID for the treatment of FL and these clinical pre-filing regulatory agency meetings are anticipated to confirm the next steps and requirements in the regulatory process. In preparing for these meetings, we are continuing our analyses of the data available from our Phase 2 and Phase 3 clinical trials, so that we can have as comprehensive as possible discussions regarding the safety and efficacy results for BiovaxID.

89. The quoted statements in the March 30, 2012 registration statement were false and misleading for the same reasons set forth in paragraphs 57, 58, 61 and 65 above.

90. On August 14, 2012, Biovest issued a press release announcing what it euphemistically described as a "formal clinical guidance meeting with the U.S. FDA," and disclosing that the FDA required that Biovest conduct a second Phase 3 clinical trial of BiovaxID.

91. The August 14, 2012 press release identified Biovest as a majority-owned subsidiary of Accentia with Accentia's trading symbol.

92. Also on August 14, 2012, Biovest filed its Form 10-Q with the SEC for the quarter ended June 30, 2012, in which Biovest belatedly disclosed that it had met with the FDA and that the FDA had recommended a second Phase 3 clinical trial.

93. Neither the August 14, 2012 press release nor Form 10-Q disclosed that the FDA had recommended at the September 8, 2010 meeting cited above "that [Biovest] submit a proposal for a new study that would constitute an adequate and well-controlled study."

94. The closing price of Biovest shares declined by almost 27% on extremely high volume on August 14, 2012. The shares dropped by another 43% the following day, again on higher than average volume.

95. The closing price of Accentia's shares similarly declined on unusually high volume on August 14, 2012 and again on August 15, 2012, dropping approximately 23% on August 14 and another 35% on August 15.

96. The FDA's requirement of a new clinical trial was highly material to the stock price of Accentia and Biovest on account of the enormous expense and amount of time necessary to conduct a Phase 3 clinical trial.

COUNT I

For Violations of Section 10(b) of the Securities Exchange Act and Rule 10b-5 (Against All Defendants on behalf of the Biovest Class)

97. Plaintiffs repeat and reallege each allegation set forth herein.

98. This count is brought pursuant to Section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

99. During the Class Period, Defendants carried out a plan, scheme and course of conduct which throughout the Class Period: (1) deceived the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) caused Plaintiffs and other members of the Class to purchase Biovest common stock at artificially inflated prices.

100. 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 course of conduct to make material misrepresentations and to conceal adverse material information about the business, operations and future prospects of Biovest as alleged herein.

101. 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, 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 Biovest, in light of the circumstances under which they were made, not misleading, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Biovest's common stock during the Class Period.

102. 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. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the true facts concerning Biovest from the investing public and supporting the artificially inflated price of its common stock.

103. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price for Biovest's common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Biovest's publicly-traded common stock 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 Company's common stock traded, 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, Plaintiffs and the other members of the Class acquired Biovest common stock during the Class Period at artificially high prices and were damaged thereby.

104. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth, Plaintiffs and other members of the Class would not have purchased or otherwise acquired Biovest common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices at which they did.

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

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

107. This action was filed within two years of discovery of the fraud and within five years of Plaintiffs' purchases of securities giving rise to the cause of action.

COUNT II

For Violations of Section 20(a) of the Exchange Act (Against All Defendants on behalf of the Biovest Class)

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

109. This count is brought pursuant to Section 20(a) of the Exchange Act.

110. Each Defendant acted as a controlling person of Biovest within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of Accentia's majority control of the stock of Biovest, the common senior management of Accentia and Biovest, the individual Defendants' high-level positions as officers and/or directors of Biovest, and their participation in and/or awareness of the circumstances concerning Biovest's principal business activity (the development of the BiovaxID vaccine), each Defendant had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Biovest, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading.

111. Biovest's business consisted principally of the development of the Biovax ID vaccine. Accordingly, each Defendant would have been knowledgeable concerning Biovest's meetings with the FDA as FDA approval of BiovaxID was critical to Biovest's financial survival. The importance of the BiovaxID program is reflected in the fact that Duffey and Santos attended the July 31, 2012 meeting with the FDA along with other Biovest officers.

112. Defendant Santos, the Senior Vice President for Product Development & Scientific and Regulatory Affairs at Biovest, and the Chief Science Officer for Accentia, was listed as the Sponsor for the Phase 3 clinical trial.

113. Each Defendant was provided with or had unlimited access to copies of Biovest's press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. Accentia was also aware of the true facts concerning BiovaxID and the false and misleading statements alleged herein, by virtue of

the fact that defendants O'Donnell, Duffey and Santos were senior executives of both Biovest and Accentia.

114. Each Defendant had direct and supervisory involvement in the day-to-day operations of Biovest and, therefore, is presumed to have had the power to control or influence the statements giving rise to the securities violations as alleged herein, and exercised the same.

115. As set forth above, Biovest violated Section 10(b) and Rule 10b-5. By virtue of their positions as controlling persons, Defendants are liable pursuant to Section 20(a) of the Exchange Act as they culpably participated in the fraud alleged herein. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Biovest's common stock during the Class Period.

COUNT III

For Violations of Section 10(b) of the Securities Exchange Act and Rule 10b-5 (Against All Defendants Except Bottjer on behalf of the Accentia Class)

116. Plaintiffs repeat and reallege each allegation set forth herein.

117. This count is brought pursuant to Section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 promulgated thereunder. "Defendants" as used in this Count III includes all Defendants except Bottjer.

118. During the Class Period, Defendants carried out a plan, scheme and course of conduct which throughout the Class Period: (1) deceived the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) caused Plaintiffs and other members of the Class to purchase Accentia common stock at artificially inflated prices.

119. 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

course of conduct to make material misrepresentations and to conceal adverse material information about the business, operations and future prospects of Accentia as alleged herein.

120. 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, 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 Accentia, in light of the circumstances under which they were made, not misleading, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Accentia's common stock during the Class Period.

121. 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. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the true facts concerning Accentia from the investing public and supporting the artificially inflated price of its common stock.

122. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price for Accentia's common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Accentia's publicly-traded common stock 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 Company's common stock traded, 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, Plaintiffs and the other members of the Class acquired Accentia common stock during the Class Period at artificially high prices and were damaged thereby.

123. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth, Plaintiffs and other members of the Class would not have purchased or otherwise acquired Accentia common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices at which they did.

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

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

126. This action was filed within two years of discovery of the fraud and within five years of Plaintiffs' purchases of securities giving rise to the cause of action.

COUNT IV

For Violations of Section 20(a) of the Exchange Act
(Against All Defendants Except Accentia and Bottjer on behalf of the Accentia Class)

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

128. This count is brought pursuant to Section 20(a) of the Exchange Act. "Defendants" as used in this Count III includes all Defendants except Accentia and Bottjer.

129. Each Defendant acted as a controlling person of Accentia within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of Defendants' high-level positions as officers and/or directors of Accentia, each Defendant had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Accentia, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading.

130. The development of the Biovax ID vaccine was a major, if not the most important, component of Accentia's business. Accordingly, each Defendant would have been knowledgeable concerning Biovest's meetings with the FDA as FDA approval of BiovaxID was critical to Biovest's financial survival and highly material to Accentia's business and financial condition. The importance of the BiovaxID program is reflected in the fact that Defendants Duffey and Santos attended the July 31, 2012 meeting with the FDA. Moreover, each Defendant was knowledgeable concerning the meetings with the FDA as each was also a senior executive of Biovest in addition to their senior positions at Accentia.

131. Defendant Santos, the Senior Vice President for Product Development & Scientific and Regulatory Affairs at Biovest, and the Chief Science Officer for Accentia, was listed as the Sponsor for the Phase 3 clinical trial.

132. Each Defendant was provided with or had unlimited access to copies of Accentia's public filings and other statements alleged herein, as well as Biovest's public filings and other statements, all of which are alleged by Plaintiffs to be misleading, prior to and/or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

133. Each Defendant had direct and supervisory involvement in the day-to-day operations of Accentia and, therefore, is presumed to have had the power to control or influence the statements giving rise to the securities violations as alleged herein, and exercised the same.

134. As set forth above, Accentia violated Section 10(b) and Rule 10b-5. By virtue of their positions as controlling persons, Defendants are liable pursuant to Section 20(a) of the Exchange Act as they culpably participated in the fraud alleged herein. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Accentia's common stock during the Class Period.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the other members of the Classes, request that the Court enter judgment against Defendants as follows:

A. Declaring that this is a properly maintainable class action under Federal Rule of Civil Procedure 23(a) and (b)(3) and declaring Plaintiffs to be proper representatives of each Class;

B. Awarding Plaintiffs and members of each Class damages together with interest thereon;

C. Awarding Plaintiffs the costs and disbursements of this action, including reasonable attorneys' and experts' fees; and

D. Granting such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiffs hereby demand trial by jury on all issues so triable.

Dated: July 24, 2013

By their attorneys: