1 2 3 4 5 6 7	MILBERG WEISS BERSHAD HYNES & LERACH LLP WILLIAM S. LERACH (68581) DARREN J. ROBBINS (168593) MARY K. BLASY (211262) 401 B Street, Suite 1700 San Diego, CA 92101 Telephone: 619/231-1058 619/231-7423 (fax)			
8	UNITED STATES D	ISTRICT COURT		
9	NORTHERN DISTRICT OF CALIFORNIA			
10				
11	JANICE WHITKENS, On Behalf of Herself and ) All Others Similarly Situated,	No.		
12	Plaintiff,	CLASS ACTION		
13	vs.	COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS		
14	VAXGEN, INC., LANCE K. GORDON and	I EDEKAL SECORITIES EAWS		
15	DONALD P. FRANCIS, M.D.,			
16	Defendants.	DEMAND FOR JURY TRIAL		
17		DEMAND FOR JUNI TRIAL		
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
ı,				

1. This is a securities fraud class action on behalf of all purchasers of the securities of VaxGen, Inc. ("VaxGen" or the "Company") between August 6, 2002 and February 26, 2003 (the "Class Period"), against VaxGen and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the "1934 Act").

- 2. VaxGen is engaged in the development and commercialization of AIDSVAX, a vaccine designed to prevent infection or disease caused by HIV (Human Immunodeficiency Virus), the virus that causes AIDS. During the Class Period, defendants were completing the final stages of AIDSVAX's Phase III clinical trials required to obtain Food and Drug Administration ("FDA") approval to market AIDSVAX as an AIDS vaccine. Clinical trials were being run simultaneously in the U.S. and Thailand, with the results of the U.S. trial to be released in early 2003 and results from the Thailand trial to be released in late 2003. Throughout the Class Period, defendants caused VaxGen to make a number of positive statements about the status of the trial and describing their eventual plans to manufacture and market AIDSVAX, causing VaxGen's stock to trade at artificially inflated prices.
- 3. However, the true facts which were known by each of the defendants, but were concealed from the investing public during the Class Period, included:
- (a) That the number of strains of HIV was increasing exponentially and AIDSVAX was proving ineffective in the clinical trials;
- (b) That, by the beginning of the Class Period, the clinical trials in the U.S. were over 80% complete and defendants knew that the rate of HIV infection occurring in the clinical trials indicated an efficacy rate which was statistically irrelevant as compared to the infection rate being experienced in the general population; and
- (c) That the efficacy rate being experienced in the Clinical trials would not meet FDA approval standards, nor those of the U.S. and world medical communities, so the "vaccine" was not commercially viable.
- 4. On the evening of Sunday, February 23, 2003, VaxGen shocked the market by reporting the long-anticipated results of the U.S. trials, disclosing that the "study did not show a

5

4

6 7

8

9

10 11

12

13 14

15

16

17 18

19

20

2.1

22

23

24

25

26 27

28

statistically significant reduction of HIV infection within the study population as a whole, which was the primary endpoint of the trial." The partial disclosure of the overall failure of the U.S. clinical trial caused VaxGen's shares to plummet, declining over 50% to approximately \$3 per share on February 24, 2003.

- 5. However, even when defendants released the results on February 24, 2003, they claimed that while the vaccine failed to demonstrate efficacy on U.S. caucasians, the trials had demonstrated 30%-84% efficacy rates in U.S. blacks and Asians. That analysis, the Company said, had less than a 1% chance of being due to random chance, making it highly statistically significant. VaxGen President Donald P. Francis touted the results as evidence that AIDSVAX could protect against HIV infection. As reported by *The Wall Street Journal* on February 24, 2003, the "results overall won't lead the Food and Drug Administration to approve the vaccine for use in the wider public, but the company hopes that further analysis, as well as results from another trial being conducted in Thailand on injection drug users, may prompt the agency to approve the vaccine for some ethnic minorities." These corrective statements had their intended effect and VaxGen's stock closed at close to \$7 per share on February 24, 2003.
- 6. However, on February 26, 2003, defendants were forced to admit that the reliability of their earlier reports of higher efficacy rates for non-caucasians were impaired because they had not taken the requisite "penalties" to account for the fact that less than 500 of the 5000 clinical trial participants were non-caucasians, resulting in an extremely small subset of data being analyzed for non-caucasions. Such penalties are designed to reduce the statistical significance of results obtained from slicing a body of data into many smaller pieces. As the news that earlier promises that AIDSVAX could prove useful for non-caucasions fell apart, the stock declined further, resulting in a total loss in market cap since November 18, 2002 of approximately 85%.

## JURISDICTION AND VENUE

7. Jurisdiction exists pursuant to §27 of the Securities and Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §78aa, and 28 U.S.C. §1331. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t, and Rule 10b-5.

7

10

9

12

11

13 14

16

17

15

18

19

20

2.1 22

23

24

25

26

27

8. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts giving rise to the violations complained of occurred in this District.

Defendants used the instrumentalities of interstate commerce, the U.S. mails and the facilities of the national securities markets.

#### THE PARTIES

- 10. Plaintiff Janice Whitkens purchased VaxGen publicly traded securities as described in the attached certification and was damaged thereby.
- 11. Defendant VaxGen is engaged in the development and commercialization of AIDSVAX, a vaccine designed to prevent infection or disease caused by HIV, the virus that causes AIDS. VaxGen has approximately 14.5 million shares outstanding and trades on the NASDAQ.
- 12. Defendant Lance K. Gordon, Ph.D. ("Gordon") is Chief Executive Officer and a director of VaxGen. Gordon serves on the Executive Committee of the VaxGen Board of Directors.
- 13. Defendant Donald P. Francis, M.D. ("Francis") is President and a director of VaxGen. Francis sits on the Executive Committee of the VaxGen Board of Directors.
- 14. The individuals named as defendants in ¶12-13 are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of VaxGen's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein at ¶19-20 and 30, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

15. In addition to the above-described involvement, each Individual Defendant had knowledge of the true status of the AIDSVAX clinical trials. Defendant Gordon, as CEO, and defendant Francis, as President, were responsible for the financial results and press releases issued by the Company.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

16. Feach defendant is liable for (i) making felse statements, ar (ii) feiling to disclose

16. Each defendant is liable for (i) making false statements, *or* (ii) failing to disclose adverse facts known to him about VaxGen. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of VaxGen publicly traded securities was a success, as it (i) deceived the investing public regarding VaxGen's prospects and business; (ii) artificially inflated the prices of VaxGen's publicly traded securities; (iii) allowed Company insiders to obtain larger bonuses; and (iv) caused plaintiff and other members of the Class to purchase VaxGen publicly traded securities at inflated prices.

#### **BACKGROUND**

- 17. VaxGen was founded in November 1995 to complete the development of, and to commercialize, an AIDS vaccine in partnership with Genentech, Inc., which reserved the rights to market any AIDS vaccine ever developed. Genentech licensed to VaxGen the technology necessary for development and commercialization of GP-120 (now called AIDSVAX).
- 18. Clinical trials of AIDSVAX were run virtually simultaneously in the U.S. and Thailand commencing in 1999:

	North America/Europe	Thailand
Participants	5,400	2,500
Began Enrollment	June 1998	March 1999
Completed Enrollment	October 1999	August 2000
Volunteers	5,100 gay men 300 women	2,500 injection drug users
Trial Length	36 months	36 months
<b>Primary Results Expected</b>	First quarter 2003	Fourth quarter 2003

2.1

# DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

19. On August 6, 2002, VaxGen issued a press release entitled "VaxGen Releases Second-Quarter Financial Results; Development Expenses In Line with Company's Expectations." VaxGen posted a net loss of \$ 6.7 million, or \$ 0.46 per share for its second quarter 2002, ending June 30, 2002. The loss was attributed by the Company to costs relating to additional personnel and infrastructure needed to facilitate the completion of the firm's Phase III trials, associated regulatory filings and advanced development of VaxGen's AIDSVAX. The release contained misleading statements which intimated that the Phase III trials were succeeding, stating in relevant part that,

Since the beginning of the second quarter, VaxGen has:

- Completed the seventh consecutive safety and conduct review of its Phase III trials;
- Revised its license and supply agreement with Genentech, Inc. on more favorable terms; and
- Hired Piers Whitehead, a leading vaccine industry expert, as vice president of Corporate and Business Development.

Additionally, the company's manufacturing joint venture, Celltrion, Inc., has secured 26 acres of land in Incheon, South Korea, on which to build a large-scale biopharmaceutical manufacturing facility for VaxGen's AIDS vaccine candidates and other biologic products. VaxGen, on behalf of Celltrion, hired Fluor Daniel, one of the world's largest design-construction firms, to lead the design and engineering of Celltrion's Incheon facility and a pilot plant in South San Francisco, Calif. VaxGen intends to use the pilot plant to complete production development and commercial launch of its AIDS vaccine candidates and/or other products.

20. On August 14, 2002, VaxGen filed its 10-Q for the period ended June 30, 2002. In the 10-Q defendants stated:

In its first phase of development, expected to be completed by 2005, we believe the Incheon facility will be capable of producing up to 200 million doses of AIDSVAX annually. Our facility in the South San Francisco area could produce up to 10 million doses of the AIDS vaccine annually and may also be used to develop other pharmaceutical products *when it is licensed and operational, which we believe will occur in 2005.* We expect to complete construction of our facility by the middle of 2003 and Celltrion the Incheon facility by the end of 2004. Additional time will be required to validate and license each facility. If AIDSVAX proves to be safe and effective, we intend to use the South San Francisco area facility to validate its manufacturing process, which would be a key component of its subsequent regulatory submission to the FDA. This facility, which will be located near our research and development facility, is expected to be used for commercial manufacturing of AIDSVAX at least through commissioning of the Incheon facility.

27

28

- 21. The statements described in ¶¶19-20 were false and misleading because by August 6, 2002, defendants knew that the AIDSVAX clinical trials were more than 80% complete and that the infection rates of trial participants virtually matched those being experienced in the general population, meaning the so-called "vaccine" had little or no efficacy and as such would not be commercially viable.
- 22. On November 5, 2002, VaxGen issued its third quarter 2002 earnings results and held an earnings conference call. The relevant portions of the transcript follow:

Carter Lee, Senior Vice President Finance and Administration, VaxGen: Good morning, everyone, and again welcome to our conference call. Beginning in 2002 we began preparing for success by spending for personnel infrastructure costs to support completion of the company's pivotal clinical trials. The costs incurred have been for the creation of regulatory, controlling systems group and adding personnel dedicated to the advance development of our production processes. Therefore, as expected our net operating losses have decreased for the fourth quarter and for the nine month period which is the same year last period [sic].

\* \* \*

Lance Gordon, Director and CEO; VaxGen: Thank you very much, Carter. I'm very pleased to be with you all today by telephone and the magic of computers.

\* \* \*

Moving on, Dr. Francis will be giving you more detail on the progress of our two phase III trials and I think the essential highlights here are that the company has completed on schedule in very high quality fashion the last safety review of the phase III pivotal clinical trial in Thailand, and is making preparations for completing the collection of data and analysis of the North American study. The final point, I'll give you a little more detail on here, VaxGen received very recently a contract with the U.S. National Institute of Health to supply vaccine for a large field trial which is anticipated to start in March of next year in Thailand. This additional field study is incremental to the studies being done on Aidsvax, and may result in additional indications in market expansions for VaxGen's product. The Army and the NIH are collaborating on a study looking at the combined use of our vaccine, which as I'm sure you're familiar is a preventive or prophylactic vaccine to prevent infection, using it in combination with a live viral approach being developed by, in this case, a convenient Aventis [sic] and that live viral approach is intended to have treatment impact. So we'll be looking at the combination of prevention of infection which has always been our goal, with a treatment regime. So that is anticipated to start shortly. The NIH contracted to purchase \$3.3 million worth of product from VaxGen for that study.

\* \* \*

Donald Francis, President and Director, VaxGen: Thank you, Lance. The next slide is entitled Aidsvax update which is indeed intended just for that, update you on our oldest ... product which is in development now, our AIDS vaccine which I think as everyone knows are the first and only phase III trials of a candidate AIDS

1
 2
 3

vaccine. I think, as all of you know, we have an outside data safety monitoring board that reviews these two trials, both the North American and European trials and the Thai trial, called the Data and Safety Monitoring board, and they have now reviewed this every six months from the beginning of the trial, and each time we get remarkable information, and that information is – has been good news at each meeting and those reviews really deal with two issues.

One is the safety of the vaccine, and as you all know, vaccine safety is absolutely critical. If we get up to now 30,000 doses with this vaccine, it is really reassuring to know there have been no adverse events associated with the vaccine ... in excess of what we've seen in the placebo. So it's wonderful news. It got a large number of doses, [and] we do not see adversity associated with the vaccine. I think that lays the groundwork for a safe and hopefully effective vaccine. Equally important as to the successful company, is the successful trials in the logistical line conduct way [sic]. They have reviewed the trials and showed the follow-up of the volunteers in the trial, both the people at risk of sexual exposure in [the] North American and European trial and through intravenous drug use in Thailand, is extremely high. We will get an answer [as] to the efficacy of the vaccine and given that this is the first time in history that an AIDS vaccine trial has been done, that is reassuring from these outside experts that review our trial that we will have an answer.

The first one to come to completion will be the North American/European Phase III trial [and] all the data is coming in now, and will continue to come in, get cleaned up through the end of the year. That will be finishing the – all the clinical database, get it in the computer, ready for analysis, and then beginning early next year we will begin the analysis of that phase III trial and announce ... the results of that analysis sometime in Q1.

The Thai trial will follow several months behind, so 2003 will be a critical year for the Aidsvax vaccine as ... the first quarter of '03 will be the North American/European trial and the second half of '03 we will announce the results of the Thai trial, looking at both sexual transmission and blood borne transmission with two separate vaccines. We go to the last slide here, the time line that you have seen before and for all of you investors who have been here from the beginning, it actually goes back to the last several years with the phase I, II trials and these are the two trials in North American/European ... sexual transmission on the top and the Thai trials and intravenous drug users at the bottom. And there you see the length of time, the effort that it's taken to do these has been immense and I think it's time to really express our appreciation for the volunteers, the employees and the clinics that have staff that have worked on this and indeed the VaxGen staff that has designed and implemented this, not to mention the investors that have allowed this whole thing to happen and this groundbreaking event to really occur.

So it is a very exciting time and as we have mentioned here on previous web casts, now we can actually put other bars below this and extend it to the right. The first one that Lance mentioned will be the next phase III trial which will start in Thailand sometime in early '03. We expect being the prime boost, if you will, trial of the event of Pasteur vaccine, and VaxGen's vaccine given together and then the anthrax studies, again to the right side of this, and then hopefully we'll have other products to complement those as time goes on. So, with that, I want to again express the appreciation to everyone involved in this, the investors, the clinics, the volunteers, the staff of VaxGen and everyone who made this groundbreaking effort possible.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

2.1

22

23

24

25

26

27

28

SEAN WOODS: Again, assuming complete success and from a purely pecuniary standpoint, your stock closed around \$15 last night on the exchange. Would you anticipate a rather significant increase in the value of that stock, with the price earnings ratio of – again, as I said from a strictly pecuniary standpoint, have any of the analysts that you know of indicated a multiple in the price earnings ratio from \$15 to, I've heard comments like this stock is going to go through the roof if all this stuff is successful, or what seems to be the analysts' consensus on [that], strictly from an investor standpoint?

UNIDENTIFIED: I think you certainly have identified where those answers are going to come from. They are going to come from investors like those of you who are on the telephone, and certainly the announcement that we're looking for next year will I think take a lot of the risk out of the company as we broaden the business, [add] additional products, as we validate our product opportunities through large clinical field trials such as Doctor Francis described. As to how the stock will react to product advancement, first - what we hope will be positive outcome for the pivotal clinical trials, and subsequent license application and we hope market launch in the not too distant future, those are things that can control and we're working very diligently, and I think [we're] very proud of our track record over the last several years of really meeting expectations and performing and making our marks.

DALE DEED: Yes. Then could we assume, that if this had a very high efficacy on the chimpanzee, provided now that we have very high levels of safety with the vaccine within humans, could we extrapolate out we could have a pretty high efficacy in the human beings as well?

UNIDENTIFIED: I think we can start extrapolating we're going to have high safety indications, all indications are we're going to have a very high safety profile. The ... the indication of 100% protection of our chimpanzees is certainly an indication that the vaccine has a high likelihood of being efficacious. But the question of how efficacious it is and for how long really will depend on the results of the ongoing studies.

23. The statements in ¶22 were false and misleading because the AIDSVAX clinical trials were now more than 97% complete and defendants knew that they demonstrated little or no efficacy. As a result, omission of any reference to the known abysmal efficacy rate of AIDSVAX rendered false and misleading defendants' statements that: (i) the Company was "preparing for success by spending for personnel infrastructure costs to support completion of the company's pivotal clinical trials ... and adding personnel dedicated to the advance development of our production processes"; (ii) AIDSVAX was an effective "preventative or prophylactic vaccine to prevent infection" that could be potentially be combined with live agents to treat existing persons who had already contracted AIDS; (iii) the "remarkable information" being returned by the "Data and Safety Monitoring board"

did not disclose to defendants' AIDSVAX's abysmal efficacy rate; and (iv) the announcement of the trial's final results would "take a lot of the risk out of the company" by validating the Company's "product opportunities through large clinical field trials."

- 24. Particularly disturbing was defendants' response to the question about what effect the release of the trial results which was rapidly approaching— would have on VaxGen's stock price. On that point, defendants' positive intimations as to the product soon being licensed, that there would be a "market launch in the not to distant future," and referring to the Company's "track record over the last several years of really meeting expectations and performing and making [their] marks," were false and misleading because defendants knew that disclosure of the efficacy rate in the not to distant future would be the death knell to AIDSVAX.
- 25. Similarly, defendants' response to the analyst's question that efficacy rates in chimpanzees could be extrapolated to provide efficacy rates in humans was misleading to the extent defendants equated the "100% protection of [their] chimpanzees" with "a high likelihood of being efficacious" in humans. Because defendants knew the efficacy rate being demonstrated was actually abysmal and because the market understood that defendants had access to the actual infection rates since at least November 2001, it was false and misleading to state that AIDSVAX had anywhere near a "high likelihood of being efficacious" in humans.
- 26. On these false statements, VaxGen's stock price rose to a Class Period high of \$23.25 on November 18, 2002.
- 27. Defendant Francis appeared on CNN on Sunday December 1, 2002, making more positive reassurances about the marketability of AIDSVAX:
  - BLAKEY: Many experts believe the best way to stop the spread of the disease is a vaccine. So far, there is none but that may soon change. Don Francis of VaxGen is leading the race for an AIDS vaccine and plans to soon finish the final stage of human testing. VaxGen began testing the vaccine more than seven years ago. It would be the first to complete human testing for FDA approval in January. Though no vaccine is 100 percent effective, Francis would be pleased with only one-third efficacy.
  - DR. DON FRANCIS, VaxGen: There is certainly very good data out there in computer models that a 30 percent effective vaccine will ultimately drive the epidemic into the ground.
    - BLAKEY: The next hurdle, getting it manufactured.

1	FRANCIS: It will take us another couple years to actually bring up the manufacturing, get the licensing for the vaccine and move it forward.		
2 3	BLAKEY: Still, different strains of HIV require different vaccines.		
4	DR. PAT FAST, INTERNATIONAL AIDS VACCINE INITIATIVE: One can also make a new version of this vaccine that is applicable in other parts of the world.		
5	FRANCIS: It will take us a year and a half, two years, to do that and think		
6	about how many infections are going to occur in that year and a half, two years, while we're developing this African vaccine.		
7	* * *		
8 9	BLAKEY: If everything stays on schedule and the current vaccine is successful, it will be ready for use in the U.S. sometime around the year 2005.		
10	28. VaxGen shares traded as high as \$21.43 per share on December 2, 2002.		
11	29. The statements in ¶27 were false and misleading because the trial was now less than		
12	one-month away from being completed and abysmal efficacy rates were being reported to Francis,		
13	providing him no basis to believe that: (i) AIDSVAX's efficacy rate would ultimately "drive"		
14	anything, much less the AIDS epidemic, "into the ground"; (ii) that VaxGen's next hurdle was		
15	"actually bring[ing] up the manufacturing, get[ting] the licensing for the vaccine and mov[ing] it		
16	forward"; and (iii) that various versions of AIDSVAX could effectively be used as an AIDS vaccine		
17	around the world.		
18	30. On Monday, December 16, 2002, VaxGen announced that AIDSVAX would get fast-		
19	track review at the FDA once the applications were filed. The Company's press release stated in		
20	relevant part:		
21	VaxGen, Inc. announced today that the U.S. Food and Drug Administration (FDA) has designated HIV/AIDS vaccine candidates, AIDSVAX B/B and AIDSVAX B/E		
22	(rgp120), Fast Track Products for the prevention of HIV infection. The Fast Track designation will enable rapid regulatory review of AIDSVAX.		
23	AIDSVAX B/B and AIDSVAX B/E are the only preventive AIDS vaccine		
<ul><li>24</li><li>25</li></ul>	candidates to advance to Phase III clinical trials. AIDSVAX B/B is being tested in a randomized, double-blind, placebo-controlled study of 5,400 people in the United States, Canada, the Netherlands and Puerto Rico. Primary results from the trial are		
26	expected to be announced in the first quarter of 2003.		
27	VaxGen is also nearing completion of its Phase III trial of AIDSVAX B/E in Thailand. AIDSVAX B/E is designed to protect against HIV subtypes B and E, and the company expects to announce primary results of that trial in the second half of		
28	2003. Subtype E is prevalent in Southeast Asia and the Central African Republic.		

26

27

28

"Every day thousands of people become infected with HIV," said VaxGen President Donald P. Francis, M.D., D.Sc. "Designation of both AIDSVAX B/B and AIDSVAX B/E as Fast Track Products recognizes the severity of the pandemic and the unmet need for a vaccine to prevent new infections."

Under the FDA Modernization Act of 1997, the Fast Track Program of the FDA is designed to expedite the review of a new drug that is intended for the treatment (or prevention) of a serious or life-threatening condition, and demonstrates the potential of a drug candidate to address unmet medical needs for such a condition.

- 31. On these positive statements, shares of VaxGen surged more than 20%.
- 32. The statements in ¶30 were false and misleading as stated because the trial was now finished and defendants knew that the efficacy rate of AIDSVAX was far below any level the FDA would accept, and that as such, FDA approval would likely be denied, on a "fast track" basis or otherwise, and that AIDSVAX would not be commercially available in 2005.
- 33. On February 11, 2003, VaxGen released its financial results for the fourth quarter and year ended December 31, 2002 and held a press conference. The relevant portions of the transcript follow:

[CARTER LEE:] ... Now please refer to the slide entitled Natural Results for the time period ended December 31st, 2002 and 2001. Loss in operations was \$10.6 million compared to \$7.1 million for the year ago quarter. Increases in both R&D and G&A spending contributed to the loss. We attribute this primarily to the increase in personnel, the final closeout of expenses payable to our North American and European clinical sites and service fees associated with the completion of our trials and offset by a reduction of expenses paid through our licensing partner. The increased personnel costs and service fees include salary and benefit expenses for internal staffing and consulting services required to support our regulatory filings, the advanced development of our manufacturing processes and the monitoring and auditing expenses normally incurred at the end of the phase 3 trial. The change in G&A expenses are attributable to an increase in occupancy, personnel and insurance costs. Prior to the beginning of the fourth quarter of 2002, the Company acquired additional facilities to house the pilot manufacturing plant and support the manufacturing process and other R&D activities. Therefore, occupancy costs such as lease payments for the facilities, utilities and maintenance and repair expenses naturally increased. Excluded in the G&A line, there are \$443,000 of non-cash expense, approximately \$171,000 related to non-cash compensation and the balance is depreciation and amortization expense. As you can see, our spending increases are reflective of our preparations for success and the completion of our clinical trials.

\* \* \*

[GORDON:] Before I move to the next slide, please let me share with you the scope of our HIV clinical effort....Now lets's take a look at the future on the next slide titled "2003 Time Line." We expect to announce the results from the first of our two phase 3 AIDS vaccine trials sometime this quarter. By the end of March we also

expect to take occupancy of our GNP manufacturing facility in south San Francisco. If our AIDS vaccine trials are successful and we receive release from the F.D.A., we plan to use this facility in our efforts to gain F.D.A. approval for our manufacturing process and to provide in the range of 10 million [doses] of vaccine per year from that facility for public use.

34. The statements in ¶33 were false and misleading because they intimated that the soon-to-be-released test results would mark a "success," that the manufacturing process would soon commence, that the FDA approval process would soon commence, and that defendants had a reason to believe that AIDSVAX would be commercially viable. To the contrary, defendants knew that the trial was complete and they had know ever since October 2001 that AIDSVAX's nominal efficacy rates (well below the FDA's required 30%) demonstrated that the "vaccine" was not commercially viable.

### THE TRUTH IS REVEALED

- 35. At midnight on Sunday, February 23, 2003, VaxGen announced initial results from the Phase III trials of AIDSVAX to prevent HIV infection in the U.S. The results for the Thailand part of the study would not be released until the end of 2003. According to the results disclosed, about 2.7% of placebo-treated patients became infected each year, and there were not any meaningful differences in infection rates for the AIDSVAX-treated patients. The press release issued the next day stated simply that the "study did not show a statistically significant reduction of HIV infection within the study population as a whole, *which was the primary endpoint of the trial.*"
- 36. Trading was halted on VaxGen's stock before the beginning of trading on Monday, February 24, 2003. When trading resumed, news of the partial disclosure of the overall failure of the U.S. trial caused VaxGen shares to plummet over 50% to approximately \$3 per share.
- 37. Then, on February 26, 2003, *The Wall Street Journal* published an article entitled "VaxGen Statistic Is Weaker Than Firm Initially Claimed," which stated in relevant part:

On Monday, VaxGen revealed that a three-year test of its AIDS vaccine, Aidsvax, had on an overall basis failed to protect volunteers from infection by HIV, the AIDS virus. But in an ethnic subgroup of 498 non-white, non-Hispanic volunteers, VaxGen said the vaccine appeared to provide protection in the range of 30% to 84%.

That analysis, the company said, had less than a 1% chance of being due to random chance, making it highly statistically significant. VaxGen President Donald Francis touted the results as evidence that Aidsvax can protect against HIV infection,

1 although he also acknowledged they reflected preliminary analysis and could turn out to be a "statistical fluke." 2 Outside scientists and AIDS activists have criticized the claim of partial 3 efficacy, largely because it was based on an analysis of just 29 HIV infections distributed between vaccinated volunteers in that subgroup and those who received a placebo. 4 5 VaxGen said it had followed good statistical practice by taking "penalties" related to its analyses of multiple subgroups. Such penalties are designed to reduce the statistical significance of results obtained from slicing a body of data into many 6 smaller pieces. 7 Wednesday, however, Lance Ignon, VaxGen's vice president for communications, admitted that the company hadn't taken those penalties after all. Mr. 8 Ignon said he didn't know how the erroneous information was released, adding that 9 the company was "still trying to figure that out." 10 38. On this news, VaxGen's stock price, which had partially recovered to close at close 11 to \$7 on February 24, 2003, declined back down to the \$4 range. The stock is now trading at 12 approximately \$3 per share, marking an approximately 85% decline in the price of VaxGen's stock 13 since its Class Period high of \$23.25 on November 18, 2003. 14 FIRST CLAIM FOR RELIEF For Violation of §10(b) of the 1934 Act 15 and Rule 10b-5 Against All Defendants 16 39. Plaintiff incorporates ¶¶1-38 by reference. 17 40. During the Class Period, defendants disseminated or approved the false statements 18 specified above, which they knew or deliberately disregarded were misleading in that they contained 19 misrepresentations and failed to disclose material facts necessary in order to make the statements 20 made, in light of the circumstances under which they were made, not misleading. 21 41. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: 22 (a) Employed devices, schemes, and artifices to defraud; 23 (b) Made untrue statements of material facts or omitted to state material facts 24 necessary in order to make the statements made, in light of the circumstances under which they were 25 made, not misleading; or 26 27 28

- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of VaxGen publicly traded securities during the Class Period.
- 42. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for VaxGen publicly traded securities. Plaintiff and the Class would not have purchased VaxGen publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.
- 43. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of VaxGen securities during the Class Period.

#### SECOND CLAIM FOR RELIEF

# For Violation of §20(a) of the 1934 Act Against All Defendants

- 44. Plaintiff incorporates ¶¶1-43 by reference.
- 45. The Individual Defendants acted as controlling persons of VaxGen within the meaning of §20(a) of the 1934 Act. By reason of their positions as officers and/or directors of VaxGen, and their ownership of VaxGen stock, the Individual Defendants had the power and authority to cause VaxGen to engage in the wrongful conduct complained of herein. VaxGen controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and VaxGen are liable pursuant to §20(a) of the 1934 Act.

#### **CLASS ACTION ALLEGATIONS**

- 46. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased VaxGen publicly traded securities (the "Class") during the Class Period. Excluded from the Class are defendants.
- 47. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to

1	C.	Awarding plaintiff a	nd the members of the Class pre-judgment and post-judgment
2	interest, as well as reasonable attorneys' fees, expert witness fees, and other costs;		
3	D.	D. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity,	
4	and federal statutory provisions sued hereunder, and any appropriate state law remedies; and		
5	E. Awarding such other relief as this Court may deem just and proper.		
6	JURY DEMAND		
7	Plaintiff demands a trial by jury.		
8	DATED: Ma	arch 17, 2003	MILBERG WEISS BERSHAD
9 10			HYNES & LERACH LLP WILLIAM S. LERACH DARREN J. ROBBINS
11			MARY K. BLASY
12			
13			DARREN J. ROBBINS
14			401 B Street, Suite 1700 San Diego, CA 92101
15			Telephone: 619/231-1058 619/231-7423 (fax)
16			Attorneys for Plaintiff
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28	D:\MyDocuments\Vax	(Gen1.wpd	

# CERTIFICATION OF INTERESTED ENTITIES OR PERSONS Pursuant to Civil L.R. 3-16, the undersigned certifies that as of this date, other than the named parties, there is no such interest to report. ATTORNEY OF RECORD FOR PLAINTIFF JANICE WHITKENS $D: \backslash MyDocuments \backslash VaxGen1.wpd$