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11 UNITED STATES DISTRICT COURT
12 SOUTHERN DISTRICT OF CALIFORNIA

13
14 TAMARA VAUGHN, an individual and on
behalf of herself and similarly situated
15 individuals,

16 Plaintiff,

17 vs.

18 AVANIR PHARMACEUTICALS, INC., a
19 California corporation, DR. GERALD J.
20 YAKATAN, ERIC K. BRANDT,
JONATHAN SILVERSTEIN, CHARLES A.
21 MATTHEWS, STEPHEN G. AUSTIN,
DAVID J. MAZZO, DENNIS G.
22 PODLESAK, KEITH A. KATKIN, CRAIG
23 A. WHEELER, SCOTT M. WHITCUP, JIM
CRAMER, EVAN STURZA, GINA
24 STACK, MARTIN EMMANUEL, DR.
25 JAGADISH SIRKAR, RANDALL KAY,
GREGORY P. HANSON, DAVID
26 HANSEN, AND DOES 1-25, INCLUSIVE

27 Defendants.
28

ORIGINAL

FILED

OCT 30 2009

CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

Case No.

'09 CV 2436 BEN RBB

CLASS ACTION COMPLAINT FOR
VIOLATION OF FEDERAL
SECURITIES LAWS.

DEMAND FOR JURY TRIAL

1 suffering a serious setback on one of its other drugs, Avanir was on the verge of collapsing.
2 Avanir had a very small revenue stream and was dependent on financing its operations
3 through sales of its stock. In order to stoke investor confidence in the Company, Avanir
4 needed to paint a positive picture as to the prospects of Zenvia. If Avanir disclosed to its
5 shareholders that the FDA had safety issues with Zenvia, the resulting reaction from the
6 marketplace would have been devastating to Avanir's share price.
7

8
9 5. The history of Avanir's development of Zenvia is littered with broken
10 promises, corporate misstatements, missed deadlines, huge cost overruns, as well as a
11 dubious relationship between Avanir and IriSys Research and Development, a privately-held
12 company primarily owned by Avanir's former CEO.

13
14 6. Plaintiff, and the putative class, bring this action in order to recover the
15 damages caused by Avanir's wrongful conduct.

16 **JURISDICTION AND VENUE**

17 7. This Court has jurisdiction because Defendants' wrongful conduct occurred
18 within this judicial district.

19
20 8. Venue is proper in this Court because the false statements that give rise to this
21 complaint emanated from this judicial district.

22 9. Jurisdiction is conferred by Section 27 of the Securities Exchange Act of 1934
23 (the "Exchange Act") [15 U.S.C. 78 aa] and 28 U.S.C. 1331, 1337. The claims asserted
24 herein arise under and pursuant to Section 10 (b), and 20(a) of the Exchange Act [15 U.S.C.
25 78n (a), 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by SEC, 17 C.F.R.
26 240.10b-5.
27
28

1 10. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15
2 U.S.C. 78 and 28 U.S.C. 1392 (b) and (c). Venue is proper in this District because many of
3 the acts and practices complained of herein occurred in substantial part in this District.
4

5 11. In connection with the acts, transactions and conduct alleged herein,
6 Defendants used the means and instrumentalities of interstate commerce, including the
7 United States mails, interstate telephone communications and the facilities of the national
8 securities exchanges and markets.
9

10 **THE PARTIES**

11 12. Plaintiff and others similarly situated were, at the time of the transactions
12 complained of, an owner and holders of Avanir's common stock.

13 13. Defendant Avanir is a corporation organized under the laws of California, is
14 authorized to do business within this district, and has its principal place of business at 101
15 Enterprise, Suite 300, Aliso Viejo, California 92656. During the time of the acts alleged in
16 this complaint, Avanir was headquartered in San Diego County.
17

18 14. Defendant Dr. Gerald J. Yakatan ("Yakatan") was at all relevant times an
19 employee, officer or director of Avanir Pharmaceuticals. From 1995 to 1998, Yakatan was
20 Vice President of Drug Development and served as Avanir's President and CEO from 1998
21 to 2005. Yakatan made, participated in the making of, or aided and abetted the making of,
22 the misrepresentations and concealments of material facts that were made to the public.
23

24 15. Defendant Eric K. Brandt ("Brandt") was at all relevant times an employee,
25 officer, or director of Avanir Pharmaceuticals. Brandt made, participated in the making of;
26
27
28

1 or aided and abetted the making of, the misrepresentations and concealments of material
2 facts that were made to the public.

3
4 16. Defendant Jonathan Silverstein ("Silverstein") was at all relevant times an
5 employee, officer, or director of Avanir Pharmaceuticals. Silverstein made, participated in
6 the making of, or aided and abetted the making of, the misrepresentations and concealments
7 of material facts that were made to the public.

8
9 17. Defendant Charles A. Matthews ("Matthews") was at all relevant times an
10 employee, officer, or director of Avanir Pharmaceuticals. Matthews was Chairman of the
11 Board from March 2005 until November 2006. Matthews made, participated in the making
12 of, or aided and abetted the making of, the misrepresentations and concealments of material
13 facts that were made to the public.

14
15 18. Defendant Stephen G. Austin ("Austin") was at all relevant times an employee,
16 officer or director of Avanir Pharmaceuticals. Austin has been an Avanir Director since
17 2003. Austin made, participated in the making of, or aided and abetted the making of, the
18 misrepresentations and concealments of material facts that were made to the public.

19
20 19. Defendant David J. Mazzo ("Mazzo") was at all relevant times an employee,
21 officer or director of Avanir Pharmaceuticals. Mazzo has been an Avanir Director since
22 2005. Mazzo participated in the making of, or aided and abetted the making of, the
23 misrepresentations and concealments of material facts that were made to the public.

24
25 20. Defendant Dennis G. Podlesak ("Podlesak") was at all relevant times an
26 employee, officer, or director of Avanir Pharmaceuticals. Podlesak has been an Avanir
27

28

1 Director since 2005. Podlesak participated in the making of, or aided and abetted the making
2 of, the misrepresentations and concealments of material facts that were made to the public.

3
4 21. Defendant Keith A. Katkin ("Katkin") was at all relevant times an employee,
5 officer or director of Avanir Pharmaceuticals. Katkin has been an Avanir Director since
6 2007. Kaktin participated in the making of, or aided and abetted the making of, the
7 misrepresentations and concealments of material facts that were made to the public.

8
9 22. Defendant Craig A. Wheeler ("Wheeler") was at all relevant times an
10 employee, officer, or director of Avanir Pharmaceuticals. Wheeler participated in the
11 making of, or aided and abetted the making of, the misrepresentations and concealments of
12 material facts that were made to the public.

13
14 23. Defendant Scott M. Whitcup ("Whitcup") was at all relevant times an
15 employee, officer or director of Avanir Pharmaceuticals. Whitcup has been an Avanir
16 Director since 2005. Whitcup participated in the making of, or aided and abetted the making
17 of, the misrepresentations and concealments of material facts that were made to the public.

18 Defendants Jim Cramer, Evan Sturza, Gina Stack, Martin Emmanuel, Dr. Jagadish Sirkar,
19 Randall Kay, Gregory P. Hanson, and David Hansen, were at all relevant times an
20 employees, officers or directors of Avanir Pharmaceuticals. Each individual participated in
21 the making of, or aided and abetted the making of, the misrepresentations and concealments
22 of material facts that were made to the public.

23
24
25 24. The above listed Individual Defendants, because of their positions with the
26 Company, possessed the power and authority to control the contents of Immersion's
27 quarterly reports, press releases and presentations to securities analysts, money and portfolio
28

1 managers and institutional investors, i.e., the market. They were provided with copies of the
2 Company's reports and press releases alleged herein to be misleading prior to or shortly after
3 their insurance and had the ability and opportunity to prevent their issuance or cause them to
4 be corrected. Because of their positions with the Company, and their access to material non-
5 public information available to them but not to the public, the Individual Defendants knew
6 that the adverse facts specified herein had not been disclosed to and were being concealed
7 from the public in that the positive representations being made were then materially false and
8 misleading. The Individual Defendants are liable for the false statements pleaded herein.
9

10
11 25. The true names and capacities of defendants sued herein as Does 1 through
12 25, inclusive, are presently not known to plaintiff, who therefore sue these defendants by
13 such fictitious names. Plaintiff will seek to amend this Complaint and include these Doe
14 defendants' true names and capacities when they are ascertained. Each of the fictitiously
15 named defendants is responsible in some manner for the conduct alleged herein and for the
16 injuries suffered by the Plaintiffs as a result of defendants' wanton and illegal conduct.
17

18 **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

19
20 26. Defendants are liable for: (i) making false statements; or (ii) failing to disclose
21 adverse facts known to them about Avanir Pharmaceuticals, Inc. Defendants' fraudulent
22 scheme and course of business that operated as a fraud or deceit on purchasers of Avanir
23 Pharmaceuticals, Inc. publicly traded securities was a success, as it: (i) deceived the
24 investing public regarding Avanir Pharmaceuticals, Inc., prospects and business; (ii)
25 artificially inflated the price of Avanir Pharmaceuticals, Inc. securities; (iii) caused plaintiff
26
27
28

1 and other members of the Class to purchase Avanir Pharmaceuticals, Inc. publicly traded
2 securities at inflated prices.

3
4 **CLASS ALLEGATIONS**

5 27. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil
6 Procedure 23 (a) and (b)(3) on behalf of a Class consisting of all those who purchased the
7 Common stock of Avanir Pharmaceuticals, Inc., (formerly known as Lidak Pharmaceuticals)
8 between July 1995 and October 31, 2006, the date the Company filed its form 10-k with the
9 SEC for its fiscal year ending 2006. Excluded from the Class are officers and directors of
10 the Company, at all relevant times, members of their immediate families and their legal
11 representatives, heirs, successors or assigns and any entity in which Defendants have or had
12 a controlling interest.
13

14
15 28. The members of the Class are so numerous that joinder of all members is
16 impracticable. During the Class period Avanir had more than 50 million shares of common
17 stock outstanding, which were actively traded on the NASDAQ, and tens of millions of
18 shares of common stock were traded during the Class period. While the exact number of
19 class members is unknown to Plaintiff at this time and can only be ascertained through
20 appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in
21 the proposed Class. Record owners and other members of the Class may be identified from
22 records maintained by Avanir or its transfer agent and brokerage firms and may be notified
23 of the pendency of this action by mail, using the form of notice similar to that customarily
24 used in securities class actions.
25
26
27
28

1 29. Plaintiff's claims are typical of the claims of the members of the Class as all
2 members of the Class are similarly affected by Defendants' wrongful conduct in violation of
3 federal and state law that is complained of herein.
4

5 30. Plaintiff will fairly and adequately protect the interests of the members of the
6 Class and has retained counsel competent and experienced in class and securities litigation.
7

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

- 11 (a) whether federal securities laws were violated by Defendant's acts as
12 alleged herein;
13 (b) whether statements made by Defendant to the investing public during the
14 Class Period misrepresented material facts about: (a) the viability of the
15 drug ZENVIA and whether ZENVIA was subject to fast track FDA
16 approval (b) whether Defendant failed to disclose that it had been notified
17 by the FDA that its NDA for the drug Abreva, would not be approved (c)
18 whether Defendant had willfully made false and misleading statements to
19 members of the class with the intent to deceive; and
20 (c) to what extent members of the Class have sustained damages and the
21 proper measure of damages.
22

23 32. A class action is superior to all other available methods for the fair and
24 efficient adjudication of this controversy since joinder of all members is impracticable.
25 Furthermore, as the damages suffered by individual Class Members may be relatively small,
26 the expense and burden of individual litigation make it impossible for members of the Class
27
28

1 to individually redress the wrongs done to them. There will be no difficulty in the
2 management of this action as a class action.

3
4 **FACTS COMMON TO ALL CAUSES OF ACTION**

5 **A. Background behind Avanir and Zenvia.**

6 33. Avanir is a pharmaceutical company that focuses on developing, acquiring and
7 commercializing novel therapeutic products for the treatment of chronic diseases. Avanir's
8 products and product candidates address therapeutic markets that include the central nervous
9 system, cardiovascular disorders, inflammation and infectious diseases. Its stock is traded on
10 the NASDAQ.

11
12 34. In July 1995, Avanir hired Gerald Yakatan as its Vice President of Drug
13 Development on a part-time basis. Yakatan was supposed to seek out new drugs for Avanir
14 to sublicense and develop. In breach of his duties to Avanir, in April 1997, Yakatan licensed
15 a drug from the Center for Neurological Studies ("CNS") to his own company, IriSys. That
16 drug was originally called AVP-923, later called Neurodex, and eventually called Zenvia (for
17 ease of reading, the drug is called Zenvia throughout this complaint). CNS had tried
18 unsuccessfully for years to shop this drug to other pharmaceutical companies.

19
20
21 35. The license agreement between IriSys and CNS had several development
22 milestones. If IriSys did not meet those milestones, the license would revert back to CNS.
23 Because IriSys did not have the resources necessary to clinically test drugs and take them
24 through the FDA approval process, Yakatan needed to find a company who could. So, in
25 late Summer or early Fall of 1997, Yakatan attempted to sublicense Zenvia from CNS to
26 Avanir. Yakatan failed to disclose to Avanir's Board of Directors, however, that CNS had
27

28

1 already licensed the drug to his own company IriSys. Like numerous other pharmaceutical
2 companies, Avanir rejected the drug. Yakatan then told the Board that he was going to
3 license the drug to his own company IriSys. Of course, by this time, Yakatan had already
4 done precisely that.
5

6 36. In March 1998, Yakatan orchestrated the firing of Avanir's CEO, Dr. David
7 Katz. Avanir's Board named Yakatan as Katz's replacement.
8

9 **B. Avanir struggles to survive after the FDA rejects one of its drugs.**

10 37. In the late 1990s, Avanir's main drug under development was called Abreva, a
11 topical prescription treatment for oral-facial herpes infections. Avanir filed an NDA for
12 Abreva in 1997.
13

14 38. In approximately November 1998, Yakatan received a communication from
15 the FDA indicating that the NDA for [Abreva] would not be approved. Nonetheless, on
16 November 30, 1998, Avanir issued the following press release:
17

18 AVANIR Pharmaceuticals today signed a manufacturing
19 agreement with Bausch & Lomb Pharmaceuticals, Inc. to
20 produce n-docosanol 10% cream, a topical prescription
treatment for oral-facial herpes infections. AVANIR is
anticipating a decision by the FDA on approval of the drug
before year-end.

21 Gerald J. Yakatan, Ph.D, AVANIR's chief executive officer
22 said, "We are working towards having an adequate supply of
our product warehoused and ready for launch in the first
quarter of 1999."
23

24 Avanir's share price rose almost 24% on this news.
25

26 39. During the month of December 1998, Avanir had several more
27 communications with the FDA in which it made clear that the NDA for Abreva was in
28 trouble. Again this information was not disclosed to the public nor did Avanir correct its

1 November 30, 1998 press release, which clearly gave the impression that the FDA was about
2 to approve the NDA for Abreva.

3
4 40. On December 22, 1998, in the last few hours of trading, Avanir's share price
5 declined nearly 20%. The following day, Avanir disclosed that the FDA had decided that
6 Avanir's NDA for Abreva was "not approvable." Avanir's share price declined another 66%
7 on this news.

8
9 41. The rejection of Avanir's NDA for Abreva had a devastating effect on Avanir
10 and its future. Indeed, in January 1999, Avanir issued its 10-K annual report. This filing
11 contained a "going concern" statement from Avanir's auditors in light of Avanir's dire
12 financial condition. Subsequent SEC filings reiterated this going concern statement and
13 continued to paint a bleak financial future for Avanir.

14
15 42. Thus, Avanir desperately needed to raise additional capital and stoke investor
16 confidence. Additionally, Yakatan's company IriSys was in danger of losing its rights to
17 Zenvia given that it had not yet met any of the milestones required under its licensing
18 agreement with CNS. Accordingly, Yakatan and Avanir embarked on a scheme to defraud
19 the investing public in order to solve both of these problems.

20
21 **C. Yakatan brings Zenvia back to the table.**

22 43. As mentioned above, in March 1998, Avanir's Board named Yakatan as
23 Avanir's President and CEO. Over the next few months, Yakatan reorganized Avanir's
24 Board by replacing four of the directors with his hand-chosen picks. By early 1999, only
25 two of the directors who were on the Board when Yakatan brought Zenvia to Avanir in 1997
26 were still there. Because the due dates for several of the milestones under IrySis's license
27
28

1 with CNS were fast approaching, Yakatan again brought the drug to Avanir. Of course,
2 Avanir agreed to license the drug now that the Board was made up of Yakatan's cronies.

3
4 44. In February 1999, Avanir announced that it had signed a Letter of Intent
5 ("LOI") to license a drug from IriSys. Because of Avanir's dire financial condition, the
6 Company could not afford or justify finalizing a licensing agreement with IriSys, a sentiment
7 that was oft-repeated in Avanir's SEC disclosure filings. These same filings also continued
8 to warn shareholders that the IriSys LOI was in no way an actual agreement and that there
9 could be no guarantees that a final agreement would be reached.
10

11 45. However, almost immediately after signing the LOI with IriSys, Avanir began
12 to fund the development of the IriSys drug without disclosing this to its shareholders. In
13 short, at a time when it was on the brink of financial collapse, Avanir was funding the
14 development of a drug that it did not own. Not only were Avanir shareholders unaware that
15 the Company was funding the development of a drug that was owned by its CEO's private
16 company, they were also unaware that that drug could be reclaimed by the original owner,
17 CNS, if IriSys did not achieve certain development milestones that were also not disclosed.
18 If share holders had been made aware of this overt misappropriation of limited resources to
19 fund the development of the drug in order to prevent the CEO's separate company, IriSys,
20 from losing its licensing rights, those shareholders would have raised serious questions about
21 the appropriateness of these expenditures.
22
23

24
25 46. In August 2000, long after Avanir's undisclosed development of the IriSys
26 drug enabled Yakatan's private company to satisfy the milestone requirement of the original
27 IriSys/CNS deal, Avanir at last finalized the LOI with IriSys.
28

1 47. Had the investing public known that Avanir was developing the drug in order
2 to prevent its CEO's separate company, IriSys, from losing its licensing rights, shareholders
3 would have raised serious questions.
4

5 **D. Avanir's misleads the public concerning the timing of its NDA for Zenvia.**

6 48. In December of 2001, Avanir initiated its Phase II/III clinical trial for Zenvia.

7 49. In September 2001, Avanir issued a press release in which it stated that the
8 NDA for Zenvia could be filed with the FDA in 2003.
9

10 50. On December 21, 2001, Avanir filed its 10-K annual report. In this filing,
11 Avanir stated that, depending upon the results of its clinical trials, the NDA for Zenvia
12 would be filed "possibly in 2003."
13

14 51. On May 15, 2002, however, Avanir filed its 10-Q quarterly report stating: "If
15 the clinical trials show positive results, we plan to file a New Drug Application (NDA) with
16 the FDA in 2004."
17

18 52. In June, 2002, Avanir announced that it had completed the Phase II/III trial for
19 Zenvia. Avanir subsequently announced that the results from the clinical trials were positive.
20

21 53. On August 13, 2002, Avanir filed its 10-Q quarterly report stating that it
22 intended to initiate additional Phase III trials for Zenvia. According to the 10-Q, if those
23 trials were successfully completed before the end of 2003, Avanir intended to file an NDA
24 with the FDA in early 2004.
25

26 54. On December 26, 2002, Avanir filed its annual 10-K report, which now
27 indicated that Avanir planned on filing an NDA in mid-2004.
28

1 55. On February 13, 2003, Avanir filed its 10-Q quarterly report. This report stated
2 that the Phase III clinical trials for Zenvia had reached approximately 15% of completion as
3 of calendar year 2004. The report again indicated that Avanir anticipated filing the NDA for
4 Zenvia “in the first half of calendar year 2003.”
5

6 56. On May 14, 2003, Avanir filed its 10-Q quarterly report, which gave an update
7 on the Phase III clinical trials for Zenvia. According to the report, the trials had reached
8 approximately 15% of completion as of March 2003. In other words, Avanir had made no
9 progress in recruiting patients for the trials in the three months since its previous quarterly
10 report. Nonetheless, Avanir still indicated that it anticipated filing its NDA for Zenvia in the
11 “first half of calendar year 2004.”
12

13 57. On August 12, 2003, Avanir’s CEO, Yakatan, participated in a conference call
14 with investors. According to Yakatan, Avanir was “still on target for submitting a new drug
15 application for [Zenvia] in the first half of next year.” Just two days later, however, Avanir
16 issued a 10-Q Quarterly Report stating that it anticipated filing the NDA for Zenvia by “mid-
17 2004.”
18

19 58. On December 23, 2003, Avanir filed its 10-K annual report. The report now
20 stated that Avanir expected to submit the NDA for Zenvia in the “second half of the 2004
21 calendar year.”
22

23 59. On February 14, 2004, Avanir issued its 10-Q quarterly report, which again
24 stated that Avanir expected to file the NDA for Zenvia in the “second half of the 2004
25 calendar year.”
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1 60. On March 31, 2004, Avanir issued a press release announcing that it had
2 completed its enrollment for the Phase III trials for Zenvia. Yakatan was quoted in the
3 release as stating “[a]ssuming the data are favorable, we expect to submit our new drug
4 application (NDA) this year.”
5

6 61. On May 7, 2004, during a conference call with investors, Yakatan stated that
7 Avanir would be filing the NDA for Zenvia “some time before the end of the year.” On May
8 14, 2004, Avanir filed its 10-Q quarterly report, again indicating that the NDA would be
9 filed in the second half of 2004.
10

11 62. On August 13, 2004, Avanir released a 10-Q quarterly report indicating, for the
12 first time, that it intended to begin submission of its NDA for Zenvia “by the end of the 2004
13 calendar year.” In a conference call that same day, in response to a question regarding the
14 continuous delays in filing the NDA, Yakatan said: “First of all, let me deal with the last one
15 first and that is that we have always given guidance that assuming that the clinical trial is
16 positive that we expect to file by the end of the year and we hold to that.” Of course, this
17 statement was not true. As detailed above, Avanir consistently pushed back the anticipated
18 date of the filing of the NDA for Zenvia from 2003 to early 2004; from early 2004 to the first
19 half of 2004; from the first half of 2004 to mid 2004; from mid 2004 to the second half of
20 2004; and finally from the second half of 2004 to by the end of 2004.
21
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25 ///

26 ///

27 ///

28

1 **E. Avanir falsely states that the FDA had granted a rolling review and**
2 **priority review to the Zenvia NDA.**

3 63. By way of background, in 1997, Congress passed the FDA Modernization Act
4 in order to expedite the review and development of drugs that treat a broad range of serious
5 diseases and fill an unmet medical need. Under this law, a drug manufacturer can request a
6 “fast track” designation for any drug intended to treat a serious disease. Once a drug
7 receives fast track designation, early and frequent communication between the FDA and the
8 drug company is encouraged throughout the entire drug development and review process.
9 The frequency of communication ensures that questions and issues are addressed quickly.
10 As part of the fast-track process, a drug company may request to submit its NDA on a
11 “rolling review” basis, which allows the company to submit completed sections of an NDA
12 individually, before all sections of the application are completed. The company may also
13 request a “priority review” from the FDA, which means that once the NDA submission is
14 complete, the FDA must review it and take action within six months, rather than the ten
15 months allowed under a standard review. Obtaining priority review for an NDA is always
16 viewed as a positive since it is a determination by the FDA that no other existing drug meets
17 the medical needs for which the new drug is intended to address.
18
19
20

21 64. On December 16, 2004, Avanir issued the following press release:
22

23 **AVANIR Announces Submission of Rolling NDA With Priority**
24 **Review For [Zenvia]**

25 San Diego, December 16, 2004 -- AVANIR Pharmaceuticals
26 (AMEX: AVN) announced today it has begun submission of a
27 New Drug Application (NDA) seeking marketing approval of
28 [ZENVIA], an investigational drug for the treatment of
 pseudobulbar affect. **The U.S. Food and Drug Administration**
 (FDA) offered a "rolling" review of a new drug application
 (NDA) for [Zenvia] and also indicated that [Zenvia] would

1 **qualify for a priority review when the submission is**
2 **complete.** AVANIR expects to complete its submission in the
3 first half of 2005.

4 AVANIR is seeking approval of [Zenvia] as a therapy for
5 patients with pseudobulbar affect (PBA), a symptom complex
6 that is characterized by uncontrollable episodes of crying or
7 laughing. An estimated one million patients with neurological
8 conditions such as ALS or Lou Gehrig's disease, Alzheimer's
9 disease, multiple sclerosis (MS), stroke and traumatic brain
10 injury may be affected by PBA. The NDA for [Zenvia] will be
11 supported by data from two controlled, multicenter Phase III
12 clinical trials conducted in the U.S. and Israel.

13 "AVANIR has worked diligently to expeditiously develop
14 [Zenvia] and we are very pleased that the FDA will allow us to
15 submit our NDA on a rolling basis with priority review when
16 the submission is complete," said James E. Berg, Vice President
17 of Clinical and Regulatory Affairs at AVANIR. "PBA is
18 becoming recognized as a condition that has a profound effect
19 on quality of life for people that suffer from neurological
20 disorders. With no drug indicated for the treatment of PBA, this
21 NDA submission represents an important step forward in the
22 potential care and treatment of patients suffering from
23 pseudobulbar affect."

24 **The company is utilizing a process that allows an NDA to be**
25 **submitted on an ongoing basis. A rolling review will allow**
26 **the FDA to evaluate modules of the NDA as they are**
27 **submitted. Additionally, the FDA has indicated that the**
28 **Neurodex NDA is eligible for a priority preview. Per the**
Prescription Drug User Fee Act (PDUFA), the FDA's goal is to
complete priority reviews within 6 months compared to 10-12
months for a standard PDUFA review.

65. In a conference call hosted by Avanir that day, Yakatan again stated that

Avanir had received a rolling review and priority review from the FDA:

21 We've certainly had a great year and I'm going to talk about
22 some of the highlights of that year a little bit later on including
23 today's announcement about our NDA filing for Zenvia **and the**
priority review it received....

24 **And certainly we expect big things out of this filing and the**
idea that it received the priority review from the FDA is an
25 **indication that they recognize pseudobulbar affect as an**
26 **important indication and they recognize that this is the first**
27 **treatment for this particular indication that they've received.**

28 **We have now started the filing of the NDA on a rolling filing**
basis and that's an exciting point and we will continue with that
filing through the first half of the year.

1 A lot of it has to do with the close working relationship we've
2 developed with the FDA.

3 66. In January 2005, Avanir published a quarterly newsletter. In this newsletter,
4 Avanir summarized the December 16, 2004 newsletter discussed above, including Yakatan's
5 comments that the FDA had granted a priority review to Zenvia.

6 67. On February 9, 2005, Avanir issued its 10-Q quarterly report, which stated the
7 following:
8

9 **We began submission of an NDA to the FDA on a "rolling"**
10 **review basis, starting on December 16, 2004 and expect to**
11 **complete its submission by mid-2005. The rolling review**
12 **process allows AVANIR to submit the NDA in modules**
13 **(reviewable units), which can then be evaluated by the FDA as**
14 **they are submitted. Although we have commenced submission**
15 **of our NDA, the FDA has not, to our knowledge, yet begun**
16 **review of the first module. The FDA has indicated that**
17 **[Zenvia] would qualify for a priority review when the**
18 **submission is complete. Once the submission is complete, and**
19 **assuming that the FDA grants us priority review, we expect the**
20 **FDA will take approximately six months to complete its review**
21 **of the entire submission.**

22 68. The following day, Avanir hosted a conference call for investors, during which
23 Yakatan again stated that the FDA had granted a priority review for Zenvia:

24 We had a fantastic year last year, and certainly we expect to do
25 everything we can to make this year an even better one. Clearly
26 the highlight of our first fiscal quarter was the start of our
27 submission for the new drug application for [Zenvia] and the
28 treatment of (inaudible), also known as emotional ability. As we
previously stated, the FDA granted us a rolling submission,
which was a real coup for us to be able to -- be able to begin
that submission much earlier than the completion of all of
the data. It is expected that that submission will be completed
by mid year and that's going to trigger a priority, our six-
month review clock as [Zenvia] would be the first drug
specifically to address this almost half a billion dollar
market opportunity.

* * * *

That assessment was granted following considerable dialogue
with the FDA I think it's another example of how well we have
been able to work from a regulatory standpoint with the agency.

1 69. On April 18, 2005, Avanir issued the following press release:

2 AVANIR Pharmaceuticals to Present at the White Mountain
3 Capital 3rd Annual Biotechnology Conference

4 San Diego, April 18, 2005 -- AVANIR Pharmaceuticals
5 (AMEX: AVN) will be presenting at the White Mountain
6 Capital Biotechnology Conference on Tuesday, April 19th in
7 New York. AVANIR's President and Chief Executive Officer
8 Dr. Gerald J. Yakatan will be presenting a corporate overview at
9 the investor conference at 1:30 p.m. Eastern time.

10 The presentation will focus on AVANIR's lead product
11 candidate, [Zenvia] for the treatment of two central nervous
12 system (CNS) disorders, pseudobulbar affect and diabetic
13 neuropathic pain. AVANIR has successfully completed two
14 pivotal Phase III trials with [Zenvia] for the treatment of
15 pseudobulbar affect, a neurological disorder that affects
16 approximately one million people in the U.S. AVANIR began
17 submission of a "rolling" new drug application (NDA) to the
18 U.S. Food and Drug Administration (FDA) at the end of 2004
19 and expects to submit the final module in mid-year 2005. **The
20 FDA has granted AVANIR's NDA a Priority Review, which
21 is an accelerated six-month review timeline.**

22 70. On May 16, 2005, Avanir filed its 10-Q quarterly report. In this report, Avanir
23 made the following statement about the Zenvia NDA:

24 Although we have commenced submission of our NDA, the
25 FDA has not, to our knowledge, yet begun review of the first
26 module. **The FDA has indicated that [Zenvia] would qualify
27 for a priority review.** Once the submission is complete, and
28 assuming that the FDA grants us priority review, we expect the
FDA will take approximately six months to complete its review
of the NDA.

29 **F. Avanir conceals the safety problems with Zenvia.**

30 71. In October 2005, the FDA released new clinical testing guidelines regarding
31 the effect of certain drugs on the human cardiovascular system. These guidelines were the
32 result of the widely publicized problems caused by Vioxx and other drugs. Amongst other
33 things, these new guidelines announced that the FDA expected drug companies to test the
34 effect of new drugs on the QTc interval. The QTc interval is a measure of the time between

1 the start of the Q wave and the end of the T wave in the heart's electrical cycle. An
2 abnormally prolonged or shortened QTc interval can cause ventricular arrhythmias and
3 ultimately cardiac arrest. As part of these guidelines, the FDA established a "threshold
4 concern" for drugs that caused a change in the QTc interval of more than five milliseconds.
5

6 72. Throughout 2005 and 2006, Avanir made a series of misrepresentations and
7 omissions about the safety and efficacy of the drug.

8 73. On August 31, 2005, Avanir issued the following press release:

9
10 Update on AVANIR's [ZENVIA] New Drug Application

11 San Diego, August 31, 2005 -- Avanir Pharmaceuticals (AMEX:
12 AVN) announced that it has been advised by the U.S. Food and
13 Drug Administration (FDA) today that it should not expect a
14 determination on the acceptability, or otherwise, of its New
15 Drug Application (NDA) for [Zenvia] for the treatment of
16 pseudobulbar affect (PBA) until October 10, 2005. **The FDA
determined that the receipt date of the filing is to be August
10, 2005 due to supplemental data provided by the Company
on that date at the request of the FDA.** In the interim, the
company anticipates continuing communication with the FDA
routinely associated with a NDA.

17 74. Avanir told shareholders who called to ask that it was "blindsided" by the
18 FDA's advisement that it would delay decision on the NDA for Zenvia. It should be noted,
19 however, that the August 31, 2005 press release indicates that the FDA had asked previously
20 asked Avanir for supplemental data, which Avanir provided on August 10, 2005. Notably,
21 there was no mention of this fact during a conference call that Avanir's new CEO, Charles
22 Matthews, had with investors on August 18, 2005, during which Matthews discussed the
23 status of the FDA's review of the Zenvia NDA.
24
25

26 75. September 22, 2005, Avanir issued the following press release:

27 Further Update On Avanir's Neurodex(TM) New Drug
28 Application

1 San Diego, September 22, 2005 -- Avanir Pharmaceuticals
2 (AMEX: AVN) announced that during discussion with the U.S.
3 Food and Drug Administration (FDA) yesterday regarding
4 Avanir's new drug application (NDA) for [Zenvia] for the
5 treatment of pseudobulbar affect (PBA), the Agency requested
6 that the Company provide an expansion of certain summary
7 analyses in its application to better support the new electronic
8 data submission guidelines. The Company will be meeting with
9 the Agency within the next few weeks to discuss the requested
10 analyses. Based on these discussions, the Company expects that
11 the FDA will reset the receipt date of the NDA filing to coincide
12 with the Company's submission of this information.

13 "This delay is unfortunate, but we are very appreciative that the
14 FDA is willing to work closely with us to make our application
15 as complete and reviewable as possible," said Eric Brandt,
16 President and CEO of Avanir.

17 76. During a conference call later that day, Avanir's new President and CEO, Eric
18 Brandt made the following statement: "Um, again, you know, it would be one thing if the
19 data were equivocal on an efficacy or safety standpoint. I'd be much more worried. They're
20 not. **So from my perspective it's not an issue of whether this becomes an approved
21 drug, it's more an issue of when it becomes an approved drug.**"

22 77. The following day, the *San Diego Union Tribune* described Brandt's comments
23 during the conference call this way: "Brandt said the clinical trial data on Neurodex 'is not
24 equivocal on efficacy or safety,' and characterized the issue as more of 'miscommunication'
25 about how the analysis should be organized."

26 78. On December 14, 2005, Avanir filed its 10-K annual report, which again stated
27 that the FDA had merely asked for a re-formatting and expansion of previously submitted
28 materials:

29 In December 2004, we began submission to the FDA of our
30 "rolling" NDA for [Zenvia] for the treatment of PBA. A rolling
31 submission allows us to submit the NDA in separate reviewable
32 modules. We recently submitted the final reviewable unit of our
33 NDA. **However, the FDA has requested that we expand
34 certain summary analyses and re-format the materials in**

1 **our application to better support the filing.** We expect that
2 the FDA will set the receipt date of the NDA filing to coincide
3 with our submission of this information, which we expect will
4 occur in January 2006. Please refer to "Management's
5 Discussion and Analysis of Financial Condition and Results of
6 Operations" for additional information regarding this
7 submission. If the FDA approves [Zenvia] for marketing in the
8 treatment of PBA, we intend to market the drug directly through
9 a sales force that we are currently in the process of building.

6 79. On January 30, 2006, Avanir issued a press release announcing that it had
7 resubmitted its NDA for Zenvia to the FDA. The press release contained the following
8 statement from Brandt:

9 "We are very pleased to announce this important
10 submission. **While the FDA's request was limited to**
11 **reorganization and expanded discussions of existing data**
12 **within the electronic document, we took the time to include**
13 **additional safety data rather than providing it as a separate**
14 **supplemental filing as originally planned.** The additional
15 safety data are consistent with the data previously submitted,"
16 said Eric K. Brandt, President and Chief Executive Officer of
17 AVANIR. "We feel the application is strengthened, and look
18 forward to hearing from the FDA over the next sixty days
19 regarding the fileability status and the review designation
20 granted for our application".

16 80. On February 9, 2006, Avanir hosted its quarterly conference call. Brandt made
17 the following statement:

18 In addition, we completed the re-filing of our NDA for
19 Neurodex on January 27th for involuntary emotional expression
20 disorder, otherwise known as IEED and formerly referred to as
21 pseudobulbar affect. **As I mentioned on our last earnings call,**
22 **we significantly enhanced the analysis and data presentation**
23 **in our ECTD. We added over 1,000 pages to the file based**
24 **on the guidance we received from the FDA and based on**
25 **updating and expanding the safety database to include over**
26 **300 patients on drug for six months.**

24 81. On April 4, 2006, Avanir issued the following press release:

25 **AVANIR'S [ZENVIA] NDA ACCEPTED WITH PRIORITY**
26 **REVIEW FOR INVOLUNTARY EMOTIONAL**
27 **EXPRESSION DISORDER**

27 San Diego, April 4, 2006 -- Avanir Pharmaceuticals (AMEX:
28 AVN.R) announced today that the U.S. Food and Drug
Administration (FDA) has accepted for filing and review its

1 New Drug Application (NDA) for [Zenvia] for the treatment of
2 involuntary emotional expression disorder (IEED), also known
3 as pseudobulbar affect or emotional lability. In addition, the
4 [Zenvia] NDA will receive priority review by the FDA. The
5 FDA grants priority review status to products that, if approved,
6 would address an unmet medical need or are considered to be
7 potentially significant therapeutic advancements over existing
8 approved therapies in the treatment, diagnosis or prevention of a
9 disease. Avanir completed the submission of its NDA to the
10 FDA on January 27, 2006 and expects the FDA will take action
11 on the NDA by July 30, 2006 (the "PDUFA date").

12 "We are very pleased that the FDA has accepted for filing the
13 NDA for Zenvia and that our submission will receive priority
14 review," said Eric Brandt, Avanir's President and Chief
15 Executive Officer. "With no currently approved treatments for
16 IEED, the agency's acceptance of our NDA represents an
17 important step forward in the potential care for those suffering
18 from IEED."

19 **The application is based on clinical data supporting that
20 Zenvia, a combination of dextromethorphan and low dose
21 quinidine, is safe and effective in reducing the frequency and
22 severity of unpredictable and uncontrollable episodes of IEED
23 that occur as a consequence of neurological disease or injury. . .**

24 82. On May 8, 2006, Avanir hosted its quarterly conference call. In response to a
25 question regarding the "safety profile" of Zenvia, particularly as it relates to "QT
26 prolongation," Brandt responded as follows:

27 With regard to QTC, you know the interesting thing about it is
28 Quinidine is very well characterized and there is actually a
published study on Quinidine as it relates to the dose response
of Quinidine per individual between men and women and it's
pretty darn close to what we saw. So it's pretty linear, we didn't
see any major outliers, we certainly didn't see any [tresad to
point], no sudden death and those sorts of things and no major
cardiovascular events in the trials. **So we're quite comfortable
with I think the QTC profile of the drug.**

83. On June 5, 2006, Avanir announced that it had submitted additional safety data
to the FDA. Again, this announcement is contrary to Avanir's previous statements that the
FDA had only asked Avanir to address formatting issues in its original NDA.

1 84. On June 19, 2006, Avanir announced that the FDA had delayed the PDUFA
2 date for the Zenvia NDA from July 30, 2006 to October 30, 2006, in order to review the
3 additional data submitted by Avanir.
4

5 85. On June 20, 2006, Avanir hosted a conference call to discuss the FDA's
6 decision to extend the PDUFA date. During the call, Brandt made the following statements:
7

8
9 In the spring of 2005, the Company decided to embark on a QT
10 study -- a thorough QT study -- following the ICH guidelines.
11 We developed a protocol consistent with those ICH guidelines
12 and sent that to the division, which I believe it has changed its
13 name, but it's the 170 division which deals with pain and
14 anesthesia. That division then sent the protocol for the QT study
15 to the cardiorenal division, who reviewed it, made some edits to
16 it which we incorporated, and then we got it back in the late fall
17 of 2005. It probably took a little longer than we would have
18 anticipated to get through the commentary, but we felt it was
19 important to go through that commentary to make sure that as
20 we worked through a QT study that it met all of the
21 requirements of the FDA.

22 * * * *

23 That study started at the very end of 2005. As you can imagine,
24 when you start a study for which there is a drug pending for an
25 NDA review, it is only ethical to inform the FDA of such a
26 study, even though it was done in a different division. So we did
27 obviously inform the neuropharm division of this study. We
28 finished the study and the study report just recently, and we
were faced with a choice -- whether we submit the final study
report to the diabetic neuropathic pain IND or the IEED/NDA,
which are in two different divisions.

* * * *

23 Secondly, the trade-off really here was a risk of a three-
24 month delay, which we were hoping wouldn't be required or an
25 eight-month risk at the end of the PDUFA date. In thinking
26 about it and thinking about the safety concerns, that was the
27 trade-off that was in our mind. Lastly, we think it clearly
28 enhances the strong safety database, which we issued a press
release I believe on June 5th which commented on that.

G. The FDA issues an Approvable Letter for Zenvia.

1 86. On October 30, 2006, the day the FDA was expected to issue its PDUFA for
2 the Zenvia NDA, Avanir's stock price closed at \$7.40.

3
4 87. On October 31, 2006, Avanir issued the following press release:

5 AVANIR Receives FDA Approvable Letter For Zenvia For The
6 Treatment Of Involuntary Emotional Expression Disorder

7 San Diego, Calif., October 31, 2006 -- AVANIR
8 Pharmaceuticals (NASDAQ: AVNR) announced that it has
9 received an approvable letter from the U.S. Food and Drug
10 Administration (FDA) for Zenvia™ (formerly referred to as
11 Neurodex™) for the treatment of involuntary emotional
12 expression disorder ("IEED"). The Company submitted a new
13 drug application ("NDA") in January 2006, seeking to market
14 Zenvia for the treatment of IEED in patients with neurologic
15 diseases and brain injuries. The communication from the FDA
16 indicates that AVANIR's application is approvable, subject to the
17 FDA and AVANIR reaching agreement on what additional safety
18 and efficacy data will be required. In accordance with FDA
19 procedures, the Company anticipates scheduling a meeting with
20 the agency to discuss the approvable letter. Until the Company
21 is able to meet with the Agency, it can not comment on the
22 specifics of the approvable requirements. Additionally, the
23 Company can not be certain that once it has met with the FDA,
24 that it will choose to continue with the development of Zenvia
25 as previously planned.

19 "We will be working closely with the agency to determine the
20 next steps required for the drug to receive marketing approval,"
21 said Eric K. Brandt, President and Chief Executive Officer of
22 AVANIR. "We believe Zenvia can significantly improve the lives
23 of patients, their families and their caregivers by reducing the
24 emotional and social toll taken by IEED."

23 88. On October 31, 2006, following the announcement of the FDA's Approvable
24 Letter, Avanir's stock price closed at \$3.98, a drop of more than 50% from the day before.

25
26 89. On December 11, 2006, Avanir hosted a conference call for analysts and
27 investors. During this call, Brandt made the following statements:
28

1 As I mentioned, the FDA completed the priority review of our
2 new drug application for Zenvia for the treatment of
3 involuntary emotional expression disorder, and provided us
4 with an approvable letter for the drug on October 30, 2006.

5 **While receipt of an approvable letter was always viewed**
6 **as a possibility, the letter was clearly a negative surprise.**
7 This was particularly disappointing for many of us, after the
8 NDA's original filing in June of 2005, with the primary
9 objective of commercializing Zenvia. The letter we received
10 from the Agency raised concerns around safety and efficacy.
11 While most of the issues were clear, the path forward was not.

12 * * * *

13 As it stands. I don't know that quinidine to be honest with you
14 will become something that you can't use. **I think that it was**
15 **always a question in our mind of, should we pursue another**
16 **2D6 inhibitor as a way to sort of go down an NCE path, and**
17 use that 2D6 inhibitor which is not, the ones that we are
18 considering are actually not ones that are on the market and do
19 have fresh IP around them. And I think that was something that
20 we were going to do, but we were going to do it later. I do think
21 it's something that moves more forward in our thinking and
22 strategically as we look at the drug.

23 90. Avanir has eventually admitted that the FDA's primary concern with Zenvia
24 was potential changes in the QT interval and that the FDA also had concerns about adverse
25 side effects such as nausea and dizziness.

26 91. The FDA has yet to approve Zenvia.

27 92. As a final aside, Zenvia was not the only time that Avanir lied to the investing
28 public regarding the safety of one of its drugs. As mentioned above, Avanir concealed the
FDA's concerns about its oral-herpes cream, Abreva. Further, in 2002, Avanir submitted an
Investigational New Drug Application ("IND") for an allergy and asthma drug called IgE.
By rule, the FDA has 30 days to either approve an IND or place a clinical hold on any
testing. After 30 days had expired without any news from Avanir regarding the FDA's
decision, shareholders began asking whether the FDA had placed a clinical hold on the IND

1 for IgE. A shareholder specifically asked Yakatan that question at Avanir's 2003 annual
2 shareholder meeting and was told "no." Plaintiff has come to learn that the FDA did, in fact,
3 place a clinical hold on the IND for IgE.
4

5 **AVANIR'S FALSE STATEMENTS**

6 **A. Avanir's false statements about rolling review.**

7 93. Avanir's December 16, 2004 press release, February 9, 2005 10-Q, April 18,
8 2005 press release, and May 16, 2005 10-Q all stated, in one way or another, that Avanir
9 began submitting the NDA for Zenvia on a "rolling review" basis in December 2004.
10 Yakatan made similar statements during his conference calls with investors on December 16,
11 2004 and February 10, 2005. These representations were false.
12

13 94. As mentioned above, the FDA only grants rolling reviews for drugs intended to
14 treat serious diseases. It is questionable whether PBA fits that category. One industry expert
15 told the *Union Tribune*: "There are a lot of good companies tackling important disease
16 indications – Avanir is not among them. The company had a drug and were searching for
17 something they could treat."
18

19 95. Moreover, one of the FDA's requirements for granting rolling review is that
20 the applicant pay the entire filing fee with the submission of the first portion of the new drug
21 application. In other words, when Avanir submitted the first portion of the NDA for Zenvia
22 in December 2004, it needed to submit the \$672,000 filing fee at the same time.
23

24 96. However, according to the 10-Q Avanir filed with the SEC in August 2005,
25 Avanir did not pay the filing fee until as late as June 2005. Specifically, the 10-Q read in
26 pertinent part:
27
28

1 *Research and development ("R&D") expenses.* R&D expenses
2 for the third quarter of fiscal 2005 were \$6.5 million and
3 included a \$672,000 filing fee for our new drug application for
 [Zenvia] in the treatment of PBA.

4 97. Avanir knew its representations about rolling review were false or had no
5 reasonable basis to believe they were true. Avanir is in the business of submitting drug
6 applications to the FDA. Indeed, Avanir continually told investors that it had a good
7 working relationship with the FDA and was working closely with the agency in connection
8 with the Zenvia NDA. Moreover, as described above, Avanir had already gone through the
9 drug approval process with its Abreva and IgE drugs. Thus, Avanir was certainly aware that
10 drug approval process with its Abreva and IgE drugs. Thus, Avanir was certainly aware that
11 it had to pay the entire filing fee in order to receive a rolling review. Avanir was also
12 certainly aware that it did not pay the \$672,000 filing fee until several months after it told the
13 investing public that the FDA had granted a rolling review.
14 investing public that the FDA had granted a rolling review.

15 **B. Avanir's false statements about priority review.**

16 98. Avanir's December 16, 2004 press release, January 2005 newsletter, February
17 9, 2005 10-Q, April 18, 2005 press release, and May 16, 2005 10-Q all contained
18 unequivocal statements that the FDA "has granted AVANIR's NDA a Priority Review" or
19 "indicated that [Zenvia] would qualify for a priority review." In addition, during the
20 conference calls with investors on December 16, 2004 and February 10, 2005, Yakatan
21 again unequivocally stated that the FDA had granted Zenvia a priority review. These
22 statements were false. By rule, the FDA cannot grant a priority review until after the entire
23 NDA submission is completed. As discussed below, Avanir's NDA submission for Zenvia
24 was not completed until June 2005.
25 was not completed until June 2005.
26 was not completed until June 2005.
27 was not completed until June 2005.
28 was not completed until June 2005.

1 99. Avanir knew its representations about priority review were false or had no
2 reasonable basis to believe they were true. Avanir is in the business of submitting drug
3 applications to the FDA. Indeed, Avanir continually told investors that it had a good
4 working relationship with the FDA and was working closely with the agency in connection
5 with the Zenvia NDA. Moreover, as described above, Avanir had already gone through the
6 drug approval process with is Abreva and IgE drugs. Thus, Avanir was certainly aware of
7 how the FDA's drug approval process works.
8

9
10 100. Further, Avanir's misstatement about priority review was not an isolated
11 incident or simple slip of tongue. Avanir made the misstatement *seven* separate times. In
12 addition, several Avanir executives reviewed a draft version of the April 18, 2005 press
13 release, including Avanir's director of clinical and regulatory affairs. These executives made
14 changes to the press release; however, left the false statement "[t]he FDA has granted
15 AVANIR's NDA a Priority Review . . ." unaltered.
16

17 101. Avanir's intent to defraud is further evidenced by the fact that Avanir tried to
18 cover up its misstatements about priority review. For example, in April 2005, Avanir
19 published its quarterly newsletter, which purported to summarize the February 10, 2005
20 conference call discussed above. However, the newsletter changed the critical language of
21 Yakatan's statement as follows:
22

- 23
- 24 • **Conference call:** "It is expected that that submission will be
completed by mid year and that's going to trigger a priority . . ."
 - 25 • **Newsletter:** "[I]t is expected that our [NDA] submission will be
26 completed by mid year. That is expected to trigger a priority
27 review . . ."
28

1 102. More incriminating is Avanir's actions with respect to the April 18, 2005 press
2 release. Like all of its press releases, this press release is available on Avanir's website. At
3 some point before May 2005, Avanir changed this press release to read in pertinent part:
4 "Upon completion of submission AVANIR expects the NDA will receive a Priority Review,
5 which is an accelerated six-month timeline." In other words, Avanir surreptitiously changed
6 its press release in order to correct its false statement "that the FDA has granted AVANIR's
7 NDA a Priority Review, which is an accelerated six-month review timeline." However,
8 Avanir's scheme was eventually revealed and Avanir changed the press release back to
9 (almost) its original version: "The FDA has granted AVANIR's NDA a Priority Review,
10 which is an accelerated [sic] six-month review timeline. Notably, in its haste to cover its
11 tracks, Avanir misspelled the word "accelerated" in the replacement press release.
12
13
14

15 103. Further, on May 16, 2005, Yakatan unexpectedly "resigned" as President and
16 CEO of Avanir. Yakatan's "resignation", which occurred the same day he made the last in a
17 long line of misrepresentations about rolling and priority review, certainly suggests that he
18 was fired for improper behavior. Indeed Yakatan has since testified that he was told he
19 would be terminated if he did not resign.
20

21 **C. Avanir's false statements about Zenvia's safety and efficacy.**

22 104. On September 22, 2005, Avanir's then CEO, Eric Brandt, told investors: "Um,
23 again, you know, it would be one thing if the data were equivocal on an efficacy or safety
24 standpoint. I'd be much more worried. They're not. So from my perspective it's not an
25 issue of whether this becomes an approved drug, it's more an issue of when it becomes an
26 approved drug." Brandt's statements were repeated in the *San Diego Union Tribune* the
27
28

1 following day: "Brandt said the clinical trial data on [Zenvia] 'is not equivocal on efficacy or
2 safety,' and characterized the issue as more of a 'miscommunication' about how the analysis
3 should be organized." In truth, however, the problems with Zenvia went far beyond
4 organizational issues.

5
6 105. In connection with his investigation of this lawsuit, Plaintiff has communicated
7 with several former Avanir employees. According to one employee, "you should have heard
8 Eric Brandt's voice message we all had in our inboxes" after the FDA delayed the PDUFA
9 date in August 2005. Brandt told Avanir's employees, the FDA's issues were "too numerous
10 to define at the time" and "they had to go and hire a bunch of experts to interpret the
11 decision." This is of course a far cry from Brandt's statement to investors that the clinical
12 data was not equivocal on efficacy or safety and that the reasons for the delay were
13 organizational issues.
14

15
16 106. In addition, in October 2005, the FDA issued new guidelines for acceptable
17 QTc levels. Avanir was well aware of the FDA's new guidelines. Indeed, after October
18 2005, all of its SEC filings contained the following disclosure:
19

20 Recent public announcements regarding safety problems with
21 certain approved drugs may also affect the FDA's policies
22 regarding safety data for all new drug applications and may
23 result in the FDA requiring additional safety data before
24 approving [Zenvia], and FDA may require closer surveillance
25 after commercialization if the drug is approved.

26 107. In connection with his investigation of this lawsuit, Plaintiff has discovered
27 that, during one of the clinical tests in 2004, Zenvia produced results showing that it caused a
28 change in the QTc interval that was in excess of the FDA's October 2005 guidelines. The
fact that the clinical testing done in 2004 produced results in excess of the FDA's QTc

1 guidelines was never disclosed to the investing public. To the contrary, Avanir made several
2 statements concealing Zenvia's QTc problems.

3
4 108. First, Avanir's April 4, 2006 press release announcing that the FDA had finally
5 accepted Avanir's NDA for Zenvia quoted Brandt as saying "[t]he application is based on
6 clinical data supporting that Zenvia . . . is safe and effective . . ." Brandt's statement was
7 false because it concealed the fact that Avanir's clinical testing in 2004 produced results that
8 were in excess of the FDA's QTc guidelines.

9
10 109. Likewise, during Avanir's May 8, 2006 quarterly conference call, Brandt was
11 asked a question regarding the "safety profile" of Zenvia, particularly as it relates to "QT
12 prolongation." Brandt responded, "we're quite comfortable with I think the QTC profile of
13 the drug." Again, this statement was false for failing to disclose that the 2004 clinical test
14 results exceeded the FDA's threshold level of concern.

15
16 110. As discussed above, the FDA issued its October 31, 2006 Approvable Letter
17 because of QTc problems with Zenvia. Despite Brandt's statement that the FDA's
18 Approvable Letter was a "negative surprise," Avanir was well aware that the FDA had
19 serious concerns about Zenvia's QTc issues. Plaintiff is informed and believes that Avanir
20 received numerous communications from the FDA during the approval process outlining the
21 FDA's concerns about the drug. Further, even Brandt admitted that the use of quinidine (the
22 agent that affects the QTc interval) was "always a question in our mind."
23
24

25 111. Avanir's intent to defraud is further evidenced by the fact that Avanir
26 consistently mislead investors as to the reason why the FDA's approval process was taking
27
28

1 so long. As mentioned above, Avanir consistently told investors the FDA was delaying the
2 PDUFA date for Zenvia so that Avanir could reorganize its submission and address various
3 “formatting” issues. At the same time, Avanir admitted it was submitting “1,000 pages” of
4 new materials “based on the guidance we received from the FDA.” The clear implication is
5 that the FDA had safety concerns about Zenvia.
6

7 112. Further, the actions of Yakatan and Avanir’s largest shareholder, Orbimed
8 Advisors, LLC, confirm that Avanir was aware that the FDA had serious problems with
9 Zenvia.
10

11 a. Specifically, on March 19, 2005, Avanir purchased the licensing rights
12 from Yakatan’s company, IriSys, for approximately \$7.25 million in cash
13 and Avanir stock. Notably, Avanir had previously stated on numerous
14 occasions that potential market for Zenvia could lead to sales between
15 \$500 million and \$3 billion. Under the terms of its licensing agreement
16 with CNS, IrySis stood to make approximately 10-15% of Zenvia’s sales.
17 Thus, selling the licensing rights for only \$7.25 million made little sense
18 from IrySis’s perspective; unless, of course, there were significant
19 problems with the drug.

20 b. On May 31, 2005, Orbimed disposed of 25% of its Avanir holdings, or
21 629,000 shares. Notably, one of Orbimed’s general partners, Jonathan
22 Silverstein, was a member of Avanir’s board of directors at the time. As
23 such, Silverstein had access to the FDA’s communications with Avanir
24 and was aware of the problems with Zenvia. The fact that Orbimed
25 dumped a quarter of its holding is clear evidence that Avanir was aware
26 the FDA had safety concerns about Zenvia, a fact which was concealed
27 from Avanir’s shareholders.
28

VAUGHN'S RELIANCE

1
2 113. Vaughn purchased several thousand shares of Avanir stock during the relevant
3 time period.
4

5 114. Plaintiff first purchased Avanir shares in 2005.
6

7 115. Another putative class member, Richard Kralick, purchased several thousand
8 shares during the class period, beginning in 2000. By 2004, he had over 280,000 shares.
9

10 116. On December 16, 2004, Avanir issued its first false statement about rolling and
11 priority review.
12

13 117. On April 18, 2005, Avanir issued another false press release about rolling and
14 priority review. Plaintiff reviewed this press release at or near the time it was issued. In
15 response, she purchased shares of Avanir's stock.
16

17 118. On September 22, 2005, Brandt falsely stated that the safety and efficacy data
18 for Zenvia was not equivocal. Plaintiff reviewed this press release at or near the time it was
19 issued. In response, she purchased shares of Avanir's stock.
20

21 119. In January 2006, Avanir did a reverse 4:1 stock split, which converted every
22 four of Plaintiff's Avanir shares into one share. In exchange, the price of each share
23 quadrupled.
24

25 120. On April 4, 2006, Avanir issued a false press release falsely stating its NDA
26 for Zenvia was based on clinical data showing the drug was safe and effective. Vaughn
27 reviewed this press release at or near the time it was issued and relied on it.
28

1 121. On May 8, 2006, Avanir hosted a conference call, in which Brandt concealed
2 Zenvia's QTc problems.

3 122. Plaintiff relied on the statements and concealment of material facts made by
4 Defendants.
5

6 123. The stock activity described above was conducted through a trading account
7 that Vaughn had with Charles Schwab.

8 124. Vaughn is still ascertaining the precise details of his trading activity in these
9 accounts and will seek leave to amend her complaint once the process is completed.
10

11 **DEFENDANTS' FRAUD AND VIOLATION OF RULE 10B5 OF 1934**
12 **SECURITIES EXCHANGE ACT**

13 125. Defendants, and each of them, were aware that the FDA had safety concerns
14 regarding the NDA for Zenvia and that the FDA had not granted priority review to the
15 Zenvia NDA. In order to deceive the investing public, Defendants made, participated in the
16 making of, or aided and abetted the making of, the misrepresentations and concealments of
17 material facts described above.
18

19 126. The misrepresentations and concealments described above were not true and
20 Defendants knew, or should have known that they were not true.

21 127. Plaintiff and/or putative class members read each of the press releases,
22 newsletters, and SEC filings described above at, or near the time, they were published.
23 Further, Plaintiff participated in many of the conference calls and attended some of the
24 meetings described above. In reliance of the statements made in those publications or during
25 the conference calls/meetings, Plaintiff purchased a substantial number of additional shares
26 in Avanir. Had Plaintiff been aware of the Company's behavior with regard to Zenvia from
27
28

1 the beginning, she would not have purchased any shares in Avanir. Further, had Plaintiff
2 known the true facts, including the safety issues and the Company's misrepresentations
3 about rolling and priority review, she would have sold all of her Avanir shares prior to
4 October 31, 2006.
5

6 128. Plaintiff, and the putative class, suffered damages in excess of the jurisdictional
7 minimum of this Court, which amount will be proven with more certainty at the time of trial.
8

9 129. During the Class Period, Defendants, and each of them, carried out a plan,
10 scheme and course of conduct that was intended to and/or did: (i) deceive the investigating
11 public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflated
12 the market price of Avanir common stock; and (iii) caused Plaintiff and other members of
13 the Class to buy Avanir stock at specifically inflated prices. In furtherance of this unlawful
14 scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth
15 herein.
16

17 130. These Defendants: (a) employed devices, schemes and artifices to defraud; (b)
18 made untrue statements of material fact and or omitted to state material facts necessary to
19 make the statements not misleading; and (c) engaged in acts, practices and a course of
20 business which operated as a fraud and deceit upon buyers of Avanir common stock in
21 violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
22

23 131. Defendants' material misrepresentations and/or omissions were done
24 knowingly or recklessly.
25

26 132. As a result of Defendants' dissemination of deceptive and misleading
27 information regarding Avanir's true status with the FDA fast track approval of Zenvial;
28

1 the nature and extent of the secret self dealing between YAKATAN and his predecessors and
2 successors; as well as the concealment of safety issues with Zenvial, Plaintiff and the Class
3 were damaged. In ignorance of the fact that the market price of Avanir's shares were
4 artificially inflated and relying upon the integrity of the market in which Avanir common
5 stock trades, and/or on the absence of material information that was known to and/or
6 recklessly disregarded by Defendants but not disclosed in public statements by Defendants
7 during the Class Period, Plaintiff and the other members of the Class bought Avanir common
8 stock during the Class Period at artificially inflated prices and were damages thereby.
9
10

11 **FIRST CAUSE OF ACTION**
12 **AGAINST THE INDIVIDUAL DEFENDANTS PURSUANT**
13 **TO SECTION 20(a) OF THE EXCHANGE ACT**

14 133. Plaintiff repeats and alleges each and every allegation set forth above.

15 134. This claim is asserted against the Individual Defendants pursuant to Section
16 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

17 135. During the Class Period, the Individual Defendants, were "controlling persons"
18 of Defendant Avanir within the meaning of Section 20(a) of the Exchange Act.

19
20 136. The Individual Defendants were "controlling persons" of Avanir because, due
21 to the officer and/or director positions they held within Avanir, they had the influence and
22 power over Avanir to cause, and they did cause, Avanir to engage in the wrongful conduct
23 complained of herein, and because they had the power to have prevented Avanir from
24 engaging in the unlawful conduct alleged herein, but they purposely, intentionally and
25 recklessly did not use that power to do so.
26
27
28

1 137. As set forth above Avanir violated Section 10(b) of the Exchange Act and Rule
2 10b-5 promulgated thereunder by its acts or omissions as alleged in this Complaint. By
3 virtue of their status as a "controlling person" of Avanir, the Individual Defendants are
4 liable, to the same extent as is Avanir for its violations of Section 10(b) of the Exchange Act
5 and Rule 10b-5 promulgated thereunder, pursuant to Section 20(a) of the Exchange Act.
6

7 138. As set forth above, Avanir violated Section 14(a) of the Exchange Act by its
8 acts and omissions. By virtue of their status as a "controlling person" of Avanir, the
9 Individual Defendants are liable, to the same extent as is Avanir for its violations of Section
10 14(a) of the Exchange Act, pursuant to Section 20(a) of the Exchange Act.
11

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Plaintiff on behalf of herself and the Class, prays for judgment as
14 follows:
15

16 A. Declaring this action to be a class action properly maintained pursuant to Rule
17 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

18 B. Finding that Defendants violated Section 10(b) of the Exchange Act and Rule
19 10b-5 promulgated thereunder and Sections 20(a) and 14(a) by their acts and omissions as
20 alleged in the complaint;
21

22 C. Awarding Plaintiff and the members of the Class damages, together with
23 interest thereon;

24 D. Awarding Plaintiff and the other members of the Class their costs and expenses
25 of the litigation, including reasonable attorney's fees and expert's fees and other costs and
26 disbursements; and
27
28

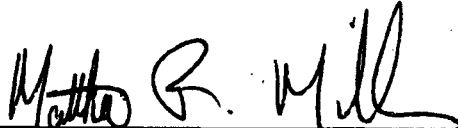
1 E. Awarding Plaintiff and other members of the Class such other and further
2 releief as may be just and proper under the circumstances.

3
4 **JURY DEMAND**

5 Plaintiff demands a trial by jury.

6 DATED: October 30, 2009

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8 DREHER LAW FIRM

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10 

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