UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

[redacted]	:	
Individually and on Behalf of All Similarly Situated,	:	CIVIL ACTION 03-10165-RWZ
Plaintiffs,	:	
	:	CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS
vs.	:	
Transkaryotic Therapies, Inc., and Richard F. Selden	:	JURY TRIAL DEMANDED
Defendants.	:	

Plaintiffs, [redacted] individually and on behalf of all others similarly situated, by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief are based upon, among other things, his, their and/or counsel's investigation, which included without limitation: (a) review and analysis of filings made by Transkaryotic Therapies, Inc. ("TKT" or the "Company") with the Securities and Exchange Commission ("SEC"); (b) review and analysis of securities analysts' reports concerning TKT; (c) review and analysis of press releases and other publications disseminated by certain of the Defendants; (d) review of news articles and shareholder communications concerning TKT; and (e) review of other publicly available information concerning TKT. Plaintiffs believe that further substantial evidentiary support will exist for the allegations herein after a reasonable opportunity for discovery. Many of the facts supporting the allegations contained herein are known only to Defendants or are within their control.

NATURE OF THE ACTION

1. Plaintiffs [redacted] bring this action as a class action on behalf of a class (the "Class") consisting of themselves and all other persons or entities that purchased the common stock or call options, or who sold put options, of TKT during the period January 4, 2001 through January 14, 2003, inclusive (the "Class Period"). Plaintiffs seek to recover damages caused to the Class by defendants' violations of the federal securities laws.

2. Throughout the Class Period, defendants engaged in a scheme to inflate artificially the market price of TKT securities and to defraud class members by making misrepresentations and nondisclosures of material fact concerning TKT's prospects for FDA approval of the marketing of TKT's Replagel enzyme therapy for the treatment of Fabry disease.

3. Defendants knew by virtue of their ongoing communications with the FDA that the FDA considered TKT's data on the primary pain reduction endpoint of TKT's Phase II study to be uninterpretable, and further that the FDA considered that TKT's cardiac and renal data did not support approval. More specifically, according to testimony at the January 14, 2003 Advisory Committee hearing, the FDA had advised TKT in a letter dated December 22, 2000 that "the clinical study data [from the Phase II studies] had not provided substantial evidence of efficiency and fully detailed the facts leading to that conclusion. [The FDA's Center for Biologics Evaluation and Research] recommended that additional clinical studies be conducted." Notwithstanding these clear directives from the FDA, defendants continually represented throughout the class period that they were optimistic of achieving FDA approval to market Replagal, based on the Phase II studies that had, unbeknownst to the investing public, been rejected by the FDA in December 2000.

4. Some of the true facts began to be revealed after the close of the securities markets on October 2, 2002, when TKT admitted that the FDA had determined that TKT's data on pain reduction was "uninterpretable," and that TKT had determined not to rely on that data to seek FDA approval for marketing of Replagal. Rather, defendants stated that TKT would rely primarily on its data for cardiac and renal improvement in Phase II tests for patients receiving Replagal. Defendants further acknowledged, at a conference for investors conducted at the Plaza Hotel on October 8, 2002, that the FDA had advised TKT in early 2001 that it did not consider the cardiac or renal data to support approval of Replagal.

5. In response to defendants' October 2, 2002 announcement, the market price of TKT common stock plummeted from its closing price on October 2, 2002 of $33.25 per share to a closing price on October 3, 2002 of $12.75 per share.

6. Additional facts were disclosed by TKT and the FDA in connection with the January 14, 2003 Advisory Committee meeting. At that meeting, the FDA stated its reasons for believing that the pain data was uninterpretable and further, that it had informed TKT of its reasoning at least as early as January 2001. The FDA further confirmed that it had informed TKT that the renal and liver data did not support approval as early as January 2001.

7. TKT common stock had been halted for trading during the course of the Advisory Committee meeting. TKT closed at $6.49 per share on January 15, 2003, the first trading day after the January 14, 2003 hearing.

8. As a result of defendants' misconduct, plaintiffs and the Class members have suffered substantial damages.

9. TKT was motivated to make the materially false and misleading statements during the Class Period, among other things, to sell $267 million in common stock in secondary public offerings. Defendant Richard F. Selden was similarly motivated to sell 90,000 shares of his personal holdings of TKT common stock during the Class Period for total consideration of $2,800,000.

JURISDICTION AND VENUE

10. This action arises under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. 240.10b-5.

11. This Court has jurisdiction of this action under Section 27 of the Exchange Act and 15 U.S.C. § 78aa, 28 U.S.C. § 1331.

12. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Many of the acts alleged herein, including the dissemination to the investing public of false and misleading statements, occurred in substantial part in this District. In addition, defendants' principal place of business and executive offices are located in this District.

13. In connection with the acts and conduct complained of, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails, interstate telephone communications, and the facilities of a national securities exchange.

CLASS ACTION ALLEGATIONS

14. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the Class consisting of all persons or entities that purchased common stock

or call options, or who sold put options, of TKT on the open market during the Class Period January 4, 2001 through January 14, 2003. Excluded from the Class are the defendants herein, members of their immediate families, any subsidiary, affiliate, or control person of any such person or entity, officers and directors of TKT and the legal representatives, heirs, successors or assigns of any such excluded party.

15. The members of the Class are so numerous that the joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are, at a minimum, over one thousand members of the Class. During the Class Period, the Company reported that it had approximately 34.3 million shares of its common stock outstanding. The holders of these shares are believed to be geographically dispersed throughout the United States. TKT common stock is listed and actively traded on the NASDAQ National Market System, widely recognized as an efficient market. During the Class Period, millions of shares of TKT common stock were traded.

16. TKT common stock options (calls and puts) are similarly actively traded on the American Stock Exchange and other markets.

17. Plaintiffs' claims are typical of the claims of the Class, as plaintiffs purchased common shares or sold put options of TKT on the open market during the Class Period and sustained damages arising out of defendants' conduct in violation of federal law as complained of herein.

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

19. Common questions of law and fact exist as to all members of the Class and

predominate over any questions affecting only individual members of the Class. Among the questions of law and fact common to the Class that predominate over any questions affecting individual members of the Class are:

(i) whether defendants violated Sections l0(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder;

(ii) whether defendants participated in and pursued the common course of conduct complained of herein;

(iii) whether documents, filings, releases and statements disseminated to the investing public, during the Class Period, omitted and/or misrepresented material facts about the Company;

(iv) whether the market price of TKT's common stock and call options during the Class Period were artificially inflated (and TKT's put options were artificially depressed) due to the nondisclosures and/or misrepresentations complained of herein;

(v) whether defendants acted knowingly, wilfully, or recklessly in omitting to state and/or misrepresenting material facts; and

(vi) whether the members of the Class have sustained damages and, if so, what is the proper measure of such damages.

20. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Since the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for the Class members to seek redress for the wrongful conduct alleged. Plaintiffs know of no difficulty that will be

encountered in the management of this litigation that would preclude its maintenance as a class action.

THE PARTIES

21. Plaintiffs, Larry N. Price and Edgar R. Marrero, bought and sold securities of defendant TKT on the open market during the Class Period, as set forth in the annexed certifications, and suffered damages thereby.

22. Defendant TKT is a corporation organized and existing under the laws of Delaware. TKT maintains its principal executive offices at 195 Albany Street, Cambridge, MA 02139. TKT represents itself in SEC filings to be a biopharmaceutical company developing protein- and cell-based therapeutics for the treatment of a wide range of human disease.

23. Defendant Richard F. Selden is the founder of TKT. He has served as Chief Scientific Officer, Chairman of the Scientific Advisory Board and a Director since TKT's inception in 1988 and as President and Chief Executive Officer since June 1994. In 2001, Selden was paid a salary of $400,000 and a cash bonus of $150,000, and was granted options to acquire 50,000 shares of TKT common stock. In 2000, Selden was paid a salary of $350,000 and a cash bonus of $140,000, and was granted options to acquire 40,000 shares of TKT common stock. Selden also received in 2000, $348,054 in other annual compensation, consisting primarily of the forgiveness of a loan and reimbursement of the related tax liability for such forgiveness. Selden's base cash salary for 2002 was $450,000.

24. During the Class Period, Selden, as Chairman and CEO of TKT, was privy to confidential and proprietary information concerning TKT, its operations, and present and future

business prospects. Selden had access to material adverse non-public information about TKT's business, including the prospects for U.S. approval of Replagal. Selden knew or recklessly disregarded that the adverse facts specified herein were misrepresented and concealed from the investing public.

25. Selden is liable as a direct participant in the violations of law complained of herein. In addition, Selden was a "controlling person" within the meaning of Section 20 of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein.

26. As a senior executive officer and director and as a controlling person of a publicly-traded company whose securities were and are registered with the SEC pursuant to the Exchange Act, and were traded over the NASDAQ National Market System, and governed by the federal securities laws, defendant Selden had a duty to speak the truth with respect to the prospects for FDA approval of Replagal, and to correct any previously issued statements that had become materially misleading, so that the market price of TKT's securities would be based upon truthful and accurate information. Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

BACKGROUND

27. Fabry disease is an inherited lysosomal storage disorder caused by the deficiency of the enzyme alpha-galactosidase A. Patients with Fabry disease show diverse clinical manifestations beginning as early as adolescence. These manifestations include severe pain and cardiovascular and renal complications.

28. The Company believes that there are approximately 5,000 Fabry disease patients worldwide.

29. Current treatment of the disease is limited to the reduction of symptoms. The Company believes that enzyme replacement therapy could result in an improvement in the clinical manifestations of the disease.

30. TKT, in collaboration with the National Institutes of Health ("NIH"), completed a 26 patient pivotal Phase II study in patients with Fabry disease in December 1999 (TKT 003). The goal of the study was to assess safety and clinical activity of Replagal, TKT's enzyme replacement therapy, particularly its effect on pain and kidney function.

31. A second pivotal Phase II study involving 15 patients was conducted in 1999 - 2000 at the Royal Free Hospital in London (TKT 005). The goal of the study was to assess safety and clinical activity, particularly to improve cardiac function in patients with Fabry disease.

32. On June 16, 2000, TKT submitted a Biologics License Application ("BLA") to the FDA seeking marketing approval of Replagal. The BLA presented the test results of TKT 003 and TKT 005.

33. In October 2000, TKT reported pivotal Phase II clinical results of Replagal from the NIH study, indicating that the enzyme replacement therapy had broad clinical effects in treating Fabry disease. According to defendants, patients receiving Replagal had comprehensive clinical and biochemical improvement including a reduction in pain and stabilization or improvement in renal function.

34. According to defendants, data from these two pivotal studies, as well as data from an

additional six months of treatment from an open-label maintenance study at the NIH, supported TKT's submission to the FDA for marketing approval in the United States.

35. In 2000, TKT received orphan drug designation for Replagal in the U.S. As a result, if Replagal is the first product to receive FDA marketing approval for the indication for which it has designation as an orphan drug, the FDA may not approve any other applications to market the same product for the same indication, except in limited circumstances, for a period of seven years.

36. A rival product produced by Genzyme Corp. also received orphan drug status from the FDA in 2000 for its Fabry disease treatment in the U.S. Neither of the two drugs have to date been approved for marketing in the U.S. If Genzyme's Fabry disease product receives marketing approval in the U.S. before TKT, TKT may be excluded from marketing Replagal in the U.S., except in limited circumstances.

SUBSTANTIVE ALLEGATIONS

The January 4, 2001 Press Release Announcing Receipt of an FDA Complete Review Letter

37. On January 4, 2001, TKT issued a press release announcing that it had "received a complete review letter" from the FDA concerning its BLA for Replagal. According to the press release, "in the letter, the FDA asked for further explanation in several areas and requested additional data. TKT has initiated the collection of these data but until there is an opportunity for further discussion with the FDA, TKT cannot make projections about the timing of future FDA decisions concerning the approval of Replagel."

38. Defendant Selden was quoted in the press release as stating that:

> While we are disappointed that the FDA did not approve Replagal at this time, we are working diligently to respond quickly to their requests for additional data. We believe Replagal is the best hope for patients suffering from this life-threatening disease, and we remain firmly committed to bringing a safe and effective therapy to market for the thousands of patients affected by Fabry disease. We will continue to do everything we can to make this therapy available as soon as possible and we look forward to working with the FDA towards attaining this goal.

39. Defendants belatedly disclosed in October 2002, that among the FDA's comments in response to the BLA was that it did not believe that the cardiac or renal data supported approval of the drug. The FDA further indicated at the January 14, 2003 meeting that as early as January 2001, it had informed TKT that the pain data from the NIH study was uninterpretable. The FDA's expressed concerns made it significantly less likely that TKT would obtain FDA approval to market Replagal. Notwithstanding the clear materiality of the FDA's concerns, defendants, in the January 4, 2001 press release and throughout the class period, continued to express optimism that TKT would achieve regulatory approval to market Replagal.

40. Defendants' January 4, 2001 press release was materially false and misleading because it failed to disclose the FDA's concerns with regard to the pain, cardiac and renal data.

41. On May 8, 2001, defendant Selden sold 20,000 shares of TKT common stock at $22.90 for gross proceeds of $458,000. On July 2, 2001, TKT announced the completion of a follow-on public offering, raising $100,177,500. A total of 3,515,000 shares were sold at $28.50 per share. The shares were sold by defendants in May and July 2001 at inflated prices resulting from defendants' materially false and misleading statements.

The August 3, 2001 Press Release

42. On August 3, 2001, prior to the opening of the U.S. securities markets, TKT issued a press release advising investors that the European Agency for the Evaluation of Medicinal Products had granted marketing authorization for Replagal for the treatment of Fabry disease in the fifteen member countries of the European Union.

43. In an interview with Bloomberg News conducted on August 3, 2001, Selden stated that "we are working very closely with the FDA and I am quite hopeful. . . With Replagal we have proven the treatments of these kind of products."

44. According to a research report issued by Pacific Growth Equities, in a conference call with securities analysts and other investors after the August 3, 2001 announcement, defendant Selden further stated that he was unaware as to when the FDA may approve Replagal for use in the U.S., but indicated that TKT had responded to the FDA's request for additional information and that significant progress had been made over the past 6 months.

45. On September 20, 2001, defendant Selden sold 20,000 shares of TKT common stock at prices ranging from $24.43 to $25.05 per share for gross proceeds of approximately $500,000. Those shares were sold by Selden at inflated prices resulting from defendants' materially false and misleading statements.

The October 19, 2001 Press Release and Subsequent Bloomberg News Interview

46. On October 19, 2001, TKT issued a press release, prior to the opening of the U.S. securities markets, announcing that it had received marketing approval of Replagal for the long-term treatment of Fabry disease in both New Zealand and Iceland. The press release stated that:

> The approval of Replagal in New Zealand and Iceland is based on six-month data from two independent placebo-controlled clinical trials conducted in the United States and the United Kingdom, as well as long-term data of up to 18 months from open-label maintenance studies. As reflected in the product labels, these studies demonstrated multiple clinical improvements including a reduction in neuropathic pain and reduction in the use of pain medications, initial stabilization followed by improvement in kidney function, a reduction in cardiac mass and a metabolic correction of glycosphingolipid levels in urine sediment, plasma, and kidney, heart and liver cells.

47. The October 19, 2001 press release was materially false and misleading because it failed to disclose the FDA's concerns with regard to the pain, cardiac and renal data.

48. On November 1, 2001, defendant Selden sold 30,000 shares of TKT common stock at $37.70 for gross proceeds of $1,112,100. On December 18, 2001, TKT sold 3,220,000 shares of its common stock in a public offering at a price of $39.90 per share resulting in total gross proceeds of $125,580,000. On December 26, 2001, TKT sold an additional one million shares in a public offering at $42.00 per share. Those shares were sold by defendants at inflated prices resulting from defendants' materially false and misleading statements.

49. On February 14, 2002, defendant Selden sold 20,000 shares of TKT common stock at $37.33 per share for gross proceeds of $746,000. Those shares were sold by Selden at inflated prices resulting from defendants' materially false and misleading statements.

The May 2, 2002 First Quarter Fiscal 2002 Press Release

50. On May 2, 2002, TKT issued a press release, after the close of U.S. stock trading, announcing operating results for the first quarter of fiscal 2002. In an interview with Angela Zimm of Bloomberg News Radio, conducted after the issuance of the press release, defendant Selden stated

with regard to Replagal's prospects for approval in the United States, that:

ZIMM: Both [Replagal and Fabrazyme] were approved [in Europe] and it seemed unusual to some people at the time, you both won exclusive marketing rights under a rule that normally would have approved just one. Do you expect that to happen with the U.S. Food and Drug Administration, too?

SELDEN: I don't expect the same thing will happen. I think that TKT will win the race in the United States and be the only product that will be approved for this indication on the market in the States.

ZIMM: What's the status right now of Replagal in the regulatory process before the FDA?

SELDEN: We continue to have frequent and productive conversations with the FDA. And though I don't yet have a time line for approval, I do believe that we've made substantial progress.

ZIMM: OK. What's the FDA focusing on in these discussions?

SELDEN: Well, I think that the - really, the focus on Replagal concerns the - a huge amount of clinical data that we believe shows that the product helps patients quite substantially. And to integrate the data with what's known about the natural history of Fabry disease, and I do believe we've made significant progress in the area.

ZIMM: And when do you expect approval?

SELDEN: I don't know. I think that as long as we continue to make progress, I'll be content to just say that I think that we're going to win the race. And as soon as we end up receiving something definitive from the FDA, an approvable letter, we'll be thrilled to make an announcement. But until now, all I can say is that we're making progress and we don't have a specific date in mind, just yet.

[Emphasis added.]

51. Defendant Selden further stated on a conference call with investors after issuance of the May 2, 2002 earnings report that:

Now, turning to the U.S. we continue to make progress with the FDA. The

> interchange with the FDA is frequent and constructive. We believe that the approval of Replagal in the U.S. remains a when not if proposition. We remain confident as well that we will earn orphan designation and that Replagal will be the only product to earn such designation.
>
> While this is essence the same message we had for you at your year-end conference call in February, the consistency itself of our message is important, very important, and we're on the right path to bring this therapy to American Fabry patients.

52. Defendants' May 2, 2002 press release, and defendant Selden's interview on Bloomberg News Radio and statements on the investor conference call, were materially false and misleading because they failed to disclose the FDA's concerns with regard to the cardiac and renal data. Contrary to defendants' statements that TKT continued to have "frequent and productive conversations with the FDA" and make "substantial progress," the FDA was continuing to maintain that TKT's pain, cardiac and renal data did not support approval of Replagal.

The June 5, 2002 Press Release

53. On June 5, 2002, TKT issued a further press release reporting on the publication in the Journal of the American Medicine Association of pivotal clinical results evaluating Replagal enzyme replacement therapy as a treatment for Fabry disease. According to the press release, the JAMA article described the results of a pivotal Phase II clinical trial in twenty-six patients with Fabry disease in the United Kingdom.

54. According to the press release and JAMA article, patients receiving Replagal had a clinically significant reduction in severe, debilitating pain compared to no change for the placebo group. Patients on treatment also experienced a reduction in the number of days off pain medication, with several patients permanently discontinuing pain medications for the duration of the trial. Patients also

demonstrated improvement in their quality of life associated with the reduction of pain.

55. The investigators further reported that patient kidney function stabilized or improved in the group receiving Replagal, whereas patients in the placebo arm experienced a decline in kidney function consistent with the natural history of Fabry disease. This functional change was consistent with observed improvements in renal pathology in patients receiving Replagal. In particular, the fraction of normal glomeruli increased in these patients, while there was a decline in patients on placebo.

56. The article also indicated that patients experienced an improvement in cardiac function, as well as improvements in the underlying metabolic defects as reflected by a decrease in globtriaosylceramide (Gb3) storage and an increase in body weight. Treatment with Replagal was safe and well-tolerated with the most common adverse events being symptoms typically observed in patients with Fabry disease.

57. Defendants' June 5, 2002 press release was materially false and misleading because it failed to disclose the FDA's concerns with regard to the cardiac and renal data. Contrary to defendants' statements that TKT continued to have “frequent and productive conversations with the FDA" and had made "substantial progress," the FDA was continuing to maintain that TKT's pain, cardiac and renal data did not support approval of Replagal.

The July 8, 2002 Press Release

58. On July 8, 2002, TKT issued a press release over PRNewswire at 1:39 p.m., announcing that the company's BLA for Replagal would be considered before the FDA's Endocdnologic and Metabolic Drugs Advisory Committee at its scheduled meeting on September 27, 2002. Defendant Selden was quoted in the press releases as stating that TKT was "pleased

that the FDA is taking this next, important step in the review of the BLA. We look forward to the opportunity to make Replagal available to patients in the United States."

59. The July 8, 2002 press release further stated that "Advisory committees provide the FDA with independent advice on marketing applications. The FDA generally follows the recommendations of its advisory committees, but is not bound to do so."

60. Defendants' July 8, 2002 press release was materially false and misleading because it failed to disclose the FDA's concerns with regard to the pain, cardiac and renal data. Contrary to defendants' statements that TKT continued to have "frequent and productive conversations with the FDA" and had made "substantial progress," the FDA was continuing to maintain that TKT's pain, cardiac and renal data did not support approval of Replagal.

The July 31, 2002 Press Release

61. On July 31, 2002, TKT issued a press release, after the close of trading, reporting operating results for the second quarter of fiscal 2002. The press release quoted defendant Selden as stating that "the recent decision by the FDA to hold an advisory committee meeting to evaluate our [BLA] for Replagal provides us with clarity regarding the potential U.S. marketing approval, and we are actively preparing for the potential launch of Replagal in the U.S. later this year."

62. According to a Pacific Growth Equities research report dated August 1, 2002, after the release of the earnings report on July 31, 2002, defendants conducted a conference call with stock analysts and investors during which defendant Selden stated that "management believes it is possible that Replagal will gain U.S. approval later this year, and the Company is actively preparing for a successful launch."

63. The July 31, 2002 press release and statements to analysts and investors were materially false and misleading. By July 31, 2002, defendants had had extensive communications with the FDA by virtue of which they had been informed that TKT's data on pain on the NIH Phase II trial was uninterpretable, and that the data concerning cardiac and renal function did not support the efficacy of Replagal in treatment of Fabry patients. Accordingly, defendants knew or were reckless in failing to know that Replagal was unlikely to obtain the recommendation from the Advisory Committee, or approval from the FDA, for marketing in the treatment of Fabry disease.

The August 7, 2002 Amendment No. 1 to the Form S-3

64. On August 7, 2002, TKT filed an Amendment No. 1 to a Form S-3 in connection with a planned offering of 366,928 shares of TKT by Cell Genesys. The Amendment No. 1 stated that:

> In the United States, we submitted a [BLA] to the FDA seeking marketing authorization for Replagal. In January 2001, the FDA issued a complete review letter regarding the [BLA]. The FDA letter stated that the data that we had provided was not adequate for approval of the [BLA] at that time and requested additional information. In response to this letter, we have discussed the [BLA] with the FDA and have submitted additional data.

65. The August 7, 2002 Amendment to the Registration Statement was materially false and misleading. By August 7, 2002, defendants had extensive communications with the FDA and had been informed that TKT's pain data from the NIH Phase II trial was uninterpretable, and that the data concerning cardiac and renal function did not support the efficacy of Replagal in treatment of Fabry patients. Accordingly, defendants knew or were reckless in failing to know that the Advisory Committee, would not recommend approval of Replagal for the treatment of Fabry disease, and that the FDA would not approve the drug for marketing.

The September 20, 2002 Press Release

66. On September 20, 2002, TKT issued a further press release, carried over PRNewswire at 12:59 p.m., announcing that the Endocrinologic and Metabolic Drugs Advisory Committee will not meet as scheduled on September 26 and 27, 2002 to consider TKT's Replagal enzyme replacement therapy for Fabry Disease and a competing product developed by Genzyme Corp. According to the press release, the FDA "postponed the Advisory Committee meetings due to administrative reasons."

67. Defendants' September 20, 2002 press release was materially false and misleading.

68. By September 20, 2002, defendants had had extensive communications with the FDA by virtue of which they had been informed that TKT's data on pain on the NIH Phase II trial was uninterpretable, and that the data concerning cardiac and renal function did not support the efficacy of Replagal in treatment of Fabry patients. Accordingly, defendants knew or were reckless in failing to know that Replagal was unlikely to obtain the recommendation from the Advisory Committee, or approval from the FDA, for marketing in the treatment of Fabry disease.

The October 2, 2002 Press Release

69. On October 2, 2002, after the close of the U.S. securities markets, TKT issued a press release informing investors that the postponement of the September 27, 2002 meeting of the FDA will likely delay the timing of a decision on the approval of TKT's Replagal enzyme replacement therapy for the treatment of Fabry disease into the first half of 2003.

70. The October 2, 2002 press release also shocked investors by disclosing that "the FDA's review of the Replagal Biological License Application for the postponed meeting expressed

concerns regarding the TKT's clinical data, particularly with respect to pain. The FDA indicated that methodological issues made the pain data uninterpretable and that data supporting the primary pain endpoint did not support approval."

71. TKT further stated in the press release that although the company continued to believe that the pain data demonstrated an important benefit for patients, based on its discussions with the FDA, the company had "concluded that the best approach to obtain a prompt approval for Replagal in the United States is to seek approval on the basis of its renal and cardiac data."

72. Defendants further shocked investors by disclosing that notwithstanding their unfailing optimistic portrayal of the likelihood of obtained FDA approval, that the FDA had indicated to them that it did not consider that either the cardiac or renal data was sufficient to support approval of Replagal:

> TKT believes that an Advisory Committee meeting will allow TKT to address FDA's concerns with regard to the renal and cardiac data and demonstrate the medically compelling nature of these data. While TKT will seek approval based on these functional data, TKT's recent extensive communications with the FDA indicate that the FDA is also considering using kidney pathology data as a surrogate endpoint for a possible accelerated approval.

73. Defendant Selden added in the press release that "We believe that Replagal is a significant product for people suffering from Fabry Disease, and we are doing everything we can to try to make sure that patients in the United States benefit from this important product as quickly as possible. We are pleased that the FDA continues to work with us in the same spirit."

74. On a conference call conducted on October 2, 2002, after issuance of the press release, defendant Selden added that:

Since the postponement we have been in virtually daily contact with the FDA.... During the past month we have had a series of extensive discussions with the FDA regarding their review of our BLA data. The FDA has expressed concerns regarding TKT's clinical data and they were particularly critical of our pain data. Given the complexity of the trial design and the small number of patients in the studies, the FDA felt that our pain data were not interpretable and data supporting our primary pain data endpoint would not support marketing approval.

While we do not agree with much of the FDA's interpretation of the pain data and believe that patients are benefitting in terms of pain reduction from Replagal therapy, we decided that the best approach to obtain prompt approval was to agree to disagree with the FDA, to focus on our other data, and not to use the pain data as part of the basis for seeking approval at this time.

We believe the FDA made it clear that they are willing to consider Replagal approval on the basis of other data, particularly the renal pathology data. In addition we intend to vigorously pursue approval on the basis of renal and cardiac functional data and we very much look forward to discussing these issues and addressing the FDA's concerns at the upcoming panel meeting.

A serious decline in renal function leading to end stage renal disease is the main cause of mortality in Fabry patients. We believe that our studies show that Replagal initially stabilizes and subsequently improves renal functions. In addition, based on what we know about the natural history of the disease, Replagal delays and may prevent progression to end-stage renal disease for patients with Fabry disease. Also, increased cardiac mass is a predictor of early mortality and based on our cardiac data we show that treatment with Replagal is effective in initiating the reversal of the cardio-myopathy of Fabry Disease.

We believe that the totality of our renal and pathology data is compelling and we believe that Replagal can be approved on this data.

* * *

In summary, we believe we have two avenues to pursue for approval. Either using our kidney and cardiac functional data, or pursuing the use of our renal pathology data as a surrogate endpoint.

[Emphasis added.]

75. Selden stated in the press release that he remained "confident about Replagal and its prospects for U.S. approvals" and on the conference call that he "believe[d] that U.S. Replagal approval will occur in the first half of 2003."

76. Even those statements were deceptive. As demonstrated by the FDA's statements at the January 14, 2003 Advisory Committee meeting, the FDA's expressions of concern over the pain data did not commence, as Selden suggested, in September 2002, but rather was part of the FDA's initial response to TKT's BLA in late 2000.

77. The market reacted dramatically to TKT's October 2, 2002 press release and conference call, declining 62 percent on concern that Replagal would not win approval after regulators criticized the research backing it.

78. In a news report published in TheStreet.com on October 3, 2002, Adam Feuerstein reported that:

> On [the October 2, 2002] conference call to discuss the Replagal setback, TKT CEO Richard Selden came under attack from several angry fund managers who questioned his credibility in the face of prior statements that all was well with the company's FDA discussions. One particularly irate fund manager ended the question-and-answer period of the call by asking Selden if, and when, he expects to be contacted by investigators from the Securities and Exchange Commission.
>
> TKT finds itself in a particularly vulnerable position because of its competitive battle with Genzyme. The FDA is supposed to render a decision under rules defined by the Orphan Drug Act, which means that only one drug gets approval and is granted seven years of market exclusivity. If TKT's Replagal is running afoul of the FDA, that might just clear the path for Genzyme's fabrazyme to claim the top prize.

* * *

> What's got so many Wall Street followers of TKT so angry about this sudden change of fortune is that the company had not indicated that the FDA had problems with its data on Replagal.
>
> "TKT executives have sat in my office and told me to my face that their regulatory plan was superior to Genzyme's and that their discussions with the FDA were golden," said one very skeptical fund manager. "Now, all of a sudden, the FDA tells them that the pain endpoint is no good? Come on, these guys knew there was a problem all along and chose not to tell anyone."

79. At a UBS Warburg conference conducted in New York City on October 8, 2002, defendant Selden informed investors that the FDA might have more extensive concerns about its experimental Replagal medicine for Fabry disease than the company had indicated the prior week. Defendant Selden acknowledged at the conference on October 8, 2002, that the FDA, in addition to advising TKT that its data on pain reduction was "uninterpretable," had informed TKT in early 2001 that it disagreed with TKT's interpretation of the kidney and heart data from the Phase II trials. Selden told investors at the conference that, "They think that we haven't shown efficacy."

80. Selden refused to respond to questions on the October 2, 2002 conference call and at the October 8, 2002 UBS Warburg conference concerning when TKT was first informed that the data on pain reduction was uninterpretable.

81. TKT common stock closed on October 8, 2002 at $12.83 per share.

82. On October 28, 2002, TKT issued a further press release announcing that the FDA's Advisory Committee will meet to consider Replagal on January 14, 2003. Defendant Selden stated in the press release that "we remain optimistic about the prospects for Replagal approval."

83. On November 27, 2002, TKT issued a press release, before the opening of the U.S. securities markets, announcing "preliminary data from an 80 patient double-blinded, placebo-blinded, placebo-controlled Phase III study of Replagal.... Preliminary review of the six-month data did not show a statistically significant difference between treated and placebo patients for the primary endpoint of renal function...."

84. TKT also announced in that press release the receipt of a Complete Response Letter ("CRL") from the FDA. The press release stated that the CRL "indicates that the FDA believes the data are inadequate for final approval action at this time, primarily because of continuing questions concerning efficacy...."

85. The release of the additional information concerning the Phase III test and CRL caused a further decline in TKT common stock to $9.60 at the close of trading on November 27, 2002.

86. On January 13, 2003, the FDA posted on its website the FDA Briefing Document (dated December 12, 2002) for the January 14, 2003 Advisory Committee meeting. The Briefing Document summarized the FDA's basis for concluding that the pain data from TKT003 was uninterpretable:

> Study TKT003 was the main study assessing pain. The primary endpoint result for Study TKT003 (Table 3) was not statistically persuasive.
>
> * * *
>
> As described in the detailed review of Study TKT003, there are substantial limitations to interpreting this primary endpoint outcome. These include the following:
>
> 1. The primary endpoint was to be calculated from scores only obtained during periods while subjects were "off" pain medications. However, unexpected difficulties precluded verification of "off pain medication" status at

the time scores were obtained. During course of the study, many subjects were "on" and "off" pain medications. There were many inconsistent and incomplete records between subject medication diaries, hospital records, case report forms, and subject questionnaires regarding use of pain medications. There was no prospectively defined process for determining which scores constituted the primary endpoint scores when uncertainties in pain medication use arose.

2. A comprehensive study audit with correction of any data problems, and designation of which data values constitute the dataset for the primary endpoint was not done prior to the initial unblinded data analysis. Following an initial unblinded analysis of the primary endpoint result the sponsor recognized certain problems in determination of the "off medication" values, and revised which pain scores were designated the "off pain medication" scores for some assessments. The effect of this revision changed the primary endpoint's analysis p-value from 0.43 (initially) to 0.20 (final). It is not known to what extent this process introduced bias.

3. There was no prospective, explicit definition of "pain medications" which would disqualify a pain score from being used as an "off pain medication" score. The sponsor used a post-hoc definition that focused only on non-traditional analgesics, such as anti-epileptic agents. Consequently, narcotics and certain other general analgesics were not to be classified as pain medications. It is not known to what degree use of such general analgesics confound interpretation of the "off medication" scores.

Consequently, no conclusions regarding a treatment effect on pain can be drawn based on the intended primary endpoint.

The vast majority of pain-related secondary endpoints in Study TKT003 showed no evidence of a difference between the two study groups. [Id. at 9-10]

The Briefing Document further concluded that the data on cardiac and liver function were uninterpretable, not physiologically plausible, or did not demonstrate efficacy. Id. at 10-12.

87. The FDA, in its presentation to the Advisory Committee on January 14, 2003, reiterated its comments in the Briefing Document, and further specified that the substantive contents in the Briefing Document, concerning the uninterpretable data, the lack of physiological plausibility, and

the lack of proven efficacy was presented to TKT in the initial Complete Response Letter dated December 22, 1999, the subsequent CRL dated November 22, 2002, and in numerous meetings with TKT throughout the Class Period. Thus, there was no reasonable basis for defendants' expressions of optimism for achieving FDA approval, as alleged herein.

88. At the conclusion of the Advisory Committee meeting, its members voted 15-0 that TKT's BLA had not demonstrated proof of efficacy in the primary endpoints of the two Phase II studies of Replagal.

89. In contrast, on January 13, 2003, the same Advisory Committee had voted 14 to 1 to endorse Genzyme's Fabrazyme drug trial as having lowered levels of fat deposits in the kidney.

SCIENTER

90. As a result of defendants' materially misleading statements and failures to disclose the truth about Replagal's prospects for approval by the FDA, TKT common stock traded at artificially inflated prices during the entire Class Period, until the time the adverse information described above was finally provided to and digested by the securities markets. Plaintiffs and other members of the Class purchased or otherwise acquired TKT common stock or call options, or sold put options, relying upon the integrity of the market price of TKT stock and market information relating to TKT, or in the alternative, upon defendants' misleading statements, and in ignorance of the adverse, undisclosed information known to defendants, and have been damaged thereby.

91. In making the false and misleading statements and omissions of fact, and by engaging in the fraudulent scheme described herein, defendants acted with scienter. Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially

false and misleading. Defendants also knew that such statements or documents would be issued or disseminated to the investing public. Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

92. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding the likelihood of obtaining FDA approval to market Replagal, participated in the fraudulent scheme alleged herein.

93. Defendant Selden had actual knowledge of the FDA's negative reaction to TKT's BLA for Replagal and misrepresented and failed to disclose the true facts concerning the likelihood of receipt of FDA approval.

94. Defendants engaged in such a scheme to inflate the price of TKT securities in order to: (i) protect and enhance their executive positions and the substantial compensation and prestige they obtained thereby; (ii) enhance the value of their personal TKT securities; (iii) allow defendant Selden to sell 90,000 shares of TKT common stock in 2001 and early 2002, for gross proceeds of approximately $2,805,300, at prices substantially above the true value of those securities, and (iv) enable TKT to issue an additional 7,735,000 shares of its common stock for gross proceeds of $267,575,500.

95. Further, defendants were motivated to withhold the true facts concerning the FDA's response to TKT's BLA to induce European drug administrators to approve Replagal for marketing and to encourage physicians in Europe to prescribe Replagal to their patients. Defendants also sought to encourage U.S. clinicians to participate in clinical studies of Replagal.

FIRST COUNT

VIOLATIONS OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5 PROMBULGATED THEREUNDER AGAINST ALL DEFENDANTS

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

97. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were materially false and misleading in that they contained material misrepresentation and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

98. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

a. Employed devices, schemes and artifices to defraud;

b. Made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made not misleading; or

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 AmeriCredit publicly traded securities during the Class Period.

99. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Transkaryotic Therapies' securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct

charged herein or as controlling persons as alleged below.

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

101. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Transkaryotic Therapies' value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Transkaryotic Therapies and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Transkaryotic Therapies securities during the Class Period.

102. Defendant Selden's primary liability, and controlling person liability, arises from the following facts: (i) Selden was a high-level executive and/or director at the Company during the Class Period and a member of the Company's management team or had control thereof; (ii) Selden, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (ii) Selden enjoyed significant personal contact and

familiarity with other officers and directors and was advised of and had access to other members of the Company's management term, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) Selden was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

103. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and to disclose such facts, even though such facts were available to him. Such defendant's material misrepresentations and/or omissions were done knowingly or recklessly and for the purposes and effect of concealing Transkaryotic Therapies' operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendant's overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, defendant, if he did not have actual knowledge of the misrepresentations and omissions alleged, was reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false and misleading.

104. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Transkaryotic Therapies' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Transkaryotic Therapies' publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendant, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to

or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, plaintiffs and the other members of the Class acquired Transkaryotic Therapies securities during the Class Period at artificially high prices and were damaged thereby.

105. At the time of said misrepresentations and omissions, plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Transkaryotic Therapies was experiencing, which were not disclosed by defendants, plaintiffs and other members of the Class would not have purchased or otherwise acquired their Transkaryotic Therapies securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

106. By virtue of the foregoing, defendants has violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

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

COUNT TWO

PURSUANT TO SECTION 20(A) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANT

108. Plaintiffs repeats and realleges each and every allegation contained above as if fully set forth herein.

109. The executive officers of Transkaryotic Therapies prepared, or were responsible for

preparing the Company's press releases and SEC filings. Selden controlled other employees of Transkaryotic Therapies. Transkaryotic Therapies controlled Selden and each of the Company's officers, executives and all of its employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

110. Selden acted as to controlling persons of Transkaryotic Therapies within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level position, and ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Selden had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiffs contend are false and misleading. Selden was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

111. In particular, Selden had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

112. As set forth above, Transkaryotic Therapies and Selden each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of his position as controlling person, Selden is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and other members of the Class suffered

damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

Wherefore, Plaintiffs ask for relief:

1. Determining that the instant action is a proper class action maintainable under Rule 23 of the Federal Rules of Civil Procedure;

2. Awarding compensatory damages and/or rescission as appropriate against defendants, in favor of plaintiffs and all members of the Class for damages sustained as a result of defendants' wrongdoing.

3. Awarding plaintiffs and members of the Class the costs and disbursements of this suit, including reasonable attorneys', accountants' and experts' fees; and

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

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: February __, 2003