



1 Plaintiff , individually and on behalf of all others similarly situated, by  
2 plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following  
3 based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and  
4 belief as to all other matters based on the investigation conducted by and through plaintiff's  
5 attorneys, which included, among other things, a review of Securities and Exchange Commission  
6 ("SEC") filings by Affymax, Inc. ("Affymax" or the "Company"), as well as media reports about the  
7 Company and conference call transcripts. Plaintiff believes that substantial additional evidentiary  
8 support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### 9 NATURE OF THE ACTION

10 1. This is a securities class action on behalf of all purchasers of the common stock of  
11 Affymax between December 8, 2011 and February 22, 2013, inclusive (the "Class Period"), seeking  
12 remedies pursuant to §§10(b) and 20(a) of the federal securities laws. Defendants include Affymax,  
13 certain of its senior executives and/or directors and Takeda Pharmaceutical Company Limited  
14 ("Takeda"), the largest pharmaceutical company in Japan.

15 2. Defendant Affymax is a Palo Alto-based biopharmaceutical company whose primary  
16 drug offering is Omontys (peginesatide) Injection for the treatment of anemia in chronic kidney  
17 disease in adult patients on dialysis. Omontys is a synthetic, peptide-based erythropoiesis  
18 stimulating agent designed to stimulate production of red blood cells. The Company has a strategic  
19 alliance agreement with Takeda to develop and commercialize Omontys.

20 3. During the Class Period, defendants issued materially false and misleading statements  
21 regarding the Company's business practices and financial results. Specifically, defendants failed to  
22 disclose that 2% of patients who were administered Omontys experienced hypersensitivity reactions  
23 resulting in anaphylaxis, a serious and life-threatening allergic reaction, a third of which needed  
24 medical intervention – and that 0.02% of those administered the drug experienced fatal anaphylaxis  
25 reactions. As a result of these false statements, Affymax stock traded at artificially inflated prices  
26 during the Class Period, reaching a high of \$27.74 per share in intraday trading on October 17, 2012.

27 4. Suddenly, on Saturday, February 23, 2013, Affymax announced that the U.S. Food  
28 and Drug Administration ("FDA") was requiring a total recall of the drug due to reports of

1 anaphylaxis, with the FDA calling it a “serious and life-threatening” allergic reaction in the agency’s  
2 statement. “Serious and fatal” hypersensitivity reactions have been reported in some patients within  
3 30 minutes of receiving their first doses of the drug by intravenous injection, the FDA said in its  
4 statement.

5 5. On this news, the price of Affymax stock declined by *more than 85%*, closing at  
6 \$2.42 per share, down \$14.10 per share from the prior Friday night’s close, on unusually high  
7 trading volume.

8 6. The true facts, which were known by the defendants but concealed from the investing  
9 public during the Class Period, were as follows:

10 (a) Affymax’s FY 2012 financial guidance was materially overstated throughout  
11 the Class Period;

12 (b) sales of Omontys being reported throughout the Class Period were not  
13 sustainable; and

14 (c) defendants were materially overstating sales and understating the potential  
15 liabilities related to Omontys sales during the Class Period, including refunds and potential liability  
16 to injured patients.

17 7. As a result of defendants’ false statements, Affymax stock traded at inflated levels  
18 during the Class Period. However, after the above revelations seeped into the market, the price of  
19 Affymax stock was hammered by massive sales, sending them down *more than 91%* from their  
20 Class Period high.

## 21 **JURISDICTION AND VENUE**

22 8. The claims asserted herein arise under §§10(b) and 20(a) of the Securities Exchange  
23 Act of 1934 (the “Exchange Act”), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R.  
24 §240.10b-5. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa.

25 9. Venue is proper in this district pursuant to §27 of the Exchange Act. Acts and  
26 transactions giving rise to the violations of law complained of occurred in this district.

1 **THE PARTIES**

2 10. Plaintiff purchased Affymax common stock during the Class Period  
3 as described in the Certification attached hereto and incorporated herein by reference and suffered  
4 damages thereon.

5 11. Defendant Affymax is headquartered in Palo Alto, California. During the Class  
6 Period, Affymax had approximately 37 million shares of common stock outstanding, which shares  
7 traded in an efficient market on the NASDAQ under the ticker symbol "AFFY".

8 12. Defendant John A. Orwin ("Orwin") served as Affymax's CEO and a Director during  
9 the Class Period.

10 13. Defendant Herbert C. Cross ("Cross") served as Affymax's CFO during the Class  
11 Period.

12 14. Defendants Orwin and Cross are sometimes referred to herein as the "Individual  
13 Defendants."

14 15. During the Class Period, the Individual Defendants ran Affymax as managers  
15 overseeing Affymax's operations and finances and made the material false and misleading  
16 statements described herein. The Individual Defendants were intimately knowledgeable about all  
17 aspects of Affymax's financial and business operations, as they received daily reports and had access  
18 to computerized information regarding sales, costs and expenses, and adverse reactions reported  
19 concerning Omontys use. They were also intimately involved in deciding which disclosures would  
20 be made by Affymax. Indeed the Individual Defendants made various public statements for  
21 Affymax during the Class Period, and participated in all Class Period investor conferences.

22 16. Defendant Takeda Pharmaceutical Company Limited (based in Osaka, Japan), along  
23 with operating subsidiaries Takeda Pharmaceuticals U.S.A., Inc. (based in Deerfield, Illinois) and  
24 Takeda Global Research & Development Center, Inc. (based in Deerfield, Illinois) (collectively,  
25 "Takeda"), is a research-based global pharmaceutical company. Takeda is the largest  
26 pharmaceutical company in Japan. Takeda is a publicly-traded company listed on the Tokyo  
27 exchange with substantial operations in the U.S. through its two U.S. operating subsidiaries.

## BACKGROUND TO THE CLASS PERIOD

17. Affymax was founded in 2001 and is headquartered in Palo Alto, California.

18. The Company's primary drug offering is peginesatide (trade name Omontys, formerly Hematide), which was developed by Affymax and Takeda and is an erythropoietic agent, a functional analog of erythropoietin. Peginesatide is approved by the FDA for treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis.

19. In late June 2010, Affymax announced preliminary top-line results from its peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. The Company's Phase 3 clinical program included four open-label, randomized controlled clinical trials. Two of these trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a specified range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based primarily on assessments of non-inferiority to the comparator drugs. Defendants report that the primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. Defendants also report that peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 trials.

20. In October 2010, Affymax met with the FDA to discuss the regulatory path for peginesatide based on the initial analysis of the Phase 3 results. Based on these discussions with the FDA, the Company submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted Affymax's submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. According to defendants, in December 2011, the FDA Oncologic

1 Drugs Advisory Committee, or ODAC, voted 15 to 1, with 1 abstention, that peginesatide  
2 demonstrated a favorable benefit/risk profile for use in the treatment of dialysis patients with anemia  
3 due to chronic kidney disease.

4 **DEFENDANTS' MATERIALLY FALSE AND MISLEADING**  
5 **CLASS PERIOD STATEMENTS**

6 21. The Class Period starts on December 8, 2011. On that day, Affymax and Takeda  
7 issued a release entitled "FDA Advisory Committee Voted in Favor of Benefit/Risk Profile for  
8 Peginesatide for Treatment of Anemia in Chronic Kidney Disease Patients on Dialysis." The press  
9 release stated, in pertinent part, as follows:

10 "We're encouraged by the panel's positive view of the benefit/risk profile of  
11 peginesatide in the dialysis setting," said John Orwin, president and CEO of  
12 Affymax. "Anemia affects many patients in the dialysis setting, and we look forward  
13 to working with the FDA as they complete their evaluation of peginesatide. As a  
14 once-monthly treatment, peginesatide, if approved, has the potential to be an  
15 important option in the management of anemia in patients living with this condition."

16 \* \* \*

17 "Today's ODAC vote represents an important step in the peginesatide New Drug  
18 Application review process," said Azmi Nabulsi, MD, president, Takeda Global  
19 Research & Development Center, Inc. "As we heard from the discussion today,  
20 limited therapeutic options are available for the treatment of anemia in dialysis  
21 patients with chronic kidney disease. Affymax and Takeda will continue efforts to  
22 make this alternative available to dialysis patients and the providers who treat them."

23 22. The drug would be Affymax's first product if it gained regulatory approval for  
24 patients with chronic kidney disease. According to *Bloomberg*, "[i]f approved, the therapy would  
25 compete with Amgen's Epogen, which generated \$2.5 billion in revenue [in FY 2010], and J&J's  
26 Proscrit, with 2010 sales of \$1.9 billion," stating that "Affymax's medicine works as well as those  
27 treatments and had 'similar safety results' for people on dialysis, the patient group for whom  
28 Affymax seeks approval," citing a December 5, 2011 FDA staff report.

29 23. According to a report issued that day by Robert W. Baird analyst Chris Raymond:  
30 "Christmas came a little early this year. We view approval as significantly de-risked" and "remain  
31 buyers." The Baird report also explained that "[w]ith Amgen's recent exclusive DaVita contract and  
32 partnership with Fresenius," the two largest dialysis providers respectively by annual income, "about  
33 70 percent of the market appears locked up. We would point out 30 percent isn't, and we'd be very  
34

1 surprised if various out-clauses did not exist, which may be increasingly relevant if Affymax prices  
2 this drug at a discount.

3 24. On this news, the price of Affymax common stock surged 36% to close at \$7.98, the  
4 biggest increase since the stock became publicly traded in December 2006.

5 25. On March 14, 2012, Affymax issued a press release announcing its FY 2011 financial  
6 results and its FY 2012 financial guidance. The release stated, in pertinent part, as follows:

7 “2011 was a banner year for Affymax *demonstrated by our progress and*  
8 *accomplishments which set the stage for potential approval and commercial*  
9 *launch of our first marketed therapeutic product,”* said John Orwin, chief executive  
10 officer at Affymax. “Looking at planned activities in 2012, our highest priority is  
preparing for, and executing on, the potential launch of peginesatide with our partner  
Takeda in the dialysis market. *We look forward to keeping you apprised of our*  
*progress.”*

#### 11 ***2012 Financial Guidance***

12 With respect to revenue in 2012, Affymax expects to earn several milestone  
13 payments totaling approximately \$60 million from Takeda in 2012. In addition to  
14 the \$5.0 million milestone payment already received as a result of the acceptance of  
the Marketing Authorization Application for peginesatide in Europe, *Affymax also*  
*expects to receive additional milestones of \$50 million related to the approval of*  
*peginesatide in the U.S.* and approximately \$5 million from Takeda associated with  
15 reimbursements under the Janssen agreement upon the achievement of certain  
regulatory and commercial events. *Affymax also expects to continue to receive*  
*reimbursement from Takeda of 70 percent of third party expenses associated with*  
*research and development, as well as 50 percent reimbursement of both third-party*  
*and FTE related expenses associated with commercial activities as provided under*  
*the terms of the collaboration agreement.* The agreement provides that upon  
16 commercialization of peginesatide, Affymax will receive quarterly profit  
17 equalization payments from Takeda to effect a 50/50 profit split on product sales  
18 between the parties. Affymax will not be giving peginesatide product sales guidance  
19 for 2012.

20 With respect to operating expenses Affymax expects to incur \$45 million to \$50  
21 million in research and development expenses and \$90 million to \$95 million in  
22 selling, general and administrative expenses, resulting in total expected operating  
23 expenses for 2012 of \$135 million to \$145 million, excluding stock based  
compensation. For 2012, we expect to incur total stock-based compensation expense  
of approximately \$10 million dollars.

24 This increase in operating expenses relative to 2011 is primarily a result of  
25 significantly increased investment in the Affymax commercial and medical affairs  
26 organizations, partially offset by reductions in our research and development  
27 spending as the company directs resources to support the potential commercialization  
28 of peginesatide in 2012.

1 ***Affymax currently expects existing cash resources, milestone payments from***  
2 ***Takeda, ongoing Takeda reimbursement and profit equalization payments from***  
3 ***Takeda to fund its operations well into 2013.***<sup>1</sup>

4 26. On March 27, 2012, Affymax issued a press release entitled “Affymax and Takeda  
5 Announce FDA Approval of OMONTYS® (Peginesatide) Injection for the Treatment of Anemia  
6 Due to Chronic Kidney Disease (CKD) in Adult Patients on Dialysis.” The press release stated, in  
7 pertinent part, as follows:

8 Affymax, Inc. and Takeda Pharmaceutical Company Limited, today announced that  
9 the U.S. Food and Drug Administration (FDA) approved OMONTYS®  
10 (peginesatide) Injection for the treatment of anemia due to chronic kidney disease  
11 (CKD) in adult patients on dialysis. OMONTYS is the only once-monthly  
12 erythropoiesis-stimulating agent (ESA) for anemia to be made available to the  
13 dialysis patient population in the United States.

14 The FDA’s decision was based on a New Drug Application (NDA), which included  
15 results from two randomized, controlled, open-label, Phase 3 studies (EMERALD 1  
16 and 2) that demonstrated the safety and efficacy of OMONTYS dosed once monthly,  
17 compared to epoetin dosed between one-to-three times per week (according to  
18 product labels), in maintaining hemoglobin (Hb) levels in anemic CKD patients on  
19 dialysis. In these studies, the most commonly reported adverse reactions were  
20 shortness of breath, diarrhea, nausea, cough and arteriovenous fistula site  
21 complication. The EMERALD studies were part of the largest clinical program to  
22 support the NDA of an ESA in the treatment of anemia in CKD. Enrolling 2,606  
23 patients, including approximately 1,600 dialysis patients, the OMONTYS Phase 3  
24 program was also the first to prospectively compare, in a head-to-head manner, the  
25 cardiovascular safety of different ESAs. Cardiovascular safety was evaluated based  
26 on a composite cardiovascular safety endpoint adjudicated by a blinded and  
27 independent committee. See below for Important Safety Information about  
28 OMONTYS, including Boxed Warnings as well as limitations of use.

29 In the approval action letter, the FDA outlined post-marketing requirements: an  
30 observational study and a randomized controlled trial to be completed with final  
31 reports submitted in 2018 and 2019, respectively. The objectives of the studies are to  
32 evaluate cardiovascular safety and assess safety of long-term use in adult patients on  
33 dialysis, in particular in the incident patient population. In addition, the post-  
34 marketing commitment includes the initiation of pediatric studies with target dates  
35 for completion between 2016 and 2027. Letters will be sent to nephrology healthcare  
36 providers as part of a Risk Evaluation and Mitigation Strategy (REMS) to inform  
37 them that OMONTYS is not indicated in patients with CKD not on dialysis. In two  
38 trials of OMONTYS, patients with CKD not on dialysis experienced increased  
39 specific cardiovascular events.

40 ***“The approval of OMONTYS now provides a therapeutic alternative to treat***  
41 ***anemia of CKD in adult patients on dialysis, one of the most common***  
42 ***complications affecting this patient population,” said John Orwin, chief executive***

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43 <sup>1</sup> All emphasis is added unless otherwise noted.

1 *officer, Affymax.* “For over two decades, doctors have relied primarily on one  
2 erythropoietin-based treatment in the dialysis setting. ***With OMONTYS, doctors and***  
3 ***patients will have access to a once-monthly alternative for the treatment of anemia***  
4 ***in adult CKD patients on dialysis.***”

5 “The FDA’s approval of OMONTYS signifies an important milestone for the  
6 partnership between Takeda and Affymax as we fulfill our goal of providing an  
7 important new treatment option for the hundreds of thousands of CKD patients on  
8 dialysis who live with anemia,” said Azmi Nabulsi, M.D., president, Takeda Global  
9 Research & Development Center, Inc. “OMONTYS is an example of our  
10 commitment to making treatment options available that accommodate the needs of  
11 evolving healthcare markets, such as the renal community.”

12 Anemia (a condition in which blood has a lower than normal number of red blood  
13 cells) is a common complication in dialysis patients because their kidneys no longer  
14 produce enough erythropoietin, the hormone that stimulates red blood cell production  
15 in the body. According to the Centers for Medicaid and Medicare Services (CMS),  
16 nearly 95 percent of dialysis patients in the United States are being treated for anemia  
17 with ESAs. Until the approval of OMONTYS, ESAs were recombinant (genetically  
18 engineered) versions of endogenous erythropoietin (erythropoietin that is made in the  
19 patient’s body) that are injected up to three times a week. OMONTYS is a synthetic,  
20 pegylated, peptide-based ESA that is dosed once monthly.

21 “For dialysis patients, anemia is another aspect of their challenging condition that  
22 must be addressed,” said Brigitte Schiller, M.D., chief medical officer, Satellite  
23 Healthcare, Inc. “As a nephrologist who oversees the care of adult CKD patients on  
24 dialysis, I am glad to now have another option for the treatment of anemia.”

25 27. As reported by *The Wall Street Journal* on March 27, 2012, “[t]he drug, which will be  
26 sold under the brand name Omontys, ***would compete with Amgen Inc.’s Epogen, which is approved***  
27 ***for use in the same group of patients.***” On this news, the price of Affymax stock closed up  
28 \$0.58 per share from its close of \$13.73 on March 26, 2012, on extremely high trading volume of  
more than 14 million shares trading.

29 28. On April 9, 2012, Affymax issued a press release entitled “Affymax Receives a \$50  
30 Million Milestone Payment for U.S. Approval of OMONTYS® (peginesatide) Injection,” which  
31 stated in pertinent part that it had received a \$50 million development milestone payment from  
32 Takeda as part of the companies’ exclusive global agreement to develop and commercialize  
33 Omontys and that the milestone was triggered by the FDA approval of Omontys on March 27, 2012.  
34 The press release also stated that this was “in addition to the \$5 million milestone payment the  
35 company received from Takeda that was triggered by the European Medicines Agency acceptance of  
36 the Marketing Authorization Application in February.”

1           29.     On April 13, 2012, Affymax issued a press release entitled “Affymax and Takeda  
2 Announce Centers for Medicare and Medicaid Services Has Assigned a Q-Code for OMONTYS®  
3 (Peginesatide) Injection – Code Q2047 Will Streamline OMONTYS Reimbursement.” The press  
4 release stated, in pertinent part, as follows:

5           Affymax, Inc. and Takeda Pharmaceuticals U.S.A. today announced that the Centers  
6 for Medicare and Medicaid Services (CMS) has granted a unique product  
7 reimbursement code, or Q-code, for OMONTYS® (peginesatide) Injection. The  
8 OMONTYS-specific billing code, Q2047, will help streamline the billing process for  
dialysis organizations using OMONTYS. This new Q-code will become effective on  
July 1, 2012. OMONTYS is the only once-monthly erythropoiesis-stimulating agent  
(ESA) for anemia available to the dialysis patient population in the United States.

9           “We are very pleased with the level of interest in OMONTYS by providers, and the  
10 designation of this Q-code by CMS will help simplify their billing process for  
11 reimbursement when using this new once-monthly anemia treatment for chronic  
12 kidney disease (CKD) patients on dialysis,” said John Orwin, chief executive officer,  
Affymax. “The ability of dialysis centers to receive timely reimbursement for  
OMONTYS is important for the dialysis community.”

13           According to Nicole Mowad-Nassar, vice president, marketing at Takeda, “Having  
14 received U.S. Food and Drug Administration (FDA) approval just last month, the  
15 CMS assignment of a reimbursement, or Q-code, is one more significant step  
towards making OMONTYS available to the healthcare providers who treat dialysis  
patients with anemia.”

16           30.     On April 24, 2012, Affymax issued a press release entitled “OMONTYS®  
17 (Peginesatide) Injection Now Available for Adult Chronic Kidney Disease (CKD) Patients on  
18 Dialysis in the United States.” The press release stated, in pertinent part, as follows:

19           ***“Today’s announcement represents an important milestone in the field as  
20 nephrologists and anemia nurses will now be able to use the first once-monthly  
21 treatment for anemia for adult dialysis patients available in the United States,”  
said John Orwin, chief executive officer, Affymax. “We are excited to partner with  
the dialysis community and support the important work they do for patients.”***

22           “We look forward to working with the dialysis community as they implement this  
23 once-monthly medicine into their practice,” said Douglas Cole, president, Takeda  
Pharmaceuticals U.S.A. “In partnership with Affymax, we will support the providers  
and physicians as they convert their adult CKD patients on dialysis to OMONTYS.”

24           31.     On May 7, 2012, Affymax issued a release entitled “Affymax Reports First Quarter  
25 2012 Financial Results - \$58 million in milestones earned.” The press release stated, in pertinent  
26 part, as follows:

27           Affymax, Inc. today reported financial results for the first quarter ended March 31,  
28 2012. The net income for the first quarter of 2012 was \$31.5 million (or \$0.87

1 per share) compared to a net loss of \$9.6 million (or \$(0.36) per share) for the first  
2 quarter of 2011.

3 Affymax recognized total revenue for the quarter ended March 31, 2012, of  
4 \$63.2 million compared to \$16.7 million for the quarter ended March 31, 2011. The  
5 increase in revenue was the result of \$58 million in milestones earned during the  
6 quarter from the company's partner, Takeda Pharmaceutical Company Limited,  
under their 2006 collaboration agreement for Affymax's compound, OMONTYS®  
(peginesatide) Injection. Specifically, the company earned a \$5 million milestone for  
the acceptance of a Marketing Authorization Application in Europe and \$53 million  
in milestones for securing U.S. approval.

7 Research and development expenses for the quarter ended March 31, 2012, were  
8 \$16.1 million compared to \$18.2 million for the quarter ended March 31, 2011. The  
9 decrease was primarily due to reduced consulting costs as a result of the completion  
10 of the filing of our New Drug Application with the U.S. Food and Drug  
Administration (FDA) in May 2011 and reduced personnel-related costs. This was  
partially offset by ongoing clinical trial activity for the company's Phase 3b trial, and  
an ongoing Phase 2 study in Pure Red Cell Aplasia patients.

11 Selling, general and administrative expenses for the quarter ended March 31, 2012,  
12 were \$15.6 million compared to \$8.2 million for the quarter ended March 31, 2011.  
13 The increase was primarily due to increases in commercialization costs as the  
company prepared for the launch and commercialization of OMONTYS.

14 The company had cash and investments of \$93.5 million as of March 31, 2012,  
15 which only included receipt of \$5.0 million of the \$58.0 million of milestones earned  
16 during the first quarter of 2012. The remaining \$53.0 million in milestones earned in  
the first quarter were included in the \$58.3 million balance in receivables from  
Takeda, as payments of those amounts had not been received as of March 31, 2012.

17 ***“The year is off to a phenomenal start with the approval of OMONTYS on March  
18 27,” said John Orwin, chief executive officer of Affymax. “Since that time, we  
19 secured a product specific Q-code from CMS which will streamline reimbursement  
and also launched the product with two product configurations. We look forward  
to reporting progress of OMONTYS adoption and integration by dialysis  
providers.”***

20 32. On July 12, 2012, Affymax issued a press release entitled “Takeda and Affymax  
21 Announce Supply Agreement for OMONTYS® (peginesatide) Injection with Fresenius Medical  
22 Care North America.” The press release stated, in pertinent part, as follows:

23 Takeda Pharmaceuticals U.S.A. (TPUSA) and Affymax, Inc. (Nasdaq:AFFY) today  
24 announced that Takeda Pharmaceuticals America, Inc. (TPA) has entered into a  
supply agreement for sourcing and supply of OMONTYS® (peginesatide) Injection  
25 to Fresenius Medical Care North America and certain of its affiliates. OMONTYS is  
the only once-monthly erythropoiesis-stimulating agent (ESA) for anemia available  
26 to the dialysis patient population with chronic kidney disease (CKD) in the United  
States.

27 The agreement, which ends in April 2013, allows Fresenius Medical Care North  
28 America to purchase OMONTYS for use in U.S. centers within its organization and  
provides for discounts and rebates on the product, subject to certain requirements.

1 ***Fresenius Medical Care North America has stated that its initial plans are to adopt***  
2 ***the product into more than 100 dialysis centers in the U.S. over the next few weeks,***  
3 ***and then, based on its experience, evaluate the potential to expand to additional***  
4 ***centers.*** Financial terms were not disclosed.

5 “We are excited to partner with Fresenius Medical Care North America, one of the  
6 world’s leading dialysis providers, to offer a new therapeutic option for the treatment  
7 of anemia in its chronic kidney disease patients on dialysis,” said Nicole Mowad-  
8 Nassar, vice president, marketing at Takeda.

9 “As a biotechnology company dedicated to advancing new therapies for renal  
10 diseases, Affymax shares Fresenius Medical Care North America’s commitment to  
11 innovation,” stated John Orwin, chief executive officer of Affymax. “We are very  
12 pleased to support Fresenius Medical Care in these efforts to integrate OMONTYS  
13 into its organization and to collaborate with them moving forward.”

14 33. On August 8, 2012, Affymax issued a press release entitled “Affymax Reports  
15 Second Quarter 2012 Financial Results.” The press release stated, in pertinent part, as follows:

16 Affymax, Inc. today reported financial results for the second quarter ended June 30,  
17 2012. The net loss for the second quarter of 2012 was \$32.0 million (or (\$0.89)  
18 per share) compared to a net loss of \$12.5 million (or (\$0.35) per share) for the  
19 second quarter of 2011.

20 Affymax recognized total revenue for the quarter ended June 30, 2012, of  
21 \$2.8 million compared to \$14.2 million for the quarter ended June 30, 2011. The  
22 decrease in revenue was the result of lower collaboration revenue recognized as a  
23 result of significant reductions in research and development expenses reimbursable  
24 by the company’s partner, Takeda Pharmaceutical Company Limited.

25 Research and development expenses for the quarter ended June 30, 2012, were  
26 \$13.0 million compared to \$18.6 million for the quarter ended June 30, 2011. The  
27 decrease was primarily due to reduced consulting and personnel-related costs as a  
28 result of the completion of the filing of our New Drug Application for OMONTYS®  
(peginesatide) Injection with the U.S. Food and Drug Administration (FDA) in May  
2011. This was partially offset by clinical trial activity for the company’s Phase 3b  
trial.

Selling, general and administrative expenses for the quarter ended June 30, 2012,  
were \$21.2 million compared to \$8.1 million for the quarter ended June 30, 2011.  
The increase was primarily due to increases in commercialization costs, including  
personnel-related costs associated with the establishment of its field forces, as the  
company prepared for the launch and commercialization of OMONTYS.

The company had cash and investments of \$119.2 million as of June 30, 2012.

“We continue to make solid progress since the approval of OMONTYS on March  
27,” said John Orwin, chief executive officer of Affymax. “Since that time, we  
28 established our medical affairs and commercial field forces, garnered a product  
specific Q-code from CMS which is now in effect and, in collaboration with Takeda,  
have secured supply contracts with multiple key dialysis customers. ***We look  
forward to reporting continued progress on adoption and integration of  
OMONTYS by dialysis providers.***”

1 34. That same day, Affymax issued a second press release entitled “Takeda and Affymax  
2 Announce Supply Agreement for OMONTYS® (peginesatide) Injection with U.S. Renal Care, Inc.”

3 The second press release stated, in pertinent part, as follows:

4 Takeda Pharmaceuticals U.S.A. and Affymax, Inc. today announced that Takeda  
5 Pharmaceuticals America, Inc. (TPA) has entered into a supply agreement for  
6 sourcing and supply of OMONTYS® (peginesatide) Injection with U.S. Renal Care,  
7 Inc. and certain of its affiliates, representing one of the top 10 dialysis providers in  
8 the United States (U.S.). OMONTYS is the only once-monthly erythropoiesis-  
9 stimulating agent (ESA) for anemia available to the dialysis patient population with  
10 chronic kidney disease (CKD) in the U.S.

11 The agreement allows U.S. Renal Care to purchase OMONTYS for use within its  
12 organization and provides for discounts and rebates on the product, subject to certain  
13 requirements. U.S. Renal Care has indicated that they plan to initially evaluate  
14 OMONTYS in selected centers, and then, based on experience, evaluate the potential  
15 to expand to additional centers. Financial terms were not disclosed.

16 “As we anticipated, there is interest from some of the world’s leading dialysis  
17 providers to offer a new therapeutic option for the treatment of anemia in chronic  
18 kidney disease patients on dialysis,” said Nicole Mowad-Nassar, vice president,  
19 marketing at Takeda.

20 “These centers are demonstrating an interest in offering new therapies and showing  
21 their commitment to innovation,” stated John Orwin, chief executive officer of  
22 Affymax. “We intend to support their integration efforts *and believe OMONTYS*  
23 *will prove to be a once-monthly alternative in their centers moving forward.*”

24 35. On November 8, 2012, Affymax issued a press release entitled “Affymax Reports  
25 Third Quarter 2012 Financial Results.” The press release stated, in pertinent part, as follows:

26 Affymax, Inc. today reported financial results for the third quarter ended September  
27 30, 2012. The net loss for the third quarter of 2012 was \$24.6 million (or (\$0.68) per  
28 share) compared to a net loss of \$9.8 million (or (\$0.28) per share) for the third  
quarter of 2011.

Affymax recognized total revenue for the quarter ended September 30, 2012, of  
\$13.6 million compared to \$13.2 million for the quarter ended September 30, 2011.  
Revenue for the quarter ended September 30, 2012 primarily consisted of a  
\$10.4 million profit equalization payment earned from its partner, Takeda  
Pharmaceutical Company Limited (Takeda) related to OMONTYS® (peginesatide)  
Injection product sales during the period. OMONTYS net product sales, as provided  
by Takeda, were \$15.0 million for the quarter. In addition, Affymax earned a  
\$2.25 million milestone payment from Takeda during the quarter as a result of the  
commercial progress achieved with OMONTYS during its product launch. Revenue  
for the quarter ended September 30, 2011 consisted of a \$10 million regulatory  
milestone payment from Takeda and pre-approval research and development and  
commercialization expenses reimbursable by Takeda.

Research and development expenses for the quarter ended September 30, 2012, were  
\$11.4 million compared to \$14.9 million for the quarter ended September 30, 2011.  
The decrease was primarily due to reduced consultant and personnel-related costs as

1 a result of the completion of both the filing of the OMONTYS New Drug  
2 Application with the U.S. Food and Drug Administration (FDA) in May 2011 and  
3 the preparation for an FDA advisory committee meeting which occurred in  
4 December 2011. These decreases were partially offset by clinical trial activity for  
5 the company's Phase 3b trial during the current quarter.

6 Selling, general and administrative expenses for the quarter ended September 30,  
7 2012, were \$26.2 million compared to \$8.2 million for the quarter ended September  
8 30, 2011. The increase was primarily due to increases in commercial and medical  
9 affairs costs, including personnel-related costs associated with the establishment of  
10 its commercial and medical affairs field organizations, as the company continues to  
11 execute on the launch and commercialization of OMONTYS.

12 The company had cash and investments of \$100.0 million as of September 30, 2012.

13 36. On January 3, 2013, Affymax issued a press release entitled "Affymax and Takeda  
14 Announce Permanent J-Code for OMONTYS® (peginesatide) Injection is in Effect – Code J0890  
15 Effective As of January 1, 2013." The press release stated, in pertinent part, as follows:

16 Affymax, Inc. and Takeda Pharmaceuticals U.S.A., Inc. today announced that the J-  
17 code assigned by the Centers for Medicare and Medicaid Services (CMS) for  
18 OMONTYS® (peginesatide) Injection is now effective. This permanent  
19 OMONTYS-specific billing code, J0890, will continue to provide for streamlined  
20 reimbursement for dialysis organizations prescribing OMONTYS. OMONTYS is the  
21 only once-monthly erythropoiesis-stimulating agent (ESA) for anemia available to  
22 the adult dialysis patient population with chronic kidney disease (CKD) in the United  
23 States (U.S.).

24 ***"We are excited by the strong level of interest in the dialysis community for  
25 OMONTYS," said John Orwin, chief executive officer, Affymax. "We believe the  
26 J-code complements our efforts to make this once-monthly therapy broadly  
27 available to the dialysis community, and importantly, to appropriate patients."***

28 According to Nicole Mowad-Nassar, vice president, marketing at Takeda, "We are  
pleased to have an effective J-code in place approximately nine months following the  
approval of OMONTYS."

36. On January 7, 2013, Affymax issued a press release entitled "Takeda and Affymax  
Announce Supply Agreement for OMONTYS® (Peginesatide) Injection with DSI Renal." The  
press release stated, in pertinent part, as follows:

Takeda Pharmaceuticals U.S.A., Inc. and Affymax, Inc. today announced that  
Takeda Pharmaceuticals America, Inc. (TPA) has entered into a supply agreement  
for sourcing and supply of OMONTYS® (peginesatide) Injection with DSI Renal,  
one of the largest dialysis providers in the United States (U.S.). OMONTYS is the  
only once-monthly erythropoiesis-stimulating agent (ESA) for anemia available to  
the adult dialysis patient population with chronic kidney disease (CKD) in the U.S.

The agreement allows DSI Renal to purchase OMONTYS for use within its  
organization and provides for discounts and rebates on the product, subject to certain  
requirements. DSI Renal has indicated that they plan to initially evaluate

1 OMONTYS in selected centers, and then, based on experience, evaluate the potential  
2 to expand to additional centers. Financial terms were not disclosed.

3 ***“We look forward to working with DSI Renal as they integrate OMONTYS into  
4 their dialysis centers,” stated John Orwin, chief executive officer of Affymax.  
5 “With this agreement, we now have supply agreements in place with five out of the  
6 six medium-sized dialysis organizations in the U.S.”***

7 38. The true facts, which were known by the defendants but concealed from the investing  
8 public during the Class Period, were as follows:

9 (a) Affymax’s FY 2012 financial guidance was materially overstated throughout  
10 the Class Period;

11 (b) sales of Omontys being reported throughout the Class Period were not  
12 sustainable; and

13 (c) defendants were materially overstating sales and understating the potential  
14 liabilities related to Omontys sales during the Class Period, including refunds and potential liability  
15 to injured patients.

16 39. On February 14, 2013, the price of Affymax stock dropped, opening at \$11.60 per  
17 share on its disclosure, after the close of trading on February 13th, that “[o]n February 13, 2013,  
18 Fresenius Medical Care North America [had] communicated that it ha[d] accumulated experience  
19 with OMONTYS® (peginesatide) Injection in more than 56,600 administrations in over 18,000  
20 patients in its dialysis facilities and that it will pause further expansion of the OMONTYS pilot that  
21 began in late July 2012.” According to the Form 8-K Affymax filed with the SEC that day,  
22 Fresenius had “indicated that it will analyze the full set of efficacy and safety profile information and  
23 that the current scale of their experience with use of OMONTYS is adequate to complete this  
24 analysis.” A letter from Fresenius was attached to the Company’s filing with the SEC, which stated  
25 as follows:

26 February 13, 2013

27 Dear Colleagues:

28 We are writing to provide an interim update on the status of our pilot to assess the  
use of OMONTYS® in the FMCNA dialysis facilities. The purpose of the  
commercial pilot is to determine the role of OMONTYS® as an alternative  
Erythropoiesis Stimulating Agent (ESA) on the FMCNA Formulary. The assessment

1 includes efficacy, safety and logistics related to this agent that was approved for use  
2 by the Food and Drug Administration at the end of March 2012.

3 ***We will now pause expansion of the pilot that began in late July 2012. We have***  
4 ***accumulated experience in more than 56,600 administrations in over 18,000***  
5 ***unique patients. Two months into the FMCNA pilot program, the FDA released***  
6 ***revised product information that added language similar to the prescribing***  
7 ***information for EPOGEN® concerning the risk for allergic reactions, which we***  
8 ***communicated to you in November 2012. To date, we have seen infrequent***  
9 ***allergic reactions in our patient population receiving their first dose of***  
10 ***OMONTYS®. Most of these reactions have been mild, but a small number have***  
11 ***been serious. The rate of allergic reactions has been on the order of 1:1000***  
12 ***patients receiving a first dose of OMONTYS®.*** The vast majority of patients who  
13 are receiving the medication on an ongoing monthly basis are tolerating it well.

14 ***We are now working to analyze the full set of efficacy and safety profile***  
15 ***information and feel that the current scale of our experience with use of the drug***  
16 ***is adequate to complete this analysis.*** These results will be presented to our  
17 Corporate Medical Advisory Board with follow up reporting to our medical staff. In  
18 the meantime, this communication is to inform you of our confirmation of the  
19 adjusted prescribing information and the finding that such allergic reactions can  
20 occur in patients receiving the first dose of the drug. For patients on OMONTYS®,  
21 we recommend continued use of the agent as it has been providing effective anemia  
22 management. We plan to pause the rollout to additional facilities and patients at this  
23 time until the analyses are complete and reported to our medical staff. As many of  
24 you have become quite comfortable with the medication, physicians and facilities  
25 that have been using OMONTYS® who wish to continue prescribing it for new  
26 patients may choose to do so.

27 As we complete the analysis in the next week or two we plan to provide an update on  
28 the pilot experience and any future recommendations. I thank you for your  
participation in determining best protocols and practices around the use of  
OMONTYS® and we will update you with the analysis of our experience once  
complete.

With best regards,

Franklin W. Maddux, MD, FACP  
Chief Medical Officer  
Executive VP For Clinical and Scientific Affairs  
Fresenius Medical Care North America

Jeffrey L. Hymes, MD  
Associate Chief Medical Officer  
Fresenius Medical Care North America

40. In response to this news, on February 14, 2013, Affymax stock closed down at \$15.74  
with more than 11 million shares trading that day.

41. Then suddenly, on Saturday, February 23, 2013, defendants issued a press release  
entitled “Affymax and Takeda Announce a Nationwide Voluntary Recall of All Lots of  
OMONTYS® (peginesatide) Injection.” The press release stated, in pertinent part, as follows:

1 Affymax, Inc. and Takeda Pharmaceutical Company Limited today have decided to  
2 voluntarily recall all lots of OMONTYS® (peginesatide) Injection to the user level  
3 *as a result of new postmarketing reports regarding serious hypersensitivity*  
4 *reactions, including anaphylaxis, which can be life-threatening or fatal. The*  
5 *companies have been working actively with the U.S. Food and Drug*  
6 *Administration (FDA) which has indicated its agreement with this decision. The*  
7 *companies have also issued a letter to health care professionals indicating that no*  
8 *new or existing patients should receive OMONTYS.*

9 To date, fatal reactions have been reported in approximately 0.02% of patients  
10 following the first dose of intravenous administration. The reported serious  
11 hypersensitivity reactions have occurred within 30 minutes after such administration  
12 of OMONTYS. There have been no reports of such reactions following subsequent  
13 dosing, or in patients who have completed their dialysis session. Since launch, more  
14 than 25,000 patients have received OMONTYS in the postmarketing setting. The  
15 rate of overall hypersensitivity reactions reported is approximately 0.2% with  
16 approximately a third of these being serious in nature including anaphylaxis  
17 requiring prompt medical intervention and in some cases hospitalization. The  
18 companies are actively investigating these cases. In the meantime, dialysis  
19 organizations are instructed to discontinue use. *Customers will be provided*  
20 *instructions on how to return the product to the manufacturer for a refund. . . .*

21 42. As reported by *The Wall Street Journal* on February 25, 2013:

22 Affymax Inc. shares plunged 85% in midday trading Monday after reports of severe  
23 allergic reactions in some kidney-disease patients, including at least five deaths,  
24 prompted the company to recall its antianemia drug.

25 Chief Executive John A. Orwin said the company moved to pull the drug, called  
26 Omontys, after executives learned of three deaths in February tied to  
27 hypersensitivity, a sometimes fatal condition that can arise when the body's immune  
28 system reacts to drugs or other foreign intrusions, like bee stings.

*Those fatalities followed two earlier deaths that observers had associated more  
closely with cardiovascular problems rather than allergic reactions.*

It is too soon to determine how certain patients developed fatal reactions to the drug,  
Mr. Orwin told analysts on a conference call Monday, or to speculate on the  
company's next steps after the recall of its only major product.

"We really haven't identified the root cause of these reactions," Mr. Orwin said.  
"It's too early in our investigation, but we will look at every aspect of the product  
and the way it's been given."

Affymax and commercial partner Takeda Pharmaceutical Co. 4502.TO +0.21%  
disclosed the recall Saturday.

*Shares of Affymax dropped \$14.05 to \$2.47 in early afternoon trading Monday,*  
*erasing about \$525 million of market value.* The stock earlier hit an all-time low of  
\$2.34, roughly in line with the value of cash held on the company's books.

The recall shocked investors who had seen encouraging signs that the antianemia  
drug was making inroads as a cheaper and more convenient alternative to Amgen  
Inc.'s blockbuster Epogen, which holds a virtual monopoly in treating anemia in

1 patients receiving dialysis. Shares of Amgen, a much larger biotech company, rose  
2 4.5% to \$90.74 in early afternoon trading.

3 “At this point, the assumption is that the drug never comes back to the market, and  
4 that if it does come back to the market, it’s not as successful as we’d all envisioned it  
5 would be,” Piper Jaffray analyst Ian Somaiya said. “That’s what the stock’s pricing  
6 in today.”

7 The drug’s prospects looked far brighter less than two weeks ago, when a unit of  
8 German medical device maker Fresenius Medical Care AG sent a letter suggesting  
9 that doctors comfortable with the treatment could continue administering it while  
10 Fresenius paused a pilot Omontys program to pore over its safety and effectiveness  
11 data.

12 Fresenius, which treats about one-third of kidney-dialysis patients in the U.S., had  
13 treated about 18,000 patients with Omontys. The company earlier this month  
14 reported a “small number” of allergic reactions but didn’t mention any patient deaths.

15 ***The recall triggered a series of downgrades from analysts who have tied Affymax’s  
16 value to the success of its new drug. The company has no other late-stage drugs in  
17 its pipeline.***

18 ***“Very little can be said or done in the near term to repair this drug’s reputation,”***  
19 Christopher Raymond, an analyst for firm Robert W. Baird, wrote in a note to clients  
20 as he downgraded the stock to neutral.

21 Affymax said about 25,000 patients received Omontys, of whom roughly 0.2%—  
22 about 50 patients—experienced hypersensitivity. According to Mr. Raymond, the  
23 number of Omontys incidents was 100-fold greater than Amgen’s Epogen and the  
24 death rate was 8.5 times higher. “This analysis,” the Baird analyst said, “isn’t  
25 perfect, ***but we think the magnitude is such that there’s a clear signal here.***”

26 Affymax executives on Monday said all the deceased patients had received the drug  
27 intravenously, though Omontys shots were administered too rarely to rule out that  
28 method as a risk. The fatalities were tied to more than one drug lot.

***Researchers had observed some hypersensitive reactions while testing the drug,*** yet  
reported no deaths from that side effect.

43. On this news, the price of Affymax stock declined precipitously by ***more than 85%***,  
closing at \$2.42 per share on February 25, 2013, down \$14.10 from the prior Friday night’s close, on  
unusually high trading volume.

#### **NO SAFE HARBOR**

44. Affymax’s “Safe Harbor” warnings accompanying its reportedly forward-looking  
statements (“FLS”) issued during the Class Period were ineffective to shield those statements from  
liability. Because most of the false and misleading statements related to existing facts or conditions,  
the Safe Harbor has no applicability. To the extent that known trends should have been included in

1 the Company's financial reports prepared in accordance with GAAP, they are excluded from the  
2 protection of the statutory Safe Harbor. 15 U.S.C. §78u-5(b)(2)(A).

3 45. The defendants are also liable for any false or misleading FLS pleaded because, at the  
4 time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was  
5 authorized and/or approved by an executive officer and/or director of Affymax who knew that the  
6 FLS was false. In addition, the FLS were contradicted by existing, undisclosed material facts that  
7 were required to be disclosed so that the FLS would not be misleading. Finally most of the  
8 purported "Safe Harbor" warnings were themselves misleading because they warned of "risks" that  
9 had already materialized or failed to provide meaningful disclosures of the relevant risks.

#### 10 **ADDITIONAL SCIENTER ALLEGATIONS**

11 46. As alleged herein, defendants acted with scienter in that defendants knew that the  
12 public documents and statements issued or disseminated in the name of the Company were  
13 materially false and misleading; knew that such statements or documents would be issued or  
14 disseminated to the investing public; and knowingly and substantially participated or acquiesced in  
15 the issuance or dissemination of such statements or documents as primary violations of the federal  
16 securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of  
17 information reflecting the true facts regarding Affymax, their control over, and/or receipt of  
18 modification of Affymax's allegedly materially misleading misstatements and/or their associations  
19 with the Company which made them privy to confidential proprietary information concerning  
20 Affymax, participated in the fraudulent scheme alleged herein.

#### 21 **APPLICABILITY OF PRESUMPTION OF RELIANCE: 22 **FRAUD-ON-THE-MARKET DOCTRINE****

23 47. At all relevant times, the market for Affymax's common stock was an efficient  
24 market for the following reasons, among others:

25 (a) Affymax's stock met the requirements for listing, and was listed and actively  
26 traded on the NASDAQ, a highly efficient and automated market;

27 (b) according to the Company's Form 10-Q filed November 9, 2012, the  
28 Company had more than 37 million shares outstanding as of October 31, 2012. During the Class

1 Period, on average, 1.2 million shares of Affymax stock were traded on a daily basis, demonstrating  
2 a very active and broad market for Affymax stock and permitting a very strong presumption of an  
3 efficient market;

4 (c) Affymax was qualified to file a less comprehensive Form S-3 registration  
5 statement with the SEC that is reserved, by definition, to well-established and largely capitalized  
6 issuers for whom less scrutiny is required;

7 (d) as a regulated issuer, Affymax filed periodic public reports with the SEC;

8 (e) Affymax regularly communicated with public investors *via* established market  
9 communication mechanisms, including regular disseminations of press releases on the national  
10 circuits of major newswire services, the Internet and other wide-ranging public disclosures, such as  
11 communications with the financial press and other similar reporting services;

12 (f) Affymax was followed by many securities analysts who wrote reports that  
13 were distributed to the sales force and certain customers of their respective firms during the Class  
14 Period. Each of these reports was publicly available and entered the public marketplace;

15 (g) numerous National Association of Securities Dealers (“NASD”) member  
16 firms were active market-makers in Affymax stock at all times during the Class Period; and

17 (h) unexpected material news about Affymax was rapidly reflected in and  
18 incorporated into the Company’s stock price during the Class Period.

19 48. As a result of the foregoing, the market for Affymax common stock promptly  
20 digested current information regarding Affymax from publicly available sources and reflected such  
21 information in Affymax’s stock price. Under these circumstances, all purchasers of Affymax  
22 common stock during the Class Period suffered similar injury through their purchase of Affymax  
23 common stock at artificially inflated prices, and a presumption of reliance applies.

24 **LOSS CAUSATION**

25 49. During the Class Period, as detailed herein, defendants made false and misleading  
26 statements, and omitted material information, concerning Affymax’s business fundamentals and  
27 engaged in a scheme to deceive the market. Defendants knowingly misstated the safety status of  
28 Omontys to improve the market’s perception of Affymax’s worth.



1 made, materially false or misleading statements or failed to disclose material facts necessary to make  
2 the statements made, in light of the circumstances under which they were made, not misleading.

3 56. During the Class Period, defendants Affymax, Takeda and the Individual Defendants,  
4 and each of them, carried out a plan, scheme, and course of conduct using the instrumentalities of  
5 interstate commerce and the mails, which was intended to and, throughout the Class Period did: (a)  
6 artificially inflate and maintain the market price of Affymax common stock; (b) deceive the  
7 investing public, including plaintiff and other Class members, as alleged herein; (c) cause plaintiff  
8 and other members of the Class to purchase Affymax common stock at inflated prices; and (d) cause  
9 them losses when the truth was revealed. In furtherance of this unlawful scheme, plan and course of  
10 conduct, defendants Affymax, Takeda and the Individual Defendants, and each of them, took the  
11 actions set forth herein, in violation of §10(b) of the Exchange Act and Rule 10b-5, 17 C.F.R.  
12 §240.10b-5. All defendants are sued either as primary participants in the wrongful and illegal  
13 conduct charged herein or as controlling persons as alleged below.

14 57. In addition to the duties of full disclosure imposed on defendants Affymax, Takeda  
15 and the Individual Defendants as a result of their affirmative false and misleading statements to the  
16 investing public, these defendants had a duty to promptly disseminate truthful information with  
17 respect to Affymax's operations and performance that would be material to investors in compliance  
18 with the integrated disclosure provisions of the SEC, including with respect to the Company's  
19 revenue and earnings trends, so that the market price of the Company's securities would be based on  
20 truthful, complete and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, *et seq.*) and  
21 S-K (17 C.F.R. §229.10, *et seq.*).

22 58. Defendants Affymax, Takeda and the Individual Defendants had actual knowledge of  
23 the misrepresentations and omissions of material facts set forth herein or acted with reckless  
24 disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts  
25 were either known or readily available to them.

26 59. As a result of the dissemination of the materially false and misleading information  
27 and failure to disclose material facts as set forth above, the market price of Affymax common stock  
28 was artificially inflated during the Class Period. In ignorance of the fact that the market price of

1 Affymax common stock was artificially inflated, and relying directly or indirectly on the false and  
2 misleading statements made knowingly or with deliberate recklessness by defendants Affymax,  
3 Takeda and the Individual Defendants, or upon the integrity of the market in which the shares traded,  
4 plaintiff and other members of the Class purchased Affymax stock during the Class Period at  
5 artificially high prices and, when the truth was revealed, were damaged thereby.

6 60. Had plaintiff and the other members of the Class and the marketplace known of the  
7 true facts, which were knowingly or recklessly concealed by defendants Affymax, Takeda and the  
8 Individual Defendants, plaintiff and the other members of the Class would not have purchased or  
9 otherwise acquired their Affymax shares during the Class Period, or if they had acquired such shares  
10 during the Class Period, they would not have done so at the artificially inflated prices which they  
11 paid.

12 61. By virtue of the foregoing, defendants Affymax, Takeda and the Individual  
13 Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. 17  
14 C.F.R. §240.10-5.

## 15 **COUNT II**

### 16 **For Violation of §20(a) of the Exchange Act** 17 **Against the Individual Defendants**

18 62. Plaintiff repeats and realleges the above paragraphs as though fully set forth herein.

19 63. The Individual Defendants had control over Affymax and made the material false and  
20 misleading statements and omissions on behalf of Affymax within the meaning of §20(a) of the  
21 Exchange Act as alleged herein. By virtue of their controlling shareholder status, executive  
22 positions, board membership, and stock ownership, and their culpable participation, as alleged  
23 above, the Individual Defendants had the power to influence and control and did, directly or  
24 indirectly, influence and control the decision making of the Company, including the content and  
25 dissemination of the various statements which plaintiff contends were false and misleading. The  
26 Individual Defendants were provided with or had unlimited access to the Company's internal  
27 reports, press releases, public filings, and other statements alleged by plaintiff to be misleading prior  
28

1 to or shortly after these statements were issued, and had the ability to prevent the issuance of the  
2 statements or cause them to be corrected.

3 64. In particular, the Individual Defendants had direct involvement in and responsibility  
4 over the day-to-day operations of the Company and, therefore, are presumed to have had the power  
5 to control or influence the particular transactions giving rise to the securities violations as alleged  
6 herein.

7 65. By reason of such wrongful conduct, the Individual Defendants are liable pursuant to  
8 §20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants'  
9 wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with  
10 their purchases of the Company's common stock during the Class Period.

11 **PRAYER FOR RELIEF**

12 WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment as follows:

13 A. Determining that this action is a proper class action, designating plaintiff as Lead  
14 Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil  
15 Procedure and plaintiff's counsel as Lead Counsel;

16 B. Awarding compensatory damages in favor of plaintiff and the other Class members  
17 against all defendants, jointly and severally, for all damages sustained as a result of defendants'  
18 wrongdoing, in an amount to be proven at trial, including interest thereon;

19 C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this  
20 action, including counsel fees and expert fees; and

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

22 **JURY DEMAND**

23 Plaintiff demands a trial by jury.

24 DATED:

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Attorneys for Plaintiff