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 15 AMGEN INC., KEVIN W. SHARER,
 16 RICHARD D. NANULA, ROGER M.
 17 PERLMUTTER and GEORGE J. MORROW

18 **UNITED STATES DISTRICT COURT**
 19 **CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION**

20 IN RE AMGEN INC.
 21 SECURITIES LITIGATION

22 CASE NO. CV 07-2536 PSG (PLAx)
 23 **ANSWER AND AFFIRMATIVE**
 24 **DEFENSES BY DEFENDANTS**
 25 **AMGEN INC., KEVIN W.**
 26 **SHARER, RICHARD D. NANULA,**
 27 **ROGER M. PERLMUTTER AND**
 28 **GEORGE J. MORROW TO**
 CONSOLIDATED AMENDED
 COMPLAINT

1 Defendants AMGEN INC. (“Amgen”), KEVIN W. SHARER (“Sharer”),
2 RICHARD D. NANULA (“Nanula”), ROGER M. PERLMUTTER (“Perlmutter”) and
3 GEORGE J. MORROW (“Morrow”) (collectively, “Defendants”), through their
4 attorneys of record, answer the Consolidated Amended Complaint as follows. By this
5 answer Defendants do not impliedly admit anything, and do not admit the existence,
6 authenticity or Plaintiff’s characterization of any of the documents referenced in the
7 Consolidated Amended Complaint:

8 1. Defendants deny the allegations of the first sentence of paragraph 1 on the
9 ground that no class has been certified in this action. Defendants admit the allegations of
10 the second sentence of paragraph 1. Defendants deny the allegations of the third sentence
11 of paragraph 1.

12 2. Defendants deny the allegations of the first and second sentences of
13 paragraph 2 and admit the allegations of the third sentence of paragraph 2.

14 3. Defendants state that the Interim Analysis issued by the DAHANCA group
15 was publicly available and speaks for itself and otherwise deny the allegations of
16 paragraph 3.

17 4. Defendants state that the information concerning the Interim Analysis of the
18 DAHANCA 10 study was released by the DAHANCA group on their website on
19 December 1, 2006 and was publicly available at the same time as it was made known to
20 Amgen. Defendants admit that this publicly available information was further publicized
21 in *The Cancer Letter* in February, 2007. Except as expressly stated herein, Defendants
22 deny the allegations of paragraph 4.

23 5. Defendants state that the 103 Study and Defendants’ statements concerning
24 the 103 Study speak for themselves and otherwise deny the allegations of paragraph 5.

25 6. Defendants deny the allegations of the first sentence of paragraph 6.
26 Defendants state that the 2004 ODAC was a public meeting and that the transcript thereof
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1 was publicly available on the FDA's website and that the transcript thereof speaks for
2 itself. Except as stated herein, Defendants deny the allegations of paragraph 6.

3 7. Defendants admit the allegations of the first and second sentences of
4 paragraph 7. Defendants further state that the safety data referred to speaks for itself and
5 otherwise deny the allegations of the third, fourth and fifth sentences of paragraph 7.

6 8. Defendants admit that the FDA approved Epogen[®] in 1989 and Aranesp[®] in
7 2001. Defendants further state that the results of the clinical trials referred to were
8 publicly available and speak for themselves. Except as stated herein, Defendants deny
9 the allegations of paragraph 8.

10 9. Defendants deny the allegations of paragraph 9.

11 10. Defendants deny the allegations of the first sentence of paragraph 10.
12 Defendants further state that Amgen's SEC filings and the Food, Drug and Cosmetic Act
13 and accompanying regulations speak for themselves. Except as stated herein, Defendants
14 deny the allegations of paragraph 10.

15 11. Defendants deny the allegations of paragraph 11.

16 12. Defendants deny that Lead Plaintiff purchased Amgen common stock at
17 inflated prices and deny that Lead Plaintiff has been damaged by Defendants.
18 Defendants lack knowledge or information sufficient to determine the truth or falsity of
19 the remaining allegations of paragraph 12 or the accuracy of the certification referenced
20 therein, and based thereon deny the remaining allegations of paragraph 12.

21 13. Defendants admit the allegations in the first and last sentences of
22 paragraph 13. Defendants further state Amgen's website is publicly accessible and
23 speaks for itself. Except as stated herein, Defendants deny the allegations of
24 paragraph 13.

25 14. Defendants admit the allegations of the first sentence of paragraph 14.
26 Defendants further state that the public documents referenced in this paragraph speak for
27 themselves. Defendants further state that Sharer's trading in Amgen common stock
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1 during the purported Class Period are set forth in public filings by Sharer with the SEC.
2 Except as stated herein, Defendants deny the allegations of paragraph 14.

3 15. Defendants admit the allegations of the first sentence of paragraph 15.
4 Defendants further state that the public documents referenced in this paragraph speak for
5 themselves. Defendants further state that Nanula's trading in Amgen common stock
6 during the purported Class Period are set forth in public filings by Nanula with the SEC.
7 Except as stated herein, Defendants deny the allegations of paragraph 15.

8 16. Pursuant to the Court's ruling on Defendants' motion to dismiss and Lead
9 Plaintiff's failure to amend the Consolidated Amended Complaint, Dennis M. Fenton is
10 no longer a party in this case and paragraph 16 therefore requires no further response
11 from Defendants.

12 17. Defendants admit the allegations of the first sentence of paragraph 17.
13 Defendants further state that the public documents referenced in this paragraph speak for
14 themselves. Defendants further state that Perlmutter's trading in Amgen common stock
15 during the purported Class Period are set forth in public filings by Perlmutter with the
16 SEC. Except as stated herein, Defendants deny the allegations of paragraph 17.

17 18. Pursuant to the Court's ruling on Defendants' motion to dismiss and Lead
18 Plaintiff's failure to amend the Consolidated Amended Complaint, Brian M. McNamee is
19 no longer a party in this case and paragraph 18 therefore requires no further response
20 from Defendants.

21 19. Defendants admit the allegations of the first sentence of paragraph 19.
22 Defendants further state that the public documents referenced in this paragraph speak for
23 themselves. Defendants further state that Morrow's trading in Amgen common stock
24 during the purported Class Period are set forth in public filings by Morrow with the SEC.
25 Except as stated herein, Defendants deny the allegations of paragraph 19.

26 20. Pursuant to the Court's ruling on Defendants' motion to dismiss and Lead
27 Plaintiff's failure to amend the Consolidated Amended Complaint, Edward V. Fritzky is
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1 no longer a party in this case and paragraph 20 therefore requires no further response
2 from Defendants.

3 21. Pursuant to the Court's ruling on Defendants' motion to dismiss and Lead
4 Plaintiff's failure to amend the Consolidated Amended Complaint, Gilbert. S. Omenn is
5 no longer a party in this case and paragraph 21 therefore requires no further response
6 from Defendants.

7 22. Pursuant to the Court's ruling on Defendants' motion to dismiss and Lead
8 Plaintiff's failure to amend the Consolidated Amended Complaint, Franklin P. Johnson,
9 Jr. is no longer a party in this case and paragraph 22 therefore requires no further
10 response from Defendants.

11 23. Defendant deny the allegations of paragraph 23.

12 24. Defendants deny the allegations of paragraph 24.

13 25. Defendants state that Amgen's press releases, other public statements and
14 public filings with the SEC, speak for themselves. Except as stated herein, Defendants
15 deny the allegations of paragraph 25.

16 26. Defendants deny the allegations of paragraph 26.

17 27. Defendants deny the allegations of paragraph 27.

18 28. Defendants deny the allegations of paragraph 28.

19 29. Defendants deny the allegations of paragraph 29.

20 30. Defendants deny the allegations of paragraph 30.

21 31. Defendants admit that venue is proper in this District pursuant to 28 U.S.C.
22 § 1391(b) and deny the remaining allegations of paragraph 31.

23 32. Defendants deny the allegations of paragraph 32.

24 33. Defendants admit the allegations of paragraph 33.

25 34. Defendants admit the allegations of paragraph 34.

26 35. Defendants admit the allegations of paragraph 35.

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1 36. Defendants state that Amgen's Product License Agreement with J&J speaks
2 for itself. Except as stated herein, Defendants deny the allegations of paragraph 36.

3 37. Defendants admit the allegations of paragraph 37.

4 38. Defendants admit the allegations of paragraph 38.

5 39. Defendants admit the allegations of the first sentence of paragraph 39.
6 Defendants state that Amgen's Product License Agreement with J&J speaks for itself.
7 Except as stated herein, Defendants deny the allegations of paragraph 39.

8 40. Defendants admit that Amgen developed and markets Aranesp[®] and that the
9 molecular structure of darbepoetin alfa is different than that of epoetin alfa and lasts
10 longer in the bloodstream. Defendants admit the third sentence of paragraph 40. Except
11 as expressly stated herein, Defendants deny the allegations of paragraph 40.

12 41. Defendants state that the PLA between Amgen and J&J and the *Forbes*
13 article referenced in paragraph 41 speak for themselves. Except as stated herein,
14 Defendants deny the allegations of paragraph 41.

15 42. Defendants admit the first and second sentences of paragraph 42.
16 Defendants further state that information regarding Aranesp[®] is contained in public
17 documents and speaks for itself. Except as stated herein, Defendants deny the allegations
18 of paragraph 42.

19 43. Defendants admit that Amgen is a biotechnology company, generating
20 approximately \$14.3 billion in revenues in 2006, and that Amgen's public filings speak
21 for themselves. Defendants state that the *New York Times* article referenced in
22 paragraph 43 speaks for itself. Except as stated herein, Defendants deny the allegations
23 of paragraph 43.

24 44. Defendants state the *Forbes* article referenced in paragraph 44 speaks for
25 itself. Except as stated herein, Defendants deny the allegations of paragraph 44.

26 45. Defendants admit the allegations in the last sentence of paragraph 45.
27 Defendants further state that information regarding Neupogen[®] and Neulasta[®] are
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1 contained in Amgen's SEC filings and press releases. Except as stated herein,
2 Defendants deny the allegations of paragraph 45.

3 46. Defendants state that the allegations of the Complaint in the lawsuit
4 referenced in paragraph 47 speak for themselves. Except as stated herein, Defendants
5 deny the allegations of paragraph 46.

6 47. Defendants state that the *Forbes* report and Amgen's SEC filings referenced
7 in paragraph 47 speak for themselves. Except as stated herein, Defendants deny the
8 allegations of paragraph 47.

9 48. Defendants state that the Medicare reporting requirements prior to January 1,
10 2005 speak for themselves. Except as stated herein, Defendants deny the allegations of
11 paragraph 48.

12 49. Defendants state that the reporting requirements in the legislation referenced
13 in paragraph 49 speak for themselves. Except as stated herein, Defendants deny the
14 allegations of paragraph 49.

15 50. Defendants state that the studies referenced in paragraph 50 speak for
16 themselves. Except as stated herein, Defendants deny the allegations of paragraph 50.

17 51. Defendants state that the studies and the original FDA-approval labels
18 referenced in paragraph 51 speak for themselves. Except as stated herein, Defendants
19 deny the allegations of paragraph 51.

20 52. Defendants state that the FDA's statements concerning epoetin alfa and the
21 results of the study referenced in paragraph 52 speak for themselves. Except as stated
22 herein, Defendants deny the allegations of paragraph 52.

23 53. Defendants state that the studies referenced in paragraph 53 speak for
24 themselves. Except as stated herein, Defendants deny the allegations of paragraph 53.

25 54. Defendants state that the study referenced in paragraph 54 speaks for itself.
26 Except as stated herein, Defendants deny the allegations of paragraph 54.

1 55. Defendants state that the studies referenced in paragraph 55 speak for
2 themselves. Except as stated herein, Defendants deny the allegations of paragraph 55.

3 56. Defendants state that the studies referenced in paragraph 56 speak for
4 themselves. Except as stated herein, Defendants deny the allegations of paragraph 56.

5 57. Defendants state that the studies referenced in paragraph 57 speak for
6 themselves. Except as stated herein, Defendants deny the allegations of paragraph 57.

7 58. Defendants admit that an ODAC Meeting took place in May 2004. Except
8 as stated herein, Defendants deny the allegations of paragraph 58.

9 59. Defendants state that the conference call referenced in paragraph 59 was
10 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
11 Defendants deny the allegations of paragraph 59.

12 60. Defendants deny the allegations of paragraph 60.

13 61. Defendants state that the 2004 ODAC meeting was transcribed and that the
14 transcription was made publicly available on the FDA's website. Defendants state that
15 the transcription of the 2004 ODAC meeting speaks for itself. Except as stated herein,
16 Defendants deny the allegations of paragraph 61.

17 62. Defendants state that the 2004 ODAC meeting was transcribed and that the
18 transcription was made publicly available on the FDA's website. Defendants state that
19 the transcription of the 2004 ODAC meeting speaks for itself. Except as stated herein,
20 Defendants deny the allegations of paragraph 62.

21 63. Defendants admit the allegations of the first and third sentences of
22 paragraph 63 and deny the allegations of the second sentence of paragraph 63.

23 64. Defendants state that the reports concerning the DAHANCA 10 study by the
24 DAHANCA group are and were publicly available and speak for themselves. Except as
25 stated herein, Defendants deny the allegations of paragraph 64.

26 65. Defendants state that the DAHANCA groups reports on the DAHANCA 10
27 study are and were publicly available and speak for themselves. Defendants state that the
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1 FDA's reports on the DAHANCA 10 study are and were publicly available and speak for
2 themselves. Amgen admits that the DAHANCA group publicly released information
3 about the "termination" of the DAHANCA 10 study by a posting on the internet on
4 December 1, 2006 and that concurrently therewith Amgen became aware of this publicly
5 available information. Except as stated herein, Defendants deny the allegations of
6 paragraph 65.

7 66. Defendants state that *The Cancer Letter* article speaks for itself. Except as
8 stated herein, Defendants deny the allegations of paragraph 66.

9 67. Defendants state that the 2004 ODAC meeting was a public meeting and the
10 proceedings thereof were transcribed and that the transcription was made publicly
11 available on the FDA's website. Defendants state that the transcription of the 2004
12 ODAC meeting speaks for itself. Except as stated herein, Defendants deny the
13 allegations of paragraph 67.

14 68. Defendants admit the allegations of the first sentence of paragraph 68.
15 Defendants admit that Amgen's common stock closed at \$64.26 per share on
16 February 28, 2006 and at \$61.70 on March 1, 2006. Defendants state that Amgen's
17 announcement after the market closed on February 28, 2006 speaks for itself. Except as
18 stated herein, Defendants deny the allegations of paragraph 68.

19 69. Defendants deny that *The Cancer Letter* "exposed" the results of the
20 DAHANCA 10 study and further state that Amgen learned of the results of the Interim
21 Analysis on the same day it became publicly available – December 1, 2006. Defendants
22 further state that the DAHANCA 10 results referenced herein were publicly available as
23 of December 1, 2006 through a posting by the DAHANCA group on its website.
24 Defendants state that the conference call referenced in paragraph 69 was transcribed and
25 that the transcription thereof speaks for itself. Defendants admit the last sentence of
26 paragraph 69. Except as stated herein, Defendants deny the allegations of paragraph 69.

1 70. Defendants state that the January 25 conference call was transcribed and that
2 the transcription thereof speaks for itself. Defendants state that the FDA's comments
3 concerning the 103 Study speak for themselves. Except as stated herein, Defendants
4 deny the allegations of paragraph 70.

5 71. Defendants deny the allegations of paragraph 71.

6 72. Defendants state that the quarterly earnings calls referenced in paragraph 72
7 were transcribed and that the transcriptions thereof speak for themselves. Except as
8 stated herein, Defendants deny the allegations of paragraph 72.

9 73. Defendants state that the quarterly earnings calls referenced in paragraph 73
10 was transcribed and that the transcription thereof speaks for itself. Except as stated
11 herein, Defendants deny the allegations of paragraph 73.

12 74. Defendants state that Amgen's November 20, 2006 statement, Roche
13 Pharmaceutical's November 16, 2006 statement and the CHOIR and CREATE studies all
14 speak for themselves. Except as stated herein, Defendants deny the allegations of
15 paragraph 74.

16 75. Defendants state that Amgen's web posting on November 20, 2006 speaks
17 for itself. Except as expressly stated herein, Defendants deny the allegations of
18 paragraph 75.

19 76. Defendants state that the 2004 ODAC meeting was a public meeting and the
20 proceedings thereof were transcribed and that the transcription was made publicly
21 available on the FDA's website. Defendants state that the transcription of the 2004
22 ODAC meeting speaks for itself. Except as stated herein, Defendants deny the
23 allegations of paragraph 76.

24 77. Defendants state that the January 25, 2007 earnings call was transcribed and
25 that the transcription thereof speaks for itself. Except as stated herein, Defendants deny
26 the allegations of paragraph 77.

27 78. Defendants deny the allegations of paragraph 78.
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1 79. Defendants deny the allegations of paragraph 79.

2 80. Defendants state that the 2004 ODAC meeting was a public meeting and the
3 proceedings thereof were transcribed and that the transcription was made publicly
4 available on the FDA's website. Defendants state that the transcription of the 2004
5 ODAC meeting speaks for itself. Except as stated herein, Defendants deny the
6 allegations of paragraph 80.

7 81. Defendants deny the allegations of paragraph 81.

8 82. Paragraph 82 contains legal allegations regarding federal statutes rather than
9 factual assertions and therefore requires no response from Defendants. To the extent
10 paragraph 82 interprets federal statutes or makes factual allegations regarding federal
11 statutes, Defendants admit that physicians may prescribe drugs for off-label uses and
12 deny any remaining allegations of paragraph 82.

13 83. Defendants state that Amgen's SEC filing speak for themselves. Except as
14 stated herein, Defendants deny the allegations of paragraph 83.

15 84. Defendants deny the allegations of paragraph 84.

16 85. Defendants admit the second and third sentences of paragraph 85 and deny
17 the remaining allegations of paragraph 85.

18 86. Defendants deny the allegations of the first sentence of paragraph 86 and
19 admit the allegations of the last two sentences of paragraph 86. Defendants lack
20 knowledge or information concerning the truth or falsity of the allegations of the
21 remaining sentences of paragraph 86 and, based thereon, deny such allegations.

22 87. Defendants lack knowledge or information concerning the allegations of
23 paragraph 87 and, based thereon, deny such allegations.

24 88. Defendants deny the allegations of the second sentence of paragraph 88.
25 Defendants lack knowledge or information concerning the truth or falsity of the
26 remaining allegations of paragraph 88 and, based thereon, deny such allegations.

1 89. Defendants state that the purported Amgen document referenced in
2 paragraph 89 speaks for itself. Except as stated herein, Defendants deny the allegations
3 of paragraph 89.

4 90. Defendants lack knowledge or information concerning the truth or falsity of
5 the allegations of paragraph 90 and, based thereon, deny such allegations.

6 91. Defendants lack knowledge or information concerning the truth or falsity of
7 the allegations of paragraph 91 and, based thereon, deny such allegations.

8 92. Defendants lack knowledge or information concerning the truth or falsity of
9 the allegations of paragraph 92 and, based thereon, deny such allegations.

10 93. Defendants state that the *Boston Globe* article referenced in paragraph 93
11 speaks for itself. Except as stated herein, Defendants deny the allegations of
12 paragraph 93.

13 94. Defendants lack knowledge or information concerning the truth or falsity of
14 the allegations of paragraph 94 and, based thereon, deny such allegations.

15 95. Defendants lack knowledge or information concerning the truth or falsity of
16 the allegations of paragraph 95 and, based thereon, deny such allegations.

17 96. Defendants lack knowledge or information concerning the truth or falsity of
18 the allegations of paragraph 96 and, based thereon, deny such allegations.

19 97. Defendants admit the allegations of the second sentence of paragraph 97.
20 Except as stated herein, Defendants deny the remaining allegations of paragraph 97.

21 98. Defendants state that the article referenced in paragraph 98 speaks for itself.
22 Except as stated herein, Defendants deny the allegations of paragraph 98.

23 99. Defendants state that the letter referenced in paragraph 99 speaks for itself.
24 Except as stated herein, Defendants deny the allegations of paragraph 99.

25 100. Defendants lack knowledge or information concerning the truth or falsity of
26 the allegations of paragraph 100 and, based thereon, deny such allegations.

1 101. Defendants lack knowledge or information concerning the truth or falsity of
2 the allegations of paragraph 101 and, based thereon, deny such allegations.

3 102. Defendants state that the *Forbes* report referenced in paragraph 102 speaks
4 for itself. Except as stated herein, Defendants deny the allegations of paragraph 102.

5 103. Defendants state that the press release referenced in paragraph 103 speaks
6 for itself. Except as stated herein, Defendants deny the allegations of paragraph 103.

7 104. Defendants state that the Associated Press article referenced in
8 paragraph 104 speaks for itself. Except as stated herein, defendants deny the allegations
9 of paragraph 104.

10 105. Defendants state that the *New York Times* article referenced in
11 paragraph 105 speaks for itself. Except as stated herein, Defendants deny the allegations
12 of paragraph 105.

13 106. Defendants state that the Associated Press report referenced in
14 paragraph 106 speaks for itself. Except as stated herein, defendants deny the allegations
15 of paragraph 106.

16 107. Defendants state that the *Rocky Mountain News* article referenced in
17 paragraph 107 speaks for itself. Except as stated herein, defendants deny the allegations
18 of paragraph 107.

19 108. Defendants state that the press release referenced in paragraph 108 speaks
20 for itself. Except as stated herein, Defendants deny the allegations of paragraph 108.

21 109. Defendants admit that the closing price of Amgen common stock was
22 \$62.17 per share on March 8, 2007 and \$60.86 per share on March 9, 2007. Except as
23 stated herein, Defendants deny the allegations of paragraph 109.

24 110. Defendants state that the *New York Times* articles referenced in
25 paragraph 110 speak for themselves. Except as stated herein, Defendants deny the
26 allegations of paragraph 110.

1 111. Defendants state that the *Boston Globe* article referenced in paragraph 111
2 speaks for itself. Except as stated herein, Defendants deny the allegations of
3 paragraph 111.

4 112. Defendants state that the Reuters article referenced in paragraph 112 speaks
5 for itself. Except as stated herein, Defendants deny the allegations of paragraph 112.

6 113. Defendants state that the correspondence referenced in paragraph 113 speaks
7 for itself. Except as stated herein, Defendants deny the allegations of paragraph 113.

8 114. Defendants state that the press release referenced in paragraph 114 speaks
9 for itself. Defendants admit that the closing price of Amgen's common stock was \$57.12
10 per share on April 10, 2007 and \$56.34 on April 11, 2007. Except as stated herein,
11 Defendants deny the allegations of paragraph 114.

12 115. Defendants state that the Bloomberg article referenced in paragraph 115
13 speaks for itself. Except as stated herein, Defendants deny the allegations of
14 paragraph 115.

15 116. Defendants state the Amgen announcement referenced in paragraph 116
16 speaks for itself. Except as stated herein, Defendants deny the allegations of
17 paragraph 116.

18 117. Defendants state that Amgen's first quarter earnings report speaks for itself.
19 Defendants admit that the closing price of Amgen's common stock was \$62.19 per share
20 on April 23, 2007 and \$61.22 on April 24, 2007. Except as stated herein, Defendants
21 deny the allegations of paragraph 117.

22 118. Defendants state that the FDA analysis referenced in paragraph 118 speaks
23 for itself. Defendants admit that the closing price of Amgen's common stock was \$63.76
24 per share on May 7, 2007 and \$62.66 on May 8, 2007. Except as stated herein,
25 Defendants deny the allegations of paragraph 118.

1 119. Defendants state that the *New York Times* article referenced in
2 paragraph 119 speaks for itself. Except as stated herein, Defendants deny the allegations
3 of paragraph 119.

4 120. Defendants state that the proceedings of the 2007 ODAC meeting were
5 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
6 herein, Defendants deny the allegations of paragraph 120.

7 121. Defendants state that the proceedings of the 2007 ODAC meeting were
8 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
9 herein, Defendants deny the allegations of paragraph 121.

10 122. Defendants state that the proceedings of the 2007 ODAC meeting were
11 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
12 herein, Defendants deny the allegations of paragraph 122.

13 123. Defendants state that the proceedings of the 2007 ODAC meeting were
14 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
15 herein, Defendants deny the allegations of paragraph 123.

16 124. Defendants state that the news articles referenced in paragraph 124 speak for
17 themselves. Except as expressly stated herein, Defendants deny the allegations of
18 paragraph 124.

19 125. Defendants state that the proceedings of the 2007 ODAC meeting were
20 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
21 herein, Defendants deny the allegations of paragraph 125.

22 126. Defendants state that the proceedings of the 2007 ODAC meeting were
23 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
24 herein, Defendants deny the allegations of paragraph 126.

25 127. Defendants admit that the closing price of Amgen's common stock was
26 \$63.10 per share on May 9, 2007 and \$57.33 on May 10, 2007. Except as stated herein,
27 Defendants deny the allegations of paragraph 127.

1 128. Defendants deny the allegations of paragraph 128.

2 129. Defendants deny the allegations of paragraph 129.

3 130. Defendants deny the allegations of paragraph 130.

4 131. Defendants deny the allegations of paragraph 131.

5 132. Defendants state that the proceedings of the 2004 ODAC meeting were
6 transcribed and that the transcription thereof speaks for itself. Except as expressly stated
7 herein, Defendants deny the allegations of paragraph 132.

8 133. Defendants state that Amgen's statements regarding the safety and
9 effectiveness of ESAs speak for themselves. Except as stated herein, Defendants deny
10 the allegations of paragraph 133.

11 134. Defendants state that the press releases referenced in paragraph 134 speak
12 for themselves. Except as stated herein, Defendants deny the allegations of
13 paragraph 134.

14 135. Defendants deny the allegations of paragraph 135.

15 136. Defendants state that the conference call referenced in paragraph 135 was
16 transcribed and the transcription thereof speaks for itself. Except as stated herein,
17 Defendants deny the allegations of paragraph 136.

18 137. Defendants deny the allegations of paragraph 137.

19 138. Defendants state that Amgen's assertions referenced in paragraph 138 speak
20 for themselves. Except as stated herein, Defendants deny the allegations of
21 paragraph 138.

22 139. Defendants state that Amgen's website posting referenced in paragraph 139
23 speaks for itself. Except as stated herein, Defendants deny the allegations of
24 paragraph 139.

25 140. Defendants state that Amgen's press release referenced in paragraph 140
26 speaks for itself. Except as stated herein, Defendants deny the allegations of
27 paragraph 140.

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1 141. Defendants state that the earnings call referenced in paragraph 141 was
2 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
3 Defendants deny the allegations of paragraph 141.

4 142. Defendants state that the earnings call referenced in paragraph 142 was
5 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
6 Defendants deny the allegations of paragraph 142.

7 143. Defendants state that the analyst conference referenced in paragraph 143
8 was transcribed and that the transcription thereof speaks for itself. Except as stated
9 herein, Defendants deny the allegations of paragraph 143.

10 144. Defendants state that the conference call referenced in paragraph 144 was
11 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
12 Defendants deny the allegations of paragraph 144.

13 145. Defendants state that the conference call referenced in paragraph 145 was
14 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
15 Defendants deny the allegations of paragraph 145.

16 146. Defendants state that the Amgen statement referenced in paragraph 146
17 speaks for itself. Except as stated herein, Defendants deny the allegations of
18 paragraph 146.

19 147. Defendants state that the conference call referenced in paragraph 147 was
20 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
21 Defendants deny the allegations of paragraph 147.

22 148. Defendants state that any statements by Bob Bradway at the conference
23 referenced in paragraph 148 were transcribed and that the transcription thereof speaks for
24 itself. Except as stated herein, Defendants deny the allegations of paragraph 148.

25 149. Defendants deny the allegations of paragraph 149.
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1 150. Defendants state that their statements regarding growth potential for ESAs
2 speak for themselves. Except as stated herein, Defendants deny the allegations of
3 paragraph 150.

4 151. Defendants admit that Amgen issued an earnings release on July 22, 2004.
5 Defendants state that the conference call referenced in paragraph 151 was transcribed and
6 the transcription thereof speaks for itself. Except as stated herein, Defendants deny the
7 allegations of paragraph 151.

8 152. Defendants state that the conference call referenced in paragraph 152 was
9 transcribed and the transcription thereof speaks for itself. Except as stated herein,
10 Defendants deny the allegations of paragraph 152.

11 153. Defendants state that the conference call referenced in paragraph 153 was
12 transcribed and the transcription thereof speaks for itself. Except as stated herein,
13 Defendants deny the allegations of paragraph 153.

14 154. Defendants state that Dr. Gringeri's remarks at the conference referenced in
15 paragraph 154 were transcribed and that the transcription thereof speaks for itself.
16 Except as stated herein, Defendants deny the allegations of paragraph 154.

17 155. Defendants deny the allegations of paragraph 155.

18 156. Defendants deny the allegations of paragraph 156.

19 157. Defendants state that Amgen's public filings speak for themselves. Except
20 as stated herein, Defendants deny the allegations of paragraph 157.

21 158. Defendants state that Amgen's public filings speak for themselves. Except
22 as stated herein, Defendants deny the allegations of paragraph 158.

23 159. Defendants state that Defendants' public statements speak for themselves.
24 Except as stated herein, Defendants deny the allegations of paragraph 159.

25 160. Defendants state that the press release referenced in paragraph 160 speaks
26 for itself. Except as stated herein, Defendants deny the allegations of paragraph 160.

1 161. Defendants state that the conference call referenced in paragraph 161 was
2 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
3 Defendants deny the allegations of paragraph 161.

4 162. Defendants state that the conference call referenced in paragraph 162 was
5 transcribed and that the transcription thereof speaks for itself. Except as stated herein,
6 Defendants deny the allegations of paragraph 162.

7 163. Defendants deny the allegations of paragraph 163.

8 164. Defendants deny the allegations of paragraph 164.

9 165. Defendants state that the press release and SEC filings referenced in
10 paragraph 165 speak for themselves. Except as stated herein, Defendants deny the
11 allegations of paragraph 165.

12 166. Defendants state that the press release and SEC filings referenced in
13 paragraph 166 speak for themselves. Except as stated herein, Defendants deny the
14 allegations of paragraph 166.

15 167. Defendants state that the press release and SEC filings referenced in
16 paragraph 167 speak for themselves. Except as stated herein, Defendants deny the
17 allegations of paragraph 167.

18 168. Defendants state that the press release and SEC filings referenced in
19 paragraph 168 speak for themselves. Except as stated herein, Defendants deny the
20 allegations of paragraph 168.

21 169. Defendants state that the press release and SEC filings referenced in
22 paragraph 169 speak for themselves. Except as stated herein, Defendants deny the
23 allegations of paragraph 169.

24 170. Defendants state that the press release and SEC filings referenced in
25 paragraph 170 speak for themselves. Except as stated herein, Defendants deny the
26 allegations of paragraph 170.

1 171. Defendants state that the press release and SEC filings referenced in
2 paragraph 171 speak for themselves. Except as stated herein, Defendants deny the
3 allegations of paragraph 171.

4 172. Defendants state that the press release and SEC filings referenced in
5 paragraph 172 speak for themselves. Except as stated herein, Defendants deny the
6 allegations of paragraph 172.

7 173. Defendants state that the press release and SEC filings referenced in
8 paragraph 173 speak for themselves. Except as stated herein, Defendants deny the
9 allegations of paragraph 173.

10 174. Defendants state that the press release and SEC filings referenced in
11 paragraph 174 speak for themselves. Except as stated herein, Defendants deny the
12 allegations of paragraph 174.

13 175. Defendants state that the press release and SEC filings referenced in
14 paragraph 175 speak for themselves. Except as stated herein, Defendants deny the
15 allegations of paragraph 175.

16 176. Defendants state that the press release and SEC filings referenced in
17 paragraph 176 speak for themselves. Except as stated herein, Defendants deny the
18 allegations of paragraph 176.

19 177. Defendants deny the allegations of paragraph 177.

20 178. Defendants state that the trading in Amgen common stock by Defendants
21 during the purported Class Period are as reflected in their filings with the SEC, which
22 filings speak for themselves. Except as stated herein, Defendants deny the allegations of
23 paragraph 178.

24 179. Defendants deny the allegations of paragraph 179.

25 180. Defendants state that the subpoena referenced in paragraph 180 speaks for
26 itself. Except as stated herein, Defendants deny the allegations of paragraph 180.
27
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1 181. Defendants state that the Medicare announcement referenced in
2 paragraph 181 speaks for itself. Except as stated herein, Defendants deny the allegations
3 of paragraph 181.

4 182. Defendants state that the letter referenced in paragraph 182 speaks for itself.
5 Except as stated herein, Defendants deny the allegations of paragraph 182.

6 183. Defendants state that the press release referenced in paragraph 183 speaks
7 for itself. Except as stated herein, Defendants deny the allegations of paragraph 183.

8 184. Defendants state that the press release referenced in paragraph 184 speaks
9 for itself. Except as stated herein, Defendants deny the allegations of paragraph 184.

10 185. Defendants state that Bloomberg article referenced in paragraph 185 speaks
11 for itself. Defendants admit that Amgen's common stock closed at \$56.93 per share on
12 July 13, 2007 and at \$56.03 on July 16, 2007. Except as stated herein, Defendants deny
13 the allegations of paragraph 185.

14 186. Defendants state that the announcement referenced in paragraph 186 speaks
15 for itself. Except as stated herein, Defendants deny the allegations of paragraph 186.

16 187. Defendants state that the *Los Angeles Times* article referenced in
17 paragraph 187 speaks for itself. Except as stated herein, Defendants deny the allegations
18 of paragraph 187.

19 188. Defendants state that the Associated Press article referenced in
20 paragraph 188 speaks for itself. Except as stated herein, Defendants deny the allegations
21 of paragraph 188.

22 189. Defendants state that the announcement referenced in paragraph 189 speaks
23 for itself. Except as stated herein, Defendants deny the allegations of paragraph 189.

24 190. Defendants state that the *Forbes* article referenced in paragraph 190 speaks
25 for itself. Except as stated herein, Defendants deny the allegations of paragraph 190.

26 191. Defendants state that the meeting of experts on September 11, 2007
27 referenced in paragraph 191 was transcribed and that the transcription thereof speaks for
28

1 itself. Defendants state that the September 12, 2007 CNN.com article speaks for itself.
2 Except as stated herein, Defendants deny the allegations of paragraph 191.

3 192. Defendants state that the expert panel meeting referenced in paragraph 192
4 was transcribed and that the transcription thereof speaks for itself. Defendants state that
5 the analyst reports referenced in paragraph 192 speaks for themselves. Except as stated
6 herein, Defendants deny the allegations of paragraph 192.

7 193. Paragraph 193 does not contain any factual allegations and therefore
8 requires no response from Defendants. To the extent it contains any factual allegations,
9 Defendants deny the allegations of paragraph 193.

10 194. Defendants deny the allegations of paragraph 194.

11 195. Defendants deny the allegations of paragraph 195.

12 196. Defendants lack knowledge or information sufficient to determine the truth
13 or falsity of the allegations of paragraph 196 and, based thereon, deny such allegations.

14 197. Defendants deny the allegations of paragraph 197.

15 198. Defendants deny the allegations of paragraph 198.

16 199. Defendants admit the allegations of paragraph 199.

17 200. Defendants admit the allegations of the first sentence of paragraph 200 and
18 deny the allegations of the second sentence of paragraph 200.

19 201. Defendants deny the allegations of paragraph 201.

20 202. Defendants deny the allegations of paragraph 202.

21 203. Defendants state that *The Cancer Letter* article on February 16, 2007 speaks
22 for itself. Defendants admit that Amgen's common stock closed at \$68.28 per share on
23 February 15, 2007 and at \$66.73 on February 16, 2007. Except as stated herein,
24 Defendants deny the allegations of paragraph 203.

25 204. Defendants state that the announcement referenced in paragraph 204 speaks
26 for itself. Except as stated herein, Defendants deny the allegations of paragraph 204.

1 205. Defendants admit that Amgen's common stock closed at \$64.26 per share on
2 February 28, 2007 and at \$61.70 per share on March 1, 2007. Except as stated herein,
3 Defendants deny the allegations of paragraph 205.

4 206. Defendants state that the FDA announcement on March 9, 2007 speaks for
5 itself. Defendants admit that Amgen's common stock closed at \$62.17 per share on
6 March 8, 2007 and at \$60.86 per share on March 9, 2007. Except as stated herein,
7 Defendants deny the allegations of paragraph 206.

8 207. Defendants state that the proceedings of the 2007 ODAC meeting were
9 transcribed and that the transcription thereof speaks for itself. Defendants admit that
10 Amgen's common stock closed at \$63.10 per share on May 9, 2007 and at \$57.33 per
11 share on May 10, 2007. Except as expressly stated herein, Defendants deny the
12 allegations of paragraph 120.

13 208. Defendants incorporate by reference their answers to paragraphs 1 through
14 207, inclusive, as though full set forth at this point.

15 209. Defendants deny the allegations of paragraph 209.

16 210. Defendants deny the allegations of paragraph 210.

17 211. Defendants deny the allegations of paragraph 211.

18 212. Defendants deny the allegations of paragraph 212.

19 213. Defendants deny the allegations of paragraph 213.

20 214. Defendants deny the allegations of paragraph 214.

21 215. Defendants deny the allegations of paragraph 215.

22 216. Defendants deny the allegations of paragraph 216.

23 217. Defendants deny the allegations of paragraph 217.

24 218. Defendants deny the allegations of paragraph 218.

25 219. Defendants incorporate by reference their answers to paragraphs 1 through
26 218, inclusive, as though full set forth at this point.

27 220. Defendants deny the allegations of paragraph 220.

28

1 221. Defendants deny the allegations of paragraph 221.

2 222. Defendants deny the allegations of paragraph 222.

3 **AFFIRMATIVE DEFENSES**

4 Without admitting the truth of any of the allegations of the Consolidated Amended
5 Complaint, Defendants assert the following Affirmative Defenses in further defense to
6 the Consolidated Amended Complaint. By alleging the matters set forth below,
7 Defendants do not thereby admit or concede that Defendants have the burden of proof
8 and/or the burden of persuasion with respect to any of those matters.

9 **FIRST AFFIRMATIVE DEFENSE**

10 **(Failure To State A Claim Upon Which Relief Can Be Granted)**

11 223. The Consolidated Amended Complaint and every claim for relief asserted
12 therein fails to state a claim upon which relief can be granted against Defendants.

13 **SECOND AFFIRMATIVE DEFENSE**

14 **(Statutory Safe Harbor)**

15 224. Plaintiff's claims are barred, in whole or in part, because forward-looking
16 statements alleged by the Consolidated Amended Complaint to have been made by
17 Defendants were protected by the statutory safe harbor set forth in 15 U.S.C. § 78u-5.

18 **THIRD AFFIRMATIVE DEFENSE**

19 **(Control Person Liability)**

20 225. Plaintiff's control person liability claims in the Second Claim for Relief are
21 barred, in whole or in part, because the Individual Defendants at all times acted in good
22 faith and did not directly or indirectly induce any act or acts constituting a violation of
23 Section 10(b) of the Securities Exchange Act of 1934.

1 **FOURTH AFFIRMATIVE DEFENSE**

2 **(Express Warnings)**

3 226. Plaintiff's claims are barred, in whole or in part, because express warnings
4 in Amgen's public statements regarding the risks inherent in Amgen's business bespoke
5 caution.

6 **FIFTH AFFIRMATIVE DEFENSE**

7 **(Assumption Of Risk)**

8 227. Plaintiff's claims are barred, in whole or in part, because the facts that the
9 Consolidated Amended Complaint claims were concealed were publicly available and
10 Plaintiff had actual or constructive knowledge of those facts at the time it purchased its
11 Amgen shares and thus assumed the risk of a decline in value of those shares.

12 **SIXTH AFFIRMATIVE DEFENSE**

13 **(Negligence)**

14 228. Plaintiff's claims are barred, in whole or in part, because the facts that the
15 Consolidated Amended Complaint claims were concealed were publicly available and
16 therefore Plaintiff knew, or in the exercise of reasonable care should have known, those
17 facts and was thus negligent with respect to the purchase of its Amgen shares. This
18 negligence was the cause in fact and proximate cause of the alleged damages asserted in
19 the Consolidated Amended Complaint.

20 **SEVENTH AFFIRMATIVE DEFENSE**

21 **(Public Disclosure/
22 Truth on the Market)**

23 229. Plaintiff's claims are barred, in whole or in part, because the matters alleged
24 in the Consolidated Amended Complaint to be non-public and/or the subject of
25 misrepresentations and omissions were publicly disclosed and/or in the public domain,
26 and, as such, were available to Plaintiff and were at all times reflected in the price of
27 Amgen's common stock.

1 **EIGHTH AFFIRMATIVE DEFENSE**

2 **(Reasonable Reliance)**

3 230. Plaintiff's claims are barred, in whole or in part, because Plaintiff did not
4 reasonably rely on any of the statements or omissions alleged in the Consolidated
5 Amended Complaint in deciding to purchase its Amgen shares.

6 **NINTH AFFIRMATIVE DEFENSE**

7 **(Acts Or Omissions of Plaintiff)**

8 231. Plaintiff's claims are barred, in whole or in part, because any alleged injuries
9 and damages sustained or incurred by Plaintiff were caused in whole or in part by
10 Plaintiff's own acts or omissions for which Defendants are not responsible.

11 **TENTH AFFIRMATIVE DEFENSE**

12 **(Acts Or Omissions Of Others)**

13 232. Plaintiff's claims are barred, in whole or in part, because any alleged injuries
14 and damages sustained or incurred by Plaintiff were caused in whole or in part by the
15 own acts or omissions of others, for whose conduct Defendants are not responsible.

16 **ELEVENTH AFFIRMATIVE DEFENSE**

17 **(Failure To Mitigate)**

18 233. Plaintiff's claims are barred, in whole or in part, because Plaintiff failed to
19 act reasonably to mitigate their damages based on the decline of the value of its Amgen
20 shares.

21 **TWELFTH AFFIRMATIVE DEFENSE**

22 **(First Amendment)**

23 234. Plaintiff's claims are barred, in whole or in part, by the right of free speech
24 set forth in the First Amendment to the United States Constitution. Defendants, among
25 other things, had a right to express their opinions about clinical studies and the safety and
26 efficacy of Amgen's products.

1 **THIRTEENTH AFFIRMATIVE DEFENSE**

2 **(FDA Exclusive Authority)**

3 235. Plaintiff's claims are barred, in whole or in part, by the exclusive authority
4 of the FDA and the executive branch of the United States government to enforce the
5 Federal Food, Drug and Cosmetics Act.

6 **FOURTEENTH AFFIRMATIVE DEFENSE**

7 **(No Duty To Disclose)**

8 236. Plaintiff's claims are barred, in whole or in part, because Defendants had no
9 duty to disclose matters which Plaintiff claims were omitted and should have been
10 disclosed.

11 **FIFTEENTH AFFIRMATIVE DEFENSE**

12 **(No Duty To Update)**

13 237. Plaintiff's claims are barred, in whole or in part, because Defendants had no
14 duty to update disclosure on matters merely because circumstances changed.

15 **SIXTEENTH AFFIRMATIVE DEFENSE**

16 **(Loss Causation)**

17 238. Plaintiff's claims are barred, in whole or in part, by its failure to establish
18 loss causation.

19 **SEVENTEENTH AFFIRMATIVE DEFENSE**

20 **(Subsequently Discovered Defenses)**

21 239. Defendants give notice that they intend to rely upon such other applicable
22 defenses as may become apparent at a subsequent stage of this action, and hereby reserve
23 the right to assert such defenses.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray that this Court will enter judgment as follows:

1. That the Consolidated Amended Complaint be dismissed with prejudice and that Plaintiffs take nothing from Defendants by their Consolidated Amended Complaint;
2. For costs and attorneys' fees; and
3. For such other relief as the Court deems just and proper.

Dated: April 2, 2008

MAYER BROWN LLP

By: Steven O. Kramer
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