

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

V.

INSMED INCORPORATED., WILLIAM H. LEWIS, and ANDREW T. DRECHSLER,

Defendants.

Civil Action No.:

CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff [REDACTED] (“Plaintiff”), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against Defendants, alleges the following based upon personal knowledge as to herself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Insmmed Incorporated (“Insmmed” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Insmmed securities between March 18, 2013 and June 8, 2016, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Insmmed, a biopharmaceutical company, focuses on the development and commercialization of inhaled therapies for patients with serious lung diseases. The Company’s lead product candidate is Arikayce, or liposomal amikacin, for inhalation, a formulation of amikacin. Arikayce is in late-stage clinical development for treatment of nontuberculous mycobacteria (“NTM”) lung disease.

3. Insmmed was incorporated in 1999 and is headquartered in Bridgewater, New Jersey. The Company’s shares trade on the NASDAQ under the ticker symbol “INSM.”

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the data on which Insmmed’s European marketing authorization application (“MAA”) for Arikayce relied was not likely to support approval by the European Medicines Agency (“EMA”) for the treatment of NTM lung disease; (ii) Arikayce’s approval by the EMA for the treatment of NTM lung disease and subsequent commercialization in Europe were thus less likely and/or imminent than Insmmed had led investors to believe; and (iii) as a result of the foregoing, Insmmed’s public statements were materially false and misleading at all relevant times.

5. On June 8, 2016, after the market closed, Insmmed announced that it had withdrawn its MAA from the EMA for Arikayce for the treatment of NTM lung disease. The Company stated that “During the May 2016 Committee for Medicinal Products for Human Use (CHMP) meeting, the CHMP indicated that the phase 2 study did not provide a sufficient amount of evidence to support an approval. Insmmed intends to resubmit its MAA when clinical data from its ongoing global phase 3 study are available.”

6. On this news, Insmmed’s share price fell \$0.99, or 8.24%, to close at \$11.02 on June 9, 2016.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

10. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Insmmed is headquartered in this district and a significant portion of Defendants’ actions, and the subsequent damages, took place within this District.

11. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

12. Plaintiff, [REDACTED]

attached Certification, acquired Insméd securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Insméd is incorporated in Virginia, and the Company's principal executive offices are located at 10 Funderne Avenue, Building 10, Bridgewater, New Jersey 08807.

14. Defendant William H. Lewis ("Lewis") has served at all relevant times as the Company's Chief Executive Officer, President, and Director.

15. Defendant Andrew T. Drechsler ("Drechsler") has served at all relevant times as the Company's Chief Financial Officer.

16. The Defendants referenced above in ¶¶ 14-15 are sometimes collectively referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

17. Insméd, a biopharmaceutical company, focuses on the development and commercialization of inhaled therapies for patients with serious lung diseases. The Company's lead product candidate is Arikayce, or liposomal amikacin, for inhalation, a formulation of amikacin. Arikayce is in late-stage clinical development for treatment of NTM lung disease.

Materially False and Misleading Statements Issued During the Class Period

18. The Class Period begins on March 18, 2013, when Inmed filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "2012 10-K"). For the quarter, Inmed reported a net loss of \$15.45 million, or \$0.49 per diluted share, on zero revenue, compared to a net loss of \$8.16 million, or \$0.31 per diluted share, on revenue of \$1.40 million for the same period in the prior year. For 2012, Inmed reported a net loss of \$41.37 million, or \$1.56 per diluted share, on zero revenue, compared to a net loss of \$59.66 million, or \$2.95 per diluted share, on revenue of \$4.42 million for 2011.

19. In the 2012 10-K, Inmed advised investors that:

We are currently conducting a Phase 2 clinical trial in the US and Canada for ARIKACE in adult patients with NTM lung infections. We began enrolling patients in June 2012. The Phase 2 clinical trial is a randomized, placebo-controlled study of approximately 100 adult patients with recalcitrant NTM lung infections. There are two parts to the study: a randomized portion and an open-label portion.

...

In addition to the phase 2 clinical trial outlined above, we intend to pursue a limited compassionate use program starting in the second half of 2013. We currently anticipate this program's participants will consist of approximately 25 patients who have NTM lung infection but are not eligible for entry into our phase 2 clinical trial. We believe that clinical data collected from the experience with these patients will help regulatory authorities to evaluate ARIKACE's safety and suitability for treating NTM lung infection patients.

20. With respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Inmed advised investors of its intent to seek approval for and commercialize Arikayce in Europe as a treatment for NTM lung infections, stating, "If approved, we plan to commercialize ourselves initially in US and eventually in Europe and in Canada."

21. The 2012 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by the Individual Defendants, stating that the financial information contained in the 2012 10-K was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

22. On May 7, 2013, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended March 31, 2013 (the “Q1 2013 10-Q”). For the quarter, Insmmed reported a net loss of \$13.68 million, or \$0.43 per diluted share, on zero revenue, compared to a net loss of \$6.85 million, or \$0.28 per diluted share, on zero revenue for the same period in the prior year.

23. In the Q1 2013 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed reiterated its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶ 20.

24. The Q1 2013 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2013 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

25. On May 7, 2013, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q1 2013 10-Q (the “Q1 2013 8-K”). In the Q1 2013 8-K, Defendant Lewis advised investors that “We continue to advance Insmmed’s transformation into a commercial entity. During the first quarter we made significant progress in executing our hiring plan, advancing our manufacturing strategy and carrying out our clinical trials and regulatory filing preparation for [Arikayce]” and “We remain on track to report top-line clinical results from our Phase 3 trial in CF mid-year and

our Phase 2 trial in NTM before the end of the year. *Collectively, these data sets bring us closer to our goal to commercialize a potentially life-saving treatment for patients* suffering from these orphan lung diseases.” (Emphasis added.)

26. On August 6, 2013, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended June 30, 2013 (the “Q2 2013 10-Q”). For the quarter, Insmmed reported a net loss of \$8.85 million, or \$0.28 per diluted share, on revenue of \$11.50 million, compared to a net loss of \$9.7 million, or \$0.39 per diluted share, on zero revenue for the same period in the prior year.

27. In the Q2 2013 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed reiterated its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20 and 23.

28. The Q2 2013 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2013 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

29. On August 6, 2013, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q2 2013 10-Q (the “Q2 2013 8-K”), Defendant Lewis advised investors that “With positive Phase 3 data for our CF indication and our QIDP and Fast Track designations for our NTM indication, we are actively moving forward with our strategy to bring once-daily [Arikayce] to patients suffering from these orphan lung diseases in two indications in *two geographies in two years* [i.e., Europe and the United States].” (Emphasis added.)

30. On October 15, 2013, Insmmed released a press release entitled “Insmmed Completes Enrollment of Phase 2 Clinical Trial of ARIKACE to Treat Nontuberculous Mycobacteria Lung Disease in U.S. and Canada - Commences Scientific Advice Working Party Process With EMA for Clarity on Path Forward for ARIKACE to Treat Nontuberculous Mycobacteria Lung Disease in Europe.” In the press release, Insmmed advised investors that “Insmmed . . . [has] commenced the Scientific Advice Working Party (SAWP) process with the European Medicines Agency (EMA) and expects to have discussions with the EMA regarding [Arikayce] for NTM lung disease during the fourth quarter of 2013.”

31. On November 5, 2013, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended September 30, 2013 (the “Q3 2013 10-Q”). For the quarter, Insmmed reported a net loss of \$17.33 million, or \$0.46 per diluted share, on zero revenue, compared to a net loss of \$9.38 million, or \$0.38 per diluted share, on zero revenue for the same period in the prior year.

32. In the Q3 2013 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company “expect[s] to launch a single arm, open-label, supportive study in the U.S. and Europe during the fourth quarter of 2013” and reiterated its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, and 27.

33. The Q3 2013 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2013 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

34. On November 5, 2013, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q3 2013 10-Q (the “Q3 2013 8-K”). In the Q3 2013 8-K, Defendant Lewis advised investors that “During the third quarter we made significant progress advancing [Arikayce] closer to our goal of treating patients with NTM lung disease. . . . [W]e are mapping a path forward for [Arikayce] to treat NTM lung disease through the SAWP process and expect to engage in communications with the EMA during the fourth quarter of 2013.”

35. On March 6, 2014, Insmmed filed an Annual Report on Form 10-K with the SEC, announcing the Company’s financial and operating results for the quarter and year ended December 31, 2013 (the “2013 10-K”). For the quarter, Insmmed reported a net loss of \$16.21 million, or \$0.41 per diluted share, on zero revenue, compared to a net loss of \$15.45, or \$0.49 per diluted share, on zero revenue for the same period in the prior year. For 2013, Insmmed reported a net loss of \$56.07 million, or \$1.60 per diluted share, on revenue of \$11.50 million, compared to a net loss of \$41.37 million, or \$1.56 per diluted share, on zero revenue for 2012.

36. In the 2013 10-K, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company “expect[s] to enroll the first patient in our single-arm, open-label, supportive study in the United States and Europe during the second quarter of 2014” and “expect[s] to have dialogue with the FDA and the European Medicines Agency (“EMA”) in the second quarter of 2014 to discuss the regulatory pathway,” while reiterating the Company’s previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, and 32.

37. The 2013 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the 2013 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

38. On March 6, 2014, Inmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the 2013 10-K (the "2013 8-K"). In the 2013 8-K, Defendant Lewis advised investors that "2013 was a transformational year, one in which we laid the foundation to build Inmed into a leading biopharmaceutical company" and that "In the near term we plan to report top-line results from our phase 2 clinical trial of ARIKAYCE to treat NTM lung infections. From the release of these data, we expect to have discussions with regulatory authorities in the U.S. and Europe regarding a path forward to filing for approval."

39. On March 26, 2014, Inmed issued a press release entitled "Inmed Announces Results from Phase 2 Clinical Trial for Treatment Resistant Nontuberculous Mycobacterial Lung Infections." The press release advised investors that "The Company plans to incorporate these results into discussions with the regulatory agencies in the United States and Europe to determine next steps for ARIKAYCE" and further stated, in part:

"The results relating to the key secondary endpoint of culture conversion are encouraging, and I believe demonstrate that ***ARIKAYCE has the potential to be an option for treating even the most difficult treatment resistant patients with NTM lung infections***," said David Griffith, M.D., Professor of Medicine, W.A. and E. B. Moncrief Distinguished Professor at The University of Texas Health Sciences Center and a co-Principal Investigator on the study.

"We are encouraged by the achievement of culture conversion in this trial, which we believe is the ultimate goal in the treatment of mycobacterial infections," said Dr. Renu Gupta, Executive Vice President, Development and Chief Medical Officer of Inmed. "The design of this trial was such that the patients who entered the trial and received drug were clearly resistant to guideline therapy, making them the most treatment-challenged NTM patients. Therefore the hurdle for showing any improvement with a therapy is extremely high."

"While ARIKAYCE did not achieve statistical significance on the primary endpoint of bacterial density reduction, we are very pleased by the greater number of culture conversions among patients receiving ARIKAYCE," stated Will Lewis, President and Chief Executive Officer of Inmed. "We now look forward to the regulatory discussions in the US and Europe that will guide our path forward."

(Emphasis added.)

40. On May 8, 2014, Inmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2014 (the "Q1 2014 10-Q"). For the quarter, Inmed reported a net loss of \$14.30 million, or \$0.36 per diluted share, on zero revenue, compared to a net loss of \$13.68 million, or \$0.43 per diluted share, on zero revenue for the same period in the prior year.

41. In the Q1 2014 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Inmed advised investors that the Company "expect[s] to commence an additional study in the US and/or Europe in the second half of 2014" and "expect[s] to have dialogue with the FDA and the EMA in the next several months to discuss the regulatory pathway," while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, and 36.

42. The Q1 2014 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

43. On May 8, 2014, Inmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q1 2014 10-Q (the "Q1 2014 8-K"). In the Q1 2014 8-K, Defendant Lewis advised investors

that “We remain on track to discuss our recent clinical results with the U.S. Food and Drug Administration and the European Medicines Agency to determine next steps for ARIKAYCE.”

44. On May 20, 2014, Inmed issued a press release entitled “Inmed Announces Positive Open Label Data from Phase 2 Clinical Trial of ARIKAYCE for Treatment Resistant Nontuberculous Mycobacterial Lung Infections.” The press release stated, in part:

"We are encouraged by these additional and durable culture conversions which we believe is the ultimate goal in the treatment of NTM lung infections," said Will Lewis, President and Chief Executive Officer of Inmed. "The patients screened for admission to this trial are recalcitrant to treatment. While the entry criteria for this trial required a minimum of 6 months on standard of care therapy, over 75% of patients entering this trial were treated with standard of care therapy for more than a year, yet remained culture positive. In addition, a majority of these patients suffer from at least one additional pulmonary co-morbidity, such as bronchiectasis or cystic fibrosis, making the hurdle quite high for showing any improvement and making these results that much more encouraging for patients suffering from this disease. We now look forward to the regulatory discussions in the United States and Europe that will guide our path forward."

In the next several months, the Company plans to incorporate the trial results into discussions with the regulatory agencies in the United States and Europe to determine next steps for ARIKAYCE in the treatment of NTM lung infections.

45. On August 4, 2014, Inmed issued a press release entitled “Inmed Provides Regulatory Update for ARIKAYCE – Filing Marketing Authorization Application with European Medicines Agency for NTM Lung Disease and CF Indications.” The press release stated, in part:

Inmed Incorporated (Nasdaq: INSM) today announced that, following discussions with European regulatory authorities, it intends to file by the end of 2014 a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for ARIKAYCE™, or liposomal amikacin for inhalation, for the treatment of nontuberculous mycobacteria (NTM) lung infections in treatment refractory patients as well as for *Pseudomonas aeruginosa* lung infections in cystic fibrosis (CF) patients.

...

The Company believes its two-trial approach will enable both the rapid confirmation of the previous study results to provide the quickest path to filing, as well as expansion of the potential overall label for approval. Following discussions with the FDA, both trials will focus on culture conversion as the primary measure of efficacy with additional goals of demonstrating sustainability and safety. The Company expects results from the smaller confirmatory study by the first half of 2016 and results for the larger trial in 2017.

"Our planned filing in Europe is a significant step forward in our goal to bring ARIKAYCE to market to benefit the thousands of European NTM patients refractory to standard therapy, as well as cystic fibrosis patients with *Pseudomonas aeruginosa* lung infections," said Will Lewis, Insmmed's President and Chief Executive Officer. "We will continue to resource our clinical, commercial and manufacturing capabilities in order to expedite our regulatory submissions and prepare for commercial launch, initially in Europe."

...

"We are moving forward purposefully to complete our MAA submission for ARIKAYCE by the end of the year and to initiate our U.S. Phase 3 clinical trials in the coming months," stated Peggy Berry, Vice President of Regulatory Affairs for Insmmed. ***"We greatly appreciate the collaborative and supportive interactions we have had with the EMA and European agency reviewers providing clarity around their requirements to complete a timely review of ARIKAYCE."*** We also appreciate the clarity the FDA has provided with regard to a regulatory pathway, and their detailed guidance and support for this additional pivotal study work."

(Emphasis added.)

46. On August 6, 2014, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2014 (the "Q2 2014 10-Q"). For the quarter, Insmmed reported a net loss of \$23.22 million, or \$0.59 per diluted share, on zero revenue, compared to a net loss of \$8.85 million, or \$0.28 per diluted share, on revenue of \$11.50 million for the same period in the prior year.

47. In the Q2 2014 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company "intend[s] to file by the end of 2014 a MAA [marketing authorization application] with the EMA for the treatment of NTM lung infections in treatment refractory patients as well as for

Pseudomonas lung infections in CF patients,” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, and 41.

48. The Q2 2014 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2014 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

49. On August 6, 2014, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q2 2014 10-Q (the “Q2 2014 8-K”). In the Q2 2014 8-K, Defendant Lewis advised investors that “With the recent regulatory clarity, *we are moving forward with preparation for commercialization in Europe* Given these positive developments, we are pleased with the progress we are making toward our goal of bringing this potentially front line therapy to the benefit of the thousands of NTM and CF patients.” (Emphasis added.)

50. On November 6, 2014, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended September 30, 2014 (the “Q3 2014 10-Q”). For the quarter, Insmmed reported a net loss of \$23.99 million, or \$0.54 per diluted share, on zero revenue, compared to a net loss of \$17.33 million, or \$0.46 per diluted share, on zero revenue for the same period in the prior year.

51. In the Q3 2014 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company “intend[s] to file a MAA with the EMA by the end of 2014 . . . for the treatment of NTM lung infections,” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, and 47.

52. The Q3 2014 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

53. On November 6, 2014, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q3 2014 10-Q (the "Q3 2014 8-K"). In the Q3 2014 8-K, Defendant Lewis advised investors that "We are pleased with the recent regulatory clarity for our NTM program in both Europe and the U.S. *We continue to advance our regulatory filing and our preparations for commercialization in Europe.*" (Emphasis added.)

54. On December 15, 2014, Insmmed issued a press release entitled "Insmmed Provides End of Year Regulatory and Clinical Update." With respect to Arikayce, Insmmed advised investors that "Insmmed has submitted its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and is awaiting its validation."

55. On February 27, 2015, Insmmed filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "2014 10-K"). For the quarter, Insmmed reported a net loss of \$17.65 million, or \$0.36 per diluted share, on zero revenue, compared to a net loss of \$16.21 million, or \$0.41 per diluted share, on zero revenue for the same period in the prior year. For 2014, Insmmed reported a net loss of \$79.16 million, or \$1.84 per diluted share, on zero revenue, compared to a net loss of \$56.07 million, or \$1.60 per diluted share, on revenue of \$11.50 million for 2013.

56. In the 2014 10-K, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company "filed

a MAA with the EMA, which was validated in February 2015” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, 47, and 51.

57. The 2014 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the 2014 10-K was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

58. On February 27, 2015, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the 2014 10-K (the “2014 8-K”). In the 2014 8-K, Defendant Lewis advised investors that “We are pleased with our progress in Europe on several fronts. The validation of our MAA filing with the EMA starts the formal review process for ARIKAYCE.”

59. On May 7, 2015, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended March 31, 2015 (the “Q1 2015 10-Q”). For the quarter, Insmmed reported a net loss of \$27.37 million, or \$0.55 per diluted share, on zero revenue, compared to a net loss of \$14.30 million, or \$0.36 per diluted share, on zero revenue for the same period in the prior year.

60. In the Q1 2015 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company “filed a MAA with the EMA, which was validated in February 2015” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, 47, 51, and 56.

61. The Q1 2015 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2015 10-Q was

accurate and disclosed any material changes to the Company's internal control over financial reporting.

62. On May 7, 2015, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q1 2015 10-Q (the "Q1 2015 8-K"). In the Q1 2015 10-Q, Defendant Lewis stated "2015 is a year of key deliverables for Insmmed and *we remain on track to deliver our five stated corporate objectives, which include the advancement of ARIKAYCE.*"

63. On August 6, 2015, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2015 (the "Q2 2015 10-Q"). For the quarter, Insmmed reported a net loss of \$28.61 million, or \$0.47 per diluted share, on zero revenue, compared to a net loss of \$23.22 million, or \$0.59 per diluted share, on zero revenue for the same period in the prior year.

64. In the Q2 2015 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that the Company "filed a MAA with the EMA, which was validated in February 2015" and that "[t]he EMA's review is ongoing" while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, 47, 51, 56, and 60.

65. The Q2 2015 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

66. On August 6, 2015, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the

Q2 2014 10-Q (the “Q2 2014 8-K”). In the Q2 2014 8-K, the Company advised investors that “The European Medicine Agency’s (EMA) review of the company’s marketing authorization application (MAA) for ARIKAYCE is ongoing. Insmmed has received the EMA’s 120-day questions and anticipates responding before the end of 2015” and that “Throughout the first half or the year we made considerable progress advancing our stated corporate objectives.”

67. On November 6, 2015, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended September 30, 2015 (the “Q3 2015 10-Q”). For the quarter, Insmmed reported a net loss of \$30.96 million, or \$0.50 per diluted share, on zero revenue, compared to a net loss of \$23.99 million, or \$0.54 per diluted share, on zero revenue for the same period in the prior year.

68. In the Q3 2015 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that “In February 2015, the EMA validated our MAA for ARIKAYCE” and that “We received the EMA’s 120-day questions and are preparing our responses,” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, 47, 51, 56, 60, and 64.

69. The Q3 2015 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2015 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

70. On November 6, 2015, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q3 2014 10-Q (the “Q3 2014 8-K”). In the Q3 2014 8-K, Defendant Lewis

advised investors that “*We are making important progress advancing our efforts to support the approval and commercial launch of ARIKAYCE.*” (Emphasis added.)

71. On February 25, 2016, Insmmed filed an Annual Report on Form 10-K with the SEC, announcing the Company’s financial and operating results for the quarter and year ended December 31, 2015 (the “2015 10-Q”). For the quarter, Insmmed reported a net loss of \$31.25 million, or \$0.51 per diluted share, on zero revenue, compared to a net loss of \$17.65 million, or \$0.36 per diluted share, on zero revenue for the same period in the prior year. For 2015, Insmmed reported a net loss of \$118.18 million, or \$2.02 per diluted share, on zero revenue, compared to a net loss of \$79.16 million, or \$1.84 per diluted share, on zero revenue for 2014.

72. In the 2015 10-K, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that “In late 2015, we responded to the EMA’s 120-day questions, which are a standard part of the MAA evaluation process in the EU,” while reiterating its previously stated plan to commercialize Arikayce in Europe, as described *supra* at ¶¶ 20, 23, 27, 32, 36, 41, 47, 51, 56, 60, 64, and 68.

73. The 2015 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2015 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

74. On February 25, 2016, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the 2015 10-K (the “2015 8-K”). In the 2015 8-K, Defendant Lewis advised investors that “Last year, *Insmmed made important progress advancing our clinical and regulatory activities and establishing the foundation of our commercial infrastructure for ARIKAYCE in Europe.*” (Emphasis added.)

75. On May 5, 2016, Insmmed filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2016 (the "Q1 2016 10-Q"). For the quarter, Insmmed reported a net loss of \$33.53 million, or \$0.54 per diluted share, on zero revenue, compared to a net loss of \$27.37 million, or \$0.55 per diluted share, on zero revenue for the same period in the prior year.

76. In the Q1 2016 10-Q, with respect to the approval and commercialization of Arikayce for treatment of NTM lung disease in Europe, Insmmed advised investors that "We recently submitted our written responses to the CHMP's 180-day list of outstanding issues (LOIs) and we requested an oral explanation meeting to add clarification to our response. The 120-day and 180-day communications are part of CHMP's official review timetable."

77. The Q1 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

78. On May 5, 2016, Insmmed also issued a press release and filed a Current Report on Form 8-K with the SEC reiterating in part the financial and operating results announced in the Q-1 2016 10-Q (the "Q1 2016 8-K"). In the Q1 2016 8-K, Defendant Lewis advised investors that "2016 is off to a solid start with all of our clinical, regulatory, and commercial-readiness activities remaining on track with our previously stated timelines" and "In parallel with our clinical activities, our team is advancing the regulatory process for ARIKAYCE in Europe."

79. The statements referenced in ¶¶ 18-78 were materially false and misleading, and failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or

failed to disclose that: (i) the data on which Insmmed's European MAA for Arikayce relied was not likely to support approval by the EMA for the treatment of NTM lung disease; (ii) Arikayce's approval by the EMA for the treatment of NTM lung disease and subsequent commercialization in Europe were thus less likely and/or imminent than Insmmed had led investors to believe; and (iii) as a result of the foregoing, Insmmed's public statements were materially false and misleading at all relevant times.

The Truth Emerges

80. On June 8, 2016, after the market closed, Insmmed announced that it had withdrawn its MAA from the EMA for Arikayce for the treatment of NTM lung disease. The Company stated that "During the May 2016 Committee for Medicinal Products for Human Use (CHMP) meeting, the CHMP indicated that the phase 2 study did not provide a sufficient amount of evidence to support an approval. Insmmed intends to resubmit its MAA when clinical data from its ongoing global phase 3 study are available."

81. As a result of this news, Insmmed's share price fell \$0.99, or 8.24%, to close at \$11.02 on June 9, 2016.

82. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

83. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Insmmed securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are

Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, any entity in which Defendants have or had a controlling interest, and any judicial officer who handle this matter, and their immediate families.

84. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Insmid securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Insmid or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

85. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

86. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Insmid;
- whether the Individual Defendants caused Insmid to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Insmid securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

88. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

89. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Insmid securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Inmed securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

90. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

91. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

92. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

93. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

94. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and

other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Insméd securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Insméd securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

95. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Insméd securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Insméd's finances and business prospects.

96. By virtue of their positions at Insméd, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

97. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers

and/or directors of Insmmed, the Individual Defendants had knowledge of the details of Insmmed's internal affairs.

98. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Insmmed. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Insmmed's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Insmmed securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Insmmed's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Insmmed securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

99. During the Class Period, Insmmed securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Insmmed securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff

and the Class, the true value of Insméd securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Insméd securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

100. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

101. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

102. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

103. During the Class Period, the Individual Defendants participated in the operation and management of Insméd, and conducted and participated, directly and indirectly, in the conduct of Insméd's business affairs. Because of their senior positions, they knew the adverse non-public information about Insméd's misstatement of income and expenses and false financial statements.

104. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Insméd's

financial condition and results of operations, and to correct promptly any public statements issued by Insméd which had become materially false or misleading.

105. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Insméd disseminated in the marketplace during the Class Period concerning Insméd's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Insméd to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Insméd within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Insméd securities.

106. Each of the Individual Defendants, therefore, acted as a controlling person of Insméd. By reason of their senior management positions and/or being directors of Insméd, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Insméd to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Insméd and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

107. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Insméd.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 15, 2016
