

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

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated,	:	Civil Action No.:
	:	
<i>Plaintiff,</i>	:	<u>CLASS ACTION</u>
	:	
v.	:	COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS
	:	
IMMUNOMEDICS, INC., MICHAEL PEHL, USAMA MALIK,	:	
	:	<u>Jury Trial Demanded</u>
<i>Defendants.</i>	:	
	:	

Plaintiff, by and through his attorneys, alleges upon personal knowledge as to himself, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Defendant Immunomedics, Inc. (“Immunomedics” or the “Company”) common stock between August 23, 2018 and December 20, 2018, inclusive (the “Class Period”). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. §§ 78j(b) and 78t(a) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. Immunomedics purports to be a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer.

3. During the Class Period, and unbeknownst to investors, Immunomedics misled investors by stating in its SEC filings beginning on August 23, 2018, that, “the FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections” without disclosing to investors the fact that between August 6, 2018, and August 14, 2018 the FDA cited Immunomedics for a host of violations observed at its Morris Plains, New Jersey, drug substance manufacturing facility. These violations included manipulated bioburden samples, misrepresentation of an integrity test procedure in the batch record, and backdating of batch records, such as dates of analytical results.

JURISDICTION AND VENUE

4. The federal law claims asserted herein arise under §§ 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, as well as under the common law.

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

6. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

7. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b). Immunomedics principal executive offices are in this district, and many of the acts charged herein, including the dissemination of materially false and misleading information, occurred in substantial part in this District.

8. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the Nasdaq, a national securities exchange.

PARTIES

9. Plaintiff acquired and held shares of the Company at artificially inflated prices during the Class Period and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

10. Defendant Immunomedics is a Delaware company with its principal place of business in Morris Plains, New Jersey. The Company's stock trades on the Nasdaq under the ticker symbol "IMMU".

11. Defendant Michael Pehl ("Pehl") has been the President and Chief Executive Officer of Immunomedics since December 7, 2017.

12. Defendant Usama Malik ("Malik") has been the Acting Chief Financial Officer of Immunomedics since August 23, 2018.

13. Collectively, Pehl and Malik, are referred to throughout this complaint as the “Individual Defendants”.

14. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company’s annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their positions with the Company and access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

15. The Class Period begins on August 23, 2018, when Immunomedics filed its Form 10-K for the fiscal year ended June 30, 2018, which stated in pertinent part:

If we, or any of our collaboration partners, or our or their contract manufacturers, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.

Our ability to conduct our preclinical and clinical research and development programs depends, in large part, upon our ability to manufacture our proprietary compounds in accordance with the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing at this site,

whether by natural acts or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

We and our collaboration partners also depend on third parties to provide certain raw materials, and contract manufacturing and processing services. All manufacturers of biopharmaceutical products must comply with current Good Manufacturing Practice regulations or cGMPs, required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities, including in connection with the review of a BLA. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections, to which the facility must adequately respond in order to avoid escalated regulatory concerns. If our manufacturing facility or those facilities of our collaboration partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, in addition to regulatory enforcement, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development and of potential approval and commercialization.

16. Immunomedics continued to mislead investors by way of its Form 10-Q for the period ended September 30, 2018, which was filed with the SEC on November 7, 2018, and which stated in pertinent part:

If we, or any of our collaboration partners, or our or their contract manufacturers, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.

Our ability to conduct our preclinical and clinical research and development programs depends, in large part, upon our ability to manufacture our proprietary compounds in accordance with the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing at this site, whether by natural acts or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

We and our collaboration partners also depend on third parties to provide certain raw materials, and contract manufacturing and processing services. All manufacturers of biopharmaceutical products must comply with current Good Manufacturing Practice regulations or cGMPs, required by the FDA and other

regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities, including in connection with the review of a BLA. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections, to which the facility must adequately respond in order to avoid escalated regulatory concerns. If our manufacturing facility or those facilities of our collaboration partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, in addition to regulatory enforcement, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development and of potential approval and commercialization.

17. Defendant Pehl signed certifications for each of the 10-Qs and each of the 10-Ks described above.

18. Defendant Malik signed certifications for each of the 10-Qs and each of the 10-Ks described above.

19. Each of statements identified above were materially false and misleading when issued.

20. Among other things, the above-mentioned certifications, which were made pursuant to the Sarbanes-Oxley Act of 2002, required the signer to attest that they have reviewed the report, that it does not contain untrue statements, that it fairly represents the financial condition of the company, and that the company's internal controls are effective.

21. The truth was partially revealed on December 17, 2018, when FDAnews.com published an article titled "FDA Hits Immunomedics for Data Integrity Breach." According to this article, "[t]he FDA cited Immunomedics for a host of violations - including its handling of a data integrity breach - observed at its Morris Plains, New Jersey, drug substance manufacturing facility between August 6 and 14." The article states that this breach included "manipulated

bioburden samples, misrepresentation of an integrity test procedure in the batch record, and backdating of batch records, such as dates of analytical results."

22. On December 17, 2018, following the publication of the FDAnews.com story, Immunomedics shares fell from an opening price of \$18.54 to close at \$17.86, a decline of 4%.

23. On December 20, 2018, the truth was fully revealed to the market when Favus Institutional Research issued a Report (the "Favus Report") discussing the data integrity breach.

24. Following the Favus Report the Company's stock price fell drastically, from \$17.64 at close on December 19, 2018 to \$14.17 at close on December 20, 2018, a drop of 20%.

CLASS ACTION ALLEGATIONS

25. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Immunomedics common stock between August 23, 2018 and December 20, 2018, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

26. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. More than 169,000,000 Immunomedics shares trade on the Nasdaq.

27. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- a. Whether the Exchange Act was violated by Defendants;
- b. Whether Defendants omitted and/or misrepresented material facts;

- c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
 - d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;
 - e. Whether the price of the Company's stock was artificially inflated; and
 - f. The extent of damage sustained by Class members and the appropriate measure of damages.
28. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.
29. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.
30. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

FRAUD ON THE MARKET

31. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:
- a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - b. The omissions and misrepresentations were material;
 - c. The Company's common stock traded in efficient markets;
 - d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

- e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

32. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

33. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

LOSS CAUSATION

34. On December 17, 2018, following the publication of the FDAnews.com story, Immunomedics shares fell from an opening price of \$18.54 to close at \$17.86, a decline of 4%.

35. Following the Favus Report the Company's stock price fell drastically, from \$17.64 at close on December 19, 2018 to \$14.17 at close on December 20, 2018, a drop of 20%.

36. Both of these drops were directly attributable to the false and misleading statements alleged above.

CAUSES OF ACTION

Count I

Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

37. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

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

39. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the Class Period.

40. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count II
Violation of § 20(a) of the Exchange Act
(Against The Individual Defendants)

41. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

42. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the documents where false or misleading statements were made and other statements alleged by Plaintiffs to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action of all issues so triable.