IMMUNOMEDICS INC
Form 8-K
February 07, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 4, 2019**

IMMUNOMEDICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-12104**	**61-1009366**
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

300 The American Road **Morris Plains, New Jersey**	**07950**
(Address of Principal Executive Offices)	(Zip Code)

(973) 605-8200

Registrant s telephone number, including area code

(Former name or former address if changed since last report,)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 8.01 **Other Events.**

On February 4, 2019, Immunomedics, Inc., a Delaware corporation (the Company), received a written communication from the U.S. Food and Drug Administration (FDA) enclosing the establishment inspection report (EIR) from the chemistry, manufacturing and controls Biologics License Application (BLA) pre-approval inspection conducted by the FDA at the Company s Morris Plains, New Jersey drug substance manufacturing facility, which took place from August 6, 2018 through August 14, 2018. The FDA also notified the Company that the FDA will be conducting a re-inspection of the Company s Morris Plains, New Jersey manufacturing facility as part of the BLA resubmission process. The Company is finalizing its plans with respect to the matters raised in the Complete Response Letter received from FDA on January 17, 2019 and the EIR, and subsequently expects to request a meeting with the FDA in the near term.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 7, 2019

By: /s/ Michael Pehl
Name: Michael Pehl
Title: President and Chief Executive Officer