

IMMUNOMEDICS INC
Form 8-K
April 08, 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): **April 5, 2019**

IMMUNOMEDICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

000-12104
(Commission File Number)

61-1009366
(IRS Employer Identification No.)

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

07950
(Zip Code)

(973) 605-8200

Registrant's telephone number, including area code

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(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:

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

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

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

- 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

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.

Item 1.01 Entry into a Material Definitive Agreement.

On April 5, 2019, Immunomedics, Inc. (the Company) entered into a promotion agreement (the Agreement) with Janssen Biotech Inc., (Janssen), pursuant to which the Company will provide non-exclusive product detailing services to Janssen for erdafitinib (the Product). Pursuant to the Agreement, the Company will provide a dedicated sales team to market the Product, if the Product is approved by the U.S. Food and Drug Administration (FDA), to oncologists and other targeted health care providers in the United States.

Under the terms of the Agreement, Janssen maintains ownership of the New Drug Application for the Product as well as legal, regulatory, distribution, commercialization and manufacturing responsibilities for the Product, while the Company will provide product detailing services to Janssen. Following the achievement of certain sales targets in 2019 and 2020, Janssen will pay the Company (a) a service fee equal to a percentage in the low double digits of the portion of Cumulative Net Sales (as defined in the Agreement) in excess of a baseline amount during each of 2019 and 2020, and (b) potential milestone payments of up to \$15 million when Cumulative Net Sales exceed certain thresholds during each of 2019 and 2020.

Pursuant to the Agreement, the Company and Janssen will establish a joint commercial team (the Joint Commercial Team) and a Sales Advisory Team (the Advisory Team) to act as a forum for representatives of each party to discuss the promotion and detailing of the Product. Neither the Joint Commercial Team nor the Advisory Team has any decision-making authority but will make recommendations to each party for carrying out obligations under the Agreement.

Subject to earlier termination as described below, the term of the Agreement began on April 5, 2019 and expires on March 30, 2020, provided that Janssen's obligations to pay service fees and milestones to the Company shall survive such expiration. The Agreement contains customary termination provisions, including that either party may terminate the Agreement (a) upon 30 days' written notice in the event marketing approval for the Product is not obtained from the FDA by June 30, 2019, (b) upon the material breach of the other party, subject to a 30-day cure period, (c) upon a force majeure event, (d) upon 30 days' written notice in the event the Company is acquired by or merges with a company that is a competitor of Janssen with respect to the sale of the Product, (e) upon 30 days' written notice in the event that Janssen is required to withdraw or voluntarily permanently withdraws the Product from the market for safety or regulatory reasons, or (f) in the event an insolvency petition of the other party is pending for more than 90 days. Janssen may also terminate the Agreement, effective December 31, 2019 or January 31, 2020, in the event that Janssen has entered into a licensing, collaboration, divestiture or other similar agreement with a third party for the Product. In such event, Janssen agrees to pay a termination fee to the Company, as well as all outstanding and owed fees and milestone payments. During the term of the Agreement, the Company agreed to not provide detailing services to a competing product in the United States.

The Agreement also contains customary representations, warranties and covenants, including provisions relating to regulatory matters, reporting obligations, indemnity, non-solicitation of employees, limitation of liability, confidentiality and other matters.

The Company expects to file the Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019. The foregoing description is qualified in its entirety by reference to the complete text of the Agreement, when filed.

Item 8.01 Other Events.

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The Company issued a press release on April 8, 2019 in connection with the Agreement. The press release is filed as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

| Exhibit Number | Description |
|-------------------|---|
| 99.1 | <u>Press Release of Immunomedics, Inc., dated April 8, 2019, titled Immunomedics Announces Promotion Agreement with Janssen for erdafitinib in the U.S. .</u> |

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: April 8, 2019

By: /s/ Usama Malik
Name: Usama Malik
Title: Chief Financial Officer