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): May 15, 2019

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**0-17999**	**04-2726691**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

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 (*see* General Instruction A.2. below):

☐ 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 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	IMGN	NASDAQ Global Select Market

ITEM 8.01. – OTHER EVENTS

On May 15, 2019, ImmunoGen, Inc. (also referred to as “we” and “us”) disclosed that the United States Food and Drug Administration (FDA) has recommended that we conduct a new Phase 3 randomized trial to evaluate the safety and efficacy of mirvetuximab soravtansine in patients with high folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer as a part of a Type C meeting held this week.

We requested the meeting to discuss the results of the Phase 3 FORWARD I trial and a potential path to registration for mirvetuximab monotherapy. FDA advised that, because FORWARD I did not meet its primary endpoint under the pre-specified statistical analysis plan, the data generated assessing the secondary endpoints from the study could not be used to support an application for accelerated approval. FDA acknowledged that platinum-resistant ovarian cancer is a disease with unmet need, provided guidance regarding the design and endpoints of a potential registration study, and encouraged us to return to discuss a proposed study design.

Based on the feedback received from FDA, we are evaluating potential next steps with mirvetuximab monotherapy in platinum-resistant ovarian cancer patients with high FRα expression levels. In parallel, we have generated encouraging data with mirvetuximab combination regimens and will evaluate our ongoing studies as an independent path forward to support a registration in ovarian cancer.

Forward-Looking Statements

This report includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, our expectations with respect to the future development of mirvetuximab soravtansine as a monotherapy or in combination regimens. For these statements, we claim the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause our actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this report. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in our Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

SIGNATURES

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.

ImmunoGen, Inc.
(Registrant)

Date: May 15, 2019

/s/ Mark J. Enyedy

Mark J. Enyedy
President and Chief Executive Officer