Ignyta, Inc.
Form 8-K
April 04, 2017

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 4, 2017

IGNYTA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36344**	**45-3174872**
(State of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4545 Towne Centre Court

San Diego, California 92121

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: (858) 255-5959

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))

Item 7.01 Regulation FD Disclosure

On April 4, 2017, Ignyta, Inc., (the Company) announced preclinical data on RXDX-106 which represents a novel class of immunomodulatory agents that appears to restore innate immunity in preclinical models via potent inhibition of the TYRO3, AXL and MER (or TAM) family of receptors presented at the 2017 Annual Meeting of the American Association for Cancer Research (AACR) in Washington D.C. In addition, the Company will also showcase its first ever data in hematological malignancies for entrectinib an orally available, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK, ROS1 or ALK fusions in molecularly defined acute myeloid leukemia (AML). The press release, dated April 4, 2017, announcing the new data is attached hereto as Exhibit 99.1.

The information contained in this Item 7.01 and in Exhibit 99.1 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On April 4, 2017, the Company announced preclinical data on RXDX-106 which represents a novel class of immunomodulatory agents that appears to restore innate immunity in preclinical models via potent inhibition of the TAM family of receptors presented at the 2017 Annual Meeting of the AACR in Washington D.C. In addition, the Company will also showcase its first ever data in hematological malignancies for entrectinib an orally available, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK, ROS1 or ALK fusions in molecularly defined AML.

In the presented RXDX-106 data, researchers studied the activity of RXDX-106 in a commonly studied syngeneic mouse colon carcinoma model in matched immunocompetent and immunocompromised mice, finding that RXDX-106 had greater tumor growth inhibition in the immunocompetent animals, which suggested that RXDX-106 effects in this system were modulated by the immune system. Immuno-phenotypic modulation by RXDX-106 was also observed in the mouse model, including an increase in tumor infiltrating lymphocytes (TILs), an increase in the ratio of M1/M2 macrophages, and an increase in expression of CD69 and PD-1 on CD8 T Cells. In another syngeneic mouse model, RXDX-106 inhibited tumor growth as a single agent and demonstrated further tumor growth inhibition in combination with anti-PD-1 or anti-CTLA-4 antibodies, which was accompanied by increased levels of IFN in the blood. In a separate preclinical investigation of RXDX-106 targets, AXL and MER fusion proteins were shown to independently act as oncodrivers and, therefore, may be viable therapeutic targets for patients harboring such molecular alterations. The preclinical data to be presented at the AACR Annual Meeting suggest that RXDX-106 can act as both an anti-tumor immuno-modulator and TAM oncodriver inhibitor and support clinical development of RXDX-106 in a wide variety of cancers.

Researchers will also present new preclinical data investigating entrectinib as a potential treatment for patients with NTRK rearranged acute myeloid leukemias. Entrectinib treatment inhibited cell proliferation in vitro with sub-nanomolar EC_{50} values. In a mouse model, entrectinib treatment at clinically relevant doses resulted in tumor regression, which was accompanied by elimination of residual cancer cells from the bone marrow. Based on these data, the Company intends to evaluate entrectinib further in molecularly defined hematological malignancies.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 4, 2017.

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.

Dated: April 4, 2017

IGNYTA, INC.

By: /s/ Jonathan E. Lim, M.D.
Name: Jonathan E. Lim, M.D.
Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated April 4, 2017.