Ignyta, Inc.
Form 8-K
September 06, 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): September 6, 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))

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.

Item 7.01 Regulation FD Disclosure

On September 6, 2017, Ignyta, Inc. (Ignyta or the Company) announced a regulatory update on the ROS1 lung cancer development program for entrectinib - an investigational, orally bioavailable, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK or ROS1 fusions. The press release, dated September 6, 2017, announcing the program update is attached hereto as Exhibit 99.1 and an investor presentation made on September 6, 2017 highlighting the program update is attached hereto as Exhibit 99.2.

The information contained in this Item 7.01 and in Exhibits 99.1 and 99.2 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 September 6, 2017, the Company announced a regulatory update on the ROS1 lung cancer development program for entrectinib - an investigational, orally bioavailable, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK or ROS1 fusions.

Ignyta has completed enrollment of the NDA registration efficacy data set of over 50 patients with ROS1 fusion-positive NSCLC for entrectinib, currently being studied in a registration-enabling Phase 2 clinical trial known as STARTRK-2. In total, Ignyta has treated more than 70 ROS1 fusion-positive NSCLC patients with entrectinib across its ALKA, STARTRK-1, and STARTRK-2 studies. The U.S. Food and Drug Administration s (the FDA) most recent guidance confirmed that these studies will form the basis of a registrational dataset in ROS1 fusion-positive NSCLC; no additional studies were requested by FDA.

The latest interaction with FDA has clarified the regulatory pathway for entrectinib in ROS1 NSCLC:

- Written feedback from the FDA confirmed that the NDA submission for ROS1-positive NSCLC will be based on three single arm studies, including two Phase 1 studies, ALKA and STARTRK-1, and the Phase 2 STARTRK-2 basket trial. No additional studies or confirmatory data were requested.

- Objective response rate (ORR), as assessed by blinded independent central review, was confirmed as the primary endpoint. FDA requested that all responding patients be followed for 12 months to assess durability of response.

- Entrectinib was intentionally designed to cross the blood-brain barrier and has demonstrated central nervous system (CNS) activity. Specific guidance was provided by FDA on inclusion of entrectinib CNS efficacy data in future prescribing information.

This current report on Form 8-K contains forward-looking statements about Ignyta as that term is defined in Section 27A of the Securities Act and Section 21E of the Exchange. Statements in this current report on Form 8-K that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to the development of and path to potential regulatory approval of entrectinib. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; Ignyta s ability to develop, initiate or complete preclinical studies and clinical trials for,

obtain approvals for and commercialize any of its product candidates; changes in Ignyta s plans to develop and commercialize its product candidates; the ability of our contract manufacturers to produce the active pharmaceutical ingredient and/or drug product necessary for clinical trials or commercialization of entrectinib or our other product candidates; the potential for final results of the ongoing clinical trials of entrectinib or other product candidates, or any future clinical trials of entrectinib or other product candidates, to differ from preliminary or expected results;

Ignyta s ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United States and foreign countries; Ignyta s ability to obtain and maintain intellectual property protection for its product candidates; the risk that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; the potential for the company to fail to maintain the CAP accreditation and CLIA certification of its diagnostic laboratory; the loss of key scientific or management personnel; competition in the industry in which Ignyta operates; and market conditions. These forward-looking statements are made as of the date of this current report on Form 8-K, and Ignyta assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the company files with the SEC available at www.sec.gov, including without limitation Ignyta s Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent Quarterly Reports on Form 10-Q.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 6, 2017.
99.2	Investor Presentation, made September 6, 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: September 6, 2017

IGNYTA, INC.

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

EXHIBIT INDEX

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