Ignyta, Inc.
Form 8-K
October 17, 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): October 17, 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 October 17, 2017, Ignyta, Inc. (Ignyta or the Company) announced that the European Medicines Agency (the EMA) has granted Priority Medicines (PRIME) designation for entrectinib in the treatment of NTRK fusion-positive, locally advanced or metastatic solid tumours in adult and paediatric patients who have either progressed following prior therapies or who have no acceptable standard therapy. The press release, dated October 17, 2017, 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 October 17, 2017, the Company announced that the EMA has granted PRIME designation for entrectinib in the treatment of NTRK fusion-positive, locally advanced or metastatic solid tumours in adult and paediatric patients who have either progressed following prior therapies or who have no acceptable standard therapy. Through the PRIME initiative, Ignyta will have enhanced EMA support, including optimizing the entrectinib development pathway, potentially accelerating assessment of the Marketing Authorisation Application, and engaging in early discussion with EMA and health technology assessments regarding reimbursement pathways. PRIME designation for entrectinib was substantially based on data from the Phase 2 global study, STARTRK-2.

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, the impact of entrectinib s PRIME designation on Ignyta s interactions with EMA and the EMA s commitment to the advancement 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 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; our dependence on third party manufacturers for supply of our product candidates and any approved products; 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 October 17, 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: October 17, 2017

IGNYTA, INC.

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