Ignyta, Inc.
Form 8-K
October 18, 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 18, 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 18, 2017, Ignyta, Inc. (Ignyta or the Company) announced updated results from its clinical trials, including the STARTRK-2 trial, of entrectinib - an investigational, CNS-active, potent, and selective tyrosine kinase inhibitor being developed for tumors that harbor NTRK fusions or ROS1 fusions. The press release, dated October 18, 2017, is attached hereto as Exhibit 99.1 and an investor presentation made on October 18, 2017 highlighting these results 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 (the Securities Act), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On October 18, 2017, the Company announced updated results from its clinical trials, including the STARTRK-2 trial, of entrectinib - an investigational, CNS-active, potent, and selective tyrosine kinase inhibitor being developed for tumors that harbor NTRK fusions or ROS1 fusions. In this interim analysis, entrectinib demonstrated a 78% (25 out of 32, by Investigator) confirmed objective response rate (ORR) (95% CI: 60.0, 90.7) and a 69% (22 out of 32, by Blinded Independent Central Review, or BICR) confirmed ORR (95% CI: 50.0, 83.9) in 32 patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that harbored ROS1 fusions. Entrectinib demonstrated compelling durability in these patients, with a median duration of response of 28.6 months (by BICR; 95% CI: 6.8, 34.8; median follow-up of 12.9 months) and a median progression free survival of 29.6 months (by BICR; 95% CI: 7.7, 36.6; median follow-up of 8.5 months). Of the patients evaluated, 11 had CNS metastases at baseline as assessed by Investigator, and 83% (5 out of 6; by BICR) of the patients with measurable CNS metastases at presentation had confirmed intracranial RECIST responses to treatment with entrectinib.

Safety was consistent with previous studies of entrectinib. With over 200 patients treated at the recommended phase 2 dose, most adverse events (AEs) were Grade 1-2 and reversible, and only 3% of patients discontinued from the study due to treatment-related AEs (TRAEs). The most common TRAEs were dysgeusia (38%), fatigue (29%), constipation (23%), dizziness (23%), and increased weight (19%). The most common Grade 3 TRAEs were increased weight (5%), anemia (4%), and fatigue (3%). There were no Grade 4 events occurring in greater than 1% of patients and no Grade 5 TRAEs.

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 Act. 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 and our other product candidates, including potential differentiating factors; the clinical and/or non-clinical data or plans underlying entrectinib or any of our other development programs, the potential for entrectinib to be a best-in-class therapeutic, and the corporate milestones and timelines associated with such programs; our ability to design and conduct development activities for entrectinib and our other development programs; our ability to obtain regulatory approvals in order to market any of our product candidates; and our ability to successfully commercialize any approved products. 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 18, 2017.
99.2	Presentation, made October 18, 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 18, 2017

IGNYTA, INC.

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