Ignyta, Inc.
Form 8-K
September 11, 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 11, 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 11, 2017, Ignyta, Inc. (Ignyta or the Company) announced program updates for entrectinib - an investigational, orally bioavailable, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK or ROS1 fusions and RXDX-105 an investigational, VEGFR-sparing, potent RET inhibitor. The press release, dated September 11, 2017, announcing the program updates is attached hereto as Exhibit 99.1 and a presentation to be made on September 11, 2017 at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain highlighting the entrectinib and RXDX-105 program updates 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 11, 2017, the Company announced program updates for entrectinib - an investigational, orally bioavailable, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK or ROS1 fusions and RXDX-105 an investigational, VEGFR-sparing, potent RET inhibitor.

Entrectinib program updates:

Based on written feedback from the FDA, Ignyta confirms completion of enrollment of the efficacy data sets for both the NTRK tissue-agnostic (i.e., fusion-positive solid tumor) cohort and the ROS1 NSCLC cohort to support dual NDA submissions in 2018.

No additional studies were requested for these submissions.

Entrectinib was intentionally designed to cross the blood-brain barrier and has demonstrated CNS activity. Specific guidance was provided by FDA on inclusion of entrectinib CNS efficacy data in future prescribing information for both NTRK and ROS1.

Additionally, a recent joint meeting with the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation Research (CDER) on companion diagnostic strategy for entrectinib confirms the premarket approval submission plan and timeline for Trailblaze Pharos are tracking with the dual NDA submissions in NTRK and ROS1.

RXDX-105 program updates:

New Phase 1b clinical data on RXDX-105 presented this week at the ESMO 2017 Congress in Madrid, Spain demonstrated clinical activity in RET fusions and compelling response rate in an ultra-rare lung cancer population.

Safety

A total of 152 patients, with a range of solid tumors, have been treated in the Phase 1/1b clinical trial, including 74 patients treated at the recommended Phase 2 dose of 275mg daily in the fed state, and 43 patients treated at a dose of 350mg daily in the fed state.

RXDX-105 continues to be well tolerated, with the most common treatment-related adverse events Grade 1 or 2 and reversible with dose modifications. The most common Grade 3 treatment-related adverse events (>5 percent) were rash (10 percent), hypophosphatemia (7 percent) and elevated ALT (7 percent).

Importantly, toxicities commonly associated with VEGFR inhibition, such as hypertension, hypothyroidism, proteinuria and neurotoxicity were rarely observed (<5 percent); and RXDX-105 was not associated with Qt/QTc prolongation.

Efficacy

Of those treated, 22 patients had NSCLC harboring RET fusions and were RET inhibitor naïve, making them evaluable for response.

A preliminary objective response rate of 75 percent was observed in patients with non-KIF5B-RET fusions, with six of eight patients achieving a confirmed partial response. In contrast, those with KIF5B-RET fusions (14 patients) did not demonstrate a RECIST response. These data are consistent with previous studies that suggest that KIF5B-RET fusions may be less susceptible to RET inhibition.

The longest duration of response (DOR) in a responding patient with non-KIF5B-RET fusion was 10.2 months and ongoing; two-thirds of responding patients currently continue on treatment in active response; median DOR therefore has not yet been reached.

Development plan

This robust clinical trial design has employed next generation sequencing to identify the precise patient populations most likely to benefit from RXDX-105 those with non-KIF5B-RET fusions which is estimated to be approximately 800 new patients per year in the United States.

The RXDX-105 Phase 1b study will be concluded with no further enrollment. Those currently receiving treatment will remain on study.

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 and the safety, efficacy and development of and path to potential regulatory approval of RXDX-105. 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 11, 2017.
99.2	Presentation, made September 11, 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 11, 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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