Ignyta, Inc.
Form 8-K
February 09, 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): February 9, 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 February 9, 2017, Ignyta, Inc., (the Company) announced that updated results from two Phase 1 trials of entrectinib the Company s investigational, orally available, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK, ROS1 or ALK fusions were published in the journal *Cancer Discovery*. The press release, dated February 9, 2017, announcing the updated results 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 February 9, 2017, the Company announced that updated results from two Phase 1 trials of entrectinib the Company s investigational, orally available, CNS-active tyrosine kinase inhibitor targeting tumors that harbor TRK, ROS1 or ALK fusions were published in the journal *Cancer Discovery*.

As of the September 20, 2016, data cutoff, the findings showed:

Efficacy

CNS activity

RECIST responses were noted in 63% of patients (5 out of 8) with primary or metastatic disease involving the brain.

A complete CNS response was achieved in a patient with NTRK1 fusion-positive non-small cell lung cancer, or NSCLC , with an ongoing response at 15.1 months at the time of data cutoff, with the patient continuing on therapy at 17.1 months.

Duration of response

Responses to entrectinib therapy were shown to be durable.

Among responding patients with *NTRK*-rearranged cancer, the longest duration of response was ongoing at 15.1 months as of the data cutoff, with the patient continuing on therapy at 17.1 months.

A median duration of response of 17.4 months and 7.4 months was seen for *ROS1* and *ALK*-rearranged cancers, respectively. Among 13 patients with *ROS1*-rearranged NSCLC, the median duration of response was 17.3 months.

The longest duration of clinical benefit in patients with fusions observed in the Phase 1 setting was a patient with ROS1-rearranged lung cancer remaining on therapy in confirmed response at 32.2 months as of the data cutoff.

RECIST Response rate

In three *NTRK1/2/3*-rearranged solid tumors (NSCLC, mammary analog secretory carcinoma, or MASC , and colorectal cancer) with RECIST-measurable disease, the objective response rate (ORR) was 100%, including complete resolution of brain metastases in the patient with NSCLC. An additional patient with an *NTRK1*-rearranged glioneuronal tumor experienced 60% reduction in tumor burden by 3-dimensional volumetric assessment (stable disease by RECIST, which is not validated for primary brain tumors).

An ORR of 86% was observed in 14 ROS1-rearranged solid tumors (13 NSCLC patients, one melanoma patient), including two complete responses; an ORR of 85% was observed in the 13 patients with ROS1-rearranged NSCLC.

In seven ALK-rearranged solid tumors, the ORR was 57%, and responses were observed in ALK-rearranged NSCLC, renal cell carcinoma and colorectal cancer.

Safety

The publication summarized entrectinib data from a total of 119 patients with advanced solid tumors, the largest published patient safety experience of any TRK inhibitor in clinical development. Entrectinib was well tolerated, with no responding patients discontinuing the study due to adverse events and no evidence of cumulative toxicity, renal or hepatic toxicity, or QTc prolongation. The majority of treatment-related adverse events (AEs) were Grade 1 or 2 in severity; Grade 3 events were reversible with dose modifications. Only one Grade 4 and no treatment-related Grade 5 AEs were reported across the two studies. The most common treatment-related AEs of any grade were fatigue/asthenia (46%), dysgeusia (42%), paresthesias, (29%), nausea (28%) and myalgias (23%).

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated February 9, 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: February 9, 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 February 9, 2017.