Ignyta, Inc.
Form 8-K
April 18, 2016

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): April 17, 2016

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.)**

11111 Flintkote Avenue

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 April 17, 2016, Alexander Drilon, M.D. of the Memorial Sloan Kettering Cancer Center, New York, New York, presented updated results from the Phase 1 clinical trials of entrectinib, the Company s proprietary oral tyrosine kinase inhibitor targeting solid tumors harboring activating alterations to *NTRK1, NTRK2, NTRK3, ROS1* or *ALK*, in an oral plenary presentation session at the 2016 Annual Meeting of the American Association for Cancer Research (AACR) in New Orleans, Louisiana. The slide presentation used by Dr. Drilon 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 April 17, 2016, Alexander Drilon, M.D. of the Memorial Sloan Kettering Cancer Center, New York, New York, presented updated results from the Phase 1 clinical trials of entrectinib, the Company s proprietary oral tyrosine kinase inhibitor targeting solid tumors harboring activating alterations to *NTRK1, NTRK2, NTRK3, ROS1* or *ALK*, in an oral presentation session at the 2016 Annual Meeting of the AACR in New Orleans, Louisiana.

The Phase 1 clinical trials included the ALKA-372-001 study and the STARTRK-1 study, which is the first of the Studies of Tumor Alterations Responsive to Targeted Receptor Kinases. Both trials were designed to determine the maximum tolerated dose and/or recommended Phase 2 dose (RP2D), as well as preliminary anti-cancer activity, of single agent entrectinib in patients with solid tumors with the relevant target alterations: TrkA (encoded by *NTRK1*), ROS1 or ALK for ALKA-372-001 and TrkA/TrkB/TrkC (encoded by *NTRK1/2/3*), ROS1 or ALK for STARTRK-1.

The data cut-off for the AACR presentation was March 7, 2016. Highlights of the data included:

Safety

A total of 119 patients with a range of solid tumors had been dosed across both clinical trials, with 45 patients treated at the RP2D of 600 mg, taken orally once per day (QD).

Entrectinib was well tolerated:

- Across both studies, the most frequent (>10% incidence) treatment-related adverse events were fatigue (44%), dysgeusia (41%), paresthesia (28%), nausea (24%), and myalgia (22%).
- The vast majority of treatment-related adverse events were Grade 1 or 2 in severity.
- The most frequent (>2% incidence) Grade 3 treatment-related adverse events were fatigue (4%) and anemia (3%).
- Adverse events were reversible with dose modification.

There was no evidence of cumulative toxicity, hepatic or renal toxicity, or QTc prolongation.

Efficacy

Across both studies, there were 25 patients treated who met the company s Phase 2 clinical trial eligibility criteria, which include:

Presence of *NTRK1/2/3, ROS1* or *ALK* gene rearrangements, as opposed to other types of molecular alterations (e.g., SNPs, amplifications, deletions);

ALK-inhibitor and/or ROS1-inhibitor naïve; and

Treatment at or above the RP2D.

Among the 25 patients treated who met the company s Phase 2 clinical trial eligibility criteria, tumor regression was seen in 80% (20 out of 25 treated patients):

24 patients had tumors that were evaluable by RECIST criteria. The overall response rate was 79% (19 responses, including 2 complete responses, out of 24 treated patients, as assessed and confirmed by the clinical sites).

One patient had astrocytoma. Assessment by RECIST criteria demonstrated stable disease. However, since RECIST criteria are not validated for primary brain tumors, the clinical site performed three-dimensional volumetric analysis of this patient s tumor to determine changes in tumor size, which resulted in an estimated 45% decrease in tumor size from baseline.

Many of these responses occurred rapidly, within the first four weeks of entrectinib treatment. Seventeen of the patients remained on study treatment, having received up to 27 months of treatment. Of note, three of four patients with primary or metastatic central nervous system (CNS) disease responded.

With respect to specific subsets of patients:

Trk patients

There were four patients included in the clinical studies with NTRK1/2/3 gene rearrangements that met the company s Phase 2 eligibility criteria, including patients with non-small cell lung cancer (NSCLC), colorectal cancer (CRC), salivary gland cancer and astrocytoma. All four of these patients demonstrated tumor regression (three confirmed responses by RECIST and one by volumetric assessment).

Two of these Trk patients remained on study, one of whom had been on study for longer than 12 months.

In addition, the company included in the AACR presentation a case study of a 20-month old baby boy with NTRK3-rearranged infantile fibrosarcoma that had metastasized to the brain and who had exhausted all available therapies. The patient was first dosed in February 2016, and after five weeks of treatment experienced a decrease in his brain lesions of approximately 58%, as estimated from radiology assessment, with accompanying clinical improvement.

Three of these five patients with NTRK1/2/3 gene rearrangements had either primary or metastatic CNS disease, and all three demonstrated substantial CNS tumor regression, underscoring the importance of entrectinib s CNS penetration and clinical activity for this patient population.

ROS1 patients

There were 14 patients included in the clinical studies with ROS1 gene rearrangements who met the company s Phase 2 eligibility criteria, including 13 patients with NSCLC and one patient with malignant melanoma.

Eleven of the 13 patients with NSCLC and the patient with malignant melanoma responded, including two complete responses. The resultant overall response rate for these ROS1 patients was 86%, and the response rate for the subset of patients with NSCLC was 85%.

Eleven of the ROS1 responders remained on study in response, with the longest at 27 months; one ROS1 NSCLC patient has met the criteria for RECIST progression but has remained on study due to clinical benefit.

ALK patients

There were seven patients included in the clinical studies with ALK gene rearrangements who met the company s Phase 2 eligibility criteria, including four patients with NSCLC, one patient with CRC, one patient with renal cell carcinoma (RCC) and one patient with a thoracic tumor of unknown primary.

Two of the four patients with NSCLC, the patient with CRC and the patient with RCC had clinical responses. Another NSCLC patient had stable disease. The resultant overall response rate for these ALK patients was 57%.

Two of the responders remained on study in response, as did the patient with stable disease.

Item 9.01. Financial Statements and Exhibits
(d) Exhibits.

Exhibit No.	Description
99.1	Slide Presentation, dated April 17, 2016.

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: April 18, 2016

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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