Ignyta, Inc.
Form 8-K
December 02, 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): December 2, 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.)**

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 December 2, 2016, Alexander Drilon, M.D., of the Memorial Sloan Kettering Cancer Center, New York, New York, presented data examining the combination of entrectinib, Ignyta, Inc. s orally available, CNS-penetrant tyrosine kinase inhibitor, targeting tumors that harbor TRK, ROS1 or ALK fusions, and trametinib in overcoming resistance to TRK inhibition during a late-breaking oral plenary presentation (during the Exceptional Response and Expected Resistance Session) at the 2016 EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in Munich, Germany. The press release, dated December 2, 2016, announcing the data is attached hereto as Exhibit 99.1 and the slide presentation used by Dr. Drilon 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 December 2, 2016, Alexander Drilon, M.D., of the Memorial Sloan Kettering Cancer Center, New York, New York, presented data examining the combination of entrectinib, Ignyta, Inc. s orally available, CNS-penetrant tyrosine kinase inhibitor, targeting tumors that harbor TRK, ROS1 or ALK fusions, and trametinib in overcoming resistance to TRK inhibition during a late-breaking oral plenary presentation (during the Exceptional Response and Expected Resistance Session) at the 2016 EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in Munich, Germany.

Data presented describe results from a single patient protocol designed to allow co-administration of entrectinib and trametinib, a commercially-approved MEK inhibitor. The patient, diagnosed with mammary analog secretory carcinoma (or MASC) with an NTRK3 fusion ~90-100% of MASC cases have TRK fusions and previously treated with multiple surgeries, radiation, vinorelbine, carboplatin/paclitaxel, doxorubicin and crizotinib, experienced a rapid and confirmed partial response (89% reduction) with single-agent entrectinib treatment and remained on therapy for nine months. However, during the course of therapy, the patient s tumor developed a solvent front point mutation, the predicted mechanism of resistance to first generation TRK inhibitors and analogous to a common mechanism of resistance for other TKIs against other fusion targets.

Based on both *in vitro* and *in vivo* data, developed by Ignyta, indicating that entrectinib plus a MEK inhibitor could overcome such TRK inhibitor resistance, a single patient protocol was created, reviewed by the FDA and implemented to allow for dose escalation of entrectinib in combination with trametinib. While on the combination, all drug-related adverse events (AEs) were grade 1 or 2, and no new AEs specific to the combination were encountered. The patient achieved a 22% reduction in tumor volume and remained on the combination regimen for nearly seven months.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 2, 2016.
99.2	Slide Presentation, made December 2, 2016.

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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: December 2, 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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