Ignyta, Inc.
Form 8-K
December 01, 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 1, 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 1, 2016, Ignyta, Inc., (the Company) announced data from its ongoing Phase 1/1b study of RXDX-105, the Company s VEGFR-sparing, potent RET inhibitor at the 2016 EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in Munich, Germany. The press release, dated December 1, 2016, announcing the data is attached hereto as Exhibit 99.1 and an investor presentation made on December 1, 2016 highlighting this and other data 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 1, 2016, the Company announced data from its ongoing Phase 1/1b study of RXDX-105, the Company s VEGFR-sparing, potent RET inhibitor at the 2016 EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in Munich, Germany.

As of the November 2016, data cut-off, the findings showed:

Safety

A total of 91 patients with a range of solid tumors have been treated in the Phase 1/1b clinical trial, with 55 patients treated in the Phase 1 study and 36 patients treated in the Phase 1b study.

RXDX-105 continues to demonstrate a safety profile similar to what has been previously reported: across both studies, the most common treatment-related adverse events (>10% incidence) were rash (31%), fatigue (22%), diarrhea (20%), nausea (18%), hypophosphatemia (14%), vomiting (14%), muscle spasms (13%), and decreased appetite (10%).

The majority of treatment-related adverse events were Grade 1 or 2, and were reversible with dose modification.

The most common Grade 3 treatment-related adverse events (>5% incidence) were rash (9%), hypophosphatemia (7%), and ALT increase (6%).

One patient experienced a Grade 3 drug reaction with eosinophilia and systemic symptoms, in which the patient recovered with drug discontinuation. One patient experienced Grade 3 rash complicated by fatal alveolar hemorrhage. No other treatment-related Grade 4 or higher events were observed.

Toxicities commonly associated with VEGFR inhibition, such as hypertension, hypothyroidism, proteinuria, and neurotoxicity, were rarely observed (<5%).

Efficacy

Of the 36 patients treated in the Phase 1b study, 35 had RET or BRAF molecular alterations.

Nine RET inhibitor-naïve patients (n = 8 in the Phase 1b cohort; n = 1 in the Phase 1 cohort) with RET fusion-positive tumors were treated at a daily dose of 275 mg or 350 mg in the fed state, and were evaluable for response.

A preliminary ORR of 56% was observed in patients with RET fusion-positive solid tumors who were RET inhibitor-naïve (five out of nine treated patients had a RECIST response).

Of the five patients demonstrating a RECIST response, one patient with metastatic colorectal cancer (mCRC) achieved a complete response; three patients, all with non-small cell lung cancer (NSCLC), achieved a partial response; and one patient with NSCLC had an unconfirmed partial response.

Among the seven patients with RET fusion-positive NSCLC who were RET inhibitor-naïve, three achieved a partial response and one achieved an unconfirmed response (a second scan had not been obtained at the date of data cutoff), for a preliminary ORR of 57%.

Duration of response to RXDX-105 ranged from 2+ to 7+ months, with all responder patients currently continuing on treatment in active response; median duration of response, therefore, has not yet been determined.

Additionally, a previously disclosed Phase 1 patient with RET-mutated M918T medullary thyroid cancer had a confirmed partial response and continues on treatment after ten cycles.

These data confirm that RXDX-105 is active across a range of different histologies, with confirmed RECIST responses now observed in medullary thyroid cancer, NSCLC, and mCRC, and across a range of RET molecular alterations, including the M918T point mutation, and CCDC6-, EML4-, and PARD3-RET fusions.

Among the remaining patients treated in Phase 1b who were either RET fusion-positive and received prior RET inhibitor treatments (n = 4) or had BRAF molecular alterations (n = 23), durable disease control but no objective responses have been observed to date.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 1, 2016.
99.2	Investor Presentation, made December 1, 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: December 1, 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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