Ignyta, Inc.
Form 8-K
September 30, 2015

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 27, 2015

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 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

As previously reported in the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission (the SEC) on October 1, 2014 (the October 2014 8-K), Ignyta, Inc. (the Company) entered into a Second Amended and Restated Loan and Security Agreement (the Loan and Security Agreement) with Silicon Valley Bank (SVB). Upon the signing of the Loan and Security Agreement, the Company borrowed $21.0 million from SVB and had the conditional option to borrow an additional $10.0 million at any time prior to September 30, 2015, subject to certain conditions. The description of the Loan and Security Agreement contained in Item 2.03 of the October 2014 8-K is incorporated herein by reference and is qualified in its entirety by reference to the Loan and Security Agreement, which was filed as Exhibit 10.1 to the October 2014 8-K.

On September 30, 2015, the Company drew down the second tranche of $10.0 million under the Loan and Security Agreement. The Company now has total indebtedness of approximately $31.0 million under the loan facility.

Pursuant to the Loan and Security Agreement, in connection with the draw down the Company issued to SVB and its affiliate, Life Science Loans, LLC, warrants to purchase an aggregate of 15,432 shares of the Company s common stock (the Warrants). The Warrants are exercisable immediately, have a per-share exercise price of $8.78 and have a term of seven years. The foregoing is only a brief description of the Warrants, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Warrants, which are filed as Exhibits 4.1 and 4.2 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities

The Company relied on the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act), and Rule 506 of Regulation D, in connection with the issuance of the Warrants. The Warrants and the shares of common stock issuable under the Warrants have not been registered under the Securities Act, or state securities laws, and may not be offered or sold in the United States without being registered with the SEC or through an applicable exemption from SEC registration requirements.

The other information called for by this item is contained in Item 2.03, which is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

On September 27, 2015, Salvatore Siena, M.D., Director, Niguarda Hospital Cancer Center, Milan, Italy, presented updated results from the Phase 1 clinical trials of entrectinib, the Company s proprietary oral tyrosine kinase inhibitor targeting solid tumors that harbor activating alterations to *NTRK1, NTRK2, NTRK3, ROS1* or *ALK*, in an oral presentation session at the 2015 European Cancer Congress (ECC) in Vienna, Austria. The slide presentation used by Dr. Siena 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 27, 2015, Salvatore Siena, M.D., Director, Niguarda Hospital Cancer Center, Milan, Italy, presented updated results from the Phase 1 clinical trials of entrectinib, the Company s proprietary oral tyrosine kinase inhibitor targeting solid tumors that harbor activating alterations to *NTRK1, NTRK2, NTRK3, ROS1* or *ALK*, in an oral presentation session at the ECC in Vienna, Austria.

The clinical trials included the ALKA-372-001 study and the STARTRK-1 study, which is the first of the Company s _Studies Targeting Alterations Responsive to Targeted Receptor Kinase inhibition. 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 molecular alterations: *NTRK1* (encoding TrkA), *ROS1* or *ALK* for ALKA-372-001 and *NTRK1/2/3* (encoding TrkA/TrkB/TrkC), *ROS1* or *ALK* for STARTRK-1.

As of the August 15, 2015 data cut-off for the presentation, the findings showed:

A total of 92 patients with a range of solid tumors had been dosed across both clinical trials, with nine patients treated at or above the RP2D beyond six months and one patient beyond one year.

Entrectinib was well tolerated to date:

Across both studies, the most frequent (>10% incidence) treatment-related adverse events were fatigue, dysgeusia, paresthesia, nausea, and myalgia. Seven of these were Grade 3 in severity, consisting of fatigue (4 patients), cognitive impairment (2 patients), and diarrhea (1 patient). No Grade 4 treatment-related adverse events were observed; and

Across both studies, there were three treatment-related serious adverse events: Grade 3 cognitive impairment and Grade 3 myocarditis, both of which occurred above the RP2D, and Grade 2 fatigue. All events were reversible and resolved upon dose modification.

Pharmacokinetic measurements showed dose-proportional increases across the daily dosing regimens evaluated, with a half-life compatible with once-daily dosing.

The fixed daily dose RP2D was determined to be 600 mg, taken orally once per day (QD).

18 patients across both clinical trials met the company s expected Phase 2 eligibility criteria, which include:

Presence of NTRK1/2/3, ROS1 or ALK fusions, 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.

The response rate in the 18 patients who met these criteria across both studies was 72% (13 responses out of 18 treated patients, as assessed by the clinical sites). Nine of these responders remain on study treatment with durable responses of up to 21 treatment cycles. An additional 3 patients remain on study with stable disease. The responses included:

3 responses out of 4 patients with *NTRK1/2/3* gene rearrangements, including patients with non-small cell lung cancer (NSCLC), colorectal cancer and salivary gland cancer, with one of the responding patients remaining on treatment at 6 months; a fourth patient with an astrocytoma remains on treatment after two months with stable disease;

6 responses, including one complete response, out of 8 patients with *ROS1* gene rearrangements, all of which were in NSCLC. All of the patients who responded remain on treatment, the longest at 21 months; and

4 responses out of 6 patients with *ALK* gene rearrangements, including two NSCLC patients and two patients with other solid tumors; two of the 4 responders subsequently progressed.

Entrectinib has demonstrated objective tumor response in the central nervous system, a frequent site of metastases and progression of advanced solid tumors.

On September 30, 2015, the Company announced the initiation of its Phase 2 clinical trial of entrectinib. This clinical trial is called STARTRK-2, the second of the Studies of Tumor Alterations Responsive to Targeting Receptor Kinases. It is a global, multicenter, open label, potentially registration-enabling Phase 2 clinical trial of entrectinib that utilizes a basket design with screening of patient tumor samples for the relevant targets.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
4.1	Warrant dated September 30, 2015, issued to Silicon Valley Bank.
4.2	Warrant dated September 30, 2015, issued to Life Science Loans, LLC.
99.1	Slide Presentation, dated September 27, 2015.

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 30, 2015

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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