Ignyta, Inc.
Form 8-K
June 09, 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): May 30, 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 1.01 Entry into a Material Definitive Agreement.

On June 5, 2015, Ignyta, Inc. (the Company) entered into the First Amendment (the Amendment) to Second Amended and Restated Loan and Security Agreement (the Loan and Security Agreement) dated as of September 30, 2014, by and between the Company and Silicon Valley Bank.

Pursuant to the Amendment, the second tranche of $10,000,000 that may be drawn down by the Company under the Loan and Security Agreement is conditioned upon Ignyta initiating any Phase II clinical trial of its lead product candidate entrectinib prior to September 30, 2015, provided that other customary conditions for funding are also complied with, such as no material adverse change occurring.

The foregoing description of the Amendment is qualified in its entirety by reference to the full text of the Amendment, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K.

Item 1.02 Termination of a Material Definitive Agreement.

On June 8, 2015, the Company and City Hill Venture Partners I, LLC (City Hill) mutually agreed to terminate the Registration Rights Agreement, dated November 6, 2013 (the Registration Rights Agreement), by and between the Company, City Hill and certain other stockholders of the Company. As a result of the termination, the Registration Rights Agreement is of no further force or effect and neither the Company nor the stockholders who are parties thereto have any further rights, duties or obligations thereunder. A copy of the Registration Rights Agreement was filed as Exhibit 10.2 to the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission (SEC) on November 7, 2013.

On June 5, 2015, the Company delivered written notice to Cantor Fitzgerald & Co. that it was terminating its Controlled Equity Offering[SM] Sales Agreement, dated March 2, 2015 (the Sales Agreement), pursuant to Section 13(b) of the Sales Agreement, effective as of June 15, 2015. No shares were, or will be, offered or sold pursuant to the Sales Agreement. A copy of the Sales Agreement was filed as Exhibit 1.2 to the Company s Registration Statement on Form S-3 (File No. 202403) filed with the SEC on March 2, 2015.

Item 5.07 Submission of Matters to a Vote of Security Holders.

The 2015 Annual Meeting of Stockholders of Ignyta, Inc. (the Annual Meeting) was held on June 9, 2015. As of the close of business on April 20, 2015, the record date for the Annual Meeting, there were 25,262,023 shares of common stock entitled to vote, of which there were 18,574,353 shares present at the Annual Meeting in person or by proxy. At the Annual Meeting, stockholders voted on two matters: (i) the election of a Class I Director for a term of three years expiring at the Company s 2018 Annual Meeting of Stockholders and (ii) the ratification of the appointment of Mayer Hoffman McCann P.C. as the Company s independent registered public accounting firm for the fiscal year ending December 31, 2015. The voting results were as follows:

Election of a Class I Director for a term of three years expiring at the 2018 Annual Meeting of Stockholders:

Heinrich Dreismann, Ph.D. For 15,179,131 Against 2,000 Abstain 0

Dr. Dreismann was elected as a Class I Director. The Class II Directors, Alexander Casdin and James Freddo, M.D., will continue in office until the Company s 2016 Annual Meeting of Stockholders. The Class III Directors, Jonathan E. Lim, M.D. and James Bristol, M.D., will continue in office until the Company s 2017 Annual Meeting of Stockholders.

There were 3,393,222 broker non-votes related to the director nominee for election.

Ratification of the appointment of Mayer Hoffman McCann P.C. as the Company s independent registered public accounting firm for the fiscal year ending December 31, 2015

For 18,573,053 Against 1,300 Abstain 0

There were no broker non-votes related to the ratification of the appointment of Mayer Hoffman McCann P.C.

Item 8.01 Other Events.
Interim Results from the Company s Two Phase 1 Clinical Trials of Entrectinib

On May 30, 2015, the Company presented interim results from the Company s two Phase I clinical trials of entrectinib in poster presentations, including a poster discussion, at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois.

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 II dose, 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 May 1, 2015, which was the data cut-off for the presentation, the interim results showed:

A total of 67 patients with a range of solid tumors had been dosed across both clinical trials;

Entrectinib was well tolerated to date, with no treatment-related serious adverse events. Most treatment-related adverse events have been Grade 1 or Grade 2 and reversible. There was no evidence of cumulative adverse events, hepatic or renal toxicity, or QTc prolongation. Other safety findings to date included:

In the ALKA-372-001 study, two Grade 3 treatment-related adverse events were observed: asthenia and muscle weakness, each of which subsided with dose reduction. The most frequent adverse events were paresthesia, nausea, myalgia, asthenia, dysgeusia, and vomiting; and

In the STARTRK-1 study, three Grade 3 treatment-related adverse events were observed: neutropenia, which resolved with dose reduction, and two dose-limiting toxicities of reversible cognitive impairment and fatigue, both of which occurred at 800 mg fixed dose and resolved upon study drug interruption. The most frequent adverse events were fatigue, dysgeusia, constipation, nausea, and paresthesia.

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

The body surface area (BSA)-based recommended Phase II dose was determined to be 400 mg/m^2 once per day (QD); both studies are continuing in order to determine a fixed daily dose regimen;

11 patients across both clinical trials met the Company s expected Phase II 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 recommended Phase 2 dose of 400 mg/m^2.

The response rate in the 11 patients that met these criteria across both studies was 91% (10 of 11 responses as assessed by the clinical sites), with nine patients remaining on study treatment with durable responses of up to 16 treatment cycles. The responses included:

- three of three responses in patients with NTRK1/2/3 fusions, including patients with non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and acinic cell cancer;
- five of six responses, including one complete response, in patients with ROS1 fusions, all of which were in NSCLC; and
- two of two responses in patients with ALK fusions, including one NSCLC patient and one patient with another solid tumor.

Estimated Patient Populations for Entrectinib and RXDX-105

The Company estimates that over 11,000 patients in 11 biomarker positive cohorts of NSCLC and CRC represent potential first-in-class opportunities for entrectinib or RXDX-105, a small molecule inhibitor of B-Raf proto-oncogene, serine/threonine kinase (BRAF), epidermal growth factor receptor and RET proto-oncogene that is currently in a Phase I/II dose escalation clinical trial. The Company also estimates B-Cell Integration Cluster BRAF-mutant metastatic CRC has the potential to double the addressable market with an upside of over 10,000 patients for RXDX-105, or over 22,000 patients for entrectinib and RXDX-105.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this Current Report on Form 8-K that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to promising signs of antitumor activity and safety and other data from the Phase 1 clinical trials of entrectinib, potential study designs and plans for future Phase II clinical trials of entrectinib, and

estimates of patient population sizes for our product candidates. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the potential for results of current or future clinical trials of entrectinib or other product candidates to differ from preliminary or expected results; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; the Company s ability to develop, complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates; changes in the Company s plans to develop and commercialize its product candidates; the Company s ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United

States and foreign countries; the Company s ability to obtain and maintain intellectual property protection for its product candidates; the risk that orphan drug exclusivity may not be maintained or may not effectively protect a product from competition; the potential for the Company to fail to maintain the Clinical Laboratory Improvement Amendments (CLIA) registration of its diagnostic laboratory or to fail to achieve full CLIA accreditation of such laboratory; the loss of key scientific or management personnel; competition in the industry in which the Company operates; and market conditions. These forward-looking statements are made as of the date hereof, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov, including without limitation the Company s Annual Report on Form 10-K for the year ended December 31, 2014 and subsequent Quarterly Reports on Form 10-Q.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
10.1	First Amendment to Second Amended and Restated Loan and Security Agreement, dated as of June 5, 2015, between Ignyta, Inc. and Silicon Valley Bank.

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: June 9, 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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