Ignyta, Inc.
Form 8-K
November 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): November 6, 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.

License, Development and Commercialization Agreement

On November 6, 2015, Ignyta, Inc. (the Company) entered into a license, development and commercialization agreement (the License Agreement) with Eli Lilly and Company (Lilly) pursuant to which the Company received exclusive, global rights to develop and commercialize pharmaceutical products under certain licensed technology (Licensed Products), including Lilly s product candidate taladegib. Taladegib is a potent, orally bioavailable small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase 2 dose in a Phase 1 dose escalation clinical trial. The Company also licensed the exclusive worldwide rights to the topical formulation of taladegib, which is a late preclinical program being developed for the potential treatment of patients with superficial and nodular basal cell carcinoma. The Company granted back to Lilly an exclusive license to develop and commercialize pharmaceutical products comprising taladegib in combination with certain other molecules (Combination Products).

The Company s rights under the License Agreement are exclusive for the term of the License Agreement. Both parties rights under the License Agreement include the right to grant sublicenses. The Company is obligated under the License Agreement to use commercially reasonable efforts to develop and commercialize Licensed Products at its expense.

The terms of the License Agreement provide for an up-front payment by the Company to Lilly of $2.0 million and issuance by the Company to Lilly in a private placement of 1,213,000 unregistered shares of the Company s common stock (the Issuance Shares) pursuant to a Share Issuance Agreement at the closing of the transaction. The closing is expected to occur on November 10, 2015, subject to customary closing conditions. The Share Issuance Agreement provides that Lilly will not, without the Company s prior written consent, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of the Issuance Shares on or before May 10, 2016. The Share Issuance Agreement also includes customary representations and warranties. The issuance of the Issuance Shares has not been registered under the Securities Act of 1933, as amended (the Securities Act), and the Issuance Shares may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Issuance Shares will be issued in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

When and if commercial sales of Licensed Products begin, the Company will be obligated to pay Lilly a royalty based on net sales. When and if commercial sales of Combination Products begin, Lilly will be obligated to pay the Company a royalty of net sales of Combination Products. Both parties royalty obligations are subject to standard provisions for royalty offsets to the extent a party is required to obtain any rights from third parties to commercialize the applicable products, or in the event of loss of exclusivity or generic competition. The License Agreement also requires that the Company make development and sales milestone payments to Lilly of up to $38.0 million. The Company may elect to pay a portion of such amounts by issuing to Lilly shares of its common stock in a private placement, subject to certain conditions.

The License Agreement also includes customary representations, warranties and covenants. Subject to certain exceptions and limitations, each of the Company and Lilly has agreed to indemnify the other for breaches of representations, warranties and covenants and other specified matters. Unless terminated earlier, the License Agreement will remain in effect, on a country-by-country and product-by-product basis, until the parties royalty obligations end. Both parties have a right to terminate the License Agreement if the other party enters bankruptcy, upon an uncured breach by the other party or if the other party challenges its patents relating to the licensed technology.

Stock Purchase Agreement

Concurrently with the entry into the License Agreement, on November 6, 2015, the Company entered into a Stock Purchase Agreement with Lilly whereby the Company agreed to issue 1,500,000 unregistered shares of its common stock (the Purchase Shares, and together with the Issuance Shares, the Shares) at a price of $20.00 per share for an aggregate purchase price of $30.0 million. The purchase and sale of the Purchase Shares is expected to close on November 10, 2015, subject to customary closing conditions.

The Stock Purchase Agreement provides that Lilly will not, without the Company s prior written consent, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of the Purchase Shares on or before May 10, 2016. The Stock Purchase Agreement also includes customary representations and warranties.

The issuance of the Purchase Shares has not been registered under the Securities Act, and the Purchase Shares may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Purchase Shares will be issued in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

Registration Rights Agreement

Concurrently with the entry into the License Agreement and Stock Purchase Agreement, on November 6, 2015, the Company entered into a Registration Rights Agreement with Lilly pursuant to which the Company has agreed to register the Shares. Under the terms of the Registration Rights Agreement, the Company is required to use best efforts to promptly file a registration statement with the Securities and Exchange Commission (the SEC) and to cause such registration statement to be declared effective by the SEC on or before May 10, 2016. The Company also agreed to other customary obligations regarding registration of the Shares, including matters relating to indemnification, maintenance of the registration statement and payment of certain expenses.

The Company may be liable for liquidated damages to the holders of registrable securities if the registration statement (i) has not been declared effective by May 10, 2016 or (ii) ceases to remain effective after being declared effective, subject to certain exceptions. The amount of the liquidated damages per applicable 30-day period is one percent of the aggregate purchase price of the registrable securities then held by each holder, subject to an aggregate cap of ten percent.

The foregoing summaries of the License Agreement, Stock Purchase Agreement and Registration Rights Agreement are subject to, and qualified in their entirety by reference to, the License Agreement (including the ancillary agreements that are exhibits thereto), Stock Purchase Agreement and Registration Rights Agreement. The Company expects to file the License Agreement, Stock Purchase Agreement and Registration Rights Agreement with its Annual Report on Form 10-K for the year ended December 31, 2015, requesting confidential treatment for certain portions of the License Agreement.

Item 2.02. Results of Operations and Financial Condition

On November 9, 2015, the Company issued a press release announcing its results of operations for the quarter ended September 30, 2015. The full text of such press release is furnished as Exhibit 99.1 to this report.

The information contained in this Item 2.02 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 3.02. Unregistered Sales of Equity Securities

Reference is made to the disclosure under Item 1.01 of this Current Report on Form 8-K, which is incorporated in this Item 3.02 by reference.

Item 7.01 Regulation FD Disclosure

On November 8, 2015, interim results from the Company s ongoing Phase I/Ib clinical trial of RXDX-105, the Company s orally-available, small molecule multikinase inhibitor with potent activity against such key targets as RET and BRAF, were presented at the 27th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts. The poster presentation is attached hereto as Exhibit 99.2.

On November 9, 2015, the slide presentation attached as Exhibit 99.3 was presented in an investor meeting by Jonathan E. Lim, M.D., Chairman, President and Chief Executive Officer of the Company and other members of the Company s management. Information from this slide presentation may also be used by management of the Company in future meetings regarding the Company.

The information contained in this Item 7.01 and in Exhibits 99.2 and 99.3 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of 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 November 8, 2015, interim results from the company s ongoing Phase I/Ib clinical trial of RXDX-105 were presented at the 27th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts.

The dose escalation clinical trial was designed to determine the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), as well as preliminary anti-cancer activity, of single agent RXDX-105 in patients with advanced or metastatic solid tumors that were not selected based on any molecular alteration.

As of the October 26, 2015, data cut-off for the presentation, the findings showed:

A total of 41 patients with a range of solid tumors were dosed in the clinical trial;

RXDX-105 was well tolerated to date:

The most frequent treatment-emergent adverse events were fatigue, vomiting, nausea, decreased appetite, constipation, diarrhea, hypertension and muscle spasms;

Three Grade 3 dose-limiting toxicities were observed: maculopapular rash, fatigue and diarrhea, each of which resolved upon study drug interruption;

There were no treatment-related serious adverse events. Two Grade 4 adverse events had occurred, consisting of intestinal obstruction and anemia, neither of which was considered to be treatment-related. No Grade 5 treatment-related adverse events or cumulative adverse events were observed;

The MTD and RP2D had not yet been determined;

Pharmacokinetic measurements showed increased exposure with increasing dose, with a half-life compatible with once-daily dosing. Dosing in the fed state appears to further increase exposure;

Exposure was reaching levels expected to be efficacious based on tumor growth inhibition in animal models of RET- and BRAF-driven tumors; and

Tumor regression was observed in six patients treated with 275 mg, including one confirmed partial response (40% reduction) in a patient with non-small cell lung cancer with a KRAS G12C mutation. Two additional patients with thyroid cancer and squamous cell lung cancer exhibited reductions of 20% and 27%, respectively. In patients with tumor regression, there appears to be an exposure/response correlation.

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 and Section 21E of the Exchange Act. 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 the closing of the transactions described under Item 1.01 of this Current Report on Form 8-K. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the risk and uncertainties associated with the satisfaction of customary closing conditions relating to the transactions described under Item 1.01 of this Current Report on Form 8-K, as well as risks and uncertainties in the Company s business, including those risks described in the Company s periodic reports it files with the SEC. 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
99.1	Press Release, dated November 9, 2015.
99.2	Poster Presentation, dated November 8, 2015
99.3	Slide Presentation, dated November 9, 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: November 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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