

Ignyta, Inc.
Form 8-K
April 27, 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): April 27, 2016

IGNYTA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State of Incorporation)

001-36344
(Commission

45-3174872
(IRS Employer

File Number)
11111 Flintkote Avenue

Identification No.)

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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 8.01 Other Events.

Updated Clinical Data for Taladegib and RXDX-105

In the ongoing Phase 1 clinical trial of oral taladegib in patients with solid tumors, a complete response was observed in a patient with medulloblastoma. Ignyta, Inc. (the Company) intends to initiate a Phase 1b basket study of oral taladegib in patients with solid tumors outside of basal cell carcinoma that harbor clinically relevant molecular alterations in the hedgehog pathway.

In the Company's Phase 1 clinical trial of RXDX-105, tumor regression was observed in three patients with non-small cell lung cancer:

a partial response (40% tumor reduction) was observed in a patient with non-small cell lung adenocarcinoma with a KRAS G12C mutation; the patient has been on study for over 8 treatment cycles;

a 28% tumor reduction was observed in a patient with non-small cell lung adenocarcinoma with a BRAF D594G mutation; the patient remained on the study for one treatment cycle before coming off study due to an idiosyncratic drug reaction; and

a 27% tumor reduction was observed in a patient with squamous non-small cell lung cancer; the patient has been on study for 11 treatment cycles.

The Company previously announced the selection of a recommended Phase 2 dose, which is 350 mg in the fed state, as well as initiation of the Phase 1b expansion of this clinical trial. The Company intends to build into its ongoing Phase 1b expansion one or more baskets to evaluate RXDX-105 in both squamous non-small cell lung cancer and non-small cell lung adenocarcinoma.

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, the ability to implement the planned baskets into the Phase 1b expansion trial. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the Company's ability to successfully implement its plans, and risks and uncertainties in the Company's business, including those risks described in the Company's periodic reports filed 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, 2015 and subsequent Quarterly Reports on Form 10-Q.

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: April 27, 2016

IGNYTA, INC.

By: /s/ Jonathan E. Lim, M.D.

Name: Jonathan E. Lim, M.D.

Title: President and Chief Executive Officer