Ignyta, Inc.
Form 8-K
March 23, 2017

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): March 22, 2017

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 1.01 Entry into a Material Definitive Agreement.

On March 22, 2017, Ignyta, Inc. (the Company) entered into an amended and restated license, development and commercialization agreement (the A&R License Agreement) with Eli Lilly and Company (Lilly). The A&R License Agreement amends and restates the prior license, development and commercialization agreement, dated November 6, 2015, by and between the Company and Eli Lilly (the Original License Agreement).

Under the Original License Agreement, Eli Lilly granted to the Company the 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 (BCC). 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). In February 2016, the Company ceased all development activities relating to the topical taladegib program.

The A&R License Agreement represents a restructuring of certain potential milestone payments to Lilly under the Original License Agreement and the result of our discussions with Lilly regarding the optimal path forward for taladegib in the context of pipeline priorities. As consideration for the amending and restating of the Original License Agreement, including the removal of $18.0 million in near-term development milestone payments to Lilly previously triggered by certain development-related activities pertaining to the taladegib oncology program in advanced BCC, and in consideration for granting the Release (as defined below), the Company agreed to pay to Lilly $15.0 million in timing-based milestones, of which $3.0 million will be due and payable on March 27, 2017, and the remaining portion would be payable over the subsequent three calendar years, subject to offsetting adjustment if the Company shall have received cash consideration in connection with an assignment, sale of the Licensed Products to a third party (other than in connection with the sale of substantially all of the assets of the Company), or grant of a sublicense prior to March 31, 2020.

In connection with the A&R License Agreement, the Company and Lilly agreed to a mutual release (the Release) from any and all claims, demands, sums of money, actions, rights, causes of action, obligations and liabilities of any kind or nature whatsoever which either party may have had or claim to have had, arising out of the Original License Agreement.

The Company s rights under the A&R License Agreement are exclusive for the term of the A&R License Agreement. Both parties rights under the A&R License Agreement include the right to grant sublicenses. The Company is obligated under the A&R License Agreement to use commercially reasonably efforts to develop the Licensed Products at its expense, provided, however, that if the Company is not actively developing the Licensed Products as of December 31, 2018, then the A&R License Agreement shall immediately terminate and the licenses granted to the Company shall terminate.

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 by Lilly 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 A&R 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 A&R 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 A&R 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.

The foregoing summary of the A&R License Agreement is subject to, and qualified in its entirety by reference to, the A&R License Agreement (including the ancillary agreements that are exhibits thereto), which the Company expects to file with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, requesting confidential treatment for certain portions contained therein.

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: March 23, 2017

IGNYTA, INC.

By: /s/ Jonathan E. Lim, M.D.
Name: Jonathan E. Lim, M.D.
Title: President and Chief Executive Officer