

## IGNYTA, INC.

### Orphan Drug Grant May Accelerate Time to Market; ASCO to Offer Important Catalyst

RXDX (NASDAQ)

#### Company & Market Data

Closing Price (as of 02/04/2015):	\$6.71
Rating:	BUY
Price Target:	\$20.00
52 Week Range:	\$5.36 - \$12.50
Shares Outstanding (MM):	20
Market Capitalization (MM):	\$131
Cash (MM):	\$94.7
Debt (MM):	\$20.3
Fiscal Year End:	Dec

#### Estimates

	2013A	2014E	2015E
EPS			
1Q	—	\$(0.28)A	\$(0.59)
2Q	—	\$(0.28)A	\$(0.62)
3Q	—	\$(0.55)A	\$(0.64)
4Q	—	\$(0.53)	\$(0.68)
Full Year	\$(1.94)	\$(1.68)	\$(2.53)
Revenue (MM)	\$0.0	\$0.2	\$0.0

Ignyta is developing personalized oncology drugs using diagnostic tests to identify patients most likely to respond to therapy. The company's lead product RXDX-101, is a TrkA/B/C, ROS1, ALK inhibitor in Phase I development for the treatment of solid tumors. Ignyta hopes to move the program into Phase II development in 2015 for multiple indications including NSCLC. The San Diego-based company is also in pre-clinical development of other targeted cancer therapies based on proprietary Oncolome molecular expression database.

On 2/5/15, RXDX's entrectinib (RXDX-101) received orphan drug designation from FDA for the treatment of non-small cell lung cancer (NSCLC) patients with mutations for TrkA/B/C, ROS1 or ALK. We view the data as important independent validation of the strength of RXDX's Phase I data for entrectinib. As a reminder, data presented at ESMO in September 2014 demonstrated 3 clinical responses, including one complete response, in ROS1+ NSCLC. We believe these patients may have been an important component in RXDX winning orphan drug status in NSCLC. This is the second orphan designation for entrectinib. In December, the drug was granted FDA orphan drug designation and rare pediatric disease designation for the treatment of neuroblastoma. In terms of future regulatory strategy for NSCLC, we expect RXDX to seek potential regulatory clearance based on a defined sub-population of a single molecularly-defined patient population. We expect that population to be defined by results from the Phase II "basket" study, which should begin enrolling in 2H15. Lastly, we continue to expect an update on 4 different Phase I cohorts of entrectinib in 1H15, most likely at ASCO in early June, to serve as an important potential catalyst for RXDX shares. Reiterate Buy and \$20.00 PT.

- **What's New?** RXDX received FDA orphan drug designation for lead product candidate entrectinib for the treatment of TrkA-positive, TrkB-positive, TrkC-positive, ROS1-positive or ALK-positive NSCLC. The designation enables RXDX to receive 1) up to 7 years of market exclusivity upon drug approval, 2) potential for priority review, 3) tax incentives for clinical costs, and 4) waiver of PDUFA filing fees. Previously, entrectinib received orphan drug designation for treatment of neuroblastoma.
- **Orphan Drug Status Potentially Extends First Mover Advantage:** Our Buy rating for shares of RXDX is based, at least in part, on entrectinib being among the most advanced Trk inhibitors currently in clinical development and potential for the drug to be the first Trk inhibitor on the market. Granting of orphan drug status may allow RXDX to seek a priority review from FDA, which would reduce review time by up to 4 months compared to a standard review and potentially extend entrectinib's first-to-market position.
- **Important Clinical Update at ASCO in May/June:** We expect RXDX to provide updates on entrectinib at ASCO including data from three European cohorts exploring different intermittent dosing schedules and a U.S. cohort exploring continuous dosing of entrectinib. ASCO abstracts are scheduled for release May 13th. The ASCO meeting is May 29-June 2. We are cautiously optimistic the update will include data from additional Trk+ patients. Additionally, we expect the ASCO data to provide clarity on dosing schedule for a Phase II "basket" study of TrkA/B/C, ROS1 and ALK mutated solid tumor patients to begin in 2H15.

Disclosures and Analyst Certifications can be found in Appendix A.

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Table 1.

Ignyta Income Statement											
(in \$ millions)	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E
Total product revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Revenue	0.0	0.0	0.2	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0
Total Revenue	\$0.0	\$0.0	\$0.2	\$0.0	\$0.0	\$0.2	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross profit	\$0.0	\$0.0	\$0.2	\$0.0	\$0.0	\$0.2	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
G&A	3.7	1.8	2.0	2.2	2.1	8.1	2.1	2.2	2.6	2.5	9.5
Research & development	3.2	2.2	3.6	8.6	8.0	22.4	9.0	9.5	9.5	10.5	38.5
Operating profit (loss)	(\$6.9)	(3.9)	(5.5)	(10.8)	(10.1)	(\$30.4)	(11.1)	(11.7)	(12.1)	(13.0)	(\$48.0)
Interest income	0.0	0.0	0.1	0.1	0.1	0.3	0.1	0.0	0.0	0.0	0.2
Interest expense	(0.2)	(0.1)	0.0	0.0	(0.4)	(0.5)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)
Other	(0.1)	(0.0)	(0.0)	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (loss)	(7.2)	(4.1)	(5.4)	(10.7)	(10.4)	(30.7)	(11.5)	(12.1)	(12.5)	(13.4)	(49.5)
Earnings (loss) per share from continuing ops	(\$1.94)	(\$0.28)	(\$0.28)	(\$0.55)	(\$0.53)	(\$1.68)	(\$0.59)	(\$0.62)	(\$0.64)	(\$0.68)	(\$2.53)
One-time gains (expenses)	(\$0.57)	\$0.00	\$0.00	\$0.00	(\$0.51)	(\$0.51)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Net income (loss) as reported	(14.2)	(4.1)	(5.4)	(10.7)	(20.4)	(40.7)	(11.5)	(12.1)	(12.5)	(13.4)	(49.5)
Earnings (loss) per share as reported	(\$3.83)	(\$0.28)	(\$0.28)	(\$0.55)	(\$1.04)	(\$2.22)	(\$0.59)	(\$0.62)	(\$0.64)	(\$0.68)	(\$2.53)
Weighted average common shares	3.7	14.5	19.6	19.6	19.6	18.3	19.6	19.6	19.6	19.6	19.6

Source: Company reports and Ladenburg Thalmann estimates

## Company and Industry-Specific Risks

We think the primary risks of an investment in RXDX shares include, but are not limited to:

**Clinical:** While efficacy and safety of other ALK inhibitors for NSCLC has been well characterized in both clinical trials and commercial experience, there can be no assurance entrectinib will demonstrate clinically meaningful activity in NSCLC and other solid tumors. Additionally, entrectinib also inhibits ROS1 and TrkA/B/C. While there is a theoretical connection between inhibition of these tyrosine kinases and anti-tumor activity for a range of solid tumors including NSCLC, colon and glioblastoma, among others, there can be no assurances that future studies can be designed to evaluate the potential efficacy of co-inhibition of these tyrosine kinases or will confirm a positive impact on disease progression or survival, if a study is conducted. In the absence of clinical outcomes data, there can be no assurance that clinicians will accept or recognize the benefit of entrectinib over existing ALK inhibitors such as crizotinib. Additionally, the company is developing additional targeted cancer therapies based on its proprietary Oncolome database and acquired drug candidates including RXDX-103. There can be no assurance any future studies of pipeline programs will be adequate to support regulatory approval, reimbursement or commercial acceptance of pipeline programs. Lastly, RXDX relies on a virtual clinical development business model based on a small in-house management group and third party contractors. Loss of one or more executives could have an adverse impact of future clinical trials management.

**Regulatory:** RXDX is subject to oversight by multiple groups at the U.S. FDA including the Oncologic Drugs Advisory Committee for oncology drug development and Office of In Vitro Diagnostic Device Evaluation and Safety for companion diagnostics. There can be no assurance registration studies will be adequate to support regulatory filing with ODAC for entrectinib or any other pipeline product. Additionally, we expect the companion to diagnostic for entrectinib and other pipeline programs to be commercialized through diagnostic partners. There can be no assurance RXDX or its diagnostic partners will win timely PMA clearance for companion to entrectinib or any other pipeline product.

**Competition:** We are not aware of any other company developing a pan-inhibitor of ALK, ROS1 and TrkA/B/C. Additionally, there are currently no ROS1 or TrkA/B/C inhibitors approved for treatment of solid tumors in the U.S. or Europe. However, several companies have disclosed plans to develop therapies targeting TrkA/B/C. We believe RXDX-101 is currently the most advanced TrkA/B/C program in clinical development. There can be no assurance RXDX will be successful in maintaining its current leadership for timely commercialization of a TrkA/B/C inhibitor. Finally, several companies are developing second-generation ALK inhibitors with better blood-brain barrier than crizotinib. Some of these programs are more advanced than entrectinib.

**Financing:** The company believes its financial resources will fund operations into at least 2017. However, depending on the pace of business development, RXDX may need additional capital to fund operations through Phase II proof-of-concept studies of entrectinib. If Phase II studies are successful, RXDX may need access to additional capital through either internal sources or partnerships to fund registration studies and to fund commercialization. There can be no assurance RXDX will have access to capital in the future on adequate terms, or at all.

**Partnership:** RXDX will rely on partnerships with CROs, diagnostic product companies and other service providers to support clinical development and U.S. regulatory filings for entrectinib and its other pipeline programs. Additionally, we expect the company to seek commercial partners for entrectinib and its other pipeline programs in geographies outside the United States including Europe and Asia. There can be no assurance the partners will be successful in maintaining a steady supply of drug product, provide adequate support for clinical trials enrollment, optimize appropriate companion diagnostics or offer appropriate commercialization support in Europe, Asia and other regions outside the U.S. Lastly, the company licensed rights to entrectinib and RXDX-102 from Nerviano Medical Sciences. There can be no assurance Nerviano will provide adequate support for timely future development of entrectinib.

**Product Liability:** Pharmaceutical companies may face potential product liability lawsuits associated with adverse events – both currently identified and identified through future clinical trials and commercial experience. Product liability claims may result in limiting future product promotion, removal of one or more products from the market and potential for financial penalties and fines that may adversely impact RXDX's cash flow and financial position, including cash balance and ability to meet various debt covenants.

**Limited Operating History:** While the company was formed in 2012, RXDX had limited operations as a drug development company prior to May 2013. This limited operating history may restrict the scope of information available for investors to form an investment opinion. RXDX is classified as an emerging growth company and is entitled to more limited disclosure requirements, which may make shares of RXDX less attractive to investors. The company went public in November 2013 through a reverse merger and trading volume in shares of RXDX has limited due in part to the small number of registered shares. There can be no assurance that there will be a liquid and orderly market for trading of RXDX shares in the near term, or ever. Additionally, if one or more holders of common stock covered by an effective registration statement seeks to sell stock, the share price may be adversely impacted.

**Debt Repayment:** The company has a \$21M debt facility with Silicon Valley Bank Corp. that matures in April 2018. There can be no assurance RXDX will have adequate funds to repay the loan facility or that alternative debt financing will be available on acceptable terms, if at all.

# APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

## ANALYST CERTIFICATION

I, Kevin DeGeeter, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

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## COMPANY BACKGROUND

Ignyta is developing personalized oncology drugs using diagnostic tests to identify patients most likely to respond to therapy. The company's lead product RXDX-101, is a TrkA/B/C, ROS1, ALK inhibitor in Phase I development for the treatment of solid tumors. Ignyta hopes to move the program into Phase II development in 2015 for multiple indications including NSCLC. The San Diego-based company is also in pre-clinical development of other targeted cancer therapies based on proprietary Oncolome molecular expression database.

## VALUATION METHODOLOGY

Our \$20.00 price target is based on a DCF analysis assuming 25% discount rate, 21.5 million shares on a fully diluted basis, terminal year (2022) FCF of \$168M and 15% long-term growth rate.

## RISKS

These risk factors (clinical, regulatory, competition, financing, partnership, product liability, limited operating history, and debt repayment) do not constitute all the potential risks of investing in the subject company's shares. Investors should refer to the company's SEC filings including the most recent forms 10-K and 10-Q for further details on the risks associated with an investment in the subject company's shares.

## STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

## RATINGS DISPERSION AND BANKING RELATIONSHIPS AS OF (February 5, 2015)

Rating	%	IB %
BUY	73.7	58.5
NEUTRAL	26.3	37.7
SELL	0.0	0.0

## COMPANIES UNDER KEVIN'S COVERAGE

ADMA Biologics, Inc. (ADMA)  
 Codexis, Inc. (CDXS)  
 Novavax, Inc. (NVAX)  
 Parnell Pharmaceuticals Holdings LTD (PARN)  
 Vericel Corporation (VCEL)

Aeolus Pharmaceuticals Inc. (AOLS)  
 Mesoblast Ltd. (MBLTY)  
 Opko Health, Inc. (OPK)  
 Ignyta, Inc. (RXDX)

**COMPANY SPECIFIC DISCLOSURES**

Ladenburg Thalmann & Co. Inc. makes a market in Ignyta, Inc..

Ladenburg Thalmann & Co. Inc. has managed or co-managed a public offering for Ignyta, Inc. within the past 12 months.

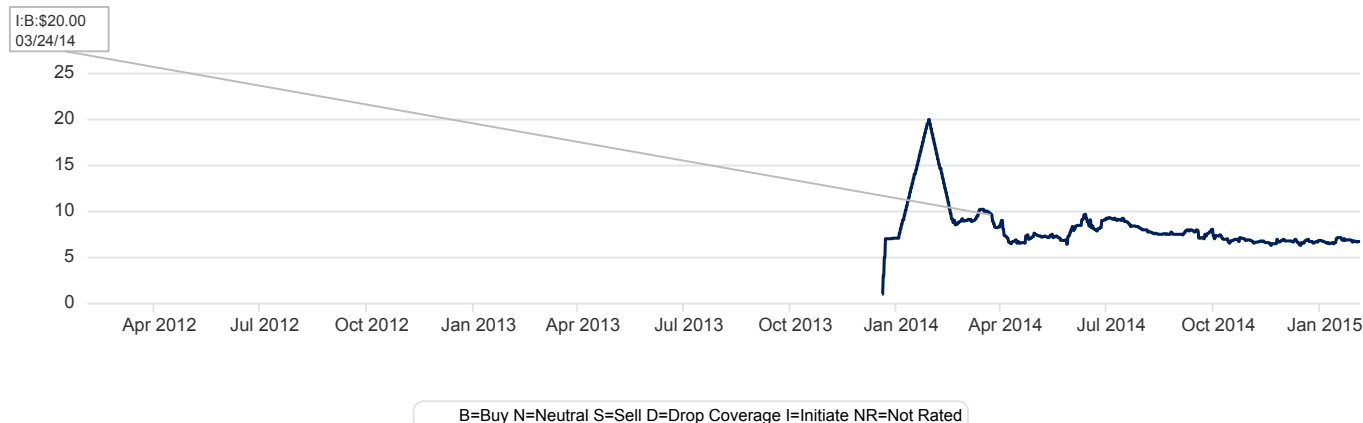
Ladenburg Thalmann & Co. Inc. intends to seek compensation for investment banking and/or advisory services from Ignyta, Inc. within the next 3 months.

Ladenburg Thalmann & Co. Inc received compensation for investment banking services from Ignyta, Inc. within the past 12 months.

Ladenburg Thalmann & Co. Inc had an investment banking relationship with the Ignyta, Inc. within the last 12 months.

**INVESTMENT RATING AND PRICE TARGET HISTORY****Ignyta, Inc. Rating History as of 02/04/2015**

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