

IGNYTA, INC.

RXDX-101 Demonstrates Clear TrkA Activity at ASCO; Reiterate Buy

RXDX (NASDAQ)

Company & Market Data	
Closing Price (as of May 30, 2014):	\$7.40
Rating:	BUY
Price Target:	\$20.00
52 Week Range:	\$1.00 - \$20.00
Shares Outstanding (MM):	20
Market Capitalization (MM):	\$145
Cash (MM):	\$100.4
Debt (MM):	\$9.0
Fiscal Year End:	Dec

Estimates			
EPS	2013A	2014E	2015E
1Q	—	\$(0.28)A	\$(0.31)
2Q	—	\$(0.24)	\$(0.33)
3Q	—	\$(0.27)	\$(0.34)
4Q	—	\$(0.27)	\$(0.34)
Full Year	\$(1.94)	\$(1.06)	\$(1.33)
Revenue (MM)	\$0.0	\$0.0	\$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 5/14/14 at the ASCO meeting, investigators presented an oral abstract with positive new data from the ALKA-372-001 Phase I study for the pan Trk/ROS1/ALK inhibitor RXDX-101. RXDX-101 showed signals of efficacy including the following: 1) a partial response (PR) after one cycle for the first TrkA+ patient dosed with RXDX-101, 2) PRs for patients with each mutation variant (ALK, ROS1 and TrkA), 3) PRs in several tumor types (colorectal, neuroblastoma, NSCLC and pancreatic), and 4) good safety profile. Specifically, we view the PR from the first TrkA+ patient treated with RXDX-101 as an early but promising sign of efficacy and potential source of differentiation for RXDX-101. As a reminder, there are currently no therapies targeting TrkA/B/C, which has recently been identified as an oncogene driver mutation involved in growth and cell survival. RXDX-101 is among the most advanced therapies targeting TrkA/B/C and the only Trk inhibitor selected for presentation at ASCO. In terms of next steps, we expect RXDX to enroll the first patient in July for STARTRK-1, a U.S. Phase I/II continuous dosing study. Additionally, we are cautiously optimistic RXDX will provide an update at ESMO or another 2H14 medical meeting on 6 patients still receiving therapy in the ALKA-372-001 study. We believe this update may provide important insight into durability of response and, in our view, could serve as a catalyst for RXDX shares. RXDX has \$100M in cash, which, in our view, should fund operations into 2017. Reiterate Buy rating and \$20.00 PT.

- What's New?** Investigators presented data at ASCO in an oral abstract from 20 patients enrolled in ALKA-372-001, an Italian Phase I study of RXDX-101 in treatment of solid tumors. The presentation included data from patients not described in the abstract (3 new patients including the first TrkA patient) and an additional 3-4 months of follow up for all patients. the study dosed 12 NSCLC, 3 neuroblastoma, 2 colorectal cancer, 1 pancreatic cancer and 1 Leiomyosarcoma. A total of 6 of 19 patients that completed dosing had a clinical response (4 PRs and 2 stable disease) compared to 2 patients described in the abstract (1 PR and 1 stable disease). Excluding 3 patients treated at 100mg/m2 (sub-therapeutic dose) and 3 patients with point mutations (typically less likely to respond to tyrosine kinase inhibitors than gene rearrangements), there were 13 patients that received both therapeutic doses and had clinically actionable mutations for an implied overall response rate of 46%. Responders included 1) an ALK+ neuroblastoma patients with PR at 16 cycles, 2) ALK+ NSCLC patient with stable disease at 14 cycles, 3) ROS1+ pancreatic patient with stable disease through 11 cycles, 4) ALK+ NSCLC (intolerant to crizotinib) with a PR through 6 cycles, 5) ROS1+ NSCLC patient with PR through 5 cycles and 6) TrkA+ colorectal cancer patient with PR after 2 cycles. All patients received between 800mg/m2 and 1200mg/m2. Additional details on P. 2
- Clear Pharmacokinetic Profile to Support Once Daily Dosing:** The ASCO presentation also defined a clear pharmacokinetic profile to guide future studies. Maximum plasma exposure appeared to plateau at 800mg/m2 twice daily. Steady state was achieved after 4 days. Plasma exposure was impacted by change in pH. RXDX believes the 800mg/m2 dose from the intermittent ALKA-372-001 dose should translate to 200mg/m2 once daily in future continuous dosing studies. One patient had grade 4 lipase increase and another had grade 3 asthenia. The most common drug related adverse event was parasthesia and nausea.

Disclosures and Analyst Certifications can be found in Appendix A.

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Background on ALKA-372-001 Study Design

The protocol, which was drafted by partner Nerviano, called for patients to be dosed once daily for 4 days of a weekly cycle and for 3 weeks of a 4 week schedule for a total of 12 days of a 28 day cycle. The study dosed patients at 100mg/m², 200mg/m², 400mg/m², 800mg/m², 1200mg/m² and the maximum dose of 1600mg/m² twice daily. The protocol allowed for inpatient up-titration of dose. 20 patients were enrolled and 19 completed dosing (one could not tolerate capsule burden).

A total of 11 patients were dosed prior to the program being transferred to RXDX in November 2013. In February 2014 at the IASLC meeting, investigators from Massachusetts General presented preliminary Phase I data suggesting a clean safety profile and signs of clinical activity. A total of 18 patients had been enrolled with 17 in six different dose cohorts receiving at least one dose. A total of 7 patients were still receiving RXDX-101. Investigators reported 2 ALK+ patients in the second dose cohort demonstrated sustained clinical response. A NSCLC patient had stable disease after 12 cycles while a neuroblastoma patient had a partial response after 13 cycles. One ROS1+ pancreatic cancer patient in the 3rd cohort had stable disease after 8 cycles.

Compelling Profile of First TrkA Patient Dosed with RXDX-101

The most notable patient in the Phase I study, in our view, was a 75 year old colorectal cancer patient with liver mets that had failed three prior therapies (FOLFOX, FOLFIRI in combination with cetuximab and irinotecan monotherapy). After testing positive for TrkA the woman was enrolled in the 1600 mg/m² cohort. The patient had a partial response after one cycle. This was the first patient with a TrkA mutation treated with RXDX-101.

Table 1.

Ignyta Income Statement											
(in \$ millions)	2013A	1Q14A	2Q14E	3Q14E	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$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	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
G&A	3.7	1.8	1.5	1.5	1.4	6.1	1.6	1.8	1.7	1.7	6.8
Research & development	3.2	2.2	3.3	4.0	4.0	13.5	4.7	4.9	5.2	5.2	20.0
Operating profit (loss)	(\$6.9)	(3.9)	(4.8)	(5.5)	(5.4)	(\$19.6)	(6.3)	(6.7)	(6.9)	(6.9)	(\$26.8)
Interest income	0.0	0.0	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.0	0.2
Interest expense	(0.2)	(0.1)	(0.2)	(0.2)	(0.2)	(0.7)	(0.2)	(0.2)	(0.2)	(0.2)	(0.7)
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)	(4.9)	(5.6)	(5.5)	(20.1)	(6.4)	(6.8)	(7.1)	(7.0)	(27.3)
Earnings (loss) per share from continuing ops	(\$1.94)	(\$0.28)	(\$0.24)	(\$0.27)	(\$0.27)	(\$1.06)	(\$0.31)	(\$0.33)	(\$0.34)	(\$0.34)	(\$1.33)
One-time gains (expenses)	(\$0.54)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Net income (loss) as reported	(14.2)	(4.1)	(4.9)	(5.6)	(5.5)	(20.1)	(6.4)	(6.8)	(7.1)	(7.0)	(27.3)
Earnings (loss) per share as reported	(\$3.83)	(\$0.28)	(\$0.24)	(\$0.27)	(\$0.27)	(\$1.06)	(\$0.31)	(\$0.33)	(\$0.34)	(\$0.34)	(\$1.33)
Weighted average common shares	3.7	14.5	20.5	20.5	20.5	19.0	20.5	20.5	20.5	20.5	20.5

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 RXDX-101 will demonstrate clinically meaningful activity in NSCLC and other solid tumors. Additionally, RXDX-101 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 RXDX-101 over existing ALK inhibitors such as crizotinib. Additionally, the company is developing additional targeted cancer therapies based on its proprietary Oncolome database. 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 RXDX-101 or any other pipeline product. Additionally, we expect the companion to diagnostic for RXDX-101 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 RXDX-101 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 RGDX-101.

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 RXDX-101. 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 RXDX-101 and its other pipeline programs. Additionally, we expect the company to seek commercial partners for RXDX-101 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 RXDX-101 and RXDX-102 from Nerviano Medical Sciences. While Nerviano is not responsible for conducting any future clinical development, the two companies have signed a service agreement for additional manufacturing and clinical support services through 2014. There can be no assurance Nerviano will provide adequate support for timely future development of RXDX-101.

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 \$10M debt facility with Silicon Valley Bank Corp. that matures in December 2017. 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 (June 2, 2014)

Rating	%	IB %
BUY	75.4	52.8
NEUTRAL	24.6	38.3
SELL	0.0	0.0

COMPANIES UNDER ANALYST'S COVERAGE

ADMA Biologics, Inc. (ADMA)
 BG Medicine, Inc. (BGMD)
 diaDexus, Inc. (DDXS)
 Genetic Technologies, Ltd. (GENE)
 Mesoblast Ltd. (MBLTY)
 Navidea Biopharmaceuticals Inc. (NAVb)
 Opko Health, Inc. (OPK)
 Sequenom Inc. (SQNM)

Aeolus Pharmaceuticals Inc. (AOLS)
 CombiMatrix Corporation (CBMX)
 Exact Sciences Corp. (EXAS)
 Genomic Health Inc. (GHDX)
 Myriad Genetics Inc. (MYGN)
 Novavax, Inc. (NVAX)
 Ignyta, Inc. (RXDX)

COMPANY SPECIFIC DISCLOSURES

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

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

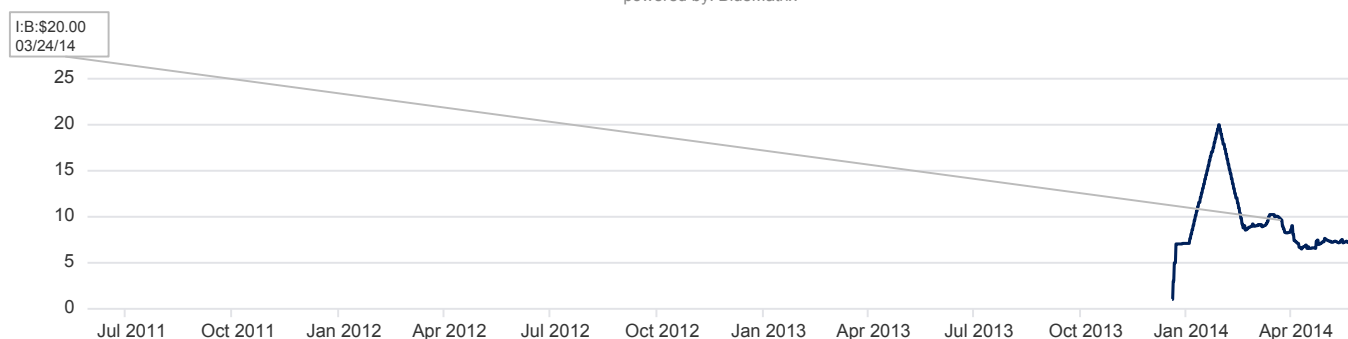
Ladenburg Thalmann & Co. Inc. intends to seek compensation for investment banking and/or advisory services from Ignyta, Inc. within the next 3 months.

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 05/30/2014**

powered by: BlueMatrix



B=Buy N=Neutral S=Sell D=Drop Coverage I=Initiate NR=Not Rated

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