

## IGNYTA, INC.

### RXDX-101 Update at ESMO Offers Near-Term Catalyst; Uneventful 2Q14 Results

RXDX (NASDAQ)

#### Company & Market Data

Closing Price (as of August 12, 2014):	\$7.60
Rating:	BUY
Price Target:	\$20.00
52 Week Range:	\$1.00 - \$20.00
Shares Outstanding (MM):	20
Market Capitalization (MM):	\$149
Cash (MM):	\$95.1
Debt (MM):	\$9.1
Fiscal Year End:	Dec

#### Estimates

EPS	2013A	2014E	2015E
1Q	—	\$(0.28)A	\$(0.34)
Prior			\$(0.31)
2Q	—	\$(0.28)A	\$(0.36)
Prior		\$(0.24)	\$(0.33)
3Q	—	\$(0.48)	\$(0.38)
Prior		\$(0.27)	\$(0.34)
4Q	—	\$(0.31)	\$(0.39)
Prior		\$(0.27)	\$(0.34)
Full Year	\$(1.94)	\$(1.36)	\$(1.47)
Prior		\$(1.06)	\$(1.33)
Revenue (MM)	\$0.0	\$0.2	\$0.0
Prior		\$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 8/12/14, RXDX reported uneventful 2Q14 financial results and confirmed an update on the European Phase I ALKA-372-001 study will be presented at the European Society of Medical Oncology (ESMO) meeting September 26-30 in Madrid. We expect the ESMO presentation to provide important insights into the durability of response from 7 patients still on RXDX-101 as of ASCO meeting in early June. Additionally, management noted that alternative dosing regimens to the 12 days of a 28 cycle presented at ASCO, may be explored in additional European cohorts. RXDX declined to comment on whether any data from these additional cohorts will be presented at ESMO. We view regular weekly dosing with a 4-day-a-week dosing regimen (i.e., 16 days of a 28 cycle) as a commercially interesting alternative schedule and look forward to learning more about RXDX's plans for additional studies in Europe. As a reminder, any future dosing cohorts in Europe are in addition to the previously announced U.S. continuous daily dosing study, STARTRK-1. We expect the combination of dose escalation cohorts from the Phase I component of STARTRK-1 and the additional European cohorts to provide a more fully informed view of the potential dose level and schedule for a Phase IIa "basket study" component of STARTRK-1, which will enroll patients with mutations in TrkA/b/c, ROS1 or ALK with various histologies. We continue to expect preliminary data from the Phase IIa component of STARTRK-1 as early as ASCO 2015. Reiterate Buy rating and \$20.00 PT.

- **What's New?** RXDX reported uneventful 2Q14 financial results and confirmed an update for RXDX-101 will be presented at the ESMO meeting, September 26-30.
- **3 Sites Enrolling Patients for STARTRK-1:** Last month RXDX announced the first patient had been enrolled in STARTRK-1, a single-arm open-label clinical trial of continuous daily dosing of oral RXDX-101. Based on the most recent update on the FDA's clinical trials web site, two sites in the Sarah Cannon Research Institute network (Nashville and Sarasota) and Lombardi Comprehensive Cancer Center at Georgetown are actively recruiting patients. The Phase I component will include up to 6 sites including, UC Irvine, Dana Farber, Memorial Sloan Kettering and M.D. Anderson. The Phase I component will evaluate maximum tolerated dose (MTD) and dose limiting toxicities (DLTs) at 28 days and should be completed in roughly 6 months.
- **Additional EU Cohorts to Inform STARTRK-1 "Basket Study":** We view the decision to dose additional patients in Europe as a positive strategic step to help more fully inform the optimal dose and schedule for the planned Phase IIa "basket study" component of STARTRK-1, which will provide the first insights into potential clinical response of RXDX-101 at an optimal dose, in our view. All patients in STARTRK-1 must have locally advanced or metastatic cancer confirmed to be positive for alterations in TrkA/B/C, ALK or ROS1. Patients must have a relatively good prognosis with an ECOG status of 2 or less, life expectancy of at least 3 months and no evidence of brain metastases. Prior treatment with crizotinib is allowed.
- **Detailed review of 2Q14 financial results on P. 2**

Disclosures and Analyst Certifications can be found in Appendix A.

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## 2Q14 Review

**G&A:** Administrative spending increased 287% to \$2.0M and was above our estimate of \$1.5M. The increase in administrative spending was primarily a result of increases in personnel costs as well as costs relating to the legal, investor relations, intellectual property and audit functions resulting from operating as a public company.

**R&D:** Research expenses totaled \$3.6M, compared to \$0.5M for 2Q13, an increase of 511% and \$0.3M above our estimate. The increase related to the development of RXDX-101 and the company's Spark discovery programs.

**EPS:** RXDX reported EPS of (\$0.28), \$0.04 below our (\$0.24) estimate drive by higher-than-expected G&A expenses.

Table 1.

Ignyta 2Q14 EPS Review				
(\$ in millions except per share)	2Q13A	2Q14A	Change	2Q14 - LTS Est.
Product Revenues	\$0.0	\$0.0		\$0.0
Other Revenues	0.0	0.2		0.0
Total Revenue	\$0.0	\$0.2		\$0.0
COGS	0.0	0.0		0.0
Gross profit	0.0	0.2		0.0
G&A	0.5	2.0	286.6%	1.5
Research & development	0.6	3.6	511.3%	3.3
Operating profit (loss)	(1.1)	(5.5)		(5.0)
Net Interest Income (expense)	(0.0)	0.0		(0.1)
Taxes	0.0	0.0		0.0
Net profit (loss)	(1.1)	(5.4)		(4.9)
Earnings (loss) per share from continuing ops	(\$0.84)	(\$0.28)		(\$0.24)
One-time Gains (expenses)	0.0	0.0		0.0
Net profit (loss) as reported	(1.1)	(5.4)		(4.9)
Earnings (loss) per share as reported	(\$0.84)	(\$0.28)		(\$0.37)
Weighted average common shares	1.4	19.6		20.5

Source: Company reports and Ladenburg Thalmann estimates

## Financial Model Revisions

**G&A:** We are increasing our administrative expense assumptions from \$6.1M and \$6.8M to \$7.4M and \$8.3M for 2014 and 2015, respectively. The increases are based on higher expected business development expenses and to a lesser extent a build out of RXDX's finance department to address regulatory requirements of being a publicly traded company.

**R&D:** We are increasing our 2014 R&D expense assumption from \$13.5M to \$17.3M primarily based on an expected \$3.5M 3Q14 milestone payment associated with the recent in-licensing of RXDX-103 and RXDX-104.

**EPS:** On net, our EPS forecast goes from (\$1.06) to (\$1.36) and from (\$1.33) to (\$1.47) for 2014 and 2015, respectively.

Table 2.

Ignyta Income Statement											
(in \$ millions)	2013A	1Q14A	2Q14A	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	0.2	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	1.7	1.9	7.4	1.9	2.1	2.0	2.2	8.3
Research & development	3.2	2.2	3.6	7.5	4.0	17.3	4.7	4.9	5.2	5.2	20.0
Operating profit (loss)	(\$6.9)	(3.9)	(5.5)	(9.2)	(5.9)	(\$24.5)	(6.6)	(7.0)	(7.2)	(7.4)	(\$28.3)
Interest income	0.0	0.0	0.1	0.1	0.1	0.2	0.1	0.1	0.0	0.0	0.2
Interest expense	(0.2)	(0.1)	0.0	(0.2)	(0.2)	(0.5)	(0.2)	(0.2)	(0.2)	(0.2)	(0.7)
Other	(0.1)	(0.0)	(0.0)	0.0	0.0	(0.1)	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)	(9.3)	(6.0)	(24.8)	(6.8)	(7.1)	(7.4)	(7.6)	(28.8)
Earnings (loss) per share from continuing ops	(\$1.94)	(\$0.28)	(\$0.28)	(\$0.48)	(\$0.31)	(\$1.36)	(\$0.34)	(\$0.36)	(\$0.38)	(\$0.39)	(\$1.47)
One-time gains (expenses)	(\$0.57)	\$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)	(5.4)	(9.3)	(6.0)	(24.8)	(6.8)	(7.1)	(7.4)	(7.6)	(28.8)
Earnings (loss) per share as reported	(\$3.83)	(\$0.28)	(\$0.28)	(\$0.48)	(\$0.31)	(\$1.36)	(\$0.34)	(\$0.36)	(\$0.38)	(\$0.39)	(\$1.47)
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 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 and acquired drug candidates including RXDX-103 and RXDX-104. 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 (August 13, 2014)

Rating	%	IB %
BUY	74.9	57.7
NEUTRAL	25.1	40.0
SELL	0.0	0.0

## COMPANIES UNDER KEVIN'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)

Ignyta, Inc. (RXDX)

Aeolus Pharmaceuticals Inc. (AOLS)

CombiMatrix Corporation (CBMX)

Exact Sciences Corp. (EXAS)

Genomic Health Inc. (GHDX)

Myriad Genetics Inc. (MYGN)

Novavax, Inc. (NVAX)

Parnell Pharmaceuticals Holdings LTD (PARN)

Sequenom Inc. (SQNM)

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

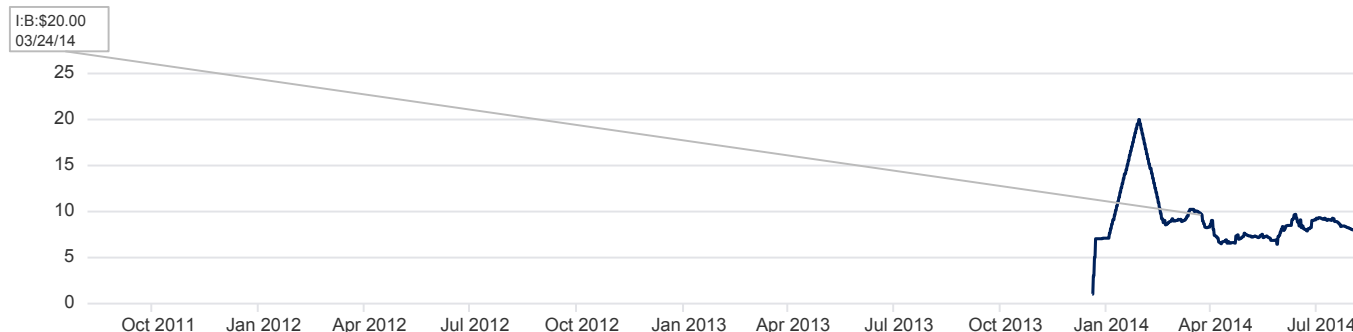
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**INVESTMENT RATING AND PRICE TARGET HISTORY****Ignyta, Inc. Rating History as of 08/07/2014**

powered by: BlueMatrix



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

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