

IGNYTA, INC.

In-House CLIA Certification to Enable Rapid Screening for RXDX-101 Studies

RXDX (NASDAQ)

Company & Market Data

| | |
|-----------------------------------|------------------|
| Closing Price (as of 12/01/2014): | \$6.97 |
| Rating: | BUY |
| Price Target: | \$20.00 |
| 52 Week Range: | \$1.00 - \$20.00 |
| Shares Outstanding (MM): | 20 |
| Market Capitalization (MM): | \$136 |
| Cash (MM): | \$94.7 |
| Debt (MM): | \$20.3 |
| Fiscal Year End: | Dec |

Estimates

| EPS | 2013A | 2014E | 2015E |
|--------------|----------|-----------|----------|
| 1Q | — | \$(0.28)A | \$(0.39) |
| 2Q | — | \$(0.28)A | \$(0.40) |
| 3Q | — | \$(0.55)A | \$(0.43) |
| 4Q | — | \$(0.38) | \$(0.43) |
| Full Year | \$(1.94) | \$(1.51) | \$(1.65) |
| 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 12/2/14, RXDX received CLIA certification for its diagnostic laboratory in San Diego. The announcement was in line with our forecast. We believe the investment in an in-house diagnostic laboratory should 1) accelerate patient screening for ongoing clinical trials for RXDX-101 and 2) accelerate optimization of new companion diagnostics for both RXDX-101 and the company's pre-clinical drug candidates. We believe this in-house diagnostic expertise is unique among targeted cancer drug discovery companies and may de-risk the company's clinical development model. We expect the next clinical data presentation for RXDX-101 in 1H15. Reiterate Buy and \$20.00 PT.

- **What's New?** RXDX announced the company's San Diego diagnostic laboratory passed the State of California survey for CLIA certification allowing RXDX to begin offering molecular diagnostic services to patients, including those enrolled in its clinical trials. RXDX does not have any immediate plans to offer commercial diagnostic testing services to third parties.
- **Lab Enables In-House Screening for Phase IIa STARTRK-1 Study:** CLIA certification will allow RXDX to provide rapid and standardized screening for the Phase IIa component of the STARTRK-1 continuous dosing study of RXDX-101 in patients with ALK, ROS1 or TRKA/B/C variants. We believe in-house testing may accelerate the screening process and increase the probability of more TRKA/B/C patients being enrolled in the study (ie standardized TRKA/B/C assays are not available in some hospitals). As a reminder, STARTRK-1 is a single-arm open-label Phase I/IIa clinical trial of RXDX-101. The Phase I dose escalation component will include up to 6 sites and should be completed in 1H15. These patients will be screened by the investigator's laboratory. The Phase IIa "basket study" component is expected to enroll a wide range tumor histologies at 20+ sites.
- **Accelerates Optimization of Diagnostics for Pipeline Programs:** In addition to enabling in-house screening for clinical trials of RXDX-101, we expect the investment in a CLIA lab to enable more rapid validation of companion diagnostics for RXDX's pipeline programs including RXDX-103 (a 2nd generation Cdc7 inhibitor), RXDX-104 (a highly selective inhibitor of RET) and the 3 lead SPARK programs (targeted therapies against undisclosed molecular alterations). While, in our view, most investors are focused on RXDX-101 we continue to believe the productivity of RXDX's pipeline will be a critical area of focus for creation of long-term shareholder value.
- **Important Strategic Milestone in RXDX Business Model:** RXDX's business model is focused on combining diagnostic technology with small molecule oncology drug development expertise to commercialize targeted therapies for the treatment of cancer, particularly solid tumors. The company started as a molecular diagnostic company and has retained and expanded its molecular testing acumen to include additional senior scientists with experience creating translational applications for next-generation sequencing. We believe this deep commitment to understanding diagnostic technologies is unique among drug companies, particularly smaller biotechs, and may translate to faster time-to-market for newly identified molecular targets such as TRKA/B/C. Additionally, we believe there may be an opportunity to integrate RXDX's diagnostic team into early drug discovery to identify differentiated new drug candidates. As such, we encourage investors to focus on preclinical development of RXDX's in-house Spark programs over the next 12-24 months for a clearer sense of potential synergies between the diagnostic and therapeutic groups.

Disclosures and Analyst Certifications can be found in Appendix A.

570 Lexington Avenue 11th Floor • New York, New York 10022 • Telephone: 212-409-2000 • 800-LAD-THAL

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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 | 5.0 | 19.4 | 5.1 | 5.3 | 5.5 | 5.5 | 21.4 |
| Operating profit (loss) | (\$6.9) | (3.9) | (5.5) | (10.8) | (7.1) | (\$27.4) | (7.2) | (7.5) | (8.1) | (8.0) | (\$30.9) |
| Interest income | 0.0 | 0.0 | 0.1 | 0.1 | 0.1 | 0.3 | 0.1 | 0.1 | 0.1 | 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) | (7.4) | (27.7) | (7.6) | (7.9) | (8.5) | (8.4) | (32.3) |
| Earnings (loss) per share from continuing ops | (\$1.94) | (\$0.28) | (\$0.28) | (\$0.55) | (\$0.38) | (\$1.51) | (\$0.39) | (\$0.40) | (\$0.43) | (\$0.43) | (\$1.65) |
| 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) | (10.7) | (7.4) | (27.7) | (7.6) | (7.9) | (8.5) | (8.4) | (32.3) |
| Earnings (loss) per share as reported | (\$3.83) | (\$0.28) | (\$0.28) | (\$0.55) | (\$0.38) | (\$1.51) | (\$0.39) | (\$0.40) | (\$0.43) | (\$0.43) | (\$1.65) |
| 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 (December 2, 2014)

| Rating | % | IB % |
|---------|------|------|
| BUY | 75.0 | 57.1 |
| NEUTRAL | 25.0 | 42.9 |
| SELL | 0.0 | 0.0 |

COMPANIES UNDER KEVIN'S COVERAGE

| | |
|--|---|
| ADMA Biologics, Inc. (ADMA) | Aeolus Pharmaceuticals Inc. (AOLS) |
| BG Medicine, Inc. (BGMD) | CombiMatrix Corporation (CBMX) |
| diaDexus, Inc. (DDXS) | Exact Sciences Corp. (EXAS) |
| Genetic Technologies, Ltd. (GENE) | Genomic Health Inc. (GHDX) |
| Mesoblast Ltd. (MBLTY) | Myriad Genetics Inc. (MYGN) |
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| Opko Health, Inc. (OPK) | Parnell Pharmaceuticals Holdings LTD (PARN) |
| Ignyta, Inc. (RXDX) | Sequenom Inc. (SQNM) |
| Vericel Corporation (VCEL) | |

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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.

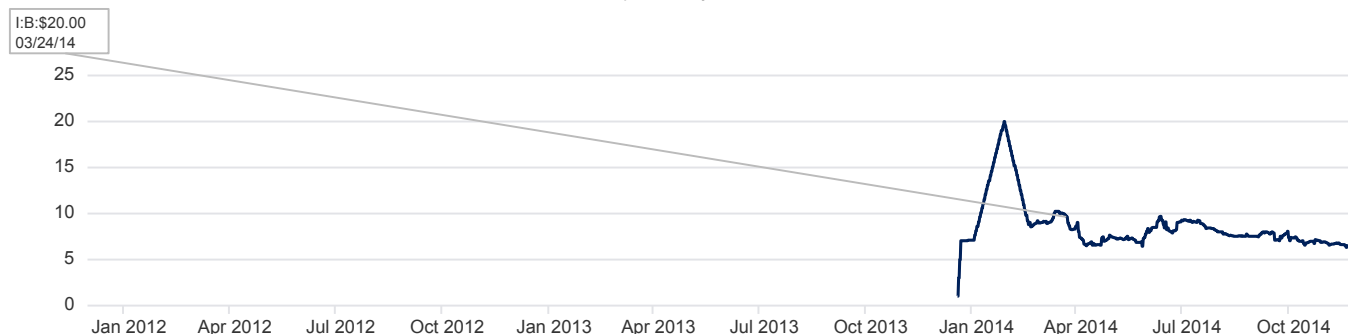
Ladenburg Thalmann & Co. Inc. intends to seek compensation for investment banking and/or advisory services from Ignyta, Inc. within the next 3 months.

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 12/01/2014**

powered by: BlueMatrix



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

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EQUITY RESEARCH

ENERGY, POWER & INFRASTRUCTURE

Power & Electric Utilities

| | | |
|-------------------------|----------------|----------------------|
| Brian J. Russo, CFA | (646) 432-6312 | brusso@ladenburg.com |
| Vinod Srinivasaraghavan | (212) 409-2085 | vsrin@ladenburg.com |

Energy Exploration & Production, Master Limited Partnerships, Upstream

| | | |
|----------------------|----------------|------------------------|
| Noel A. Parks | (212) 409-2023 | nparks@ladenburg.com |
| Michael Schmitz, CFA | (212) 409-2028 | mschmitz@ladenburg.com |

Master Limited Partnerships, Midstream

| | | |
|--------------|----------------|---------------------|
| Eduardo Seda | (212) 409-2034 | eseda@ladenburg.com |
|--------------|----------------|---------------------|

Master Limited Partnerships, Downstream & Others

| | | |
|------------------|----------------|----------------------|
| Richard A. Verdi | (212) 409-2060 | rverdi@ladenburg.com |
|------------------|----------------|----------------------|

Closed-End MLP Funds

| | | |
|--------------|----------------|---------------------|
| Eduardo Seda | (212) 409-2034 | eseda@ladenburg.com |
|--------------|----------------|---------------------|

Water & Sustainable Infrastructure

| | | |
|------------------|----------------|----------------------|
| Richard A. Verdi | (212) 409-2060 | rverdi@ladenburg.com |
|------------------|----------------|----------------------|

HEALTHCARE

Biotechnology

| | | |
|-------------------|----------------|-----------------------|
| Matthew L. Kaplan | (212) 891-5247 | mkaplan@ladenburg.com |
|-------------------|----------------|-----------------------|

Biotechnology (BioPharmaceuticals)

| | | |
|-------------------------------|----------------|------------------------|
| Robert (Bert) C. Hazlett, III | (212) 409-2062 | rhazlett@ladenburg.com |
|-------------------------------|----------------|------------------------|

Biotechnology (Personalized Medicine)

| | | |
|----------------|----------------|-------------------------|
| Kevin DeGeeter | (212) 409-2027 | kdegeeter@ladenburg.com |
|----------------|----------------|-------------------------|

Healthcare Equipment & Medical Technologies

| | | |
|------------------|----------------|----------------------|
| Jeffrey S. Cohen | (305) 572-4110 | jcohen@ladenburg.com |
|------------------|----------------|----------------------|

FINANCIAL INSTITUTIONS

Financial Services – Business Development Cos. & Specialty Finance

| | | |
|-------------------------|----------------|-------------------------|
| Mickey M. Schleien, CFA | (305) 572-4131 | mschleien@ladenburg.com |
|-------------------------|----------------|-------------------------|

Financial Services – Equity REITs

| | | |
|------------------|----------------|-------------------------|
| Daniel P. Donlan | (212) 409-2056 | ddonlan@ladenburg.com |
| John J. Massocca | (212) 409-2543 | jmassocca@ladenburg.com |

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| | | |
|-------------------|----------------|-----------------------|
| David Walrod, CFA | (212) 409-2031 | dwalrod@ladenburg.com |
|-------------------|----------------|-----------------------|

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| | | |
|----------------|----------------|------------------------|
| Jon R. Hickman | (510) 918-4045 | jhickman@ladenburg.com |
|----------------|----------------|------------------------|

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|----------------|----------------|---------------------|
| Daniel L. Amir | (415) 726-5900 | damir@ladenburg.com |
|----------------|----------------|---------------------|

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| | | |
|------------------|----------------|------------------------|
| Glenn G. Mattson | (212) 409-2073 | gmattson@ladenburg.com |
|------------------|----------------|------------------------|

TECHNICAL ANALYSIS

| | | |
|----------------------|----------------|----------------------|
| Adolfo R. Rueda, CMT | (212) 409-2039 | arueda@ladenburg.com |
|----------------------|----------------|----------------------|

ADDITIONAL CONTACTS

| | | |
|--------------------------------|----------------|------------------------|
| Kenneth Brush, Head of Trading | (212) 409-2011 | kbrush@ladenburg.com |
| Eric Novotny | (212) 409-2011 | enovotny@ladenburg.com |

570 Lexington Avenue 11th Floor New York, NY 10022 (212) 409-2000

NEW YORK, NY MELVILLE, NY BOSTON, MA MIAMI, FL NAPLES, FL BOCA RATON, FL HOUSTON, TX