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IGNYTA, INC.

Acquisition of 4 Targeted Cancer Drugs Transforms Pipeline; All Eyes on ASCO

RXDX (NASDAQ)

Company & Market Data	
Closing Price (as of 03/17/2015):	$7.92
Rating:	BUY
Price Target:	$20.00
52 Week Range:	$5.36 - $10.64
Shares Outstanding (MM):	20
Market Capitalization (MM):	$155
Cash (MM):	$76.6
Debt (MM):	$20.7
Fiscal Year End:	Dec

Estimates			
EPS	**2013A**	**2014A**	**2015E**
1Q	—	$(0.28)	$(0.57)
Prior			*$(0.59)*
2Q	—	$(0.28)	$(0.53)
Prior			*$(0.62)*
3Q	—	$(0.55)	$(0.53)
Prior			*$(0.64)*
4Q	—	$(0.50)	$(0.59)
Prior		*$(0.53)E*	*$(0.68)*
Full Year	$(1.94)	$(1.64)	$(2.21)
Prior		*$(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 entrectinib, 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 3/17/15, RXDX in-licensed 4 oncology drugs from Teva Pharmaceutical (TEVA, $61.45, Not Rated) in a transaction that broadens RXDX's pipeline and enables the company to conduct Master Protocol study designs that, in our view, will accelerate enrollment for both entrectinib (RXDX-101) and the newly acquired assets. Specifically, the acquisition includes compounds targeting important oncogene driver mutations including RET, EGFR and BRAF (RXDX-105), cMET and AXL (RXDX-106) and mutant KRAS (RXDX-108). Management believes together these mutations account for 80% of known driver mutations for NSCLC and a significant portion of known driver mutations for colorectal cancer. Importantly, RXDX plans to initiate a Master Protocol study design in 2H15 with the STARTRK-2 clinical trial to screen NSCLC patients for a range of histologies. Patients will be randomized to entrectinib or RXDX-106, as appropriate, based on mutational profile. The company anticipates designing a similar Master Protocol study for colorectal cancer patients. The net effect of these study designs is to increase the probability that a patient screened will be enrolled in targeted therapy clinical trial. The study design is likely to be attractive to academic cancer centers and, in our view, may lead to more aggressive enrollment in future studies of entrectinib and other pipeline programs. Lastly, we would note that Teva only received RXDX common stock as a consideration for the asset purchase. We view this structure as a vote of confidence in RXDX shares ahead of the expected presentation of data at ASCO in June on an additional 25 patients dosed with entrectinib. Reiterate Buy and $20.00 PT.

- **What's New?** RXDX acquired four programs from Teva: RXDX-105 (BRAF, EGFR and RET inhibitor in Phase I/II), RXDX-106 (an inhibitor of AXL and cMET for EGFR inhibitor-resistant populations; IND in 2H15), RXDX-107 (a nanoformulation of bendamustine for solid tumors; IND 2H16), and RXDX-108 (preclinical program targeting a new oncogene in the RAS/RAF pathway, atypical kinase PKCiota). Teva received 1.5 million shares of common stock valued at $11.9M based on the prior day's closing price. Additionally, Teva purchased 1.5 million shares at $10 per share, a 26% premium to the prior closing price. Several institutional investors purchased 2.7 million newly issued shares at $10. In total, RXDX received the 4 programs and $41.6M in cash in exchange for 5.7M shares. Teva will control 3 million shares or 11.9% of the shares outstanding. There are no milestones or royalties due to Teva, but RXDX will assume existing sublicense obligations including $22M in development milestones and tiered mid single-digit to low double-digit royalties on both RXDX-105 and RXDX-106
- **Our Take: Strategic Deal Accelerates Pipeline:** While we believe several of the TEVA programs, including RXDX-105, offer differentiated profiles, we view the purchase primarily as a strategic transaction. RXDX now has the scale to be a partner of choice for KOLs and commercial partners interested in targeted therapy. With the additional scale we believe RXDX is positioned to enroll clinical trials more quickly and make faster go/no-go decisions for specific programs.
- **All Eyes on ASCO:** Based on the strong vote of confidence from Teva and financial investors purchasing stock at a 26% premium, we are incrementally more confident in the near-term development outlook for entrectinib. 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. ASCO abstracts are scheduled for release May 13th. The ASCO meeting is May 29-June 2.

RXDX 105 and RXDX 106 Overview

RXDX management indicated discussions with Teva began in December 2014 following a decision by Teva to de-prioritize oncology drug development. Management indicated the process was competitive with other biotech firms and that RXDX emerged as a leading potential partner based in significant measure on the company's in-house diagnostic and therapeutic development teams, which may allow RXDX to move more aggressively through clinical development.

RXDX-105
RXDX-105 is a small molecule BRAF, EGFR and RET inhibitor currently in a Phase I dose escalation study. The program was initiated by Ambit (now part of Daiichi Sankyo) and licensed to Cephalon, which was acquired by Teva in 2011. As mentioned above. RXDX will assume the sublicense obligations including $22M in development milestones and tiered mid single-digit to low double-digit royalties.

Points of Differentiation
The RXDX-105 compound, which was formerly known as CEP-32496, offers two potential areas of differentiation: 1) the drug regulates both BRAF and EGFR (believed to be a resistance mechanism for BRAF inhibitors) and 2) the compound is a potent inhibitor of RET with limited off target regulation of VEGF-R2, which can lead to hypertension that has been a dose limiting toxicity in many other RET inhibitors. The EFGR-BRAF mechanism is particularly interesting in colorectal cancer due to limited efficacy profile of single agent BRAF inhibitors. RET inhibition has been demonstrated to be clinically important in NSCLC.

Clinical Development Plan
Teva is currently enrolling patients in study 1105, which is a Phase I/II study with a standard 3+3 Phase I safety study of RXDX-105. The study is not selecting patients based on histology or mutational status which should allow for rapid enrollment and for RXDX to reach max tolerated dose by mid 2015. The 33 patient Phase II component of the study, which is expected to begin enrolling in 2H15, will enroll relapsed or refractory colorectal cancer patients with BRAF V600E and V600D mutations. All patients will be naïve to prior treatment with a BRAF inhibitor.

Separately, RXDX plans to initiate a NSCLC Master Protocol in 2H15 to screen for a broad range of NSCLC mutations. The Master Protocol will initially enroll patients on entrectinib. However, once an optimal dose of RXDX-105 has been identified the company will seek to enroll NSCLC patients presenting with BRAF, EGFR and RET mutations to RXDX-105.

RXDX-106
RXDX-106 is a pseudo-irreversible small molecule cMET and AXL inhibitor currently in late stage preclinical development with an expected IND filing in 2H15. The program was also initiated by Ambit. RXDX will assume the sublicense obligations including $22M in development milestones and tiered mid single-digit to low double-digit royalties.

Points of Differentiation
cMET and AXL mutations are known to be two of the primary mechanisms of resistance to EGFR inhibitors for NSCLC patients. While RXDX-106 is not the only drug candidate in development for these targets, RXDX believes the drug's pseudo-irreversible covalent bonding may allow for longer half life than competing drugs which may translate to a more favorable dosing profile. If the drug is active in a subset of NSCLC patients, in our view, there is a strong rationale for exploring development in other indications for which EGFR inhibitors are currently prescribed including metastatic colorectal cancer, melanoma, breast cancer, pancreatic cancer and certain hematologic malignancies.

Clinical Development Plan
Development of RXDX-106 will focus on patients with EGFR mutations that are resistant to first-generation EGFR inhibitors. Specifically, management believes AXL mutations are present in 22% of these EGFR inhibitor resistant patients and cMET mutations are present in 11% of patients.

4Q14 Review

G&A: Administrative spending increased 48% to $3.5M compared to our estimate of $2.1M. The increase was related to 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 $6.1M, compared to $1.2M for 4Q13, an increase of 400% and $1.9M below our estimate of $8M. The year-over-year increase was primarily a result of pipeline development activities and associated employee expenses.

EPS: RXDX reported EPS of ($1.01) included a previously announced $10M milestone payment to Nerviano. Excluding this charge, EPS from continuing operations of ($0.50) compared to our estimate of ($0.53).

Table 1.

Ignyta 4Q14 EPS Review				
($ in millions except per share)	**4Q13A**	**4Q14A**	**Change**	**4Q14 - LTS Est.**
Product Revenues	$0.0	$0.0		$0.0
Other Revenues	0.0	0.0		0.0
Total Revenue	$0.0	$0.0		$0.0
COGS	0.0	0.0		0.0
Gross profit	0.0	0.0		0.0
G&A	2.3	3.5	48.4%	2.1
Research & development	1.2	6.1	399.5%	8.0
Operating profit (loss)	(3.6)	(9.6)		(10.1)
Net Interest Income (expense)	(0.2)	(0.2)		(0.3)
Taxes	0.0	0.0		0.0
Net profit (loss)	(3.8)	(9.8)		(10.4)
Earnings (loss) per share from continuing ops	($0.31)	($0.50)		($0.53)
One-time Gains (expenses)	(7.0)	(10.0)		(10.0)
Net profit (loss) as reported	(10.8)	(19.8)		(20.4)
Earnings (loss) per share as reported	($0.89)	($1.01)		($1.04)
Weighted average common shares	12.2	19.7		19.6

Source: Company reports and Ladenburg Thalmann estimates

Financial Model Revisions

G&A: We are increasing our administrative expense assumptions from $9.5M to $14.6M for 2015. The $5.1M increase in expected spending is based primarily on higher expected business development expenses related to the assets recently acquired from Teva.

R&D: Our 2015 R&D expense assumption decreased to $37M from $38.5M based on timing of Phase II clinical trial expenses for entrectinib.

Share Count: We are increasing the share count from 19.7M to 25.4 million to account for newly issued shares to Teva and the financing with institutional investors.

EPS: On net, our EPS forecast goes from ($2.53) to ($2.21) for 2015.

Table 2.

Ignyta Income Statement												
(in $ millions)	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014A	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	3.5	9.5	3.3	3.6	3.7	4.0	14.6
Research & development	3.2	2.2	3.6	8.6	6.1	20.5	7.5	9.5	9.5	10.5	37.0
Operating profit (loss)	($6.9)	(3.9)	(5.5)	(10.8)	(9.6)	($29.8)	(10.8)	(13.1)	(13.2)	(14.5)	($51.6)
Interest income	0.0	0.0	0.1	0.1	(0.2)	0.0	0.1	0.1	0.1	0.1	0.3
Interest expense	(0.2)	(0.1)	0.0	0.0	(0.0)	(0.1)	(0.4)	(0.4)	(0.4)	(0.4)	(1.7)
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)	(5.4)	(10.7)	(9.8)	(30.0)	(11.2)	(13.4)	(13.5)	(14.8)	(52.9)
Earnings (loss) per share from continuing ops	($1.94)	($0.28)	($0.28)	($0.55)	($0.50)	($1.64)	($0.57)	($0.53)	($0.53)	($0.59)	($2.21)
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)	(19.8)	(40.0)	(11.2)	(13.4)	(13.5)	(14.8)	(52.9)
Earnings (loss) per share as reported	($3.83)	($0.28)	($0.28)	($0.55)	($1.01)	($2.18)	($0.57)	($0.53)	($0.53)	($0.59)	($2.21)
Weighted average common shares	3.7	14.5	19.6	19.6	19.7	18.3	19.7	25.4	25.4	25.4	23.9

Source: Company reports and Ladenburg Thalmann estimates

Valuation Update

We are maintaining our $20.00 price target and rolling our DCF model forward 12 months to use 2016 as our base year. Our $20.00 price target was established on March 24, 2014. Additionally, we have decreased our discount rate by 1% to 24% as a result of the company now having a broader pipeline, which limits product-specific risk. Additionally we are increasing our fully diluted share count to 26.9 million from 21.5 million based on the recent equity raise led by Teva. Our terminal year FCF estimate goes from $168M to $110M based on higher expected R&D expenses for the broader pipeline of early stage assets. Long term growth rate of 15% remains unchanged.

Table 3.

Ignyta Discounted Cash Flow Assumptions										
($ in millions)	**2014E**	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**TERMINAL**
Operating profit	$0.0	$0.0	($73.0)	($87.4)	($77.8)	$19.3	$160.3	$194.9	$177.5	
Depreciation & amortization	0.0	0.0	1.2	1.2	1.3	1.3	1.4	1.6	1.7	
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(74.3)	(68.0)	
Interest income - net	0.0	0.0	(1.5)	(1.8)	(2.1)	(2.4)	(2.2)	(1.3)	(0.4)	
Change in working capital	0.0	0.0	2.6	1.8	(6.3)	(21.3)	(30.3)	(8.4)	1.6	
Capital expenditures	0.0	0.0	(1.2)	(1.4)	(1.6)	(1.8)	(2.0)	(2.2)	(2.4)	
Total free cash flow	$0.0	$0.0	($71.8)	($87.6)	($86.5)	($4.9)	$127.3	$110.3	$109.9	$1,256.5
Revenue growth rate	NA	NA	NA	NA	NA	309%	104%	17%	2%	15%
Discount rate	24%	24%	24%	24%	24%	24%	24%	24%	24%	24%
Discount factor	0.0	0.0	1.0	1.0	0.8	0.7	0.5	0.4	0.3	0.3
Discounted cash flow	$0.0	$0.0	($71.8)	($87.6)	($69.9)	($3.2)	$67.1	$47.0	$37.9	$433.0

Source: 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, RXDX-105, RXDX-106, RXDX-107 and RXDX-108. 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 entrectinib 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. 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 entrectinib. The company has no direct operating additional obligations to Teva.

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 entitles 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.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 570 Lexington Avenue, 11th floor, New York, New York 10022 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

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 entrectinib, 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 24% discount rate, 26.9 million shares on a fully diluted basis, terminal year (2022) FCF of $109.9M 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 (March 18, 2015)

Rating	%	IB %
BUY	75.0	58.2
NEUTRAL	25.0	37.3
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)

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

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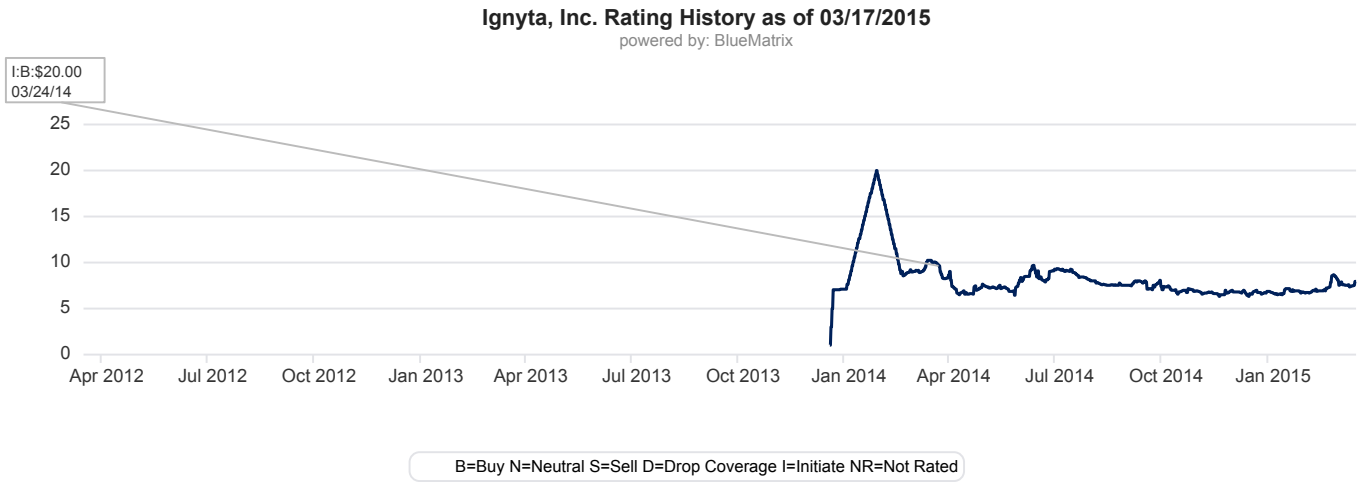
Ladenburg Thalmann & Co. Inc had an investment banking relationship with the Ignyta, Inc. within the last 12 months.

INVESTMENT RATING AND PRICE TARGET HISTORY



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