

Reason for report:

**EARNINGS****IGNYTA, INC.****Transaction Validates Platform, More Upside in 2015, PT to \$17**

• **Bottom Line:** In conjunction with 4Q:14 earnings call, RXDX announced acquisition of 4 oncology assets (1 Phase 1, 3 preclinical) from TEVA (OP) for 1.5M RXDX common shares. With a non-cash transaction and additional 4.2M share purchase at \$10 per share (26% premium at yesterday's closing price), we view the deal as favorable for RXDX because 1) it independently validates RXDX's platform; 2) newly acquired assets complement existing products in precision medicine, expanding from Trk/ALK/ROS1/Cdc7 to additional 7 targets (BRAF, EGFR, RET, AXL, cMET, DNA, PKC $\alpha$ ); 3) two Phase II assets expected in 2H:15; 4) synergistic clinical development across all assets leveraging its in house companion diagnostics. While drug development is highly competitive in targeted therapy and clinical activity yet to be established for these new assets, this acquisition could further differentiate RXDX from other oncology companies. As discussed in our prior note ([LINK](#)), we continue to view RXDX as our top pick in 2015 with additional upside from a favorable risk/reward profile for entrectinib (panTrk, Ros1, ALK) heading into ASCO (5/29-6/2). We are increasing our PT from \$14 to \$17 to reflect newly acquired assets.

• **Acquisition provides synergistic clinical development addressing large market potential.** RXDX acquired from TEVA four assets ('105 – BRAF, EGFR, RET inhibitor; '106 – AXL, cMET inhibitor; '107 – nanoformulation of a modified bendamustine with potential activity in solid tumor; '108 – atypical kinase PKC $\alpha$  inhibitor). While each asset (except '107) targets small percentage of genetic alteration, RXDX's pipeline addresses in aggregates over 50% of adenocarcinoma lung cancer. The company plans to initiate a Master Protocol with its multiplex assay (Trailblaze) to identify multiple genetic alterations for parallel clinical development. Although drugs have been approved for some genetic alterations and clinical profiles still need to be established for newly acquired assets, preclinical data suggest potentially first or better in class opportunities.

• **No royalties and milestones to TEVA; however, assuming TEVA's obligations to the 3rd parties.** Both '105 and '106 were TEVA's partner programs with AMBI/Daiichi Sankyo. Although actual numbers were not disclosed, management noted small milestone payments and mid-single-to-low-double digit royalties to the 3rd party.

• **Key catalysts in 2015.** 1) Entrectinib STARTRK-1 and ALKA-001 data at ASCO. 2) Identify Phase II dose and initiate entrectinib STARTRK-1 Phase IIa in 3Q:15. 3) Initiate STARTRK-2 NSCLC master protocol for entrectinib, '105, +/- '106 in 2H:15. 4) '105 Phase I data at ESMO or ENA. 5) Identify RXDX-105 Phase II dose and initiate Study 1105 in mBRAF mCRC in 2H:15.

**Key Stats:****(NASDAQ:RXDX)**

**S&P 600 Health Care Index:** 1,612.47  
**Price:** \$7.92

Price Target: \$17.00 from \$14.00

Methodology: Probability-weighted DCF analysis,  
10% discount rate

52 Week High: \$10.64

52 Week Low: \$5.36

Shares Outstanding (mil): 25.2

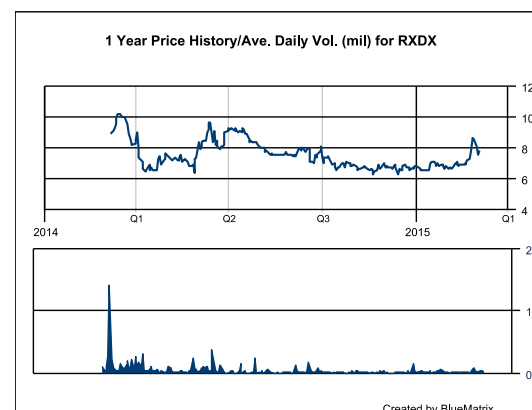
Market Capitalization (mil): \$199.6

Cash Per Share: \$3.92

Dividend (ann): \$0.00

Dividend Yield: 0.0%

*General: Pro forma*



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	0.0	\$0.2	0.0	0.0	\$0.2	(\$0.28)	(\$0.28)	(\$0.55)	(\$1.01)	(\$2.18)	NM
2015E - New	0.0	0.0	0.0	0.0	0.0	(\$0.79)	(\$0.79)	(\$0.79)	(\$0.80)	(\$3.17)	NM
2015E - Old	--	--	--	--	0.0	--	--	--	--	(\$2.09)	NM
2016E	--	--	--	--	0.0	--	--	--	--	(\$2.39)	NM

Source: Company Information and Leerink Partners LLC Research  
Revenues in millions.  
GAAP EPS.

## INVESTMENT THESIS

RXDX is a biotech company with a focus on targeted therapies and molecular diagnosis in oncology. RXDX's approach of targeting molecular oncogenic drivers has historically resulted in highly effective agents. Despite low incidence of many genetic alterations including Trk and ROS1 rearrangement, molecular screening started to become a standard practice in non-small cell lung cancer (NSCLC) where oncogenic driver mutations have been identified in ~70% of adenocarcinoma patients. Clinical successes with EGFR, ALK, ROS1, HER2, BRAF inhibitors have shown high efficacy in several cancer types. Although RXDX's lead candidate RXDX-101 (oral pan-Trk, ROS1 and ALK inhibitor) is still in early stage clinical development, we believe historical precedence suggests a higher-than-average chance of success in identifying highly effective agents which we believe is increasingly the direction for the development of new cancer therapies. We believe the main value for RXDX-101 lies in the market potential for cancers with Trk genetic alteration, an emerging target for NSCLC. Although many compounds have activity against Trk, so far, only a handful of companies have focused clinical programs targeting Trk, whereas RXDX has dedicated efforts to target Trk in multiple tumor type with the potential to develop a first-in-class Trk inhibitor. Although still early with limited clinical data, observed ALK activity and initial Trk activity (seen in one patient) bode well for RXDX-101 as a Trk inhibitor, where in vitro activity is ~10X more potent vs. ROS1 and ALK. The new global Phase I study with modified continuous dosing schedule could provide insight on safety and clinical activity. Recent licensing deal with Nerviano further expand the pipeline targeting Cdc7 (cell cycle kinase inhibitor) and RET (tyrosine kinase inhibitor). Additionally, Technology platform and integrated Rx/Dx strategy with genomic and epigenomic mining of oncolome provide potential six targeted therapies with companion diagnostics in 2015 and beyond.

**Model update.** For 4Q:14, RXDX reported \$16M in R&D expenses and \$3.5M in SG&A. EPS was (\$1.01). The company ended the quarter with \$76.6M. With recent capital investment of \$41.6M by TEVA and other investors, total cash should support operation into 2H:16, in our view. We update our model to reflect these changes.

**RXDX – Upcoming Events**

Timing	Event
<b>Entrectinib (RXDX-101, Pan-Trk, ROS1, ALK inhibitor)</b>	
ASCO	STARTRK-1 and ALKA-372-001 data
mid'15	Identify Phase 2 dose
ESMO or ENA	STARTRK-1 and ALKA-372-001 update
3Q:15	STARTRK-1 Phase 2a initiation
2H:15	Initiate STARTRK-2 NSCLC master protocol for entrectinib, '105, +/- '106
2016	Data from STARTRK-1 Phase 2a
2016	Data from STARTRK-2 Phase 2 in NSCLC
<b>RXDX-103 (Cdc7 inhibitor)</b>	
Early '16	Initiating Phase 1 study
<b>RXDX-105 (CEP-32496, BRAF, EGFR, RET inhibitor)</b>	
ESMO or ENA	Phase 1 data
3Q:15	Identify Phase 2 dose
2H:15	Study 1105 Phase 2 initiation in mBRAF mCRC
2016	Data from Study 1105 Phase 2 in mBRAF mCRC
<b>RXDX-106 (CEP-40783, AXL, cMET inhibitor)</b>	
2H:15	IND filing
<b>RXDX-107 (CEP-40125, nano-formulation of modified bendamustine)</b>	
1H:16	IND filing
<b>Spark-1 (Rx/Dx novel target)</b>	
2015	IND candidate

Source: Company Reports

**RXDX – Pipeline**

Stage of Development	Current Status/Upcoming Developments
<b>RXDX-101 (Pan-Trk, ROS1, ALK inhibitor)</b>	
ALKA-372-001	Phase I dose escalation study of intermittent dosing in Italy with 20-30 pts in each of ALK, ROS1 or TrkA alterations.
STARTRK-1	Global Phase I/II dose escalation study in US, EU and Asia with continuous dosing in 6-24 pts with Trk, ROS, or ALK alterations initiated in July, '14
	Basket trial expansion cohorts at RP2D with 15-20 pts in each cohort with TrkA, TrkB, TrkC, ROS1 or ALK alterations
STARTRK-2	Pivotal registration trials in NSCLC with master protocol for entrectinib, '105, +/- '106
<b>RXDX-102 (Pan-Trk inhibitor)</b>	
Preclinical	Back-up to RXDX-101
<b>RXDX-103 (Cdc7 inhibitor)</b>	
Preclinical	Enter clinical in 2016
<b>RXDX-105 (CEP-32496, BRAF, EGFR, RET inhibitor)</b>	
Phase I	
<b>RXDX-106 (CEP-40783, AXL, cMET inhibitor)</b>	
Preclinical	IND filing in 2H:15
<b>RXDX-107 (CEP-40125, nano-formulation of modified bendamustine)</b>	
Preclinical	IND filing in 1H:16
<b>RXDX-108 (TEV-44229, aPKC<math>\alpha</math> inhibitor)</b>	
Preclinical	
<b>Spark-1 Rx/Dx program</b>	
Discovery	IND candidate in 2015
<b>Spark-2 Rx/Dx program</b>	
Discovery	
<b>Spark-3 Rx/Dx program</b>	
Discovery	

Source: Company Reports

## VALUATION

We are increasing our valuation from \$14 to \$17 to reflect recent acquisition of four oncology assets from TEVA. Our price target is derived from a probability-weighted DCF analysis. We project US launch for RXDX-101 in NSCLC (both ROS1+ and TrkA re-arrangement, 50% probability) in 2018, and EU launch in 2019. We assume full internal commercialization in both the US and EU with 8% sales royalty to Nerviano. We assign \$100M valuation (vs. prior \$40M) to pipeline. We assign no terminal value to RXDX-101. We believe 10% discount rate is appropriate given probability-weighted sales estimates.

## RISK TO VALUATION

- RXDX-101 is at early stage with limited clinical efficacy data in patients with ROS1 and ALK genetic alteration.
- Although some preclinical data showed RXDX-101 activity against crizotinib resistant cell lines, activity in crizotinib resistant patients is still unknown.
- New toxicity may emerge under the modified continuous dosing regimen in STARTRK Phase I/IIa study.
- Underlying market opportunity for Trk remains to be clarified.
- Competitive landscape remains wide open and other competitors could emerge rapidly.
- Even with good efficacy as a monotherapy, RXDX-101 may need to be combined with other agents to be competitive.
- Financing risk – Current cash only supports operations into 2016 and RXDX will require additional capital raise before turning to profitability.

RXDX - Income Statement (\$000, except per share value)	2012A	2013A	Mar-14A	Jun-14A	Sep-14A	Dec-14A	2014A	Mar-15E	Jun-15E	Sep-15E	Dec-15E	2015E	2016E	2017E	2018E	2019E
RXDX-101 sales - US							0					0	0	0	8,471	58,747
% to RXDX							92%					92%	92%	92%	92%	92%
RXDX-101 sales - Ex-US							0					0	0	0	0	21,173
% to RXDX							92%					92%	92%	92%	92%	92%
<b>Total revenue</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>150</b>	<b>0</b>	<b>0</b>	<b>150</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>7,793</b>	<b>73,526</b>
COGS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	678	6,394
% gross margin							8%					8%	8%	8%	8%	8%
growth q/q																
R&D	708	10,171	2,183	3,576	8,623	16,123	30,505	16,284	16,447	16,612	16,778	66,121	69,427	72,898	76,543	77,308
% growth q/q				64%	141%	87%	200%	1%	1%	1%	1%	117%	5%	5%	5%	1%
SG&A	548	3,731	1,756	2,039	2,223	3,476	9,494	3,511	3,546	3,581	3,617	14,255	15,681	28,225	42,338	46,571
% growth q/q				16%	9%	56%	154%	1%	1%	1%	1%	50%	10%	80%	50%	10%
% of revenue															543%	63%
<b>Total expenses</b>	<b>1,256</b>	<b>13,902</b>	<b>3,939</b>	<b>5,615</b>	<b>10,846</b>	<b>19,599</b>	<b>39,999</b>	<b>19,795</b>	<b>19,993</b>	<b>20,193</b>	<b>20,395</b>	<b>80,376</b>	<b>85,107</b>	<b>101,123</b>	<b>119,558</b>	<b>130,273</b>
<b>Operating Income</b>	<b>(1,256)</b>	<b>(13,902)</b>	<b>(3,939)</b>	<b>(5,465)</b>	<b>(10,846)</b>	<b>(19,599)</b>	<b>(39,849)</b>	<b>(19,795)</b>	<b>(19,993)</b>	<b>(20,193)</b>	<b>(20,395)</b>	<b>(80,376)</b>	<b>(85,107)</b>	<b>(101,123)</b>	<b>(111,765)</b>	<b>(56,747)</b>
Other income (expenses)	0	(106)	(163)	42	143	(9)	13	0	0	0	0	0	0	0	0	0
Interest income (expenses)	(23)	(204)				(142)	(142)									
Tax	1	2	5	0	0	7	12									
% Tax rate								35%	35%	35%	35%	35%	35%	35%	35%	35%
<b>Net income to common shares</b>	<b>(1,280)</b>	<b>(14,214)</b>	<b>(4,107)</b>	<b>(5,423)</b>	<b>(10,703)</b>	<b>(19,757)</b>	<b>(39,990)</b>	<b>(19,795)</b>	<b>(19,993)</b>	<b>(20,193)</b>	<b>(20,395)</b>	<b>(80,376)</b>	<b>(85,107)</b>	<b>(101,123)</b>	<b>(111,765)</b>	<b>(56,747)</b>
<b>EPS - basic</b>	<b>(2.00)</b>	<b>(3.83)</b>	<b>(0.28)</b>	<b>(0.28)</b>	<b>(0.55)</b>	<b>(1.01)</b>	<b>(2.18)</b>	<b>(0.79)</b>	<b>(0.79)</b>	<b>(0.79)</b>	<b>(0.80)</b>	<b>(3.17)</b>	<b>(2.39)</b>	<b>(2.22)</b>	<b>(2.01)</b>	<b>(1.02)</b>
<b>EPS - dilutive</b>	<b>(2.00)</b>	<b>(3.83)</b>	<b>(0.28)</b>	<b>(0.28)</b>	<b>(0.55)</b>	<b>(1.01)</b>	<b>(2.18)</b>	<b>(0.79)</b>	<b>(0.79)</b>	<b>(0.79)</b>	<b>(0.80)</b>	<b>(3.17)</b>	<b>(2.39)</b>	<b>(2.22)</b>	<b>(2.01)</b>	<b>(1.02)</b>
Basic shares	640	3,712	14,501	19,579	19,580	19,652	18,328	25,200	25,326	25,453	25,580	25,390	35,605	45,641	55,687	55,742
Dilutive shares	640	3,712	16,186	21,268	21,270	21,344	20,017	26,894	27,021	27,150	27,279	27,086	37,306	47,343	57,391	57,448

Sources: Company Reports, Leerink Partners

## Disclosures Appendix

### Analyst Certification

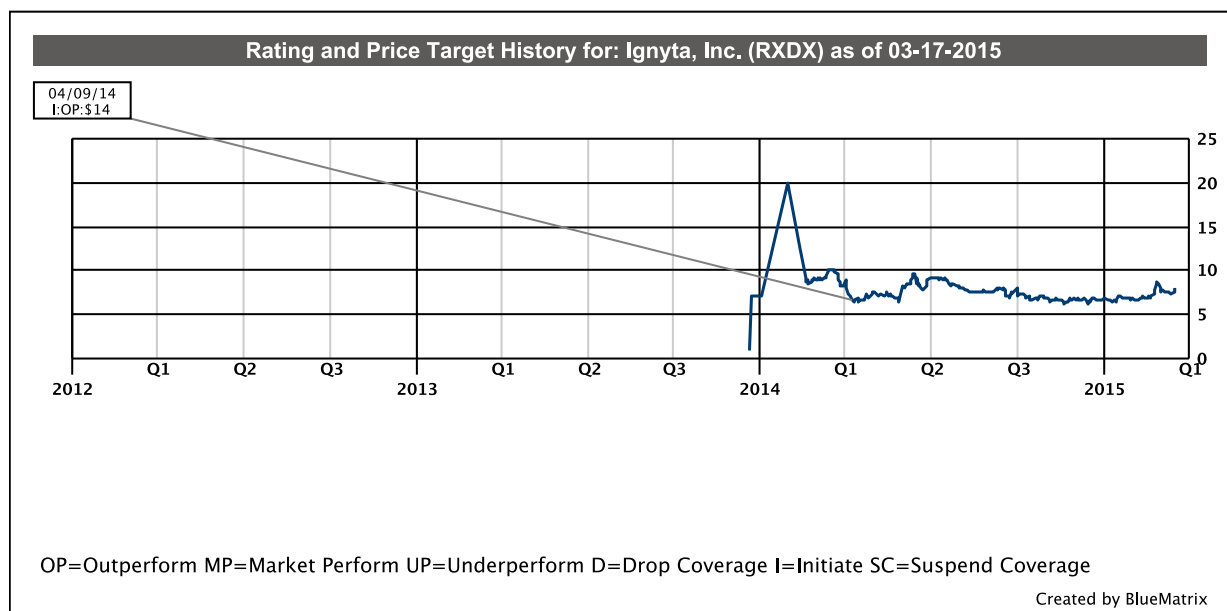
I, Gena Wang, Ph.D., CFA, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

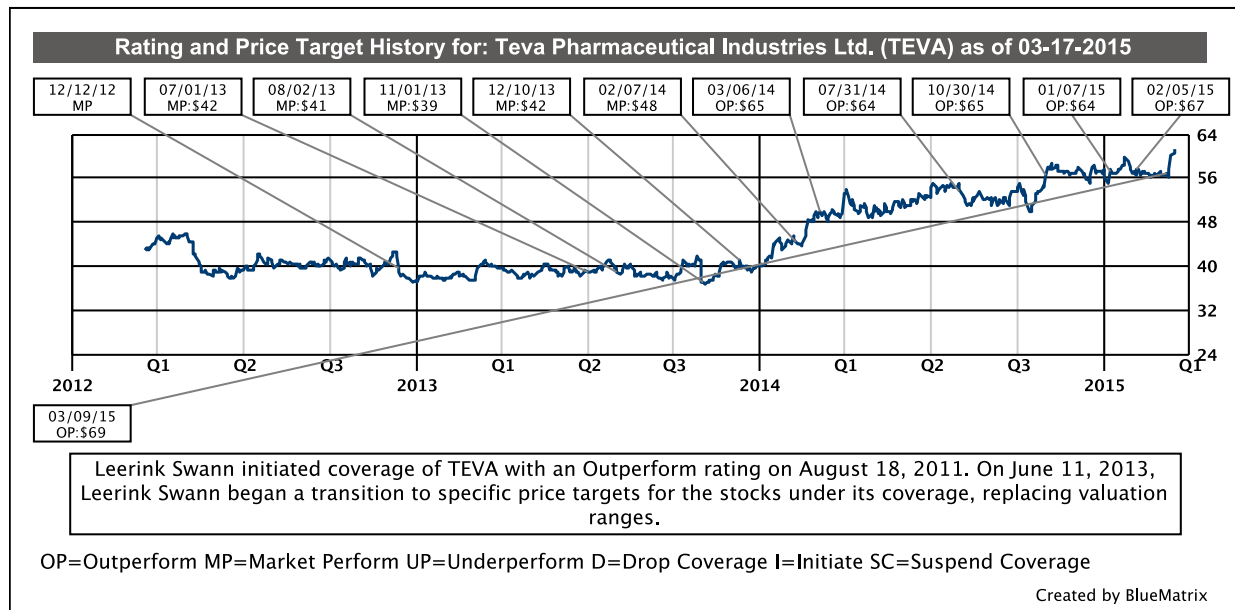
### Valuation

Our valuation \$17/share to reflect recent acquisition of four oncology assets from TEVA. Our price target is derived from a probability-weighted DCF analysis. We project US launch for RXDX-101 in NSCLC (both ROS1+ and TrkA re-arrangement, 50% probability) in 2018, and EU launch in 2019. We assume full internal commercialization in both the US and EU with 8% sales royalty to Nerviano. We assign \$100M valuation to pipeline. We assign no terminal value to RXDX-101. We believe 10% discount rate is appropriate given probability-weighted sales estimates.

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	150	70.00	60	40.00
HOLD [MP]	64	30.00	1	2.00
SELL [UP]	0	0.00	0	0.00

## Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

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Leerink Partners LLC makes a market in Ignyta, Inc. and Teva Pharmaceutical Industries Ltd.

Leerink Partners LLC has acted as the manager for a public offering of Ignyta, Inc. in the past 12 months.

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