August 12, 2014

OUTPERFORM

Reason for report:

EARNINGS

Gena Wang, Ph.D., CFA
(212) 277-6073
Gena.Wang@Leerink.com

Howard Liang, Ph.D.
(617) 918-4857
Howard.Liang@Leerink.com

LEERINK

IGNYTA, INC.

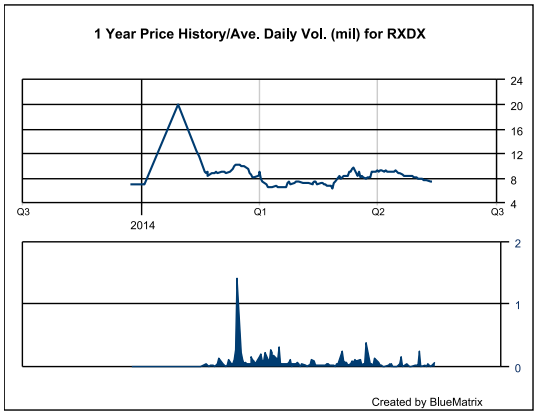
On Track Development, ESMO to Provide More Color on Durability of Response

• **Bottom Line:** Following the recent announcement of the Nerviano licensing deal, there were incremental updates at RXDX's 2Q:14 earnings call. Our key takeaways include: (1) on track Phase I STARTRK-1 initiation (July 2014) for the lead candidate RXDX-101 (oral pan-Trk, ROS1, ALK inhibitor); (2) update from RXDX-101 Phase I Italian trial at the upcoming European Society for Medical Oncology 2014 Congress (ESMO, Sept 26-30, 2014, Madrid) should provide more color on durability of the activity (particularly in one Trk+ patient) and data from additional patients with dose modification. As discussed in our prior 8/11 note (LINK), we view the recent licensing deal in line with RXDX's focus on targeted therapy and expanding the pipeline to include Cdc7 and RET inhibitors. We reiterate our OP rating and $14 price target for RXDX.

• **Longer follow up could provide more color on durability of RXDX-101 activity.** An update of the Italian Phase I trial (ALKA-372-001) will be presented as a poster at ESMO (#448PD, Sept 28). We expect to see longer follow-up data (additional ~4 months at the time of presentation), particularly in one TrkA+ patient. We believe a durable response should have read through to potential clinical activity in the ongoing STARTRK-1 trial (with continuous dosing).

• **Model update.** For 2Q:14, RXDX reported $0.2M in revenue vs. our estimate of $0M. R&D and SG&A expenses were $3.6/2.0M vs. our estimates of $3.1/2.1M. EPS was ($0.28) vs. our estimate of ($0.26). The company ended the quarter with $95.1M cash, sufficient to support operation into 2016 despite the recent licensing deal with Nerviano ($3.5M upfront payment to be recorded Aug 14, 2014). We adjust our estimates to reflect these updates. As a result, our 2014 EPS estimate changes from ($1.35) to ($1.63).

Key Stats:	**(NASDAQ:RXDX)**
S&P 600 Health Care Index:	**1,298.82**
Price:	**$7.50**
Price Target:	$14.00
Methodology:	Probability-weighted DCF analysis, 10% discount rate
52 Week High:	$20.00
52 Week Low:	$1.00
Shares Outstanding (mil):	19.6
Market Capitalization (mil):	$147.0
Book Value/Share:	$5.37
Cash Per Share:	$4.86
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	--	--	--	--	0.0	--	--	--	--	($3.83)	NM
2014E - New	**0.0A**	**$0.2A**	**0.0**	**0.0**	**$0.2**	**($0.28)A**	**($0.28)A**	**($0.58)**	**($0.46)**	**($1.63)**	**NM**
2014E - Old	0.0A	0.0	0.0	0.0	0.0	($0.28)A	($0.26)	($0.37)	($0.41)	($1.35)	NM
2015E - New	**--**	**--**	**--**	**--**	**0.0**	**--**	**--**	**--**	**--**	**($2.00)**	**NM**
2015E - Old	--	--	--	--	0.0	--	--	--	--	($1.81)	NM

Source: Company Information and Leerink Partners LLC Research
Revenues in MM.

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 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 effort to target Trk in multiple tumor types 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 expands 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 potentially six targeted therapies with companion diagnostics in 2015 and beyond.

RXDX – Upcoming Events

Timing	Event
RXDX-101 (Pan-Trk, ROS1, ALK inhibitor)	
2H:14	Phase I update from the Italian trial
2H:14	Ongoing STARTRK-1 Phase I/II dose escalation study with continuous dosing
	Basket Trial expansion cohorts in TrkA, TrkB, TrkC, ROS1, ALK
ASCO 2015	STARTRK data
RXDX-103 (Cdc7 inhibitor)	
Early '16	Initiating Phase I study
RXDX-104 (RET inhibitor)	
2015	Define a candidate
2016	Initiating Phase I study
Spark-1 (Rx/Dx novel target)	
2015	IND candidate

Source: Company Reports

RXDX – Pipeline

Stage of Development	Current Status/Upcoming Developments
RXDX-101 (Pan-Trk, ROS1, ALK inhibitor)	
Phase I	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 most promising tumor types and targets based on ORR and other clinical observations
RXDX-102 (Pan-Trk inhibitor)	
Preclinical	Back-up to RXDX-101
RXDX-103 (Cdc7 inhibitor)	
Preclinical	Enter clinical in 2016
RXDX-104 (RET inhibitor)	
Preclinical	Define candidate in 2015, enter clinical in 2016
Spark-1 Rx/Dx program	
Discovery	IND candidate in 2015
Spark-2 Rx/Dx program	
Discovery	
Spark-3 Rx/Dx program	
Discovery	

Source: Company Reports

VALUATION

Our $14 price target is derived from a probability-weighted DCF analysis. We project US launch for RXDX-101 in non-small cell lung cancer (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 include $100M cash in 1Q:14 following recent IPO and assign $40M valuation to pipeline. We assign no terminal value to RXDX-101. We believe a 10% discount rate is appropriate given probability-weighted sales estimates.

RISKS 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 widely 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 operation into 2016, and RXDX will require additional capital raise before turning profitable.

RXDX - Income Statement ($000, except per share value)	2012A	2013A	Mar-14A	Jun-14A	Sep-14E	Dec-14E	2014E	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%*
Total revenue	**0**	**0**	**0**	**150**	**0**	**0**	**150**	**0**	**0**	**0**	**7,793**	**73,526**
COGS	0	0	0	0	0	0	0	0	0	0	678	6,394
R&D	708	10,171	2,183	3,576	8,864	6,205	20,828	35,630	51,664	64,580	64,580	62,643
% growth q/q				*64%*	*50%*	*-30%*	*105%*	*71%*	*45%*	*25%*	*0%*	*-3%*
SG&A	548	3,731	1,756	2,039	2,651	2,916	9,361	14,885	16,374	32,748	49,121	54,034
% growth q/q				*16%*	*30%*	*10%*	*151%*	*59%*	*10%*	*100%*	*50%*	*10%*
% of revenue											*630%*	*73%*
Total expenses	**1,256**	**13,902**	**3,939**	**5,615**	**11,515**	**9,121**	**30,189**	**50,516**	**68,038**	**97,328**	**114,379**	**123,070**
Operating Income	**(1,256)**	**(13,902)**	**(3,939)**	**(5,465)**	**(11,515)**	**(9,121)**	**(30,039)**	**(50,516)**	**(68,038)**	**(97,328)**	**(106,586)**	**(49,543)**
Other income (expenses)	0	(106)	(163)	42	0	0	(121)	0	0	0	0	0
Interest income (expenses)	(23)	(204)										
Tax	1	2	5	0	0	0	5	0				
% Tax rate								*35%*	*35%*	*35%*	*35%*	*35%*
Net income to common shares	**(1,280)**	**(14,214)**	**(4,107)**	**(5,423)**	**(11,515)**	**(9,121)**	**(30,165)**	**(50,516)**	**(68,038)**	**(97,328)**	**(106,586)**	**(49,543)**
EPS - basic	**(2.00)**	**(3.83)**	**(0.28)**	**(0.28)**	**(0.58)**	**(0.46)**	**(1.63)**	**(2.00)**	**(2.23)**	**(2.40)**	**(2.20)**	**(1.02)**
EPS - dilutive	**(2.00)**	**(3.83)**	**(0.28)**	**(0.28)**	**(0.58)**	**(0.46)**	**(1.63)**	**(2.00)**	**(2.23)**	**(2.40)**	**(2.20)**	**(1.02)**
Basic shares	640	3,712	14,501	19,579	19,775	19,973	18,457	25,236	30,455	40,486	48,526	48,575
Dilutive shares	640	3,712	16,186	21,268	21,467	21,668	20,147	26,940	32,166	42,198	50,240	50,291

Sources: Company Reports, Leerink Partners

Disclosures Appendix

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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.

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
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 Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	**Howard Liang, Ph.D.**	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
Specialty Pharmaceuticals	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
Medical Devices, Cardiology	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
& Orthopedics	**Richard Newitter**	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com
Research Assistant	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164