November 9, 2014

**OUTPERFORM**

Reason for report:

**EARNINGS**

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# IGNYTA, INC.

## 3Q:14 Clinical Development on Track, Major Data Update at ASCO 2015

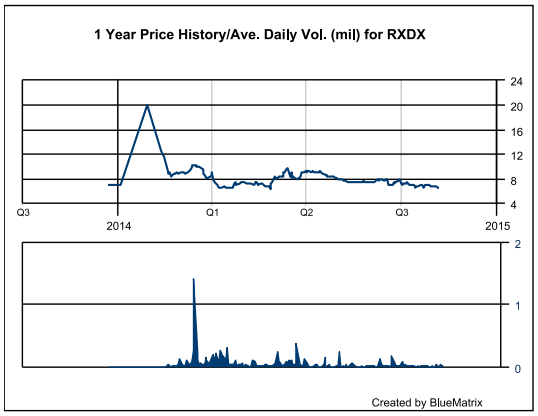
• **Bottom Line:** At RXDX's 3Q:14 earnings call, management provided incremental updates following the recent Investor Day (LINK). Our key takeaways include: (1) RXDX-101 (oral pan-Trk, ROS1, ALK inhibitor) initial data from STARTRK-1 (initiated in July 2014) and an update from ALKA-372-001 (the Italian trial) are likely to be presented at ASCO 2015; (2) a CLIA (clinical laboratory improvement amendments) lab certificate approval is expected by YE:14. With two parallel Phase I trials ongoing and on track in-house development of companion diagnostics, we expect significant body of clinical data to support rapid progress for the '101 program later in 2015, which would continue to position RXDX as the leader in the Trk targeted therapy. We reiterate our OP rating and $14 price target for RXDX.

• **Two parallel Phase I trials should provide body of clinical data by mid-15.** Recent update of the ALKA Phase I data at ESMO (LINK) provided three dosing regimens for '101 (Schedule A – 4-day on, 3-day off, 3-week on, 1-week off; Schedule B – continuous dosing; Schedule C – 4-day on, 3-day off, no 1-week drug holiday). Data at ASCO 2015 should provide an update of the ALKA trial at higher doses with Schedule B and C, as well as initial data of Schedule B from the STARTRK-1 trial. Safety/activity data from Schedule C so far are promising, which could serve as a back-up regimen if severe toxicity emerges with Schedule B.

• **CLIA lab approval preparing for in-house diagnostics.** Management plans to develop in-house companion diagnostics for most targeted therapies. RXDX is on track to receive a CLIA certificate (by YE:14), which is critical to establish in-house diagnostics for the Phase II STARTRK trial.

• **Model update.** For 3Q:14, RXDX reported R&D and SG&A expenses of $8.6/2.2M vs. our estimates of $8.9/2.7M. EPS was ($0.55) vs. our estimate of ($0.58). The company ended the quarter with $94.7M cash, sufficient to support operations into 2016 despite the recent licensing deal with Nerviano ($3.5M upfront payment to Nerviano in 3Q:14). We adjust our estimates to reflect these updates. As a result, our 2014 EPS estimate changes from ($1.63) to ($1.56).

| **Key Stats:** | **(NASDAQ:RXDX)** |
|---|---|
| **S&P 600 Health Care Index:** | **1,348.10** |
| **Price:** | **$6.65** |
| 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): | $130.3 |
| 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** | **0.0A** | **0.0** | **$0.2** | **($0.28)A** | **($0.28)A** | **($0.55)A** | **($0.43)** | **($1.56)** | **NM** |
| **2014E - Old** | 0.0A | $0.2A | 0.0A | 0.0 | $0.2 | ($0.28)A | ($0.28)A | ($0.58) | ($0.46) | ($1.63) | NM |
| **2015E - New** | **--** | **--** | **--** | **--** | **0.0** | **--** | **--** | **--** | **--** | **($2.09)** | **NM** |
| **2015E - Old** | -- | -- | -- | -- | 0.0 | -- | -- | -- | -- | ($2.00) | NM |

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

**Please refer to pages 6 - 8 for Important Disclosures, Price Charts and Analyst Certification.**

## 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.

**RXDX – Upcoming Events**

| Timing | Event |
|---|---|
| **Diagnostics** | |
| YE:14 | Receive a CLIA lab certificate |
| **RXDX-101 (Pan-Trk, ROS1, ALK inhibitor)** | |
| 4Q:14 | Ongoing ALKA-372-001 and STARTRK-1 Phase I/II 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)** | |
| 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 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 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 assume additional capital raise in 2015 and assign $40M valuation 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-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 | 8,623 | 6,036 | 20,418 | 34,662 | 50,259 | 62,824 | 62,824 | 60,939 |
| *% growth q/q* | | | | *64%* | *141%* | *-30%* | *101%* | *70%* | *45%* | *25%* | *0%* | *-3%* |
| SG&A | 548 | 3,731 | 1,756 | 2,039 | 2,223 | 2,445 | 8,463 | 12,484 | 13,732 | 27,464 | 41,196 | 45,315 |
| *% growth q/q* | | | | *16%* | *9%* | *10%* | *127%* | *48%* | *10%* | *100%* | *50%* | *10%* |
| *% of revenue* | | | | | | | | | | | *529%* | *62%* |
| **Total expenses** | **1,256** | **13,902** | **3,939** | **5,615** | **10,846** | **8,481** | **28,881** | **47,145** | **63,991** | **90,288** | **104,697** | **112,648** |
| **Operating Income** | **(1,256)** | **(13,902)** | **(3,939)** | **(5,465)** | **(10,846)** | **(8,481)** | **(28,731)** | **(47,145)** | **(63,991)** | **(90,288)** | **(96,904)** | **(39,122)** |
| Other income (expenses) | 0 | (106) | (163) | 42 | 143 | 0 | 22 | 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)** | **(10,703)** | **(8,481)** | **(28,714)** | **(47,145)** | **(63,991)** | **(90,288)** | **(96,904)** | **(39,122)** |
| **EPS - basic** | **(2.00)** | **(3.83)** | **(0.28)** | **(0.28)** | **(0.55)** | **(0.43)** | **(1.56)** | **(2.09)** | **(2.54)** | **(2.56)** | **(2.14)** | **(0.86)** |
| **EPS - dilutive** | **(2.00)** | **(3.83)** | **(0.28)** | **(0.28)** | **(0.55)** | **(0.43)** | **(1.56)** | **(2.09)** | **(2.54)** | **(2.56)** | **(2.14)** | **(0.86)** |
| Basic shares | 640 | 3,712 | 14,501 | 19,579 | 19,580 | 19,776 | 18,359 | 22,530 | 25,224 | 35,250 | 45,285 | 45,330 |
| Dilutive shares | 640 | 3,712 | 16,186 | 21,268 | 21,270 | 21,468 | 20,048 | 24,227 | 26,925 | 36,952 | 46,989 | 47,036 |

*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 $14 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 assume additional capital raise in 2015 and assign $40M valuation to pipeline. We assign no terminal value to RXDX-101. We believe 10% discount rate is appropriate given probability-weighted sales estimates.

## Risks to Valuation

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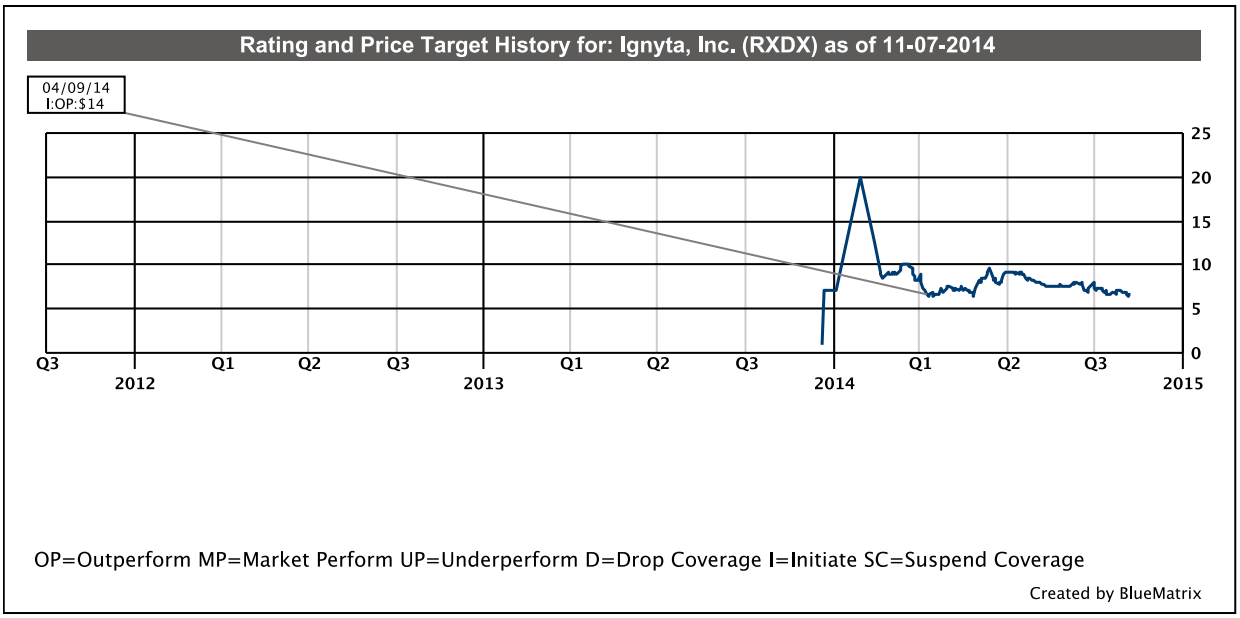

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| Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14 | | | | |
|---|---|---|---|---|
| | | | IB Serv./Past 12 Mos. | |
| Rating | Count | Percent | Count | Percent |
| BUY [OP] | 138 | 69.30 | 51 | 37.00 |
| HOLD [MP] | 61 | 30.70 | 2 | 3.30 |
| 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.

## Important Disclosures

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Leerink Partners LLC makes a market in Ignyta, Inc.

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

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