FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

November 14, 2014

Jefferies

Radius Health (RDUS)

Attractive Risk/Reward Ahead of Ph3 Data for Abaloparatide in Late-December

BUY
Price target $26.00
Price $21.75

EQUITY RESEARCH AMERICAS

Key Takeaway

While current valuation implies ~80% probability for Ph3 success for lead drug abaloparatide (ABL) in PMO, at limited downside risks (Ph3 failure very unlikely per experts), we see potentially significant upside from (1) a call option for ABL showing superiority to competitor Forteo in reducing non-vertebral fracture (albeit low probability; not required for FDA approval) and/or (2) yet-to-be recognized full potential of 2nd drug RAD1901 (SERD) in BC.

We view risk/rewards for RDUS as attractive ahead of Ph3 data for lead drug abaloparatide-SC (ABL) in late-December. RDUS current valuation of ~$750M implies ~80% probability of Ph3 success for ABL in postmenopausal osteoporosis (PMO). Experts' discussions point to unlikely failure of Ph3 (≤10% probability in our view), thus limited downside risks. However, we see meaningful upside potential from current levels from: (1) a call option for ABL potentially showing superiority over competitor Forteo in reducing new non-vertebral fractures (albeit low likelihood, a high bar per experts), providing likely >50% upside (not in current expectations/not required for FDA approval); and/or (2) yet-to-be fully recognized potential of its second drug RAD1901 (SERD) in breast cancer (BC in Ph1) showing early differentiation (vs. Seragon's SERD ARN-810 in Ph1; Seragon was acquired by Roche for a value up to $1.725B).

Endocrinologists/rheumatologists discussions indicate high likelihood of Ph3 success for abaloparatide-SC (ABL) in PMO. Ph3 ACTIVE study compares ABL 80ug vs. placebo vs. Forteo 20ug (~800 pts on each arm). Primary endpoint is reduction in new vertebral fractures for ABL vs. placebo at 18 months; secondary endpoints include (1) reduction in new non-vertebral fractures for ABL vs. placebo at 18 mo, (2) difference in spine, total hip and femoral neck BMD for ABL vs. Forteo, and (3) difference in hypercalcemia rates in ABL vs. Forteo. With widely anticipated superiority of ABL vs. placebo for approval, focus is on potential ABL benefits vs. Forteo. Based on Ph2 data, including continued greater BMD gains at 12mo (ABL 12.9% vs. Forteo 8.6% for spine & ABL 4.1% vs. Forteo 2.2% for femoral neck) and ~50% less hypercalcemia, likelihood for achieving secondary endpoints (vs. Forteo) seem high. Ph3 study is 90% powered to show ~56% reduction in vertebral fractures with ABL vs. placebo (~7% vs. ~3%) (vs. ~65% reduction in previous Forteo study) & assumes a ~20% dropout rate (similar to historical rates). For non-vertebral fractures, Forteo showed ~40% relative risk reduction for ≥1 fractures over placebo (~10% vs. ~6%).

Experts expect relative reductions of ~70% in vertebral & ~30-40% non-vertebral fractures with ABL (vs. placebo); discussions indicate our ABL assumption of ~40% Forteo market share at peak is achievable. With only one anabolic agent currently on market (Forteo, ~$1.25B in 2013 sales), experts view new products entry (e.g., ABL, romosozumab) will likely expand the anabolic market (by ~15-20%). In addition, ex-bisphosphonate users (resulting from ~30% decline in bisphosphonate use from 2008 to 2013 due to long-term adverse events) could be candidates for new therapy. Experts also note ABL's potential benefits of higher BMD and lower hypercalcemia (vs. Forteo) will likely help capture Forteo market share.

If ABL shows superiority over Forteo in reducing non-vertebral fractures (our best-case scenario, but not in current expectations; a high bar in 18mo study period per experts), we estimate ~50% potential upside to our current estimates (WW peak sales of ~$500M). Forteo efficacy in non-vertebral fracture reduction (i.e., hip, wrist, pelvis, humerus, rib, foot, and ankle) is not as strong as in vertebral sites. With higher BMD increases, its ability to strengthen cortical bones, no bone remodeling & bone resilience (in monkeys), ABL has potential to show superior non-vertebral fracture reduction (vs. Forteo). As Forteo maximal benefits are gained with anti-resorptive treatment following Forteo, experts felt an 18-mo study period might not be long enough to see efficacy separation between ABL & Forteo, although possible in ~2-3 year period.

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Company Description

Radius Health, Inc. is a biopharmaceutical company focused on developing therapies for osteoporosis and other endocrine diseases. The company's lead product is abaloparatide-SC (BA058), a novel synthetic peptide analog of parathyroid hormone-related protein (PTHrP), with topline data readout for ongoing Phase 3 for osteoporosis expected in December 2014. Additional pipeline products include a transdermal patch of abaloparatide, abaloparatide-TD; RAD1901, an oral selective estrogen receptor down-regulator/degrader (SERD) for the treatment of breast cancer brain metastases and vasomotor symptoms; and RAD140, a nonsteroidal selective androgen receptor modulator. Radius was founded in 2003 and is headquartered in Cambridge, Massachusetts.

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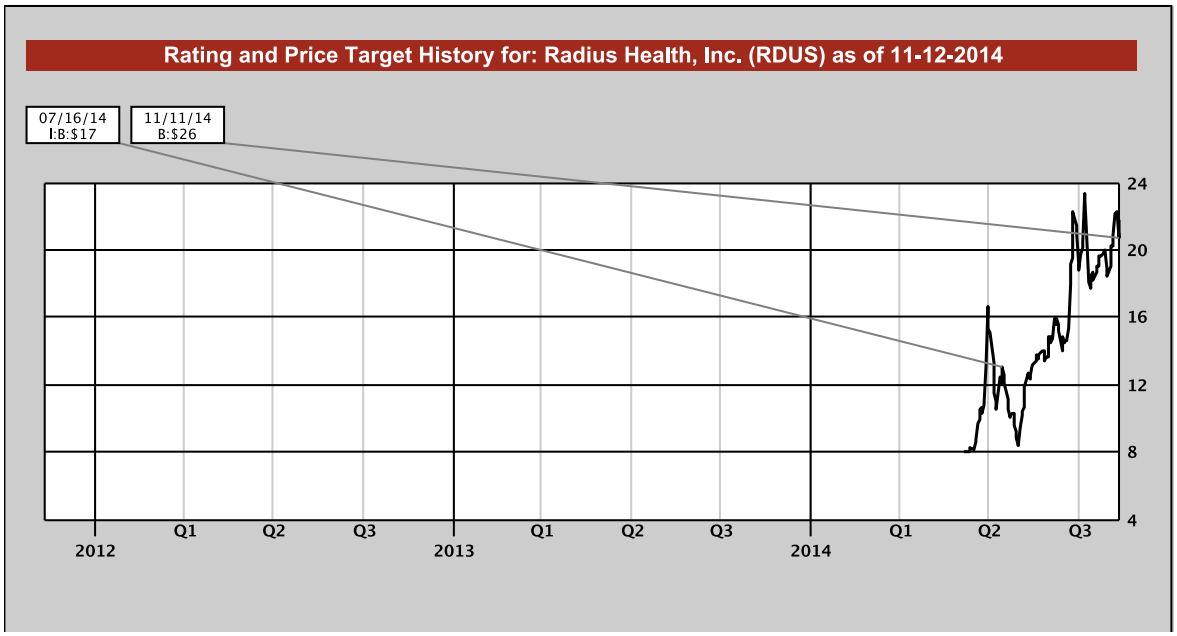

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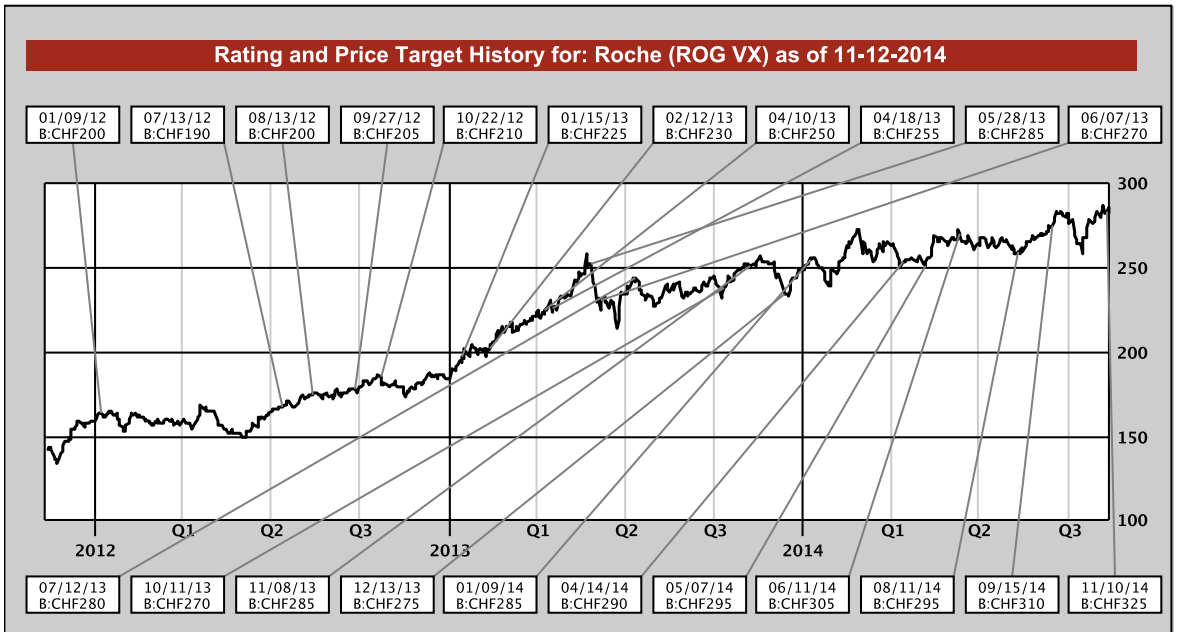

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