FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

December 6, 2013

Jefferies

Five Prime Therapeutics, Inc. (FPRX)
Update from Management Meetings

BUY
Price target $20.00
Price $11.01

EQUITY RESEARCH AMERICAS

Key Takeaway

FPRX discussed potential safety advantages of lead product FP-1039 (only biologic targeting FGFR in clinic) vs. oral FGFR TKIs (lucitanib, dovitinib). For new targets in immunotherapy program, FPRX expects a partnership in 2014. With multiple ongoing programs, at its EV of $100M, FPRX is attractive, particularly compared to CLVS recent acquisition cost for lucitanib (oral FGFR/VEGFR TKI in Ph1/2), $200M upfront plus $220M in potential milestones.

FPRX is in the process of identifying new targets in its immunotherapy program, with a potential early drug discovery partnership in 2014. FPRX notes that there are additional targets in immunotherapy aside from PD1, PD-L1 and CTLA4. Given that immunotherapy is fast-moving and highly competitive, FPRX may not disclose targets near term. However, it notes a likely partnership in immunotherapy next year.

FP-1039 (FGF ligand trap) is the only biologic targeting FGFR in clinic (vs. oral TKIs such as lucitanib, dovitinib), with potential safety/tolerability advantages. FPRX notes non-selective inhibition of FGFRs with oral TKIs is associated with known side effects (e.g., hyperphosphatemia) via blockade of ligand FGF23 signaling. However, FP-1039 does not block all FGFR-dependent ligands, and importantly it does not block FGF23 (as FP-1039 does not have co-receptor required for FGF23). One of the drawbacks with oral FGFR TKIs is dose-limiting toxicities (DLTs), in the case with Novartis' (NOVN VX, Buy) dovitinib (orally active FGFR (1-3)/VEGFR/PDGFR TKI) - potentially limiting efficacy.

CLVS recently acquired lucitanib (oral dual selective FGFR1/2-VEGFR1-3 TKI) is an active agent, but may be more active against VEGFR vs. FGFR. On 11/19/13, Clovis Oncology (CLVS, NC) acquired Ethical Oncology Science (EOS) for $200M ($10M cash+$190M in CLVS stock) for lucitanib in the U.S./Japan (Les Laboratoires Servier for Europe and RoW), plus $220M in potential milestones. This underscores potential/rising interest for FGFR pathway as new drug target for cancer. Interim Ph1/2a study (n=~110), lucitanib (10,15, or 20mg daily) showed 50% PR (n=6/12) in heavily treated breast cancer patients (median 6 lines of prior therapy) with FGF aberrations (either FGFR1 or 11q amplified); CLVS plans to initiate POC Ph2 in FGFR1-amplified squamous lung cancer (timeline undisclosed). With lucitanib, there has been no hyperphosphatemia observed to date. However, FPRX management indicates that lucitanib may be a more potent inhibitor of VEGFR (VEGF inhibition related DLTs such as hypertension, GI side effects) vs. FGFR. Thus, at the dose used, it may not sufficiently inhibit FGFR to cause hyperphosphatemia.

Preliminary efficacy data for partner GSK-run Ph1b for FP-1039 is on track for 2H14; there is no strict go/no go criteria yet given the single-arm trial design (FP-1039+paclitaxel/carboplatin in first-line NSCLC or FP-1039+docetaxel in 2nd-line NSCLC) in FGFR1-amplified squamous NSCLC (~20% of the cases). In 1st-line NSCLC, ORR with current treatment is ~20-25%; in 2nd-line, it is ~5-10%. It remains to be seen if FP-1039 will increase ORR, duration of response, and/or PFS.

FPRX decision to pursue FPA008 (anti-CSF1R mAb) in inflammation vs. cancer is based on more clearly defined role of macrophage in inflammation. While potential in cancer remains (tumor-associated macrophage (TAM) infiltration in cancer invasion), the function of TAMs remains controversial with growing evidence for their involvement in both promotion of growth/metastasis via angiogenesis as well as anti-tumor activity. Thus, FPRX notes inflammation is a more straightforward indication, whereas a lot of assumptions need to be made for cancer. FPA008 is designed more for anti-macrophage vs. anti-tumor (via ADCC), compared to Eli Lilly's (LLY, Underperform) CSF1R mAb with ADCC (antibody-dependent cell-mediated cytotoxicity, in Ph1). Ph1 for FP008 is designed for preliminary safety/biomarker, with two key biomarkers of macrophage and bone turnover. Data is expected by YE14.

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Company Description

Five Prime Therapeutics, Inc. is an early clinical stage biotechnology company focused on discovering and developing new protein therapeutics in cancer and inflammatory diseases. Five Prime's product candidates include FP-1039/GSK3052230, a biologic (FGF ligand trap) for trapping and neutralizing cancer-promoting fibroblast growth factors (FGFs) involved in cancer cell proliferation and new blood vessel formation, which is partnered with GlaxoSmithKline; FPA008, an antibody that inhibits colony stimulating factor-1 receptor (CSF-1R); and FPA144, an antibody for inhibiting FGF receptor 2b (anti-FGFR2b mAb). In addition, Five Prime has early drug discovery partnerships with GlaxoSmithKline and UCB Pharma S.A. Founded in 2001 and IPOed in September 2013, Five Prime is headquartered in San Francisco, California.

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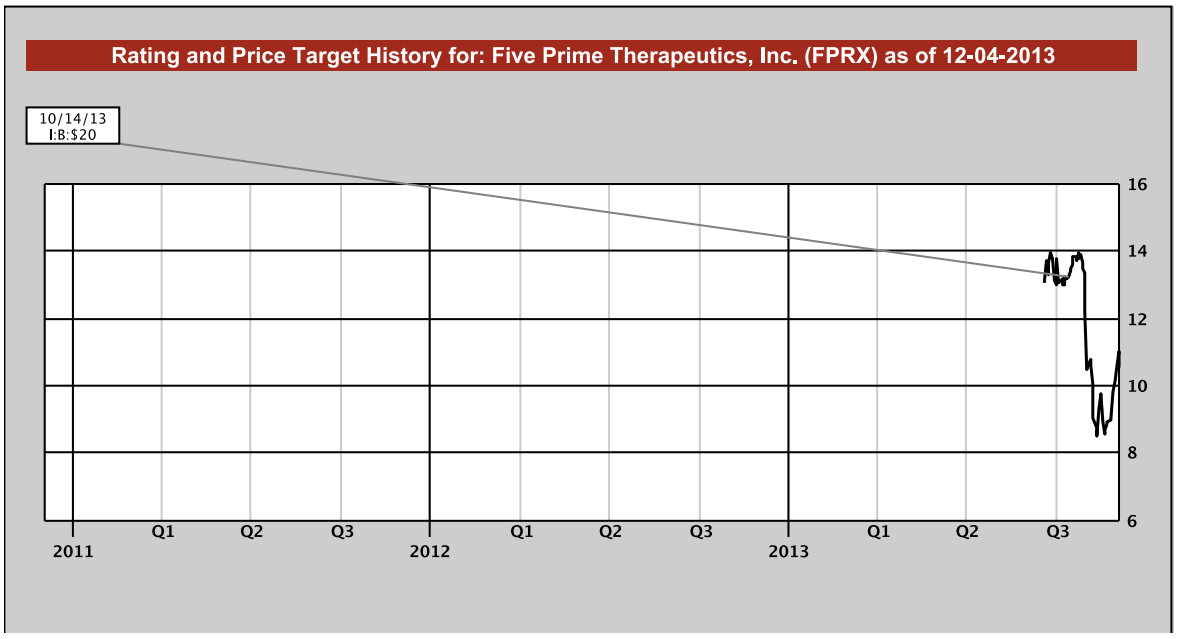
- Eli Lilly & Co. (LLY: $49.96, UNDERPERFORM)
- Novartis AG (NOVN VX: CHF70.15, BUY)



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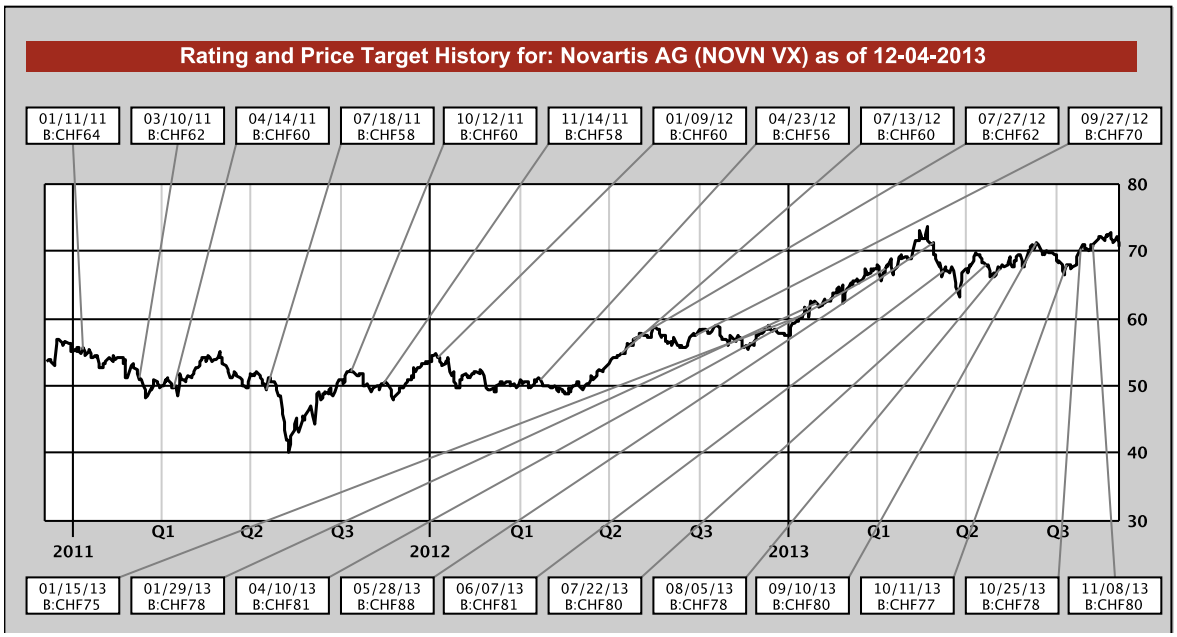

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