

Equity Research

Five Prime Therapeutics, Inc.

FPRX: We Are Initiating Coverage With An Outperform Rating

Outperform / V

Sector: Biotechnology

Market Weight

Initiation of Coverage

• **Summary:** We are initiating coverage of Five Prime with an Outperform rating on the shares and a \$17-19 valuation range. We believe FP-1039 and FPA008 have considerable promise in cancer and inflammatory diseases, respectively, and expect these agents and the likely sustainable stream of other biologics flowing out of their differentiated discovery platform to drive long-term value. Our valuation is based on a blend of probability-adjusted, discounted out-year EPS and sales multiples, combined with technology value.

• **We believe FPRX's biologics discovery platform provides the foundation for a sustainable pipeline and long-term revenue growth.** Five Prime's core technology is a comprehensive and efficient platform for the discovery of protein-based therapeutics, or biologics, incorporating a broad expression library of potential drug targets and high-throughput screening and validation systems. Through a combination of expertise, effort, and inventiveness, we believe FPRX has overcome shortcomings of other biologics engines, enabling a differentiated ability to discover and develop novel drugs for cancer and inflammatory diseases. We believe the platform's capabilities have been validated by the clinical and preclinical agents, and novel targets that have stemmed from it, as well as multiple collaborations with large pharma companies.

• **Lead asset FP-1039 has the potential to be an effective, safe therapy for a range of targeted cancer indications.** '1039's mechanism of inhibiting FGFs, signaling factors known to promote tumor growth and angiogenesis, has good scientific rationale, in our view, and FPRX's approach of using a ligand trap could improve the therapeutic window versus other developmental drugs targeting this pathway. Indeed, '1039 appeared well tolerated in an initial phase I solid tumor study, and we believe the recently initiated phase Ib in patients with FGFR-1 amplification should enable clearer proof of concept of its potential activity when data are available in H2 2014. Though early, we believe '1039's long-term potential in both FGFR-1-amplified and angiogenesis-driven tumors could be considerable, and estimate probability-adjusted sales of \$360+ million by 2023, on which FPRX would receive royalties from partner GSK.

• **We view FPA008 as promising for a number of inflammatory diseases.** '008, a wholly owned antibody against CSF-1R expected to enter the clinic by year-end, showed robust preclinical evidence of activity. This, combined with its direct effects on monocytes/macrophages--upstream of several tried-and-true anti-inflammatory targets--makes it more likely the agent will ultimately demonstrate clinical benefits, in our view. Assuming FPRX can successfully optimize its efficacy/safety balance and confirm its potential areas of differentiation, we believe it could have a broad market opportunity in a number of inflammatory indications such as rheumatoid arthritis and psoriasis.

Valuation Range: \$17.00 to \$19.00 from NE to NE

Our valuation range is based on applying a 30x multiple to our 2023 estimated EPS and discounting at 15%, blended with 2.5x multiple of 2023 estimated sales, and discounting 10-12%, plus \$4 for technology/pipeline value. Key risks, in our view, are clinical and regulatory failure of its programs, competition, and financing.

Investment Thesis:

We believe Five Prime's technology platform and biologics stemming from it will drive long-term value.

Please see page 8 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 10/14/13 unless otherwise stated.

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	2012A	2013E	2014E	
EPS		Curr. Prior	Curr. Prior	
Q1 (Mar.)	NE	NE A	NE	
Q2 (June)	NE	NE A	NE	
Q3 (Sep.)	NE	(0.43)	NE	NE
Q4 (Dec.)	NE	(0.47)	NE	NE
FY	(\$23.05)	(\$3.27)	NE	(\$1.68) NE
CY	(\$23.05)	(\$3.27)		(\$1.68)
FY P/E	NM	NM		NM
Rev.(MM)	\$10	\$12		\$15

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

Ticker	FPRX
Price (10/11/2013)	\$13.19
52-Week Range:	\$12-16
Shares Outstanding: (MM)	16.8
Market Cap.: (MM)	\$221.6
S&P 500:	1,703.20
Avg. Daily Vol.:	356,588
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	NE
CY 2013 Est. P/E-to-Growth:	NM
Last Reporting Date:	09/05/2013
	After Close

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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Together we'll go far



Company Description:

Five Prime Therapeutics (FPRX), Inc., headquartered in South San Francisco, California, is a biotechnology company focused on discovering and developing protein therapeutic candidates based on its extensive library of 5,600+ extracellular proteins, including ligands and receptors. Its lead development candidate is FP-1039 [ph.I(b)], an FGFR1-targeted ligand trap in development for solid tumors and partnered with GlaxoSmithKline. Behind '1039, its unpartnered pipeline includes FPA008 (ph.I) a monoclonal antibody in development for inflammatory diseases (e.g., rheumatoid arthritis), and FPA144 (preclinical), an antibody for gastric cancer. Beyond its three lead programs, Five Prime has discovery collaborations with GSK for muscle diseases (sarcopenia and cachexia) and respiratory diseases (refractory asthma and COPD) and UCB Pharma for fibrotic-related immunologic and CNS diseases.

For more details, please see our full-length report, to be published shortly.

Investment Thesis

We are initiating coverage of Five Prime Therapeutics with an Outperform rating and a \$17-19 valuation range. We believe FP-1039 and FPA008 have considerable promise in cancer and inflammatory diseases, respectively, and expect these agents and the likely sustainable stream of other biologics, including FPA144 and novel cancer immunotherapies, flowing out of their differentiated discovery platform, to drive long-term value.

We believe Five Prime's discovery platform provides a differentiated foundation for the company, enabling organic pipeline growth and external partnerships to drive long-term, sustainable value. Five Prime's core technology is a comprehensive and efficient platform for the discovery of protein-based therapeutics, or biologics. Although there are other companies with existing protein-based discovery engines, they have shortcomings that Five Prime has been able to address, we believe, through a combination of experience, time, effort, and inventiveness. One cornerstone is the company's comprehensive protein expression library containing 5,600 proteins--the majority of the receptors and secreted proteins amenable to biologic intervention--in complete, full-length, and functional form, which enables a vast database for drug screening and limits artifacts. Five Prime has also developed a highly automated, high-throughput protein screening system to rapidly interrogate potential drug targets within this library, as well as an efficient *in vivo* system to validate such targets in disease-relevant animal models. We believe that these elements will provide Five Prime with a differentiated ability to discover, optimize, and develop novel biologics for cancer and inflammatory diseases, a considerable market (such drugs had sales of more than \$71 billion in 2012). Discovery partnerships with several major pharmas, such as GSK and UCB Pharma, in our opinion, validate the attractiveness of Five Prime's platform and have also demonstrated its ability help Five Prime generate nondilutive capital (\$220 million since 2006).

Lead drug FP-1039, in our view, has the potential to be an effective and safe therapy for a broad range of targeted cancer indications. FP-1039 is a fusion protein that uses the fibroblast growth factor receptor 1 (FGFR-1) as a "decoy" receptor to serve as a ligand trap for FGFs, signaling factors known to promote tumor growth and angiogenesis. Partnered with GSK, it recently entered a phase Ib study. Although there are no marketed cancer drugs that inhibit FGF this specifically, we believe animal studies, mutational screening of human cancers, and signals of clinical activity observed with other developmental mediators of the pathway provide solid evidence it is a valid approach. By virtue of being constructed as a ligand trap, we believe '1039 also has the potential for an improved profile compared to other FGF-pathway targeted agents currently or previously in development. This includes less off-target side effects on tyrosine kinases like VEGF compared to small molecules, and fewer interactions with hormonal FGFs; these could enable higher dosing, greater activity, and better tolerability. Indeed, in an initial phase I study in advanced cancer patients, '1039 looked safe, at doses that conferred adequate inhibition of FGF signalling. Although the nonselected patient population made it difficult to get a read on activity, we believe we could see clearer efficacy signals in the recently initiated phase Ib study in NSCLC and other solid tumors, as it will enroll patients with FGFR-1 amplification who--by virtue of having tumors likely more dependent on this pathway--should benefit more from '1039. Though a subpopulation, there are still a meaningful (6-22%) portion of patients with common solid tumors who are believed to have FGFR-1 amplification, providing substantial market opportunity. Considerable additional market potential could come from '1039's use in angiogenesis-mediated tumors such as renal cell carcinoma (RCC) and hepatocellular carcinoma (HCC), where preclinical data have shown the drug's potential to be complementary to VEGF inhibitors by preventing a potential angiogenesis escape pathway. Overall, we estimate blended probability-weighted sales of more than \$360 million by 2023, with more than \$1 billion in overall potential if successful in multiple tumor types.

We believe FPA008, Five Prime's next asset, has promise in a number of inflammatory diseases. FPA008 is a wholly owned antibody against CSF1-R expected to enter the clinic by year-end. The CSF-1R pathway has become a more closely studied target, as survival and proliferation of monocytes and macrophages--cells that are key in the inflammatory process--are mediated through the CSF-1 receptor and its signaling ligands, CSF-1 and IL-34 (the latter of which was discovered through Five Prime's platform). Preclinical data indicated strong activity of Five Prime's antibody in the validated CIA mouse model of rheumatoid arthritis (RA), where the agent reduced joint swelling and bone damage vs. marketed biologic Enbrel, in our view increasing the likelihood that it will show clinical efficacy. As with any immunomodulatory approach for inflammatory diseases, Five Prime would need to optimize the efficacy/safety balance for each indication. Still, several factors, including its natural preference for inflammatory versus anti-infective cells, low ADCC activity, and dosing cushion before a liver biomarker might be observed, increase our confidence the drug will have a therapeutic window that is clinically and commercially acceptable. Though there are many drugs on the market or in development for inflammatory diseases, there remains a considerable unmet need across diseases including lupus, RA, MS, and psoriasis, where there is also strong scientific rationale for CSF-1R inhibition. Additionally, '008 has the potential to be differentiated through better structural benefits in diseases like RA, owing to its more direct inhibition of bone-eroding osteoclasts, and through the possibility of using activated monocyte levels in a companion diagnostic to predict response. '008 is set to enter a phase I by year-end exploring safety, PK, and monocyte reductions, with a subsequent transition into RA patients. Though the drug is early, we believe the longer-term opportunity for '008 could be considerable, and estimate nearly \$300 million worldwide in RA and psoriasis early in its launch, with blockbuster potential beyond this.

FPA144, as well as other programs in early-stage development, illustrate the pipeline breadth that Five Prime's platform has the potential to create. FPA144 is a monoclonal antibody targeting FGFR2b, designed to have ADCC activity against cells expressing the FGFR2b receptor, which has been found to be overexpressed in certain solid tumors such as a subset of gastric cancers. Xenograft data for the mAb demonstrated dose-dependent tumor suppression in an FGFR2-amplified gastric cancer model, suggestive of its potential activity. Given its early stage of development (it is slated to enter the clinic in H2 2014), we do not currently include the program in our valuation. However, we believe it could have the potential for both an accelerated development path in the United States, due to the small patient population, as well as a broader market opportunity in Asia, where gastric cancer is more common. Beyond FPA144, Five Prime also has multiple other targeted biologic agents in preclinical development stemming from its discovery platform, which we believe could provide a steady stream of value-generating assets, including novel cancer immunotherapies and drugs for steroid-resistant asthma.

Valuation

We have established a \$17-19 valuation range for Five Prime. We based our valuation analysis on our probability-adjusted revenue projections for FP-1039 in various solid tumor types and FPA008 in RA and psoriasis. We assume 15-35% probabilities of success for FP-1039, depending on the indication and extensiveness of the clinical and preclinical evidence, and a 20% probability of success for FPA008 in light of its early stage. Assuming approximately 25.7 million diluted shares outstanding, which accounts for several potentially dilutive capital raises as well as a \$75 million upfront payment for an FPA008 partnership, we arrived at a probability-adjusted 2023 EPS of \$1.53. Applying a 30x multiple, which we believe is appropriate for a biotechnology company of Five Prime's size and potential, and discounting at 15% for slightly over nine years, would yield a valuation of \$13. Using a valuation analysis based on sales multiples, applying a 2.5x multiple (assuming all programs are partnered) on our estimated probability-adjusted worldwide product sales of \$422 million, and discounting back slightly over nine years at 10-12% yields a potential valuation range of \$16. Blending these two methodologies and adding \$4.00 for the company's technology value, would yield a valuation range of \$17-19.

Exhibit 1. Valuation Analysis

Year:	2023E	Discount (yrs)	9.2	EPS:	\$1.53	Shares out:	25,700
Product:	Indication:	Region	Probability of success:	Prob-weighted sales	Net to company:	Probability-weighted EPS contribution:	
FP-1039	Various solid tumors	Worldwide	13-35%	\$363M	9%	\$1.31	
FPA008	RA, psoriasis	Worldwide	20%	\$59M	9%	\$0.21	
Total				\$422M		\$1.53	
Discount Rate:							
EPS Multiple:	5%	10%	15%	20%	25%		
15	\$15	\$9	\$6	\$4	\$3		
20	\$19	\$13	\$8	\$6	\$4		
25	\$24	\$16	\$10	\$7	\$5		
30	\$29	\$19	\$13	\$9	\$6		
35	\$34	\$22	\$15	\$10	\$7		
40	\$39	\$25	\$17	\$11	\$8		
Discount Rate:							
Sales Multiple:	9%	10%	11%	12%	13%		
1.5	\$11	\$10	\$9	\$9	\$8		
2.5	\$19	\$17	\$16	\$14	\$13		
3.5	\$26	\$24	\$22	\$20	\$19		

Blended EPS and sales multiples	\$14
Technology/early-stage pipeline value	\$4
Implied fair value	\$18

Source: Wells Fargo Securities, LLC estimates

Upcoming Milestones And Product Pipeline**Exhibit 2. Upcoming milestones**

Product	Event	Timeline
FP-1039	Top-line results from ph.Ib study	2H14
	Potential pre-ph.IIb study meeting with FDA	2H14/1H15
	Consider initiating ph.II/III randomized study of SOC +/-1039 in NSCLC	2015
	Explore studies in other cancer indications (GIST, mesothelioma, GBM, RCC, HCC)	2014/2015
FPA008	Complete manufacture of drug substance for ph.I	End-2013
	Initiate ph.I study	End-2013
	Ph.I top-line PK and safety results	2H14
	Expand ph.I study to include RA patients	2H14
	Introduce SC formulation	2H14/2015
	File IND, initiate ph.II study likely in biologics failures	2015
	Explore other inflammatory diseases (IPF, lupus nephritis, etc.)	2015
FPA144	File IND	2014
	Initiate ph.I study	2H14
	Top-line ph.I results	2015

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 3. Product pipeline

Product (partner)	Indication/mechanism	Status
FP-1039 (GSK)	Oncology (multiple solid tumors); FGF Ligand Trap	Phase Ib
FPA008	Autoimmune disease; CSF1R antibody	Entering phase I
FPA144	Gastric cancer; FGFR2b antibody	Pre-IND
GSK	Muscle wasting (sarcopenia and cachexia), respiratory (refractory asthma and COPD)	Discovery
UCB	Fibrosis, immunologic, and CNS diseases	Discovery
Multiple candidates	Antibodies and ligand traps vs. cancer, immunotherapy, steroid resistant asthma	Discovery

Source: Company reports and Wells Fargo Securities, LLC

Key Risks

- **Clinical risk**--Given the early stage of Five Prime's biologics programs, there is risk that a number of them could face setbacks on their respective clinical development paths. For FP-1039, inhibition of FGFR has been scientifically validated, but it has not been clinically proven to be an effective mechanism in humans, including those with FGFR1 overexpression and while FP-1039 was specifically designed to overcome the limitations of similar approaches, it is possible there could be undesired adverse events/effects such as interaction with hormonal FGF receptors, weight loss, and/or retinal epithelial detachment seen with other agents. While not observed in the initial ph.I study, emergence of such toxicities could limit dose escalation, requiring dosing at lower and possibly less beneficial doses. In addition, there are no extensive historical battery of clinical results in FGFR1 over-expressed squamous NSCLC, which could make the phase Ib data more difficult to put into context and to help guide future clinical development (e.g., powering assumptions in phase II and III studies, and treatment effects). If the incidence of patients with FGFR1 over-expression is lower than Five Prime expects, this could also push out recruitment timelines for the ph.Ib and future studies, development timelines, and potentially future revenue. For FPA008, though natural selectivity for monocytes involved in inflammation should help, infection risk is always as possibility with immunomodulatory approaches, especially those directly targeting monocytes/macrophages.
- **Regulatory risk**--In cancer, development of new therapies means the standards of care for each tumor type often change rapidly, which could complicate future trial designs for '1039 and '144. Five Prime, GSK, and other potential partners would need FDA buy-in for a potential faster path to market for '1039 in refractory squamous NSCLC and for '144 with amplified gastric cancer to enable those agents to reach the market more quickly, or the development timelines and time to revenue generation would become longer. For '008, the autoimmune markets are crowded, especially in RA, which is likely to raise the efficacy and safety bars for regulatory approval.
- **Commercial risk**--FP-1039 and FPA144 are designed to be targeted toward specific populations with overexpression or amplification of certain genes/proteins; if these population are smaller than what is projected based on the literature, this could limit Five Prime's revenue opportunity. For FPA008, the RA market is crowded, thus it will be important for Five Prime to formulate '008 as a subcutaneous injection rather than an intravenous infusion, and to demonstrate a meaningful improvement in important bone endpoints (which has been a challenge to prove in recent studies of other agents), in order to maximize differentiation from other therapies and gain meaningful market share.
- **Financial risk**--Five Prime's candidates are at an early stage of development, and while the company has been able to generate cash from non-dilutive platform collaborations, it will need additional funding as it advances '008 and '144 into human studies on its own. Raising cash in the equity markets would result in dilution to current shareholders.

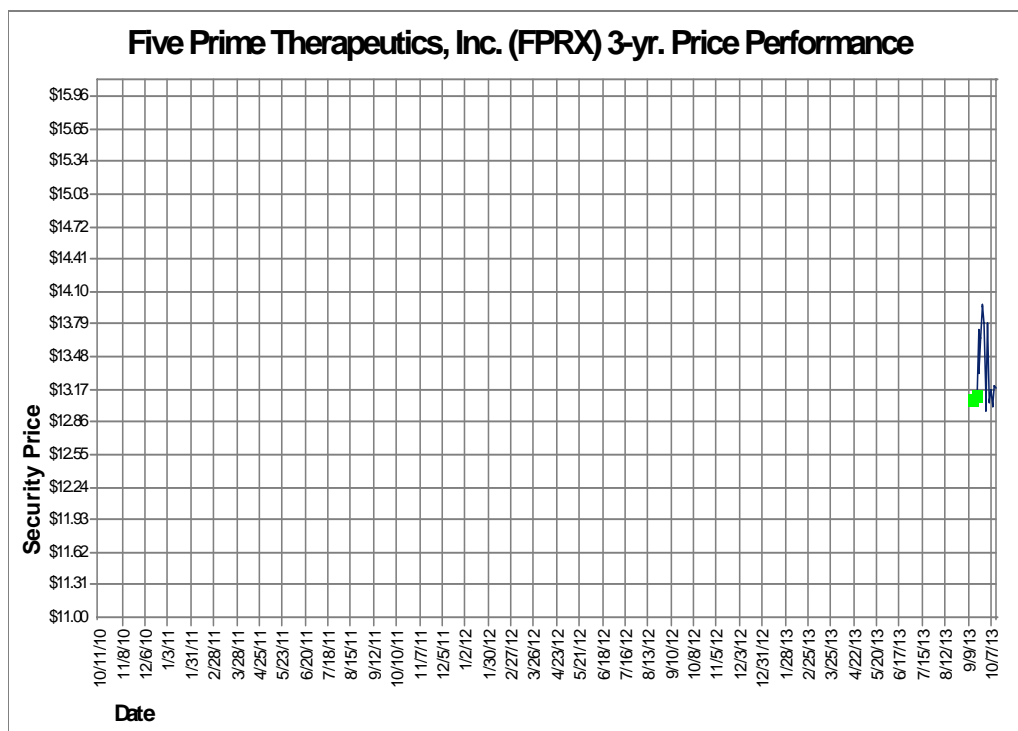
Income Statement

(in thousands except per share amounts)

	2010A	2011A	2012A	1HA	3QE	4QE	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenues																	
Total Global FP-1039 sales (15-35% prob-weighted by tumor type)																	
Total Global FPA008 sales (20% prob-weighted)																	
Collaborative revenue	\$23,740	\$64,916	\$9,983	\$6,524	\$2,500	\$2,500	\$11,524	\$15,100	\$26,800	\$97,800	\$21,500	\$34,000	\$21,500	\$39,000	\$54,000	\$34,000	\$362,757
FP-1039 (royalties; probability weighted by tumor type)																	\$58,746
FPA008 (royalties; probability weighted)																	\$34,000
Total revenues, net	\$23,740	\$64,916	\$9,983	\$6,524	\$2,500	\$2,500	\$11,524	\$15,100	\$26,800	\$97,800	\$21,500	\$34,000	\$21,500	\$39,000	\$54,000	\$34,000	\$362,757
Expenses																	
Research and development	\$29,417	\$34,039	\$28,778	\$16,515	\$7,800	\$8,300	\$32,615	\$34,246	\$35,988	\$37,756	\$39,266	\$40,837	\$42,062	\$43,324	\$44,624	\$45,962	\$47,341
Selling, general and administrative	\$8,338	\$11,216	\$9,009	\$4,778	\$2,150	\$2,300	\$9,228	\$10,151	\$10,557	\$10,979	\$11,418	\$11,875	\$12,350	\$12,844	\$13,358	\$13,892	\$14,448
Total operating expenses	\$37,755	\$45,255	\$37,787	\$21,293	\$9,950	\$10,600	\$41,843	\$44,397	\$46,545	\$48,735	\$50,684	\$52,712	\$54,412	\$56,168	\$57,981	\$59,854	\$61,789
Operating income	(\$14,015)	\$19,661	(\$27,804)	(\$14,769)	(\$7,450)	(\$8,100)	(\$30,319)	(\$29,297)	(\$19,745)	\$49,065	(\$29,184)	(\$17,796)	(\$31,083)	(\$14,570)	\$6,972	\$4,489	\$37,352
Interest income	\$58	\$114	\$68	\$28	\$151	\$137	\$316	\$187	\$410	\$875	\$1,231	\$1,143	\$980	\$838	\$911	\$1,026	\$1,642
Other income (expense) net	\$491	(\$65)	\$121	\$420	\$0	\$0	\$420	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
(Loss) income before benefit from income taxes	(\$13,466)	\$19,710	(\$27,595)	(\$14,321)	(\$7,299)	(\$7,963)	(\$29,583)	(\$29,109)	(\$19,305)	\$49,940	(\$27,953)	(\$16,653)	(\$30,103)	(\$13,731)	\$7,883	\$5,515	\$38,994
Benefit (expense) from income taxes	\$5	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$390
Net (loss) income	(\$13,461)	\$19,710	(\$27,595)	(\$14,321)	(\$7,299)	(\$7,963)	(\$29,583)	(\$29,109)	(\$19,305)	\$49,940	(\$27,953)	(\$16,653)	(\$30,103)	(\$13,731)	\$7,883	\$5,515	\$39,384
Earnings Per Share (GAAP)	(\$12.22)	\$10.35	(\$23.05)	(\$11.55)	(\$0.43)	(\$0.47)	(\$3.27)	(\$1.68)	(\$1.01)	\$2.28	(\$1.40)	(\$0.82)	(\$1.36)	(\$0.62)	\$0.32	\$0.22	\$1.53
Shares Outstanding (Basic)	1,102	1,152	1,197	1,240	16,800	16,900	9,045	17,300	19,200	19,600	20,000	20,400	21,800	22,200	22,600	23,000	23,400
Shares Outstanding (Diluted)	1,102	1,904	1,197	1,240	19,100	19,200	10,195	19,600	21,500	21,900	22,300	22,700	24,100	24,500	24,900	25,300	25,700

Source: Company reports and Wells Fargo Securities, LLC estimates

Required Disclosures



	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
■	9/18/2013		IPO at \$13.00			

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
- ▲ Rating Upgrade
- Valuation Range Change
- ◆ Initiation, Resumption, Drop or Suspend
- Analyst Change
- Split Adjustment

Rating Code Key

- 1 Outperform/Buy
- 2 Market Perform/Hold
- 3 Underperform/Sell
- SR Suspended
- NR Not Rated
- NE No Estimate

Additional Information Available Upon Request

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FPRX: Key risks, in our view, are clinical and regulatory failure of its programs, competition, and financing.

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As of: October 11, 2013

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