

Pfenex Inc. (PFNX)

Initiating Coverage at Market Outperform; Pure-Play Biosimilar Opportunity with Attractive Lead Candidate

MARKET DATA

Price	\$6.50
52-Week Range:	\$5.28 - \$6.57
Shares Out. (M):	20.5
Market Cap (\$M):	\$133.3
Cash (M):	\$50
Cash/Share:	\$2.43
Enterprise Value (M):	\$83
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$6.50 | Target Price: \$15.00

INVESTMENT HIGHLIGHTS

We are initiating coverage on Pfenex with a Market Outperform rating and \$15 price target. Pfenex is a biopharmaceutical company with core expertise in protein manufacture and therapeutic development that recently completed its IPO on July 24, 2014. The company's lead development program is PF582, a biosimilar candidate to Lucentis. We believe that regulatory clarity and commercial opportunity (i.e., patent expirations), together with Pfenex's technical/analytical expertise, position the company well to execute on its biosimilar strategy. Additionally, we anticipate that increased visibility on biosimilars more broadly can highlight the differentiated platform Pfenex has developed. The company intends to initiate a pivotal trial for PF582 by mid-2015, with results expected in 2017, and to launch globally as Lucentis patents expire in the 2018-2022 timeframe. Our \$15 price target is derived through an NPV analysis of global PF582 sales, with pipeline programs and the platform representing upside.

Biosimilar era is approaching – why we think now is the right time to pay attention to this emerging opportunity set. We believe that several key hurdles to achieving development, regulatory, and commercial success have been overcome, or at least the goal posts have been firmly set. As such, we anticipate there will be increased newsflow and investor awareness/education/interest in the space over the next five years. As we discuss in more detail in this report, the regulatory pathway in Europe is established and we believe there is clarity in the U.S. with five guidance documents published by FDA. Additionally, by 2020, an estimated 40% of approved biologics are expected to come off patent, representing sales potential of ~\$45 billion.

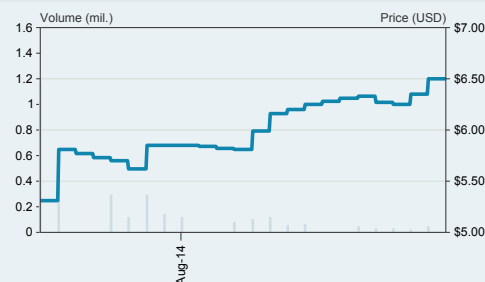
PF582 has potential to become the first FDA-approved biosimilar for Lucentis for the treatment of wet-AMD. With clarity on European and now U.S. regulatory pathways for biosimilars and patent expirations approaching, we believe the primary hurdle to market entry is establishing bioanalytical similarity of a candidate to the reference drug. We believe Pfenex's protein expression technology and bioanalytical capabilities position it well to execute on its biosimilar strategy. Furthermore, given the technological hurdles in producing Lucentis (and therefore, high hurdles for other biosimilars), clear endpoints for registration and substantial commercial opportunity, we view this as an attractive initial target candidate for the company. Worldwide Lucentis sales were ~\$4.3 bil in 2013 and ~\$2.3 bil in 1H14. The company intends to initiate a Phase 3 trial in mid-2015 and results are anticipated in 2017. We believe the clinical plan and possible approval in 2018 fits well with known patent expirations in key markets in the 2018-2022 timeframe.

Valuation focused on PF582 opportunity with pipeline and platform representing upside. We project that PF582 will be launched in 2018 and by 2023, the first year following the last patent expiration in key markets, we project sales of ~\$500MM.

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$3.4	\$2.6A	--
	2Q	\$0.0	\$2.5A	--
	3Q	\$0.0	\$2.5	--
	4Q	\$0.0	\$2.5	--
	FY	\$11.9	\$10.1	\$9.0
EPS	1Q	--	(\$0.14)A	--
	2Q	--	(\$0.21)A	--
	3Q	--	(\$0.27)	--
	4Q	--	(\$0.29)	--
	FY	(\$0.37)	(\$0.92)	(\$1.26)
	P/E	NM	NM	NM

Source: Company reports and JMP Securities LLC

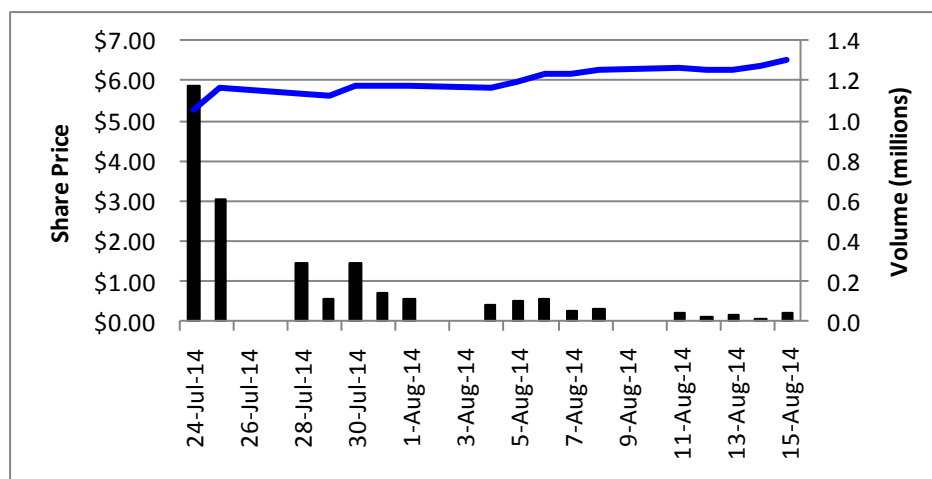
STOCK PRICE PERFORMANCE



COMPANY DESCRIPTION

Pfenex is a clinical-stage biotechnology company engaged in the development of difficult-to-manufacture and high-value proteins, focused on biosimilars. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab). Lucentis, marketed by Roche Ltd. and Novartis AG, for the treatment of retinal diseases, achieved approximately \$4.3 billion in global product sales in 2013. PF582 is currently undergoing a Phase 1b/2a trial in patients with wet-AMD (age-related macular degeneration), with data expected in 4Q14. Initiation of a Phase 3 trial is anticipated in mid-2015 with data expected in 2017. Additional pipeline candidates include PF530, a biosimilar candidate to Betaseron (interferon beta-1b, multiple sclerosis), vaccine development programs for anthrax and malaria, and next-generation biologics further leveraging the protein production platform.

FIGURE 1. Pfenex Stock Chart



Source: Thomson Reuters

KEY UPCOMING MILESTONES

4Q14	PF582	Top-line results from Phase 1a/2b trial
2H14	PF530	Initiation of Phase 1 trial vs. Betaseron
2H14	Anthrax	Initiate Phase 1 trial of recombinant anthrax vaccine
2H14	Malaria	Initiate Phase 1 trial of malaria vaccine
Mid-2015	PF582	Initiation of Phase 3 equivalence trial vs. Lucentis
1H15	PF530	Results from Phase 1 trial vs. Betaseron
2H15	PF708	Initiation of ANDA-enabling bioequivalence trial vs. Forteo
2017	PF582	Data from Phase 3 equivalence trial vs. Lucentis

INVESTMENT THESIS

We expect biosimilars to become a mainstay of the Pharma/Biotech industry, consistent with generic small molecules. Generic versions of small molecule drugs are a well-established component of the global healthcare system. The advancement of generic versions of biologic drugs (e.g., antibodies, peptides), or “biosimilars” is now a significant focus for the industry, regulators, and payers. More than 20 biosimilars have been approved in Europe and adoption has been substantial in certain markets. Different to small molecule generics, where there is typically rapid and extensive price erosion, the limited number of companies in the space and high hurdles to entry have enabled pricing to be largely maintained for these products, and their branded counterparts. Most large Pharma companies are pursuing biosimilar capabilities (including Pfizer, Novartis/Sandoz, and Teva); however, there are limited public small/mid-size companies in the space.

There are multiple reasons why we believe the biosimilar opportunity is emerging now. Just as we have seen patent cliffs for pharma companies with small molecules, patent expirations for biologics are occurring and approaching. By 2020, 40% of approved biologic products, representing sales of ~\$45 billion, will have come off patent globally. There is also substantially greater regulatory clarity now, especially in the U.S. The biosimilar regulatory pathway is established in Europe and other WW countries (e.g., Australia, Canada, Japan, South Korea, and South Africa) have adopted very similar biosimilar paths. In the U.S., the FDA has now issued five guidance documents providing regulatory clarity, the most recent of which was published ~3 months ago. Technological advances have improved manufacturing capabilities and controls and cost efficiencies. In addition to the ability to produce a biosimilar it is important to have the ability to demonstrate similarity (i.e., analytical capability is very important).

Pfenex’s solution is a well-validated platform with the potential to drive pipeline candidates over the long term. The Pfenex Expression Technology is a microbial (bacteria)-based platform that can be engineered to produce therapeutic proteins, including monoclonal antibodies and peptides. Pfenex was spun out of Dow Chemical Company in December 2009 and the technology platform has been validated commercially through multiple collaborations with large pharma and biotech companies (e.g., AstraZeneca, Bristol-Myers, Merck, and Sanofi). The company has demonstrated success in producing proteins where other expression systems have failed. The company has also established robust bioanalytical capabilities to characterize its biologic products and address regulatory needs.

Pfenex’s lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab). Lucentis is currently marketed by Roche Ltd. and Novartis AG for the treatment of retinal diseases, and achieved approximately \$4.3 billion in global product sales in 2013. Pfenex is currently conducting a Phase 1b/2a trial in patients with wet-AMD (age-related macular degeneration), with data expected in 4Q14. Initiation of a Phase 3 trial is anticipated in mid-2015, with data expected in 2017. Patent expirations for Lucentis are expected in major global markets in the 2018-2022 timeframe and Pfenex is focused on a commercial roll-out that follows this timeline. We anticipate peak worldwide sales potential of ~\$500MM, including U.S. sales of ~\$265MM.

VALUATION

We value Pfenex based on the global opportunity for PF-582. As detailed on page 11, we assume the product is launched in Canada in 2018, as well as in certain ROW countries, followed by launches in the U.S. in 2020 and Europe in 2022, based on respective patent expirations. We project that sales will reach ~\$500MM in 2023, following patent expiration in all key markets. Our NPV analysis assumes a 65% probability of success, taking into consideration clinical, regulatory, and commercial risk, and a 15% discount rate. After 2023, we assume a terminal growth rate of 3% as we expect the duration of the asset to be prolonged and at present, there is no visible biosimilar competition for the product.

As shown in Figure 2, we calculate an NPV of ~\$300MM, or \$15 per share.

FIGURE 2. Pfenex Sum-of-the-Parts NPV Valuation

	Revenue (MM)	Revenue year	Economics	Probability of success	Discount rate	NPV	NPV per share	Contribution
PF582	493.8	2023	100%	65%	15.0%	305.2	\$14.90	100%
Price target							\$14.90	100%

Source: JMP Securities LLC

Capital Structure

Following the completion of its IPO last month, Pfenex had approximately 19.2 million shares outstanding. A further 1.25 million shares may be issued per the IPO over-allotment option. Additionally, as of March 31, 2014, there were an additional ~0.7 million stock options with an average exercise price of \$0.57 per share, 0.3 million stock options with an average exercise price of \$11.59 per share, and ~1.7 million shares reserved for future grants under stock-based compensation plans.

Balance Sheet

Pfenex received net proceeds from the IPO of ~\$46.5MM and exercise of the over-allotment option would provide an additional ~\$7MM net. Including ~\$5MM in cash at the end of 1Q14, we anticipate a pro forma cash position of ~\$52-\$59MM. We believe that current cash is sufficient to fund operations into mid-2016. We expect that the primary driver of spending over the next 2-3 years will be the Phase 3 trial for PF582, which the company estimates will cost ~\$40MM.

INVESTMENT RISKS

Clinical risk. Pfenex may not be successful in the full development and launch of its product candidates. There may be enrollment, dosing, efficacy, or safety issues that would preclude development. It is a possibility that the drug candidates may fail to reach endpoints in their respective clinical trials or an improved version of the reference drugs, Lucentis or Betaseron, may be developed. Any of the aforementioned issues would cause a delay, or discontinuation of development. If the product candidates do make it through clinical trials, the company may yet encounter manufacturing issues, including challenges with the scale-up to commercial quantities. All of the above circumstances should be taken into consideration when assessing clinical risk.

Regulatory risk. To date, there have been no FDA approved biosimilars; however, we expect the 351(k) regulatory pathway to be validated prior to the review of PF582. The company's drug candidates still may not receive approval from the FDA or from ex-U.S. agencies. They may request additional pre-clinical or clinical trials to provide validation for approval, which would delay approval timelines and increase expenses. If approval is granted, the regulatory agency may impose restrictions on the label, or require a REMS program for a drug candidate. This may limit commercial uptake and delay commercial progress.

Market risk. We assume that the market dynamic and share for Lucentis remains stable vs. current conditions. We note that this could be impacted by changes in the competitive landscape with drugs available today (e.g., Eyelea, Avastin) or those in development. The market opportunity for products may not accurately reflect current estimates and there may be challenges with market adoption. This would impact the ability to reach revenue and profitability projections. The company must obtain and protect its intellectual property rights in order to effectively compete in the marketplace. Pfenex could get involved in patent lawsuits, which would be time consuming and expensive.

Financial risk. Pfenex has no commercial products generating revenue, thus it has not been and is not yet profitable. It has incurred losses each year since inception due to research and development expenses. These expenses are expected to increase in the near future as product candidates advance through the pipeline. The company will likely need to raise additional capital to fund these trials and continue operations. If there are any issues with acquiring needed financing, commercializing its product candidates, and achieving sales revenue, the company may not reach profitability, which may jeopardize the business.

BIOSIMILARS TO BECOME A FOCUS IN THE BIOPHARMA INDUSTRY

There are already established markets for biosimilars outside of the U.S., including in Europe, Russia, Japan, India, China, and Brazil. In the EU, over 20 biosimilars have been approved and adoption has been substantial in certain markets. The approved products include biosimilar equivalents to Epogen (epoetin alfa), Neupogen (filgrastim), Gonal-F (follitropin alfa), Nutropin (somatropin), and Remicade (infliximab). In Europe, the biosimilar market has highlighted the opportunity for cost savings and expanded access to newer therapies. We believe it should be noted that the use of biosimilars in Europe has been substantially driven by policy makers and payers focused on competition and pricing. As a result, there have been multiple commercially successful biosimilar product launches, including G-CSF in the UK, with an 83% market share vs. branded, erythropoietin (EPO) in Germany, which has a greater than 50% market share vs. branded, and somatotropin in Denmark which also has a greater than 50% market share vs. branded. At least, in part, these biosimilar adoptions have been driven by government/payer policies, where, for example, in France, legislation has been implemented allowing pharmacists to substitute biosimilar products for branded products in certain circumstances.

In our view, the primary reasons the focus on biosimilars is emerging now include: 1) biologics are reaching their patent cliffs; 2) biosimilar regulatory pathways are now becoming more clearly defined; and 3) technological advances in manufacturing and bioanalytics have increased the feasibility of developing biosimilars.

While the regulatory environment is often considered to be the most significant speed bump to the emergence of the biosimilar industry, we believe technological hurdles and advances are commonly underestimated. As discussed below, we view this as an important reason why Pfenex, and its proprietary Protein Expression Technology, is optimally positioned to be a leader in this industry. In addition, when considering the drive to establish approval and adoption road maps, it should be remembered that the biologics industry remains in its adolescence and patent protection has muted the need to address the issues of biosimilars until recently.

Regulatory clarity in the U.S. for biosimilars

In the U.S., development of generic versions of biologics, or biosimilars, has now also become a significant focus for the industry, regulators and payors. We believe a primary hurdle of regulatory clarity has now been addressed through the establishment of the 351(k) pathway in 2010 and the subsequent issuance of five guidance documents by FDA. It should be noted that this pathway has been developed with dialogue between regulators in Europe and the FDA.

These guidance documents stress the need for clear bioanalytical data supporting the candidate and require that biosimilarity to the reference product typically be demonstrated through data derived from analytical studies, animal studies (including an assessment of toxicity), and clinical studies (including an assessment of immunogenicity and pharmacokinetics or pharmacodynamics). Companies sponsoring biosimilar marketing applications should also be able to demonstrate the sameness of strength, dosage form, and route of administration to the reference product, as well sameness of mechanism(s) of action. Although approval is based on the totality of evidence, the bioanalytical assessment, which defines degree of similarity, is the central component to the data package for biosimilar market authorization. It also determines whether the 351(K) pathway is available for a particular compound.

Through the end of 2013, the FDA had received 10 investigational drug applications for biosimilars, and held 32 biosimilar product development meetings. Recently, Novartis (Sandoz) has also submitted a marketing application for its biosimilar candidate to Neupogen, with an approval date anticipated in 2Q15. This biosimilar was approved in Europe in February 2009. The application is based on a ~220 patient randomized, double-blind Phase 3 trial comparing the biosimilar candidate to Neupogen in breast cancer patients who received myelosuppressive chemotherapy. While this application is not directly relevant to Lucentis, given the differences in product manufacturing and approved indications, we believe that it may provide important regulatory precedent and increase investor awareness, and possibly confidence in, the biosimilar 351(k) pathway.

Another important consideration for biosimilars, we believe, is that patent litigations do not trigger a 30-month delay, as in the generic space, and FDA review may continue simultaneously.

PFENEX EXPRESSION TECHNOLOGY FOR BIOSIMILARS

Pfenex was founded to leverage the Expression Technology and know-how that has resulted from approximately 20 years of investment and development. The platform was primarily developed at The Dow Chemical Company, by a substantial contingent of the current Pfenex team. Pfenex was spun out of Dow in 2009 based on a strategic decision.

Therapeutic proteins and peptides are developed using engineered microorganisms, commonly mammalian or bacterial cell lines. This is typically achieved by genetically modifying microorganisms to produce protein in complicated procedures that take into consideration how a protein should correctly fold, be “fine-tuned” and therefore, function. While current technologies have been successful in producing safe and effective therapeutic proteins and peptides, at a commercial scale they are inherently inefficient. Current technologies have adopted a “trial and error” approach in which variables such as strain, nutrients, and environmental conditions are manipulated to optimize a production process. While this has achieved success, it may limit the number of product candidates that can be explored due to high costs of development and manufacturing, and extended timelines.

Pfenex's solution

We believe Pfenex's Expression Technology is differentiated and can achieve target evaluation, and development/manufacturing optimization in a faster and cheaper manner. The technology adopts a rationalized process of automated and robotically enabled, high-throughput screening. This is coupled with the company's bioanalytical testing capabilities, resulting in a platform that can systematically conduct and evaluate thousands of parallel experiments to achieve an optimized process. This enables a high-quality, scalable process to be developed for a target protein or peptide in approximately nine weeks, compared to an average of one year for current technologies (Figure 3).

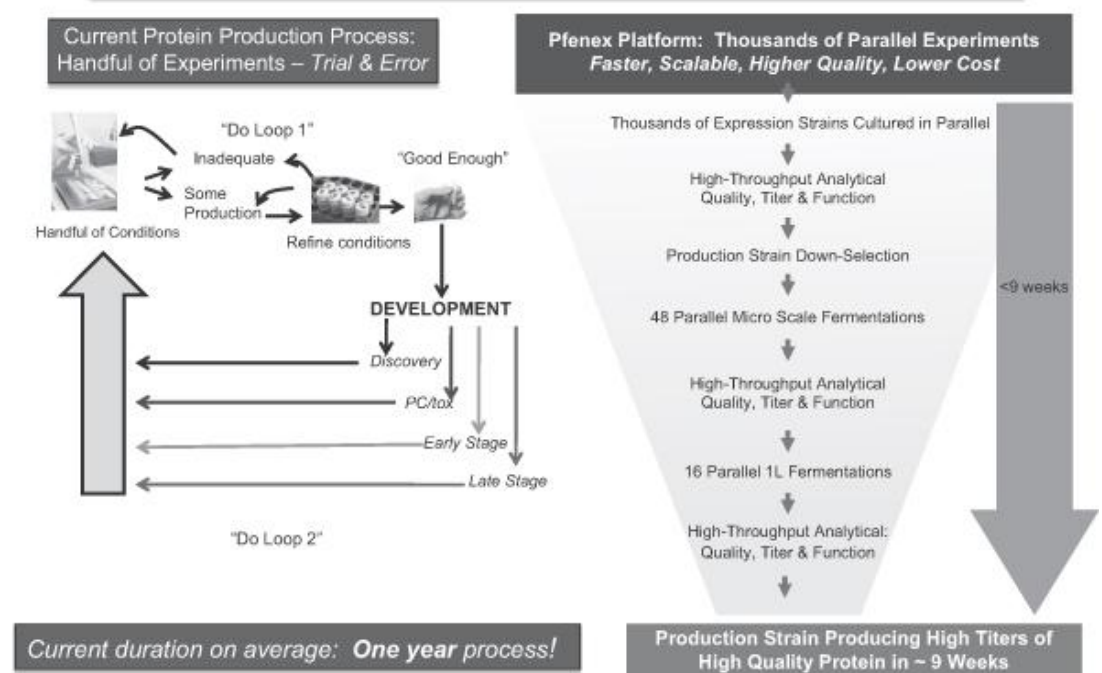
The platform is based on the company's proprietary genetically engineered *P. fluorescens* bacterial expression strains. The selected strains undergo extensive fermentation scouting experiments. We believe that bacterial expression systems can provide advantages in flexibility and time of manipulation compared to mammalian cell production systems. While bacterial expression strains may not be preferential for all target production molecules, we believe the platform can efficiently generate a wealth of proteins of interest with optimal yields, purity, and potency.

The *P. fluorescens* strain used by Pfenex in its protein expression platform has been used industrially to efficiently produce complex proteins. This bacterial strain has multiple favorable attributes, including:

- Increased production yields and properly folded protein due to secretion of soluble protein into the bacterial periplasm.
- Increased quality and production of properly folded, active, full-length proteins due to flexibility to genetically manipulate the *P. fluorescens* strain, including deleting protease genes, or nucleotides that provide instructions for synthesis of RNA into a specific protease, and inserting chaperone and/or disulfide bond isomerase genes, or nucleotides that provide instructions for synthesis of RNA into a specific chaperone or disulfide isomerase.
- Increased production yields, consistent scale-up, and favorable cost of goods due to high cell density fermentation, enabled by the obligate aerobe growth nature of the *P. fluorescens* strain.

FIGURE 3. Pfenex Platform Technology

Differentiation of Today's Process v. Pfenex Platform



Source: Company reports

Pfenex uses the *P. fluorescens* strains to generate libraries of thousands of unique expression strain variants using expression vectors. The company has developed a "toolbox" of protein production variants that can be manipulated to determine which will improve production of any target protein. The engineered *P. fluorescens* strains have reduced expression of protein-degrading enzymes and/or increased levels of folding elements while the expression vectors consist of plasmids with engineered genetic elements including promoters, ribosome binding sites, and secretion leaders. These strains are subjected to an automated high-throughput screening protocol to select the strain that produces proteins of interest at optimal purity, yield, and potency.

While Pfenex is focused on leveraging its protein expression platform to develop biosimilar drugs, we note that the platform is protected by a strong patent portfolio. This covers the P. fluorescens strain, as well as the processes to develop and scale up production of proteins and peptides. Additionally, the company is executing new patents for individual product candidates. We view Pfenex's intellectual property portfolio as an important differentiating attribute.

PF582 – BIOSIMILAR LUCENTIS

Pfenex's most advanced product candidate is PF582, a biosimilar to Lucentis (ranibizumab) for the treatment of wet-AMD. Pfenex plans to initiate a pivotal Phase 3 trial in mid-2015 and we expect results to be available in 2017, with potential regulatory approvals beginning in 2018.

Given the focus by both FDA and EMA on the importance of bioanalytics, Pfenex has already conducted several studies comparing PF582 to multiple lots of Lucentis, sourced from both the United States and the European Union. In addition, comparability studies between multiple lots of PF582 at the pilot scale and commercial scale were also conducted. These preclinical studies comparing PF582 to Lucentis have established similarity in tolerability and in pharmacological profiles. We believe these studies have predictive value relevant to the planned pivotal trial for PF582.

FDA interactions provide further confidence in clarified approval pathway

In January 2014, Pfenex was granted a Biosimilar Initial Advisory Meeting with the FDA. We view this as important as the FDA will not grant such a meeting under the 531(k) pathway until it has reviewed a product's preclinical data package. The FDA has deemed that the analytical data for PF582 are acceptable to support the clinical development of PF582 as a biosimilar candidate to Lucentis. This meeting also served as a forum to discuss the strategy for a Phase 3 trial design, as detailed below. Additionally, the company has engaged in related discussions with the CHMP (European Union's Committee for Medicinal Products for Human Use).

The planned clinical development program for PF582 includes the ongoing Phase1b/2a trial and a pivotal Phase 3 trial, expected to begin in mid-2015. The Phase1b/2a trial is a randomized study comparing PF582 to Lucentis in 24 wet-AMD patients (1:1). Patients are administered with PF582 or Lucentis on days 1, 28, and 56 and while the primary objective is to assess safety in this first-in-man study, efficacy endpoints are also being evaluated. These efficacy endpoints include measurements of retinal thickness, leakage from CNV, and visual acuity (the established regulatory endpoint from wet-AMD).

Encouragingly, in our view, the sentinel patient treated with PF582 showed a five-letter increase in visual acuity on an eye chart with a five-letter improvement at one month and a reduction in retinal thickness. These results are consistent with Lucentis. The company expects to complete the study in 4Q14.

Planned Phase 3 protocol

Positive results from this trial may provide sufficient data to attain regulatory approval. We believe PF582 has the potential to become the first biosimilar to Lucentis in the ophthalmology market.

Pfenex plans to initiate a pivotal Phase 3 trial in mid-2015. The trial will be of 12-months duration and have ~400 patients randomized 1:1 between PF582 and Lucentis. Results are expected in 2017. Pfenex anticipates FDA feedback on the methodology of this trial. It anticipates that a 95% CI of improved number of letters in visual acuity will be required. Importantly, bioanalytical comparability between lots of the reference products will be mandatory. No requirements, however, are expected for population PK due to the nature of the therapeutic area.

The currently ongoing Phase 1b/2a trial, is a double-blind, parallel-group, controlled study of PF582 for the treatment of neovascular wet-AMD. Target enrollment is 25 patients, from multiple sites in New Zealand. The primary endpoint is to evaluate the safety, tolerability, and efficacy of intra-vitreous PF582 (ranibizumab) versus Lucentis. Secondary endpoints include retinal thickness, leakage from CNV (choroidal neovascularization) and improvement in visual acuity from baseline to Day 80. Subjects will be administered injections of PF582 on Day 1, 28, and 56 and will undergo visual acuity and OCT evaluations. The trial is currently enrolling in New Zealand. The sentinel patient showed a 5-letter improvement in visual acuity on an eye chart at four weeks following injection and a reduction in retinal thickness at one and three months. The patient showed a ~40% improvement in retinal thickness and more than 90% reduction in lesion size after three months. These initial results are consistent with the results expected from Lucentis. Top-line data is anticipated in 4Q14.

Commercial opportunity in wet-AMD

Wet-AMD (age-related Macular Degeneration) is a chronic eye disease caused by blood vessel leakage (fluid or blood) into the macula of the retina. This causes patients to lose central vision, though their peripheral vision remains. Wet-AMD impacts ~30-50 million people worldwide, of which ~15 million are in the U.S. It is the leading cause of severe vision loss in people over age 60. Approximately, 600,000 new cases of wet AMD are diagnosed each year worldwide.

In 2013, Lucentis generated ~\$4.3 billion in global revenue. Lucentis IP expirations include 16 countries today, with Canada, China, U.S., and Western EU expiries in 2Q2018 – January 2022. According to IMS, by 2Q18, ~\$530MM of the Lucentis market will lose patent protection, opening up opportunities for biosimilars. Additional patents will expire in 2020 and again in 2022, at which time Lucentis will no longer have patent protection. Pfenex plans to coordinate PF582 launches to follow the IP expiry timeline for Lucentis around the world. Infrastructure for commercialization in the U.S. and Western EU includes ~100 internal and contract sales reps that are prepared to target retinal specialists. For Canada and Turkey, the company has a small internal and contract sales force in place. It plans to collaborate with commercialization partners in the following regions: China, India, Eastern Europe, CIS/Russia, and South America.

PF582 Revenue model

Global sales of Lucentis were ~\$4.3 bil in 2013. For the purpose of our model, we assume sales increase by only 3% annually. The primary competition in the wet-AMD market is currently Regeneron's Eyelea. While there are additional potential competitors in development, we assume that Lucentis maintains its current sales run rate until PF582 is approved.

We assume that the product is launched in Canada in 2018, followed by a U.S. launch in 2020 and Europe in 2022 (based on relevant patent expirations). We anticipate that Pfenex will assemble a specialty sales and medical affairs infrastructure to commercialize the product. Given the need to educate consumers about the biosimilar opportunity, we anticipate that marketing efforts will be more substantial than for small molecule generics. However, we do not yet have clarity on the size of the sales force or marketing costs.

Based on the commercial experience of biosimilars in Europe, where there have been, on average, 20% pricing discounts to innovator branded products, we conservatively assume that PF582 is launched at a 30% discount to the price of Lucentis (which is ~\$2,000 per treatment in the U.S. and \$1,500 in Europe). We project that the product can achieve market penetrations of up to 20% in key markets, which we also believe may be conservative given the experience to date in Europe and other ex-U.S. countries.

Our penetration and sales projections for PF582 are summarized in Figure 4.

FIGURE 4. PF582 Revenue Model, 2014E – 2024E

Penetration rate	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
U.S.							5%	15%	20%	20%	20%
Europe (~EU5)									5%	10%	15%
Canada					5%	10%	15%	15%	15%	15%	15%
Other					2%	5%	7%	7%	7%	7%	7%
Total											
Sales (\$MM)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
U.S.	0.0	0.0	0.0	0.0	0.0	0.0	66.2	198.7	264.9	264.9	264.9
Europe (~EU5)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	59.5	119.0	178.5
Canada	0.0	0.0	0.0	0.0	13.1	26.3	39.4	39.4	39.4	39.4	39.4
Other	0.0	0.0	0.0	0.0	1.5	3.7	11.0	11.0	11.0	11.0	11.0
Total	0.0	0.0	0.0	0.0	14.6	29.9	116.6	249.1	374.8	434.3	493.8

Source: JMP Securities LLC

BIOSIMILAR PIPELINE

In addition to PF582, Pfenex is developing a pipeline of at least six other biosimilar candidates, as summarized in Figure 5. We look to increased visibility on these emerging candidates over the next 12-24 months. As discussed in our valuation section, our price target is based on PF582 alone, with additional pipeline programs representing upside to our assumptions.

FIGURE 5. Biosimilar Pipeline Candidates

Product	Branded Reference Drug	Approximate 2013 Global Branded Sales	Collaboration Partner	Expected Status/Milestones
<i>Biosimilar</i>				
PF582 – Ranibizumab	Lucentis	\$4.3B	Wholly-Owned	Phase 1b/2a in-process – commencing in mid-2015 with data expected in 2017
PF530 – Interferon beta-1b	Betaseron	\$1.4B	Strides Arcolab	Phase 1 commencing in the second half of 2014
PF694 – Peg-interferon alpha-2a	Pegasys	\$1.5B	Strides Arcolab	Phase 1 commencing in the second half of 2015
PF756 – Peg-interferon beta ⁽¹⁾	N/A	N/A	Strides Arcolab	Formulation development
PF529 – Peg-filgrastim	Neulasta	\$4.4B	Strides Arcolab	Process development
PF444–Human growth hormone	Genotropin	\$3.0B	Strides Arcolab	Process development
PF688 – Certolizumab-pegol	Cimzia	\$820MM	Wholly-Owned	Process development
PF690 – Peg-asparaginase	Oncaspar	\$175MM	Strides Arcolab	Entering process development

Source: Company reports

PF530 – Biosimilar Betaseron

PF530 is a biosimilar to betaseron (interferon beta-1b) indicated for Multiple Sclerosis. Interferon beta products are the standard of care for first-line treatment in patients with Relapsing Remitting Multiple Sclerosis (RRMS) to reduce the number of relapses. Multiple sclerosis affects ~2.3 million people worldwide and is increasing in prevalence and incidence. Pfenex estimates that the global multiple sclerosis market is projected to grow from \$14.4 billion to \$21 billion by 2022. Betaseron is marketed by Bayer AG and sales of the product were \$1.4 billion in 2013.

PF530 is being developed in collaboration with Strides Arcolab, pharmaceutical company headquartered in India. Strides is responsible for expenses related to development of PF530 through Phase 3, at which time, the companies will share in expenses and revenue.

Together with Strides, Pfenex has conducted extensive in vitro bioassays and quality assessment studies to compare PF530 vs. Betaseron and establish analytical biosimilarity. The company does not expect to have to conduct preclinical animal studies.

PF530 Clinical development plan

Pfenex plans to initiate a Phase 1 trial of PF530 vs. Betaseron in 2H14 with results expected in 1H15. The trial will enroll a target of 45 patients in Australia and will be funded by Strides. The primary endpoint will be pharmacokinetics and pharmacodynamics in healthy volunteers in accordance with the draft EMA guidance for interferon beta.

If the Phase 1 trial is successful, the company will initiate a Phase 3 trial in 1H16 in Eastern Europe, CIS and Central Asia. The primary endpoint of this trial will be to evaluate biosimilarity of PF530, versus Betaseron in treatment naive multiple sclerosis patients.

Pfenex plans to initially seek regulatory approval in India, Malaysia, Russia and countries located in Central and Eastern Europe in 4Q18/1Q19 and plans to seek approval in the United States and the EU by 2021.

ADDITIONAL PIPELINE ASSETS

Beyond Pfenex's pipeline of biosimilar candidates, the company is also leveraging its protein expression technology to develop generic peptides under the ANDA pathway and certain vaccines (Figure 6).

FIGURE 6. Pfenex Pipeline

<i>Generic</i>				
PF708 – Teriparatide	Forteo	Wholly-Owned	Osteoporosis	ANDA enabling PK study commencing in the second half of 2015
<i>Novel Vaccines</i>				
Px563L – rPA based anthrax vaccine	N/A	U.S. Government Funded	Anthrax vaccine	Phase 1 commencing in the second half of 2014
Px533 – Malaria vaccine	N/A	U.S. Government Funded	Malaria vaccine	Phase 1 commencing in the second half of 2014

Source: Company reports

PF708 – Generic Forteo

PF708 is a generic candidate to Forteo (teriparatide), marketed by Eli Lilly for the treatment of severe osteoporosis. Teriparatide is a shortened version of the parathyroid hormone (amino acids 1-34) that activates osteoblasts to promote bone growth. According to the NIH, ~44 million Americans either have or are at increased risk of osteoporosis due to low bone mass, and global sales of Forteo were approximately \$1.25 billion in 2013. Pfenex expects to initiate cGMP manufacturing of its generic Forteo candidate in 1H15.

Pfenex is developing PF708 as a generic drug through the well-established ANDA pathway. The company intends to conduct a bioanalytical comparative analysis of PF708 to Forteo and then initiate a PK bioequivalence study in the U.S. in 2H15. Given the extended timelines for FDA review of injectable drugs under the ANDA pathway, we do not expect approval/launch of PF708 before 2019.

Vaccines

Px563L for Anthrax

Pfenex is developing Px563L, a novel anthrax vaccine that is based on a recombinant modified form (mutant) of the protective antigen from *Bacillus anthracis* (anthrax), to help fulfill government demand for an improved anthrax vaccine. Pfenex has conducted preclinical animal studies of Px563L that demonstrated higher immune responses than BioThrax, the only available anthrax vaccine. It expects to begin a Phase 1 trial in 2H14.

In 2013, PAHPRA (Pandemic and All-Hazards Preparedness Reauthorization Act) authorized \$2.8 billion for the procurement of countermeasures for biological, chemical, radiological, and nuclear attacks. As such, the development of the Px563L vaccine has been funded by the U.S. Department of Health and Human Services, through BARDA. Pfenex plans to enter into a procurement relationship with the U.S. government to supply the Strategic National Stockpile and target first responders.

Px533 for Malaria

Pfenex is developing Px533, a prophylactic vaccine for malaria. Although 500-600 million clinical infections of malaria occur each year worldwide, there is no approved vaccine. We note that GlaxoSmithKline recently filed for regulatory approvals of its candidate malaria, developed in collaboration with Agenus. The three stages of malaria transmission include the mosquito stage, the liver stage, and the blood stage. Px533 is based on the liver stage antigen, circumsporozoite protein, or CSP, derived from *Plasmodium falciparum*. Pfenex has developed a scalable cGMP manufacturing process for the production of bulk CSP. In preclinical studies, Px533 has demonstrated in vivo response. Pfenex plans to conduct a Phase 1 trial in 2H14.

Px533 is being funded by a subcontract with Leidos through its Malaria Vaccine Production and Support Services contract with NIAID. The company plans to secure a partner for later stage development and commercialization of the Px533 vaccine.

MANAGEMENT TEAM

Bert Liang, MD, Ph.D., MBA.- Chief Executive Officer

Dr. Bertrand C. Liang is the Managing and Executive Director of LCC Ventures, an advisory company in the biotech, pharma, and venture areas. He was previously Vice Chairman, Paramount Biosciences, LLC, where he led the private equity activities, including licensing, investments, and internal development capabilities of the seven global offices, from Shanghai to London. He was President, CEO and Director of Tracon Pharmaceuticals, Inc., an oncology-focused development company located in San Diego; previously, he was Vice President, New Ventures at Biogen Idec. Dr. Liang is clinically trained in Neurology and Oncology, with basic science work in molecular genetics and molecular pharmacology. Dr. Liang has held academic positions at the NCI, University of Colorado, and University of Vermont, where he was the head of Human Medical Genetics. His previous research involved the role of mitochondria and the mitochondrial genome in the tumorigenic phenotype, translational research in cancer and neurology patients, and patented platform technology work in genomics discovery. Dr. Liang serves on the Board of Directors for several companies, including Tracon Pharmaceuticals, Asphelia Pharma, and Pico Pharmaceuticals.

Paul Wagner, Ph.D, CFA.- Chief Financial Officer

Paul Wagner joined Pfenex in April 2014 as Chief Financial Officer. Prior to joining Pfenex, Dr. Wagner held the position of Director and Portfolio Manager/Sr. Equity Analyst with Allianz Global Investors, a diversified active investment manager where he worked from 2006 to 2014. Prior to that, Dr. Wagner was the Head of Development Licensing at PDL BioPharma, a diversified biopharmaceutical company from 2005 until 2006. Prior to PDL BioPharma, Dr. Wagner held the position of Vice President at Lehman Brothers, a global financial services firm, starting in 1999 until 2005. Dr. Wagner received a B.S. from the University of Wisconsin and a Ph.D. in Chemistry from the California Institute of Technology. Dr. Wagner is also a CFA charterholder.

Patrick Lucy – Chief Business Officer

Patrick Lucy has served as Pfenex's Chief Business Officer since 2009. Prior to joining Pfenex, Mr. Lucy held the position of Director of Business Development at DowPharma, a business within The Dow Chemical Company, a chemicals manufacturer, from 2002 to 2009. From 1999 to 2002, he held the position of Director of Business Development at Collaborative BioAlliance, Inc., a biotechnology company, which was acquired by The Dow Chemical Company. From 1998 to 1999, Mr. Lucy worked as a Validation Manager and Capital Project Manager and from 1996 to 1998, as a Quality Control Biochemistry Supervisor at Lonza Biologics Inc., a chemicals and biotechnology company. From 1991 to 1996, Mr. Lucy held the position of Biochemistry Quality Control Supervisor at Repligen Corporation, a life sciences company. Mr. Lucy holds a Bachelor's degree in Biology from Villanova University.

Patricia Lady, M.B.A., CPA -Chief Accounting Officer

Patricia Lady has served as Chief Accounting Officer since 2011. Prior to serving in her current role, Ms. Lady served as our Director of Finance and Corporate Controller from 2009 to 2011. From 2007 to 2009, she served as Director of Finance and Accounting at Neurocrine Biosciences, Inc., a biopharmaceutical company. From 2006 to 2007, Ms. Lady held the position of Corporate Controller of Avanir Pharmaceuticals, Inc., a pharmaceutical company. From 2001 to 2005, Ms. Lady held the position of Vice President of Finance at 3E Company, a technology company. From 2000 to 2001, she served as Vice President of Business Development of Everypath, Inc., a technology company. From 1999 to 2000, Ms. Lady held the position of Vice President of Business Development and Marketing at iOwn, Inc., a technology company. From 1997 to 1999, she served as Vice President of Business Development at Careerbuilder, a technology company. Ms. Lady is a certified public accountant, a chartered global management accountant and a certified management accountant. Ms. Lady holds a Bachelor's degree in Accounting from California State University, Fullerton and an M.B.A. from the University of California, Los Angeles.

Henry W. Talbot – Vice President of Research and Operations

Henry Talbot has served as Vice President of Research and Operations since 2009. Prior to joining Pfenex, Dr. Talbot held the position of Biotechnology Site Leader at The Dow Chemical Company, a chemicals manufacturer, from 1999 to 2009. From 1994 to 1998, Dr. Talbot was Director of Fermentation and Manufacturing at Mycogen Corporation, an agricultural sciences company, prior to it being acquired by The Dow Chemical Company in 1998. Dr. Talbot holds a Bachelor's degree in Biology from the University of Colorado, Boulder, a Master of Science degree in Microbiology from the University of Missouri and a Ph.D. in Microbiology from Oregon State University.

Source: Excerpted from company reports

FIGURE 7. Pfenex Earnings Model

(\$ in thousands 000's)	2012	2013	1Q:14	2Q:14	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E
Revenue											
Product sales		0	0	0	0	0	0	0	0	0	14,595
Other revenue	11,294	11,914	2,558	2,500	2,500	2,500	10,058	9,000	8,000	8,000	8,000
Total Revenue	11,294	11,914	2,558	2,500	2,500	2,500	10,058	9,000	8,000	8,000	22,595
Cost of goods sold	7,253	6,423	1,908	1,875	1,875	1,875	7,533	6,750	6,000	6,000	16,946
Gross Profit	4,041	5,491	650	625	625	625	2,525	2,250	2,000	2,000	5,649
Operating expenses											
R&D	1,792	5,490	678	1,017	2,543	3,560	7,797	15,594	19,493	21,442	23,586
SG&A	6,876	6,698	1,495	1,944	3,498	2,974	9,910	12,388	13,627	14,308	21,462
Total Operating Expenses	8,668	12,188	2,173	2,961	6,041	6,533	17,707	27,982	33,119	35,750	45,048
Operating income (loss)	(4,627)	(6,697)	(1,523)	(2,336)	(5,416)	(5,908)	(15,182)	(25,732)	(31,119)	(33,750)	(39,399)
Other expense (income)	7	36	18	0	0	0					
Net Income Before Taxes	(4,634)	(6,733)	(1,541)	(2,336)	(5,416)	(5,908)	(15,182)	(25,732)	(31,119)	(33,750)	(39,399)
Income tax provision	(2,041)	(2,671)	1	0	0	0	1	0	0	0	0
Net income (loss)	(2,593)	(4,062)	(1,542)	(2,336)	(5,416)	(5,908)	(15,183)	(25,732)	(31,119)	(33,750)	(39,399)
EPS											
Basic		(\$0.37)	(\$0.14)	(\$0.21)	(\$0.27)	(\$0.29) ✓	(\$0.92)	(\$1.26)	(\$1.01)	(\$1.07)	(\$1.23)
Diluted		(\$0.37)	(\$0.14)	(\$0.21)	(\$0.27)	(\$0.29) ✓	(\$0.92)	(\$1.26)	(\$1.01)	(\$1.07)	(\$1.23)
Weighted shares outstanding											
Basic		10,860	10,877	10,901	20,000	20,100	15,469	20,502	30,912	31,530	32,161
Diluted		10,860	10,877	10,901	20,000	20,100	15,469	20,502	30,912	31,530	32,161
Cash Flow											
Net Income				(2,336)	(5,416)	(5,908)	(15,183)	(25,732)	(31,119)	(33,750)	(39,399)
Depreciation and amortization				0	0	0 ✓	0	0	0	0	0
Stock-based compensation				500	1,000	1,000	2,500	4,000	4,000	4,000	4,000
Other adjustments				0	0	0	0	0	0	0	0
Operating burn	0	0		(1,836)	(4,416)	(4,908)	(12,683)	(21,732)	(27,119)	(29,750)	(35,399)
Cash at start of period				5,135	49,799	45,384 ✓	0	33,817	12,085	78,965	49,216
Cash from operations				(1,836)	(4,416)	(4,908)	(12,683)	(21,732)	(27,119)	(29,750)	(35,399)
Cash from investing				0	0	0	0	0	0	0	0
Cash from financing				46,500	0	0	46,500		94,000		
Shares issued				8,333					10,000		
Price per share				6.00					10		
Effect of FX				0	0	0	0	0	0	0	0
Cash at end of period				5,135	49,799	45,384	33,817	12,085	78,965	49,216	13,816
Investment securities				0	0	0	0	0	0	0	0
Cash and investment securities				5,135	49,799	45,384	33,817	12,085	78,965	49,216	13,816

Source: Company reports, JMP Securities LLC

JMP FACTS AND DISCLOSURES

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

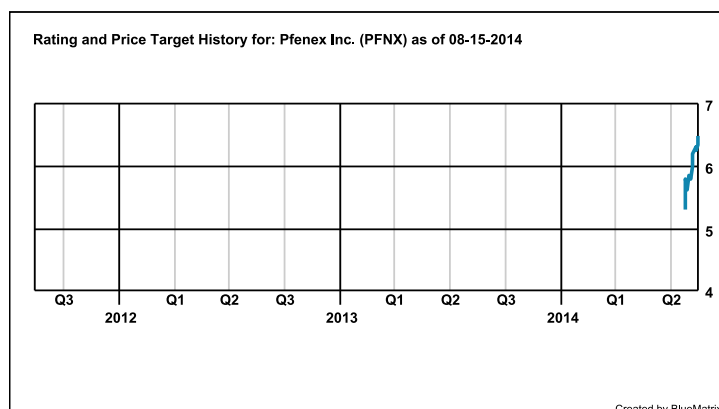
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MARKET OUTPERFORM	Buy	267	60.00%	Buy	267	60.00%	98	36.70%
MARKET PERFORM	Hold	138	31.01%	Hold	138	31.01%	18	13.04%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.09%		36	8.09%	0	0%
TOTAL:		445	100%		445	100%	116	26.07%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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