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Equity Research

Healthcare | U.S. Specialty Pharmaceuticals

18 May 2015

Pfenex

A timely & differentiated brew

We believe PFNX represents a compelling investment idea based on its differentiated platform for the development of biosimilars and complex generics; we initiate on PFNX with an OW rating and $28 price target. A crescendo of events, including approval of the first biosimilar in the US, has driven increasing investor focus on biosimilars. Picking "winners" among the myriad players isn't easy since many credible players are targeting the same molecules and it's unclear if there's anything to differentiate them competitively. PFNX stands out for having a differentiated pipeline and, more importantly, a proprietary technology platform which offers key competitive advantages. PFNX's platform for non-glycosylated proteins speeds development and provides cost advantages based on its ability to produce complex biologics at high yields. Our valuation is based on PFNX's priority R&D projects although we see meaningful upside from using its platform for other high-value opportunities such as insulin.

HSP partnership for PFNX's biosimilar to Lucentis de-risks development expense & validates platform. In February, PFNX signed a partnership with HSP to co-develop & commercialize its biosimilar to Lucentis. The partnership limits PFNX's development exposure to $20M and HSP bears all litigation costs. Strong economics remain with $241M in remaining development/commercial milestones and double-digit royalties on sales. We believe the HSP partnership validates PFNX's platform to produce high fidelity biosimilars, a point reinforced by our conversations with other strategic players.

A portfolio of wholly-owned biosimilar and complex generics should drive meaningful value; near-term pipeline opportunities include Forteo, Betaseron and Neulasta. PFNX's Betaseron, now in Phase 1, should enter a comparative clinical trial in '16, although recent approval for generic Copaxone raises the question whether an abbreviated pathway is available. An abbreviated pathway for Neulasta seems possible based on recent commentary by CHRS that the FDA is only asking for PK/PD data in healthy volunteers. Not to be overlooked, we see significant value in the generic Forteo.

PFNX: Quarterly and Annual EPS (USD)

	2014	2015			2016			Change y/y	
FY Dec	Actual	Old	New	Cons	Old	New	Cons	2015	2016
Q1	-1.28A	N/A	-0.29A	-0.29A	N/A	-0.39E	-0.30E	77%	-34%
Q2	-1.67A	N/A	-0.35E	-0.37E	N/A	-0.46E	-0.30E	79%	-31%
Q3	-0.16A	N/A	-0.36E	-0.43E	N/A	-0.34E	-0.31E	N/A	6%
Q4	-0.18A	N/A	-0.36E	-0.51E	N/A	-0.38E	-0.31E	-100%	-6%
Year	-3.29A	N/A	-1.37E	-1.80E	N/A	-1.56E	-1.89E	58%	-14%
P/E	N/A		N/A			N/A			

Source: Barclays Research.
Consensus numbers are from Thomson Reuters

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PLEASE SEE ANALYST CERTIFICATION(S) AND IMPORTANT DISCLOSURES BEGINNING ON PAGE 17.

Stock Rating	OVERWEIGHT from N/A
Industry View	POSITIVE Unchanged
Price Target	USD 28.00 from N/A

Price (15-May-2015)	USD 13.70
Potential Upside/Downside	+104%
Tickers	PFNX

Market Cap (USD mn)	317
Shares Outstanding (mn)	23.13
Free Float (%)	61.04
52 Wk Avg Daily Volume (mn)	0.1
52 Wk Avg Daily Value (USD mn)	1.28
Dividend Yield (%)	N/A
Return on Equity TTM (%)	N/A
Current BVPS (USD)	2.93

Source: Thomson Reuters

Price Performance	Exchange-NYSE
52 Week range	USD 19.95-5.28

Link to Barclays Live for interactive charting

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U.S. Specialty Pharmaceuticals — **Industry View: POSITIVE**

Pfenex (PFNX)

Stock Rating: OVERWEIGHT

Income statement ($mn)	2014A	2015E	2016E	2017E	CAGR
Revenue	11	10	12	11	-0.3%
EBITDA (adj)	-9	-31	-37	-40	N/A
EBIT (adj)	-10	-32	-38	-41	N/A
Pre-tax income (adj)	-10	-32	-38	-41	N/A
Net income (adj)	-11	-32	-38	-41	N/A
EPS (adj) ($)	-3.29	-1.37	-1.56	-1.58	N/A
Diluted shares (mn)	9.4	23.6	24.6	26.5	41.1%
DPS ($)	0.00	0.00	0.00	0.00	N/A

Margin and return data					Average
EBITDA (adj) margin (%)	-86.9	-299.4	-312.0	-377.7	-269.0
EBIT (adj) margin (%)	-91.3	-309.8	-322.2	-390.1	-278.3
Pre-tax (adj) margin (%)	-92.0	-310.4	-322.8	-390.8	-279.0
Net (adj) margin (%)	-100.3	-310.6	-322.8	-390.8	-281.1
ROIC (%)	N/A	-35.4	-38.2	-45.5	-39.7
ROA (%)	N/A	-33.2	-36.6	-43.6	-37.8
ROE (%)	-27.2	-74.5	-471.9	128.7	-111.2

Balance sheet and cash flow ($mn)					CAGR
Tangible fixed assets	2	3	3	4	18.3%
Intangible fixed assets	6	6	5	5	-9.0%
Cash and equivalents	46	98	60	77	19.1%
Total assets	71	124	86	103	13.2%
Short and long-term debt	4	0	0	0	-100.0%
Other long-term liabilities	3	3	3	3	0.0%
Total liabilities	11	8	8	7	-14.2%
Net debt/(funds)	-42	-98	-60	-77	N/A
Shareholders' equity	60	27	-11	-53	N/A
Change in working capital	38	56	-38	18	-21.8%
Cash flow from operations	-10	19	-37	-40	N/A
Capital expenditure	0	-1	-1	-1	N/A
Free cash flow	-10	18	-39	-42	N/A

Valuation and leverage metrics					Average
P/E (adj) (x)	N/A	N/A	N/A	N/A	N/A
EV/sales (x)	8.2	3.0	5.9	4.9	5.5
EV/EBITDA (adj) (x)	-9.5	-1.0	-1.9	-1.3	-3.4
FCF yield (%)	-8.0	5.6	-11.4	-11.5	-6.3
P/BV (x)	2.2	11.8	-30.4	-6.9	-5.8
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Total debt/capital (%)	6.0	0.0	0.0	0.0	1.5

Selected operating metrics					Average
SG&A/sales (%)	84.6	N/A	N/A	N/A	84.6
R&D/sales (%)	84.6	164.1	167.9	208.6	156.3
R&D growth (%)	-24.9	402.2	20.7	4.0	100.5
SG&A growth (%)	34.4	90.7	16.5	10.0	37.9

Source: Company data, Barclays Research
Note: FY End Dec

Price (15-May-2015) **USD 13.70**
Price Target **USD 28.00**

Why Overweight? We believe PFNX's propietary expression platform gives them meaningful competitive advantages in the development and commercialization of therapeutic biologics. PFNX has used its platform to develop a unique portfolio of biosimilar candidates. PFNX's technology was validated with its partnership with HSP on the development of a biosimilar to Lucentis.

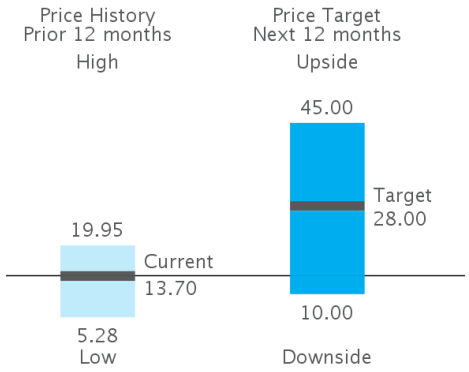
Upside case **USD 45.00**

We see upside from the opportunity for PFNX to accelerate the development of its wholly-owned biosimilar candidates to Betaseron and Neulasta. Abbreviated development pathways would improve sentiment and pull forward PFNX's revenue ramp.

Downside case **USD 10.00**

Downside would come from delays or unsuccessful clinical development work on PFNX's biosimilar candidates.

Upside/Downside scenarios



An investment idea for the "year of biosimilars"

We initiate on PFNX with an Overweight rating and $28 price target. Our $28 price target is based on 15x our FY20 EPS estimate of $5.90 discounted back to the present and applying a 65% probability of success. We chose FY20 since it represents the first year in which PFNX will demonstrate its full earnings power.

Investor interest in biosimilars has certainly increased and recent events, including the first approval using the abbreviated pathway, suggest 2015 will be the year that biosimilars penetrated the U.S. investors' conscious. That interest is driven by recognition that biosimilars represent a threat to key innovative company product portfolios, as well as the emergence of several new publicly-traded biosimilar pure plays, including Pfenex, Coherus and Epirus. Pfizer's proposed acquisition of Hospira certainly provided key validation of the strategic value of a well-developed biosimilar portfolio as clearly brand companies assign value to these follow-on products.

Pfenex, in our view, stands out for having a differentiated pipeline and, perhaps more importantly, a proprietary technology platform which offers key competitive advantages. Pfenex's expression platform for non-glycosylated molecules speeds development and provides cost advantages based on its ability to produce complex biologics at high titers (i.e. high volumes of soluble protein without inclusion bodies). Our conversations with several market participants in the biosimilars space have spoken well of Pfenex's expression platform and what that ultimately means for competitive manufacturing costs.

FIGURE 1
Pfenex Pipeline

	Reference Drug	Collaboration Partner	Indication	Expected Status/Milestones	Market Entry	PFNX Revenue Opportunity ($ millions)
Biosimilars						
PF582 (Ranibizumab)	Lucentis	Hospira	Wet age-related macular degeneration, diabetic macular edema	Phase 1b/2a in-process; Phase 3 commencing in 2016	2020	$150
PF530 (Interferon beta-1b)	Betaseron	Wholly-Owned	Relapsing multiple sclerosis	Phase 1 initiated in March 2015	2019	$336
PF529 (Peg-filgrastim)	Neulasta	Wholly-Owned	Neutropenia in cancer patients	Process Development	2018	$420
PF688 (Certolizumab-pegol)	Cimzia	Wholly-Owned	Crohn s disease (U.S. only) and arthritis	Process Development	2022	$400
PF694 (Peg-interferon alpha-2a)	Pegasys	Strides Arcolab	Chronic Hepatitis B and C	Process Development	2022	$100
PF444 (Human growth hormone)	Genotropin	Strides Arcolab	Growth disturbance	Process Development	2022	$100
PF690 (Peg aspargase)	Oncaspar	Strides Arcolab	Acute Lymphoblastic Leukemia	Entering Process Development	2022	$100
PF726 (Peg-interferon beta)	Novel	Wholly-Owned	Relapsing multiple sclerosis	Formulation Development	2022	$900
Complex Generics						
PF708 (Teriparatide)	Forteo	Wholly-Owned	Osteoporosis	ANDA enabling PK study commencing in the in the second half	2019	$400

of 2015

Source: Barclays Research, company reports

Many of the biosimilar players have drawn attention to their analytical capabilities. Momenta clearly states that this is their competitive advantage. We wouldn't deny the importance of analytical prowess as the "similarity" of products will likely affect both the size of the biosimilar pie (i.e. penetration) as well as the how that pie is divided (market share in a particular product category).

Yet we believe the importance of "front end" capabilities in terms of developing cell lines capable of producing highly-similar products and then making them at competitive costs is not appreciated enough. Effective biology will trump brute industrial scale. In our view, the Pfenex platform should allow the company to produce high-quality biosimilars with meaningful cost advantages compared to both other biosimilar manufacturers and even innovators in some instances.

In a 2011 article in the journal *Protein Expression and Purification,* Pfenex outlined some of the advantages in producing GCSF in *Pseudomonas fluorescens* compared to *E. Coli* which is the expression system used by Amgen to produce Neupogen. Pfenex highlighted that the soluble periplasmic expression of the *Pseudomonas fluorescens* system obviated the need for renaturation from the inclusion bodies. Renaturation from inclusion bodies is undesirable because of the requirement for optimization of renaturation conditions and expensive reagents and time consuming downstream purification. While not knowing the exact yield and cost for production of Neupogen, their analysis suggested a 50% cost savings. It's not unreasonable to think that Pfenex has improved yields further by refining the production strain in the interim period.

The Pfenex platform can only be applied to bacteriologically-expressed proteins but we don't believe that represents a significant hindrance given the number and value of targets for the company to pursue. Monoclonal anti-bodies are typically created in mammalian expression systems such as CHO (Chinese Hamster Ovarian). Lucentis, which Pfenex is developing as a monoclonal antibody, is a monoclonal antibody fragment. The company's current pipeline represents just a fraction of opportunities for its technology, in our view. In addition to those in development today, insulin and the GLLP-1 class represent significant downstream opportunities for Pfenex to pursue.

Near-term pipeline opportunities include biosimialrs to Bayer's Betaseron and Amgen's Neulasta as well as a generic version of Eli Lilly's Forteo. Pfenex's Betaseron, now in Phase 1, should enter a comparative clinical trial in '16, although recent approval for generic Copaxone raises the question whether an abbreviated pathway is available. An abbreviated pathway for Neulasta seems possible based on recent commentary by CHRS that the FDA is only asking for pharmacokinetic/pharmacodynamic (PKL/PD) data in healthy volunteers. Not to be overlooked, we see significant value in the generic Forteo. We believe this will likely remain a very limited generic market.

While we'd argue that Pfenex's product portfolio carries significantly less risk since it simply needs to meet biosimilarity/bioequivalence for its lead assets, we think its earnings profile is not that dissimilar to similarly-sized development stage biopharmaceutical companies. The company makes up for the limited size of each individual product by being able to develop several assets concurrently in a capital efficient manner. This results in an attractive revenue and earnings ramp-up as Pfenex's pipeline matures over the next several years.

Moreover, while the company might limit its economic upside from some wholly-owned product candidates through de-risking partnerships, we expect that would result in accelerated development for high-value opportunities that aren't in our model at the present, such as insulin.

FIGURE 2
Barclays Pfenex Model Summary

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Revenue	$10	$12	$11	$50	$364	$594	$600	$766	$766	$859
EBITDA	($31)	($37)	($40)	($34)	$129	$229	$253	$373	$368	$412
EPS	($1.37)	($1.56)	($1.58)	($1.76)	$2.51	$5.90	$6.21	$9.14	$9.02	$10.09

Source: Barclays Research

The Year of Biosimilars

Biosimilars took center stage immediately as the calendar turned to 2015 when the FDA's Oncologic Drugs Advisory Committee considered Sandoz's application for approval of its filgrastim, a biosimilar to Amgen's Neupogen. The FDA panel recommended approval unanimously and two months later the FDA granted final approval to Zarxio.

Five weeks later, the FDA approved the first generic version of Teva's Copaxone. Approval of Sandoz/Momenta's Glatopa came through the traditional Abbreviated New Drug Application (ANDA) pathway, but, in our view, spoke to the FDA's increasing confidence in using analytical data to understand the physiochemical properties of a molecule in establishing equivalence/similarity even when the mechanism of action is not well understood.

We should also see FDA action on Hospira's application for a biosimilar to Johnson and Johnson's Remicade in the coming months. Obviously the first approval of a biosimilar monoclonal antibody in the U.S., so soon after the approval of the first recombinant protein biosimilar would provide evidence that the U.S. is catching up to Europe, where the first Erythropoietin (EPO) biosimilars were approved in 2007.

In the context of the FDA's approval of Momenta's Copaxone, it shouldn't be surprising that the FDA indicated to biosimilar-focused Coherus that it could be allowed to bring its biosimilar to Amgen's Neulasta through an accelerated pathway which doesn't require comparative clinical trials and approval is based wholly on PK/PD studies in healthy volunteers.

We also believe the legal pathway has begun to gain clarity. In particular, the original Federal District court decision indicating that the so-called patent dance was optional could prove very beneficial to biosimilar applicants. Additionally, we believe the Inter Partes Review process will prove important for biosimilar challengers. Through an IPR, biosimilar makers can void a particular claim within a patent based on prior art without needing to invalidate the entire patent which is obviously much more difficult to do.

FIGURE 3
Key Biosimilar Events in 2015

Product	Branded targeted	Timing	Event
Remsima (HSP; Celltrion; PFE)	JNJ's Remicade	Q2 2015	FDA Advisory Committee meeting (delayed from 17 March)
Various	AbbVie's Humira	Q2 2015	Potential for inter partes review requests on recently issued Humira patents (e.g. '135 patent, which affords protection through to Jan 2025)
SB2 (Biogen/Samsung)	JNJ/MRK's Remicade	March 2015 (est)	Filing expected following completion of 584 patient RA trial in August 2014
Remsima (HSP; Celltrion; PFE)	MRK's Remicade	28 April 2015	Merck Q1 results and European Remicade revenue update –visibility on pricing (-25-30% discount expected) and initial update

Remsima (HSP; Celltrion; PFE)	JNJ's Remicade	8 June 2015	FDA Approval Decision
Various	AbbVie's Humira	23-25 June	European Opposition Division oral hearing on the EP '933 formulation patent which affords protection through to August 2023
Various	Various	10-13 June	Biosimilar data presented at EULAR – potential to see SB4 (biosimilar Enbrel; 498 RA patients), ABP-501 (biosimilar Humiral 350 psoriasis patient; 526 RA patients)
Glatopa (Sandoz/Momenta)	Teva's Copaxone	Q2 2015	Potential pricing, launch and uptake of biosimilar Copaxone
Remsima (HSP; Celltrion; PFE)	MRK's Remicade	28 July 2015	Merck Q2 results and European Remicade revenue update
GP2015 (Sandoz)	AMGN/PFE Enbrel	Mid/H2 2015	Filing GP2015 with pivotal rheumatoid arthritis data
ABP-501 (Amgen)	AbbVie's Humira	Mid/H2 2015	Filing ABP-501 with pivotal rheumatoid arthritis and psoriasis data (long-term RA data expected Feb'17)
Pegfilgrastim (Apotex)	AMGN's Neulasta	Mid-August	FDA approval decision
Various	AbbVie's Humira	H2 2015	European Opposition Division oral hearing on the EP '656 patent, the European equivalent to the US '135, which affords protection through to June 2022
Various	AbbVie's Humira	H2 2015	FDA approval decision on new Humira formulation – visibility could emerge on new device strategy
SB5 (Biogen/Samsung)	AbbVie's Humira	H2 2015	Filing SB5 with 490 patient pivotal rheumatoid arthritis data (trial completes May 2015)
Epoetin alfa(Hospira)	AMGN's Epogen	16-October	FDA approval decision
Pegfilgrastim (Apotex)	AMGN's Neupogen	Mid-October	FDA approval decision
Various	Various	6-11 November	Biosimilar data presented at ACR – potential to see SB4 (biosimilar Enbrel; 498 RA patients), SB2 (biosimilar Remicade,584 RA patients), ABP-501 (biosimilar Humiral 350 psoriasis patients; 526 RA patients), GP2015 (546 RA patients)
SB4 (Biogen/Samsung)	AMGN/PFE Enbrel	Q4 2015	EU approval decision expected following completion of 498 patient RA trial with filing acceptance January 2015
GP2017 (Sandoz)	AbbVie's Humira	End 2015	Filing GP2017 with 448 patient pivotal psoriasis data
SB2 (Biogen/Samsung)	JNJ/MRK's Remicade	Early 2016	EU approval decision expected following completion of 584 patient RA trial with filing acceptance March 2015

Source: Barclays Research, company reports

PF582

We believe PF582 is the most advanced Lucentis biosimilar in development for the treatment of wet age-related macular degeneration (wet AMD), diabetic macular edema and retinal vein occlusion. In February, Pfenex signed a partnership with Hospira for the product's development. The partnership gave Pfenex $51 million upfront as well as $241 in remaining development and commercial milestones (skewed towards commercial). Along with its recent secondary offering, the upfront payment allows Pfenex to accelerate development of its other pipeline assets.

In addition to milestone payments, Pfenex is entitled to tiered double-digit royalties on sales. Hospira and Pfenex will split Phase 3 development costs and Pfenex costs are capped at $20 million and the company's cash-exposure is limited to $10 million until approval. Hospira is responsible for manufacturing, commercialization and litigation expenses.

We expect Hospira and Pfenex to initiate a Phase 3 trial in wet AMD next year. Based on that, we expect PF582 will achieve label extrapolation across AMD into diabetic macular edema and retinal vein occlusion as well. Pfenex recently completed enrolment in Phase 1b/2a trial. The sentinel patient in the Phase 1 trial saw clinical response as would be expected for a Lucentis-treated patient.

We recognize that Lucentis has been facing competitive pressure from Regeneron's Eylea. However, we believe the availability of a biosimilar would be attractive and see robust

adoption assuming it is competitively priced. We also believe that a biosimilar will take share from physicians using Avastin off-label. While Avastin costs considerably less, it does require the use of compounding pharmacies which create safety concerns. We also believe the use of PF582 would be attractive in combination with other agents, such as Ophthotech's anti-platlet derived growth factor (PDGF) Fovista.

FIGURE 4
PF582 (Biosimilar Lucentis) U.S. Revenue Build

	2020E	2021E	2022E	2023E	2024E	2025E	2026E
PF582 patients (thousands)	31	41	52	52	53	53	53
PF582 penetration into Lucentis market	30%	40%	50%	50%	50%	50%	50%
PF582 annual cost	$7,605	$7,605	$7,605	$7,605	$7,605	$7,605	$7,605
PF582 revenues ($, M)	**$235.8**	**$312.5**	**$395.1**	**$398.3**	**$ 399.9**	**$401.5**	**$403.2**
Royalty rate	**10%**	**12%**	**13%**	**15%**	**15%**	**15%**	**15%**
PF582 royalties	**$23.6**	**$37.5**	**$51.4**	**$59.7**	**$60.0**	**$60.2**	**$60.5**

Source: Barclays Research

FIGURE 5
PF582 (Biosimilar Lucentis) OUS Revenue Build

	2022E	2023E	2024E	2025E	2026E
PF582 patients(thousands)	114	112	110	108	106
PF582 penetration into Lucentis market	60%	60%	60%	60%	60%
PF582 annual cost	$4,077	$4,037	$3,996	$3,956	$3,917
PF582 revenues ($, M)	**$464.9**	**$452.9**	**$440.9**	**$429.0**	**$417.0**
PFNX Royalties	**$60.4**	**$67.9**	**$66.1**	**$64.3**	**$62.6**
Royalty rate	**13%**	**15%**	**15%**	**15%**	**15%**

Source: Barclays Research

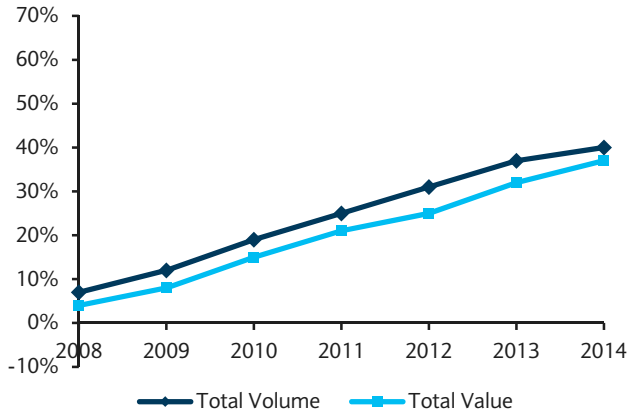
PF529

One of the key assets for Pfenex is PF529 which is the company's proposed biosimilar to Amgen's Neulasta (pegfilgrastim) for the treatment of neutropenia. This is a product that Pfenex brings significant expertise to since CEO Bert Liang worked on the Neulasta program when he was at Amgen.

The Granulocyte-colony stimulating factor (GCSF) class, inclusive of short-acting filgrastim, has seen very strong biosimilar adoption in Europe. Pricing has become competitive for the short-acting GCSF in many of the markets with government run tenders in place, although the long-acting pricing has remained more stable. It's worth noting that even though short-acting GCSF pricing has proven very competitive, that decline in "value" has been somewhat offset by increased use of those molecules since their introductions as physicians have better access to the class since it has become more affordable.

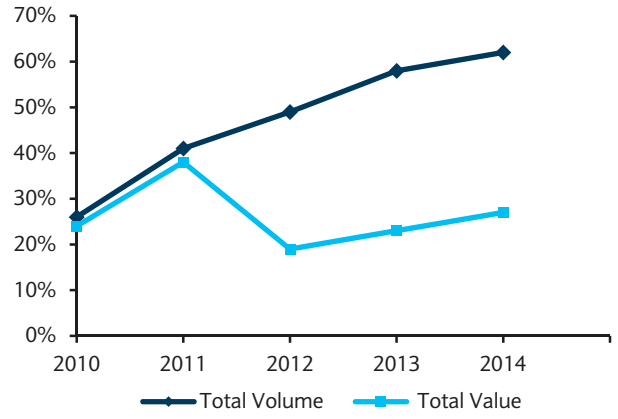
We expect there to be other competitors for Neulasta, including Sandoz and Coherus (Apotex has also filed but we'd argue it brings less credibility in biologics). However, we believe that Pfenex will bring to bear important cost advantages in production which will assure it a strong market share at robust gross margins.

FIGURE 6
EPO biosimilar penetration (short-acting only)



Source: Barclays Research, IMS Health

FIGURE 7
GCSF biosimilar penetration (including Neulasta)



Source: Barclays Research, IMS Health

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Given the potential availability of an "accelerated" development pathway for a Neulasta biosimilar based on feedback that the FDA gave to Coherus, we believe it's possible that Pfenex will be able to get to market by 2018 with PF582. While this would be behind others, we believe its potential cost advantages will allow it to capture a 30% market share or better.

FIGURE 8

U.S. Long-Acting GCSF Opportunity for PF529

	2018	2019	2020	2021	2022	2023	2024	2025
Long-Acting addressable population (thousands)	496	501	506	511	516	521	527	532
% treated	93%	93%	93%	93%	93%	93%	93%	93%
Long-Acting Market Share								
Neulasta	88%	80%	70%	67%	60%	60%	60%	60%
Biosimilars	12%	20%	30%	33%	40%	40%	40%	40%
PF529								
Market Share of Biosimilar Market	10%	25%	30%	30%	30%	30%	30%	30%
PF529 Patients (thousands)	6	23	42	47	57	58	58	59
Discount to branded Neulasta	50%	50%	50%	50%	50%	50%	50%	50%
Annual price	$3,600	$3,420	$3,249	$3,086	$2,932	$2,785	$2,646	$2,514
PF529 sales ($, M)	**$20**	**$79**	**$137**	**$144**	**$168**	**$161**	**$155**	**$148**
PF529 Gross Margin	**60%**	**65%**	**70%**	**70%**	**70%**	**70%**	**70%**	**70%**
PF529 Gross Profit contribution ($, M)	**$12**	**$51**	**$96**	**$101**	**$118**	**$113**	**$108**	**$104**

Source: Barclays Research

FIGURE 9

OUS Long-Acting GCSF Opportunity for PF529

Long-Acting G-CSF Segment	2018	2019	2020	2021	2022	2023	2024	2025
Long-acting addressable population	613	619	625	631	638	644	650	657
% treated	92%	92%	92%	92%	92%	92%	92%	92%
% on long-acting G-CSF	75%	75%	75%	75%	75%	75%	75%	75%
Long-Acting Market Share								
Neulasta	51%	48%	45%	42%	40%	37%	35%	33%
Biosimilars	49%	52%	55%	58%	60%	63%	65%	67%
PF529								
Market Share of Biosimilar Market	5%	10%	15%	15%	15%	15%	15%	15%
PF529 Patients	14	30	48	50	53	56	58	61
Discount to branded Neulasta	60%	60%	60%	60%	60%	60%	60%	60%
Annual price	$1,613	$1,613	$1,613	$1,613	$1,613	$1,613	$1,613	$1,613
PF529 sales ($, M)	**$22**	**$48**	**$77**	**$81**	**$86**	**$90**	**$94**	**$98**
PF529 Gross Margin	**20%**	**30%**	**40%**	**40%**	**40%**	**40%**	**40%**	**40%**
PF529 Gross Profit contribution ($,M)	**$4**	**$14**	**$31**	**$33**	**$34**	**$36**	**$38**	**$39**

Source: Barclays Research, Company reports

PF530

In March, Pfenex initiated a Phase I trial for its biosimilar to Betaseron for the treatment of multiple sclerosis. While Betaseron has been losing market share, accelerated recently by Biogen's introduction of Plegridy, we think the availability of a biosimilar to Betaseron would be attractive to managed care as it tries to gain some control over the multiple sclerosis market. While Betaseron has less market share than Copaxone, neurologists might be more comfortable with a biosimilar to that molecule than a generic version of glatimer acetate. Even if Betaseron's overall share declines to 1% globally, we assume robust adoption of a biosimilar would drive meaningful and attractive revenues to Pfenex. Likewise, we think this could be promoted effectively with a sales force of under 100 since we think much of adoption would be driven by payers.

Pfenex expects to initiate a Phase 3 trial in 2016. However, the FDA's recent approval of a generic Copaxone without a comparative clinical trial raises the question whether the Agency would be willing to consider an abbreviated pathway. If an abbreviated pathway isn't available, Pfenex could consider signing a partnership to limits its costs and avail itself of an infusion of cash which would allow them to pursue development of other biosimilar/generics such as insulin or GLP-1s.

FIGURE 10
PF530 Revenue Build

	2019E	2020E	2021E	2022E	2023E	2024E
Betaseron Patients	1,000	8,912	6,914	6,948	6,983	7,018
PF530 Pricing	$30,000	$30,000	$30,000	$30,000	$30,000	$30,000
PF530 Share of Betaseron Market	50%	50%	50%	50%	50%	50%
PF530 Sales ($, M)	**$15**	**$134**	**$104**	**$104**	**$105**	**$105**
PF530 Gross Profit ($, M)	**$11**	**$98**	**$78**	**$78**	**$79**	**$79**
PF530 Gross Margin	70%	73%	75%	75%	75%	75%

Source: Barclays Research, company reports

PF708

Not to be overlooked, the Pfenex platform can used for drugs such as Eli Lilly's Forteo (teriparatide) which is a portion of human parathyroid hormone (PTH), amino acid sequence 1 through 34, of the complete molecule (containing 84 amino acids). Forteo is indicated for the treatment of osteoporosis. Forteo generated sales of $1.2 billion in 2014.

Approval of Forteo would not be through the biosimilar pathway but through the traditional ANDA approach. This significantly speeds development as well as limits costs since only a bioequivalence study will be needed. Pfenex expects to initiate an ANDA-enabling PK study in the second half of 2015. Eli Lilly has an Orange Book patent for its pen-device going to 2025, although we don't believe that is a blocking patent since a non-infringement pathway is available.

Given the challenges in producing a peptide drug like Forteo, we believe this will prove to be a limited competition opportunity for Pfenex. Few of the major generic manufacturers have the internal capabilities to make a product like Forteo. Even assuming two other competitors alongside Pfenex and even aggressive pricing levels, we see this as being greater than $200 million a year in revenues for Pfenex at very attractive gross margins. Pfenex would benefit from automatic substitution for this product which would obviate the need for any material marketing expense and so gross profits would largely fall to the company's operating income.

Vaccine development

Pfenex's expression platform can also be used for vaccine development. Capitalizing on the ability of Pfenex to rapidly identify production strains for proteins that cannot be readily expressed in other systems, Pfenex has a comprehensive portfolio of antigens that have been difficult or impossible to express in other host systems or organisms. This enables infectious disease research and vaccine development previously not possible.

Pfenex has received funding by the U.S. Department of Health and Human Services for the development of Px563L, a novel anthrax vaccine candidate, in response to the United States government's unmet demand for increased quantity, stability and dose sparing regimens of anthrax vaccine.

Pfenex is also developing Px533 as a prophylactic vaccine candidate against malaria infection, for which there is currently no available vaccine. The development of Px533 has been funded by Leidos, formerly Science Applications International Corporation, or SAIC, through its Malaria Vaccine Production and Support Services contract with the National Institute of Allergy and Infectious Diseases, or NIAID. Clinical trials for Px533 are managed by NIAID.

We don't expect vaccines to be a major focus for the company, although opportunities like these could represent good opportunities, especially given the fact that the projects will largely be funded by the government or other organizations.

The Pfenex Expression Platform

Traditional techniques for protein production use an iterative approach to cell-line selection and process optimization which is both inefficient and often produces results which carry compromises. Pfenex's proprietary and patented Expression Technology offers advantages over other methods for producing proteins. The platform is based on automated high-throughput screening of large libraries of novel, genetically engineered *Pseudomonas fluorescens* bacterial expression strains. The libraries contain thousands of expression strains which are constructed from a large inventory of expression vectors, or genetic elements, incorporated into engineered *P. fluorescens* host strains.

FIGURE 11

Standard expression systems for protein therapeutics

Standard expression systems		
Mammalian cells	Bacteria	Yeast
• CHO	• E. coli	• Saccharomyces cerevisiae
• BHK		• Pichia pistoris
Applications:		
Glycosylated, complex recombinant proteins	Antibody fragments	Non-glycosylated proteins
monoclonal antibodies	Non-glycosylated proteins	Limited complex proteins
fusion proteins		

Source: Barclays Research

FIGURE 12
Key characteristics in protein expression systems

Protein properties	• Size • Complexity • Solubility • Stability • Aggregation • Disulfide bonds • Glycosilation • Bioactivity and toxicity
Clinical demand & market forecast	• Titer • Yield • COGS

Source: Barclays Research

Pfenex then employs automated, robotically enabled parallel high-throughput screening, incorporating extensive bioanalytical testing, in order to select strains from the library which express the protein of interest at optimal yields, purity and potency. Extensive fermentation scouting on the selected strains allows for the identification of a final production strain with further improvements in the yield of the active therapeutic protein.

Pfenex's technology was originated at Mycogen Corporation and further developed at the Dow Chemical Company. Mycogen and Dow used this technology to commercially manufacture a broad range of proteins for industrial applications which we believe speak to the platform's scalability and cost-efficiency.

The company believes its Expression Platform is able of identifying a final production strain in approximately nine weeks compared to approximately one year or more in the typical case, if even possible, through a traditional trial and error approach. The platform offers a significant competitive advantage for protein production, including higher accuracy, a greater degree of protein purity, speed and lower costs. The speed of the Pfenex system allows the company to continue to refine its production strains rather than stopping at "good enough."

Pfnex's platform is based on automated high-throughput screening of large libraries of novel, genetically engineered *P. fluorescens* bacterial expression strains. The libraries contain thousands of expression strains which are constructed from a large inventory of expression vectors, or genetic elements, incorporated into engineered P. fluorescens host strains. Pfnex then employs automated, robotically enabled parallel high-throughput screening, incorporating extensive bioanalytical testing, in order to select strains from the library which express the protein of interest at optimal yields, purity and potency. Extensive fermentation scouting experiments on the selected strains allows for the identification of a final production strain with further improvements in the yield of the active therapeutic protein.

The Pfenex Expression Technology platform consists of three primary elements that when combined deliver a significant competitive advantage for protein production that differentiates the company from others competing in the space. The value of cost-competitive manufacturing cannot be underestimated. Momenta, another highly-regarded biosimilar player known for its analytical capabilities, has said it is looking for partners that can provide low-cost manufacturing solutions.

The three elements include Robust Protein Production Organism; creation of extensive library of protein expression variants; and robotically enabled High-Throughput-Screening. The Pfenex platform leverages the P, fluorescens bacteria which are particularly well-suited for this purpose. The favorable attributes of the P. fluorescens bacterium include:

1) Secretion of soluble protein into the bacterial periplasm, or the space between the inner and outer membrane in gram negative bacteria, resulting in increased recovery yields of properly folded protein;

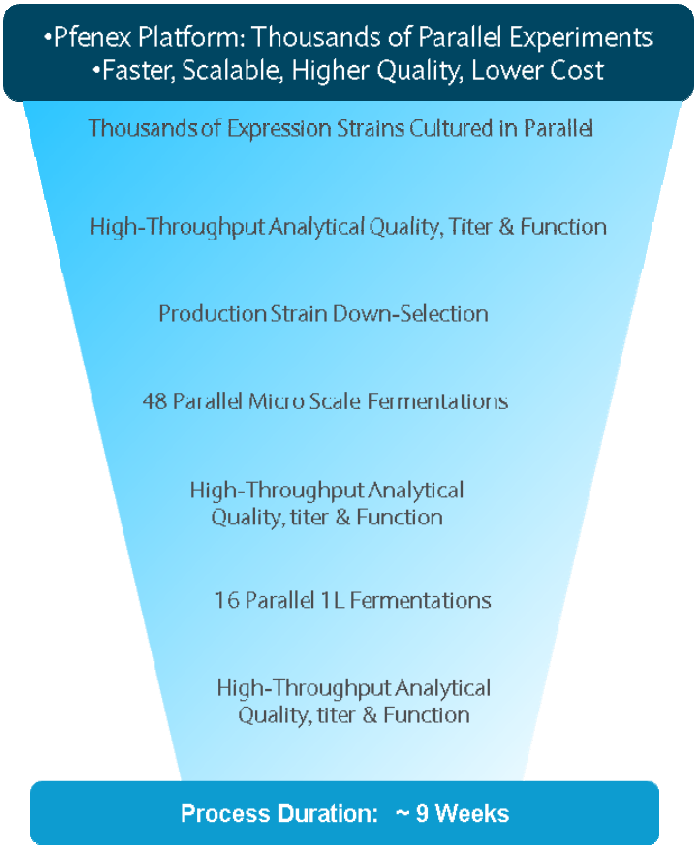
2) P. fluorescens genome allows for modifications, including deleting protease genes, or nucleotides that provide instructions for synthesis of RNA into a specific protease, and inserting chaperone and/or disulfide bond isomerase genes, or nucleotides that provide instructions for synthesis of RNA into a specific chaperone or disulfide isomerase, which overall increase the quality and production of properly folded active full length proteins;

3) Selection of expression strains without the use of antibiotics;

4) High cell density fermentation due to its obligate aerobe growth nature, or bacterium that can only grow in the presence of oxygen, which improves the protein production for characterization, enables consistent scale-up and long-term low cost of goods.

FIGURE 13

Pfenex Technology Platform Allows Rapid Cell Line Development



Source: Barcalys Research, company reports

Creation of Extensive Library of Protein Expression Variants

Pfenex has developed a "toolbox" of protein production variants that can be accessed for finding the best choice for manufacturing of a specific protein. The tool box continues to grow as an outgrowth of the company's ongoing product development efforts. The company constructs libraries of thousands of unique expression strain variants by combining engineered *P. fluorescens* host strains with proprietary expression vectors.

The engineered *P. fluorescens* strains have reduced expressions 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. Determining which of these variants will improve production of any particular protein cannot be determined from the amino acid sequence of the protein of interest. As a result, the company uses automated high throughput screening to select the strain that produces the protein of interest at optimal purity, yield and potency.

Robotically Enabled High Throughput Screening

Classical strain development traditionally practices a linear and iterative approach to strain screening: evaluating recombinant protein expression in one or a few strains, and moving to alternative host or expression platform or including ''solubility tags'' if not successful, or denaturing and attempting to refold the target protein. The success rate for the expression of soluble, properly folded protein evaluating a single E. coli expression construct is generally quite low, only 25–35%, which forces the protein to be isolated under denaturing conditions.

By taking a parallel screening approach to strain development, Pfenex shown very high rates (we found a journal article in which Pfenex noted up 85% of over 75 lead protein cases tested to date in 2012) of soluble expression of difficult to express proteins that either failed to express or were expressed in an inactive form in other systems.

The ability to take advantage of these tools depends on the development of high throughput methods for growth and analysis as well as streamlined methods for scale-up and purification. Strain screening is performed at the 96-well scale from cloning of expression plasmids through expression sample analyses. Genes are optimized for expression in *P. fluorescens*.

P. fluorescens is an obligate aerobe, which means that under oxygen limiting conditions, growth and protein production may slow down but the organism does not switch to fermentative growth and begin to accumulate acetate like E. coli does. This allowed Pfenex to develop a robust 96-well growth and expression platform that allows growth of P. fluorescens at robust levels standard shaking incubators without oxygen supplementation. In the case of development of a highly expressing strain for production of clinical material, Pfenex can screen over 1000 strains in parallel.

The individual components selected for the study are dependent on the nature of the protein, for example the presence of disulfide bonds, known proteolytically sensitive sites, complex folding or structure. However, each protein is different and it is difficult to identify exactly which combinations will work well to generate soluble, active target. Therefore, we use information from the peptide sequence to identify a subset of the toolbox that will be applied to any particular protein.

Strides Arcolab Partnership

In December 2012, Pfenex entered into a joint development and license agreement (JDLA) with Strides Arcolab, to develop biosimilar products according to development plans to be mutually agreed upon. Pfenex will generally be responsible for establishing and characterizing a research cell bank of the protein production strain and developing a manufacturing process and analytical methods, while Strides Arcolab would bear responsibility for developing master and working cell banks for the applicable protein production strain, developing a formulation for the applicable biosimilar product, manufacturing the biosimilar for Phase 1 trials, conducting preclinical and Phase 1 trials and managing regulatory matters. Pfenex and Strides will each bear its own costs for their segment of early development but would split costs beginning in Phase 3.

In March 2013, Pfenex entered into a joint venture agreement, or JVA, with Strides Arcolab to form a joint venture company, or JV, to develop and commercialize biosimilar products developed under the JDLA. Under the terms of the JVA, Pfenex will own a forty-nine percent equity interest in the JV, while Strides Arcolab owns a fifty-one percent equity interest in the JV. Both parties have equal board representation and equal voting rights. Once a biosimilar product successfully completes a Phase 1 trial and Strides Arcolab and Pfenex agree to contribute the biosimilar to the JV.

FIGURE 14
Pfenex/Strides Arcolabs Joint Venture Pipeline

`	Reference Drug	Collaboration Partner	Indication	Expected Status/Milestones
PF694 (Peg-interferon alpha-2a)	Pegasys	Strides Arcolab	Chronic Hepatitis B and C	Process Development
PF444 (Human growth hormone)	Genotropin	Strides Arcolab	Growth disturbance	Process Development
PF690 (Peg aspargase)	Oncaspar	Strides Arcolab	Acute Lymphoblastic Leukemia	Entering Process Development

Source: Company reports

Upon successful completion of the first Phase 1 trial for each biosimilar candidate, Pfenex and Strides Arcolab will transfer to the JV the applicable biosimilar candidate and all associated data, rights and assets, including any inventions developed by Pfenex or Strides Arcolab under the joint development and licensing agreement (JDLA) and all intellectual property rights therein. After transfer of a biosimilar product to the JV, Strides Arcolab will be responsible for manufacturing such biosimilar product and the JV; Strides Arcolab will be responsible for all regulatory filings and approvals, clinical trials, commercialization strategies and distribution of the applicable biosimilar product upon approvals.

Importantly, Pfenex retains the right to pullback product candidates from the JDLA/JV. After strengthening its balance sheet through its secondary offering as well as the capital infusion from the Hospira partnership, we suspect that over time we could see the company focus on developing assets apart from the Strides partnership. Earlier this year, Pfenex took back the rights to the PF529 (Peg-filgrastim/Neulasta) and PF530 (interferon beta-1b/Betaseron) from the joint venture with Strides so the company could develop them as wholly-owned assets and enjoy the full economic potential.

Investment risks

Pfenex's key products remain unapproved and have undergone limited clinical testing to date. Even though Pfenex's focus on biosimilars reduces regulatory risk, the complexity of biologics could cause unexpected clinical outcomes, preventing FDA approval and commercial launch. Pfenex's products have had limited clinical testing to date and issues such as immunogenicity could emerge and prevent approval.

Pfenex faces many large competitors in the biosimilars market: The biosimilars market could prove highly competitive, resulting in meaningful price discounts which diminish the revenue opportunity for the company.

Additionally, Pfenex will be competing with companies with greater commercial resources, putting them at a discount in promoting products to physicians. Several of the major global pharmaceutical companies, including Pfizer, Novartis, and Amgen, are making significant investments in biosimilars. Those companies could use their greater scale and marketing presence to take market share.

There are several smaller biosimilar companies such as Momenta and Coherus. Additionally, alternative expression technologies could emerge which limit the advantages of the Pfenex technology.

Innovators could prevent or delay commercial launch of biosimilars. The branded products which Pfenex is targeting for biosimilars are protected by patents which could delay or block timely commercial launch. Eli Lilly has Orange Book patents for Forteo until 2025, so our expectation of a launch in 2019 hinges on the company's ability to either establish non-infringement or invalidate that intellectual property.

Products opportunities could be diminished by innovation. The market opportunity for some of PFNX's biosimilar candidates could be diminished by new innovative therapies. In particular, Lucentis has been losing market share to Regeneron's Eylea and could face additional competition from other innovative therapies in the wet-AMD market. Betaseron has been losing market share steadily in recent years and the emergence of new oral therapies (as well as potential generic challenges to some of the recently launched oral agents such as Tecfidera) could limit the market opportunity.

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Primary Stocks (Ticker, Date, Price)

Pfenex (PFNX, 15-May-2015, USD 13.70), Overweight/Positive, A/C/D/J/L

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Mallinckrodt (MNK)	Mylan Inc. (MYL)	Pacira Pharmaceuticals Inc. (PCRX)
PAREXEL International (PRXL)	Pfenex (PFNX)	Phibro Animal Health Corp. (PAHC)
Quintiles Transnational (Q)	Teva Pharmaceutical Industries (TEVA)	Valeant Pharmaceuticals International Inc. (VRX)
Zoetis Inc. (ZTS)		

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IMPORTANT DISCLOSURES CONTINUED

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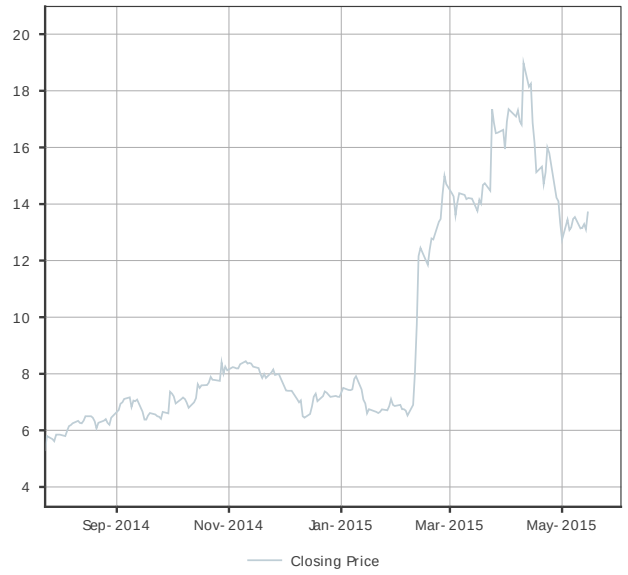
Pfenex (PFNX)	Stock Rating	Industry View
USD 13.70 (15-May-2015)	**OVERWEIGHT**	**POSITIVE**

Rating and Price Target Chart - USD (as of 15-May-2015) **Currency=USD**



Date	Closing Price	Rating	Adjusted Price Target

Source: IDC, Barclays Research

Link to Barclays Live for interactive charting

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Valuation Methodology: Our $28 price target is based on 15x our FY20 EPS estimate of $5.90 discounted back to the present and applying a 65% probability of success.

Risks which May Impede the Achievement of the Barclays Research Price Target: PFNX's key products remain unapproved: Even though PFNX's focus on biosimilars reduces regulatory risk, the complexity of biologics could cause unexpected clinical outcomes, preventing FDA approval and commercial launch. PFNX faces many large competitors in the biosimilars market: The biosimilars market could prove highly competitive, resulting in meaningful price discounts which diminish the revenue opportunity for the company. Additionally, PFNX could be competing with companies with greater commercial resources, putting them at a discount in promoting products to physicians. Innovators could prevent or delay commercial launch of biosimilars. The branded products which PFNX is targeting for biosimilars are protected by patents which could delay or block timely commercial launch. Products opportunities could be diminished by innovation. The market opportunity for some of PFNX's biosimilar candidates could be diminished by new innovative therapies.

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