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Equity Research

It's Complicated:
Wall Street's View of Biosimilars

Association for Accessible Medicines' Biosimilars Conference

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September 12, 2017

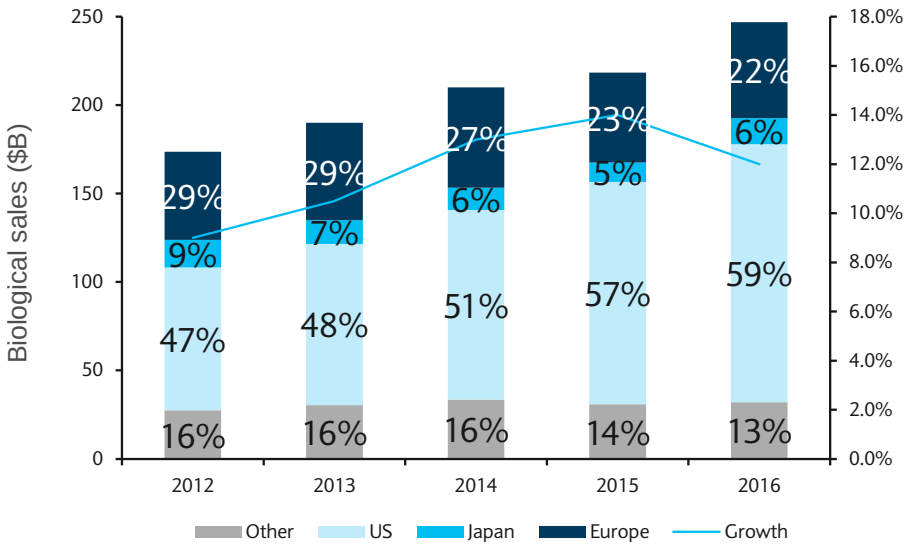
U.S. has lagged Europe, but has momentum

The U.S. market has been slow to form, but the pace of approvals is picking up which should (eventually) result in approvals

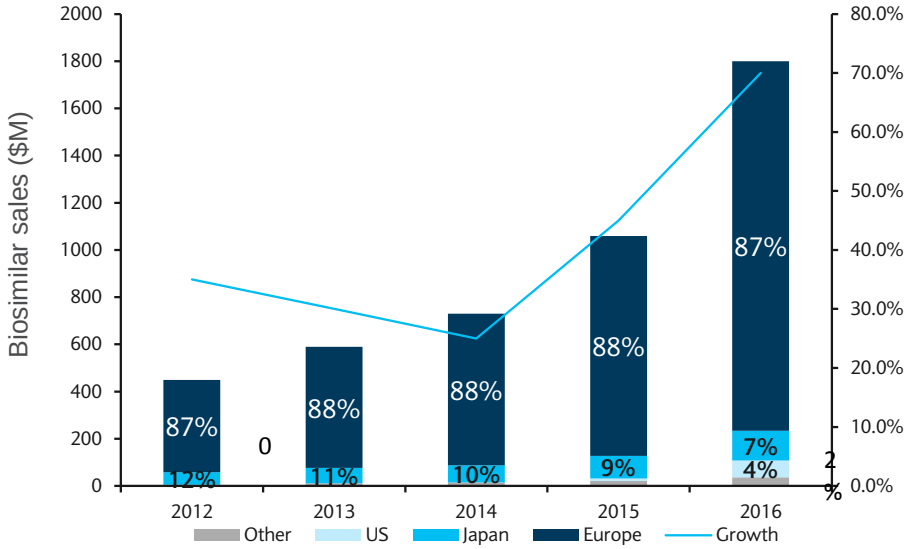
- We're seeing biosimilars approved, and even some launches
- Notably, we're finally seeing "competitive" markets in the U.S. with the approval & launch of the second infliximab, Renflexis.
  - 35% discount suggests a more aggressive stance on price

U.S. makes up 59% of biologics sales but just 4% of biosimilar sales

Global Biologic market dynamics - $247B in '16



Global Biosimilar market dynamics - $1.8B in '16



Source: IMS Health

There things investors like about biosimilars

Many investors see biosimilars as an interesting market opportunity and one that has key differences compared to small molecule generics.

- Unlike small molecule generics which investors view as “decaying,” biosimilars are viewed to be more durable assets
- Cost, technical skill, and commercialization infrastructure will limit the number of companies able to compete in the U.S. market
  - Initially skepticism that generic manufacturers had the technical capabilities to develop biosimilars
  - That premise has been challenged with recent AdCom vote supporting MYL’s aBLA for Herceptin
- “Quasi-branded” products
  - Large pharma companies position biosimilars as natural complements to their innovative portfolios; can position biosimilars alongside newer, more potent agents, especially in the same class
  - “Brand qualities” will make it difficult for traditional small molecule generic players to compete effectively

Important to remember that most investors have more to “lose” from biosimilars success than gain.

U.S. Competitive Landscape

- Five physician-administered biosimilars approved to date:

Biosimilar	Reference Product	Approval
Zarxio (Sandoz)	Neupogen	March 6, 2015
Inflectra (Hospira)	Remicade	April 5, 2016
Renflexis (Samsung)	Remicade	April 24, 2017
Erelzi (Sandoz)	Enbrel	August 30, 2016
Amjevita (Amgen)	Humira	September 23, 2016

- Intellectual property (IP) concerns have kept most approved products off-market and in the court room

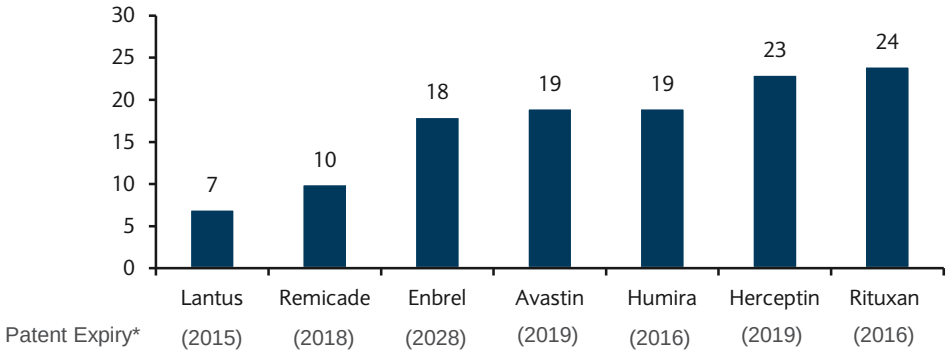
Humira Litigation

- AbbVie v. Amgen: *Fall 2019 Bench Trial*
- AbbVie v. Boehringer Ingelheim

Enbrel litigation

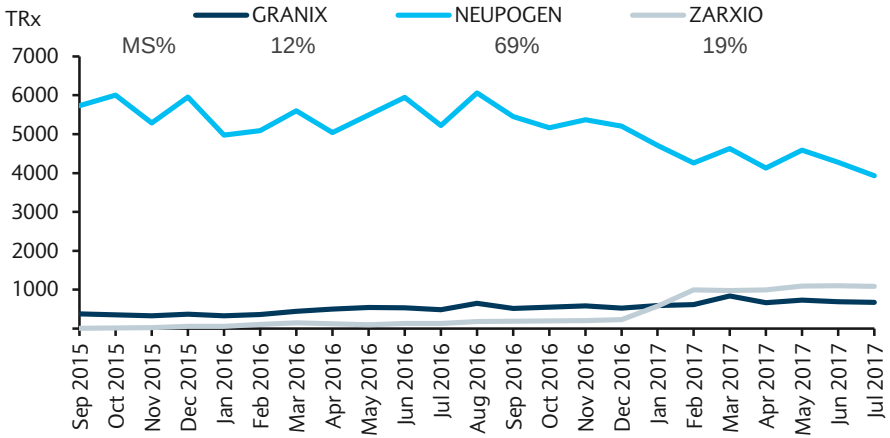
- Immunex v. Sandoz : *April 2018 Bench Trial*

- Most biosimilars in development fall within oncology or immunology and metabolic disorders, due to patent expiry



- Survey by Avalere Health revealed 81% of managed care plans cover at least one biosimilar product and cost is key factor in equation

Neupogen Volume Trends (TRx MS%)



- As reflected in IMS Health data, Inflectra has gained only 2% market share to date; Renflexis data not yet reflected in market database

**Note: Represents key formulation patent; exclusivity may be prolonged by other patents*

Sources: Bloomberg Intelligence, Avalere, FDA, IMS Health, Barclays Research

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Biosimilars Pricing in the US

Key questions on pricing:

- Is one biosimilar entrant enough to sufficiently lower pricing?
- If at all, how will originator players counter lower-priced biosimilar entrance?
- Will we see a first-mover advantage in US where first entrant captures majority biosimilar market share?

Strategic Options for Biologic Innovator

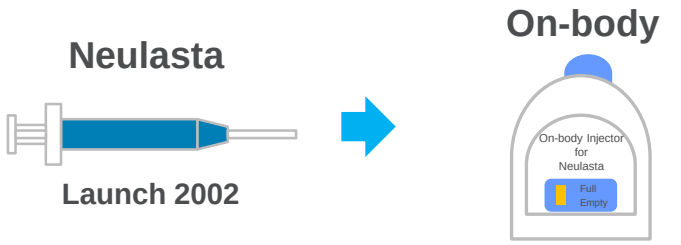
Increase/Adjust Managed Care Contracting

Example: response to Renflexis Pricing

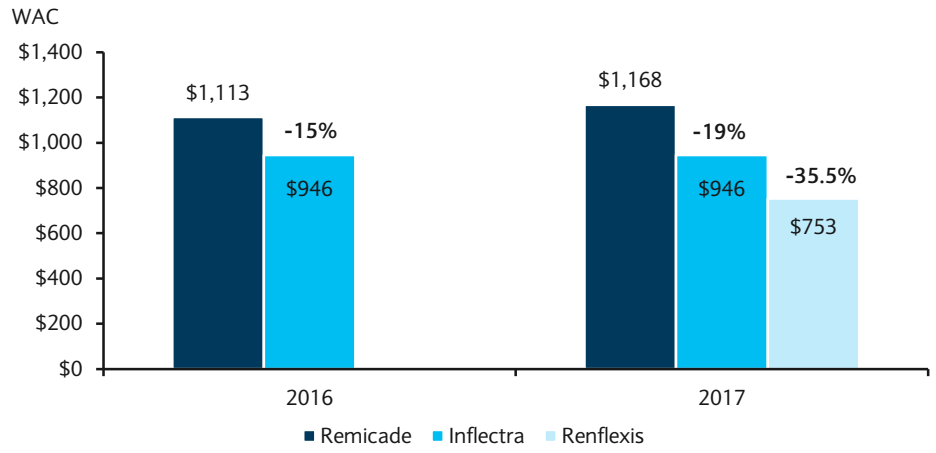
2Q17 JNJ saw only a 5% decline from Inflectra:
"We have contracting in place, so we feel pretty good that Remicade erosion even with the entrance of a new biosimilar will be less than previously expected"

Focus on Next Generation Products

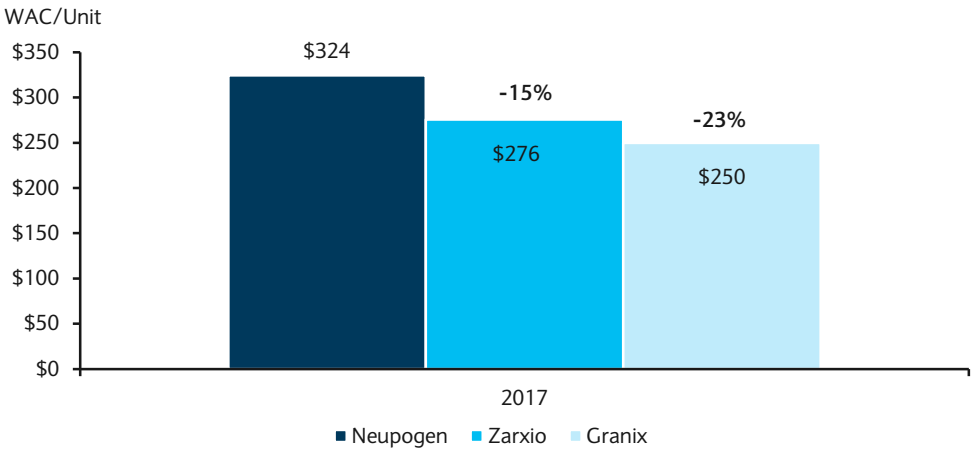
Example: Amgen's efforts with Neulasta / OnPro



Remicade Pricing - WAC (Discount to brand%)



Neupogen Pricing – WAC/Unit (Discount to brand%)



Note: No pricing action taken in category since 2015 (Zarxio launch 2015)

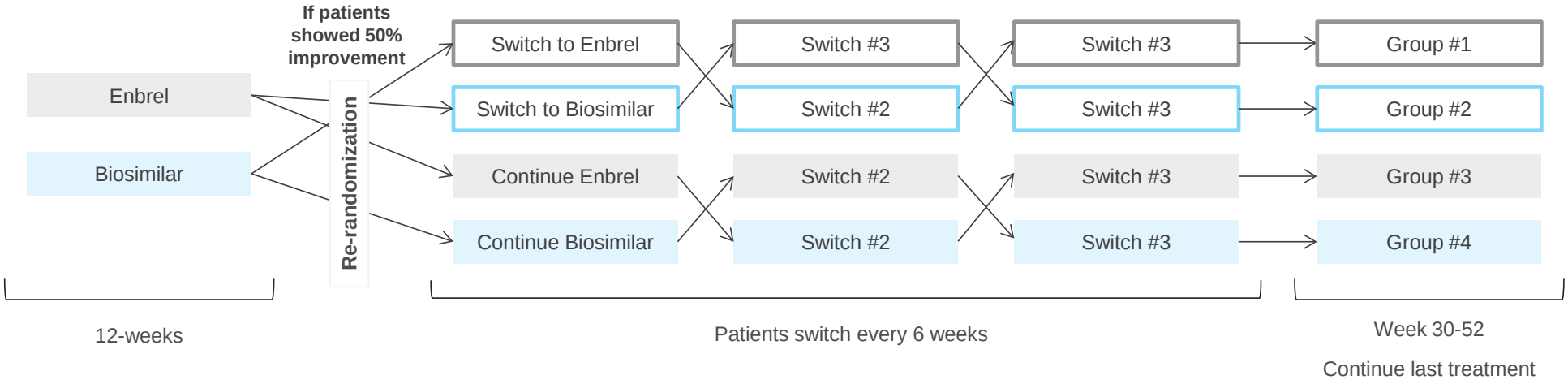
Source: ProspectoRx, Barclays Research

Interchangeability: Will it matter?

Key Considerations

- If multiple interchangeable biosimilars come to market, it may place a strain on procurement since specialty pharmacies would need to stock multiple manufacturer products in order to provide lowest-cost option
- FDA draft guidance suggests need for 3 switches in a clinical trial to satisfy requirements for interchangeability:

Sandoz Erelzi (etanercept) EGALITY trial design



Boehringer Ingelheim Humira VOLTAIRE-X trial

Source: Barclays Research, clinicaltrials.gov

- Specifics of study design (i.e. time point at switches) is not available
- Study will compare PK similarity between patients receiving Humira continuously v. patients alternating between BI 695501 and Humira; 58 week study duration

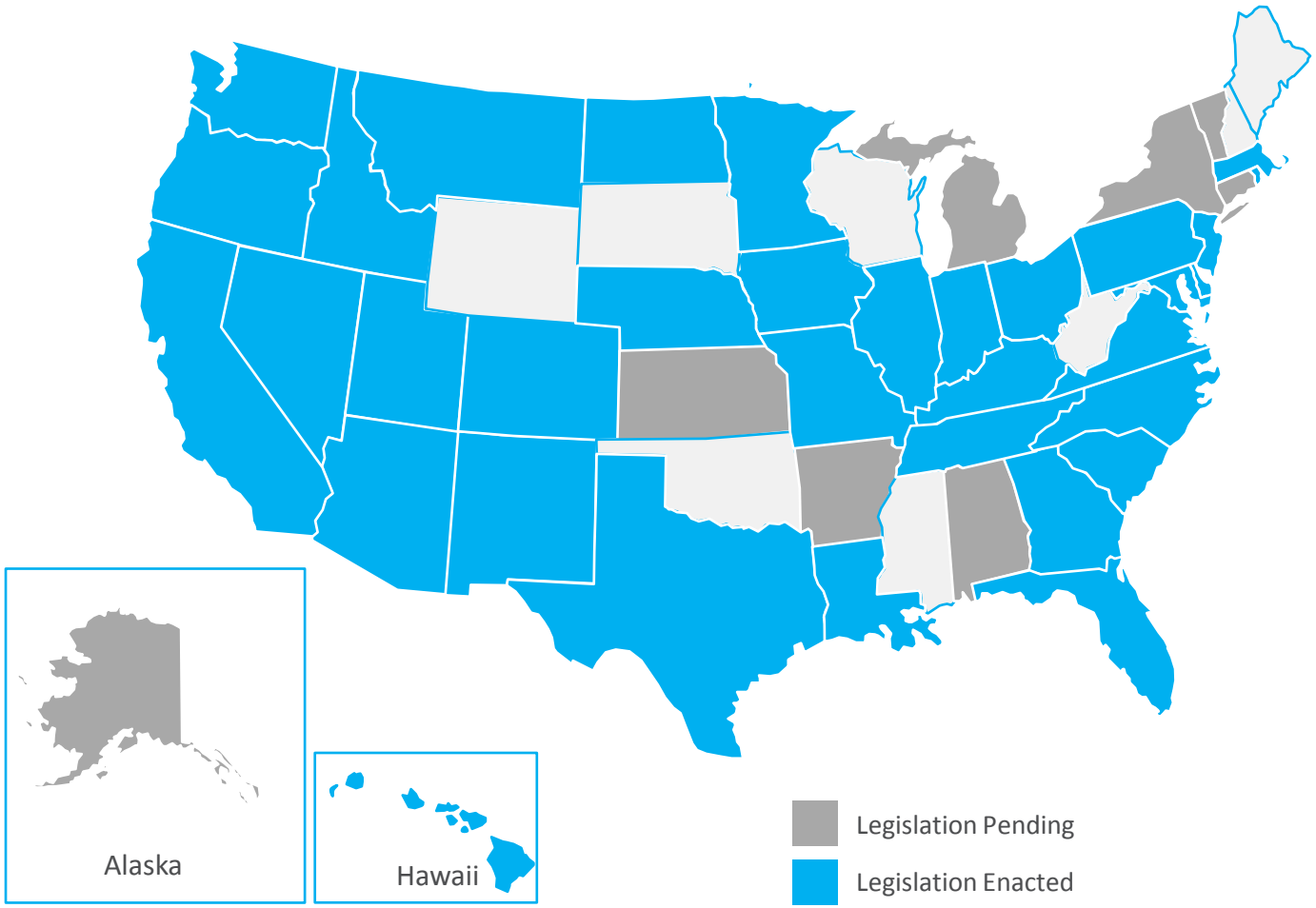
- Possibility for “nocebo” effects if patients offered choice in biosimilar/branded product?
  - Netherlands Case Study* found 23% of patients on biosimilar infliximab discontinued treatment due to “perceived” inefficacy or adverse events; however, no changes in efficacy or safety were observed

*Case Study: Tweehysen, L et al. Arthritis Rheumatology (2016)

Source: Thomson Reuters, Barclays Research

Substitution comes back to interchangeability

35 states (and Puerto Rico) have enacted biosimilar substitution laws which pertain to only retail pharmacist dispensing, whereas physician-administered drugs are not specified within legislation



**Not pictured: Puerto Rico which has adopted substitution laws*

Common Features

Most states enacted laws that align with 5 BIO Principles :

1. **FDA Approval/Interchangeable**: Product must be approved as "interchangeable" by FDA
2. **Prescriber allowance:** Prescriber can block substitution by writing "DAW"
3. **Physician Notification:** Prescriber should be notified of substitution by pharmacy ;
4. **Patient Notification:** Patient must be notified (included in 12 state laws; some states require patient consent)
5. **Recordkeeping:** Pharmacist/Physician keep records of substituted medication

State Nuances

- **No patient notification:** GA, ID, KY, MT, NV, NJ, NC
- **No physician notification:** FL
- **Explanation of cost savings / Cost rationale for substitution (i.e. biosimilar is cheaper):** CO, CA, GA, HI, MT
- **IA law draws distinction between Medicaid and non-Medicaid patients:** Substitution is required for Medicaid patients whereas pharmacist has discretion in non-Medicaid patients (non-Medicaid patients can also request innovator)

Source: Thomson Reuters, Barclays Research

Source: Barclays Research

Biosimilars introduce new issues for investors

While many investors find biosimilars attractive in the abstract, there are differences with small molecule generics which investors need to gain comfort.

- Molecules themselves are more complex
  - Even companies viewed as “leaders” have experienced setbacks
  - Sandoz’s pegfilgrastim appears delayed until close to 2020
- Development costs remain high (for the most part)
  - While the FDA is willing to consider development programs without Phase 3 trials in patients, we’ve yet to see it produce an approval (CHRS looks close)
- We’ve seen approvals but we’ve also seen products delayed for reasons unique to biosimilars
  - CHRS received a CRL based on insufficient sensitivity of the assay used in its immunogencity study
  - With few precedents, investors struggle to handicap how easily that can be remedied
- Manufacturing costs can be high
  - Significant upfront investment in manufacturing capacity
  - Alternative-use technologies have the potential to lower costs

Biosimilars introduce new issues for investors

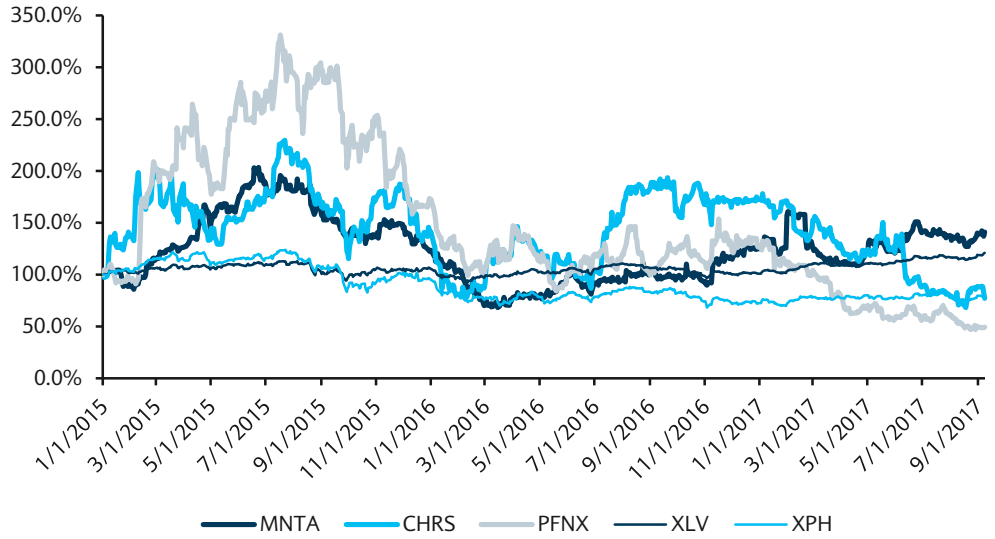
While many investors find biosimilars attractive in the abstract, there are differences with small molecule generics which investors need to gain comfort.

- The legal pathway remains uncertain; it is difficult for investors to determine what will prove to be blocking patents versus “speed bumps”
- Branded companies have built complex patent estates
  - Humira dosing patent invalidated during IPR process, yet formulation patents have stood up to challenge in IPRs
- In addition to patents seen with small molecules (composition of matter, formulatione, use), biologics introduce process/manufacturing patents which may or may not prove barriers to entry
  - Inflectra was launched “at risk” suggesting patents better be strong
  - Apotex found not to infringe refolding patent

Paying for it…

Despite signs of momentum in the U.S. market, share prices of companies focused on biosimilars reflects investor lack of certainty regarding market evolution

- We've seen a range of companies develop biosimilars including large pharma companies, generics manufacturers, CMOs, and a host of startups.
  - Large, diversified companies are best able to deal with uncertainty since existing/legacy businesses can fund operations
- The biggest challenge for startups has been access to capital; investors are less willing to fund uncertainty in the current environment
  - We've seen a range of companies develop biosimilars including large pharma companies, generics manufacturers, CMOs, and a host of startups.



Source: Thomson, Barclays Research

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