BIOSIMILARS
Prospects and challenges

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BIOSIMILARS
Prospects and challenges

Foreword from
Kevin Bottomley

The market impact of biosimilars has been predicted for many years, but it is only recently that they have started to realise their potential for patients, and have a positive commercial impact. Biosimilars are more challenging to develop and commercialise than small molecule generics, as they can never be truly identical to the patent protected biological they are competing with in the market. Although the first biosimilars were approved in Europe back in 2006 and 2009 in Japan, the path to market in the US has been much slower, and it is only in the past couple of years that they have started to reach American patients.

The price of new drugs, especially biologics indicated for hard to treat conditions, has risen sharply over the past 10 years. This has contributed to healthcare costs rising, putting mounting pressure on payors to reduce the amount of money that is spent on medicines. Generic and biosimilar drugs provide a very welcome way for payors to pay less for proven therapeutics, once the innovator has lost patent coverage and bequeathed the therapeutic to the generic market.

As the process and business case for developing and commercialising biosimilars is becoming better defined, investors have become more certain about the risks and rewards associated with these products. There were numerous biosimilar approval milestones in 2017 and 2018, and regulatory frameworks are now in place to support biosimilar product launches. Our research anticipates more biosimilar launches in mature markets and increased competition amongst the major products, as well as a trickle through of lower value biosimilars.

This report, looking at the clinical and commercial potential of the field, is particularly timely. We have reached an important watershed in the clinical and commercial acceptance of biosimilars, and their future is bright.

Kevin Bottomley
Partner
Executive summary

This report presents a review of the opportunities promised by biosimilars, and their potential to offer more affordable and accessible healthcare. However, it is not an easy task to map a path to market, in the light of significant intellectual property, clinical and regulatory challenges.

The adoption of biosimilars varies from country to country, which is invariably linked to regulatory and market access issues. These differences have made it difficult for many investors to make decisions about entering the market with confidence. The situation should improve as more biosimilars reach the market, their benefits become embedded in healthcare systems, and regulatory pathways become more established.

Market forecasts for biosimilars vary considerably, but in all cases predict strong, double-digit growth in excess of 23% annually over the next 5 years. By 2023, estimates of global annual sales range from $14 billion and $31 billion. Although many leading companies have invested in the sector, it cannot yet be considered mature, and many more biosimilars are expected to enter the market in coming years. Although there have been numerous joint ventures and licensing transactions, the challenges involved in making biosimilars limits competition in major markets. In the US, market entry of biosimilars has been slowed by many lawsuits filed by patent holders of reference biologics, and a regulatory pathway that has been less than clear. As a result, some companies appear to be waiting for the larger biosimilar manufacturers to clear the way before they enter the market themselves. As this litigation hurdle gets resolved, biosimilars should find the path to market easier, and more significant revenue generation can be expected.

Companies that have less experience in biologics have used partnerships and M&A to gain know-how, and in some cases used biosimilars to fill newly established biologics production capacity. Commercial partnerships have also been important for manufacturers that do not have a global commercial infrastructure.

Moving forward, opportunities remain for investors to acquire interests and partners in this growing sector. With the nuances that are highlighted in this report, the investment case is still not completely clear. However, with careful selection of assets in a growing market, there are obvious opportunities for profitable products in this wave, or future waves, of biosimilars. Careful monitoring of developments as the market matures is essential if investors are to succeed in the sector as risks reduce and returns become easier to define.

1 Biosimilars Market: Global Market Estimation, Dynamics, Regional Share, Trends, Competitor Analysis 2012 to 2016 and Forecast 2017 to 2023, Wiseguy Research, 2018
2 Biosimilars Market by Product, Manufacturing Type, Disease - Global Forecast to 2023, Markets and Markets, 2018
3 Global Biosimilar Market - Segmented by Treatment Type and Geography - Growth, Trends, and Forecast (2018 - 2023), Market Intelligence, 2018
4 Biosimilars Market Analysis by Product, by Application and Segment Forecasts To 2024, Grand View Research, 2016
Introduction

The biosimilar market, reached $4.4 billion in annual sales in 2017 and is expected to grow to $25 billion in 2023 (CAGR of 34%), according to a Results Healthcare review of analyst reports.1 2 3 4

Many biosimilar companies have made significant investments, and in 2017 a record number of biosimilar product approvals were granted by the Food and Drug Administration (FDA). The number of applications under consideration by the European Medicines Agency (EMA) also continues to rise. This report presents a positive outlook for investing in biosimilars, assuming appropriate due diligence and an understanding of the nuances of the numerous biologics that are reaching patent expiry.

Biosimilars are an attractive market segment for a number of key reasons:

- **Growing demand for healthcare**
  The growing and ageing population is driving a greater demand for medical treatment, not least because of the rising incidence of chronic diseases. This is aligned with a general increase in the ability of patients to pay for all medicines, including biosimilars.

- **Increasing emphasis on reducing costs by payors**
  Biosimilar drugs are eagerly awaited by many payors for their cost-effectiveness, allied to potential price reductions compared to originator biologics.

- **Patent expiries**
  Patents have already expired on many of the leading blockbuster biologics products in major markets, and more are set to expire in coming years.

- **Potential for higher returns than for generic small molecule drugs**
  Complexities in manufacturing and regulatory approval should reduce competition in the short and medium term, particularly where regulations create substantial hurdles.

- **Growth in market reach and access**
  Price reductions should support opportunities in emerging markets.
With positive fundamentals, the overall market is expected to grow strongly. However, the development of biosimilars is significantly more complex and costly than is the case for generic small molecules. New entrants into the market need to carefully consider the existing market and development landscape to assess whether the risk to reward ratio makes for a compelling investment case. Competition from other biosimilar products and the incumbent originator, which will often retain flexibility in its pricing and market strategy, could lead to a squeeze on margins and significantly reduced profitability.

It is important to understand what biosimilars are and how they differ from small molecule generics. A biosimilar is defined by the European Medicines Agency as a "biological medicine that is similar to another biological medicine that has already been authorised for use". Biosimilars are aiming to capture sales from biologic products that are losing patent protection and have undergone the full development process required for New Biological Entities (NBEs), which act as the reference product.\(^5\) The biosimilar is developed to be therapeutically equivalent to the reference biologic product.

Biosimilars are not generics; they are not exact copies of the reference product and consequently have a more complicated regulatory pathway that includes a requirement for clinical trials to be carried out. In addition, they have different production and marketing needs to generics. The difference between biosimilars and generics is further explained in 'How are biosimilars different to generics?' as it provides an important basis for understanding the risks of biosimilar development.

In 'Why are biosimilars attractive?' we discuss the attractiveness of biosimilars in greater detail, and the market potential of biosimilars is highlighted. Next, we review the competitive landscape within the biosimilar segment, as it has developed from a number of directions. Finally, the challenges for biosimilar competitors are summarised.

Opportunities for licensing and equity investment still exist, as long as appropriate due diligence and strategy development are carefully carried out. This report’s aim is to provide investors and pharmaceutical industry leaders with some of the insights we have gleaned from our work and research in this growing field.

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\(^5\) In the US, the stage was set by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). A number of guidelines are available, in addition to European Union legislation.
How are biosimilars different to generics?

Biologics are large, complex molecules such as proteins that are produced by cells or living organisms. Owing to their complexity it is not possible to produce an exact copy of a biologic drug; instead, competitor products are highly similar, and tests and clinical trials have to be carried out to prove their similarity in clinical effect.

The primary structure of a biosimilar has to be identical to the biologic\(^6\) while non-clinically significant variations in the higher-order structures are allowable\(^7\). We highlight some of the key differences between small molecules and biologics in Table 1.

A generic product will be an exact copy of a molecule whose clinical effect has already been established, and its bioequivalence can be established by pharmacokinetic testing. The starting point for biosimilar development is also an established molecule, but as the two products are not exactly the same, further testing and analysis is required to prove that the differences are not clinically significant. In addition to establishing bioequivalence, the process includes further assays on quality, bioactivity, efficacy and safety.\(^9\) The clinical trial for a biosimilar should largely be confirmatory, as in vitro assays should be sufficiently sensitive to detect any significant differences to the reference molecule.

The development of new drug candidates, whether they are small molecules or biologics, involves pre-clinical work as well as a full suite of clinical trials. The bioequivalence clinical trial for a

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### Small molecules vs. Biologics\(^*\)

<table>
<thead>
<tr>
<th></th>
<th>Small molecules</th>
<th>Biologics</th>
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<tbody>
<tr>
<td><strong>Example</strong></td>
<td>Aspirin (180 Da)</td>
<td>Avastin (mAB ~150 kDa)</td>
</tr>
<tr>
<td><strong>Type</strong></td>
<td>Small molecule</td>
<td>Protein</td>
</tr>
<tr>
<td><strong>Structure</strong></td>
<td>Small, simple, homogeneous</td>
<td>Large, complex, heterogeneous</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Can be stable at room temperature</td>
<td>Unstable, generally cold storage</td>
</tr>
<tr>
<td><strong>Mode of administration</strong></td>
<td>Often amenable to ingestion</td>
<td>Normally via injection or infusion</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td>Manufacturing process is reproducible, and makes exactly the same product each time</td>
<td>Produced by living cells, batch-to-batch variation, sensitive to storage and handling</td>
</tr>
<tr>
<td><strong>Immunogenicity</strong></td>
<td>Mostly non-immunogenic</td>
<td>Immunogenic potential</td>
</tr>
<tr>
<td><strong>Approval process</strong></td>
<td>NDA (Generic = ANDA)</td>
<td>BLA (Biosimilars = BPCIA)</td>
</tr>
</tbody>
</table>

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biosimilar involves significantly fewer patients than the numbers required in the multiple clinical trials for a new biologic. The cost of developing a biosimilar is therefore significantly lower, and is typically in the region of $100 million to $250 million over five to eight years, rather than a billion dollars-plus and more than a decade.\(^\text{10}\)

A biosimilar product may be approved for more than one indication for which the reference product is already licensed by extrapolation, even though the abbreviated clinical trials may not cover all the reference product’s approved indications. Regulatory guidelines from the FDA, EMA and WHO for biosimilar development all endorse using “patient populations, treatment settings, and clinical endpoints that are adequately sensitive to detect all clinically meaningful differences in efficacy, safety, and immunogenicity between a biosimilar and reference product.”\(^\text{11}\) However, there are agency-by-agency variations in how extrapolation is granted across indications.\(^\text{12}\) Based on FDA and EMA approvals, extrapolation is permitted, but it does need to be scientifically justified with appropriate data.

When compared to generics, biosimilars have a greater development risk. Each step has the potential to reveal issues that may lead to the program being halted or becoming commercially unviable. Cell lines and process development need to replicate the biologic product, and many technical and legal hurdles need to be overcome on the road to market. In order to maximise approval success rates, biosimilar players need to ensure they have sufficient expertise in the development of biologics products and knowledge of the intellectual property landscape, whose requirements vary geographically. In addition to the normal patient recruitment challenges for clinical trials, there is the additional complication that the drug is a copy of an existing product, which may reduce practitioner and patient motivation to enrol. The approval of a biosimilar is far from guaranteed, and the approval rate to date remains lower than might have been expected just a few years ago.

Overall, these difficulties may create an opportunity for those companies who have sufficient financial backing and relevant technical expertise. This should limit competition in the sector and thus price discounts will not be as hefty as they are for generics. Healthy returns on investment should be possible in biosimilar development for those who succeed. Recent FDA rejections should not be viewed as entirely negative when considering entry into this market, as will be further discussed in ‘Challenges for players’.

\(^{10}\) The Economics of Biosimilars, Blackstone EA, Joseph PF, American Health & Drug Benefits, 2013,6(8):469-478

\(^{11}\) The Global Need for a Trastuzumab Biosimilar for Patients With HER2-Positive Breast Cancer, Clinical Breast Cancer; Volume 18, Issue 2, 2018

\(^{12}\) Biosimilars and the extrapolation of indications for inflammatory conditions, Tesser JR, Furst DE, Jacobs I, Biologics: Targets & Therapy, 2017;11:5-11
Why are biosimilars attractive?

The 2017 annual reports of biologics manufacturers who are facing biosimilar competition highlight the uptake of biosimilars. The Merck & Co annual report states that sales of Remicade, the treatment for inflammatory diseases it markets in Europe, Russia and Turkey, dropped to $835m in 2017, a 34% fall.

Revenue for Rituxan in Europe fell by 26% in the fourth quarter of 2017, after a 16% third-quarter drop following patent losses.  

In parallel, biosimilar manufacturers have recorded increases in revenue. Pfizer reported that its worldwide revenues from Inflectra, its biosimilar to Remsima, had more than doubled to $419 million in 2017 compared to $192 million in 2016, most notably in the US.  

These are all positive indications that the biosimilar market is on a growth trajectory, which is estimated to reach between $14 billion and $31 billion in sales in 2023. The overall proportion of the biopharmaceuticals market taken up by biosimilars is estimated to reach 4% in 2018.  

The ability of biosimilars to capture market share has already been demonstrated, particularly in Europe, where the sector is more strongly established, and the wider upward trend in the pharmaceutical sector is likely to form a solid basis for growth. In 2015, the total size of the worldwide pharmaceutical market was about $1.1 trillion and this is estimated to reach $1.5 trillion by 2021, a CAGR of 5.5%. The total market share for biologics is set to increase from 16.6% in 2015 to 22.4% in 2021.  

The high cost of biologics has put them firmly in the spotlight of payors and regulators as healthcare spending comes under increasing pressure. In light of this, biosimilars have been welcomed by payors as a way to reduce costs while continuing to deliver benefits to patients. This market drive towards biosimilar use should make it an attractive sector for competition, particularly as 12 major biologic products with combined global sales of more than $67 billion will be exposed to biosimilar competition by 2020, once their patents have expired (Table 2). The five to eight year development time for a biosimilar means it may already be too late to start work on many of the blockbuster biologics that are well into their lifecycle. However, there are many advanced biosimilar programs that could be targeted for investment. Furthermore, the next generation of biologics that lose patent protection after 2020, not included here in Table 2, will provide opportunities for biosimilar developers.

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13  www.reuters.com/article/us-roche-results-biosimilars/roche-says-rising-biosimilar-threat-will-speed-up-rituxan-sales-fall-idUSKBN1FL5Z0  
14  Pfizer Inc. Financial Report 2017  
15  Biosimilars Market: Global Market Estimation, Dynamics, Regional Share, Trends, Competitor Analysis 2012 to 2016 and Forecast 2017 to 2023, Wiseguy Research, 2018  
16  Global Biosimilar Market - Segmented by Treatment Type and Geography - Growth, Trends, and Forecast (2018 - 2023), Mordor Intelligence, 2018  
17  Stada Annual Report 2017  
18  Invoice price basis from Outlook for Global Medicines through 2021, QuintilesIMS  
19  http://www.gabionline.net/Biosimilars/General/Top-8-blockbuster-biologicals-2013
In contrast, a number of companies have exited the space for strategic reasons, such as Baxalta and Merck KGaA, after they determined that biosimilars did not fit with their innovation strategy. Epirus Biopharmaceuticals, which had a late-stage Remicade biosimilar for the Indian market, filed for bankruptcy following issues with suppliers and development delays. This led to a cash crunch, resulting in the company initially attempting to restructure towards a focus on biosimilars for rare diseases, but ultimately having to file for bankruptcy as funding dried up.

This outflow of companies from the biosimilars market should be viewed positively by those committed to the market for two reasons. Firstly, it reduces competition and secondly it may allow investors to pick-up legacy programs at potentially attractive price points.

Overall, we see growing demand for lower cost biologics, and biosimilars are set to fulfil some of this need. The expected growth of the pharmaceutical market, driven by factors including a growing population, age and wealth, also support a positive growth trajectory for biosimilars. Investors in the biosimilar market can therefore have some confidence that significant returns on investment are achievable.

### Table 2

<table>
<thead>
<tr>
<th>Name</th>
<th>Active Ingredient</th>
<th>Therapeutic Area</th>
<th>Originator company</th>
<th>Patent expiry EU/US</th>
<th>Revenue 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>adalimumab</td>
<td>Arthritis</td>
<td>AbbVie</td>
<td>Apr 2018/ Dec 2016</td>
<td>$18.9bn</td>
</tr>
<tr>
<td>Enbrel</td>
<td>etanercept</td>
<td>Arthritis</td>
<td>Amgen / Pfizer / Takeda</td>
<td>Feb 2015/ Nov 2028</td>
<td>$8.2bn</td>
</tr>
<tr>
<td>Rituxan/MabThera</td>
<td>rituximab</td>
<td>Arthritis / NHL</td>
<td>Roche</td>
<td>Nov 2013/ Dec 2018</td>
<td>$7.5bn</td>
</tr>
<tr>
<td>Remicade</td>
<td>infliximab</td>
<td>Arthritis</td>
<td>J&amp;J / MSD / Mitsubishi</td>
<td>Aug 2014/ Sep 2018</td>
<td>$7.2bn</td>
</tr>
<tr>
<td>Herceptin</td>
<td>trastuzumab</td>
<td>Breast Cancer</td>
<td>Roche</td>
<td>Jul 2014/ Jun 2019</td>
<td>$7.1bn</td>
</tr>
<tr>
<td>Avastin</td>
<td>bevacizumab</td>
<td>Cancer</td>
<td>Roche</td>
<td>Jan 2022/ Jul 2019</td>
<td>$6.8bn</td>
</tr>
<tr>
<td>Lantus</td>
<td>insulin glargine</td>
<td>Diabetes</td>
<td>Sanofi</td>
<td>May 2015/ Jun 2016</td>
<td>$5.2bn</td>
</tr>
</tbody>
</table>

In contrast, a number of companies have exited the space for strategic reasons, such as Baxalta and Merck KGaA, after they determined that biosimilars did not fit with their innovation strategy. Epirus Biopharmaceuticals, which had a late-stage Remicade biosimilar for the Indian market, filed for bankruptcy following issues with suppliers and development delays. This led to a cash crunch, resulting in the company initially attempting to restructure towards a focus on biosimilars for rare diseases, but ultimately having to file for bankruptcy as funding dried up.
Who is the competition?

It is broadly possible to split the various players in the biosimilars market into groups to give a better understanding of the market dynamics and strategies different companies operate under.

Of course, such categorisations cannot be perfect, as not all companies will fit into a single group, but it is useful to highlight some of the general strengths and differences between companies and the strategies they pursue.

Several competing biosimilars are in development for many of those biologics that are approaching patent expiry, sometimes targeting different markets for launch. Generally speaking, the biosimilar landscape splits into two broad groups: those targeting FDA/EMA approval and, those targeting less developed markets with products that are better described as 'intended copies' than biosimilars, as the launch country does not as yet have a formal procedure for biosimilars.

The first group of companies are targeting major markets with regulatory packages that normally include a fuller set of pre-clinical data, manufacturing data and clinical studies that meet the requirements of the FDA and EMA. The second group are largely companies established in less developed markets that may not require clinical trials and are targeting less stringently regulated markets. These intended copies (Figure 2) can be commercially available, but they may not have been evaluated using the defined criteria of WHO guidelines for biosimilars.

A product that is an intended copy may have differences that could result in a clinically significant impact on efficacy and/or safety.20 Despite concerns, they have been approved and are being used in countries where access to healthcare is more limited. Investors should take care when considering such drug candidates, as they at the very least pose a reputational risk.

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in the light of the less stringent nature of approval processes. Development and study protocols are not likely to meet standards of the EMA or FDA, but some companies may work towards building up their dossiers for gaining approval in mature markets.

Companies looking to sell intended copies are unlikely to have the regulatory experience of companies with historical biologics expertise, which may cause delays in development of products for more regulated markets. Companies in this category include a number of mass-market generics companies whose biologics experience is limited. However, they have the potential to become major players in biosimilars in the future as they acquire the technical skills required to meet US and European market standards. In addition, they are in direct competition with other groups of biosimilar companies in markets where their dossiers will be accepted. Moreover, the reduced dossiers of intended copies mean it is more likely that lower value biologics will be targeted for copying, as the lower development cost makes it more commercially viable despite the lower potential revenue.

In contrast to intended copies, which can target relatively small markets, biosimilars currently approved in the US market target the larger therapy areas only and are all aimed at originator products with sales in excess of US$ 4 billion. In the European market the situation is a little more diverse, with approved biosimilars for products with a range of sales revenues. Biosimilar companies that are targeting more highly regulated markets broadly fit into three categories:

1 **Biologics companies** with their own originator biologics that may be under threat from biosimilars. They have the experience of developing and selling innovative biologics and the market reputation that goes along with that, but they may lack know-how in the business of copying drugs. They are likely to be better positioned to understand regulatory expectations that may be open to interpretation in regulations and guidelines. In addition, their sales forces and key account managers can be used to accelerate product roll-out. However, these companies may have conflicts of interest between prolonging the exclusivity of their innovator molecules and the early market entry of their biosimilars. For some biosimilars, they may not have the therapeutic area knowledge or availability of existing sales forces.

2 **Generic businesses** with existing portfolios of small molecule drugs who have decided to get into the biologics business as a way to expand their strategy of challenging drugs that go off-patent. They do not have any experience in biologics, but they do have the experience of selling products based on price and are likely to have experience of intellectual property litigation. They generally have the networks or sales forces that will be required to bring biosimilars to market. As they are established in small molecules, they will need to partner, hire or contract-out for the development and manufacturing expertise required to bring a biosimilar to market.

3 **Pure-play biosimilar companies** are those that have been formed with business plans that depend expressly on biosimilar development. Some are largely virtual. They are often staffed by experts from the biologics industry and should, therefore, have the required in-house experience to bring a biosimilar to market. They are likely to out-license products to companies with the ability and/or funding to go through commercialisation. As companies in this group can be financially constrained, they may have optimised the development process in such a way that does not meet the checklists of pharmaceutical majors.

Companies do not always fit neatly into one of these four groups and each category has particular operational and commercial advantages and disadvantages. Generics companies may not know what costs and risks to expect in biosimilars development. Small biotechs are unlikely to have the resources or reach that bigger players have to gain acceptance of their biosimilars with regulators, payors, prescribers and patients. The need for these companies to share know-how and resources is evident through an increasing drive towards risk-sharing arrangements, such as partnerships and licensing deals.

It is worth mentioning the biologics capacities of Asian companies such as Biocon, Samsung, Celltrion, WuXi Biologics and Fujifilm Kyowa Kirin Biologic. Their capacities for biologics production, particularly in mammalian cell culture, have been built up on the back of the promise of rapid biosimilar market growth, as well as offering the potential to manufacture novel drug products. Many Korean companies have invested in biologics as a result of a national drive to become leaders in the biopharma industry. As these companies often lack commercialisation infrastructure, many have entered into commercial agreements with more experienced biologics industry partners to commercialise their portfolios.21,22

Biosimilar producers face further competition and threats from new treatments in the development pipeline. New treatments might be more effective, safer and easier for patients to administer, and thus have advantages that outweigh the cost factor. The precise threat varies depending on the biosimilar that is being considered. However, assuming that new treatments are likely to be more expensive, there should be room in the market for companies that help payors reduce costs. Future competition should always be factored in when considering the development of a biosimilar, and being competitive in the future may rely on significant price discounts.

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21 [www.gabionline.net/Biosimilars/Research/Partnerships-driving-similar-biologics-development-in-India](www.gabionline.net/Biosimilars/Research/Partnerships-driving-similar-biologics-development-in-India)
Challenges for players

As highlighted in the earlier comparison between generics and biosimilars, the process of developing a biosimilar is much more complex, but approval requirements are still significantly abbreviated when compared to a novel product.

The probability of successfully bringing a biosimilar to market has been estimated at 50-75%, compared with 95% for small molecule generics, but development risks will vary depending on the particular biosimilar. A number of choices will need to be made regarding the production cell line, as well as the regulatory requirements that must be met. In addition, the process needs to consider those IP implications that may hinder a launch, and different alternatives may affect quality and cost of production. Recent biosimilar rejections by the FDA demonstrate the development risks and setbacks that will need to be factored into an investment case (Table 3).

A science-based regulatory framework to ensure high-quality biosimilars has been established in Europe since 2005 and is monitored and updated on an ongoing basis. The biosimilar approval pathway has taken a lot longer to evolve in the US. Litigation about the correct process to approve and market a biosimilar, such as providing notifications to the originator, highlight the uncertainty that still exists.

Each biosimilar has its own characteristics, and each market has its own dynamics. Launch and marketing plans need to be tailored to each individual biosimilar, and market drivers vary between therapeutic areas and target patient populations. Geographical drivers may also affect demand, based on price or disease prevalence. In addition, there are varying degrees of adoption or acceptance of biosimilars amongst payors and physicians, such as the willingness or legal basis to substitute to a biosimilar.

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<table>
<thead>
<tr>
<th>FDA rejections</th>
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<td>Date</td>
</tr>
<tr>
<td>April 2018</td>
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<tr>
<td>May 2018</td>
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<td>April 2018</td>
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<td>April 2018</td>
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<tr>
<td>October 2017</td>
</tr>
<tr>
<td>June 2017</td>
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<tr>
<td>July 2016</td>
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Table 3

28. investors.coherus.com/phoenix.zhtml?t=253635&c=15&newsArticleID=2288284
30. US Biosimilars 2018: Opportunities and Challenges, Back Bay Whitepaper, January 2018
There are examples of immediate price drops on market entry, such as the 30-40% cuts when biosimilars to EPO and G-CSF reached the market in Europe.31 Expectations in the US market are that biosimilars will need to provide discounts of 15–30% compared to the reference product, based on the European experience.32 The owner of the originator product may reduce its price to compete on the introduction of a biosimilar, which could lead to price wars, erosion of margins and profitability. The slow development of the market to date may not be a reflection of future price cuts, and the prospect of multiple biosimilars to the same originator may drive down prices further. However, there is evidence to suggest that the first biosimilar to market will usually take the highest biosimilar market share.33

An interesting example of pricing strategy is the battle for market share by Remicade biosimilars. Whilst price discounts of 20-30% versus the reference biologic are the generally accepted norm, a distributor of Celltrion’s biosimilar offered a price discount of c. 70% versus Remicade in the Norwegian market. This aggressive and ultimately successful pricing strategy was designed to grab market share from Remicade and Hospira’s competing biosimilar, resulting in Celltrion securing approximately 50% of the market. Trading margin for market share in such a way needs to be a carefully considered approach, as price wars will significantly affect the long-term profitability of a product. It can however be a viable approach when competition comes not only from the reference product but also from other biosimilars already in the market or entering the market at the same time.

Introducing a brand identity is another way to mitigate the negative effects a later launch might have on market share, particularly in markets where a prescription specifies a precise product and cannot be switched. Each biosimilar can, of course, have its own brand name in addition to the individualised generic name, and these brands can be used to emphasise quality and improve adoption by prescribers. Celltrion is even using multiple brands for the same product.34

Despite biosimilars having had a market presence in the EU for more than a decade, surveys have found that awareness and knowledge among physicians, pharmacists and patients remains relatively limited.35 and a need for evidence-based education has been identified.36 Even though payors may wish to save on costs, the adoption of biosimilars will continue to depend on the buy-in of multiple stakeholder and interest groups.

Physicians need to be sufficiently comfortable with biosimilar alternatives so that they are happy to not specify the exact brand name. Pharmacists need to be correctly informed about when they are able to switch between originators and biosimilars. Patients and patient groups should be comfortable with the medicine they are being given, regardless of whether they are making a co-payment or not. If there is a co-pay, awareness of biosimilars may help patients understand the choices available to them. Key opinion leaders and patient groups have an important part to play here, and both payors and government agencies should provide clear guidance.

Biologic therapies have become central to the long-term management of many chronic diseases, notably autoimmune diseases such as rheumatoid arthritis and psoriasis, where they will be taken for extended periods of time. Although it is possible to switch patients who are on a long-term course of treatment with a biologic to a biosimilar, there may be resistance from patients to do so. Whilst a patient’s side effects and response to the biologic are generally well understood once it has been administered for a while, switching to a biosimilar carries the risk (even if it is only perceived) of unwanted complications for the patient, especially if there is a new delivery mechanism to adjust to. The NOR-SWITCH trial37 has given some confidence to physicians that switching is ‘not inherently dangerous’, at least for one biosimilar and a paper published in Drugs in 2018 concluded that, “The extensive data collected to date suggest that the act of switching from a reference medicine to a biosimilar is not inherently dangerous, and that patients, healthcare professionals, and the public should not assume that it is problematic.”38 The acceptance of switching may well be less important to treatments that are indicated in the shorter term, or for new patients who are only just beginning treatment.

In the US, switching is closely related to the discussion on interchangeable products that meet additional requirements outlined by the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The FDA states that switching back and forth between an interchangeable product and a reference product needs to be evaluated. Products approved as being interchangeable may be substituted for the reference product without consulting the prescriber.

Unsurprisingly, originators have established defence mechanisms to incoming biosimilars through intellectual property portfolios, marketing strategies and the benefits of being the existing brand. Such defence strategies have varying

32 Biosimilars May Change the Treatment Landscape for Inflammatory Diseases, Specialty Pharmacy Times, September 2017
33 The Impact of Biosimilar Competition in Europe, QuintilesIMS, May 2017
35 Patient attitudes and understanding about biosimilars: an international cross-sectional survey, Jacobs I, Singh E, Sewell KL, Al-Sabbagh A, Shane LG, Patient preference and adherence, 2016;10917.948
37 Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial Jørgensen, Kristin KBerset, Ingrid P et al. The Lancet, Volume 389, Issue 10086, 2304 - 2316
38 Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes, Drugs, 2018;78:463–478
## Launch status of FDA approved products

<table>
<thead>
<tr>
<th>Name</th>
<th>Applicant</th>
<th>Reference</th>
<th>Approval Date</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zarxio (filgrastim-sndz)</td>
<td>Sandoz</td>
<td>Mar 2015</td>
<td></td>
<td>Launched in US September 2015; ongoing patent litigation</td>
</tr>
<tr>
<td>Inflectra (infliximab-dyyb)</td>
<td>Celltrion/Pfizer</td>
<td>Apr 2016</td>
<td></td>
<td>Launched in US November 2016; ongoing patent litigation. $419m sales globally</td>
</tr>
<tr>
<td>Erelzi (etanercept-szss)</td>
<td>Sandoz</td>
<td>Aug 2016</td>
<td></td>
<td>No launch until 2018 at earliest pending outcome of litigation</td>
</tr>
<tr>
<td>Amjevita (adalimumab-atto)</td>
<td>Amgen</td>
<td>Sep 2016</td>
<td></td>
<td>Launch in US in Q1 2023, following global settlement agreement</td>
</tr>
<tr>
<td>Renflexis (infliximab-abda)</td>
<td>Samsung Bioepsis/Merck</td>
<td>Apr 2017</td>
<td></td>
<td>Launched in US July 2017</td>
</tr>
<tr>
<td>Cytezo (adalimumab-adbm)</td>
<td>Boehringer Ingelheim</td>
<td>Aug 2017</td>
<td></td>
<td>US launch expected in 2023; litigation pending</td>
</tr>
<tr>
<td>Mvasi (bevacizumab-awwb)</td>
<td>Amgen/Allergan</td>
<td>Sept 2017</td>
<td></td>
<td>No launch date announced; litigation pending</td>
</tr>
<tr>
<td>Ogivir (trastuzumab-dkstl)</td>
<td>Mylan/Biocon</td>
<td>Dec 2017</td>
<td></td>
<td>Launch date undisclosed under settlement agreement</td>
</tr>
<tr>
<td>Ixifi (infliximab-qbtx)</td>
<td>Pfizer</td>
<td>Dec 2017</td>
<td></td>
<td>No current plans for US launch</td>
</tr>
<tr>
<td>Retacrit (epoetin alfa-epbx)</td>
<td>Pfizer</td>
<td>May 2018</td>
<td></td>
<td>Planned US launch in 2018</td>
</tr>
<tr>
<td>Fulphila (pegfilgrastim-jmdb)</td>
<td>Mylan/Biocon</td>
<td>Jun 2018</td>
<td></td>
<td>Planned US launch in 2018</td>
</tr>
<tr>
<td>Nivestym (filgrastim-aafi)</td>
<td>Pfizer</td>
<td>Jul 2018</td>
<td></td>
<td>No launch date announced. Currently subject to BPCIA patent litigation with Amgen</td>
</tr>
<tr>
<td>Ixifi (infliximab-qbtx)</td>
<td>Pfizer</td>
<td>Dec 2017</td>
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</tr>
</tbody>
</table>

### Table 4

degrees of geographical effectiveness, which is evidenced by the lower number of launched products in the US.

As shown in Table 4, the regulatory and intellectual property landscape has made the launch of biosimilars in the US more complicated than it is in Europe. Even as far back as 2005, EMA produced a defined approval pathway for biosimilars, which provided confidence to developers. The market in Europe has also been supported by the relatively more centralised structure, and earlier patent expiries for some biologics.

The US was much slower to provide guidance on biosimilar development. In 2010, the BPCIA was established to create an abbreviated approval pathway for biosimilars that are shown to be highly similar to or interchangeable with an FDA-licensed reference biologic product. The passage of this Act was motivated by the potential cost savings for patients by the creation of a means for the production, use and sale of biosimilars in the US.40 BPCIA’s intellectual property provisions resemble in part the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) that encouraged the production of generics.

In order to smooth the litigation process for biosimilars, the BPCIA introduced a process of information exchange between a biosimilar applicant and a reference product sponsor. Known as the “patent dance”, it provides a framework to resolve potential patent disputes in an orderly and expeditious fashion. However, disputes between originators and biosimilar companies on the obligation to carry out the patent dance and whether it has benefits contributed to the uncertainty on the path to market for biosimilars.41

### 2009, Sandoz Inc. v. Amgen Inc.

The U.S. Supreme Court had to interpret the BPCIA in the case of 2009, Sandoz Inc. v. Amgen Inc. and concluded that (i) biosimilar applicants cannot be forced under federal law to engage in the Biologics Act’s information exchange and (ii) that they need not await FDA approval before providing the statutorily required notice of commercial marketing.42 However, the compliance with the BPCIA has demonstrated benefits for the biosimilar applicant, as the Act helps it cap the scope of litigation.43

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41 www.biosimilardevelopment.com/doc/shall-we-patent-dance-key-considerations-for-biosimilar-applicants-0001
Concluding remarks

Existing and future investors have a complex business case to consider when contemplating the biosimilars market. As with all investments, due diligence is required, including a careful consideration of all potential nuances.

Biosimilars are not generics; they are not exact copies of the reference product and have a more complicated regulatory pathway that includes clinical trials. In addition, they have vastly different production and marketing needs that are more in line with the originator biologic.

The biosimilar sector is not without its risks, and the industry has experienced several failures that investors should draw important lessons from. Despite evident challenges, the prospect of reducing treatment costs for payors supports a positive future for biosimilars. The challenges involved in producing biosimilars provide opportunities for companies with the relevant know-how, capacity and financial resources to make products that meet regulatory requirements and can take market share from originator products.

A number of biosimilar ventures have been established that have varying degrees of biologics know-how and financial resourcing. Partnerships have also been established to plug gaps in competences and infrastructure, as well as to save time for companies that are late entrants to the biosimilars market.

This review of the biosimilar market highlights many of the challenges and nuances that need to be considered when making investment decisions. As the fundamentals remain supportive and approval processes, in particular in the US market, become more well defined, the prospects for the growth of the biosimilar market should make it increasingly attractive for investment. Depending on the nature of the investor, this can be captured through investing in listed companies, private companies or partnerships.
Appendix

Mergers and acquisitions

Year: 2017  
Target: Merck KGaA’s biosimilars business (DE)  
Acquirer: Fresenius Kabi (DE)  
- Entire biosimilar oncology and autoimmune pipeline.  
- The purchase price of €656 million was mainly cash flow financed. Thereof, €156 million has been paid upon closing.  
- Two advanced products: (i) adalimumab submitted for MA approval at the end of 2017 and (ii) pegfilgrastim at Phase III.

www.fresenius.com/6087

Year: 2015  
Target: Hospira (UK)  
Acquirer: Pfizer (USA)  
- Acquisition for $17 billion.  
- Included generic sterile injectables and biosimilars.  
- Biosimilar product includes infliximab, which is a second approved biosimilar in the United States.

www.marketrealist.com/2016/09/pfizers-hospira-deal-catching-up-a-year-later

Year: 2016  
Target: Finox (CH)  
Acquirer: Gedeon Richter (HU)  
- Consideration of CHF190 million.  
- Product Bemfola is a biosimilar r-hFSH, which stimulates the ovaries in order to treat infertility.  
- Bemfola has marketing authorization granted in EU in May 2014, transaction exclusions related to USA/FDA.


Joint ventures

Year: 2014  
JV name: YL Biologics (JP)  
Partners: Lupin (IND) & Yoshindo (JP)  
- Responsible for conducting clinical development of certain biosimilars including regulatory filings and obtaining marketing authorisations in Japan.  
- Lupin will be entitled to milestone-based licensing income in addition to commercial supplies of the drug substance.  
- Both Lupin and Yoshindo are reported to market the product under their own brand names by leveraging their respective sales network.


Year: 2011  
JV name: Samsung Bioepis  
Partners: Biogen and Samsung Bioepis  
The two companies pledged to invest US$300 million to establish the joint venture, with the intention of developing, manufacturing and marketing biosimilars.

www.gabionline.net/Biosimilars/News/Merck-makes-biosimilars-deal-with-Samsung-Bioepis
Licensing deals

The below list provides an overview of significant licensing deals. Small, local or regional commercialisation agreements are not included, so this list should not be considered comprehensive.

<table>
<thead>
<tr>
<th>Year</th>
<th>Partners</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>Sandoz (Novartis) and Biocon</td>
<td>Through a cost and profit share arrangement, they will share responsibility for the development, manufacturing and approvals of a portfolio of next wave products. Sandoz to lead commercialisation in North America and the EU, while Biocon will lead in Rest of the World. <a href="www.sandoz.com/news/media-releases/sandoz-announces-exclusive-global-collaboration-biocon-next-generation">Source</a></td>
</tr>
<tr>
<td>2017</td>
<td>Celltrion and Nippon Kayaku</td>
<td>Nippon Kayaku will sell Truxima, Celltrion's biosimilar of Rituxan (rituximab), in Japan. This adds to the portfolio of Celltrion biosimilars that Nippon Kayaku will market in Japan, including biosimilar versions of Remicade (infliximab) and Herceptin (trastuzumab). <a href="www.koreaherald.com/view.php?ud=20170427000898">Source</a></td>
</tr>
<tr>
<td>2017</td>
<td>Aurobindo (IND) and TL Biopharmaceutical (CH)</td>
<td>TL Biopharmaceutical will supply all developmental data for the four molecules and Aurobindo will develop, commercialise, and market them globally. <a href="www.aurobindo.com/docs/press-room/company-news/2016-2017/aurobindo-pharma-forays-into-biosimilars-development-through-an-acquisition-of-four-products-from-tl-biopharmaceutical-ag.pdf">Source</a></td>
</tr>
<tr>
<td>2017</td>
<td>Mylan and Mabion</td>
<td>Exclusive right to commercialise Mabion’s Phase III rituximab biosimilar candidate in EU and non-EU Balkan states. Upfront of $10 million as well as milestone payments and royalties up to $35 million. <a href="www.gabionline.net/Pharma-News/Mabion-signs-agreement-with-Mylan-for-rituximab-biosimilar">Source</a></td>
</tr>
<tr>
<td>2016</td>
<td>Xbrane Biopharma and Helvetic BioPharma</td>
<td>Sales and distribution deal for Xbrane’s ranibizumab biosimilar in Iran. <a href="www.xbrane.com/xbrane-signs-deal-with-helvetic-biopharma-for-its-lead-ranibizumab-biosimilar-xlucane/">Source</a></td>
</tr>
<tr>
<td>2016</td>
<td>Gedion Richter (HU) and DM Bio (KR)</td>
<td>Richter pay an upfront payment and further milestone payments shall be made depending on the progress of the technology transfer and clinical programme of the product. In addition, further sales related royalties will become payable to DM Bio subsequent to the launch of the product. Richter gets exclusive distribution rights for Europe, the CIS region and Latin American countries. <a href="www.richter.hu/en-US/pressroom/press-release/Pages/press-releases/pr161019.aspx">Source</a></td>
</tr>
<tr>
<td>Year</td>
<td>Partners</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
<td>-------------</td>
</tr>
</tbody>
</table>
| 2016 | Dr. Reddy’s (IND)  
TR-Pharm (TK) | Three biosimilar products will be registered and subsequently commercialised as part of this agreement by TR-Pharm in Turkey. [www.economictimes.indiatimes.com](http://www.economictimes.indiatimes.com/industry/healthcare/biotech/dr-reddys-tr-pharm-announce-collaboration-for-3-biosimilars/articleshow/51358180.cms) |
| 2016 | Mylan (USA)  
Momenta (USA) | Exclusive global collaboration for Mylan to develop, manufacture and commercialise six of Momenta’s current biosimilar candidates, including Momenta’s biosimilar candidate, ORENCIA (abatacept). Mylan will make an up-front cash payment of $45m and up to $200m in contingent milestone-related payments to Momenta, with each company sharing equally in the costs and profits with respect to the products. [www.prnewswire.com](http://www.prnewswire.com/news-releases/mylan-announces-worldwide-collaboration-with-momenta-to-jointly-develop-and-commercialize-six-biosimilar-products-300201416.html) |
| 2016 | Teva (ISR)  
Celltrion (KR) | Commercial partnership for North America. Teva will pay Celltrion $160 million up front. The companies will split the profits from the sale of the two drugs, Celltrion’s biosimilar rituximab and a biosimilar Trastuzumab. [www.theinvestor.co.kr](http://www.theinvestor.co.kr/view.php?ud=20161006000848) |
| 2013 | Merck & Co  
Samsung Bioepis Co | Merck will be responsible for commercialising any resulting biosimilars. Undisclosed upfront paid. [www.pmlive.com](http://www.pmlive.com/pharma_news/merck_and_co_to_develop_biosimilars_with_samsung-biogen_joint_venture_464451) |
| 2012 | Synthon  
Amgen and Watson | Concerns Synthon’s Phase I completed trastuzumab. Amgen and Watson will assume responsibility for all future development work worldwide, including Phase III clinical trials, as well as global manufacturing and commercialisation. [www.evaluategroup.com](http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=313111) |
| 2013 - 2016 | Baxter  
Coherus | Baxter pays upfront of $30 million. Coherus will conduct development and Baxter will make payments of up to $216m contingent upon the achievement of development and regulatory events. The agreement also allows for development and commercialisation of an alternative biosimilar to etanercept, pending the outcome of clinical data. [www.baxter.com](http://www.baxter.com/news-media/newsroom/press-releases/2013/09_03_13_coherus.page) |
| 2013 | Viropro (USA)  
Oncobiologics (USA) | Viropro will manufacture six MABs, currently being developed by Oncobiologics. The products include biosimilars bevacizumab, cetuximab, trastuzumab, adalimumab, rituximab and a non-disclosed biological used for cancer and immune-disease indications. Viropro will gain the rights to commercialise the six biosimilars in more than 70 emerging market countries (excluding China), and will have exclusive commercialisation rights in Malaysia. [www.gabionline.net](http://www.gabionline.net/Biosimilars/News/Oncobiologics-and-Viropro-make-biosimilar-deal) |
<table>
<thead>
<tr>
<th>Year</th>
<th>Partners</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-2015</td>
<td>Merck KgAa, Hanwha</td>
<td>License deal for Hanwha's etanercept biosimilar product (HD203).</td>
</tr>
<tr>
<td>2012</td>
<td>Merck KGaA (DE), Dr. Reddy's (IND)</td>
<td>Portfolio of biosimilar. The partnership covers co-development, manufacturing and commercialisation of the compounds around the globe, with some specific country exceptions. Dr. Reddy's will receive royalty payments from Merck Serono upon commercialisation. In the US, the parties will co-commercialise the products on a profit-sharing basis. <strong><a href="http://www.drreddys.com/media/press-releases/june06-2012.html">www.drreddys.com/media/press-releases/june06-2012.html</a></strong></td>
</tr>
<tr>
<td>2009</td>
<td>Mylan (USA), Biocon (IND) (Trastuzumab, Pegfilgrastim, Adalimumab, Bevacizumab, Etanercept and Filgrastim).</td>
<td>Mylan and Biocon will share development, capital and certain other costs to bring products to market. Mylan will have exclusive commercialisation rights in USA, CA, JP, AU, NZ and in the EU and European Free Trade Association countries through a profit sharing arrangement with Biocon. Mylan will have co-exclusive commercialisation rights with Biocon in all other markets around the world. <strong><a href="http://www.biocon.com/biocon_inv_press_releases_29jun2009.asp">www.biocon.com/biocon_inv_press_releases_29jun2009.asp</a></strong></td>
</tr>
</tbody>
</table>
Results Healthcare at a glance

- Based in London and New York, Results Healthcare has an experienced and entrepreneurial team, which has completed over 75 healthcare transactions to date.

- Part of the globally renowned advisory firm, Results International, Results Healthcare was established in 2012, in recognition of client need for a specialist team with dedicated skills in the healthcare, pharmaceutical and biotech sectors.

- Results Healthcare offers strategic advice, fundraising, licensing, divestment and M&A support for both sellers and buyers worldwide.

- The company has a dedicated team centred in London and New York, providing international coverage through Results’ network in San Francisco, Dubai, Singapore, Tokyo, New Delhi and São Paulo.

Find out more on www.resultshealthcare.com

Our recent deals

- has been acquired by
  - ProPharma Group
  - a Sovereign Capital Partnership

- has divested its Holmes Chapel manufacturing site to
  - Recipharm

- has been acquired by
  - Precision for Medicine
  - PTX Partner Therapeutics

- have made a significant investment into
  - dotmatics
  - Knowledge Solutions

- divested its Tucson research facility and operations to
  - ICAgen

- has secured growth equity investment from
  - Baird Capital
  - Bard

- has acquired the Swords, Dublin manufacturing site from
  - Bristol-Myers Squibb

- has secured investment from
  - LDC

- has been acquired by
  - Havas Group

- has signed a definitive merger agreement, valuing inVentiv at $4.6bn with a joint enterprise value of $7.4bn

- has been acquired for £84m by
  - UDG Healthcare plc
Contributing team members

Kevin Bottomley  
Partner

Kevin has over 30 years' experience working in the healthcare sector, principally with pharmaceutical, biotechnology and business consultancy companies.

He has been involved in the successful divestment and acquisition of many businesses, acting as advisor to major pharmaceutical and biotechnology companies. Successful transactions he led whilst at PharmaVentures included the sale of 2 Sanofi research sites to Covance, divesting Dow Pharmaceuticals API manufacturing division to Dr Reddy's Ltd, the sale of manufacturing businesses from UCB to Aesica, the divestment of Merck's research site in Newhouse, Scotland to BioCity and in 2012 the divestment of Zentiva's (a Sanofi Group Company) Hlohovec plant to Wood Pharma Holding.

At Results Healthcare, Kevin has worked on Sanofi’s divestment of the Holmes Chapel manufacturing site to Recipharm, Sanofi’s divestment of the global rights to LEUKINE® and associated manufacturing assets to Partner Therapeutics, SK biotek’s acquisition of the Swords, Dublin manufacturing site from Bristol-Myers Squibb, Sanofi’s strategic collaboration agreement with Evotec, the divestment of Sanofi’s Tucson research site, UCB’s Shannon manufacturing site as well as UCB’s nitrate products as a number of fundraising and strategic consultancy deals.

Kevin also has extensive experience in licensing of research compounds, technologies, IP and pharmaceutical products.

During his career Kevin has held senior positions in pharmaceutical research, alliance management, business development and transactions. He has worked at Hoechst (Sanofi), Quintiles, Roche Pharmaceuticals, Inpharmatica and PharmaVentures.

Achim Newrzella  
Associate

Achim joined the Results Healthcare team in 2015. Achim has a BSc in Biochemistry from the University of Birmingham and completed a PhD looking at the identification and culture of prostate cancer stem cells from UCL. He also spent a brief period at Bayer Healthcare, working on process development and optimisation in biologics manufacturing.

Since joining Results he has worked on a variety of transactions across the healthcare sector, including the sale of LEUKINE® by Sanofi to Partner Therapeutics, the divestment of Sanofi's Tucson research facility to Icagen, the acquisition of BMS' Swords manufacturing facility by SK Biotek and investment by SEP in Dotmatics.

Outside work Achim is a keen squash player, competing nationally and internationally.

Daniel Mekic  
Associate Principal

Daniel is an Associate Principle in the Healthcare team with transactions experience in licensing, divestments and venture capital investments. Daniel previously worked at Merck KGaA, where he was a Director in the Biosimilar business development team, executing transactions to build and support the newly established business unit. This included scouting, due diligence and execution of transactions. Prior to this role, he was a Senior Financial Controller for Merck's licensing team, where he was responsible for asset and strategy evaluations.
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