The Biosimilars Game

A Scorecard for Opportunities, Threats and Critical Strategies
BioWorld Data
The Biosimilars Game:
A Scorecard for Opportunities, Threats and Critical Strategies

The Indispensable Guide for:
- Biopharmaceutical execs and life science attorneys who need to guard IP and identify emerging competitors
- Entrepreneurs aiming to build biosimilars companies
- Investors, bankers, analysts and venture capitalists targeting the best opportunities
- Executives at CROs, CMOs, generics and big pharma firms who all need to grasp the competitive landscape
- Regulatory professionals navigating country-by-country differences in expectations, needs, patent law and regulatory systems

The emerging biosimilars drug development market is a game changer for the entire drug development industry akin to the impact generics have had on traditional pharmaceuticals. BioWorld - the industry’s most trusted news service focused on the development of biologics for more than two decades - has identified and profiled 139 key biosimilar developers with 276 biosimilars in their pipelines as well as 25 already approved. This BioWorld Data tool provides:

- In-depth analyses of biosimilar rules and activity in both emerging and highly regulated markets (31 countries covered)
- R&D cost comparisons
- Data to spot the Big Hitters, including likely targets identified by the FDA, targeted MAbs and other biologics
- Lessons learned: failed and withdrawn biosimilars
- Deal terms for 80 key biosimilar alliances
- Insight for strategy development. Example: Biologics makers need to rethink brand strategies because attempts at product hopping (which delayed generic competition for small-molecule drugs) may not work when biosimilars are available. The Biosimilars Game: A Scorecard for Opportunities, Threats and Critical Strategies explains why and much more!

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The Biosimilars Game:
A Scorecard for Opportunities,
Threats and Critical Strategies
Table of Contents

About the Author ................................................................. 5
Biosimilars Present Huge Potential, Immense Complexity .................................................. 7
Vital Statistics ...................................................................... 13

An Overview ...................................................................... 15
About this Report ................................................................. 21

Ballparks & Rules ............................................................... 23
Lack of Harmonization Costly for Biosimilars ................................................................. 25

Asian Pacific Region .......................................................... 26
Australia, China .................................................................... 26
India, Japan ........................................................................... 27
South Korea .......................................................................... 28
Malaysia, Taiwan ................................................................... 29

Europe ................................................................................. 29
European Union .................................................................... 29
Russia ................................................................................. 30

Latin America ....................................................................... 32
Brazil ................................................................................... 32
Mexico ................................................................................. 33

MENA (Middle East and Northern Africa) ....................................................... 33

North America ..................................................................... 34
Canada, United States .......................................................... 34

FDA Drafts Biosimilar Playbook ................................................. 36

The Scorecard ................................................................... 37
Sponsors Eyeing Biologics for Biosimilar Development .................................................. 39
Biosimilars Face Stiff Competition in Anemia Space ....................................................... 43
EU Looking to End Biosimilar Slump .............................................................................. 44

The Players ........................................................................ 67
Amgen, Watson Pharma Team up on Biosimilars ......................................................... 69
Samsung Swings at Biosimilars with Joint Ventures ...................................................... 70
Actavis Group ........................................................................ 72
Aequus BioPharma Inc. ................................................................ 72
AET BioTech Ltd. ................................................................... 73
Alteogen Inc. .......................................................................... 73
AMEGA Biotech S.A. ................................................................ 74
Amgen Inc. ............................................................................ 74
Amphastar Pharmaceuticals Inc. .............................................................................. 75
Anhui Anke Biotechnology Co. Ltd. ........................................................................ 75
ApoLife Inc. ............................................................................ 75
# Table of Contents

IBC Generium.......................................................................................................................... 98
iBio Inc......................................................................................................................................... 98
Inbiopro Solutions Pvt. Ltd........................................................................................................... 98
Inno Bio Ventures Sdn Bhd.......................................................................................................... 98
InSight Biopharmaceuticals Ltd.................................................................................................. 99
Instituto Butantan......................................................................................................................... 99
Intas Biopharmaceuticals Ltd...................................................................................................... 99
ISU Abxis .................................................................................................................................... 100
JCR Pharmaceuticals Co. Ltd....................................................................................................... 100
Hangzhou Jiuyuan Gene Engineering Co. Ltd.......................................................................... 101
Julphar......................................................................................................................................... 101
Shandong Kexing Bioproducts Co. Ltd...................................................................................... 101
Kissei Pharmaceutical Co. Ltd.................................................................................................... 102
LG Life Sciences Ltd.................................................................................................................. 103
Ligacept LLC.............................................................................................................................. 103
Lonza Group AG....................................................................................................................... 103
Lupin Ltd..................................................................................................................................... 104
MabPharm Pvt. Ltd..................................................................................................................... 104
mAbxience ................................................................................................................................ 104
Marvel Life Sciences Ltd............................................................................................................ 105
Medicago Inc.............................................................................................................................. 105
Medice Arzneimittel Pütter GmbH & Co. KG........................................................................... 105
MedImmune LLC....................................................................................................................... 105
Meiji Seiki Pharma Co. Ltd......................................................................................................... 106
Merck BioVentures (MBV)........................................................................................................ 106
Merck Serono SA....................................................................................................................... 107
Mochida Pharmaceutical Co. Ltd.............................................................................................. 107
Momenta Pharmaceuticals Inc................................................................................................... 108
Mycenax Biotech Inc.................................................................................................................. 108
Mylan Inc.................................................................................................................................... 109
Nichi-Iko Pharmaceutical Co. Ltd.............................................................................................. 109
Nippon Kayaku Co. Ltd............................................................................................................... 109
Nomad Bioscience GmbH.......................................................................................................... 110
North China Pharmaceutical Group Corp. (NCPC).................................................................... 110
Novartis AG................................................................................................................................ 110
Oncobiologics Inc...................................................................................................................... 111
ORF Genetics Ltd....................................................................................................................... 111
Orygen Biotecnologia.................................................................................................................. 111
Panacea Biotech Ltd................................................................................................................... 112
PanGen Biotech Inc................................................................................................................... 112
Parexel International Corp.......................................................................................................... 112
Paralis Biopharmaceuticals LLC............................................................................................... 113
Pfenex Inc................................................................................................................................... 113
Pfizer Inc....................................................................................................................................... 113
PharmaPraxis.............................................................................................................................. 114
Pharmstandard.......................................................................................................................... 114
PlantForm Corp.......................................................................................................................... 114
Probiomed S.A. de CV................................................................................................................ 115
Protalix Biotherapeutics Inc....................................................................................................... 115
Protek Group.............................................................................................................................. 115
Quintiles Transnational Corp.................................................................................................... 116
Ranbaxy Laboratories Ltd.......................................................................................................... 116
Ratiopharm GmbH..................................................................................................................... 116
<table>
<thead>
<tr>
<th>Company Name Index</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliance GeneMedix plc</td>
<td>117</td>
</tr>
<tr>
<td>Reliance Life Sciences Pvt. Ltd</td>
<td>117</td>
</tr>
<tr>
<td>rEVO BioLogics Inc</td>
<td>118</td>
</tr>
<tr>
<td>Ricerca Biosciences</td>
<td>118</td>
</tr>
<tr>
<td>Samsung Bioepis Co. Ltd</td>
<td>118</td>
</tr>
<tr>
<td>Samsung BioLogics Co. Ltd</td>
<td>118</td>
</tr>
<tr>
<td>Sandoz International GmbH</td>
<td>119</td>
</tr>
<tr>
<td>SciGen Ltd</td>
<td>119</td>
</tr>
<tr>
<td>Shantha Biotechnics Ltd</td>
<td>120</td>
</tr>
<tr>
<td>Sicor Biotech UAB</td>
<td>120</td>
</tr>
<tr>
<td>Simcere Pharmaceutical Group</td>
<td>120</td>
</tr>
<tr>
<td>Beijing SL Pharmaceutical Co. Ltd</td>
<td>121</td>
</tr>
<tr>
<td>Spectrum Pharmaceuticals Inc</td>
<td>121</td>
</tr>
<tr>
<td>STADA Arzneimittel AG</td>
<td>121</td>
</tr>
<tr>
<td>STC Biologics Inc</td>
<td>121</td>
</tr>
<tr>
<td>Swedish Orphan Biovitrum AB (Sobi)</td>
<td>122</td>
</tr>
<tr>
<td>Synthon BV</td>
<td>122</td>
</tr>
<tr>
<td>Teva Pharmaceutical Industries Ltd</td>
<td>123</td>
</tr>
<tr>
<td>3SBio Inc</td>
<td>123</td>
</tr>
<tr>
<td>UMN Pharma Inc</td>
<td>124</td>
</tr>
<tr>
<td>Viopro International Inc</td>
<td>124</td>
</tr>
<tr>
<td>Watson Pharmaceuticals Inc</td>
<td>125</td>
</tr>
<tr>
<td>Wockhardt Ltd</td>
<td>126</td>
</tr>
<tr>
<td>Zenotech Laboratories Ltd</td>
<td>126</td>
</tr>
<tr>
<td>Zydus Cadila Healthcare Ltd</td>
<td>127</td>
</tr>
</tbody>
</table>

**The Next Season**

Europe is Training Camp for U.S. Biosimilars
Biosimilars May Foul Brand Game Plans
Players, Umpires Face Challenges of Biosimilars

**Indices**

Company Name Index
Drug Name Index
# Table of Charts

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>An Overview</strong></td>
<td>15</td>
</tr>
<tr>
<td>Daily Cost of Drugs in the U.S.</td>
<td>17</td>
</tr>
<tr>
<td>Global Biologic Sales: 2012</td>
<td>19</td>
</tr>
<tr>
<td>Projected Global Biologic Sales: 2017</td>
<td>19</td>
</tr>
<tr>
<td><strong>Ballparks &amp; Rules</strong></td>
<td>23</td>
</tr>
<tr>
<td>Biosimilars Approved in Australia</td>
<td>26</td>
</tr>
<tr>
<td>Biosimilars Approved in Japan</td>
<td>28</td>
</tr>
<tr>
<td>Biosimilar MAbs Approved in South Korea</td>
<td>28</td>
</tr>
<tr>
<td>FOBs Approved in Malaysia</td>
<td>28</td>
</tr>
<tr>
<td>Requests for EMA Scientific Advice for Proposed Biosimilars, 2008-2012</td>
<td>30</td>
</tr>
<tr>
<td>Biosimilars Approved in the European Union</td>
<td>31</td>
</tr>
<tr>
<td>Regular Biologics Approved in Brazil</td>
<td>33</td>
</tr>
<tr>
<td>Sampling of FOBs Approved in Mexico</td>
<td>33</td>
</tr>
<tr>
<td>Biosimilar Activity at the FDA</td>
<td>35</td>
</tr>
<tr>
<td><strong>The Scorecard</strong></td>
<td>37</td>
</tr>
<tr>
<td>R&amp;D Cost Comparison</td>
<td>39</td>
</tr>
<tr>
<td>Likely Targets Identified by the FDA</td>
<td>40</td>
</tr>
<tr>
<td>Failed and Withdrawn Biosimilars</td>
<td>46</td>
</tr>
<tr>
<td>Drug Failure Rates</td>
<td>47</td>
</tr>
<tr>
<td>Targeted MAbs and Other Biologics</td>
<td>48</td>
</tr>
<tr>
<td>Companies Developing Undisclosed MAb Biosimilars</td>
<td>64</td>
</tr>
<tr>
<td><strong>The Players</strong></td>
<td>67</td>
</tr>
<tr>
<td>Biosimilar Deals</td>
<td>128</td>
</tr>
</tbody>
</table>
‘Show Me the Money’ is the Focus of Biosimilar Game

By Mari Serebrov
Washington Editor

As the U.S. continues to wait for its first biosimilar to step up to the plate, global players are betting on follow-on biologics (FOBs) to be one of the biggest hits in town. To earn that star status though, biosimilars will have to show payers the money pretty quickly by delivering the power of biologics at a price economically strapped countries can afford.

Biologics, with their ability to treat many unmet needs, are seen as the future of health care. But their per-patient price tag – which can run in the hundreds of thousands of dollars per year, well above the average price of small molecule drugs and generics – has put them out of bounds for many emerging markets that are facing large, aging populations and an increase in chronic diseases such as diabetes. (See The Daily Cost of Drugs in the U.S., below.)

The impact, and inequities, will grow as more high-priced biologics enter the field. The global biologics market is expected to grow 30 percent over the next few years – from $130 billion in sales in 2012 to $169 billion by 2017, according to Sandoz International GmbH. Over the same time period, the small molecule market is expected to grow by about 11 percent – from $380 billion to $421 billion.

By 2014, half of the top-selling drugs are expected to be biologics, according to a 2012 U.S. Congressional Research Service (CRS) report. And the numbers are going to get worse for payers. While biologics accounted for about a fourth of biopharma sales in 2012, they made up nearly a third of the pipeline.

As a result, even in countries that have traditionally been able to pay more for health care, government and third-party payers are struggling to keep up with the demand for biologics. Some of them are already balking at the escalating price of the drugs, going so far as to deny or restrict access to specific new therapies.

The UK’s National Institute for Health and Clinical...
About this Report

The Biosimilars Game: A Scorecard for Opportunities, Threats & Critical Strategies provides a play-by-play of the various markets, their playbooks and the all-star biologics that are likely to see biosimilar competition in the next few years. It also looks at the statistics for many of the players already stepping onto the biosimilar field and discusses some of the issues that must be refereed in future innings.

Over the years, a variety of terms have been used to refer to FOBs. For this report, the following definitions are in play:

Alternatives are biologic copies that haven’t demonstrated comparability to a reference product. These are often approved in emerging markets as new drugs or “noninnovators,” but they are not considered biosimilars.

Biobetters are biologic copies that are safer, more effective or more convenient than the reference product. In regulated markets, they must be approved as new biologics. However, since they are based on an approved biologic, the risk of failure may be reduced significantly. Another benefit is that they can build on an already established market.

Biologics are comprised of large (at least 5,000 atoms) molecules that are derived from living cells and manufactured through biological processes. Because of their complexity, the safety and effectiveness of biologics can be significantly impacted by minor differences in the manufacturing processes. Thus, even an innovator product has inherent lot-to-lot variability.

Biosimilars must be “highly similar” to the reference product. While there can be minor differences in clinically inactive components under U.S. law, there can be no “clinically meaningful differences” between the biosimilar and the reference drug in terms of safety, purity and potency. Since a biosimilar relies on prior findings of efficacy and safety for the reference product, it has to demonstrate comparability/similarity to that product in a head-to-head trial in highly regulated markets, where they are approved on a designated abbreviated path. The level of similarity required may differ from country to country. Biosimilars are known as biocomparables in Mexico, regular biologics in Brazil and subsequent-entry biologics in Canada.

Follow-on biologic (FOB) is a broad term used to describe any drug that copies an approved/marketed biologic. Alternatives, biobetters, biosimilars and interchangeable biologics are all FOBs.

Interchangeable biologics are expected to produce the same clinical results as their reference drug in any given patient. The risk, in terms of safety or diminished efficacy, of switching between an interchangeable and reference biologic must not be greater than from consistent use of the reference product. The FDA anticipates drugmakers would have to demonstrate the sameness of a potential interchangeable through switching trials with the reference drug.

Reference products are approved/marketed originator biologics that serve as the model for FOBs. Generally in regulated markets, the reference product would be off patent by time an FOB is approved.
Lack of Harmonization Costly for Biosimilars

When the European Medicines Agency (EMA) approved Sandoz International GmbH’s Omnitrope (somatropin) in 2006, making it the first official biosimilar in the world, the EU rulebook for follow-on biologics (FOBs) became the one to follow. Its comparability requirements are reflected in rules adopted by other countries, as well as in the World Health Organization’s (WHO) 2009 guidelines on evaluating similar biotherapeutic proteins.

But given the differences in expectations, needs, patent law and regulatory systems from country to country, there still is no uniform players’ manual for biosimilars – even among highly regulated countries such as Australia, Canada, the EU, Japan and the U.S. Consequently, the cost of developing a biosimilar for more than one market can be high. And a drug approved as a biosimilar in one country may not be approved in another, or it may be considered a new drug or an alternative rather than a biosimilar.

Omnitrope, a human growth hormone, is a prime example. A few years after its EU approval, it became Japan’s first biosimilar. But it’s not considered a biosimilar in Canada and the U.S., where it was approved before their biosimilar ballparks were erected. Even if the FDA’s rulebook had been in play at the time, Omnitrope could not have been approved as a biosimilar in the U.S. because the reference product, Pfizer Inc.’s Genotropin, was approved as a new drug rather than as a biologic.

Myriad Differences

Other differences among the regulated markets include exclusivities and reference products. For instance, all new biologics approved in the U.S. get 12 years of data exclusivity, which runs concurrently with any market exclusivity granted for orphan drugs, pediatric studies, etc. That means the FDA cannot approve a biosimilar, based on data for the reference drug, for 12 years after the reference drug is approved. In the EU, the combined market and data exclusivity is 10 years. Exclusivity may be shorter, or nonexistent, in other countries.

In addition to exclusivity, the strength of patents from market to market can create an uneven playing field. The generic-drug industry has flourished in emerging markets with weak patent protections. Many of those drugmakers, and countries, are using the same strategies to jump into FOB development long before the originator biologic patents expire in the highly regulated markets.

What can serve as a reference product also differs by country or region. As of 2012, the rulebooks in each of the regulated markets required a biosimilar to reference a biologic previously approved in that market. As a result, a sponsor seeking approval for a biosimilar in more than one market would have to conduct duplicative trials – even if the reference biologic is made by a single facility for worldwide use but sold under different names and labels, said Avalere Health LLC Vice President Gillian Woollett.

That’s changing, though, as the EU is rethinking that part of its biosimilar policy. But in the U.S., the requirement for an FDA-approved reference biologic is written into the law that authorized the biosimilar path, so it would take an act of Congress to change it.

The regulatory differences are more obvious in emerging markets, many of which are just starting to draft their biosimilar rulebooks. Faced with compelling unmet medical needs and tight budgets, emerging markets tend to have less stringent requirements for FOBs, Woollett said.

Rather than requiring a demonstration of biosimilarity through head-to-head comparisons with the reference drug, some markets simply require an alternative biologic, sometimes referred to as an “intended copy,” to have the same target as the originator, she said.

Other differences in emerging markets are price controls and efforts to strengthen the home team. A number of nations have lists of essential drugs that are either subject to price caps or must be produced in-country. Therapies such as erythropoietin (EPO), filgrastim (G-CSF) and insulin are often on the essential drug lists, a fact that may make it easier for domestic companies to get copies of those products approved in their home countries, without demonstrating comparability or worrying about intellectual property rights.

Variability Leads to Challenges

The lack of regulatory uniformity among markets has tripped up some biosimilars, Woollett said, pointing to Marvel Lifesciences Ltd.’s follow-on insulin products that are sold in India, Russia and several other countries. The London-based company tried to get three of its insulin products that were approved as biosimilars in the EU in 2007. After the EMA refused to extend the timeline for providing answers to specific questions involving comparability exercises, manufacturing validation and batch traceability, Marvel withdrew the applications.

Marvel tried again in 2011. But nearly a year later, while the three insulin products were still under review, the company withdrew the applications, saying it needed sufficient time to repeat and submit bioequivalence pharmacokinetic/pharmacodynamic data on Type I diabetes studies so it could comply with a planned new insulin guideline.
# Targeted MAbs and Other Biologics

## ABATACEPT

<table>
<thead>
<tr>
<th>Biologic</th>
<th>Brand Name</th>
<th>Distributor</th>
<th>Developer</th>
<th>Indication</th>
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<tbody>
<tr>
<td>Abatacept</td>
<td>Orencia</td>
<td>Bristol-Myers Squibb Co.</td>
<td>Bristol-Myers Squibb Co.</td>
<td>Rheumatoid arthritis</td>
</tr>
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### Potential Biosimilars

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
<th>Country</th>
<th>Status</th>
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<tbody>
<tr>
<td>ND</td>
<td>BioXpress Therapeutics SA</td>
<td>Switzerland</td>
<td>In development</td>
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## ABCIXIMAB

<table>
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<th>Biologic</th>
<th>Brand Name</th>
<th>Distributor</th>
<th>Developer</th>
<th>Indication</th>
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<tbody>
<tr>
<td>Abciximab</td>
<td>ReoPro</td>
<td>Eli Lilly and Co.</td>
<td>Centocor</td>
<td>For use with cardiac PCI</td>
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### Potential Biosimilars

<table>
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<th>Name</th>
<th>Company</th>
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<th>Status</th>
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<tr>
<td>Clotinab</td>
<td>ISU Abxis</td>
<td>South Korea</td>
<td>Approved in South Korea and several other countries as a new drug; completed a Phase IV U.S. trial in 2009</td>
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## ADALIMUMAB

<table>
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<th>Biologic</th>
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<tr>
<td>Adalimumab</td>
<td>Humira</td>
<td>Abbott</td>
<td>Abbott</td>
<td>Rheumatoid arthritis, psoriasis, Crohn's, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, juvenile idiopathic arthritis</td>
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</tbody>
</table>

### Potential Biosimilars

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<td>ND</td>
<td>AET Biotech/BioXpress Therapeutics SA</td>
<td>Germany/Switzerland</td>
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<td>ND</td>
<td>Alteogen Inc.</td>
<td>South Korea</td>
<td>In process development</td>
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<td>ND</td>
<td>AXXO GmbH</td>
<td>Germany</td>
<td>Available for partnering</td>
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<tr>
<td>ND</td>
<td>Boehringer Ingelheim GmbH</td>
<td>Germany</td>
<td>U.S. Phase I PK equivalency study completed in 2012</td>
</tr>
<tr>
<td>ND</td>
<td>Fujifilm Kyowa Kirin Biologics Co. Ltd.</td>
<td>Japan</td>
<td>EU clinical trials expected to begin in the first half of 2013, with a 2017/18 launch goal</td>
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<tr>
<td>ND</td>
<td>Harvest Moon Pharmaceuticals USA Inc.</td>
<td>U.S.</td>
<td>Pedigreed cell line developed</td>
</tr>
<tr>
<td>ND</td>
<td>Mylan Inc./Biocon Ltd.</td>
<td>U.S./India</td>
<td>In cell line/process development</td>
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<tr>
<td>ND</td>
<td>Oncobiologics Inc.</td>
<td>U.S.</td>
<td>In preclinical development</td>
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<tr>
<td>AMAB</td>
<td>PharmaPraxis</td>
<td>Brazil</td>
<td>In development</td>
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</tbody>
</table>
BioMab Holdings Ltd.

Address: Unit 511, 5/F Tower 1 Silvercord 30 Canton Rd., TST KL, Hong Kong, China

A joint venture based in Hong Kong, BioMab was created by Indian drugmaker Cipla Ltd. and two Chinese drug manufacturers, Jiangsu Cdynax and Shanghai Desano Pharmaceutical Investment. BioMab’s primary focus is the development of biosimilars. Clinical trials on BioMab’s first molecules are expected to be completed in 2014-2015. The products will subsequently be launched in China, India and potentially in other markets.

Pipeline:
• Not disclosed

Bionovis S.A.

Address: Av. Do Café, 277, 7th floor, Centro Empresarial do Aço, Jabaquara, São Paulo 04311-900, Brazil
Phone: (11) 5586 2000
Website: www.uniaoquimica.com.br

A public-private joint venture founded in 2012 to produce biologics (most likely biosimilars) for the Brazilian market, Bionovis is expected to begin operations in early 2013 with a $250 million investment from Brazil’s national development bank and four of the country’s largest drugmakers – Ache, EMS, Hypermarcas and Uniao Quimica. Bionovis expects to jumpstart its biosimilar production through technology transfer agreements with Asian companies. Its first products should hit the market in 2015 or 2016.

Pipeline:
• Etanercept
• Rituximab
• 5 undisclosed

BioPartners GmbH

Address: Sihlbruggstrasse 3, 6340 Baar, Switzerland
Phone: +41 (0) 41 766 20 80
Website: www.biopartners.ch/index.htm

Now part of Bioton SA, BioPartners, of Baar, Switzerland, developed Valtropin (somatropin), the second biosimilar approved in Europe in 2006. The biosimilar, co-developed with LG Life Sciences Ltd., was launched in January 2009, but marketing efforts were temporarily halted after six months due to economic reasons. In 2011, it ended up withdrawing the biosimilar, citing commercial reasons. It has since developed a sustained-release hGH product that would be considered a new drug or biobetter.

BioPartners tried to get two other biosimilars approved in the EU, but its Alpheon (interferon alpha) was rejected in 2006 due to quality concerns and differences between it and the reference biologic. Three years later, BioPartners withdrew a biosimilar application for Biferonex (interferon beta 1a) after it received a negative opinion from the EMA’s Committee for Medicinal Products for Human Use.

Approvals:
• Valtropin – Approved in the EU in 2006, withdrawn in 2011

Pipeline:
• Not disclosed
### BioSidus S.A.

**Address:** Constitución 4234 - C1254ABX Buenos Aires, Argentina  
**Phone:** +5411 4909 8000  
**Website:** www.biosidus.com.ar

Part of the Sidus Group, the primary focus of the Buenos Aires-based biotech is the development, manufacture and supply of biosimilars, which are available, through a licensing network, in Africa, Eastern Europe, Latin America, the Middle East and South Eastern Asia. With more than two decades of biosimilar experience in emerging markets, BioSidus is looking at expanding into the EU, Japan and the U.S.

**Approvals:**
- Erythropoietin, marketed as Epoyet, Epoimmun, Hemax, Hypercrit and Zyrop  
- Filgrastim, marketed as Biofigran, Colstim, Granulostim and Neutromax  
- Blastoferon (interferon beta-1a)  
- Somatropin, marketed as GrowMax, HHT and Somatrop  
- Interferon alpha-2b, marketed as Bioferon, Citopheron, Inter 2B and Zavinex  
- Interferon alpha-2a, marketed as Inferon, Inter 2A and Inmutag

**Pipeline:**
- Agalsidase beta (based on Genzyme’s Fabrazyme)  
- Imiglucerase (based on Genzyme’s Cerezyme)  
- Rituximab  
- Etanercept

### Bioton SA

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A global biopharma based in Warsaw, Poland, Bioton (WSE:BIO) built its reputation on insulin products, novel drugs and generics. It has expanded by acquiring a number of biotechs throughout Asia and Europe. Its holdings include SciGen Ltd. and BioPartners GmbH, which produced Valtropin (somatropin), one of the first biosimilars approved in Europe.

In 2012, Bioton formed a joint venture with the Actavis Group to produce insulin products for developed and emerging markets. As part of the nearly $751 million deal, Bioton is responsible for the development and manufacture of the products and Actavis will have an exclusive license to commercialize them under its brand in much of the world.

**Approvals:**
- Recombinant insulin products – Marketed in countries in Asia, Eastern Europe and South America

**Pipeline:**
- Insulins and insulin analogues