

# Coagulation Factors 2010 – The Portfolio Aspect as Decisive Force: A Competitive Landscape and R&D Pipeline Analysis of Hemostasis Proteins

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# Abstracts

# **Product description**

The report "Coagulation Factors 2010 - The Portfolio Aspect as Decisive Force: A Competitive Landscape and R&D Pipeline Analysis of Hemostasis Proteins" provides a description, evaluation and assessment of the recombinant and plasma-derived coagulation factor pipelines as of September 2010. The authors analyze and assess the target pipeline for each of the coagulation factors used for systemic and topical administration. Companies active in the therapeutic coagulation factor business are evaluated and the strengths, weaknesses, opportunities and threats (SWOT) in their R&D pipeline benchmarked in the respective peer group. Technologies used for creation of next generation coagulation factors are discussed and assessed. The report identifies strategies to overcome weaknesses in the portfolio and suggests development strategies.

#### Background:

Global sales of the five major recombinant products of coagulation factors VIII, IX and VIIa in 2009 were US\$ 5.5 bln (with \$ conversion rate of September 2, 2010). As of 2009, substance patents have commenced to expire in the first territories and are continuing to expire over the next few years. As a consequence, established companies have intensified their efforts to defend or even expand their coagulation factor sales and new players have been entered this commercially attractive field.

#### Scope of the report



R&D pipeline overview;

in depth profiles of most promising coagulation factors in the pipeline

pipeline analysis for each coagulation factor ;

evaluation and assessment of protein engineering and drug delivery technologies

overview and analysis of marketed coagulation factors;

profiles of more than 50 companies active in this business;

corporate product portfolios and R&D pipelines;

benchmark and SWOT analysis of corporate competitors within peer group

#### **Highlights**

None of the established marketers of recombinant coagulation factors so far has achieved to get a next generation coagulation factor product approved to convert sales from the first generation product to the next generation product.

The five marketed recombinant coagulation factors (VIII, IX and VIIa) are facing a total of more than 41 different projects among the three hemophilia coagulation factors in the R&D pipeline: 12 projects (equally distributed among the three factors) are in clinical stage and another 7 molecules are in IND enabling studies or at pre-IND stage ready to enter phase I during the next 12 months. Further 22 molecules are in preclinical R&D. The field is moving rapidly and the next two years will see important progress in the development of new molecules because the drug discovery phase has provided sufficient candidates for non-clinical and clinical development.

Novo Nordisk extended its leading position in the competitive R&D landscape of next generation coagulation factor products with a highly differentiated portfolio approach.

In addition to differentiating the properties of a single coagulation factor, more than 10 companies are active with more than one of the three different coagulation factors emphasizing the importance of the portfolio aspect in the future marketing efforts. Not



only the established companies with recombinant coagulation factors on the market are developing a differentiated portfolio, but also newcomers to the field are developing more than one factor. Portfolio not only means the addition of a second or even third coagulation factor, but even within the same coagulation factor molecules with different half-life properties or administration feature.

#### Benefits from the report

Understand your position in a highly competitive environment

Avoid costly mistakes

Learn from your competitors

Challenge your strategy with a view from outside the organization

Revise weaknesses of your molecule and development plan

Identify threats to your business plan

Realize new opportunities suggested by the report

Reassure and build upon your strengths

Find applications for your technology

#### **Target audience**

Project, product and portfolio managers

Business development & licensing

Research & development

Technology evaluation



#### **Financial analysts**

Investment fund/venture capital managers

Plasma fractionation companies with coagulation factor business

Drug delivery companies

Protein engineering companies

Companies with surgery and wound healing business

Companies interested in biosimilars/biogenerics

#### Companies mentioned in the report

**Abraxis Biosciences** 

Amsterdam Molecular Therapeutics

Amunix

Angiotech

Apitope

Archemix

Arecor

Asklepios Biopharmaceutical

Baxter

**Bayer Schering Pharma** 

**Bio Products Laboratory (BPL)** 



**Biogen Idec** 

Biotest

**Catalyst Biosciences** 

China Biologic Products

CSL

Ethicon (J&J)

Fresenius Kabi

**Genavia Therapeutics** 

Green Cross

Grifols

**GTC** Biotherapeutics

Hualan Biologic Engineering

Inspiration Biopharmaceuticals

Intas Biopharmaceuticals

Ipsen

Kaketsuken

Kamada

Kedrion

King Pharmaceuticals



#### LFB

#### Lipoxen

Mochida Pharmaceutical

National Bioproducts Institute (NBI)

Novo Nordisk

Nycomed

Octapharma

**Origen Therapeutics** 

Orthovita

Pfizer

Pharming

ProFibrix

PROLOR Biotech

Recoly

Sanquin

Shanghai RAAS

SK Chemicals

Swedish Orphan Biovitrum

**Talecris Biotherapeutics** 

Thermogenesis



Thrombotargets

VIRxSYS

Vivostat

Zymogenetics



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**BAX 326 BAX 513** BAY 79-4980 BAY 86-6150 **CSL654 CSL689** GreenGene IB1001 LA-N8 NN1731 NN1810 NN1841 NN7008 NN7128 NN7129 NN7999 OBI-1 Octagenate rFIXFc rFVIIIFc rVWF **TFPI** Inhibitory Aptamer **B)** Company Profiles **Amsterdam Molecular Therapeutics** Angiotech Pharmaceuticals Apitope Archemix Arecor **Asklepios Biopharmaceutical** Baxter **Bayer Schering Pharma Bio Products Laboratory (BPL) Biogen Idec Biotest Catalyst Biosciences Celestial Biologicals** China Biologic Products CSL Ethicon (J&J)



Fresenius Kabi **Genavia Therapeutics Green Cross** Grifols **GTC** Biotherapeutics Hualan Biological Engineering **Inspiration Biopharmaceuticals** Intas Biopharmaceuticals lpsen Jerini (Shire) Kaketsuken Kamada Kedrion **King Pharmaceuticals** LFB Lipoxen Maxygen Marina Biotech Mochida Pharmaceutical National Bioproducts Institute (NBI) **Nektar Therapeutics** Novo Nordisk Novozymes Nycomed Octapharma **Origen Therapeutics** Pfizer Pharming ProFibrix **ProGenetics PROLOR Biotech** Recoly Sanquin Shanghai RAAS **SK Chemicals** Swedish Orphan Biovitrum **Talecris Biotherapeutics** Thrombotargets

VIRxSYS



## Zymogenetics

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**Asklepios Biopharmaceutical** Baxter **Bayer Schering Pharma Bio Products Laboratory (BPL)** Biogen Idec **Biotest Catalyst Biosciences** China Biologic Products CSL Ethicon (J&J) Fresenius Kabi **Genavia Therapeutics Green Cross** Grifols **GTC** Biotherapeutics Hualan Biologic Engineering Inspiration Biopharmaceuticals Intas Biopharmaceuticals Ipsen Kaketsuken Kamada Kedrion King Pharmaceuticals LFB Lipoxen Mochida Pharmaceutical National Bioproducts Institute (NBI) Novo Nordisk Nycomed Octapharma **Origen Therapeutics** Orthovita Pfizer Pharming ProFibrix **PROLOR Biotech** Recoly Sanquin Shanghai RAAS



SK Chemicals Swedish Orphan Biovitrum Talecris Biotherapeutics Thermogenesis Thrombotargets VIRxSYS Vivostat Zymogenetics



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