Gene Therapy - Global Strategic Business Report

Description: This report analyzes the Global market for Gene Therapy in US$ Million. Annual estimates and forecasts are provided for the period 2009 through 2017. The report profiles 98 companies including many key and niche players such as AnGes MG, Inc., BioSante Pharmaceuticals, GenVec, Oxford BioMedica, Shenzhen SiBiono GeneTech Co., Ltd., Transgene, and Vical Inc. Market data and analytics are derived from primary and secondary research. Company profiles are primarily based upon search engine sources in the public domain.

Please note: Reports are sold as single-site single-user licenses. Electronic versions require 24-48 hours as each copy is customized to the client with digital controls and custom watermarks.

For information on site licence pricing please click on Enquire before buying

Contents: GENE THERAPY
A GLOBAL MARKET REPORT

CONTENTS

I. INTRODUCTION, METHODOLOGY & PRODUCT DEFINITIONS
Study Reliability and Reporting Limitations I-1
Disclaimers I-2
Data Interpretation & Reporting Level I-2
Quantitative Techniques & Analytics I-3
Product Definitions and Scope of Study I-3

II. Executive Summary

1. MARKET OUTLOOK II-1
Gene Therapy - Promising Therapy for Future II-1
Approved Gene Therapies Fail to Gather Momentum II-1
Manufacturers Eye International Markets II-2

2. MARKET DYNAMICS/TRENDS II-3
2009 - A Tumultuous Year for Gene Therapy Industry II-3
Hope Floats in Gene Therapy II-3
China - First to Approve Gene Therapy Worldwide II-4
The Wait Continues for First Gene Therapy in Major Markets II-4
Table 1: Gene Therapy Clinical Development (2009): Percentage Share Breakdown by Stage (includes corresponding Graph/Chart) II-4
Cancer Remains the Key Target for Gene Therapy II-5
Table 2: Clinical Development of Gene Therapy by Targeted Indication (2009): Percentage Breakdown of Number of Trials for Cancer Diseases, Cardiovascular Diseases, Infectious Diseases, Monogenic Diseases, Neurological Diseases and Others (includes corresponding Graph/Chart) II-5
Adenovirus - The Leading Vector Employed in Gene Therapy II-5
Table 3: Gene Therapy Clinical Development by Vectors Used (2009): Percentage Breakdown of Number of Trials for Adenovirus, Retrovirus, Plasmid DNA, Vaccinia Virus, Lipofection and Others (includes corresponding Graph/Chart) II-5
Efficacy - The Key Challenge for Gene Therapy II-5
Gene Therapy Pipeline Strengthens in Asia II-6
Counting on the Success Factors II-6
Factors Influencing Gene Therapy Future Development II-7
Human Genome Analysis II-7
Gene Therapy - The Next Generation Cardiovascular Therapy II-7
Public Support for Gene Therapy II-7
RNAi Bodes Bright Prospects II-7
Factors Hampering Market Growth II-8
Stringent Regulatory Laws in US and Europe Prolong Gene Therapy Development II-8
Identifying Genetic Fault II-8
Immune Response II-8
Delivering Genetic Materials into Patient Cells II-8
Multigene Disorders II-9
Side Effects II-9
Push Towards Germline Gene Transfer II-9
Technical Limitations II-9

3. THE GLOBAL LANDSCAPE II-10
Alliances and Acquisitions - Strategy for Success II-10
Patent Pooling: Yet Another Obstacle II-10
Commercialization: A Road Uphill II-10
Time Line in Gene Therapy Drug Development II-11
Target Diseases and Players Involved II-11
Key Players by Application Area II-12
Table 4: Gene Therapy Clinical Trials Worldwide (2009):
Percentage Breakdown by Gene Type Transferred for Antigen, Cytokine, Tumor Suppressor, Growth Factor, Deficiency, Suicide, and Others (includes corresponding Graph/Chart) II-12

Table 5: Gene Therapy Clinical Trials (2007): Percentage Breakdown by Geographic Region for US, Europe, Canada, Japan and Rest of World (includes corresponding Graph/Chart) II-13
Select Gene Therapy Products in Phase I and Pre-Clinical Development (2010) II-14
Overview of Select Drugs in Pipeline II-14
Allovectin-7® (Vical Inc.) II-14
Generx (Cardium Therapeutics) II-15
Trinam® (Ark Therapeutics) II-15
TroVax® (Oxford BioMedica) II-15
Collategene™ (AnGes MG Inc.) II-16

4. REVIEW OF MAJOR MARKETS II-17
The United States II-17
Regulatory Environment II-17
Food and Drug Administration II-17
FDA Requires Additional Toxicology and Biodistribution Studies II-17
IRB and IBC II-18
NIH II-18
Europe II-20
Germany and UK- The Hub of European Gene Therapy Market II-20
Table 6: Gene Therapy Clinical Trials in Europe (2007):
Percentage Breakdown of Number of Trials by Country for UK, Germany, Switzerland, France, Belgium, Netherlands and Others (includes corresponding Graph/Chart) II-20
Regulatory Environment II-20
Gene Therapy Advisory Committee II-21
European Society of Gene and Cell Therapy (ESGCT) II-21
Study of Regulatory Environment in Select European Countries II-21
United Kingdom II-21
Germany II-22
Italy II-22
Sweden II-22
5. GENE THERAPY - AN INSIGHT II-26
Molecular Basics - The Gene II-26
Genome - The Information Pool II-26
Functional Cloning II-26
Random Sequencing II-26
Positional Cloning II-27
What is Gene Therapy? II-27
A Backdrop II-27
1990 Highlights - The Preliminary Gene Therapy Trial II-27
1995 Highlights II-27
2000 Highlights - Clinical Trials Reaches 400- Milestone II-28
2004 Witnesses the First Gene Therapy Drug II-28
Classical Theory of Gene Therapy II-28
Ex-Vivo Approach of Gene Therapy II-28
In-vivo Approach of Gene Therapy II-28
Types of Gene Therapy II-29
Monogenic Gene Therapy II-29
Suicide Gene Therapy II-29
Antisense Gene Therapy II-29
Various Approaches II-29

6. COMPONENTS OF GENE THERAPY II-30
Vector II-30
Delivery Vehicles and Challenges in Use of Viral Vectors II-30
Gene Delivery - Without Virus II-30
Non-Viral Products in Pipeline II-31
Well-known Delivery Approaches for Gene Therapy II-31
Viral and Non-viral Vectors in Use II-32
Retroviruses II-32
Adenoviruses II-32
Adenoassociated viruses II-32
Herpes simplex viruses II-32
Lentiviruses II-32
Liposomes II-32
Viral Vectors by Companies involved II-33
Gene Cassette II-33
Target cells II-33
Stem cells II-33
Differentiated cells II-33
The Disc: An Excellent Target for Gene Therapy II-34

7. REVIEW OF VARIOUS APPROACHES II-35
Antisense Technology II-35
Catalytic Ribozyme Technology II-35
Triple Helix DNA II-35

8. GENE THERAPY FOR DISEASE TREATMENT II-37
Gene Therapy for Cancer Treatment II-37
Gene Transfer and Gene Therapeutic Concepts in Cancer II-37
Competitive Landscape in Cancer Gene Therapy II-38
Gene Therapy Mechanism in Cancer II-38
Advantages Over Chemotherapy II-39
Developments in Cancer Gene Therapy II-39
P53 Gene Therapy - A Novel Approach in Cancer Treatment II-39
Gendicine - From Concept to Reality II-40
Vaccines II-40
Gene Therapy for Cardiovascular Disease II-40
Cardiovascular Gene Therapy Products under Trial II-41
Gene Therapy for Cystic Fibrosis Disease II-41
Gene Therapy for Haemophilia B II-42
Gene Therapy for AIDS/HIV II-42
Gene Therapy for Parkinson's Disease II-42
The Disease II-42
Therapy II-43
Development Pipeline of Gene Therapies in Parkinson's Disease II-44

9. REGULATORY ENVIRONMENT II-45
Gene therapy and Regulatory Environment II-45
Gene Patents - An Overview II-45

10. RESEARCH AND DEVELOPMENT II-46
Amsterdam Molecular Therapeutics to Develop Gene Therapy for Parkinsons Disease II-46
Researchers Develop Synthetic Gene Vectors to Reduce Body Immune Responses II-46
Illumina Brings Digital Gene Expression Applications II-47
MolMed Develops Gene Therapy Based Treatment for Skin Cancer II-47
Santaris Pharma Develops New Therapy to Lower Cholesterol Level II-47
Researchers Develop Gene Therapy for Severe Burns II-47
AMT Develops (AAV) Vector-Based Gene Therapy II-48
Ark Comes Up with New Gene Therapy Delivery Technology II-48

11. RECENT INDUSTRY ACTIVITY II-49
Sanofi-Aventis Snaps Up Genzyme Corp. II-49
Ceregene Initiates Enrolment for Phase IIb Study for CERE-120 in Parkinson's Disease II-49
Oxford BioMedica Releases Phase III Trial Results of TroVax® in Renal Cancer II-49
AnGes To Carry Out Additional Trial for Collategene™ II-50
Vical Receives Positive Review for Allovectin-7® Phase III Trial II-50
Cardium and bioRASI Ink Master Services Agreement for Generx II-50
Ceregene Commences New Phase I/II Trial for CERE-120 in Parkinsons Disease II-50
GeneVec Discontinues TNErFerade Trial in Pancreatic Cancer II-51
Transgene Grants Novartis an Option to Acquired License to TG4010 II-51
Helmholtz and SIRION Team Up to Develop Gene Therapy for Lymphoid Tumors II-52
Targeted Genetics to Merge with Biocontrol II-52
BioSante Merges with Cell Genesys II-52
Targeted Genetics Sells Off Gene Therapy IP to Genzyme II-52
Ark Therapeutics Obtains Clearance for Cerepro for Named Patient Use II-53
StemCells Acquires Stem Cell Sciences II-53
FDA Clears Ark Therapeutics to Commence Phase III Clinical Trial of Trinam® II-53

12. STRATEGIC CORPORATE DEVELOPMENTS - A HISTORIC PERSPECTIVE BUILDER II-54
Introgen Therapeutics Files for Bankruptcy II-54
Cell Genesys Terminates ITAL-2 Trial of GVAX Vaccine in Advanced Prostate Cancer II-54
Roche Takes Over Mirus Bio Corp. II-54
FDA Declines Accepting Approval Application for Advexin II-55
Transgenes TG4010 Therapeutic Vaccine Meets Primary Endpoint in NSCLC II-55
Ark Therapeutics Obtains SPA for Phase III Study of Trinam®
from FDA II-55
International Consolidated Acquires China Gene II-55
Ark Therapeutics Acquires Lymphatix II-56
Oxford BioMedica Obtains Rights for RNAi Technology II-56
Gene Bridges Inks Licensing Agreement with Genencor II-56
AMT Enters into R&D Agreement with NIH II-57
VGX Inks Supply Agreement with a U.K. Consortium II-57
Cardium Therapeutics Receives Fast Track Designation for Generx™ II-57
Oxford Biomedica's ProSavin Enters Phase I/II Trial II-57
Lentigen Acquires Gene Delivery Technology from Cell Genesys II-58
VIRxSYS Acquires SMaRT™ RNA Technology II-58
Gene Logic Divests Genomics Assets II-58
Genzyme Inks Agreement with Ceregene II-58
Silence Therapeutics Extends Agreement with Quark II-59
Benda Inks HIV Vaccine Joint Venture with DNAVEC II-59
Research Dynamics Bags Contract for Multicenter Clinical Study II-59
Thermo Fischer Collaborates with Lentigen to Develop Gene-Silencing Technology II-59
Fovea Enters into Collaboration with GENZYME Corporation II-60
Oxford BioMedica Inks Licensing Agreement with Children's Hospital II-60
Sigma and Oxford Sign Joint License Agreement for LentiVector Technology II-60
Benda Attains Additional Stake in SiBiono II-60
Oxford BioMedica Acquires Oxxon II-61
Oxford BioMedica and Sanofi-Aventis Agrees to Co-Develop and Market TroVax II-61
Illumina Completes Acquisition of Solexa II-61
RheoGene Plans Merger with Intrexon II-61
Covalon Acquires Gene Therapy Technology from Perfusion II-62
Inovio Takes Over DNA Expression and Delivery Assets of Valentis II-62
Molgen Inks Agreement with ONCO II-62
Aida Acquires Controlling Stake in Qiaer II-62
Neurologix Inks Licensing Agreement with Diamyd Medical's Subsidiary II-63
Takara Inks Collaboration Agreement with Chinese Center for Disease Control II-63
JDRF Collaborates with Genzyme Corp and AGTC II-63
Galapagos Collaborates with Arthrogen II-64

13. FOCUS ON SELECT GLOBAL PLAYERS II-65
AnGes MG, Inc. (Japan) II-65
BioSante Pharmaceuticals (US) II-65
GenVec (US) II-66
Oxford BioMedica (UK) II-67
Shenzhen SiBiono GeneTech Co., Ltd (China) II-67
Transgene (France) II-67
Vical, Inc. (US) II-68

14. GLOBAL MARKET PERSPECTIVE II-69
Table 7: World Current & Future Market Analysis for Gene Therapy - Annual Sales Figures in US$ Million for Years 2009 through 2017 (includes corresponding Graph/Chart) II-69

III. COMPETITIVE LANDSCAPE

Total Companies Profiled: 98 (including Divisions/Subsidiaries - 104)

Region/Country Players

The United States 60
Canada 4
Japan 4
Europe 34
France 4
Germany 5
The United Kingdom 15
Italy 1
Spain 2
Rest of Europe 7
Asia-Pacific (Excluding Japan) 2

Ordering:
Order Online - http://www.researchandmarkets.com/reports/338434/

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Gene Therapy - Global Strategic Business Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web Address:</td>
<td><a href="http://www.researchandmarkets.com/reports/338434/">http://www.researchandmarkets.com/reports/338434/</a></td>
</tr>
<tr>
<td>Office Code:</td>
<td>SC</td>
</tr>
</tbody>
</table>

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Electronic (PDF) -</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single User:</td>
<td></td>
<td>USD 4500</td>
</tr>
<tr>
<td>1 - 15 Users:</td>
<td></td>
<td>USD 10800</td>
</tr>
<tr>
<td>1 - 10 Users:</td>
<td></td>
<td>USD 8550</td>
</tr>
<tr>
<td>1 - 5 Users:</td>
<td></td>
<td>USD 6300</td>
</tr>
</tbody>
</table>

* The price quoted above is only valid for 30 days. Please submit your order within that time frame to avail of this price as all prices are subject to change.

Contact Information
Please enter all the information below in BLOCK CAPITALS

<table>
<thead>
<tr>
<th>Title:</th>
<th>Mr ☐</th>
<th>Mrs ☐</th>
<th>Dr ☐</th>
<th>Miss ☐</th>
<th>Ms ☐</th>
<th>Prof ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email Address: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Job Title:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postal / Zip Code:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax Number:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card:
You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check:
Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by Wire Transfer:
Bank details will be provided on the invoice which you will receive after you place your order with us.

If you have a Marketing Code please enter it below:

Marketing Code: ____________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World