GBI Research analysis shows that the endocrinology market is one of the competitive therapeutic segments with strong growth potential. Expensive biological therapies used in the treatment of endocrine disorders, the launch of novel drugs and increased usage of easy to use improved formulations of biologics are set to drive the endocrinology market.

Global Endocrinology Market is Set to Show Moderate Growth in Near Future

GBI Research valued the global endocrinology market at $XX billion in 2010, a CAGR of XX% from 2004 to 2010. The market is estimated to reach $XX billion in 2018, indicating a CAGR of XX% during the period 2010-2018. The acceptability of newer formulations of existing drugs, increased use of easy to use prefilled injection devices and expected launches of novel drug molecules in major therapy areas will contribute to the growth in the endocrinology market in the forecast period.

Acromegaly and growth hormone deficiency are the two major revenue generating therapy areas in the endocrinology market. The patent expiries of recombinant human growth hormone drugs such as Pfizer’s Genotropin, Eli Lilly’s Humatrope and F. Hoffmann La Roche’s Nutropin have already paved way for the entry of biogenerics in the growth hormone deficiency market. Furthermore, patent expiries of Novartis’s acromegaly drug Sandostatin LAR (2014 in the US) and Novo Nordisk’s Norditropin (2015) in the forecast period will accentuate the biogeneric erosion in forecast period in the endocrinology market.
1 Table of Contents

1 Table of Contents ................................................................. 4
1.1 List of Tables ...................................................................... 6
1.2 List of Figures ................................................................... 8
2 Endocrinology Market to 2018 - Introduction ..................... 10
2.1 GBI Research Report Guidance ........................................ 11
3 Endocrinology Market to 2018 - Market Overview ............... 12
3.1 Introduction .................................................................... 12
3.2 Revenue Forecasts for the Global Endocrinology Market .... 13
  3.2.1 Revenue .................................................................. 13
  3.2.2 Annual Cost of Therapy ............................................ 14
  3.2.3 Treatment Usage Patterns ........................................... 15
3.3 Global Endocrinology Market Drivers .............................. 17
  3.3.1 Rapid Uptake of New Formulation Products and Improved Injection Devices .... 17
  3.3.2 Maintenance of Market Exclusivity and Revenues of Blockbuster Drugs by Extending Patent Life through Novel Drug Delivery Technologies .......... 17
3.4 Global Endocrinology Market Restraints ......................... 18
  3.4.1 Patent Expiries of Major Blockbuster Drugs Including Sandostatin LAR and Norditropin ........................................ 18
  3.4.2 Low Treatment Adherence in Growth Hormone Deficiency and Acromegaly Patients ........................................ 18
3.5 Generics Share in the Global Endocrinology Market ......... 19
4 Endocrinology Market to 2018 - Geographical Landscape . 20
4.1 Revenue Analysis by Country ........................................... 20
  4.2 The US ....................................................................... 22
    4.2.1 Revenue ............................................................... 22
    4.2.2 Annual Cost of Therapy .......................................... 23
    4.2.3 Treatment Usage Patterns ........................................ 24
  4.3 Top Five Countries in Europe .......................................... 26
    4.3.1 Revenue ............................................................... 26
    4.3.2 Revenue Analysis by Country ................................. 27
    4.3.3 Annual Cost of Therapy .......................................... 28
    4.3.4 Treatment Usage Patterns ........................................ 29
  4.4 Japan ........................................................................... 31
    4.4.1 Revenue ............................................................... 31
    4.4.2 Annual Cost of Therapy .......................................... 32
    4.4.3 Treatment Usage Patterns ........................................ 33
5 Endocrinology Market to 2018 - Therapeutic Landscape .... 35
5.1 Growth Hormone Deficiency ........................................... 35
  5.1.1 Introduction ............................................................. 35
  5.1.2 Treatment Flow Algorithm for Growth Hormone Deficiency .................. 36
  5.1.3 Revenue ............................................................... 37
  5.1.4 Revenue Analysis by Country .................................... 38
  5.1.5 Annual Cost of Therapy .......................................... 40
  5.1.6 Treatment Usage Patterns ........................................ 41
5.2 Acromegaly ................................................................. 43
  5.2.1 Introduction ............................................................. 43
  5.2.2 Treatment Flow Algorithm for Acromegaly .................. 44
  5.2.3 Revenue ............................................................... 45
  5.2.4 Revenue Analysis by Country .................................... 46
  5.2.5 Annual Cost of Therapy .......................................... 48
  5.2.6 Treatment Usage Patterns ........................................ 49
5.3 Male Hypogonadism ...................................................... 50
  5.3.1 Introduction ............................................................. 50
1.1 List of Tables

Table 1: Endocrinology Market, Global, Revenue, $bn, 2004-2010................................. 13
Table 2: Endocrinology Market, Global, Revenue Forecasts, $bn, 2010-2018................. 13
Table 3: Endocrinology Market, Global, Annual Cost of Therapy, $, 2004-2010............. 14
Table 4: Endocrinology Market, Global, Annual Cost of Therapy, $, 2010-2018............. 14
Table 5: Endocrinology Market, Global, Treatment Usage Patterns, Millions, 2004-2010.... 15
Table 6: Endocrinology Market, Global, Treatment Usage Patterns, Thousands, 2010-2018 ... 16
Table 7: Endocrinology Market, Global, Revenue by Country, $m, 2004-2010.................. 20
Table 8: Endocrinology Market, Global, Revenue Forecasts by Country, $m, 2010-2018.... 21
Table 9: Endocrinology Market, The US, Revenue, $m, 2004-2010.............................. 22
Table 10: Endocrinology Market, The US, Revenue Forecasts, $m, 2010-2018................ 22
Table 11: Endocrinology Market, The US, Annual Cost of Therapy, $, 2004-2010........... 23
Table 12: Endocrinology Market, The US, Annual Cost of Therapy, $, 2010-2018........... 23
Table 13: Endocrinology Market, The US, Treatment Usage Patterns, Millions, 2004-2010.. 24
Table 14: Endocrinology Market, The US, Treatment Usage Patterns, Millions, 2010-2018... 24
Table 15: Endocrinology Market, Top Five Countries of Europe, Revenue, $m, 2004-2010.... 26
Table 16: Endocrinology Market, Top Five Countries of Europe, Revenue Forecasts, $m, 2010-2018................................ .......................................................... 26
Table 17: Endocrinology Market, Top Five Countries of Europe, Revenue by Country, $m, 2004-2010 ................................ ................................................................. 27
Table 18: Endocrinology Market, Top Five Countries of Europe, Revenue Forecasts by Country, $m, 2010-2018................................ ................................................................. 27
Table 19: Endocrinology Market, Top Five Countries of Europe, Annual Cost of Therapy, $, 2004-2010................................ ................................................................. 28
Table 20: Endocrinology Market, Top Five Countries of Europe, Annual Cost of Therapy, $, 2010-2018................................ ................................................................. 29
Table 21: Endocrinology Market, Top Five Countries of Europe, Treatment Usage Patterns, Millions, 2004-2010 ................................ ......................................................... 30
Table 22: Endocrinology Market, Top Five Countries of Europe, Treatment Usage Patterns, Millions, 2010-2018................................ ......................................................... 30
Table 23: Endocrinology Market, Japan, Revenue, $m, 2004-2010................................. 31
Table 24: Endocrinology Market, Japan, Revenue Forecasts, $m, 2010-2018.................. 31
Table 25: Endocrinology Market, Japan, Annual Cost of Therapy, $, 2004-2010............... 32
Table 26: Endocrinology Market, Japan, Annual Cost of Therapy, $, 2010-2018............... 32
Table 27: Endocrinology Market, Japan, Treatment Usage Patterns, Millions, 2004-2010.... 33
Table 28: Endocrinology Market, Japan, Treatment Usage Patterns, Millions, 2010-2018... 34
Table 29: Growth Hormone Deficiency Therapeutics Market, Global, Revenue, $bn, 2004-2010 .37
Table 30: Growth Hormone Deficiency Therapeutics Market, Global, Revenue Forecasts ($bn), 2010-2018................................ ................................................................. 37
Table 31: Growth Hormone Deficiency Therapeutics Market, Global, Revenue by Country, $m, 2004-2010................................ ................................................................. 39
Table 32: Growth Hormone Deficiency Therapeutics Market, Global, Revenue by Country, $m, 2010-2018................................ ................................................................. 39
Table 33: Growth Hormone Deficiency Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2010................................ ................................................................. 40
Table 34: Growth Hormone Deficiency Therapeutics Market, Global, Annual Cost of Therapy, $, 2010-2018................................ ................................................................. 40
Table 35: Endocrinology Market, Growth Hormone Deficiency Therapeutics Market, Global, Treatment Usage Patterns, Thousands, 2004-2010......................................................... 41
Table 36: Growth Hormone Deficiency Therapeutics Market, Global, Treatment Usage Patterns, Thousands, 2010-2018................................ ......................................................... 42
Table 37: Acromegaly Therapeutics Market, Global, Revenue, $m, 2004-2010.................. 45
Table 38: Acromegaly Therapeutics Market, Global, Revenue Forecasts, $m, 2010-2018...... 45
Table 39: Acromegaly Therapeutics Market, Global, Revenue by Country, $m, 2004-2010..... 46
Table 40: Acromegaly Therapeutics Market, Global, Revenue Forecasts by Country, $m, 2010-2018 ................................ ................................................................. 47
Table 41: Acromegaly Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2010... 48
Table 42: Acromegaly Therapeutics Market, Global, Annual Cost of Therapy, $, 2010-2018... 48
Table 43: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, Thousand, 2004-2010................................ ................................................................. 49
Table 44: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, Thousand, 2010-2018................................ ................................................................. 49
Endocrinology Market to 2018 - Advanced Injection Devices for Growth Hormone and Somatostatin will Improve Ease of Use for Patients

Table 45: Male Hypogonadism Therapeutics Market, Global, Revenue, $m, 2004-2010

Table 46: Male Hypogonadism Therapeutics Market, Global, Revenue Forecasts, $m, 2010-2018

Table 47: Male Hypogonadism Therapeutics Market, Global, Revenue by Country, $m, 2004-2010

Table 48: Male Hypogonadism Therapeutics Market, Global, Revenue by Country, $m, 2010-2018

Table 49: Male Hypogonadism Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2010

Table 50: Male Hypogonadism Therapeutics Market, Global, Annual Cost of Therapy, $, 2010-2018

Table 51: Male Hypogonadism Therapeutics Market, Global, Treatment Usage Patterns, Millions, 2004-2010

Table 52: Male Hypogonadism Therapeutics Market, Global, Treatment Usage Patterns, Millions, 2010-2018

Table 53: Hypothyroidism Therapeutics Market, Global, Revenue, $m, 2004-2010

Table 54: Hypothyroidism Therapeutics Market, Global, Revenue Forecasts, $m, 2010-2018

Table 55: Hypothyroidism Therapeutics Market, Global, Revenue by Country, $m, 2004-2010

Table 56: Hypothyroidism Therapeutics Market, Global, Revenue by Country, $m, 2010-2018

Table 57: Hypothyroidism Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2010

Table 58: Hypothyroidism Therapeutics Market, Global, Annual Cost of Therapy, $, 2010-2018

Table 59: Hypothyroidism Therapeutics Market, Global, Treatment Usage Patterns, Millions, 2004-2010

Table 60: Hypothyroidism Therapeutics Market, Global, Treatment Usage Patterns, Millions, 2010-2018

Table 61: Endocrinology Market, Global, R&D Pipeline by Phase and by Indication, 2011

Table 62: Endocrinology Market, Global, Licensing Agreements for Drugs in Phase II and Phase III, 2005-2011

Table 63: Endocrinology Market, Global, Licensing Agreements for Approved Drugs, 2005-2011
1.2 List of Figures

Figure 1: Endocrinology Market, Global, Drivers and Restraints, 2011 .............................................. 12
Figure 2: Endocrinology Market, Global, Revenue Forecasts, $bn, 2004-2018 ........................................ 13
Figure 3: Endocrinology Market, Global, Annual Cost of Therapy, $, 2004-2018 ............................... 14
Figure 4: Endocrinology Market, Global, Treatment Usage Patterns, Millions, 2004-2018 ............. 15
Figure 5: Endocrinology Market, Global, Branded versus Generic Drugs (%), 2010 ............................. 19
Figure 6: Endocrinology Market, Revenue Forecasts by Country, $m, 2004-2018 .............................. 20
Figure 7: Endocrinology Market, The US, Revenue, $bn, 2004-2018 ............................................... 22
Figure 8: Endocrinology Market, The US, Annual Cost of Therapy, $, 2004-2018 ......................... 23
Figure 9: Endocrinology Market, The US, Treatment Usage Patterns, Millions, 2004-2018 ............ 24
Figure 10: Endocrinology Market, Top Five Countries of Europe, Revenue Forecasts, $m, 2004-2018 . 26
Figure 11: Endocrinology Market, Top Five Countries of Europe, Revenue Forecasts by Country, $m, 2004-2018 ................................................................. 27
Figure 12: Endocrinology Market, Top Five Countries of Europe, Annual Cost of Therapy, $, 2004-2018 ......................................................................................... 28
Figure 13: Endocrinology Market, Top Five Countries of Europe, Treatment Usage Patterns, Millions, 2004-2018 ................................................................................. 29
Figure 14: Endocrinology Market, Japan, Revenue Forecasts, $m, 2004-2018 ............................... 31
Figure 15: Endocrinology Market, Japan, Annual Cost of Therapy, $, 2004-2018 ........................... 32
Figure 16: Endocrinology Market, Japan, Treatment Usage Patterns, Millions, 2004-2018 ........... 33
Figure 17: Growth Hormone Deficiency Therapeutics Market, Global, Treatment Flow Algorithm, 2011 ........................................................................................................ 36
Figure 18: Growth Hormone Deficiency Therapeutics Market, Global, Revenue Forecasts, $bn, 2004-2018 ........................................................................................................ 37
Figure 19: Growth Hormone Deficiency Therapeutics Market, Global, Revenue by Country, $m, 2004-2018 ........................................................................................................ 38
Figure 20: Growth Hormone Deficiency Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2018 ........................................................................................................ 40
Figure 21: Growth Hormone Deficiency Therapeutics Market, Global, Treatment Usage Patterns, Thousands, 2004-2018 ................................................................. 41
Figure 22: Acromegaly Therapeutics Market, Global, Treatment Flow Algorithm, 2011 ................. 44
Figure 23: Acromegaly Therapeutics Market, Global, Revenue Forecasts, $m, 2004-2018 ............... 45
Figure 24: Acromegaly Therapeutics Market, Global, Revenue by Country, $m, 2004-2018 ............. 46
Figure 25: Acromegaly Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2018 ........ 48
Figure 26: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, 2004-2018 ...... 49
Figure 27: Male Hypogonadism Therapeutics Market, Global, Treatment Flow Algorithm, 2011 .... 51
Figure 28: Male Hypogonadism Therapeutics Market, Global, Revenue Forecasts, $m, 2004-2018 . 52
Figure 29: Male Hypogonadism Therapeutics Market, Global, Revenue by Country, $m, 2004-2018 ........................................................................................................ 53
Figure 30: Male Hypogonadism Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2018 ........................................................................................................ 55
Figure 31: Male Hypogonadism Therapeutics Market, Global, Treatment Usage Patterns, Thousands, 2004-2018 ........................................................................................ 56
Figure 32: Hypothyroidism Therapeutics Market, Global, Treatment Flow Algorithm, 2011 ....... 59
Figure 33: Hypothyroidism Therapeutics Market, Global, Revenue Forecasts, $m, 2004-2018 ........ 60
Figure 34: Hypothyroidism Therapeutics Market, Global, Revenue by Country, $m, 2004-2018 ...... 62
Figure 35: Hypothyroidism Therapeutics Market, Global, Annual Cost of Therapy, $, 2004-2018 ..... 64
Figure 36: Hypothyroidism Therapeutics Market, Global, Treatment Usage Patterns, Millions, 2004-2018 ................................................................................................. 65
Figure 37: Endocrinology Market, Global, Market Share by Company, %, 2010 .............................. 67
Figure 38: Endocrinology Market, Global, SWOT - Pfizer, 2011 ......................................................... 69
Figure 39: Endocrinology Market, Global, SWOT - Novartis, 2011 ..................................................... 70
Figure 40: Endocrinology Market, Global, SWOT - Abbott, 2011 ...................................................... 71
Figure 41: Endocrinology Market, Global, SWOT - Novo Nordisk, 2011 ............................................ 72
Figure 42: Endocrinology Market, Global, SWOT - Eli Lilly, 2011 ..................................................... 73
Figure 43: Endocrinology Market, Global, R&D Pipeline by Indication, %, 2011 ............................... 74
Figure 44: Endocrinology Market, Global, R&D Pipeline by Phase, %, 2011 ..................................... 75
Figure 45: Endocrinology Market, Global, M&A Deals by Type, %, 2005-2011 .............................. 80
Figure 46: Endocrinology Market, Global, Major Licensing Agreements By Indication (%), 2005-2011 . 81
Endocrinology Market to 2018 - Advanced Injection Devices for Growth Hormone and Somatostatin will Improve Ease of Use for Patients

Figure 47: Endocrinology Market, Global, Major Licensing Agreements By Phase (%), 2005-201182
Figure 48: Endocrinology Market, Global, Major Licensing Agreements By Geography, %, 2005-2011 ................................ ................................ ................................ ......................... 83
Figure 49: GBI Research Market Forecasting Model ................................ ................................ ...91
2 Endocrinology Market to 2018 - Introduction

The global endocrinology market is expected to show moderate growth due to patent expiries of top selling drugs in the coming years. The endocrinology market includes therapeutics used for the treatment of growth hormone deficiency, acromegaly, male hypogonadism and hypothyroidism. The high annual cost of treatment and low patient compliance for hormone replacement therapy are the major issues observed in the market. Pharmaceutical companies have launched novel easy to use formulations and drug delivery devices which led to an increase in patients undergoing treatment. In 2010, the global endocrinology market was estimated to be worth $XX billion, representing a Compound Annual Growth Rate (CAGR) of XX% between 2004 and 2010. The growth hormone deficiency market occupies the largest share with $XX billion revenues in 2010, followed by the hypothyroidism market, which generated $XX billion in 2010. The high prevalence rate of hypothyroidism and consequently high number of people on hypothyroid drugs resulted in high revenues in the hypothyroidism market, despite high genericization. The acromegaly market is the third largest therapeutic area in the endocrinology market with revenues of $XXm in 2010, followed by the male hypogonadism market, worth $XXm.

The endocrinology market is expected to grow steadily and reach $XX billion by 2018, indicating a CAGR of XX% during the forecast period. The growth hormone deficiency market is highly lucrative, and is expected to increase to $XX billion in 2018. The acromegaly market will witness the launch of novel drugs and formulations and is expected to reach $XX billion by 2018. The hypothyroidism market will witness low growth in the forecast period as there are no promising drug launches and the market is mature with generic levothyroxine. The male hypogonadism market will witness high growth due to the launch of late stage molecules and increased uptake of current products. The market is expected to generate revenue of $XX billion in 2018.

The global endocrinology market is competitive, with the top five market players accounting for XX% of the total market in 2010. Pfizer, with its key products Genotropin, Somavert and Levoxyl, leads the global endocrinology market with XX% of the market share. Abbott, with its key products Synthroid and Androgel XX%, occupies second position with about XX% of the market share. Novartis occupies third position with about XX% of the market share with its blockbuster drugs Sandostatin (Octreotide) and Sandostatin Long Acting Release (LAR). Eli Lilly stands fifth in the endocrinology market with XX% of the market share. Eli Lilly’s Humatrope is one of the leading brands of human growth hormone. Eli Lilly launched Axiron in 2011 for the treatment of male hypogonadism.

The endocrinology Mergers and Acquisitions (M&A) landscape demonstrated low levels of activity between 2005 and mid-2011, with less number of major deals signed each year. The major focus for M&A deals during this period was for novel drugs and newer formulations for growth hormone deficiency, acromegaly and male hypogonadism.

The endocrinology market is more attractive with wide opportunities for biogenerics manufacturing companies and companies that deliver novel drugs. The market will witness steady growth between 2010 and 2018. Biogenericization will become the greatest threat to the market. Increased uptake of the new formulations and rapid use of improved drug delivery systems for the hormone delivery along with launches of the most promising late stage molecules are the key drivers of the endocrinology market.
2.1 GBI Research Report Guidance

- The report starts with an executive summary describing the key points that are driving the global endocrinology market.


- Chapter four analyzes the markets across various regions for the endocrinology market. This section details the endocrinology market in the major geographical regions: the US, the top five countries in Europe, and Japan.

- Chapter five describes the therapeutic landscape of the endocrinology market. This section includes detailed market sizing and analysis of the trends in four endocrinology indications: growth hormone deficiency, acromegaly, male hypogonadism and hypothyroidism.

- Chapter six includes detailed analysis of the top companies operating in the endocrinology market. It also includes benchmarking and detailed profiles of the top five companies operating in the growth hormone deficiency, acromegaly, male hypogonadism and hypothyroidism markets on the basis of revenue.

- Chapter seven provides analysis for the therapeutics in the endocrinology market. The section also contains a detailed analysis of the most promising pipeline products.

- Chapter eight describes the major M&A deals that took place in the global endocrinology market during 2005 and late 2011. The section is supplemented with coverage of some of the major licensing deals between 2005 and late 2011. Licensing deals are segmented on the basis of therapeutic focus, Phase, geography, licensing type and value.
4.2.2 Annual Cost of Therapy

The annual cost of therapy for the treatment of endocrine disorders in the US was estimated at $XX in 2010, which grew from $XX in 2004 at a CAGR of XX%. The drug treatment costs for growth hormone deficiency, acromegaly and male hypogonadism are comparatively higher than the drug treatment costs for hypothyroidism. The hypothyroidism treatment cost per year in the US was estimated at $XX in 2010, whereas the treatment costs for growth hormone deficiency, acromegaly and male hypogonadism in the US were estimated to $XX, $XX and $XX. The average annual cost of therapy of all the four therapeutic areas of endocrinology was $XX in 2010.

The annual cost of therapy in the US for the treatment of endocrine disorders is expected to increase to $XX in 2018, indicating a CAGR of XX% from 2010 to 2018. The expected launch of new therapeutic molecules which are currently in late stages of clinical development will result in an increase in the annual cost of therapy.
5.2.6 Treatment Usage Patterns

The acromegaly treatment usage patterns are as follows:

Figure 26: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, 2004-2018

Table 43: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, Thousand, 2004-2010

<table>
<thead>
<tr>
<th>Year</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>CAGR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Seeking Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosed Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Table 44: Acromegaly Therapeutics Market, Global, Treatment Usage Patterns, Thousand, 2010-2018

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Seeking Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosed Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.3 R&D Licensing Agreements

8.3.1 Deals by Indication

A total of XX major licensing deals took place during 2005-2011 in the four therapeutic areas within the endocrinology market. The majority of licensing agreements were in the acromegaly market, with about XX% of the total licensing agreements signed for acromegaly drugs. This was followed by male hypogonadism with XX%, hypothyroidism with XX% and growth hormone deficiency with XX% of the total licensing agreements.
9  Endocrinology Market to 2018 - Appendix

9.1  Market Definitions

Global endocrinology market: It is the sum of the revenues of the drugs catering to the following indications: growth hormone deficiency, acromegaly, male hypogonadism and hypothyroidism in the US, Germany, Spain, Italy, France, the UK and Japan.

Growth hormone deficiency market: It is the sum of the revenues of the drugs catering only to growth hormone deficiency in the US, Germany, Spain, Italy, France, the UK and Japan.

Acromegaly market: It is the sum of the revenues of the drugs only catering to the acromegaly market in the US, Germany, Spain, Italy, France, the UK and Japan.

Male hypogonadism therapeutics market: It is the sum of the revenues of the drugs only catering to male hypogonadism in the US, Germany, Spain, Italy, France, the UK and Japan.

Hypothyroidism market: It is the sum of the revenues of the drugs only catering to hypothyroidism in the US, Germany, Spain, Italy, France, the UK and Japan.

9.2  Abbreviations

BMD: Bone Mineral Density
BMI: Body Mass Index
CAGR: Compound Annual Growth Rate
DA: Dopamine Antagonists
DHT: Dihydrotestosterone
DXA: Dual energy X-ray Absorptiometry
FDA: Food Drug Administration
FSH: Follicle Stimulating hormone
GH: Growth Hormone
IBSA: Institut Biochimique S.A.
IGF: Insulin like Growth Factor
IGFB: Insulin like Growth Factor Binding Protein
ITT: Insulin Tolerance Test
LAR: Long Acting Release
LGLS: LG Life Sciences
LH: Luteinizing Hormone
MRI: Magnetic Resonance Imaging
NDA: New Drug Application
NDDS: Novel Drugs Delivery Systems
PEG: Poly Ethylene Glycol
rDNA: Recombinant Deoxyribose Nucleic Acid
R&D: Research and Development
SDI: Solid Dose Injector
SHOX: Short stature Homeobox
T4: Thyroxine/Levothyroxine
T3: Triiodothyronine
TPOab*: Thyroperoxidase Antibodies
9.3 **Research Methodology**

GBI Research’s dedicated research and analysis teams consist of experienced professionals with marketing, market research and consulting backgrounds in the medical devices industry as well as advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society ([www.mrs.org.uk](http://www.mrs.org.uk)) and the Society of Competitive Intelligence Professionals ([www.scip.org](http://www.scip.org)).

All GBI Research databases are continuously updated and revised.

9.3.1 **Coverage**

The objective of updating GBI Research coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues and media attention/innovation/market potential.

- An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization;
- The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage; and
- Companies which are making the news, or which are of particular interest due to their innovative approach are prioritized.

GBI Research aims to cover all major news events and deals in the medical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).

9.3.2 **Secondary Research**

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC Filings.
- Industry trade journals, scientific journals and other technical literature;
- Internal and external proprietary databases;
- Relevant patent and regulatory databases;
- National government documents, statistical databases and market reports;
- Procedure registries; and
- News articles, press releases and web-casts specific to the companies operating in the market.
9.3.3 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook
- It helps in validating and strengthening the secondary research findings; and
- It further develops the analysis team’s expertise and market understanding.

Primary research involves email interactions and telephone interviews as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers
- Hospital stores, laboratories, pharmacies, distributors and paramedics
- Outside experts: Investment bankers, valuation experts, research analysts specializing in specific medical equipment markets
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.

The report consists of the following four major sections:

- Therapeutic Landscape
- Geographic Landscape
- Pipeline Analysis
- Competitive Analysis

9.4 Therapeutic Landscape

- Revenues for each indication, geography-wise is arrived at by utilizing the GBI Research market forecasting model. The global revenue is the sum value of revenues for each indication of all seven regions.
- The annual cost of therapy for each indication is arrived at by considering the cost of the drugs, dosage of the drugs and the duration of the therapy.
- The generic share of the market for each indication is obtained by calculating the prescription share for generic drugs and the respective cost of treatment.
- The treatment usage pattern which includes quantitative data on the diseased population, treatment-seeking population, diagnosed population and treated population for an indication, is arrived at by referring to various sources as mentioned below.
- The marketed drugs section contains an overview of the drugs, their mechanism of action, efficacy and safety issues related to the drugs. The drugs profiled in this section are chosen based on estimated revenues and their mechanism of action.

GBI Research uses the epidemiology-based treatment flow model to forecast market size for therapeutic indications.
9.4.1.1 Epidemiology-Based Forecasting

The forecasting model used at GBI Research makes use of epidemiology data gathered from research publications and primary interviews with physicians to represent the treatment flow patterns for individual diseases and therapies. The market for any disease segment is directly proportional to the volume of units sold and the price per unit.

\[ \text{Sales} = \text{Volume of Units sold} \times \text{Price per Unit} \]

The volume of units sold is calculated on the average dosage regimen for that disease, duration of treatment and number of patients who are prescribed drug treatment (prescription population). Prescription population is calculated as the percentage of population diagnosed with a disease (diagnosis population). Diagnosis population is the population diagnosed with a disease expressed as a percentage of the population that is seeking treatment (treatment-seeking population). Prevalence of a disease (diseased population) is the percentage of the total population who suffer from a disease/condition.

Data on treatment seeking rate, diagnosis rate and prescription rate, if unavailable from research publications, are gathered from interviews with physicians and are used to estimate the patient volumes for the disease under consideration. Therapy uptake and compliance data are fitted in the forecasting model to account for patient switching and compliance behavior.

To account for differences in patient affordability of drugs across various geographies, macroeconomic data such as inflation and GDP; and healthcare indicators such as healthcare spending, insurance coverage and average income per individual are used.

Annual cost of treatment is calculated using product purchase frequency and the average price of the therapy. Product purchase frequency is calculated from the dosage data available for the therapies and drug prices are gathered from public sources.

The epidemiology-based forecasting model uses a bottom-up methodology and it makes use of estimations in the absence of data from research publications. Such estimations may result in a final market value which is different from the actual value. To correct this ‘gap’ the forecasting model uses ‘triangulation’ with the help of base year sales data (from company annual reports, internal and external databases) and sales estimations.

**Analogous Forecasting Methodology**

Analogous forecasting methodology is used to account for the introduction of new products, patent expiries of branded products and subsequent introduction of generics. Historic data for new product launches and generics penetration are used to arrive at robust forecasts. Increase or decrease of prevalence rates, treatment seeking rate, diagnosis rate and prescription rate are fitted into the forecasting model to estimate market growth rate.

The proprietary model enables GBI Research to account for the impact of individual drivers and restraints in the growth of the market. The year of impact and the extent of impact are quantified in the forecasting model to provide close-to-accurate data sets.

**Diseased Population**

The diseased population for any indication is the prevalence. The prevalence rates are usually obtained from various journals, online publications, sources such as the World Health Organization (WHO) or associations and foundation websites for that particular disease.

**Treatment Seeking Population**

The treatment seeking population is always calculated as a percentage of prevalence. The number denotes the actual number of patients who are going to hospitals to get diagnosis reports for any disease. The treatment seeking population is primarily driven by the onset of symptoms, patient awareness and the severity of the disease.

**Diagnosis Population**

Out of the patients who undergo diagnostic tests to confirm a disease, only a few people get diagnosed with the disease. This number as a percentage of the treatment seeking population is the diagnosis rate. The diagnosis population is primarily driven by the sensitivity of the diagnostic tests, state-of-the-art technology, patient access to these diagnostic tests and cost of the diagnostic tests.
Prescription Population

For any disease, multiple treatment options exist. For example, in cancer treatment various treatment options such as surgery, radiation therapy, and drug therapy are available. Prescription population is defined as the number of patients who are prescribed drug therapy. This is calculated as a percentage of the diagnosis population. The prescription population is primarily driven by the age at which the disease is diagnosed, the disease stage, patient health and cost of drug treatment.

9.4.2 Market Size by Geography

The treatment usage pattern and annual cost of treatment in each country has been factored in while deriving the individual country market size.

Forecasting Model for Therapeutic Areas

Figure 49: GBI Research Market Forecasting Model

The above figure represents a typical forecasting model followed in GBI Research. As discussed previously, the model is built on the treatment flow patterns. The model starts with the general population, then diseased population as a percentage of the general population and then follows the treatment seeking population as a percentage of the diseased population and diagnosed population as a percentage of the treatment seeking population. Finally, the total volume of units sold is calculated by multiplying the treated population by the average dosage per year per patient.
9.5 Geographical Landscape

GBI Research analyzes only seven major geographies: the US, the top five countries in Europe (the UK, Germany, France, Spain, and Italy) and Japan. The total market size for each country is provided which is the sum value of the market sizes of all the indications for that particular country.

9.6 Pipeline Analysis

This section provides a list of molecules at various stages in the pipeline for various indications. The list is sourced from internal database and validated for the accuracy of phase and mechanism of action at clinicaltrials.gov and company websites. The section also includes a list of promising molecules which is narrowed down based on the results of the clinical trials at various stages and the novelty of mechanism of action.

9.7 Competitive Landscape

Profiles of leading players are provided along with an overview of key products marketed by the companies for various indications. An analysis of strengths, weaknesses, opportunities and threats of each company with respect to various indications is also listed.

GBI Research aims to cover all major M&A, licensing deals and co-development deals related to the market. This section is sourced from the companies’ websites and internal databases.

9.7.1 Expert Panel Validation

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research expert panel comprises marketing managers, product specialists, international sales managers from medical device companies; academics from research universities and key opinion leaders from hospitals.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and are adjusted in accordance with their feedback.
9.9 Disclaimer

All Rights Reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior permission of the publisher, GBI Research.

The facts of this report are believed to be correct at the time of publication but cannot be guaranteed. Please note that the findings, conclusions and recommendations that GBI Research deliver will be based on information gathered in good faith from both primary and secondary sources, whose accuracy we are not always in a position to guarantee. As such GBI Research can accept no liability whatsoever for actions taken based on any information that may subsequently prove to be incorrect.

9.10 Sources

The following sources were referred to build this report:

- Annual Reports and Company Websites
- American Association of Clinical Endocrinologists
- British Medical Journal
- Centre for Disease Control and Prevention
- ClinicalTrials.gov
- European Journal of Endocrinology
- Fierce Pharma
- International Federation of Pharmaceutical Manufacturers & Associations
- Japan Thyroid Association
- Merck Manual
- New England Journal of Medicine
- Oxford Journal
- The Endocrine Society
- The Growth Hormone Research Society
- The Journal of Clinical Investigation
- The Lancet
- Thyroid Today
- US Food and Drug Administration
- World Health Organization