



Botanical and Plant-derived Drugs: *Global Markets*

December 2017

Kim Lawson



Report Code: B10022H

Table of Contents

Chapter 1: Introduction	1
Study Goals and Objectives	1
Reasons for Doing This Study	1
Scope of Report	2
Information Sources	3
Methodology	3
Geographic Breakdown	3
Analyst's Credentials	5
Related BCC Research Reports	5
Chapter 2: Summary and Highlights	7
Trends and Drivers for Botanical Drug Development	14
Chapter 3: Market and Technology Background	16
Brief History of Plant-Derived Medicines	17
Opportunity Lies Beyond What Is Known	19
Getting Started	23
Key Drivers	24
Key Challenges	25
U.S. Government Investment	26
Industry Investment	27
Nutrition Science Partners Ltd. (Nestlé Health): A Case Study	36
Botanical Drugs Defined	37
Understanding the Regulatory Process	39
Investigational New Drug Applications	40
Clinical Trials	41
New Drug Application	41
The First and Second U.S. Approved Botanical Drug	42
Veregen (Chinese Green Tea Catechins)	42
Mytesi, Formerly Fulyzaq (Crofelemer)	43
Botanical Candidates in the Pipeline	44
Samital	44
Danshen Dripping Pill (Cardiotonic Pill)	45
EISO (East Indian Sandalwood Oil)	47
Microbio and WH-1, MB-6 and OB318	48
A Growing Pipeline	51
Overall Pharma Landscape	52
Major Classes of Plant Drugs	55
Terpenes and Steroids	56
Alkaloids and Glycosides	57
Phenols	58
Proanthocyanidins	59
The Emergence of Cannabinoids	59
Intellectual Property	60
Production	62
A New Type of Production: Plant-Made Drugs	65
Moving Production Forward	66
Supply and Legal Issues	69

Drug Development and Manufacture	71
Chapter 4: Market Breakdown by Technology Type	75
Sales of Plant-derived Drugs by Region	75
Plant-derived Drugs by Therapeutic Area	76
Value of Plant-derived Drugs by Therapeutic Area	77
A Pipeline Perspective: Composition of Botanical Drugs in Clinical Development	79
Chapter 5: New Developments and Market Opportunities	82
Hormone Therapy and Metabolism Applications	82
Infectious Disease Applications	83
Pain and Central Nervous System Disease Applications	85
Cardiovascular and Metabolic Applications	88
Respiratory, Inflammation (Both Nonrelated and Related to Orthopedic) and Autoimmune Applications	89
Dermatology Applications	90
Gastrointestinal Applications	92
Oncology Applications	94
Botanical Drugs in Clinical Development	100
Promising Candidates for Botanical Drugs	104
Chapter 6: Company Profiles	107
Chapter 7: Appendix	167
About BCC Research	173
About BCC Research	174
BCC Membership	174
BCC Custom Research	174

List of Tables

Summary Table: Global Market for Botanical and Plant-derived Drugs*, by Type, Through 2022 (\$ Millions)	12
Table 1 Key Events Related to Botanical Medicine	18
Table 2 Notable Plant-derived Drugs	19
Table 3 Number of Botanicals Pre-INDS and INDs Submitted to the FDA, by Type, Through 2013 (Units)	22
Table 4 SWOT Analysis of Botanical Drug Development	31
Table 5 Key Investments in Botanical and Other Plant-derived Drugs.....	32
Table 6 Distinctions Among Products That Use Plants Medicinally	40
Table 7 Botanical Composition of Menerba (MF 101)*.....	50
Table 8 Top Pharma Companies, by Revenue, 2016 (\$ Billions)	54
Table 9 Major Upcoming U.S. Patent Expiries, 2014-2022.....	55
Table 10 Major Producers of Raw Materials for Plant-Based Medicine.....	69
Table 11 Key Companies with Natural Product Libraries	72
Table 12 Number of FDA-Approved Botanical Drugs, Through 2022.....	76
Table 13 Global FDA-Approved Botanical Drugs Market, by Therapeutic Area, Through 2022 (\$ Millions)	78
Table 14 Plant-derived Hormone Therapy and Metabolism Drugs in Late-Stage Development.....	83
Table 15 Plant-derived Infectious Disease Drugs in Late-Stage Development	84
Table 16 Brain Disorders That are Refractory to Small Molecule Drugs	86
Table 17 Plant-derived Pain and CNS Drugs in Late-Stage Development.....	87
Table 18 Plant-derived Cardiovascular and Metabolic Drugs in Late-Stage Development	88
Table 19 Plant-Derived Respiratory, Inflammation (Both Nonrelated and Related to Orthopedic) and Autoimmune Drugs in Late-Stage Development	89
Table 20 Plant-derived Dermatology/Wound Care Drugs in Late-Stage Development	91
Table 21 Plant-derived Gastrointestinal Drugs in Late-Stage Development	93
Table 22 Estimated U.S. New Cancer Cases, by Gender, 2016	94
Table 23 Plant-derived Oncology Drugs in Late-Stage Development	96
Table 24 Botanical Drugs in Clinical Development with Possible FDA-Approved Commercialization, Through 2022.....	100
Table 25 Promising Compounds Being Studied for Medicinal/Therapeutic Potential	104
Table 26 Plant-derived Drugs: Their Origin and Actions.....	167
Table 27 Useful Resources for the Botanical Industry.....	172

List of Figures

Summary Figure: Global Market for Botanical and Plant-derived Drugs*, by Type, 2016-2022 (\$ Millions)	13
Figure 1 Top Therapeutic Areas of FDA Drug Approvals, 2016 (Number, Total = 22).....	51
Figure 2 Composition of FDA-Approved Botanical Indications, by Therapeutic Area, 2017 and 2022 (No./%).....	77
Figure 3 Global FDA-Approved Botanical Drugs Market, by Therapeutic Area, 2017 and 2022 (\$ Millions)	78
Figure 4 Therapeutic Areas Targeted for Botanical Drugs in Phase 2 or Later, 2017* (%)	80



About BCC Research

About BCC Research

With our unparalleled 45-year history, BCC Research provides comprehensive analysis of global market sizing, forecasting and industry intelligence, covering markets where advances in science and technology are improving the quality, standard and sustainability of businesses, economies and lives.

BCC Membership

From market sizing and forecasts, to opportunity assessments and competitive analyses, our ever-expanding library gives you the data, insights and intelligence required to ensure your project is a success. Members benefit from ongoing, unlimited access to the category or collections of their choice, and most membership packages pay for themselves within two to three reports being accessed.

Did you buy this report? You may qualify to apply your purchase price towards a full membership. Call 866/285-7215 or email info@bccresearch.com to request a demo.

BCC Custom Research

Our experts provide custom research projects to those working to identify new markets, introduce new products, validate existing market share, analyze competition and assess the potential for products to impact existing markets. With impressive academic credentials and broad and deep knowledge of global industrial markets, our independent analysts and consultants develop the facts, figures, analysis and assessments to inform the decisions that will move your company ahead. Confidential inquiries to: custom@bccresearch.com or 781/205-2429.

DISCLAIMER

The information developed in this report is intended to be as reliable as possible at the time of publication and is of a professional nature. This information does not constitute managerial, legal or accounting advice, nor should it be considered as a corporate policy guide, laboratory manual or an endorsement of any product, as much of the information is speculative in nature. BCC Research and the author assume no responsibility for any loss or damage that might result from reliance on the reported information or from its use.

ISBN: 978-1-62296-593-9
December 2017