

BOTANICAL AND PLANT-DERIVED DRUGS: GLOBAL MARKETS



BIO022F
January 2013

Kim Lawson
Project Analyst

ISBN: 0-89336-246-8

bcc | Research
Market Forecasting

BCC Research
49 Walnut Park, Building 2
Wellesley, MA 02481
866-285-7215, 781-489-7301
www.bccresearch.com
Custom Reports: carol.laverty@bccresearch.com

TABLE OF CONTENTS

TOPIC	PAGE NO.
CHAPTER 1 INTRODUCTION	1
STUDY BACKGROUND	1
STUDY GOAL AND OBJECTIVES	1
INTENDED AUDIENCE	1
SCOPE OF REPORT	2
METHODOLOGY AND INFORMATION SOURCES	3
COMMERCIAL DRUGS	3
DEVELOPMENTAL DRUGS	3
<i>TABLE A FDA APPROVAL PROCESS FOR NEW DRUGS</i>	3
ANALYST CREDENTIALS	4
RELATED BCC PUBLICATIONS	4
BCC ONLINE SERVICES	4
DISCLAIMER	5
CHAPTER 2 SUMMARY	7
<i>SUMMARY TABLE GLOBAL FORECAST FOR BOTANICAL* AND PLANT-DERIVED DRUGS, THROUGH 2017 (\$ BILLIONS)</i>	8
<i>SUMMARY FIGURE GLOBAL FORECAST FOR BOTANICAL* AND PLANT-DERIVED DRUGS, 2010-2017 (\$BILLIONS)</i>	8
CHAPTER 3 OVERVIEW	12
BRIEF HISTORY OF PLANT-DERIVED MEDICINES	12
<i>TABLE 1 KEY DATES IN BOTANICAL MEDICINE</i>	13
<i>TABLE 2 WELL KNOWN PLANT-DERIVED DRUGS</i>	14
OPPORTUNITY LIES BEYOND WHAT IS KNOWN	14
<i>FIGURE 1 TYPE OF NATURAL PRODUCT DRUGS SUBMITTED AS IND APPLICATIONS TO THE FDA, 2008 (% SHARES)</i>	14
GETTING STARTED	16
KEY DRIVERS	17
KEY CHALLENGES	18
U.S. GOVERNMENT INVESTMENT	19
INDUSTRY INVESTMENT	20
<i>TABLE 3 SWOT ANALYSIS OF BOTANICAL DRUG DEVELOPMENT</i>	24
<i>TABLE 4 KEY INVESTMENTS IN BOTANICAL AND OTHER PLANT-DERIVED DRUGS</i>	25
BOTANICAL DRUGS DEFINED	27
UNDERSTANDING THE REGULATORY PROCESS	29
<i>TABLE 5 DISTINCTIONS AMONG PRODUCTS THAT USE PLANTS MEDICINALLY</i>	30
INVESTIGATIONAL NEW DRUG APPLICATIONS	30
CLINICAL TRIALS	30
NEW DRUG APPLICATION	31
THE FIRST APPROVED BOTANICAL	31
ADVICE FROM FDA BASED ON VEREGEN APPROVAL	33
BOTANICAL CANDIDATES IN THE PIPELINE	33
CROFELEMER	33
FEMARELLE AND MENERBA	35
SHINBARO CAPSULE	36

TOPIC	PAGE NO.
DANSHEN DRIPPING PILL (CARDIOTONIC PILL)	37
EISO (EAST INDIAN SANDALWOOD OIL)	37
FAHF-2	39
<i>TABLE 6 BOTANICAL COMPOSITION OF MENERBA (MF 101)</i>	40
A GROWING PIPELINE	40
<i>FIGURE 2 THERAPEUTIC AREAS OF FDA DRUG APPROVALS, 2011 (NO. OF DRUG APPROVALS)</i>	41
<i>FIGURE 3 SNAPSHOT OF U.S. FDA BOTANICAL PIPELINE, 2011</i>	42
OVERALL PHARMA LANDSCAPE	42
<i>TABLE 7 TOP PHARMA COMPANIES BY SALES, 2011 (\$BILLIONS)</i>	44
<i>TABLE 8 MAJOR UPCOMING U.S. PATENT EXPIRIES, 2012-2016</i>	44
<i>FIGURE 4 PHARMA DRUG SALES BY REGION, 2011 AND 2016 (% OF MARKET SHARE)</i>	45
MAJOR CLASSES OF PLANT DRUGS	45
Terpenes and Steroids	46
Terpenes	46
Steroids	46
Alkaloids and Glycosides	47
Alkaloids	47
Ergot Alkaloids	47
Morphine Alkaloids	48
Vinca Alkaloids	48
Glycosides	48
Cardiac Glycosides	48
Anthraglycosides	48
Phenols	48
E. Cava Algae	49
Flavonoids	49
Resveratrol	49
Coumarin	49
Catechins	49
Proanthocyanidins	49
INTELLECTUAL PROPERTY	50
PRODUCTION	51
A NEW TYPE OF PRODUCTION: PLANT-MADE DRUGS	53
MOVING PRODUCTION FORWARD	53
ARTEMISININ: A CASE STUDY	55
SUPPLY AND LEGAL ISSUES	55
<i>TABLE 9 MAJOR PRODUCERS OF RAW MATERIALS FOR PLANT-BASED MEDICINALS</i>	56
DRUG DEVELOPMENT AND MANUFACTURE	57
<i>TABLE 10 KEY COMPANIES WITH NATURAL PRODUCT LIBRARIES</i>	58
CHAPTER 4 MARKET SEGMENTATION	61
GEOGRAPHIC SEGMENTATION	61
SALES OF PLANT-DERIVED DRUGS BY REGION	61
THERAPEUTIC AREA SEGMENTATION	61
NUMBER OF PLANT-DERIVED DRUGS BY THERAPEUTIC AREA	61
<i>TABLE 11 FDA APPROVED BOTANICAL DRUGS FORECAST, THROUGH 2017 (NO.)</i>	61

TOPIC	PAGE NO.
<i>FIGURE 5 COMPOSITION OF FDA APPROVED BOTANICAL INDICATIONS FORECAST BY THERAPEUTIC AREA, 2012 AND 2017 (% OF TOTAL BOTANICALS)</i>	62
Value of Plant-Derived Drugs by Therapeutic Area	63
<i>TABLE 12 RELATIVE VALUES OF FDA APPROVED BOTANICAL DRUGS FORECAST BY THERAPEUTIC AREA, THROUGH 2017 (\$BILLIONS)</i>	63
<i>FIGURE 6 RELATIVE VALUES OF FDA APPROVED BOTANICAL DRUGS FORECAST BY THERAPEUTIC AREA, 2012 AND 2017 (% OF MARKET SHARE BY DOLLAR VALUE)</i>	64
CHAPTER 5 THERAPEUTIC AREAS FOR PLANT-DERIVED AND BOTANICAL DRUGS	66
HORMONE THERAPY AND METABOLISM APPLICATIONS	66
<i>TABLE 13 PLANT-DERIVED HORMONE THERAPY AND METABOLISM DRUGS IN LATE STAGE DEVELOPMENT</i>	67
INFECTIOUS DISEASE APPLICATIONS	67
<i>TABLE 14 PLANT-DERIVED INFECTIOUS DISEASE DRUGS IN LATE STAGE DEVELOPMENT</i>	68
PAIN AND CENTRAL NERVOUS SYSTEM DISEASE APPLICATIONS	72
<i>TABLE 15 BRAIN DISORDERS THAT ARE REFRACTORY TO SMALL MOLECULE DRUGS</i>	73
<i>TABLE 16 PLANT-DERIVED PAIN AND CNS DRUGS IN LATE STAGE DEVELOPMENT</i>	74
CARDIOVASCULAR AND METABOLIC DISEASE	75
<i>TABLE 17 PLANT-DERIVED CARDIOVASCULAR AND METABOLIC DRUGS IN LATE STAGE DEVELOPMENT</i>	76
RESPIRATORY, INFLAMMATION (BOTH NON-RELATED AND RELATED TO ORTHOPEDIC) AND AUTOIMMUNE	77
<i>TABLE 18 PLANT-DERIVED RESPIRATORY, INFLAMMATION (BOTH NON-RELATED AND RELATED TO ORTHOPEDIC) AND AUTOIMMUNE DRUGS IN LATE STAGE DEVELOPMENT</i>	78
DERMATOLOGY APPLICATIONS	79
<i>TABLE 19 PLANT-DERIVED DERMATOLOGY/WOUND CARE DRUGS IN LATE STAGE DEVELOPMENT</i>	80
GASTROINTESTINAL APPLICATIONS	81
<i>TABLE 20 PLANT-DERIVED GASTROINTESTINAL DRUGS IN LATE STAGE* DEVELOPMENT</i>	81
ONCOLOGY APPLICATIONS	82
<i>TABLE 21 ESTIMATED U.S. CANCER CASES BY GENDER, 2012</i>	83
<i>TABLE 22 PLANT-DERIVED ONCOLOGY DRUGS IN LATE STAGE DEVELOPMENT</i>	85
<i>TABLE 23 BOTANICAL DRUGS IN LATE STAGE DEVELOPMENT WITH POSSIBLE FDA-APPROVED COMMERCIALIZATION, THROUGH 2017*</i>	89
CHAPTER 6 COMPANY PROFILES	94
ABBOTT LABORATORIES	94
SOLVAY PHARMACEUTICALS	94
ADVANCED LIFE SCIENCES	95
AMAREX CLINICAL RESEARCH	95
AMERICAN ORIENTAL BIOENGINEERING	95
ANALYTICON DISCOVERY GMBH	96
ARTECEF BV	97
AVESTHAGEN INC.	97
BAYER HEALTHCARE PHARMACEUTICALS	98
BEIJING PEKING UNIVERSITY WBL BIOTECH CO. LTD.	99
BIONORICA SE	99
BIONUMERIK PHARMACEUTICALS INC.	99
BIONOVO INC.	100

TOPIC	PAGE NO.
BOEHRINGER INGELHEIM	101
PHARMATON SA	102
BOTANICAL DRUG CORP.	102
BRISTOL MYERS SQUIBB	103
CARDAX PHARMACEUTICALS	103
CHI-MED	104
CHINA BOTANIC PHARMACEUTICAL	104
CHONG KUN DANG PHARMACEUTICAL CORP.	105
CUBIST PHARMACEUTICALS INC.	106
CURAPHARM INC.	106
EISAI INC.	107
EKOMED LLC	107
ELI LILLY	108
FYTOKEM PRODUCTS INC.	108
GALAPAGOS NV	109
GENSPERA INC.	110
GLAXOSMITHKLINE	110
GREEN CROSS CORP.	112
GW PHARMACEUTICALS PLC	112
HANMI PHARM CO. LTD.	113
HETEROGENEITY LLC	114
INDENA	114
INDUS BIOTECH	116
JOHNSON & JOHNSON	116
LANZHOU FOCI PHARMACEUTICALS CO. LTD.	117
LIFEPHARMS INC.	117
LEO PHARMA	118
LUPIN LTD.	118
LUPIN PHARMACEUTICALS INC.	119
ROTTAPHARM MADAUS	119
MADAUS GMBH	119
MEDICUS RESEARCH	120
MERLION PHARMACEUTICALS	120
MEDIGENE	121
MEDIGENE INC.	121
MERCK & CO. INC.	122
MICROBIO CO. LTD.	122
MYREXIS, INC	123
NAPO PHARMACEUTICALS INC.	123
NEUROGESX INC.	124
NOVARTIS INTERNATIONAL AG	124
PFIZER	125
PHARMANUTRIENTS BOTANICAL CORP.	127
PHYNOVA	127
<i>TABLE 24 PHYNOVA PIPELINE</i>	127
PHYTOCEUTICA INC.	128
PHYTOMYCO RESEARCH PVT. LTD.	129

TOPIC	PAGE NO.
PHYTOPHARM PLC	129
PHYTOPHARMACON INC.	130
PHYTRIX	130
PIRAMAL LIFE SCIENCES	131
PUNISYN PHARMACEUTICALS LTD. (RIMONEST LTD.)	131
PURGENESIS	132
RANBAXY LABORATORIES LTD.	132
SALIX PHARMACEUTICALS, INC	132
SANOFI	134
SCHWABE PHARMACEUTICALS	135
SE-CURE PHARMACEUTICALS LTD.	135
SEQUOIA SCIENCES INC.	136
SIRTRIS	136
SUNTEN PHYTOTECH CO. LTD.	137
<i>TABLE 25 SUNTECH PHYTOTECH PIPELINE</i>	137
TASLY PHARMACEUTICALS INC.	138
TCM BIOTECH INTERNATIONAL CORP.	138
VEDIC LIFESCIENCES PVT. LTD.	139
VIROXIS	140
VR LABORATORIES LLC	140
ZHEJIANG KANGLAITE GROUP CO LTD.	141
CHAPTER 7 APPENDIX	143
<i>TABLE 26 PLANT-DERIVED DRUGS: THEIR ORIGIN AND ACTIONS</i>	143
<i>TABLE 27 USEFUL RESOURCES FOR THE BOTANICAL DRUG INDUSTRY</i>	148

LIST OF TABLES

TABLE HEADING	PAGE NO.
TABLE A FDA APPROVAL PROCESS FOR NEW DRUGS	3
SUMMARY TABLE GLOBAL FORECAST FOR BOTANICAL* AND PLANT-DERIVED DRUGS, THROUGH 2017 (\$ BILLIONS)	8
TABLE 1 KEY DATES IN BOTANICAL MEDICINE	13
TABLE 2 WELL KNOWN PLANT-DERIVED DRUGS	14
TABLE 3 SWOT ANALYSIS OF BOTANICAL DRUG DEVELOPMENT	24
TABLE 4 KEY INVESTMENTS IN BOTANICAL AND OTHER PLANT-DERIVED DRUGS	25
TABLE 5 DISTINCTIONS AMONG PRODUCTS THAT USE PLANTS MEDICINALLY	30
TABLE 6 BOTANICAL COMPOSITION OF MENERBA (MF 101)	40
TABLE 7 TOP PHARMA COMPANIES BY SALES, 2011 (\$BILLIONS)	44
TABLE 8 MAJOR UPCOMING U.S. PATENT EXPIRIES, 2012-2016	44
TABLE 9 MAJOR PRODUCERS OF RAW MATERIALS FOR PLANT-BASED MEDICINALS	56
TABLE 10 KEY COMPANIES WITH NATURAL PRODUCT LIBRARIES	58
TABLE 11 FDA APPROVED BOTANICAL DRUGS FORECAST, THROUGH 2017 (NO.)	61
TABLE 12 RELATIVE VALUES OF FDA APPROVED BOTANICAL DRUGS FORECAST BY THERAPEUTIC AREA, THROUGH 2017 (\$BILLIONS)	63
TABLE 13 PLANT-DERIVED HORMONE THERAPY AND METABOLISM DRUGS IN LATE STAGE DEVELOPMENT	67
TABLE 14 PLANT-DERIVED INFECTIOUS DISEASE DRUGS IN LATE STAGE DEVELOPMENT	68
TABLE 15 BRAIN DISORDERS THAT ARE REFRACTORY TO SMALL MOLECULE DRUGS	73
TABLE 16 PLANT-DERIVED PAIN AND CNS DRUGS IN LATE STAGE DEVELOPMENT	74
TABLE 17 PLANT-DERIVED CARDIOVASCULAR AND METABOLIC DRUGS IN LATE STAGE DEVELOPMENT	76
TABLE 18 PLANT-DERIVED RESPIRATORY, INFLAMMATION (BOTH NON-RELATED AND RELATED TO ORTHOPEDIC) AND AUTOIMMUNE DRUGS IN LATE STAGE DEVELOPMENT	78
TABLE 19 PLANT-DERIVED DERMATOLOGY/WOUND CARE DRUGS IN LATE STAGE DEVELOPMENT	80
TABLE 20 PLANT-DERIVED GASTROINTESTINAL DRUGS IN LATE STAGE* DEVELOPMENT	81
TABLE 21 ESTIMATED U.S. CANCER CASES BY GENDER, 2012	83
TABLE 22 PLANT-DERIVED ONCOLOGY DRUGS IN LATE STAGE DEVELOPMENT	85
TABLE 23 BOTANICAL DRUGS IN LATE STAGE DEVELOPMENT WITH POSSIBLE FDA-APPROVED COMMERCIALIZATION, THROUGH 2017*	89
TABLE 24 PHYNOVA PIPELINE	127
TABLE 25 SUNTECH PHYTOTECH PIPELINE	137
TABLE 26 PLANT-DERIVED DRUGS: THEIR ORIGIN AND ACTIONS	143
TABLE 27 USEFUL RESOURCES FOR THE BOTANICAL DRUG INDUSTRY	148

LIST OF FIGURES

FIGURE TITLE	PAGE NO.
SUMMARY FIGURE GLOBAL FORECAST FOR BOTANICAL* AND PLANT-DERIVED DRUGS, 2010-2017 (\$BILLIONS)	8
FIGURE 1 TYPE OF NATURAL PRODUCT DRUGS SUBMITTED AS IND APPLICATIONS TO THE FDA, 2008 (% SHARES)	14
FIGURE 2 THERAPEUTIC AREAS OF FDA DRUG APPROVALS, 2011 (NO. OF DRUG APPROVALS)	41
FIGURE 3 SNAPSHOT OF U.S. FDA BOTANICAL PIPELINE, 2011	42
FIGURE 4 PHARMA DRUG SALES BY REGION, 2011 AND 2016 (% OF MARKET SHARE)	45
FIGURE 5 COMPOSITION OF FDA APPROVED BOTANICAL INDICATIONS FORECAST BY THERAPEUTIC AREA, 2012 AND 2017 (% OF TOTAL BOTANICALS)	62
FIGURE 6 RELATIVE VALUES OF FDA APPROVED BOTANICAL DRUGS FORECAST BY THERAPEUTIC AREA, 2012 AND 2017 (% OF MARKET SHARE BY DOLLAR VALUE)	64