

CHAPTER ONE: INTRODUCTION.....	1
STUDY GOALS AND OBJECTIVES.....	1
REASONS FOR DOING THE STUDY .....	1
SCOPE OF REPORT .....	1
MARKET ANALYSES AND FORECASTS.....	2
INTENDED AUDIENCE.....	2
INFORMATION SOURCES.....	2
ANALYST CREDENTIALS.....	2
BCC ONLINE SERVICES.....	3
DISCLAIMER .....	3
CHAPTER TWO: SUMMARY.....	4
HIV/AIDS .....	4
ECONOMIC REALITIES .....	4
PHARMACEUTICAL SUPPLIERS .....	5
<i>SUMMARY TABLE ARV MARKET ESTIMATES AND FORECASTS,</i> <i>THROUGH 2016 (\$ MILLIONS)</i> .....	5
<i>SUMMARY FIGURE ARV MARKET ESTIMATES AND FORECASTS,</i> <i>2010-2016 (\$ MILLIONS)</i> .....	6
CHAPTER THREE: OVERVIEW: BRIEFING ON HIV AND AIDS.....	7
ORIGINS OF HIV .....	7
THE VIRUS.....	8
SUBTYPES OF HIV-1 .....	9
THE STRUCTURE OF HIV .....	9
NINE GENES.....	9
VIRAL LIFE-CYCLE .....	10
REVERSE TRANSCRIPTION AND INTEGRATION.....	10
TRANSCRIPTION AND TRANSLATION .....	10
FROM HIV TO AIDS.....	11
<i>TABLE 1 RELATIONSHIP BETWEEN VIRAL LOAD AND AIDS RISK</i> .....	12
DIAGNOSIS .....	12
DIAGNOSIS (CONTINUED).....	13
TREATMENT.....	14
TREATMENT (CONTINUED) .....	15
DISEASE PROGRESSION.....	16
SYMPTOMS AND SIGNS .....	16
A NOTE ON TRANSMISSION .....	17
A NOTE ON TRANSMISSION (CONTINUED) .....	18
CHAPTER FOUR: UPDATE ON THE AIDS PANDEMIC.....	19
<i>TABLE 2 MILESTONES IN THE HISTORY OF HIV/AIDS</i> .....	19
<i>TABLE 2 (CONTINUED)</i> .....	20
REGIONAL OVERVIEW.....	20

SUB-SAHARAN AFRICA.....	21
ASIA.....	21
CARIBBEAN .....	22
EASTERN EUROPE AND CENTRAL ASIA.....	22
NORTH AFRICA AND THE MIDDLE EAST.....	22
CENTRAL AND SOUTH AMERICA .....	22
NORTH AMERICA, OCEANIA AND WESTERN AND CENTRAL EUROPE.....	23
<i>FIGURE 1 DISTRIBUTION OF HIV BY REGION, 2009.....</i>	<i>24</i>
CHAPTER FIVE: CURRENT TREATMENT AND PIPELINE .....	25
CURRENT ARV DRUGS.....	25
<i>TABLE 3 APPROVED ANTI-HIV DRUGS.....</i>	<i>26</i>
CHOOSING THE COMBINATION .....	27
FIRST- AND SECOND-LINE THERAPY.....	27
RECENTLY APPROVED DRUGS AND THE RESEARCH PIPELINE.....	28
ENTRY INHIBITORS.....	28
INTEGRASE INHIBITORS.....	29
MATURATION INHIBITORS.....	29
NNRTIS .....	29
NRTI .....	30
NRTI (Continued).....	31
AN INTRIGUING POSSIBILITY... ..	32
BUT A MYSTERY REMAINS .....	32
But a Mystery Remains (Continued) .....	33
CHAPTER SIX: GLOBAL AND NATIONAL MARKETS.....	34
EVOLUTION OF THE MARKET .....	34
THE GLOBAL FUND .....	34
ENTER THE GENERICS.....	35
<i>FIGURE 2 EFFECT OF GENERIC COMPETITION ON ARV BRAND     PRICES .....</i>	<i>36</i>
WHAT PRICE PATENTS?.....	36
AVOIDING CONFRONTATION WITH PHARMA MAJORS.....	37
Tiered Pricing .....	38
Voluntary and Compulsory Licensing .....	39
MARKET ESTIMATES AND FORECASTS .....	39
THE HIV/AIDS MARKET BY REGIONS AND COUNTRIES .....	40
NORTH AMERICA .....	40
United States .....	40
United States (Continued) .....	41
Current Status .....	42
<i>FIGURE 3 DISTRIBUTION OF AIDS CASES ACROSS THE U.S.....</i>	<i>43</i>
<i>TABLE 4 CURRENT AND FORECAST ARV MARKET IN THE U.S.,     THROUGH 2016 (\$000).....</i>	<i>44</i>

LATIN AMERICA .....	44
Latin America (Continued) .....	45
Brazil.....	46
Current Status .....	46
<i>TABLE 5 CURRENT AND FORECAST ARV MARKET IN BRAZIL,</i> <i>THROUGH 2016 (\$000).....</i>	<i>47</i>
Argentina .....	47
<i>TABLE 6 CURRENT AND FORECAST ARV MARKET IN ARGENTINA,</i> <i>THROUGH 2016 (\$000).....</i>	<i>48</i>
Mexico .....	48
<i>TABLE 7 CURRENT AND FORECAST ARV MARKET IN MEXICO,</i> <i>THROUGH 2016 (\$000).....</i>	<i>49</i>
SOURCE: BCC RESEARCH.....	49
ASIA.....	49
Japan.....	50
<i>TABLE 8 CURRENT AND FORECAST ARV MARKET IN JAPAN,</i> <i>THROUGH 2016 (\$000).....</i>	<i>51</i>
Source: BCC Research.....	51
Republic of Korea.....	51
<i>TABLE 9 CURRENT AND FORECAST ARV MARKET IN REPUBLIC</i> <i>OF KOREA, THROUGH 2016 (\$000) .....</i>	<i>52</i>
India .....	52
Distribution.....	53
Andhra Pradesh .....	53
Goa .....	54
Karnataka.....	54
Maharashtra.....	54
Tamil Nadu.....	54
Manipur .....	54
ARV Availability .....	55
<i>TABLE 10 CURRENT AND FORECAST ARV MARKET IN INDIA,</i> <i>THROUGH 2016 (\$000).....</i>	<i>56</i>
China.....	56
<i>FIGURE 4 REGIONAL DISTRIBUTION OF HIV IN CHINA.....</i>	<i>57</i>
Treatment.....	58
Current Situation.....	58
<i>TABLE 11 CURRENT AND FORECAST ARV MARKET IN CHINA,</i> <i>THROUGH 2016 (\$000).....</i>	<i>59</i>
Thailand .....	59
<i>TABLE 12 CURRENT AND FORECAST ARV MARKET IN THAILAND,</i> <i>THROUGH 2016 (\$000).....</i>	<i>60</i>
EUROPE.....	61
<i>FIGURE 5 HIV RATES ACROSS EUROPE .....</i>	<i>61</i>
Germany.....	62

Challenges.....	63
<i>TABLE 13 CURRENT AND FORECAST ARV MARKET IN GERMANY, THROUGH 2016 (\$000)</i> .....	64
France .....	64
<i>TABLE 14 CURRENT AND FORECAST ARV MARKET IN FRANCE, THROUGH 2016 (\$000)</i> .....	65
Italy .....	65
<i>TABLE 15 CURRENT AND FORECAST ARV MARKET IN ITALY, THROUGH 2016 (\$000)</i> .....	66
United Kingdom .....	66
<i>TABLE 16 CURRENT AND FORECAST ARV MARKET IN U.K, THROUGH 2016 (\$000)</i> .....	67
Spain .....	67
<i>TABLE 17 CURRENT AND FORECAST ARV MARKET IN SPAIN, THROUGH 2016 (\$000)</i> .....	68
CENTRAL AND EASTERN EUROPE.....	69
Czech Republic.....	69
<i>TABLE 18 CURRENT AND FORECAST ARV MARKET IN CZECH REPUBLIC, THROUGH 2016 (\$000)</i> .....	70
Poland .....	70
<i>TABLE 19 CURRENT AND FORECAST ARV MARKET IN POLAND, THROUGH 2016 (\$000)</i> .....	71
Hungary .....	72
<i>TABLE 20 CURRENT AND FORECAST ARV MARKET IN HUNGARY, THROUGH 2016 (\$000)</i> .....	72
Russian Federation.....	72
Russian Federation (Continued) .....	73
<i>TABLE 21 CURRENT AND FORECAST ARV MARKET IN RUSSIA, THOUGH 2016 (\$000)</i> .....	74
AFRICA .....	74
South Africa .....	74
<i>TABLE 22 CURRENT AND FORECAST ARV MARKET IN SOUTH AFRICA, THROUGH 2016 (\$000)</i> .....	75
 CHAPTER SEVEN: MARKET ANALYSIS BY PRODUCTS AND COMPANIES.....	 76
PRODUCTS.....	76
<i>TABLE 23 PRODUCT PROFILE: RETROVIR</i> .....	76
<i>TABLE 24 PRODUCT PROFILE: VIRAMUNE</i> .....	77
<i>TABLE 25 PRODUCT PROFILE: ZERIT</i> .....	78
<i>TABLE 26 PRODUCT PROFILE: EPIVIR</i> .....	78
<i>TABLE 27 PRODUCT PROFILE: INVIRASE</i> .....	79
<i>TABLE 28 PRODUCT PROFILE: NORVIR</i> .....	80
<i>TABLE 29 PRODUCT PROFILE: CRIXIVAN</i> .....	81
<i>TABLE 30 PRODUCT PROFILE: VIRACEPT</i> .....	81

<i>TABLE 31 PRODUCT PROFILE: RESCRIPTOR</i> .....	82
<i>TABLE 32 PRODUCT PROFILE: SUSTIVA</i> .....	83
<i>TABLE 33 PRODUCT PROFILE: ZIAGEN</i> .....	84
<i>TABLE 34 PRODUCT PROFILE: VIDEX</i> .....	84
<i>TABLE 35 PRODUCT PROFILE: VIREAD</i> .....	85
<i>TABLE 36 PRODUCT PROFILE: FUZEON</i> .....	86
<i>TABLE 37 PRODUCT PROFILE: REYATAZ</i> .....	86
<i>TABLE 38 PRODUCT PROFILE: EMTRIVA</i> .....	87
<i>TABLE 39 PRODUCT PROFILE: LEXIVA</i> .....	88
<i>TABLE 40 PRODUCT PROFILE: APTIVUS</i> .....	88
<i>TABLE 41 PRODUCT PROFILE: PREZISTA</i> .....	89
<i>TABLE 42 PRODUCT PROFILE: SELZENTRY</i> .....	89
<i>TABLE 43 PRODUCT PROFILE: ISENTRESS</i> .....	90
<i>TABLE 44 PRODUCT PROFILE: INTELENCE</i> .....	91
COMBINATION ANTIVIRALS.....	91
<i>TABLE 45 PRODUCT PROFILES: ANTIVIRAL COMBINATIONS</i> .....	92
MARKET PENETRATION BY PRODUCT .....	92
<i>TABLE 46 SALES OF ANTIRETROVIRAL PRODUCTS, 2008-2010 (\$</i> <i>MILLIONS, % CHANGE)</i> .....	93
<i>TABLE 47 FIRST PATENT EXPIRIES ON ARV PRODUCTS, 2011-2016</i> .....	94
<i>TABLE 48 MARKET FOR ARV PRODUCTS, THROUGH 2016 (\$</i> <i>MILLIONS)</i> .....	95
MARKET SHARE BY COMPANY .....	95
<i>FIGURE 6 ARV COMPANY SHARES, 2010 (%)</i> .....	96
THE GENERIC SECTOR .....	96
The Generic Sector (Continued).....	97
 CHAPTER EIGHT: COMPANY PROFILES .....	 98
MAJOR PHARMACEUTICAL COMPANIES .....	98
ABBOTT LABORATORIES .....	98
BOEHRINGER INGELHEIM GMBH.....	99
BRISTOL-MYERS SQUIBB .....	100
GILEAD SCIENCES INC. ....	101
GLAXOSMITHKLINE PLC.....	102
MERCK & CO INC.....	103
PFIZER INC. ....	104
TIBOTEC BABE.....	105
VIIV HEALTHCARE .....	106
THE GENERICS SECTOR.....	107
AJANTA PHARMA (MAURITIUS) LIMITED.....	107
CIPLA LTD.....	108
THE GOVERNMENT PHARMACEUTICAL ORGANIZATION .....	109
HETERO DRUGS LTD .....	110
KOREA UNITED PHARMACEUTICALS INC .....	111
LABORATORIOS RICHMOND S.A.....	111

MEDOPHARM .....	112
RANBAXY LABORATORIES LIMITED.....	113
SRS PHARMACEUTICALS .....	114
STRIDES ARCOLAB .....	115
<i>TABLE 49 STRIDES ARV PRODUCTS.....</i>	<i>115</i>
<i>TABLE 49 (CONTINUED).....</i>	<i>116</i>
VAISHNAVI LIFESCIENCE PVT LTD.....	116
CHAPTER NINE: VACCINE DEVELOPMENTS .....	117
VAXGEN .....	117
CELL-MEDIATED IMMUNITY .....	118
MERCK CANDIDATE.....	118
THAILAND STUDY .....	119
REASONS FOR OPTIMISM?.....	120
GEOVAX CANDIDATE .....	120
BIO-NOR CANDIDATE.....	120
FIT BIOTECH APPROACH .....	121
TIME IS NOT ON OUR SIDE.....	122
TIME IS NOT ON OUR SIDE (CONTINUED) .....	123
CHAPTER TEN: HIV TESTING: BACKGROUND AND MARKET.....	124
ANTIBODY TESTS.....	124
ELISA .....	124
WESTERN BLOT.....	124
INTERPRETING ANTIBODY TESTS.....	125
OTHER TESTS .....	126
P24 ANTIGEN TEST .....	126
NUCLEIC ACID BASED TESTS (NAT).....	126
CD4 TEST.....	127
HOME TESTING .....	128
Home Access Express HIV-1 Test.....	128
OraQuick.....	129
Orasure .....	129
Uni-Gold.....	129
Clearview Complete HIV 1/2 and Clearview HIV 1/2 Stat- Pak .....	129
INSTI HIV-1/HIV-2* Rapid Antibody Test .....	129
Reveal HIV.....	129
<i>TABLE 50 COMPARISON OF HIV HOME SAMPLING AND HOME TESTING SERVICES .....</i>	<i>130</i>
THE TESTING MARKET .....	130
<i>TABLE 51 RAPID HIV TEST PRODUCTS.....</i>	<i>131</i>
<i>TABLE 51 (CONTINUED).....</i>	<i>132</i>
<i>TABLE 52 HIV TESTING MARKET FORECAST, THROUGH 2016 (\$ MILLIONS).....</i>	<i>133</i>

<i>TABLE 53 REGIONAL SHARES OF HIV TESTING MARKET, THROUGH 2016 (\$ MILLIONS)</i> .....	133
COMPANIES INVOLVED IN HIV TESTING .....	134
ABBOTT DIAGNOSTICS .....	134
BIOMÉRIEUX SA .....	135
Prevention/Diagnosis.....	135
Monitoring .....	136
BIO-RAD LABORATORIES INC. ....	136
CALYPTE BIOMEDICAL CORPORATION .....	137
CELERA GROUP .....	137
GEN-PROBE INC. ....	138
INNOGENETICS NV.....	139
INVERNESS MEDICAL PROFESSIONAL DIAGNOSTICS .....	140
MEDMIRA LABORATORIES INC.....	140
ORASURE TECHNOLOGIES INC. ....	141
ORTHO-CLINICAL DIAGNOSTICS INC.....	142
ROCHE DIAGNOSTICS .....	143
SIEMENS HEALTHCARE DIAGNOSTICS INC.....	144
APPENDIX ONE: GLOSSARY .....	145
APPENDIX ONE.....	145
APPENDIX ONE (CONTINUED) .....	146
APPENDIX ONE (CONTINUED) .....	147
APPENDIX TWO: THE HUMAN IMMUNE SYSTEM .....	148
APPENDIX TWO .....	148
LYMPHOCYTES.....	149
KILLER AND HELPER T CELLS .....	149
IMMUNODEFICIENCY .....	150
APPENDIX THREE: VIRUSES.....	151
APPENDIX THREE.....	151
DNA VIRUSES.....	152
RNA VIRUSES.....	152
REVERSE TRANSCRIBING VIRUSES .....	153
HOST DEFENSE MECHANISMS.....	153
PREVENTION AND TREATMENT .....	154