

THE U.S. MARKET FOR SPECT AND PET RADIOPHARMACEUTICALS

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
1.0	MARKET STATUS, TRENDS AND FORECASTS	
1.1	INTRODUCTION AND OVERVIEW	1
1.1.1	Relative Growth Prospects for SPECT and PET	3
1.1.2	Market Prospects SPECT in Cardiology	6
1.1.3	Market Growth for PET in Cardiology	7
1.1.4	New Products for SPECT in Neurology	9
1.1.5	PET Products for Diagnosing Alzheimer's Disease	10
1.1.6	New Oncology Products for SPECT	11
1.1.7	New PET Oncology Products	13
1.2	RADIOPHARMACEUTICAL SALES SUMMARY AND FORECASTS	14
1.2.1	Technetium Shortage and Market Decline in Cardiology SPECT	23
1.2.2	Prospects for Increasing the Supply of Mo-99 and Technetium	26
1.2.3	Development of New Reactor Capacity	28
1.2.4	Technetium Pricing and Market Prospects	31
1.2.5	Market for Technetium Generators	33
1.3	Nuclear Cardiology Products and Market Forecasts	36
1.3.1	SPECT Cardiology Products	36
1.3.2	New Cardiology SPECT Agents Zemeva and Androview	40

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
1.3.3 PET Cardiology Products	41
1.3.4 New PET Cardiology Agents for Perfusion and Neuronal Imaging	42
1.3.5 Maintaining Cardiology's Platform in Office-Based Imaging	44
1.4 Neurology Imaging Products and Market Forecasts	45
1.4.1 SPECT Neurology Products	45
1.4.2 PET Neurology Products	47
1.4.2.1 PET Products in Development for Alzheimer's	51
1.4.2.2 Two Potential Areas for Amyloid Imaging	52
1.4.2.3 Future Demands on Molecular imaging	52
1.5 Oncology Imaging Products and Market Forecasts	53
1.5.1 SPECT Oncology Products	53
1.5.2 PET Oncology Products	55
1.6 GENERAL NUCLEAR MEDICINE PRODUCTS	60
1.6.1 Technetium General Nuclear Products	62
1.6.2 Technetium Cold Kits	63
1.6.3 Other Diagnostic Isotope Products	66
1.6.4 Changes in Market Activity for Primary Nuclear Studies	66
1.6.4.1 Bone Scans	66
1.6.4.2 Lung Studies	67
1.6.4.3 Thyroid Studies	68
1.6.4.4 Kidney Studies	70

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	1.6.4.5 Liver Studies	70
	1.6.4.6 Gall Bladder Studies	71
	1.6.4.7 Brain Studies	72
	1.6.4.8 White Blood Cell Labeling and Infection Imaging	73
	1.6.4.9 Other Nuclear Medicine Procedures	74
1.7	COMMERCIAL RADIOPHARMACIES	74
	1.7.1 Sales Distribution of Radiopharmacy Companies	77
	1.7.2 Effect of the Cardinal-Lantheus Alignment	79
	1.7.3 Radiopharmacy Material Costs and Gross Margins	80
	1.7.4 Pricing Strategies and Regional Competition	80
2.0	RADIOPHARMACEUTICAL PRODUCTS AND TECHNOLOGY	82
	2.1 TYPES OF RADIOPHARMACEUTICAL PRODUCTS	82
	2.2 FUNCTIONAL CHARACTERISTICS	86
	2.2.1 Radiopharmaceutical Selection	88
	2.3 RADIOISOTOPE PRODUCTION METHODS	90
	2.3.1 Nuclear Reactors	92
	2.3.1.1 Interruptions in Supply of Mo-99	93
	2.3.1.2 Other Isotope Sources	95
	2.3.2 High Energy Uranium (HEU) vs. Low Energy Uranium (LEU)	97
	2.3.3 Options for AECL in Building a New Reactor	99
	2.3.4 Accelerators	100

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	2.3.5 Radionuclide Generators	101
2.4	RADIOPHARMACEUTICAL PREPARATION	102
	2.4.1 Commercial Radiopharmacies	103
	2.4.2 Cardiology Emphasis	103
3.0	CLINICAL APPLICATIONS	105
3.1	TYPES OF NUCLEAR MEDICINE PROCEDURES	105
3.2	NUCLEAR CARDIOLOGY	106
	3.2.1 Myocardial Perfusion	107
	3.2.1.1 Thallium	107
	3.2.1.2 Cardiolite, Myoview and Sestamibi	112
	3.2.2 Stress Testing	113
	3.2.3 Cardiac Function Studies	114
	3.2.4 First-Pass Heart Studies	115
3.3	OPTIONS IN RADIOPHARMACEUTICAL SELECTION	116
	3.3.1 Technetium-Labeled Myocardial Agents	116
	3.3.2 Clinical Protocols	117
	3.3.2.1 Cardiolite and Myoview Imaging	117
	3.3.2.2 Dual Isotope Studies	119
	3.3.2.3 Pharmacologic Stressors	120
3.4	OTHER ORGAN STUDIES	120
	3.4.1 Bone Imaging	120

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	3.4.2 Liver Studies	121
	3.3.3 Thyroid Studies	122
	3.4.4 Brain Studies	123
	3.4.5 Lung Perfusion	124
3.5	PET CLINICAL APPLICATIONS	125
	3.5.1 Neurological Applications	126
	3.5.2 Stroke and Cerebrovascular Disease	126
	3.5.3 Cancer Management and Tumor Evaluation	127
	3.5.4 Cardiac Applications	128
4.0	CURRENT DEVELOPMENTS AND EMERGING TECHNOLOGYS	130
4.1	NEW TECHNOLOGY OVERVIEW	130
4.2	NUCLEAR CARDIOLOGY AND MYOCARDIAL VIABILITY	134
	4.2.1 Myocardial Viability Imaging	135
	4.2.2 I-123 BMIPP Zemiva (Molecular Insight Pharmaceuticals)	136
	4.2.3 I-123 MIBG Androview (GE Healthcare)	138
	4.2.4 New PET Myocardial Perfusion Agents	138
	4.2.5 PET Cardiac Neuronal Imaging Agents	139
4.3	SPECT Neurology Agents	140
	4.3.1 SPECT Studies of Alzheimer's Disease	140
	4.3.2 SPECT Agents for Parkinson's Disease	141
	4.3.2.1 GE's DaTSCAN	141

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	4.3.2.2 Altropane (Alseras Pharmaceuticals)	142
4.4	PET Neurology Agents	144
4.4.1	Avid Radiopharmaceuticals AV-45 for Alzheimer's Disease	145
4.4.2	GE's PET Agent GE-067 for Detecting Amyloid Plaque	146
4.4.3	Bayer Healthcare-(Florbetaben)-for Detecting Amyloid Plaque	146
4.4.4	Siemens, UCLA Alzheimer's PET Agent	147
4.4.5	Avid Radiopharmaceuticals AV-133 for Parkinson's Disease	148
4.5	NEW ONCOLOGY PRODUCTS	149
4.5.1	ApoSense ML-10 for Imaging Apoptosis	149
4.5.2	New Apoptosis Technology licensed to GE	151
4.5.2	Troflex to Image Prostate Cancer	151
4.5.3	Integrin Product for Angiogenesis (GE Healthcare)	153
4.5.4	Phospholipid Ether Analogs (PLE) Platform (Cellectar, Inc)	154
5.0	INDUSTRY ANALYSIS	156
5.1	INDUSTRY OVERVIEW AND TRENDS	156
5.2	INDUSTRY ENVIRONMENT	157
5.2.1	Market Orientation	158
5.2.2	Market Concentration	159
5.2.3	Industry Pricing	160
5.3	INDUSTRY ANALYSIS BY PRODUCT CATEGORY	161
5.3.1	Market Overview	161

TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	5.3.2 Market Distribution	163
	5.3.3 Product Orientation of the Major Companies	163
	5.3.4 Changes in Market Share of the Major Companies	167
	5.3.5 Projections for New Products	168
	5.3.6 Market Segments	168
5.4	NUCLEAR CARDIOLOGY PRODUCTS	169
	5.4.1 Thallium	169
	5.4.2 Cardiolite	172
	5.4.3 Myoview	172
	5.4.4 Sestamibi	174
	5.4.5 Cardiogen (Rubidium Generator)	177
5.5	GENERAL NUCLEAR MEDICINE PRODUCTS	182
	5.5.1 Technetium Generators	182
	5.5.2 Technetium MDP Kits for Bone Imaging	185
	5.5.3 Technetium DTPA Kits for Kidney and Brain Scans	187
	5.5.4 Technetium Sulfur Colloid Kits	189
	5.5.5 Technetium Aggregated Albumin for Lung Scans	191
	5.5.6 Technetium Biliary Agents for Gall Bladder Studies	191
	5.5.7 Technescan MAG-3 for Kidney Function	193
	5.5.8 Iodine Products	197
	5.5.9 Brain Imaging Agents	201

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
5.5.10 Gallium for Tumors, Abscesses and Inflammation	204
5.5.11 Xenon for Lung Ventilation Studies	204
5.5.12 Indium Oxine for Blood Cell Labeling	207
5.6 SPECIALIZED ONCOLOGY PRODUCTS	209
5.6.1 ProstaScint for Imaging Prostate Cancer	209
5.6.2 Octreoscan for Imaging Neuroendocrine Tumors	211
5.6.3 Indium Chloride as a Radiolabel for Cancer Imaging	213
5.6.4 FDG for Metabolic Imaging	213
6.0 END-USER ANALYSIS	217
6.1 OVERVIEW OF THE USER ENVIRONMENT	217
6.1.1 Organization of Nuclear Medicine Departments	218
6.2 ALLOCATION OF HOSPITAL NUCLEAR MEDICINE EQUIPMENT	219
6.3 COMPARATIVE UTILIZATION PARAMETERS	220
6.4 DISTRIBUTION OF IMAGING PROCEDURES	223
6.4.1 Relative Diagnostic Activity	223
6.4.2 Relative Procedure Volume	225
6.4.3 Imaging Activity Index	227
6.4.4 Distribution of Nuclear Studies in Hospitals & Clinics	227
6.5 THE IN-HOSPITAL HOT LAB VS. COMMERCIAL PHARMACIES	229
6.5.1 Unit-Dose Packaging	231
6.5.2 Pricing Practices	232

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
6.5.3 Other Services	232
6.6 NONHOSPITAL END-USERS	233
6.7 ISSUES OF BOARD CERTIFICATION	234
7.0 COMPANY PROFILES	236
7.1 INTRODUCTION	236
7.2 AECL (Atomic Energy of Canada Limited)	238
7.3 Algeta ASA (Norway)	239
7.4 A[phaMed, Inc.	241
7.5 Alseras Pharmaceuticals Molecular Imaging	243
7.6 American Russian Cancer Alliance (ARCA)	244
7.7 AMIC (American Medical Isotope Corporation)	246
7.8 ANSTO (Australian Nuclear Science and Technology Organization)	248
7.9 Aposense, Ltd. (Israel)	249
7.10 Avid Radiopharmaceuticals	251
7.11 Bio-Nucleonics, Inc.	252
7.12 Bracco Diagnostics	253
7.13 Cardinal Health	256
7.14 Celectar, LLC	258
7.15 Covidien, Inc.	260
7.16 Cytogen Corporation	262
7.17 Dow Chemical Co.	264

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
7.18 Draximage, Inc.	265
7.19 IBA Molecular	268
7.20 Immunomedics, Inc.	269
7.21 GE Healthcare	273
7.22 Lantheus Medical Imaging Inc.	277
7.23 MDS Nordion	279
7.24 Molecular Insight Pharmaceuticals Inc.	282
7.25 NTP Radioisotopes (Pty) Ltd (NTP) South Africa	285
7.26 P.E.T.Net Solutions	287
7.27 Pharmalucence, Inc.	288
APPENDIX A – LIST OF MANUFACTURERS OF RADIOPHARMACEUTICALS	291

**THE U.S. MARKET FOR
DIAGNOSTIC RADIOPHARMACEUTICALS
LIST OF EXHIBITS**

<u>Exhibit</u>		<u>Page</u>
1-1	COMPARATIVE MARKET FOR SPECT AND PET RADIOPHARMACEUTICALS, TOTAL SALES AND PROCEDURE GROWTH FROM 2002-2017	2
1-2	HISTORIC AND FORECAST SALES GROWTH OF SPECT AND PET RADIOPHARMACEUTICALS BY PRODUCT GROUP FROM 2006-2017	4
1-3	2009 DIAGNOSTIC RADIOPHARMACEUTICAL SALES SUMMARY BY PROCEDURE CATEGORY AND PRODUCT TYPE	15
1-4	2017 DIAGNOSTIC RADIOPHARMACEUTICAL SALES SUMMARY BY PROCEDURE CATEGORY AND PRODUCT TYPE	19
1-5	HISTORIC AND FORECAST SPECT CARDIOLOGY MARKET ANALYSIS BY PRODUCT CATEGORY FROM 2007-2010	25
1-6	HISTORIC AND FORECAST CHANGES IN TECHNETIUM PRICING DUE TO INCREASED DEMAND AND SUPPLY SHORTAGES FROM 2002-2017	32
1-7	HISTORIC AND FORECAST MARKET FOR TECHNETIUM GENERATORS, AVERAGE PRICE PER GENERATOR AND PRICE PER CURIE FROM 2002-2017	35
1-8	HISTORIC AND FORECAST SALES OF SPECT CARDIOLOGY PRODUCTS BY PRODUCT CATEGORY AND APPLICATION FROM 2006-2017	39
1-9	HISTORIC AND FORECAST SALES OF PET CARDIOLOGY PRODUCTS BY PRODUCT CATEGORY FROM 2006-2017	43
1-10	HISTORIC AND FORECAST SALES OF SPECT NEUROLOGY PRODUCTS BY PRODUCT CATEGORY FROM 2006-2017	48
1-11	HISTORIC AND FORECAST SALES OF PET NEUROLOGY PRODUCTS BY PRODUCT CATEGORY FROM 2006-2017	50
1-12	HISTORIC AND FORECAST SALES OF SPECT ONCOLOGY PRODUCTS BY PRODUCT CATEGORY FROM 2006-2017	56

LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
1-13	HISTORIC AND FORECAST SALES OF PET ONCOLOGY PRODUCTS BY PRODUCT CATEGORY FROM 2002-2017	59
1-14	HISTORIC AND FORECAST SALES OF GENERAL NUCLEAR PRODUCTS BY PRODUCT CATEGORY AND APPLICATION FROM 2006-2017	61
1-15	ANALYSIS HISTORIC AND FORECAST SALES OF TECHNETIUM COLD KITS BY PRODUCT CATEGORY AND APPLICATION FROM 2006-2017	65
1-16	2009 SALES AND MARKET SHARES OF RADIOPHARMACY COMPANIES AND INDEPENDENT NUCLEAR PHARMACIES	75
1-17	ANALYSIS OF RADIOPHARMACY REVENUES, COSTS AND GROSS PROFIT IN 2009	76
2-1	DIAGNOSTIC AND THERAPEUTIC ISOTOPES	84
3-1	CLINICAL INDICATIONS FOR NUCLEAR IMAGING PROCEDURES	108
5-1	2009 DIAGNOSTIC RADIOPHARMACEUTICAL SALES SUMMARY, MANUFACTURERS' SALES DOLLAR VOLUME AND MARKET SHARE	162
5-2	2009 DISTRIBUTION OF RADIOPHARMACEUTICAL SALES IN THE U.S., MANUFACTURER'S SALES DOLLAR VOLUME BY PRODUCT CATEGORY	164
5-3	2009 SALES OF THALLIUM FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	171
5-4	2009 SALES OF CARDIOLITE FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	173
5-5	2009 SALES OF MYOVIEW FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	175
5-6	2009 SALES OF SESTAMIBI FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	176
5-7	2009 SALES OF CARDIOGEN RUBIDIUM-81 GENERATOR FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	179

LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
5-8	2009 SALES OF PYP-PYROPHOSPHATE KITS FOR HEART IMAGING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	181
5-9	2009 SALES OF TECHNETIUM GENERATORS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	183
5-10	2009 SALES OF MDP AND HDP KITS FOR BONE IMAGING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	186
5-11	2009 SALES OF TECHNETIUM DTPA KITS FOR AEROSOL LUNG VENTILATION, BRAIN AND KIDNEY SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	188
5-12	2009 SALES OF TECHNETIUM SULFUR COLLOID KITS FOR LIVER SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	190
5-13	2009 SALES OF MACRO-AGGREGATED ALBUMIN FOR LUNG PERFUSION SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	192
5-14	2009 SALES OF TECHNETIUM BILIARY AGENTS FOR GALL BLADDER STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	194
5-15	2009 SALES OF TECHNESCAN MAG 3 FOR KIDNEY FUNCTION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	196
5-16	2009 SALES OF IODINE 131 FOR THYROID IMAGING, THERAPY AND KIDNEY SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	198
5-17	2009 SALES OF IODINE 123 FOR THYROID SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	199
5-18	2009 SALES OF CERETEC FOR BRAIN PERFUSION STUDIES AND WHITE BLOOD CELL LABELING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	202
5-19	2009 SALES OF NEUROLITE FOR IMAGING BRAIN PERFUSION, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	203

LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
5-20	2009 SALES OF GALLIUM 67 FOR SCANS OF TUMORS, ABCESES AND INFLAMMATION, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	205
5-21	2009 SALES OF XENON FOR LUNG VENTILATION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	206
5-22	2009 SALES OF INDIUM OXINE FOR IMAGING INFLAMMATORY PROCESSES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	208
5-23	2009 SALES OF PROSTASCINT FOR IMAGING PROSTATE CANCER RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	210
5-24	2009 SALES OF OCTREOSCAN FOR IMAGING NEUROENDOCRINE TUMORS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	212
5-25	2009 SALES OF INDIUM CHLORIDE FOR COMPOUNDING WITH CANCER IMAGING AGENTS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	214
5-26	2009 SALES DISTRIBUTION OF FDG SUPPLIERS IN THE U.S., NUMBER OF END-USERS, ANNUAL DOSES SOLD AND SALES VOLUME	216
6-1	COMPARATIVE ALLOCATION OF DIAGNOSTIC FACILITIES BY HOSPITAL BED SIZE IN 2009	221
6-2	COMPARATIVE UTILIZATION PARAMETERS FOR DIFFERENT IMAGING MODALITIES IN 2009	222
6-3	DISTRIBUTION OF HOSPITAL DIAGNOSTIC IMAGING PROCEDURES IN THE U.S. BY HOSPITAL BED SIZE IN 2009	224
6-4	RELATIVE PROCEDURE VOLUME IN DIFFERENT IMAGING MODALITIES,PERCENTAGE RELATIONSHIP BY HOSPITAL BED SIZE IN 2009	226
6-5	RELATIVE ACTIVITY INDEX AMONG DIFFERENT IMAGING MODALITIES, PROCEDURES PER BED PER YEAR BY HOSPITAL BED SIZE IN 2009	228
6-6	DISTRIBUTION OF NUCLEAR MEDICINE PROCEDURES IN HOSPITAL AND IMAGING CLINICS IN 2009	230