

# THE U.S. MARKET FOR DIAGNOSTIC RADIOPHARMACEUTICALS

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
1.0	MARKET STATUS, TRENDS AND FORECASTS	1-1
1.1	INTRODUCTION AND OVERVIEW	1-1
1.1.1	New Cardiology Products In the Pipeline	1-2
1.1.2	Change in Focus of New Product Development	1-3
1.1.3	Expiration of the Cardiolite Patent and Generic Sestamibi	1-4
1.2	MARKET ENVIRONMENT	1-6
1.2.1	Assessing Myocardial Viability	1-7
1.2.2	Increased Use of Rubidium-PET	1-8
1.2.3	Research in PET Tracers	1-9
1.3	RADIOPHARMACEUTICAL MARKET OVERVIEW	1-11
1.3.1	Current Market Overview	1-13
1.3.2	Summary Forecasts for Diagnostic Radiopharmaceuticals	1-13
1.4	DIAGNOSTIC PRODUCT SALES AND MARKET FORECASTS	1-14
1.4.1	Nuclear Cardiology Procedures And Product Sales	1-14
1.4.2	Heart Perfusion Studies	1-26
1.4.3	Cardiology PET Studies with the Rubidium Generator	1-28
1.4.4	Blood Pool Studies	1-29
1.4.5	Pharmacologic Stress Studies	1-29

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	1.4.6 Myocardial Viability Imaging	1-32
1.5	GENERAL NUCLEAR MEDICINE PRODUCTS	1-32
	1.5.1 Technetium Products and Kits	1-34
	1.5.2 Other Diagnostic Isotope Products	1-41
	1.5.3 Changes in Market Activity for Primary Nuclear Studies	1-43
	1.5.3.1 Bone Scans	1-43
	1.5.3.2 Lung Studies	1-44
	1.5.3.3 Thyroid Studies	1-45
	1.5.3.4 Kidney Studies	1-46
	1.5.3.5 Liver Studies	1-47
	1.5.3.6 Gall Bladder Studies	1-48
	1.5.3.7 Brain Studies	1-49
	1.5.3.8 White Blood Cell Labeling and Infection Imaging	1-49
	1.5.3.9 Other Nuclear Medicine Procedures	1-50
	1.5.4 In Vivo Infection Imaging	1-50
1.6	TARGETED ONCOLOGY IMAGING AGENTS	1-51
	1.6.1 FDG Imaging for Oncology	1-53
	1.6.2 Oncology Imaging with Targeted Antibodies and Peptides	1-53
1.7	COMMERCIAL RADIOPHARMACIES	1-54
	1.7.1 Sales Distribution of Radiopharmacy Companies	1-56
	1.7.2 Effect of the Cardinal-BMS Alignment	1-59

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	1.7.3 Radiopharmacy Material Costs and Gross Margins	1-60
	1.7.4 Pricing Strategies and Regional Competition	1-60
2.0	RADIOPHARMACEUTICAL PRODUCTS AND TECHNOLOGY	2-1
2.1	TYPES OF RADIOPHARMACEUTICAL PRODUCTS	2-1
2.2	FUNCTIONAL CHARACTERISTICS	2-5
	2.2.1 Radiopharmaceutical Selection	2-7
2.3	RADIOISOTOPE PRODUCTION METHODS	2-9
	2.3.1 Nuclear Reactors	2-11
	2.3.2 High Energy Uranium (HEU) vs. Low Energy Uranium (LEU)	2-14
	2.3.3 Accelerators	2-16
	2.3.4 Radionuclide Generators	2-17
2.4	RADIOPHARMACEUTICAL PREPARATION	2-18
	2.4.1 Commercial Radiopharmacies	2-19
	2.4.2 New Radiopharmaceuticals	2-20
3.0	CLINICAL APPLICATIONS	3-1
3.1	TYPES OF NUCLEAR MEDICINE PROCEDURES	3-1
3.2	NUCLEAR CARDIOLOGY	3-2
	3.2.1 Myocardial Perfusion	3-3
	3.2.1.1 Thallium	3-3
	3.2.1.2 Cardiolite and Myoview	3-8
	3.2.2 Stress Testing	3-9

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	3.2.3 Cardiac Function Studies	3-10
	3.2.4 First-Pass Heart Studies	3-11
3.3	OPTIONS IN RADIOPHARMACEUTICAL SELECTION	3-12
	3.3.1 Technetium-Labeled Myocardial Agents	3-12
	3.3.2 Clinical Protocols	3-14
	3.3.2.1 Cardiolite and Myoview Imaging	3-14
	3.3.2.2 Dual Isotope Studies	3-15
	3.3.2.3 Pharmacologic Stressors	3-16
3.4	OTHER ORGAN STUDIES	3-16
	3.4.1 Bone Imaging	3-16
	3.4.2 Liver Studies	3-17
	3.3.3 Thyroid Studies	3-18
	3.4.4 Brain Studies	3-19
	3.4.5 Lung Perfusion	3-20
3.5	PET CLINICAL APPLICATIONS	3-21
	3.5.1 Neurological Applications	3-22
	3.5.2 Stroke and Cerebrovascular Disease	3-23
	3.5.3 Cancer Management and Tumor Evaluation	3-24
	3.5.4 Cardiac Applications	3-25
4.0	CURRENT DEVELOPMENTS AND EMERGING TECHNOLOGY	4-1
	4.1 NEW TECHNOLOGY OVERVIEW	4-1

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
4.2	NUCLEAR CARDIOLOGY AND MYOCARDIAL VIABILITY	4-4
4.2.1	Myocardial Viability Imaging	4-4
4.2.2	I-123 BMIPP Zemiva (Molecular Insight Pharmaceuticals)	4-5
4.2.3	I-123 MIBG Androview (GE Healthcare)	4-7
4.2.4	Development of New Pharmacologic Stress Agents	4-7
4.3	NEW ONCOLOGY AGENTS	4-9
4.3.1	$\alpha\beta 3$ Integrin Product for Angiogenesis (GE Healthcare)	4-10
4.3.2	Phospholipid Ether Analogs (PLE) Platform (Collectar LLC)	4-11
4.3.3	ApoSense™ for Imaging Apoptosis (NST Ltd)	4-12
4.4	IMAGING INFECTION AND INFLAMMATION	4-13
4.4.1	Infecton (Draximage)	4-14
4.4.2	NeuroSpec (Palatin Technologies)	4-14
4.4.3	Leukoscan (Immunomedics)	4-15
5.0	INDUSTRY ANALYSIS	5-1
5.1	INDUSTRY OVERVIEW AND TRENDS	5-1
5.2	INDUSTRY ENVIRONMENT	5-2
5.2.1	Market Orientation	5-3
5.2.2	Market Concentration	5-4
5.2.3	Industry Pricing	5-5
5.3	INDUSTRY ANALYSIS BY PRODUCT CATEGORY	5-5
5.3.1	Market Overview	5-7

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	5.3.2 Market Distribution	5-8
	5.3.3 Product Orientation of the Major Companies	5-8
	5.3.4 Changes in Market Share of the Major Companies	5-13
	5.3.5 Projections for New Products	5-13
	5.3.6 Market Segments	5-14
5.4	NUCLEAR CARDIOLOGY PRODUCTS	5-15
	5.4.1 Thallium	5-15
	5.4.2 Cardiolite	5-17
	5.4.3 Myoview	5-19
	5.4.4 Cardiogen	5-20
	5.4.5 Pharmacologic Stress Agents	5-22
	5.4.6 Technetium Pyrophosphate (PYP) for Cardiac Performance	5-24
5.5	GENERAL NUCLEAR MEDICINE PRODUCTS	5-27
	5.5.1 Technetium Generators	5-27
	5.5.2 Technetium MDP Kits for Bone Imaging	5-30
	5.5.3 Technetium DTPA Kits for Kidney and Brain Scans	5-30
	5.5.4 Technetium Sulfur Colloid Kits	5-33
	5.5.5 Technetium Aggregated Albumin for Lung Scans	5-35
	5.5.6 Technetium Biliary Agents for Gall Bladder Studies	5-37
	5.5.7 Technescan MAG-3 for Kidney Function	5-39
	5.5.8 Iodine Products	5-41

## TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
	5.5.9 Brain Imaging Agents	5-45
	5.5.10 Gallium for Tumors, Abscesses and Inflammation	5-46
	5.5.11 Xenon for Lung Ventilation Studies	5-50
	5.5.12 Indium Oxine for Blood Cell Labeling	5-50
5.6	SPECIALIZED ONCOLOGY PRODUCTS	5-52
	5.6.1 ProstaScint for Imaging Prostate Cancer	5-52
	5.6.2 Octreoscan for Imaging Neuroendocrine Tumors	5-54
	5.6.3 Indium Chloride as a Radiolabel for Cancer Imaging	5-57
	5.6.4 FDG for Metabolic Imaging	5-59
6.0	END-USER ANALYSIS	6-1
6.1	OVERVIEW OF THE USER ENVIRONMENT	6-1
	6.1.1 Organization of Nuclear Medicine Departments	6-2
6.2	ALLOCATION OF HOSPITAL NUCLEAR MEDICINE EQUIPMENT	6-3
6.3	COMPARATIVE UTILIZATION PARAMETERS	6-5
6.4	DISTRIBUTION OF IMAGING PROCEDURES	6-5
	6.4.1 Relative Diagnostic Activity	6-7
	6.4.2 Relative Procedure Volume	6-7
	6.4.3 Imaging Activity Index	6-9
	6.4.4 Distribution of Nuclear Studies in Hospitals & Clinics	6-12
6.5	THE IN-HOSPITAL HOT LAB VS. COMMERCIAL PHARMACIES	6-14
	6.5.1 Unit-Dose Packaging	6-15

## TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
6.5.2 Pricing Practices	6-15
6.5.3 Other Services	6-16
6.6 NONHOSPITAL END-USERS	6-17
6.7 ISSUES OF BOARD CERTIFICATION	6-18
7.0 COMPANY PROFILES	7-1
7.1 INTRODUCTION	7-1
7.2 ALGETA (Norway)	7-3
7.3 ALPHAMED INC.	7-5
7.4 ANTISOMA LTD. (UK)	7-7
7.5 ASTELLAS (FUJISAWA)	7-10
7.6 BIOGEN IDEC INC.	7-12
7.7 BIO-NUCLEONICS, INC.	7-14
7.8 BOSTON LIFE SCIENCES	7-15
7.9 BRACCO DIAGNOSTICS	7-18
7.10 BRISTOL MYERS SQUIBB IMAGING	7-20
7.11 CARDINAL HEALTH	7-23
7.12 CELLECTAR, LLC	7-25
7.13 CIS BIO-INTERNATIONAL	7-28
7.14 CYTYC CORPORATION (Proxima Therapeutics)	7-30
7.15 CYTOGEN CORPORATION	7-33
7.16 DOW CHEMICAL CO.	7-36

## TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
7.17 DRAXIMAGE, INC.	7-38
7.18 GE HEALTHCARE DIAGNOSTICS	7-40
7.19 GLAXO SMITHKLINE CORPORATION	7-44
7.20 IBA MOLECULAR	7-46
7.21 IMMUNOMEDICS, INC.	7-47
7.22 LYNNTech INC.	7-50
7.23 MALLINCKRODT INC. (TYCO HEALTHCARE)	7-53
7.24 MILLENIUM PHARMACEUTICALS	7-55
7.25 MDS NORDION	7-58
7.26 MOLECULAR INSIGHT PHARMACEUTICALS	7-61
7.27 NST LTD. (Israel)	7-64
7.28 PEREGRINE PHARMACEUTICALS INC.	7-65
7.29 P.E.T.NET PHARMACEUTICALS, INC.	7-69
7.30 SIRTEX MEDICAL LTD (Australia)	7-70
7.31 THERAGENICS CORPORATION	7-75
7.32 VITA MEDICAL (Australia)	7-77
APPENDIX A – LIST OF MANUFACTURERS OF RADIOPHARMACEUTICALS	A-1

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

<u>Exhibit</u>		<u>Page</u>
1-1	HISTORIC AND FORECAST SALES GROWTH OF DIAGNOSTIC RADIOPHARMACEUTICALS BY PRODUCT GROUP FROM 2004-2014	1-12
1-1	2007 DIAGNOSTIC RADIOPHARMACEUTICAL SALES SUMMARY BY PROCEDURE CATEGORY AND PRODUCT TYPE	1-15
1-2	2014 DIAGNOSTIC RADIOPHARMACEUTICAL SALES SUMMARY BY PROCEDURE CATEGORY AND PRODUCT TYPE	1-19
1-3	HISTORIC AND FORECAST SALES GROWTH OF NUCLEAR CARDIOLOGY AND VASCULAR IMAGING BY PRODUCT CATEGORY FROM 2004-2014	1-23
1-4	RELATIONSHIP OF NUCLEAR CARDIOLOGY PROCEDURES AND SALES TO GENERAL NUCLEAR MEDICINE FROM 2004-2014	1-25
1-5	HISTORIC AND FORECAST SALES OF CARDIAC PERFUSION AND BLOOD POOL AGENTS BY PRODUCT CATEGORY FROM 2004-2014	1-27
1-6	HISTORIC AND FORECAST SALES OF PHARMACOLOGIC STRESSORS FOR CARDIAC IMAGING BY PRODUCT CATEGORY FROM 2004-2014	1-31
1-7	SALES OF CARDIOLOGY AGENTS FOR MYOCARDIAL VIABILITY, THROMBUS IMAGING AND CONGESTIVE HEART FAILURE FROM 2004-2014	1-33
1-8	SALES OF GENERAL NUCLEAR MEDICINE PRODUCTS FOR FUNCTIONAL STUDIES AND TARGETED CANCER IMAGING FROM 2004-2014	1-35
1-9	HISTORIC AND FORECAST GROWTH OF TECHNETIUM-BASED PROCEDURES FROM 2004-2014	1-36
1-10	HISTORIC AND FORECAST SALES OF TECHNETIUM AND TECHNETIUM-BASED PRODUCTS FROM 2004-2014	1-38
1-11	HISTORIC AND FORECAST SALES OF TECHNETIUM AND TECHNETIUM KITS FOR GENERAL PURPOSE IMAGING BY PRODUCT CATEGORY FROM 2004-2014	1-40

## LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
1-12	HISTORIC AND FORECAST SALES OF ISOTOPE PRODUCTS FOR FUNCTIONAL IMAGING, BY PRODUCT CATEGORY, FROM 2004-2014	1-42
1-13	HISTORIC AND FORECAST SALES OF FDG, ANTIBODIES AND PEPTIDES FOR TARGETED CANCER IMAGING BY PRODUCT GROUP FROM 2004-2014	1-52
1-14	2007 SALES AND MARKET SHARES OF RADIOPHARMACY COMPANIES AND INDEPENDENT NUCLEAR PHARMACIES	1-56
1-15	ANALYSIS OF RADIOPHARMACY REVENUES, COSTS AND GROSS PROFIT IN 2007	1-57
2-1	DIAGNOSTIC AND THERAPEUTIC ISOTOPES	2-3
3-1	CLINICAL INDICATIONS FOR NUCLEAR IMAGING PROCEDURES	3-4
5-1	2007 RADIOPHARMACEUTICAL SALES SUMMARY, MANUFACTURERS' SALES DOLLAR VOLUME AND MARKET SHARE	5-6
5-2	DISTRIBUTION OF RADIOPHARMACEUTICAL SALES IN THE U.S. IN 2007, MANUFACTURER'S SALES DOLLAR VOLUME BY PRODUCT CATEGORY	5-9
5-3	2007 SALES OF THALLIUM FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-16
5-4	2007 SALES OF CARDIOLITE FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-18
5-5	2007 SALES OF MYOVIEW FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-20
5-6	2007 SALES OF CARDIOGEN, RUBIDIUM-81 GENERATOR, FOR HEART PERFUSION STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-23
5-7	2007 SALES OF ADENOSCAN FOR PHARMACOLOGIC STRESS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-25
5-8	2007 SALES OF PYP-PYROPHOSPHATE KITS FOR HEART IMAGING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-26

## LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
5-9	2007 SALES OF TECHNETIUM GENERATORS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-29
5-10	2007 SALES OF MDP AND HDP KITS FOR BONE IMAGING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-31
5-11	2007 SALES OF TECHNETIUM DTPA KITS FOR AEROSOL LUNG VENTILATION, BRAIN AND KIDNEY SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-32
5-12	2007 SALES OF TECHNETIUM SULFUR COLLOID KITS FOR LIVER SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-34
5-13	2007 SALES OF MACRO-AGGREGATED ALBUMIN FOR LUNG PERFUSION SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-36
5-14	2007 SALES OF TECHNETIUM BILIARY AGENTS FOR GALL BLADDER STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-38
5-15	2007 SALES OF TECHNESCAN MAG-3 FOR KIDNEY FUNCTION5- STUDIES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-40
5-16	2007 SALES OF IODINE 131 FOR THYROID IMAGING AND KIDNEY SCANS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-42
5-17	2007 SALES OF IODINE 123 FOR THYROID SCANS, RADIOPHARMACEUTICAL SUPPLIER, SALES DOLLAR VOLUME AND MARKET SHARE	5-43
5-18	2007 SALES OF CERETEC FOR BRAIN PERFUSION STUDIES AND WHITE BLOOD CELL LABELING, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-47
5-19	2007 SALES OF NEUROLITE FOR IMAGING BRAIN PERFUSION, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-48
5-20	2007 SALES OF GALLIUM 67, FOR SCANS OF TUMORS, ABCESSES AND INFLAMMATION, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-49

## LIST OF EXHIBITS

<u>Exhibit</u>		<u>Page</u>
5-21	2007 SALES OF XENON FOR LUNG VENTILATION STUDIES. RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-51
5-22	2007 SALES OF INDIUM OXINE FOR IMAGING INFLAMMATORY PROCESSES, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-53
5-23	2007 SALES OF PROSTASCINT FOR IMAGING PROSTATE CANCER, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-53
5-24	2007 SALES OF OCTREOSCAN FOR IMAGING ENDOCRINE, TUMORS RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-56
5-25	2007 SALES OF INDIUM CHLORIDE FOR COMPOUNDING WITH CANCER IMAGING AGENTS, RADIOPHARMACEUTICAL SUPPLIER AND MARKET SHARE	5-58
5-26	2007 SALES DISTRIBUTION OF FDG SUPPLIERS IN THE U.S. NUMBER OF END-USERS, ANNUAL DOSES SOLD AND SALES VOLUME	5-60
6-1	COMPARATIVE ALLOCATION OF DIAGNOSTIC FACILITIES BY HOSPITAL BED SIZE	6-4
6-2	COMPARATIVE UTILIZATION PARAMETERS FOR DIFFERENT IMAGING MODALITIES IN 2007	6-6
6-3	DISTRIBUTION OF HOSPITAL DIAGNOSTIC IMAGING PROCEDURES IN THE U.S. BY HOSPITAL BED SIZE IN 2007	6-8
6-4	RELATIVE PROCEDURE VOLUME AMONG DIFFERENT IMAGING MODALITIES, PERCENTAGE RELATIONSHIP BY HOSPITAL BED SIZE IN 2007	6-10
6-5	RELATIVE ACTIVITY INDEX AMONG DIFFERENT IMAGING, MODALITIES PROCEDURES PER BED PER YEAR BY HOSPITAL BED SIZE IN 2007	6-11
6-6	DISTRIBUTION OF NUCLEAR CARDIOLOGY PROCEDURES IN HOSPITALS AND IMAGING CLINICS IN 2007	6-13