Executive Summary

Molecular imaging has become an increasingly indispensable tool in the life sciences, in translational research, and in routine medical diagnostics. Although there are several slightly differing definitions, the consensus is that molecular imaging noninvasively visualizes molecular interactions in living cells, tissues, organs, or entire organisms. The signal usually comes from a tracer that either binds to a distinct molecular target or shows uptake and retention characteristics according to the distinctive properties of the tissue to be imaged.

This covers a lot of ground, and indeed molecular imaging can be many things. Cultured cell lines, laboratory animals, and humans can all be subjected to molecular imaging with great benefit to science, drug development, and—if the human is a patient—medical benefit to individuals. Even if the scope is limited to the pharmaceutical industry, the applications start with target and lead discovery and characterization, continue into translational research, and end only with therapy monitoring for approved drugs. Equipment and methodology are equally diverse, comprising the most advanced confocal microscopes for picking up intracellular fluorescence signals, ultrasound probes with computerized attenuation correction and capability for precise Doppler velocity measurements, magnetic resonance tomographs, and nuclear tomographic equipment that detects gamma radiation from decaying probes and pinpoints their source.

As a result of this diversity in several dimensions, there is no single "molecular imaging market." Rather, there are several partially connected markets:

- A market for optical cellular imaging in R&D, consisting of a market for advanced microscopes and one for optical probes
- A market for near-infrared fluorescence and bioluminescence imaging of laboratory animals, again divided into an equipment and a probe market

- A market for tomographic scanners (based on x-rays, magnetic resonance, or nuclear isotopes, alone or in combination, and in different sizes for laboratory animals and humans)
- A market for ultrasound imaging equipment
- Those parts of the markets for x-ray, magnetic resonance, and ultrasound contrast agents that concern molecularly or metabolically differentiating agents
- A market for radioactive isotopic probes, assisted by a secondary market for the logistics of those probes that decay particularly rapidly but can only be manufactured in cyclotrons
- An overarching market of computer systems and software that take care of the processing, analysis, and storage of the captured images

These markets are partially interdependent, but also very different from each other. Cellular imaging is a typical laboratory R&D market that has developed dynamically during the past two decades, driven by a steady stream of novel technical features that are constantly incorporated into new generations of equipment, and an equally steady stream of new probes and modifications to imaging modalities. Its great potential for the pharmaceutical industry lies in target and drug discovery and characterization, including potential safety issues. Automatization and increased throughput are currently making cellular molecular imaging a particularly interesting element of high-content screening. Traditional microscope manufacturers, such as Zeiss, Leitz, Nikon, and Olympus, continue to lead this segment of the molecular imaging market; however, a very considerable number of highly innovative smaller companies offer special solutions. Labeling agent development for optical imaging is almost a world of its own, which includes quixotic developments such as quantum dots.

Small animal imaging in all its modalities is a nascent market, but is attracting broad industry interest because of its potential to characterize compounds at the transition from discovery to preclinical development. Recent years have seen the introduction of dedicated high-resolution scanners for animals up to the size of a rabbit, with features and technologies equivalent to those used in humans. It is logical that the leading developers and vendors are also essentially those that offer clinical equipment as well—a group led by GE Healthcare, Siemens, and Philips. Optical imaging of living laboratory animals has become a very dynamic field, especially for oncology and gene therapy.

Human molecular imaging is a cluster of markets in various stages of development, none of which can be considered mature. Positron emission tomography (PET) has seen the strongest expansion in recent years, a development that was almost exclusively driven by approvals and refunding in cancer diagnosis and monitoring. However, single-photon emission computed tomography (SPECT) and gamma camera installations outnumber those of PET tomographs by an order of magnitude, and their isotopes are much easier to manufacture and handle. Scanners that combine PET or SPECT with x-ray computed tomography (CT) or magnetic resonance (MR) to map the located sites of tracer emission to high-resolution three-dimensional (3D) images of the local tissue are now the main drivers in this market. These modalities are playing an increasing role in translational medicine, although they do not serve as endpoints in clinical trials. Chapter 4 of this report covers the regulatory background for molecular imaging and gives valuable examples.

Near-infrared optical molecular imaging in humans is still in its very early stages, although it has already gained a foothold in breast imaging and is starting to score in intestinal and intravascular endoscopy. Its great advantage is the relative simplicity of the technology; however, applications are limited to relatively superficial strata of tissue or to infrared-transparent tissue, such as the female breast.

Most molecular imaging modalities now attempt to capture not only the spatial distribution of the tracer signal but also its dynamics, producing "4D" time series of 3D reconstructions from tomographic slices. Temporal resolution varies widely with the technology, but is meanwhile good enough to add very considerable insight everywhere—from cellular uptake mechanisms captured by time-lapse photomicroscopy to cardiac motion. Capturing, assembling, and analyzing 4D series push computer hardware and software close to their limits, but do not require machines beyond the current commercial range. However, the constant increase of hardware power will make more (and more detailed) real-time analyses possible during the next decade.

This report ends with projections of likely developments that we believe will occur in this fascinating field during the 2010s. We also include a list of leading societies and journals, and present the results from a small Web survey that outlines the expectations of researchers and managers in the molecular imaging field.