

Sampling of Prior Engagements in Clinical Diagnostics

- ❖ Advised a young European diagnostics firm in positioning its **multiplex immunoassay system** for commercialization in the U.S. clinical laboratory market; reviewed product concepts in addressing infectious and autoimmune disease testing, reviewed plans for design control and manufacturing quality assurance, and provided detailed recommendations for least-burdensome courses of action to secure FDA regulatory clearance.
- ❖ Conducted market and technology assessments for image-based mechanical analysis and indexing of **vascular plaque** to support a potential business formation from an academic setting.
- ❖ Formulated commercialization strategies for two, unrelated development-stage companies, each of which had developed technologies for ultra-sensitive **biomolecular detection** applicable to chemical/biological defense, life science R&D, industrial microbiology and clinical diagnostics markets.
- ❖ Provided guidance on commercial collaborations generally, and on negotiations with a potential distributor/collaborator in particular, to the CEO of a firm developing innovative **nucleic acid sequencing** technology.
- ❖ Assessed the technology of an early stage firm developing a noninvasive method for **blood glucose monitoring** for a prospective seed investor.
- ❖ Conducted due diligence on a molecular imaging company, its technologies, and its served markets in **breast cancer diagnostics** and **small-animal imaging** for a prospective investor.
- ❖ Developed several reports on the state of **medical imaging** generally, and **molecular imaging** in particular, for the *BBJ Newsletter*.
- ❖ For a producer of **point-of-care coagulation diagnostics**, explored partnering mechanisms for increasing shareholder value.
- ❖ Assessed opportunities in the manufacture of **diagnostic test strips** (biosensors) for a provider of high-volume specialty coating services.
- ❖ Assessed the commercial potential of planned **molecular diagnostics** assays for infectious disease and two associated instrumentation platforms for a prospective investor in the firm.
- ❖ For a producer of diagnostic equipment used in physicians' offices, tested the commercial feasibility of a radically new approach to diagnosing certain respiratory infections by means of **noninvasive gas sensing** in the mouth, nose and external ear canal.
- ❖ For a laboratory equipment company seeking to form a clinical products business, surveyed opportunities in point-of-care **breath testing**.
- ❖ An inventor sought to form a company to develop and commercialize a noninvasive technology that can predict and monitor the risk of **sudden cardiac death**. We were engaged to assess the opportunity presented by the technology and to develop a business plan that would support fundraising and product commercialization.

- ❖ For a startup firm wishing to exploit a unique **lab-on-a-chip** technology comprised of miniaturized fluid transfer structures, automated analytical assays and integrated informatics, guided strategy development and provided executive counsel prior to the firm's first round of venture capital financing.
- ❖ Explored clinical applications and the ultimate commercial potential for new, cost-efficient technology for **cerebral oximetry** for a firm considering licensing the technology.
- ❖ As part of a multiclient study, assessed the U.S. market and corresponding opportunities for medical **image management** systems (PACS).
- ❖ Provided divestiture support and brokerage services to the owner of a business offering **pulmonary function testing** equipment to the U.S. hospital market.
- ❖ Assessed two established **clinical diagnostics** firms as potential investments for a Canadian business development agency.
- ❖ For a supplier of *in vitro* diagnostic systems for **decentralized laboratory testing**, provided assistance in defining market requirements for a new product, interpreting government regulations of clinical laboratories and pointing out how the regulations would constrain the use and marketing of these diagnostic systems, developing product concepts and design specifications, and designing a user interface for the product.
- ❖ For a venture capital firm, assessed potential research applications and associated business potential of university innovations in **laser/optical tweezers and traps**.
- ❖ Identified growth opportunities in the diagnosis and treatment of **gastrointestinal** disorders for a supplier of ostomy and wound care products.
- ❖ For a producer of laboratory instrumentation serving the food and dairy industries, determined user preferences and detailed product requirements associated with the client's planned second-generation **automated microbiology** instrument.
- ❖ Developed specifications and product concepts for a clinical laboratory **blood coagulation** analyzer, combining clotting and chromogenic methods, for a leading multinational healthcare firm.
- ❖ Devised and fully characterized three alternative concepts for a high-throughput, random access **clinical chemistry system** for hospital laboratories to assist our client, a manufacturer of diagnostic products, in meeting customer requirements.
- ❖ Characterized the competitive landscape for an *in vitro* diagnostics supplier contemplating entry into the **rapid flu testing** market.
- ❖ Determined hospital laboratory preferences among various system architectures for **blood gas data management** for a leading supplier of those systems.

