Highlights: Q3, 2018

We are pleased to share Fletcher Spaght's Q3 Highlights, summarizing recent achievements within our specialized consulting practice groups. We appreciate your continued interest and support.

HIGH TECHNOLOGY PRACTICE

Photonic Components

Provided due diligence support in a follow-on round for investors in a company with a novel swept-laser technology; developed market size and estimated probability of market penetration for a variety of applications including ophthalmology, semiconductor metrology, automotive laser welding, and autonomous vehicle LiDAR; market estimates were used by investors to consider potential exit values and the potential return on incremental investment.

High-End Component Manufacturing

Developed a growth strategy to expand the medical OEM client base for a leading provider of highly engineered component and subsystem solutions; effort included extensive secondary analysis followed by facilitated workshops with client, growth opportunities in three major medical device markets were characterized and prioritized, and specific high growth products utilizing technology components synergistic with client's core strengths were identified; analysis is being used to identify potential component manufacturer M&A targets.

HEALTHCARE PRACTICE

Cortical Stimulation

Estimated market potential for a cortical stimulation implant based on in-depth interviews with treating physicians supported by a collaboration with an epidemiologist focused on the indication.

Bioprocessing

Provided assistance to a government-led overseas factfinding mission to learn best practices and pitfalls with respect to launching a biomanufacturing innovation zone supporting early stage biotech companies.

HEALTHCARE PRACTICE (cont'd)

Patient Monitoring

Analyzed pricing latitude in the context of potential share loss for branded sensors in two scenarios: a price increase compared to other branded products, and competition from lower priced, but compatible generic or reprocessed products; effort included input from stakeholders in multiple clinical specialties as well as procurement and clinical engineering; geographic scope included US and seven other major markets.

Lung Cancer Companion Diagnostic

Interviewed pathologists regarding testing algorithms for non-small cell lung cancer and use of next-generation sequencing (NGS) versus other modalities for oncology biomarker testing and companion diagnostics; compared use of NGS diagnostics for US community and academic hospitals; discussed current testing algorithms and anticipated future changes and clinical benefits of NGS in the context of cost and reimbursement issues.

Cardiac Stents

Evaluated adoption of a novel stent in various EU countries three years post-launch; interviewed interventional cardiologists regarding factors impacting stent choices, perspectives on "new" stent, and barriers to adoption of newer stents including product performance, relevant subsets of patients, and hospital contracting.

Sleep Apnea

Conducted landscape analysis to identify devices and services offered to sleep apnea patients in the US; summarized clinical data, claims, regulatory status and pricing; provided recommendations for a CPAP product line extension and service opportunities.

Peritoneal Dialysis

Mapped out the device selection process for peritoneal dialysis in US and Germany through in-depth interviews with nephrologists and dialysis nurses; discussed current devices used, how they are selected and considerations for switching; collected infection rate data and assessed clinical factors contributing to infections and how clinics try to minimize complications; tested receptivity to a specific product under consideration for distribution.

HEALTHCARE PRACTICE (cont'd)

Chronic Kidney Disease

Tested receptivity for a preclinical drug expected to slow disease progression and extend time to dialysis for chronic kidney patients; interviewed nephrologists to understand current practice, clinical endpoints required to demonstrate meaningful benefit, compliance considerations for polypharmacy patients, and financial considerations impacting adoption (reimbursement and copays); discussed perceptions of clinical trials on a drug with a similar mechanism of action to understand if those data would impact potential adoption of the preclinical candidate; estimated market potential based on an acceptable pricing range and the addressable patient population; provided recommendations for clinical trial design to drive adoption.

Surgical Robotics

Analyzed the endoluminal surgical robotics landscape from commercial platforms to technology emerging from academic institutions through extensive secondary research and in-depth interviews with six clinical specialties to identify potential procedures for technology adoption short and long term; forecasted market potential for converting open and minimally invasive procedures to an endoluminal approach.

Minimally Invasive CABG

Assessed the potential of a novel minimally invasive CABG system through interviews with cardiologists to understand potential adoption; identified key considerations for the product development team and determined a subcomponent which could be developed as a standalone product; quantified the potential patient population; identified and described barriers to adoption and key factors for success.

Photodynamic Therapy

Evaluated the market opportunity and competitive dynamics of a urological surgery technology designed to highlight cancerous tissue during cystoscopy; considered current and potentially expanded indications, and current and incremental reimbursement on adoption and utilization; leveraged insights from urologists, as well as analysis of launches of analogous products to develop a revenue forecast model.

HEALTHCARE PRACTICE (cont'd)

Orthopedics

Performed a market assessment to identify unmet needs and customer segmentation in the implant market leading to a growth workshop to set future strategy.

Liver Surgery

Assessed unmet needs in liver surgery and the potential for novel navigation technologies to increase adoption of minimally invasive surgery; forecasted the potential incremental market growth if identification and management of incidental findings were improved through the use of new technological tools.

OEM and Distribution Strategy

Delineated strategic options for a novel patient monitoring technology company to partner with OEMs; advised on potential deal structure and terms based on analysis of comparable distribution/OEM agreements and interviews with former executives at comparable patient monitoring companies.

Peripheral Lung Biopsy

Assessed unmet needs for biopsy tools to access the periphery of the lung; interviewed interventional pulmonologists to test receptivity to novel developmental device which could provide better access and visualization than current navigation; provided guidance for product development team to address market needs; estimated revenue potential.

Behavioral Health

Conducted an actionable market assessment for an educational non-profit seeking maximal receptivity for its frameworks to address unmet needs in suicide prevention in health systems; evaluated market receptivity, requirements to serve, and willingness to purchase the Client's frameworks across IDNs, federally-funded community clinics, self-insured employers, and state health agencies.

Peripheral Vascular

Performed due diligence and forecasting for minimal invasive device used in multiple vascular indications; effort involved interviews across multiple specialties to define the patient journey and go-to-market strategy.

HEALTHCARE PRACTICE (cont'd)

Point-of-Care Diagnostics

Tested receptivity and identified the best initial market segments for a handheld blood analyzer through in-depth interviews in five clinical segments and analysis of current test volume; solicited feedback on specifications for the commercial instrument.

Pharmaceutical Company Valuation

Supported client and their investment bankers for an anticipated OUS initial public offering by providing a valuation of the company using risk-adjusted NPV analysis of five clinical-stage assets for eight indications, and comparable IPO valuations for companies in the same therapeutic areas and of similar size and development stage; provided comprehensive valuation report with detailed bibliography of over 100 citations to support market estimates in North American, Europe and Asian markets as well as various assumptions on clinical risk and methodologies used.

Genomic Testing

Summarized factors that influence coverage decisions for self-insured employers, when and why they deviate from third party administrators overall, and for genomic diagnostics specifically; quantified the market potential for genomic testing in this payer segment; proposed marketing strategies for client to increase revenue and market share.

Novel Antibiotics

For a pharma company seeking a US presence in the hospital market, performed due diligence on four publicly traded companies developing novel antibiotics; examined unmet needs, receptivity, and likely adoption of pipeline and marketed antibiotics through in-depth discussions with Infectious Disease, Emergency Department, Intensivist, and Hospitalist physicians, as well as hospital pharmacists, payers and equity analysts for a complete view of prescribing habits and barriers; also performed a quantitative survey of over 200 respondents to further inform detailed market models to 2030, leading to prioritization of M&A targets.

HEALTCHCARE PRACTICE (cont'd)

Medical Education

Evaluated US and three OUS markets with respect to the adoption of new technologies for medical education; PE client, and its portfolio company with standard teaching aids, required assistance in understanding, by country, how adoption may vary according to medical profession (physician, nurse, allied health); identified country-specific trends driven by government mandate, initiatives to improve learning effectiveness, as well as general views on use of technology; developed country-specific revenue models to estimate market potential.

Specialty Pharma

For an early stage specialty pharma company, conducted market assessments and developed forecast models for three lead product candidates in the areas of postherpetic neuralgia, subarachnoid hemorrhage and an ultra-orphan disease; leveraging this work, developed an investor presentation and "teaser" in collaboration with the client to support fundraising.

CORPORATE GROWTH PRACTICE

Academic-Industrial Partnership

Assisted a polytechnic institute in developing a marketing strategy to expand revenue from corporate partners; conducted internal interviews with department heads and leaders of different service business units to identify hypotheses on value proposition and synergies between service offerings and key customer segments; interviewed customers and non-customers to test potential value propositions and to identify key marketing messages; prioritized industrial segments to target.

Contract Manufacturing Organization

Conducted in-depth interviews with customers and noncustomers of contract manufacturing organization for a broad range of electronic medical devices; identified revenue risks and growth opportunities for selected market segments and technologies; described the competitive landscape and key market trends; outlined critical success factors and investment risks.

FSI PRACTICE GROUPS

High Technology: Internet, software, electronic commerce, communications, networking, hardware, services, *etc.*

Healthcare: Healthcare informatics, devices, healthcare information technology/services, diagnostics, therapeutics, services, *etc*.

Corporate Growth: Mature business transformation, growth options, profit improvement and acquisition support.

FSI STAFF

The professionals of FSI have expertise in both strategy consulting and the industries on which we focus. To facilitate our international assignments, members of our staff are fluent in the major European languages, Japanese and Chinese.

THE FSI SERVICE OFFERING

- Growth Strategy / Business Planning
- Market Assessment / Voice of Customer
- Strategic Positioning / Value Proposition
- M&A Search / Investment Due Diligence
- Competitive Analysis
- Innovation Commercialization
- Partnering / Funding Strategy / Valuation

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Focus

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