Lifescience Business Solutions
IMPROVING PATIENTS LIVES

Case Summary

PROGRAM DEVELOPMENT – TAVR DEVICE

Advisor to Deputy Chair & Executive Team

TECHNOLOGY
Transcatheter Aortic Valve Replacement (TAVR) indicated for Aortic Stenosis.

COMPANY
Global privately held cardiac device leader in Coronary Stent and Cardiac Rhythm markets.

CHALLENGE
Provide operational assessment and recommendations for legacy TAVI platform development and risk-adjusted market entry in line with business strategy.

ENGAGEMENT
Engaged by company leadership to evaluate development of legacy Transcatheter Aortic Valve Replacement (TAVR) technology for potential of delivering a commercially viable device. Assessment included all aspects of R&D design, supply chain operations, quality, clinical and regulatory affairs as it relates to competitive positioning. Advised on restructure for next-phase development, prerequisite investments and prospective workplan for GMP compliant go-to-market readiness.

OUTCOMES
- *Improved understanding of technology value proposition based on competitive analysis and market landscape.*
- *Facilitated adaptive mindset and decision support to redeploy R&D/Clinical roadmap, resituate resources & manage change.*
- *Proposed strategic and tactical investments in operational business processes to improve internal control, manufacturing quality and governance principles.*
- *Defined operational workplan and requirements for commercial go-to-market capability.*
- *Improved economic projections and ROI model.*

LESSONS
- *Importance of linking clinical results, improved provider economics and competitive physician/patient benefits for effective TAVI therapy launch.*
- *Enhanced perspective on establishing a robust technology platform leveraging medical affairs leadership and clinical evidence advantage.*
- *Improved tactical perspectives on compliant TAVI device development, testing, design transfer and manufacturing operations.*
- *Improved linkage of strategy to functional planning and operational capabilities.*

Lifescience Business Solutions
1187 Coast Village Road Suite 1-765
Montecito, CA 93108-2794

805-708-4449
andytymkiw@gmail.com
www.LBStymkiw.com