Lifescience Business Solutions
IMPROVING PATIENTS LIVES

Case Summary

COMMERCIAL READINESS – STRUCTURAL HEART

Consultant for Private Equity Placement

TECHNOLOGY

Transcatheter Aortic Valve Replacement (TAVR) indicated for Aortic Regurgitation.

COMPANY

Private equity firm representing privately held start-up in structural heart therapy.

CHALLENGE

Evaluate capital requirements to support clinical/regulatory milestones and US based manufacturing for commercial readiness.

ENGAGEMENT

Conduct due diligence and provide investor risk perspective on company preparedness to launch innovative TAVR platform. Assessment included management resources, GMP quality system compliance, site operating assets, process capabilities and opportunities and challenges for creating competitive go-to-market advantages. Provided preliminary next-phase recommendations and prospective workplan for operational setup of GMP compliant supply chain.

OUTCOMES

- *Aligned operational strategic imperatives with clinical and regulatory HDE, PMA and CE expectations.*
- *Established baseline for critical Manufacturing process capability and needs assessment including application of GMP Design Controls and technology transfer criteria.*
- *Clarified key investment areas necessary for operational transfer, scale up and go-to-market readiness.*
- *Secured $50M equity financing to support strategic investments in ongoing clinical programs, extended development, technical resources and manufacturing assets.*
- *Enhanced management / board relations and investor appointment to company Board of Directors.*

LESSONS

- *Gained insight on leverage opportunities for existing platform to align TAVI therapy norms and physician priorities with time to market.*
- *Clinical evidence and competitive market analysis can be better leveraged.*
- *Broadened perspective on resource and investment needs for go-to-market supply chain readiness.*
- *Strengthened technical understanding of operational transfer and scale up requirements & opportunities.*

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