STRATEGIC OUTSOURCING WORKSHOP

The Emerging Company Guide for Corporate Outsourcing Strategy

INTRODUCTIONS

Rikki Hansen Bouchard

    President

    RH Bouchard & Associates, Inc.

Karen Brennan

    Senior Director, Clinical Operations

    Nephros Therapeutics, Inc.

Lynn McGovern

    Director, Outsourcing

    Synta Pharmaceuticals, Inc.

Outsourcing Strategy-Why, When and How?

- Why do you need a corporate strategy?
  - Maximize Resources/Minimize Risk
- When should you develop your strategy?
  - Dependent upon your pipeline
    - Multiple projects at various stages
    - Single product in early development
    - Single product, single indication
    - Single product multiple indications
- How do you develop a strategy?

Development Models

l **Internal Development**

   – Evaluate internal resources

      l Short-term

      l Long-term

   – Capability to develop internal resources

      l Growth Plans

      l Funding

      l Set Priorities

Development Models

l Licensing

– Early Phase Development

– Proof of Concept

– Phase II

l Partnerships/Co-Development

– Shared resources

– Joint development agreements

Virtual Company vs. Traditional Pharma

l Skills and experience of staff

  – Early phase emphasis

  – Clinical development expertise

l Infrastructure and corporate support

  – Resources

  – Funding

  – Critical Mass

l Company Mission and Goals

  – Marketing products

  – Pure R&D

Outsourcing Strategies

- Geography-Global/International/Regional
- Preferred/Pre-Qualified Providers
- Project by Project
- Full Programs/TA/Indications
- Core Competency

Outsourcing Models

- **Full Service**
- **Functional**
- **Niche-Therapeutic Area**
- **Niche-Geography**
- **Niche-Technology Technology**
- **Multiple Providers—One Project**

Identifying the Best Service Provider for Your Needs

Requests for Information (RFI)

- **Establish and weight key decision-making criteria**
  - Therapeutic expertise
  - Team experience
  - Speed, responsiveness
  - Price
  - Cultural fit

- **Develop targeted Request for Information (RFI) eliciting feedback against those criteria**
  - Prepare side-by-side RFI comparison
  - Score RFIs, discuss, and make decision

Best Practice Outsourcing

Quality of selection process has big payoff against future time spent resolving issues

– **Selection of best team**

– **Commitment to your goals**

– **Effective communication of needs and expectations**

– **Understanding of project resourcing, contract terms and deliverables**

Evaluation tools

– **Standard RFI, targeted RFI, sample decision-making criteria, RFP, score cards, etc.**

Relationship Management

Create leverage for yourself as a customer

- **Know your strengths**
  - **Early stage pipelines are viewed as entrée to later phase projects**
  - **Small companies take partnering concept further**
  - **Biotech, small pharma growing CRO market segment**
- **Sell yourself as a customer**
  - **Discuss development programs and strategies openly**
  - **Provide context around planned development spending**

Developing Partnerships

Implement structure around key Provider relationships

- Establish Senior Level Oversight Committee with regular (quarterly) meetings and regular point-to-point contact
- Identify issue escalation and resolution path and process
- Use performance metrics to measure performance against expectations
- Develop consistent business processes for contracting, change orders, financial transparency, and discounting
- Evaluate overall relationship progress at pre-defined time points

What can you expect from your CRO?

- Quality of the team
- Set expectations for performance
- Manage expectations-revising as needed
- Build in performance checks
- Communication-when and about what?
- Recognize problems will occur-plan for them
- Mitigate Risk on both sides
- Learn from your mistakes and your successes
- Share the glory

Discussion

l   Does the CRO business model meet your needs?

l   How to get it done with limited resources and limited funds?

l   How can you effectively manage multiple providers on a single project?

l   Can a CRO be effectively managed by a Sponsor?

l   Your Questions………..

Thank You

Rikki Hansen Bouchard
401-624-7288
rikki@RHBAssociates.com
www.RHBAssociates.com

Karen Brennan
401-333-3789
kbrennan@nephrostherapeutics.com

Lynn McGovern
781-541-7107
lmcgovern@syntapharma.com