Business Development Case Template

Bizness

Patient population – large or refractory groups, untreated patients, specific genotypes/ markers, other indications posible

Efficacy – better end-point data in well designed studies, better accuracy data

Safety Profile – safer than SOC, safer than other INDs, safety in difficult to treat patients, pediatric/ geriatric, low contraindications

Administration/ Dose / Use – more convenient usage or dosing (QD), very long acting, patient administered, clever device, clever packaging, quick diagnosis turn-around

Protections – long IP life, strong IP position, global patents, trademarks/ brands, market exclusivity(ies) possible

Special rights (priority review, platform) – priority review voucher, platform

Development – easier/ cheaper/ faster to develop, regulatory friendly, accessible patient group, reduced risk of failure

Cost – cheaper for patients, payers, physicians, clinics, pharma

* 505 (b)(1) new drugs reg pathway vs 505(b)(2) improved drugs reg pathway
* Deal databases
  + EvaluatePharma, Pitchbook, Pharma Deals
* rNPV

Revenue forecasting methods

* Patient Based
  + Epidimeology based- prevalence, incidence and patient flow
  + Procedure/ test-based- historical and projected
  + Treatment protocol- Doctor’s preference and requirements
  + Dosing regimen, device/ diagnostic use, compliance and persistence
  + Bottom line- number of patients/ procedures per year and doses/units consumed x price
* Market Based
  + Competitive set
    - Marketed and in-developmente
  + Historical and forecast usage
  + Pricing and reimbursement
  + Market lifecycle, product positioning, line extensions, generic entry
  + Bottom line- market share x market value
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* Eventing
  + Loss of patent or exclusivity protection- yours or your competitors products
  + Changes in pricing and/or reimbursement strategy or policy
  + Exit of competitors
  + Entrance of competitors
  + Product goes OTC – yours or competitors
  + Labeling change of product (e.g. dosing, device usage or diagnostic warnings, or “black box”)
  + Additional indications (be sure to include R&D and risk)
* Key to event based forecasting is the use of analogs aka comps
* Uses for analogs
  + “Sanity check” peak penetration
  + Fit uptake curve to already forecast peak
  + Affect of generic competition and other IP challenges
  + Pricing and reimbursement outcomes
  + Labeling (product profile) assumptions
* Common variables often sought in analogs
  + Same indication, therapeutic area
  + Similar product profile (efficacy, safety, administration, dosing)
  + Same physician subgroup
  + Similar marketing strategy (e.g. PCP, hospital, DTC)\
* Competitive analysis
  + Major considerations
    - Product profile (MOA, efficacy, safety, accuracy, durability, side effects, dosing)
    - Indications/ uses obtained/ likely to be obtained
    - Likelihood of it being used in 1st line, 2nd line, etc…
    - Clinical unmet need
    - IP strength
    - Pricing/ reimbursement
    - Marketer strength
    - Order of entry
* Deal Terms Examples
  + Field
  + Territory
  + R&D expense subsidies
  + Manufacturing payments
    - Transfer price profit
  + Equity and/or debt Investment
    - At fair market value market
    - For a premium to fair market value
    - Contingent value rights and staged share purchases based on contingent value
* Tactical and strategic Partnering
  + Profit splitting (not so common, very complicated and problematic)
  + Share commercialization rights, co-commercialization (usually between two larger partners)
  + Shared development rights, or co-development (common in early stage)
  + Transferring R&D resources
  + Planned merger, acquisition or other strategic initiative
* Related or unrelated asset partnering
  + Quids
  + Technology platforms leverage
  + Follow-on technology rights
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