

# Establishing a Clinical Trials Finance Facility

Finance and licensing proposal

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*SecurePharma*

# Overview

## Market Assessment

Traditional equity funding model for pharmaceutical R&D under systemic pressure because of:

- Regulatory & social demands to reduce the costs of drugs
- Patent expirations and generic competition
- Increased pressure on budgets requiring augmented efficiency
- Declining R&D productivity
- Restrictive accounting treatment of R&D costs
- Absence of funding alternatives
- Increased volatility in the equity markets

**Pharmas actively seeking alternative funding sources**

# Overview

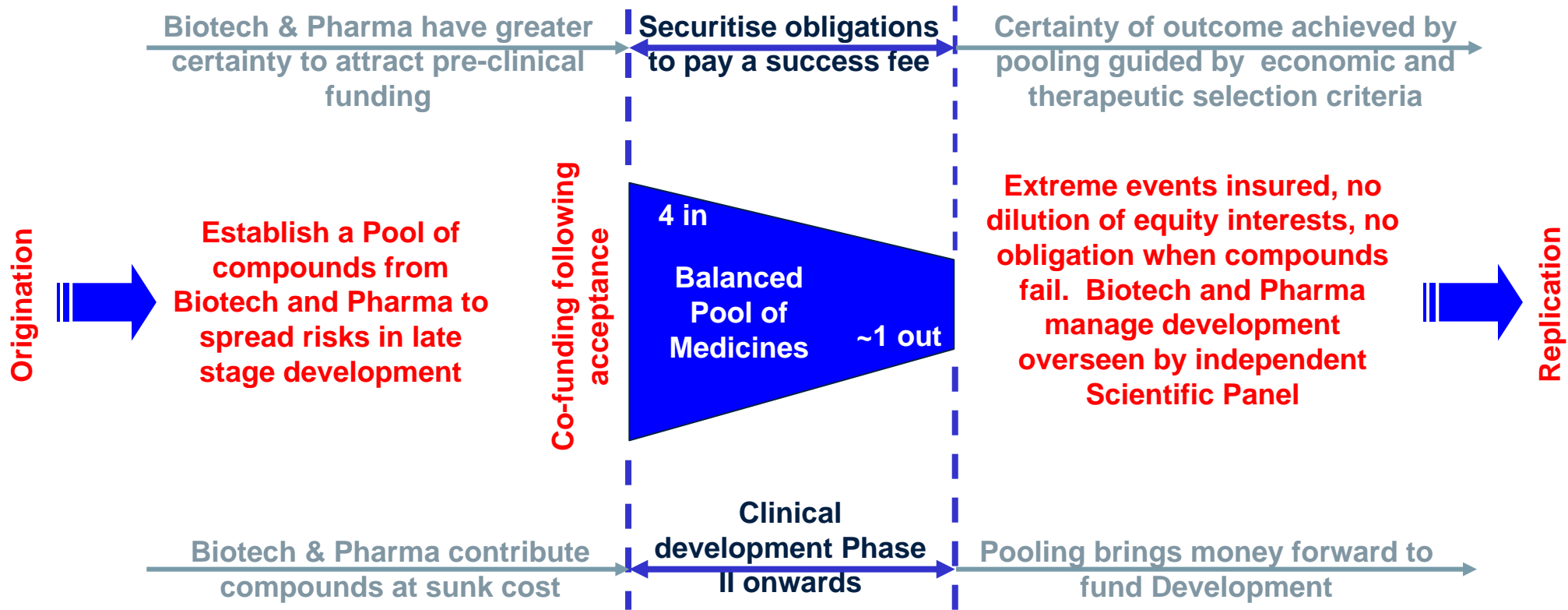
## Lessons from the Past

Previous unsuccessful attempts to implement alternative funding solutions have highlighted the need for :

- Innovative approach to risk transfer & diversification
- Availability of reliable stream of low-cost development capital
- Significant management involvement & scrutiny by independent parties
- Buy-in from both the R&D and finance functions within the Pharma
- Transparency to and buy-in from shareholders
- Collaboration between different Pharmas to create industry-wide solution and to spread portfolio development risk

**An innovative funding solution that addresses these needs**

# A Structured Finance Facility for Clinical Development



**A Reliable Stream of Low-cost Development Capital**

# Overview

## SecurePharma Solution

Unique funding solution applying structured finance techniques:

- Gives access to new sources of risk capital and liquidity at competitive cost
- Pools compounds from Pharmas (OR Funds) with strong credit ratings into an SPE, independent entity; the pool will support a bond issue that will co-fund development
- Pharmas' R&D costs reduced, as 'spend' is funded by the SPE
- Future revenue streams from successful compounds unaffected
- Pharmas' Intellectual Property is protected

**New source of risk capital with diversification achieved through pooling a range of uncorrelated compounds**

# SecurePharma Solution

## Key Features

- Rights to a percentage of revenues from successful compounds transferred to an SPE (independent entity)
- SPE co-funds the clinical development of compounds transferred into the pool
- R&D process executed by Pharma or independent CRO under service contract
- Pharmas' will provide reportage on the progress of development to SecurePharma to transmit to bondholders and rating agencies
- Pharmas' can increase the number of compounds in development

**Pharmas manage the development process**

# SecurePharma Solution

## Structured Funding

- SecurePharma will arrange to finance the clinical trial process via a rated debt issue in the capital markets, applying well established structured finance techniques
- Total amount raised will be the total projected and risk adjusted development cost for the period that compounds are expected to remain in the pool, co-funded by the Pharma
- Bondholders will be paid out from SPE's rights to a percentage of revenue from successful compounds
- Risk of no successes (the equity risk) will be shared with risk capital providers, insurers and bond investors

**Use of well established Structured Finance techniques**

# SecurePharma Solution

## Ongoing Management of Compounds

- Clinical trial process management is performed by the Pharmas based on a development schedule agreed at outset with independent Scientific Panel
- Pharmas will commit to the pool compounds that are in clinical development from late Phase I, Phase II onwards
- SecurePharma, through a panel of independent specialists, will select compounds, based on agreed criteria
- Panel will monitor the pool on behalf of the investors, ensuring that pre-agreed cost and time budgets are met
- Once compound is deemed to have 'failed', it will attract no further funding from the SPE

**Disciplined development process**

# SecurePharma Solution

## License Payments

- Pharma agrees to make payment of a percentage of revenue to the SPE for each compound that gains approval to market formulated as a success fee.
- The percentage of revenue is formulaic based on a number of factors, including anticipated total cost expended on each compound's development and the cost of 'failed' compounds in the pool
- Success fees provide cash for redemption of bonds and return for other risk capital providers
- Pharma will pay no fee in the unlikely event that none of its compounds succeeds other than the amount of its co-funding

**Pharma likely to pay only for successful compounds**

# Benefits to Pharma OR Fund Managers

- Financial
- Development
- Portfolio management
- Strategic

**Benefits across the board**

# Benefits to Pharma

## Financial

- New source of funding
- Pharma's net R&D expenses reduced for those compounds transferred to the SPE
- Allows more compounds to be developed without increased R&D expenditure, giving "More Shots on Goal"
- SPE takes no share of future revenue streams
- Certainty of funding at outset of development cycle

**New long term source of funding at competitive price**

# Benefits to Pharma

## Financial (cont'd)

- Pharma will only pay a licence fee for successful compounds
- Fees can become payable up to two years after each approval to market, matching cash outflow with revenues
- Licence fees likely to be capitalised and amortised over the appropriate revenue earning period
- No effect on gearing

**Immediate potential beneficial impact on P&L**

# Benefits to Pharma Development

- World-class development facilities can expand the number of compounds they take to market
- Development risk is shared across the pool and with risk capital providers
- Increased ability to adjust and manage risk exposure of R&D operation
- Third party input to cost and time budgets can reinforce a disciplined development environment

**Strengthens control over R&D process**

# Benefits to Pharma

## Portfolio management

- Ability to fund part of resource intensive core programs
- Opportunity to change development operations
  - Internal execution of content rich programs
  - Outsourced execution of process rich programs
- Opportunity to use own resources for innovative but less predictable programs – leverage core competencies
- Funding continuity for core programs even in M&A situations
- Avoidance of budget driven stop-go decisions on strategically important programs

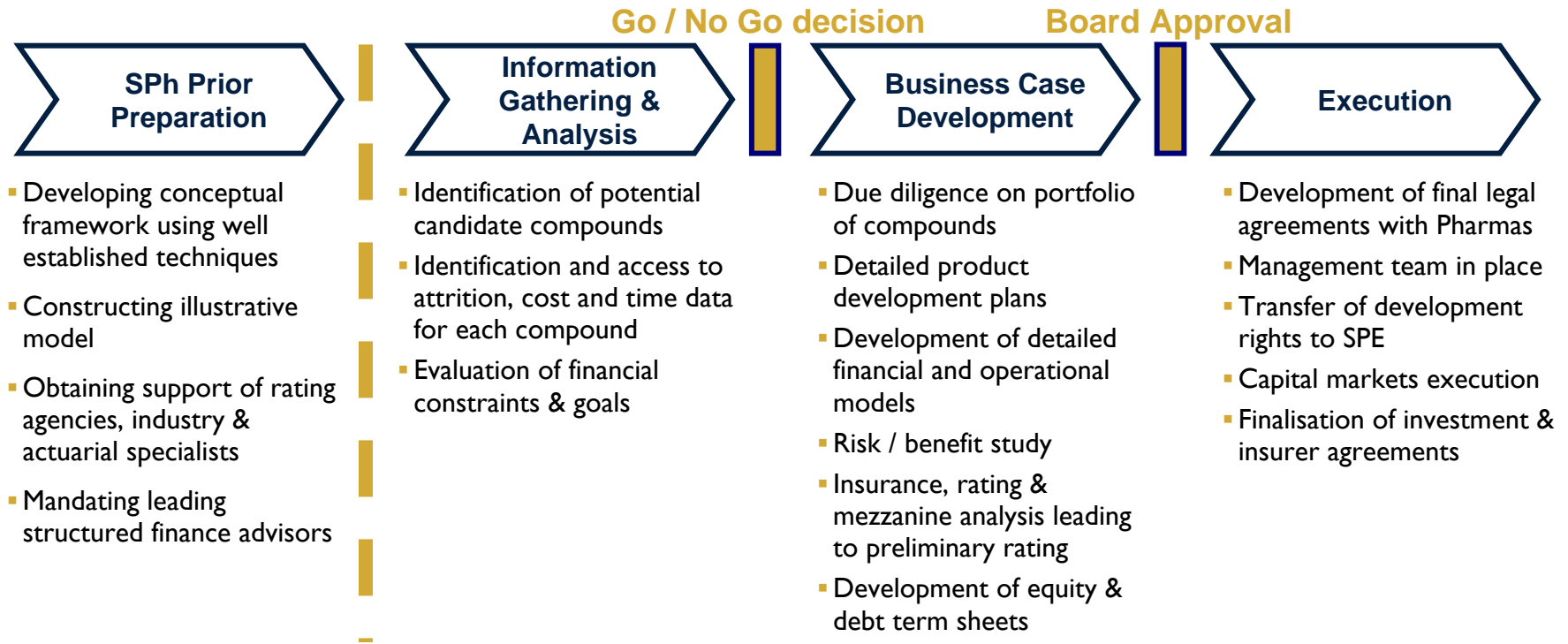
**Increased portfolio management capability**

# Benefits to Pharma Strategic

- Collaboration with fully-funded strategic partner
- Refocuses on research-driven profile of R&D organization, improving the allocation of internal and outsourced activities
- Outsourcing part of core activities will free up time and resources for new strategic initiatives such as:
  - joint ventures between big Pharmas and small Pharmas
  - in-licensing
  - acquisitions

**Benign funding for strategic action**

# Transaction Process Consulting Approach

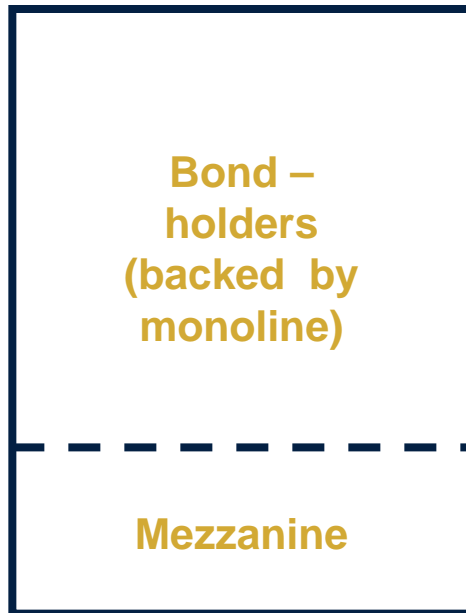


**Preparing for a new source of risk funding**

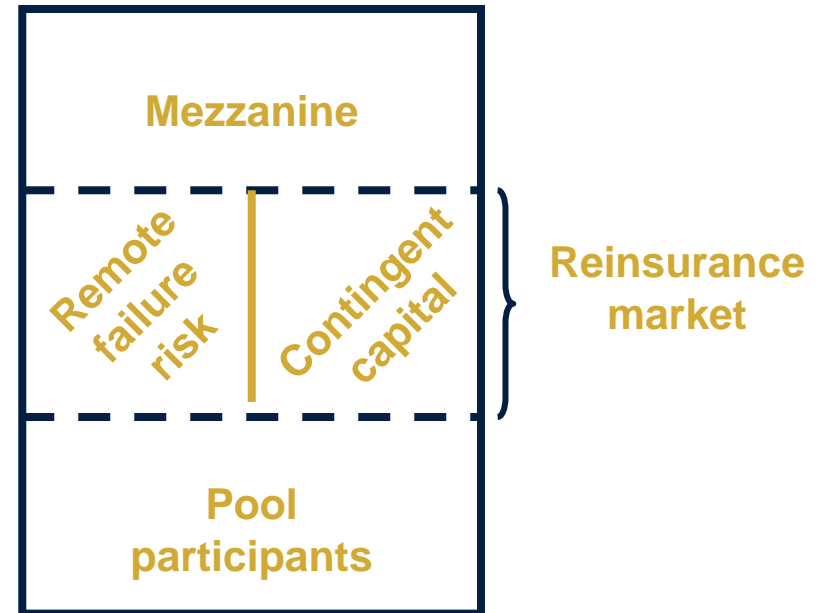
# Transaction Process

## Funding & Risk Sharing

### Funding



### 'Equity' Risk Sharing



**Indicative cost of capital 9-12%**

# Transaction Process

## Risk Factors

Successful outcome is dependent upon ability to

- Aggregate around 24 to 30 suitable target compounds
- Win support of Pharma's financial management as well as R&D and In-Licensing functions
- Attract and agree suitable terms with risk capital providers
- Satisfy rating agencies' requirements
- No adverse reaction from accounting and analyst communities

**A Strong Proposition to all Parties**