

Harvesting the Fruits

Bringing University-Industry R&D Collaborations to Life

Presented at LES/AUTM Meeting in
Philadelphia, PA on June 19, 1999

ISSUE OUTLINE

Parties to the Transaction

Info on University

Name of Entity: _____
Abbrev of Entity: _____
University Form: _____
University Location: _____
Street Address: _____
City: _____
State: _____
Zip: _____
Country: _____
Signatory: _____
Title of Signatory: _____
Notice To: : _____

Info on Biopharma Company

Name of Company: _____
Abbrev of Company: _____
Corporate Form: _____
Corporate Location: _____
Street Address: _____
City: _____
State: _____
Zip: _____
Country: _____
Signatory: _____
Title of Signatory: _____
Notice To: _____

Scope of Research

Basic Terms of Research Agreement

Execution Date: _____
Term of Agreement (years) : _____ year(s)
Renewal Term (years) : _____ years(s)
Topic of Research: _____
Diseases Covered: _____
Scope of Research: _____
Director of Research: _____
Research Facility: _____

Research Requirements

Compliance with Animal Research Policy.....
Academic Publication Policy.....
Exec of Materials Transfer Agr.....

Scope of License and Exclusivity

Scope of License Grant

License to Design Fields and Territory.....
Narrow Pre-Specified License.....
License Includes Back-ups.....
Include Carveouts and Reservation of Rights.....
Include Right to Sublicense.....

Applications/Field of Use Exclusivity

Diagnostic.....
Therapeutic.....
Industrial.....
Animal Health.....
All Uses.....

Territorial Exclusivity

Worldwide Exclusive License.....
North American (NAFTA) Exclusive License.....
United States, Possessions & Territories Excl.....
Regional Exclusive License (Specify Regions).....
Nonexclusive.....

Territorial Exclusivity (Regions)

European Community.....
Asia/Pacific Rim.....
Africa.....
South America.....
Australia.....
Other.....
Region: _____

Narrow License

Scope of License Description: _____

License Subject to Backups

Definition of Backup: _____

Carveouts & Reservations of Rights

Disease Specific Carveout.....
Compound Specific.....
Mechanism Specific.....
Geographic Specific.....

Disease Carveout

Description of Carveout: _____

Compound Carveout

Description of Carveout: _____

Mechanism Carveout

Description of Carveout: _____

Geographic Carveout

Description of Carveout: _____

Duration of License

Duration of License if Patent Issues

- Exclusive for life of the last to expire patent on Product
- Lifetime exclusive, subject to Pharma Milestones..
- Lifetime exclusive, subject to minimum royalty payments.....
- Limited time exclusive, then re-negotiation.....
- Limited time exclusive, then non-exclusive.....

Minimum Royalty Payments

Year One After Commercialization: _____
 Year Two After Commercialization: _____
 After Year Two Commercialization: _____

Exclusivity Period

Term of Exclusivity Period: _____ years

Publication/Disclosure Rights

Publication Rights

- Full publication rights by University subject to review
- Joint Publication of Results
- University can provide results to Non-US partners
- Federal Funding Obligations.....
- Academic Publication Policy.....

Data Rights

- Raw data owned by University
- Data rights tracks fields of use and geography.....
- Data rights track carveouts and reservations of rights
- Pharma owns raw data
- Pharma owns data abstracts

Funding/Payments

Basic Funding Options

- Payment of Signing Fee
- Amount of Signing Fee: _____
- Research Agreement:
 - Payment for Development Costs
 - Equity Investment/Rights
- License Agreement
 - Pharma Milestone Payments
 - Royalties.....

Funding of Development Costs by Pharma

- Pharma pays nothing.....
- Pharma covers direct costs
- Pharma covers fully-loaded costs.....
- Pharma covers direct costs and shares indirect cost
- Pharma to make additional milestone payments ...
- Pharma pays budgeted expenses

Budgeted Expenses

Budget Period {v150 budget period} years
 Year 1: \$ _____
 Year 2: \$ _____
 Year 3: \$ _____
 Year 4: \$ _____
 Year 5: \$ _____

R&D Milestones

- Proof of Concept.
- Lockout
- Milestone Payment: \$ _____
- High throughput screening assay operational
- Lockout
- Milestone Payment: \$ _____
- Combinatorial chemistry lead generated
- Lockout
- Milestone Payment: \$ _____

Pharma Milestones

- Milestone 1: Approval of an IND
- Payment: \$ _____
- Milestone 2: Initiation of Phase II
- Payment: \$ _____
- Milestone 3: Initiation of Phase III.....
- Payment: \$ _____
- Milestone 4: Filing of an NDA.....
- Payment: \$ _____
- Milestone 5: Regulatory Approval.....
- Payment: \$ _____
- Milestone 6: Commercial Launch of Product.....
- Payment: \$ _____

Equity Investment/Rights in Pharma.

- Direct investment and purchase of stock.....
- Stock warrants exercisable on anniversary dates....
- Stock warrants exercisable on milestones
- Stock options at designated purchase price
- FMV purchase
- Direct Investment: Grant of StockTotal Value of Equity: \$ _____
- Type of Equity: _____
- Number of Shares: _____
- Grant Date: _____

Stock Warrants: Anniversary Dates

Number warrant anniversary dates: _____
 _____ Anniversary
 Anniversary Date: _____
 Numbers of Shares: _____

Warrant Strike Price: \$ _____
 _____ Anniversary
 Anniversary Date: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Anniversary Date: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Anniversary Date: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Anniversary Date: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____

Stock Warrants: Milestones

Number warrant milestone dates: _____
 _____ Anniversary
 Description of Milestone: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Description of Milestone: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Description of Milestone: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Description of Milestone: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____
 _____ Anniversary
 Description of Milestone: _____
 Numbers of Shares: _____
 Warrant Strike Price: \$ _____

Stock Options Purchased

Option Purchase Price: \$ _____
 Payment Date: _____
 Type of Shares: _____
 Number of Shares: _____
 Option Strike Price: \$ _____
 Earliest Strike Date: _____
 Option Expiration Date: _____

Royalty Options

Flat Royalty
 Royalty with Annual Minimums
 Three-Tiered Royalty (Volume Discount).....
 Buyouts
 Credits for Development Funding
 Credits for Pharma Milestones
 Royalties set when license option exercised
 Anti-Stacking Protection
 Stop Loss: \$ _____

Royalty for Product

Royalty as percent of net sales of Product: _____ percent

Royalty and Minimums

Royalty as percent of net sales of Product: _____ percent
 Minimum First Year Net Sales: \$ _____
 Minimum Second Year Net Sales: \$ _____
 Minimum Annual Net Sales: \$ _____

Tiered Royalty Rates (Volume Discounts)

Number of Tiers: _____
 Base Royalty: \$ _____
 First Tier Royalty: \$ _____
 First Tier Threshold : \$ _____
 Second Tier Royalty: \$ _____
 Second Tier Threshold: \$ _____
 Third Tier Royalty: \$ _____
 Third Tier Threshold: \$ _____

Royalty Buyout Price

Buyout Price: \$ _____
 Last Exercise Date: _____

Royalty Upon Option Exercise

Royalty Floor: \$ _____
 Royalty Ceiling: \$ _____

Research, Development and Manufacturing

Research Agr Attachments

Compliance with Animal Research Policy
 Academic Publication Policy
 Exec of Materials Transfer Agr

Manufacturing and Outsourcing

Pharma controls manufacturing
 Pharma right to use third-party purification
 technology.....
 Pharma may outsource and share trade secrets
 University right to any proprietary manufacturing
 technology.....
 University grant-back right to improvements to
 Product made by Pharma during
 commercial production process

Progress Reports

- Pharma supplies regular progress reports on a/an _____ basis
- Univ supplies regular progress reports on a/an _____ basis.....

Oversight and Decisionmaking

- University oversees and controls project.....
- Joint development committee controls project
- Joint advisory committee advises on project
- Delegation to joint venture
- University participation in pharma management meetings
- Specify Subject Matter for Oversight.....

Scope of University Oversight

- Trial Study Design
- Screening Programs
- Combinatorial Chemistry
- Research on Backups

Prosecution, Maintenance and Expense of Patents

Patents Prosecution and Maintenance

- University responsible for all filings, etc
- Pharma responsible for all filings, etc
- University pays for all technology related costs
- Pharma pays all technology related costs
- Pharma pays University for req. patent prosecutions
- Joint review of relevant patent filings and activities
- Patent status reports required

Designation of Patent Counsel

- Use University in-house counsel.....
- Designate University outside counsel
- Patent Firm: _____
- Patent Counsel: _____
- Use Pharma in-house patent counsel
- Use Pharma outside counsel
- Patent Firm: _____
- Patent Counsel: _____

Attorney Issues

Termination - Exit Strategy

- Termination for cause Notice Period: _____ days
- Allow No Cause Termination.....
- Termination without Cause Notice: _____ days
- Allow Termination of Funding.....
- Termination of Funding Notice: _____ days
- Pharma improvements licensed to University royalty-free
- All rights, data, results etc revert to University.....
- University may buyout Pharma share of joint improvements

Arbitration and Dispute Resolution

- Mandatory arbitration
- Establishment of escrow fund for disputes
- Liquidated damages for certain issues
- Judicial Resolution of Disputes
- Controlling Law (Country): _____
- Controlling Law (State/Province): _____

Arbitration Provisions

- Arbitration Forum: _____
- Arbitration Controlling Law: _____
- Broad Arbitration - Arbitrate All Issues
- Narrow Arbitration - Restrict Power of Arbitrators

Judicial Resolution

- Forum (Country): _____
- Forum (State/Province): _____