BIO 2009 Member Survey

“Technology Transfer & the Biotechnology Industry”
BIO 2009 Member Survey
Technology Transfer & the Biotech Industry

• GOALS

• Collect Information on Biotechnology Industry’s Technology Transfer Portfolios
  • Who Do We In-License With?
  • What Impact Does Bayh-Dole (Ability to In-License with Univ. and Fed. Gov.) Have on the Biotech Industry?
  • How are In-License Opportunities Found & Agreements Structured?
  • How Can We Help Ensure Effective Technology Transfer in the U.S.?
KEY FINDINGS

- Majority of Companies Have License Agreements with Universities & Pharma/Biotech Companies - Most of Which Are With U.S. Entities
- Majority of Companies Do Not Have License Agreements with Federal Government
- Half of the Companies Were Founded on the Basis of a License Agreement
- After Obtaining Initial License Companies’ Employment Numbers Increase
- Companies Spend Several Years and Significant Amounts of Dollars Developing Licensed Technology Into Commercially Available Products
- Most University License Agreements Have Non-Commercial Research, Particular Field of Use, and Milestone Clauses Which Are Monitored to Ensure Compliance
- The Ability to Obtain an Exclusive License is Critical to the Ability to Research & Develop a Commercially Available Product
Profile of Survey Participants

- PROFILE OF PARTICIPANTS
  - Company Structure
  - Employees
  - Products
  - Revenues/Assets
150 BIO member companies participated in survey.
49% were public (N=74) and 51% were private (N=76).
The majority of these companies are small with fewer than 100 employees (63%). 54% had fewer than 50 employees. 19% had over 1000 employees.
Most (62%) of these companies do not yet have a commercial product (41% were private and 21% were public). 35% have a product on the market (6% were private and 29% were private). 3% gave no response (N/R).
56% of companies have lead products in Phase II and III stages of development.
Most companies with no marketed product are 3-10 years away from having a marketed product (34%). 35.3% of the companies surveyed have a product on the market.
SUMMARY OF SURVEY PARTICIPANTS

- Represents a Mix of Public & Private Companies
- Most are Small Companies with No Product on the Market that are 3-10 Years Away from Commercialization. Over Half of Lead Products are in Phase II or III Stage of Development.
- Companies with Marketed Products Represent Mid and Large Biotech Companies

Other Findings:
41% of companies’ lead product is a small molecule and 24% have a large molecule protein lead product.
36% Have a Biologic Lead Product (Lg. Protein, Sm. Protein, Vaccine).
Majority (65.4%) have 5 or less products in development.
28.7% have more than 6 products in development.
Biotechnology In-Licensing

- BIOTECH IN-LICENSES
  - Finding In-License Opportunities
  - Stage of Development In-Licenses Occur
  - Number of In-Licenses
  - Exclusive vs. Non-Exclusive
  - What Entities Biotech Has In-License Agreements With
Conferences were the most common method of identifying licensing opportunities (30%) followed by colleagues (25%) and literature sources (24%).
Almost half of the companies obtained a license in the pre-clinical stage (45%). 61% obtained license in preclinical or Phase I stage of development. 

NOTE: Other may represent licenses for compounds or manufacturing processes.
79% of companies surveyed said the ability to obtain an exclusive license is important to their ability to develop a commercially available product.
71% of companies have over half of their in-license agreements with U.S. entities. 45% have over 3/4ths of their in-license agreements with U.S. entities.
69% of the companies surveyed do not have an in-license agreement with the federal government. 19% of companies have less than 25% of their in-license agreements with the federal government.
31.4% have over half of their in-license agreements with universities (19% have more than 3/4th of their in-license agreements with universities).
36% of companies stated that 3/4th of their in-license agreements are with pharma/biotech companies, 47% stated over 1/2 of their in-license agreements are with pharma/biotech companies.
Biotech In-Licensing

- SUMMARY OF BIOTECH IN-LICENSING
  - Licensing Opportunities are Found at Conferences, Among Colleagues and in the Literature
  - Most Companies Obtain a License in Pre-Clinical or Phase I Stage of Development
  - Ability to Obtain Exclusive License is Critical to Ability to Research & Develop a Publicly Available Treatment or Therapy
Biotech In-Licensing

• SUMMARY OF BIOTECH IN-LICENSE PARTNERS
  • Most of In-License Agreements are with U.S. Entities
  • Most have In-License Agreements with Universities/Research Institutions and Pharma/Biotech Companies
  • Most DO NOT have In-License Agreements with the Federal Government
Impact of In-Licensing on Biotech Industry

- IMPACT OF IN-LICENSES ON BIOTECH INDUSTRY
  - Company History
  - Company Resources
50% of companies were founded on the basis of obtaining a license agreement and 48% were not. 62% of private companies were founded on obtaining a license vs. 40% of public companies.
58.1% of companies had <10 employees prior to obtaining first tech transfer license.
2-5 Yrs. After Obtaining License Only 19.3% of Companies had Fewer than 10 Employees

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<th>10-19</th>
<th>20-29</th>
<th>30-39</th>
<th>40-49</th>
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<td>20%</td>
<td>8.7%</td>
<td>8%</td>
<td>1.3%</td>
<td>2.7%</td>
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<td>2.7%</td>
<td>24%</td>
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<tr>
<td>All 2-5 yrs</td>
<td>19.3%</td>
<td>10%</td>
<td>8%</td>
<td>4%</td>
<td>6%</td>
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<td>18.4%</td>
<td>9.2%</td>
<td>11.8%</td>
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2-5 Yrs. after obtaining license only 19.3% of companies had fewer than 10 employees and 42% had between 10 and 100 employees.
77.4% of companies without a marketed product stated it will take 5-15 yrs. to develop lead product from time of initial product to commercialization.
17% said it will take 2-5 yrs.
42% of companies stated it took between 5-15 yrs. to develop lead product into a marketed product.
44% of companies stated it took < 5 years.
34% of companies with a marketed product stated it took 2-5 yrs.
Biotech In-Licensing & Company Resources

Companies With No Marketed Product
- 60% Project Will Spend > $100 M
- 15% Project Will Spend > $500 M

Companies With a Marketed Product
- 39% Spent > $100 M
- 21% Spent > $500 M

NOTE: Figures Represent Small Molecule, Large Molecule and Diagnostic Lead Products
SUMMARY IMPACT OF IN-LICENSES ON BIOTECH INDUSTRY

- Half of Companies Were Founded on Basis of Obtaining a License Agreement
- Prior to Obtaining a License 58% of the Companies had < 10 Employees
- 2-5 Yrs. After Obtaining License Only 19% had <10 Employees
- Majority of Companies With No Marketed Product Expect to Spend 5-15 Years Developing a Product and Spend > $100 M
BIOTECH IN-LICENSE AGREEMENTS

• Length of Time to Complete Negotiations
• Hardest/Easiest Part of Negotiations
• Calculating Value
• In-License Payment Structures
49% of companies stated it takes 3-6 mo. to complete a license agreement (31% stated it took 6-12 mo.) Same with public and private except more private companies stated it only took less than 3 mo. than public companies (12% vs. 1.3%).
36% of companies stated monetary terms are the hardest part of the negotiations. Exclusivity was second with 11% of companies identifying this as the most difficult part of negotiations.
37% of companies stated confidentiality and publications were the easiest part of the negotiations followed by patents (13%).
The majority of companies stated they use the future revenue approach to calculate value (55%). A market approach was the second most common (22%). Future Revenue Approach was defined as discount to future cash flows, market approach was defined as value of comparative technologies/assets and cost approach was defined as dollars required to bring a product to market.
90% of companies have running royalties provisions. 73% stated over 1/2 of their licenses and 62% stated over 3/4 of their licenses include running royalties. 64% of companies stated that over 1/2 of their licenses and 42% stated 9/10 of their licenses included upfront payments. 66% of companies stated that over 1/2 of their licenses and 45% stated 9/10 of their licenses included milestone payments.
49% of companies have paid out <$25 M, 16% have paid $25- $250 M, and 16% have paid out over $250 M.
(19% DK/Refused - all public companies.)
SUMMARY OF BIOTECH IN-LICENSE NEGOTIATIONS

- 49% of Companies Stated it Typically Takes 3-6 mo. to Complete Negotiations - 31% Stated it Takes 6-12 mo.

- Confidentiality/Publications was Identified as the Easiest Part of Negotiations and Monetary Terms as the Most Difficult

- 55% of the Companies Use Future Revenue Approach and 22% Use Market Approach to Calculate Value

37% of companies said confidentiality was the easiest and 36% stated monetary terms was the hardest part of negotiations. Future Revenue Approach was defined as discount to future cash flows, market approach was defined as value of comparative technologies/assets and cost approach was defined as dollars required to bring a product to market.
• SUMMARY OF BIOTECH IN-LICENSE PAYMENT STRUCTURES

• Majority of Companies Have Payments Based on Milestones, Upfront Payments and Running Royalty Payments in Over 1/2 of License Agreements

• 49% of Companies Have Paid < $25 M in Royalties, 16% Have Paid $25-$250M and 16% Have Paid >$250 M
Biotech In-Licensing With Universities

- BIOTECH IN-LICENSING WITH UNIVERSITIES
  - Exclusive vs. Non-Exclusive
  - Non-Commercial Research Provisions
  - Particular Field of Use Provisions
  - Milestone Provisions
  - Oversight
60% of companies surveyed stated 3/4 of their in-license agreements with universities are exclusive.

21.3% of companies stated less than 1/2 of in-license agreements with universities are exclusive.

5.8% of companies stated that none of their in-license agreements with universities are exclusive.
57% of Companies Stated Exclusive License Agreements With Universities Include Non-Commercial Research Provisions (46% Stated Over 1/2 Include Non-Commercial Research).

53% of Companies Stated Exclusive License Agreements With Universities Include Limited Field of Use Provisions (42% Stated Over 1/2 of License Agreements Include Limited Field of Use).

67.6% of Companies Stated Exclusive License Agreements With Universities Include Milestone With Penalty or Revocations Provisions (59% Stated Over 1/2 of License Agreements Include Milestones).

Only 17% stated they had no exclusive license agreements with universities that did not contain non-commercial research provisions (N/R=27%).
Only 31% stated they had no exclusive license agreements with limited field of use provisions (N/R=16%).
Only 13% stated they had no exclusive license agreements with milestone provisions (N/R=9%).
31% of Companies Have Had a License Revoked, Restricted, Renegotiated or Paid a Penalty Due to Non-Compliance With Milestone Clauses

21% of companies have had a license restricted or renegotiated, 7% have had a license revoked, and 3% have had to pay a penalty due to non-compliance with milestone clauses.
SUMMARY OF BIOTECH IN-LICENSES WITH UNIVERSITIES

- Majority of In-License Agreements are Exclusive But There Are Significant Numbers of Non-Exclusive Licenses
- Majority of In-License Agreements Have Non-Commercial Research Provisions, Milestones with Penalties and Particular Field of Use Provisions
- 31% of Companies Have Had a License Revoked, Restricted, Renegotiated or Paid a Penalty Due to Non-Compliance With Milestone Clauses