



# BIO 2009 Member Survey

*“Technology Transfer & the  
Biotechnology Industry”*



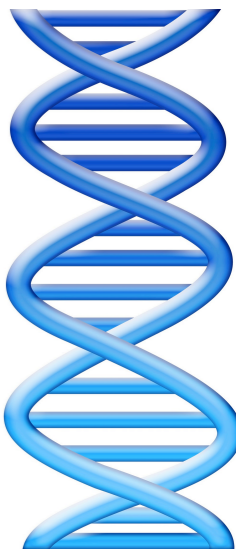
# BIO 2009 Member Survey

## 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.?**

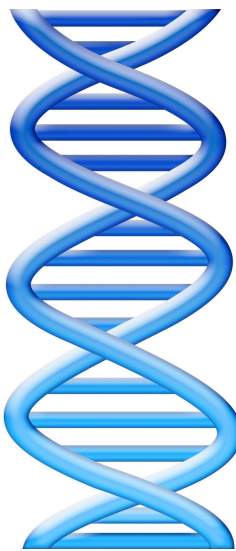


# BIO 2009 Member Survey

## Technology Transfer & the Biotech Industry

### ● 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**



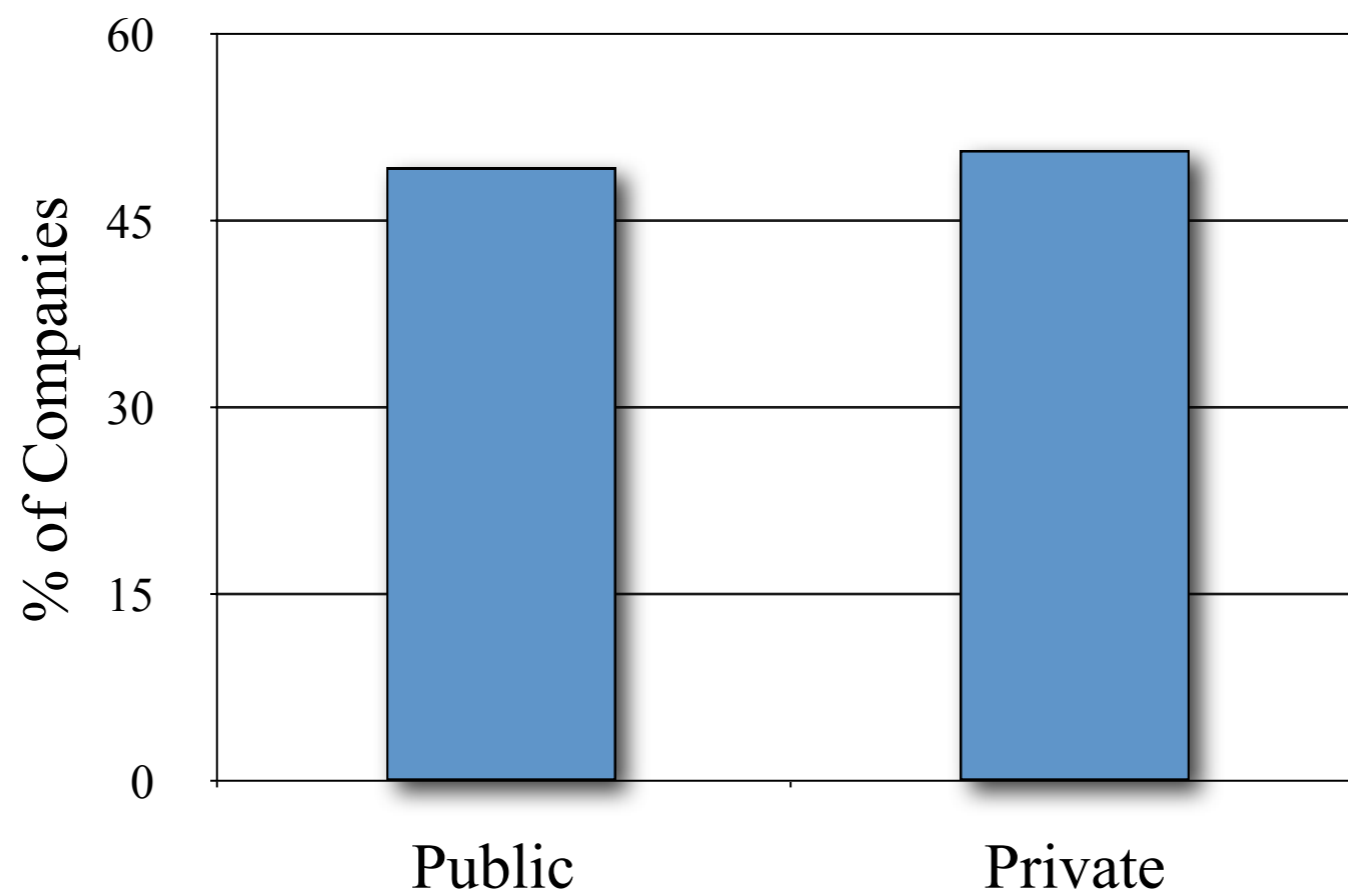
# Profile of Survey Participants

- **PROFILE OF PARTICIPANTS**
  - Company Structure
  - Employees
  - Products
  - Revenues/Assets



# Profile of Survey Participants

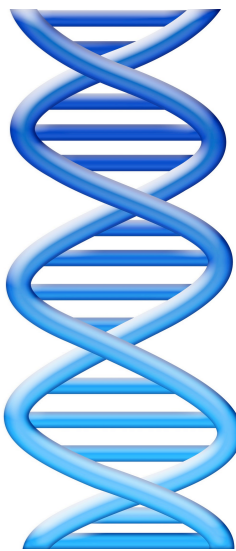
## Is Your Company Public or Private?



Type of Company

N=150 Companies

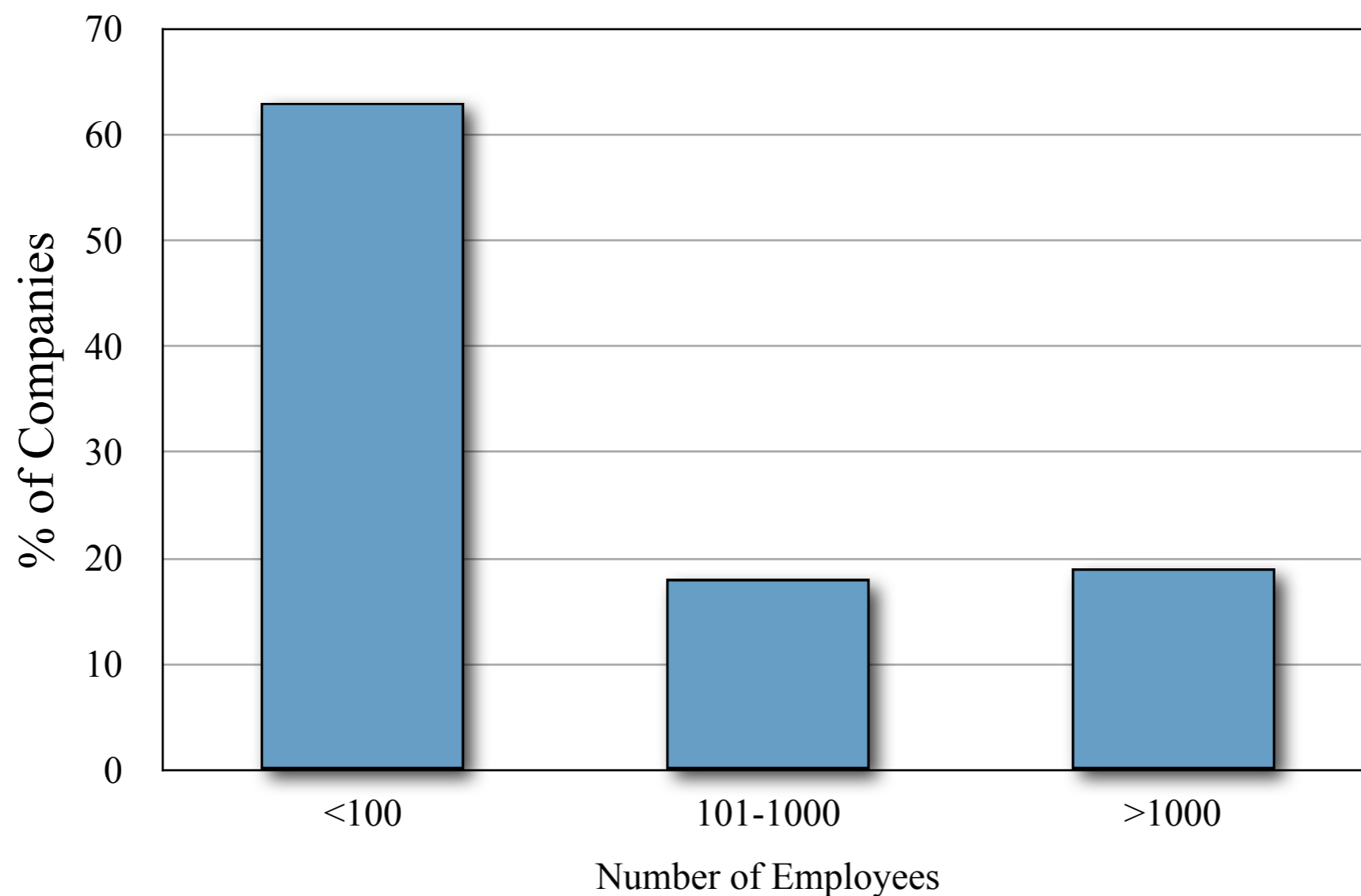
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150 BIO member companies participated in survey.  
49% were public (N=74) and 51% were private (N=76).

# Profile of Survey Participants

**How Many Employees Does Your Company Have?**



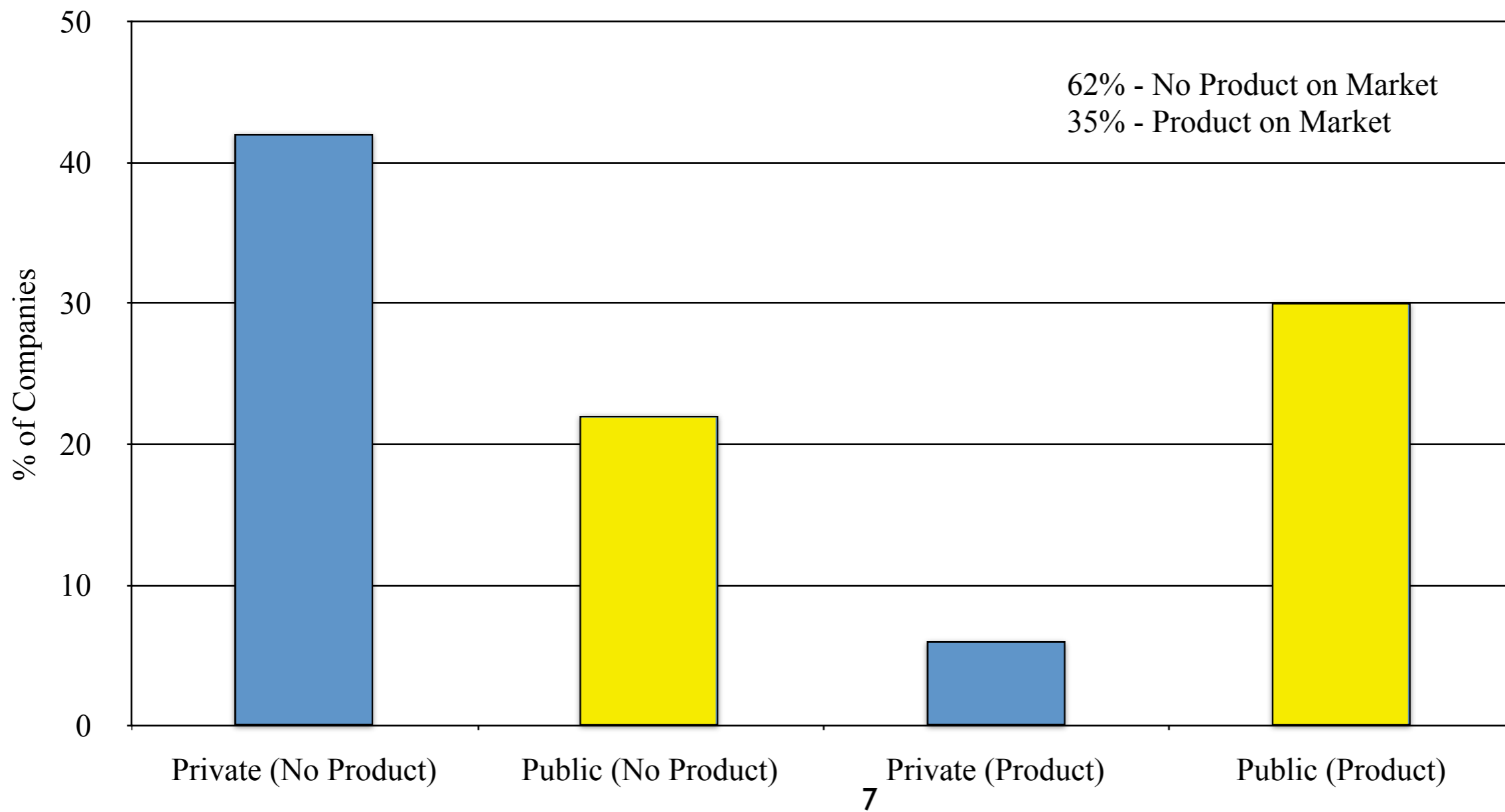
The majority of these companies are small with fewer than 100 employees (63%).

54% had fewer than 50 employees.

19% had over 1000 employees.

# Profile of Survey Participants

**Does Your Company Have a Product on the Market?**



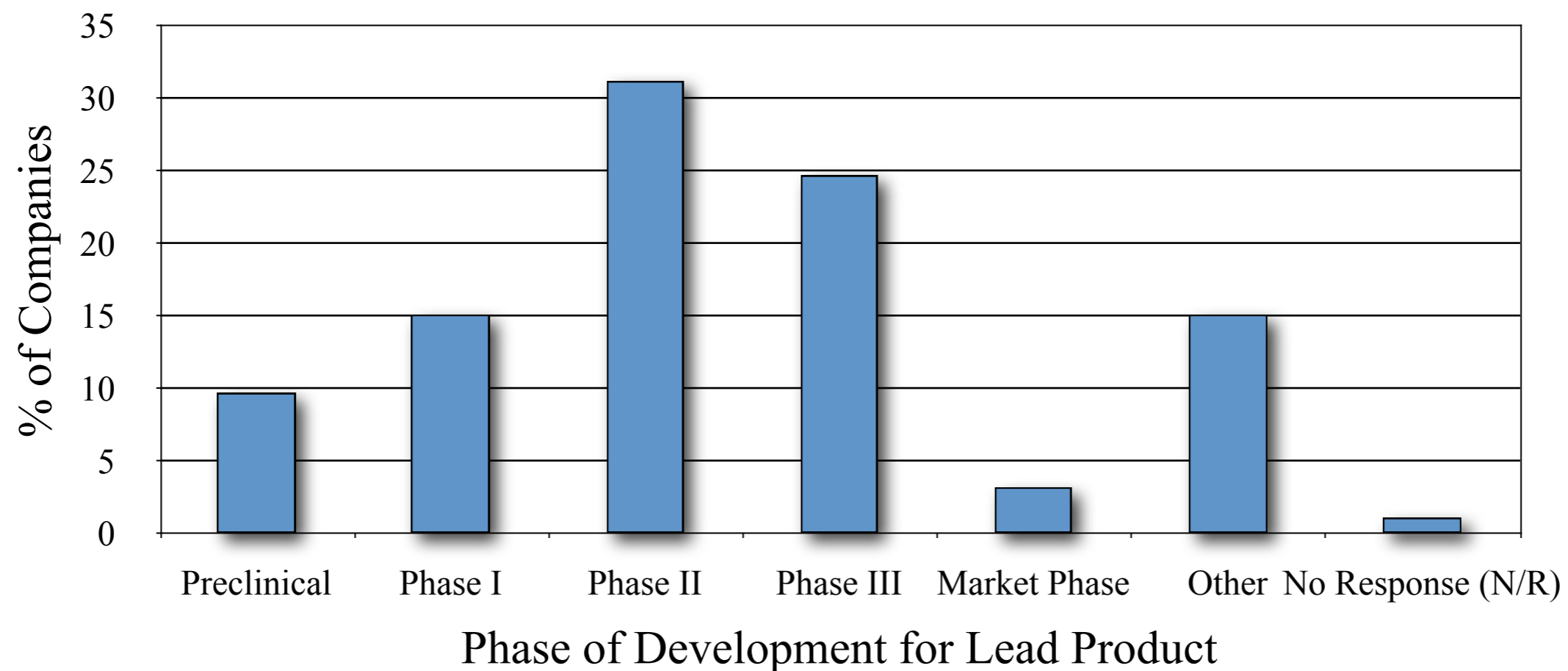
Most (62%) of these companies do not yet have a commercial product (41% were private and 21% were public).

35% have a product on the market (6% were private and 29% were public).

3% gave no response (N/R)

# Profile of Survey Participants

**What Stage of Development is Your Lead Product In? (Companies with No Marketed Product)**

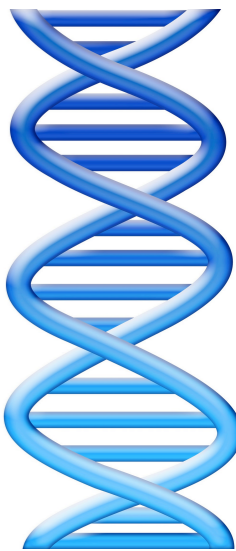
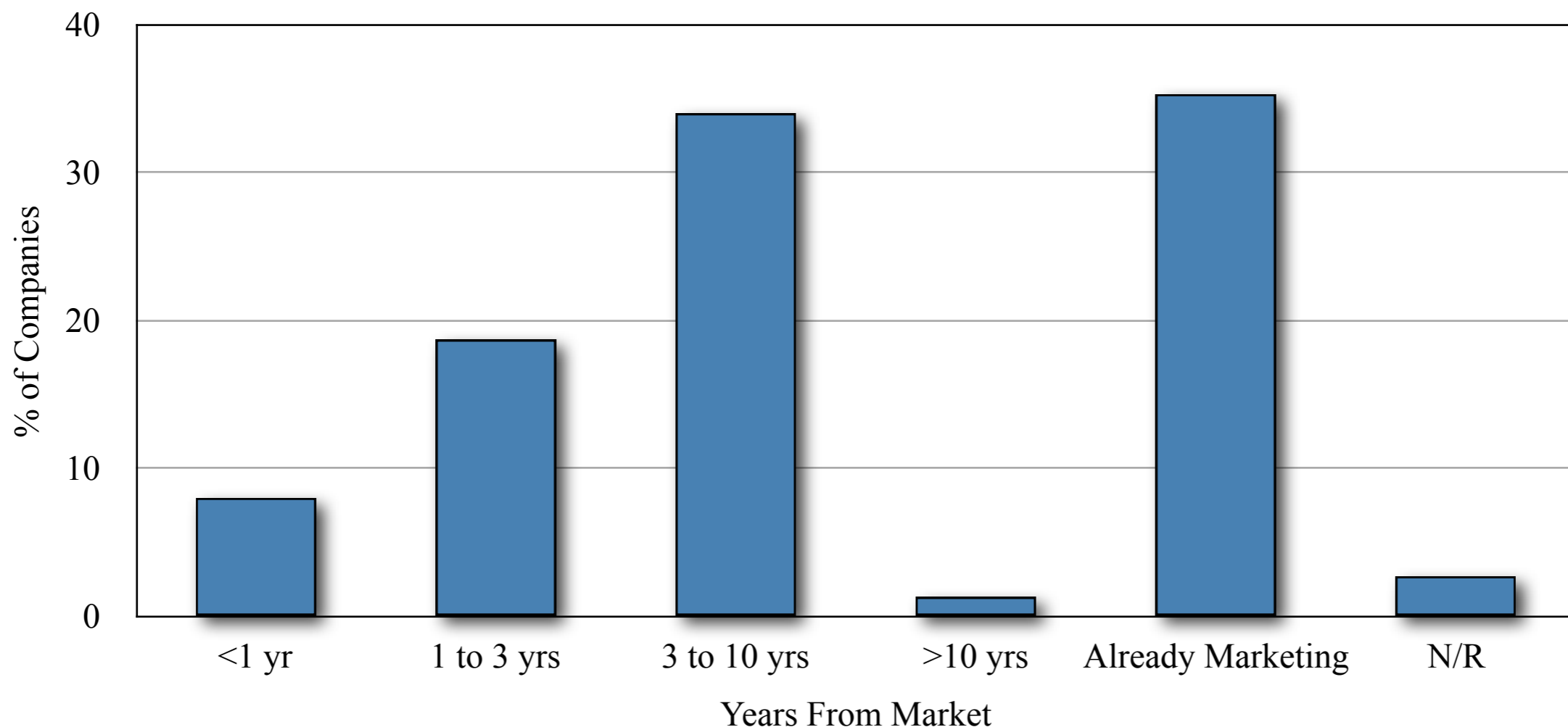


56% of companies have lead products in Phase II and III stages of development.



# Profile of Survey Participants

## How Many Years From Having a Marketed Product?



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.

# Profile of Survey Participants

- **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.

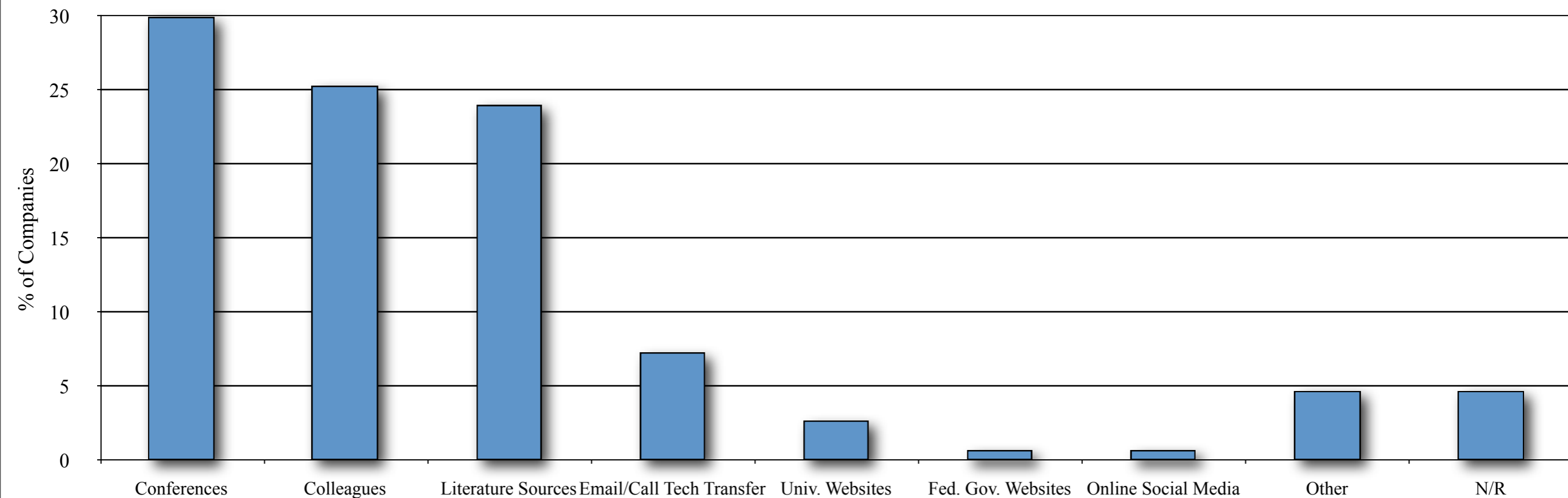
# Biotechnology In-Licensing

- **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



# Finding Biotech In-Licensing Opportunities

## Most Common Method of Identifying Licensing Opportunities

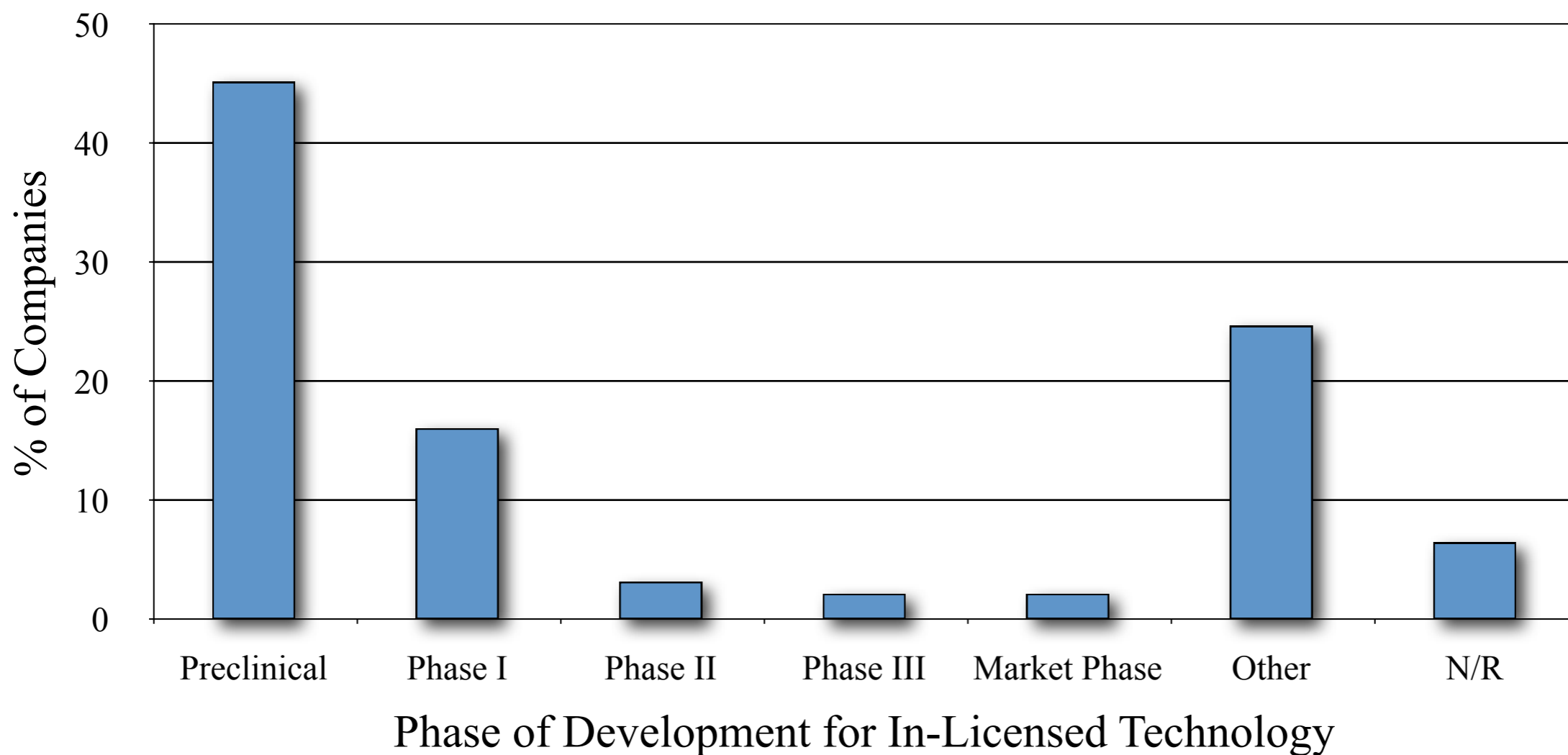


Conferences were the most common method of identifying licensing opportunities (30%) followed by colleagues (25%) and literature sources (24%).

# Biotech In-Licensing

## Companies with No Marketed Product

At What Stage of Development Does Your Company Generally In-License a Product?



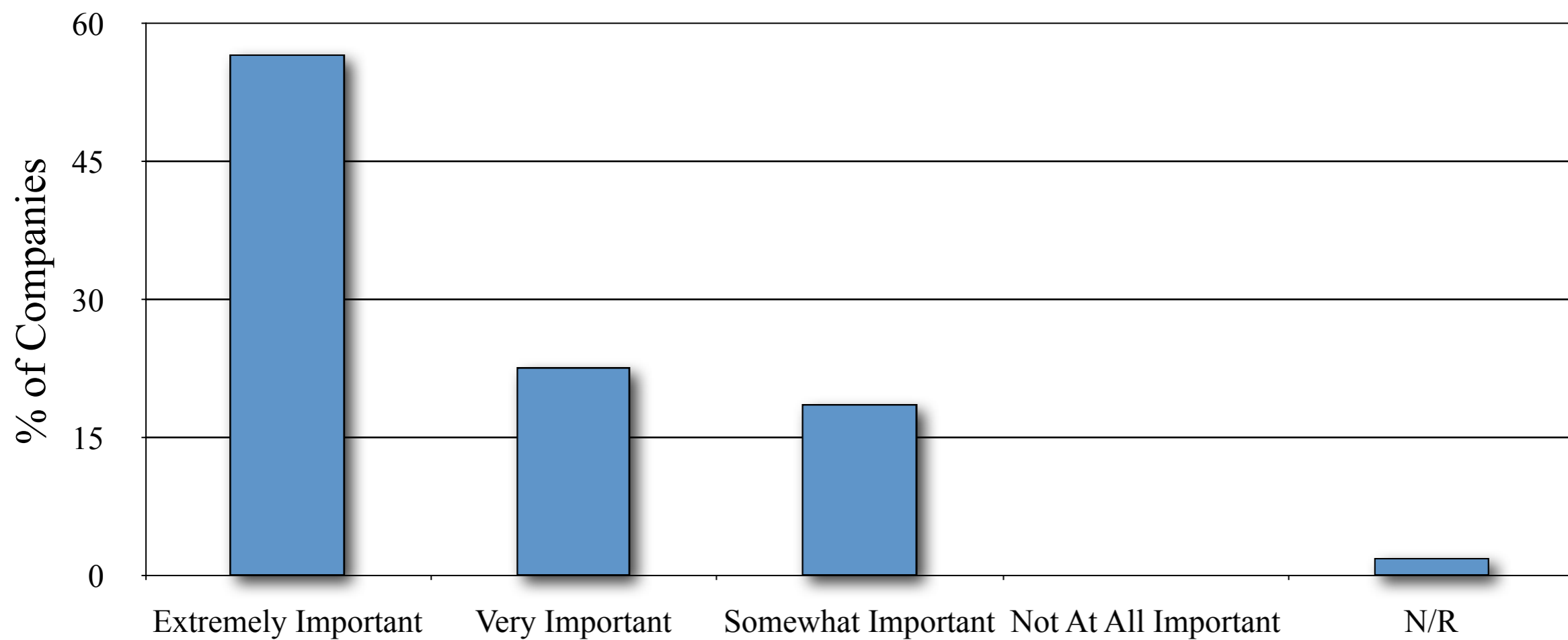
Almost half of the companies obtained a license in the pre-clinical stage (45%).

61% obtained license in preclinical or Phase I stage of development.

NOTE: Other may represent licenses for compounds or manufacturing processes.

# Biotech In-Licensing

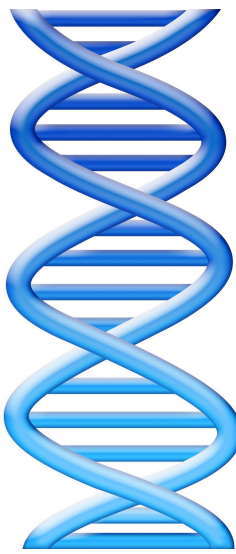
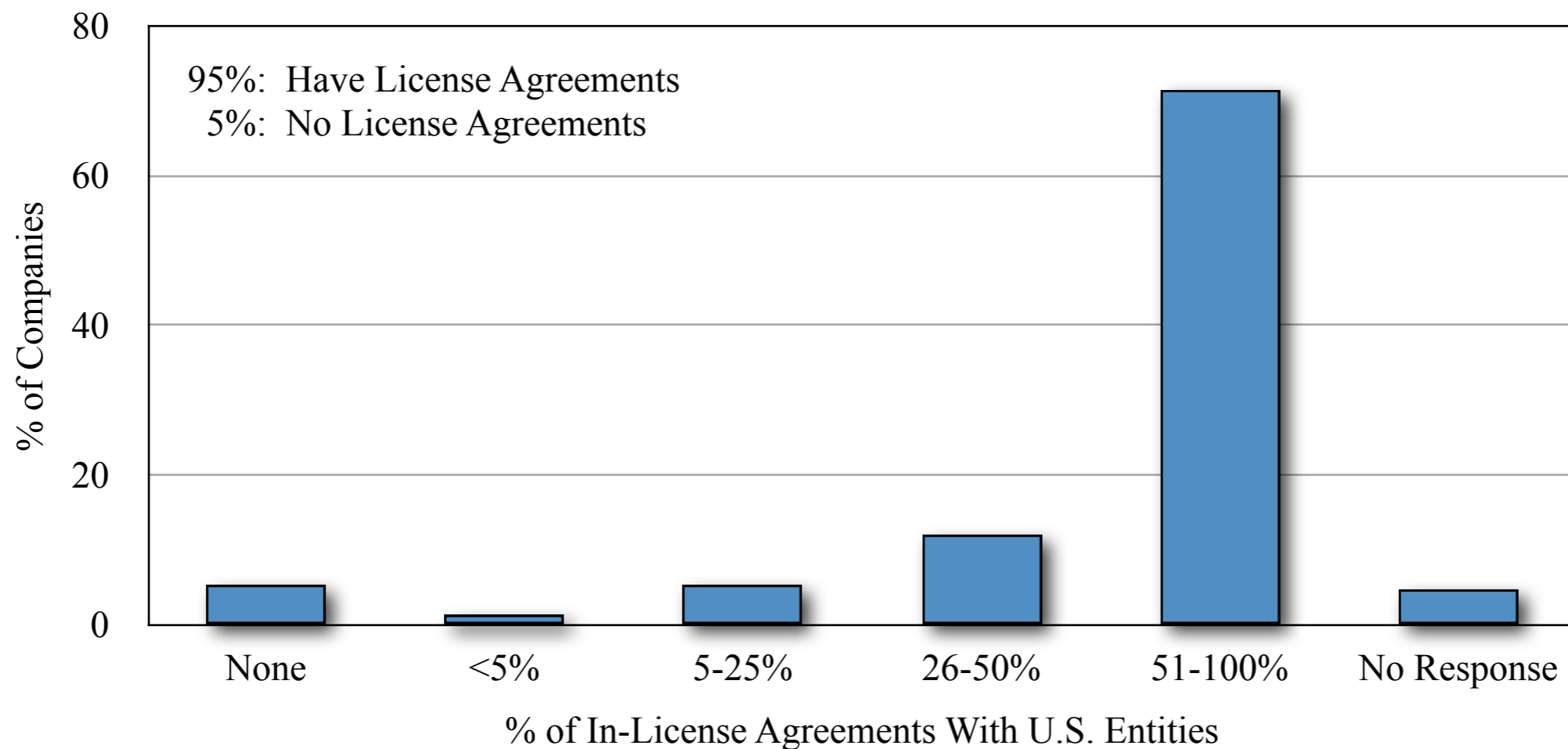
**How Important is Ability to Obtain Exclusive License to Ability to R&D a Commercially Available Product?**



79% of companies surveyed said the ability to obtain an exclusive license is important to their ability to develop a commercially available product.

# Biotech In-Licensing With U.S. Entities

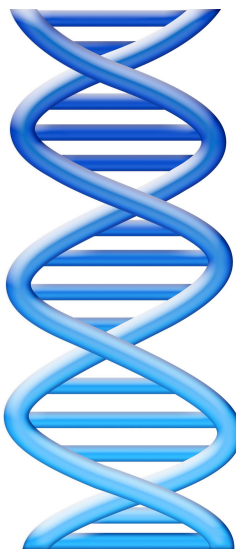
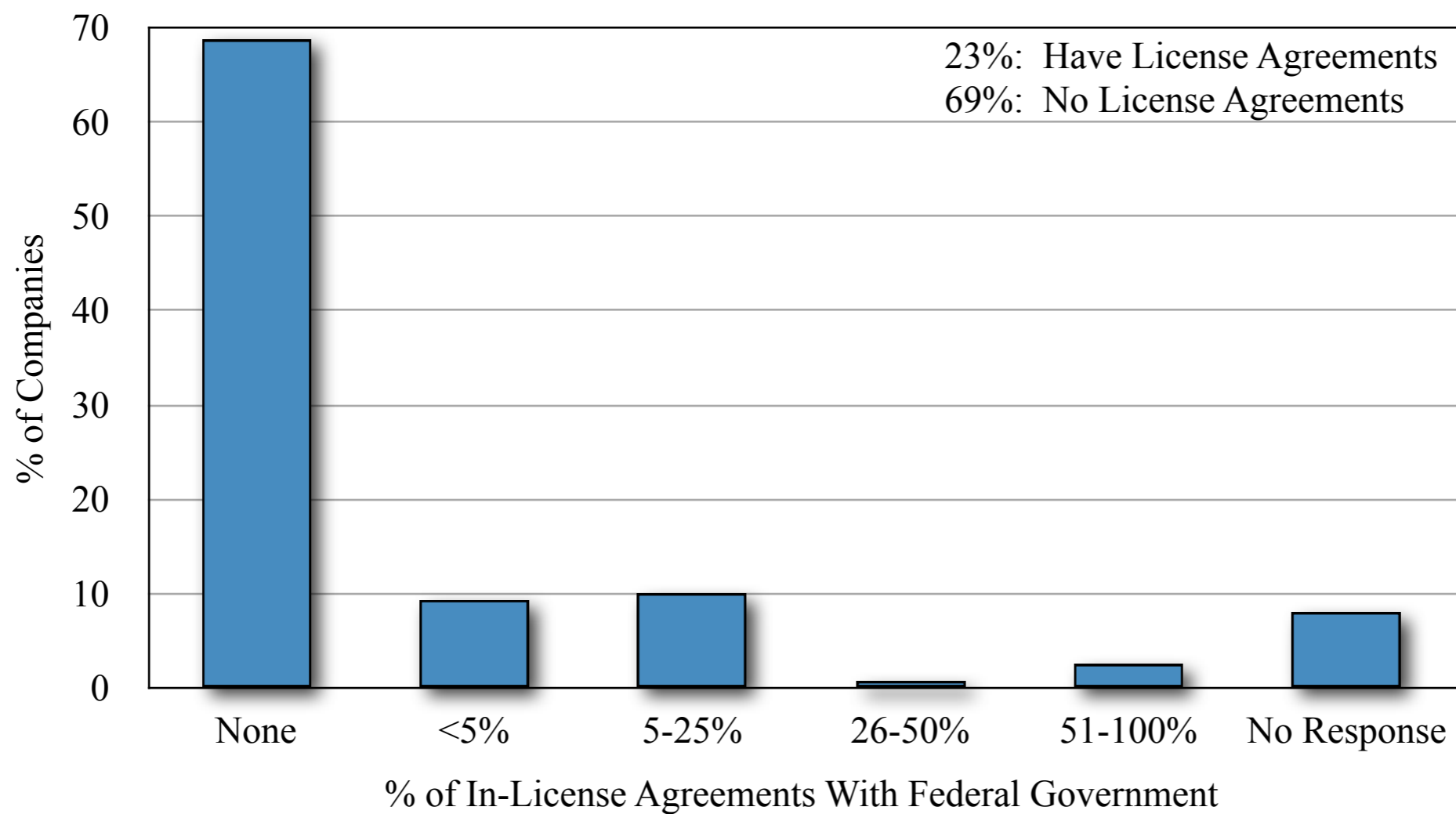
**What % of Company's In-License Agreements Are With U.S. Entities?**



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.

# Biotech In-Licensing With Federal Government

**What % of In-License Agreements Are with Federal Government?**

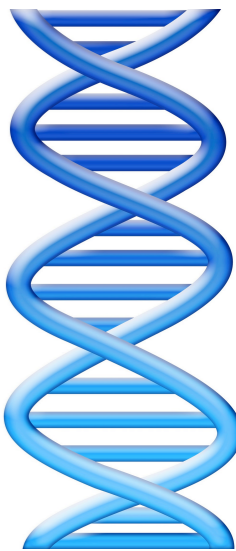
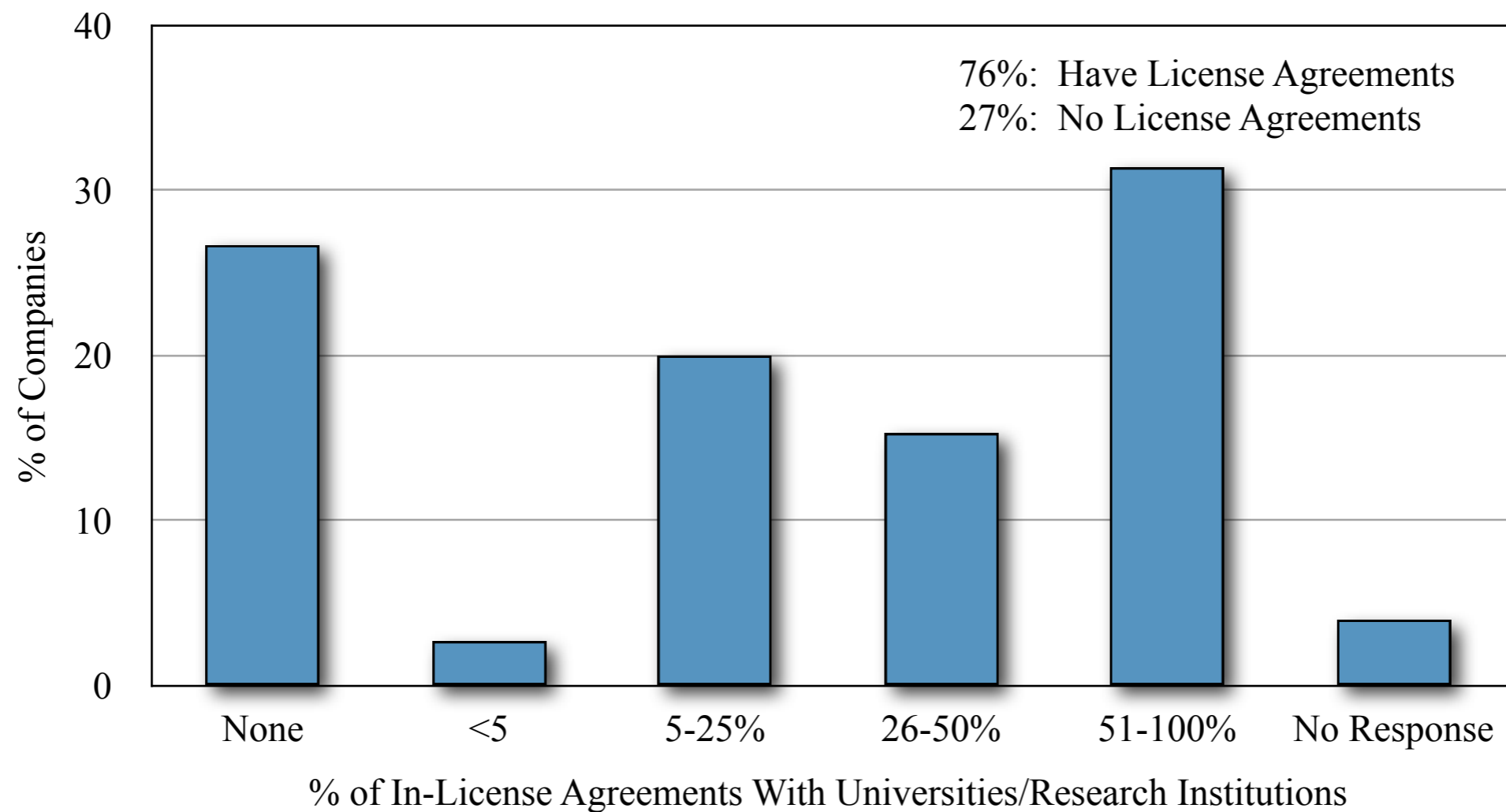


69% of the companies surveyed do not have an in-license agreement with the federal government.  
19% of companies have less than 25% of their in-license agreements with the federal government.



# Biotech In-Licensing With Universities

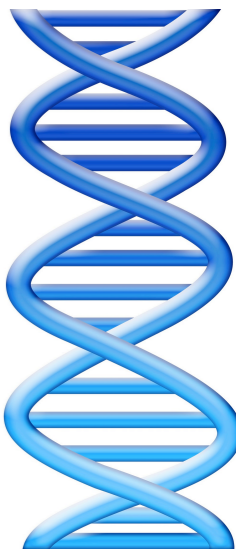
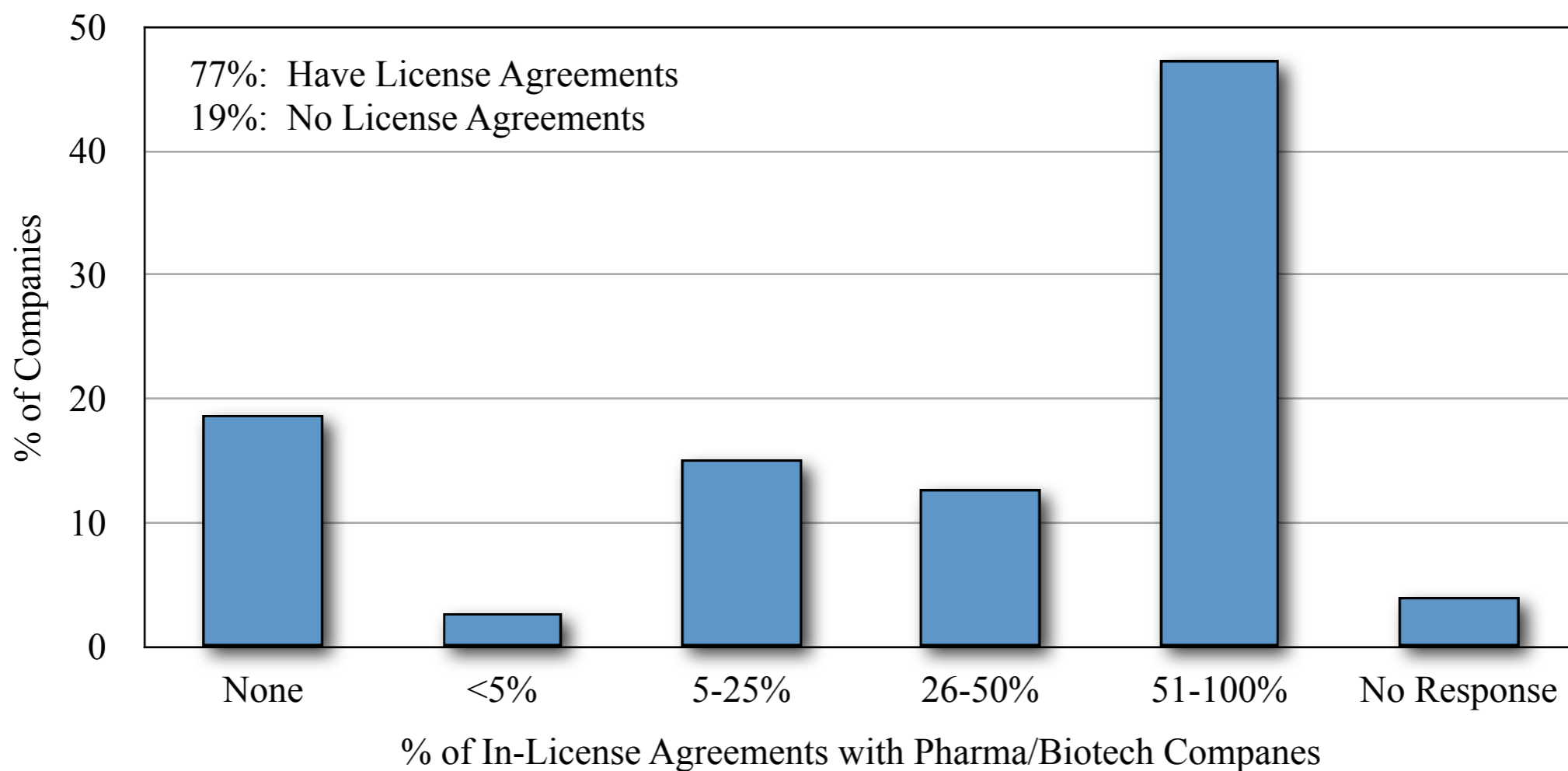
What % of In-License Agreements Are With Universities?



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).

# Biotech In-Licensing With Pharma/Biotech Companies

**What % of In-License Agreements Are With Pharma/Biotech Companies?**



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



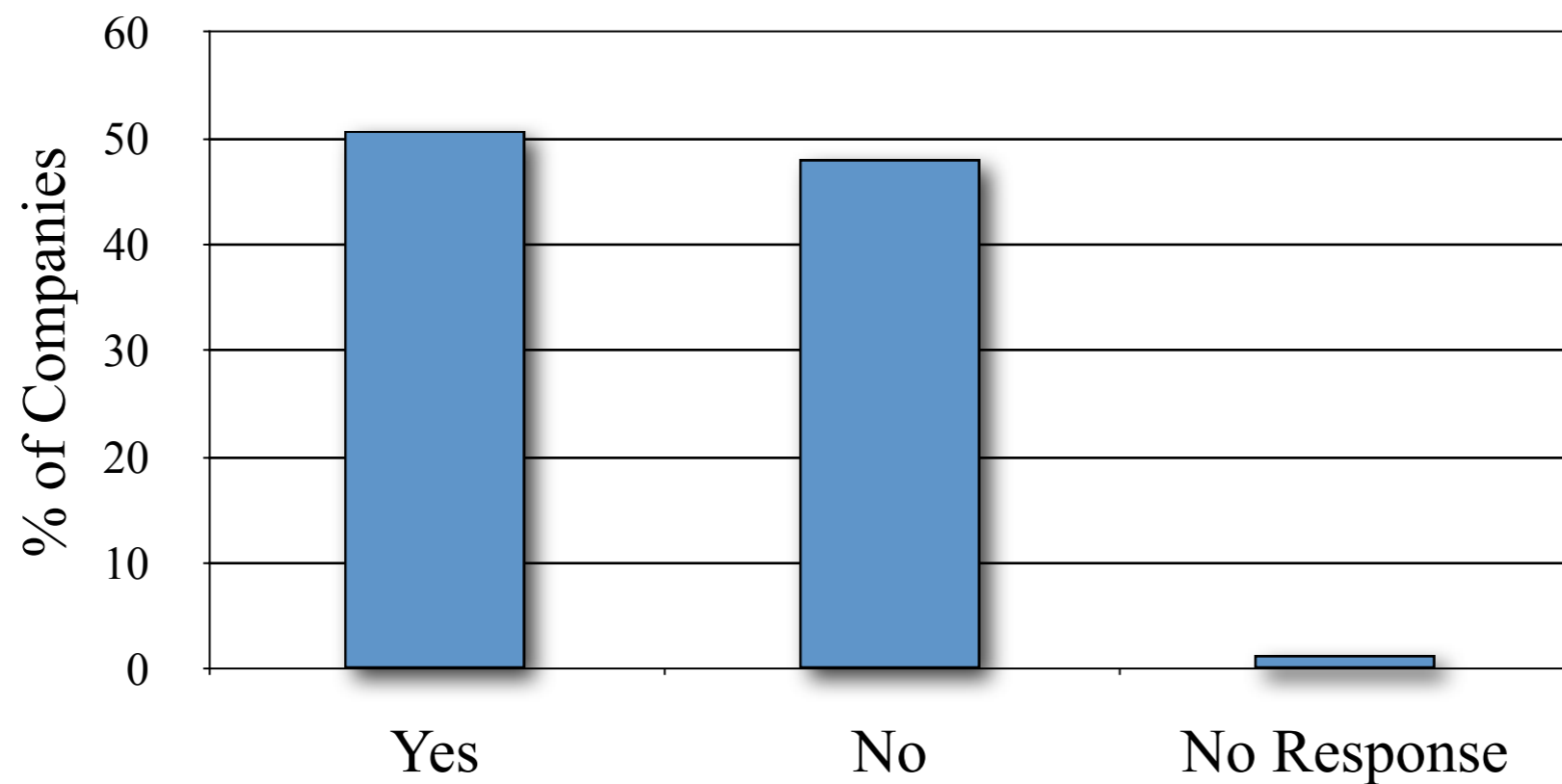
# Impact of In-Licensing on Biotech Industry

- **IMPACT OF IN-LICENSES ON BIOTECH INDUSTRY**
  - Company History
  - Company Resources



# Biotech In-Licensing & Company History

**Was Your Company Founded On the Basis of Obtaining a License Agreement?**



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.

# Biotech In-Licensing & Company History

**Number of Employees Prior to Obtaining 1st Tech Transfer License**

# Employees	<5	<10	6-15	>15	DK/ Refused
All	51.4%	58.1%	10%	12.7%	26%
Private	68.9%	77%	12.2%	8.1%	10.8%
Public	34.2%	39.5%	5.3%	17.1%	40.8%



58.1% of companies had <10 employees prior to obtaining first tech transfer license.

# Biotech In-Licensing & Company History

## Number of Employees Added 1-2 yrs. & 2-5 yrs. After Obtaining 1st Tech Transfer License

# Employees	<10	10-19	20-29	30-39	40-49	50-99	100-199	>200	DK/Refused
All 1-2 yrs	28.7%	20%	8.7%	8%	1.3%	2.7%	4%	2.7%	24%
All 2-5 yrs	19.3%	10%	8%	4%	6%	12.7%	5.3%	6%	28.7%
Private 1-2 yrs.	47.3%	27%	6.8%	9.5%	1.4%	0%	0%	0%	8.1%
Private 2-5 yrs.	32.4%	17.6%	9.5%	4.1%	12.2%	6.8%	1.4%	0%	16.2%
Public 1-2 yrs.	10.5%	13.2%	10.5%	6.6%	1.3%	5.3%	7.9%	5.3%	39.5%
Public 2-5 yrs.	6.6%	2.6%	6.6%	3.9%	0%	18.4%	9.2%	11.8%	40.8%

**2-5 Yrs. After Obtaining License Only 19.3% of Companies had Fewer than 10 Employees**



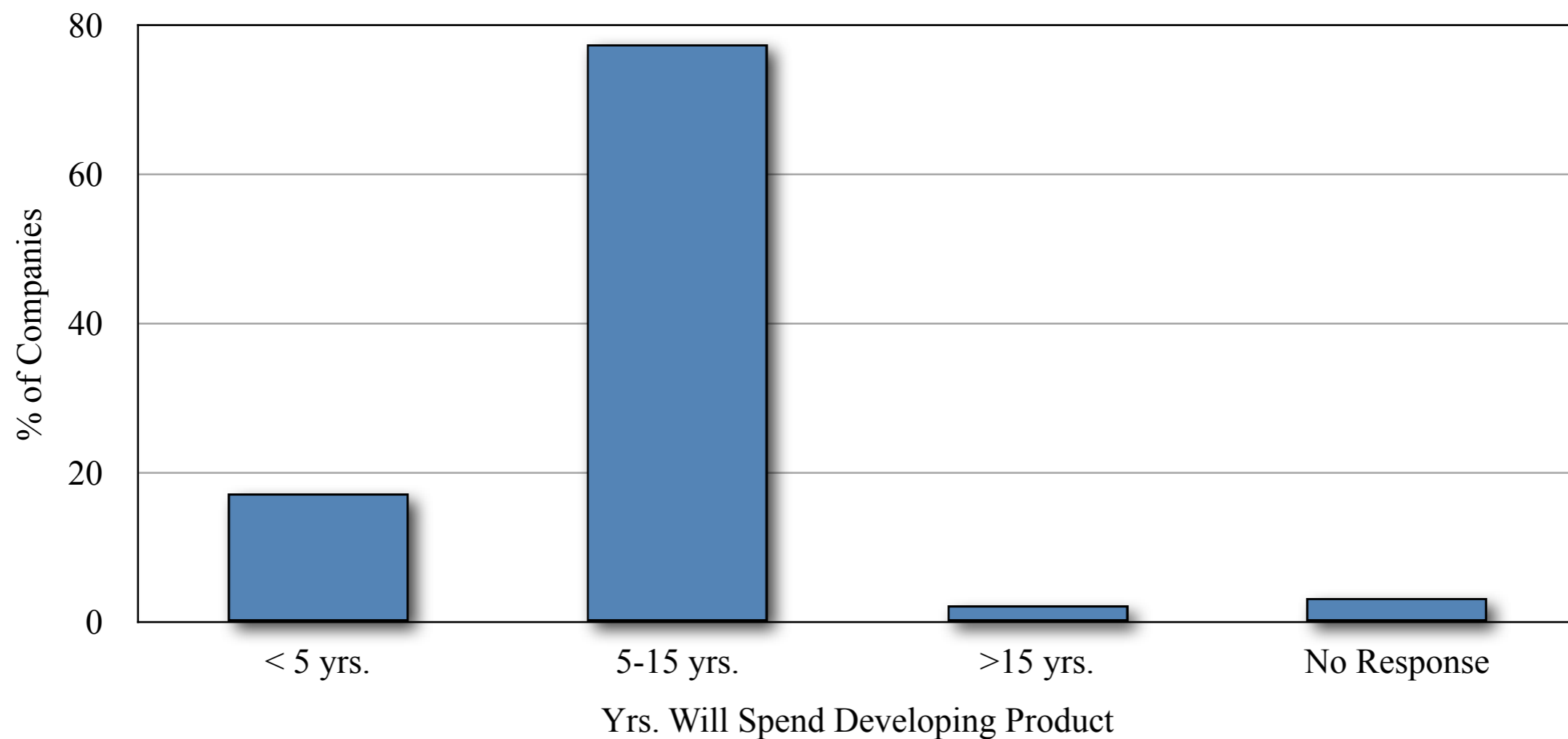
2-5 Yrs. after obtaining license only 19.3% of companies had fewer than 10 employees and 42% had between 10 and 100 employees.



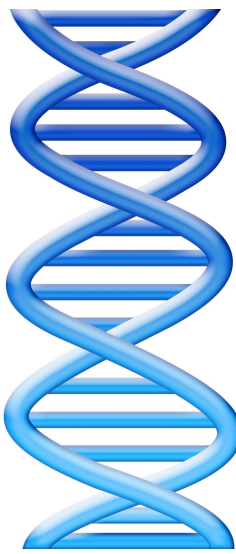
# Biotech In-Licensing & Company Resources

## Companies with No Marketed Product

Avg. # of Yrs. (Projected or Actual) Company Will Spend on R&D for Lead Product from Initial License to Commercialization



**NOTE: Figures Represent Small Molecule, Large Molecule and Diagnostic Lead Products**

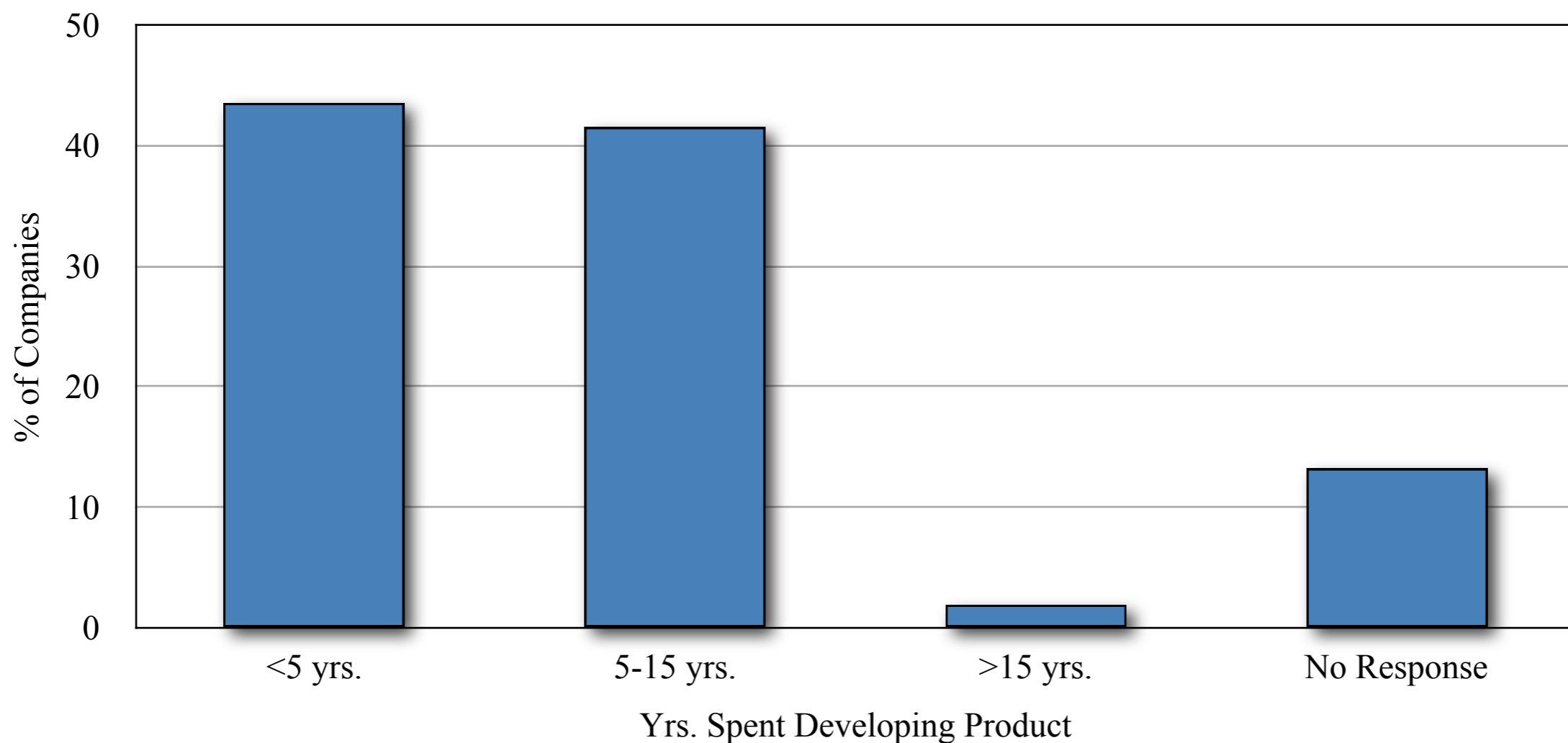


77.4% of companies without a marketed product stated it will take 5-15 yrs. to develop lead product from time of initial product to commercialization.  
17% said it will take 2-5 yrs.

# Biotech In-Licensing & Company Resources

## Companies with a Marketed Product

### Avg. # of Yrs. Spent on R&D for Lead Product from Initial License to Commercialization



**NOTE: Figures Represent Small Molecule, Large Molecule and Diagnostic Lead Products**

26



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**



# Impact of In-Licensing on Biotech Industry

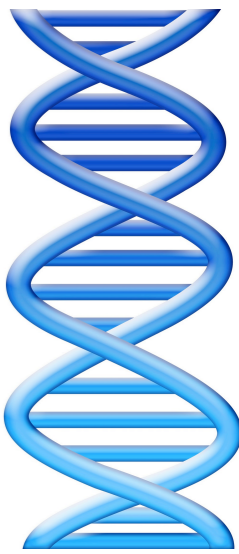
- **SUMMARY IMPACT OF IN-LICENSES ON BIOTECH INDUSTRY**

- 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



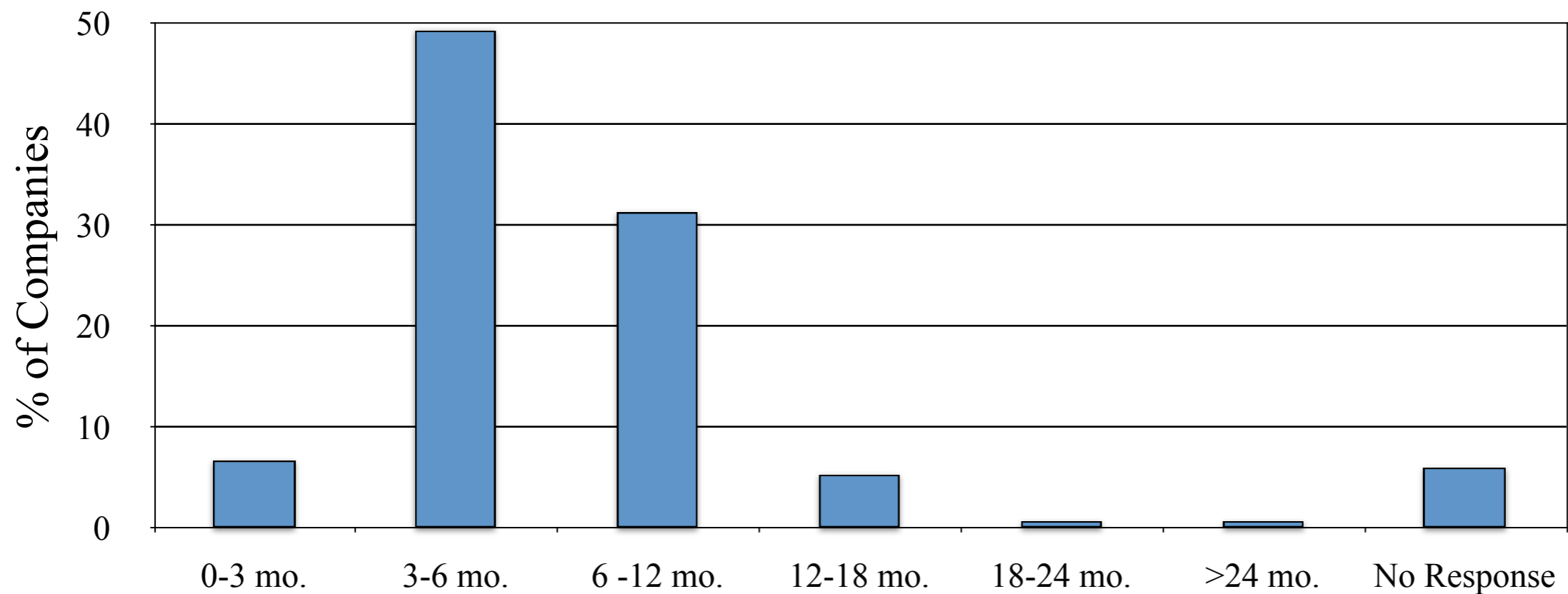
# Biotech In-License Agreements

- **BIOTECH IN-LICENSE AGREEMENTS**
  - Length of Time to Complete Negotiations
  - Hardest/Easiest Part of Negotiations
  - Calculating Value
  - In-License Payment Structures



# Biotech In-Licensing Negotiations

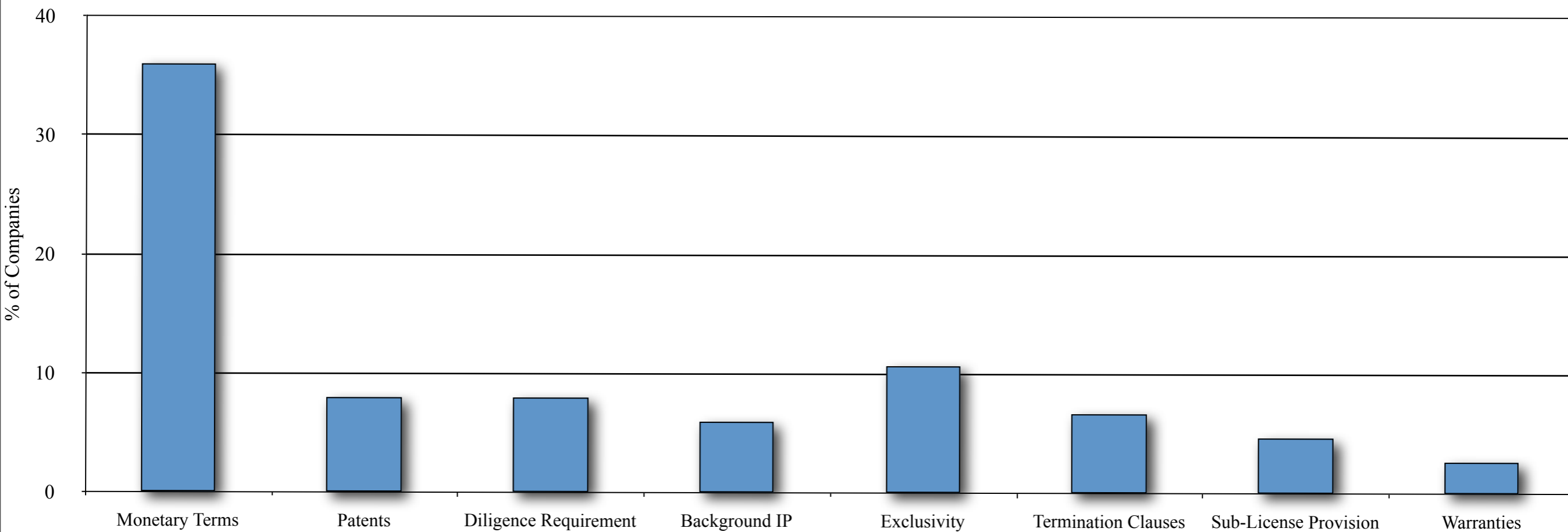
**Avg. Amount of Time to Complete an In-License Agreement**



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%).

# Biotech In-Licensing Negotiations

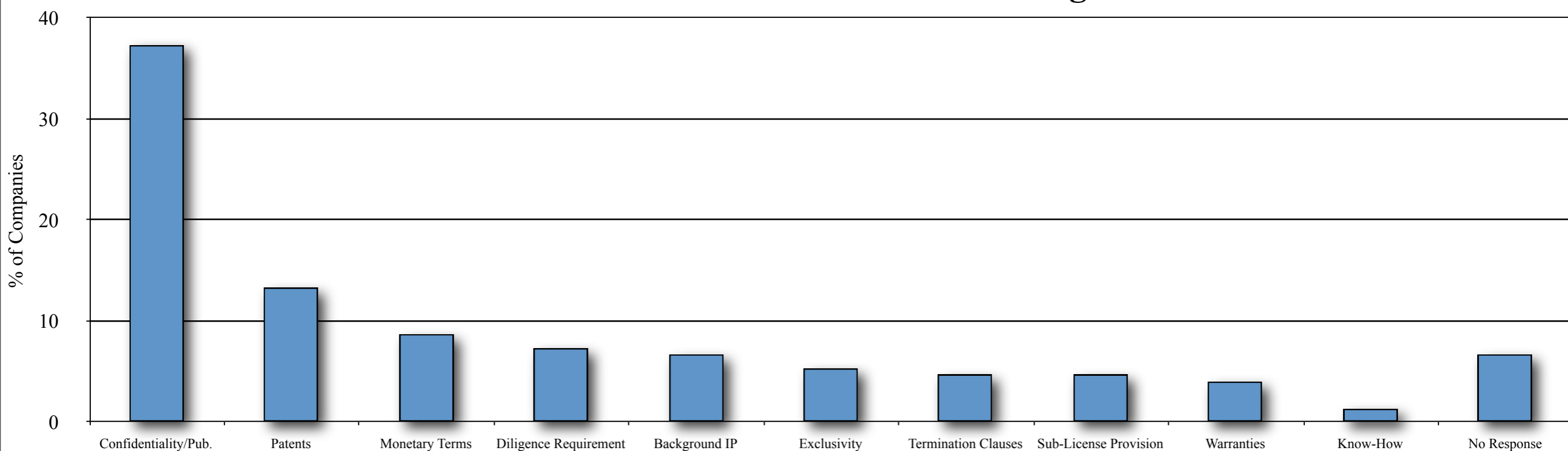
## What is the Hardest Part of In-Licensing Negotiations?



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.

# Biotech In-Licensing Negotiations

## What is the Easiest Part of In-License Negotiations?

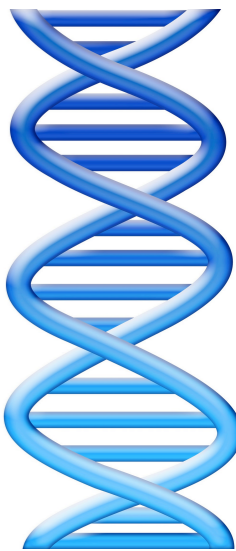
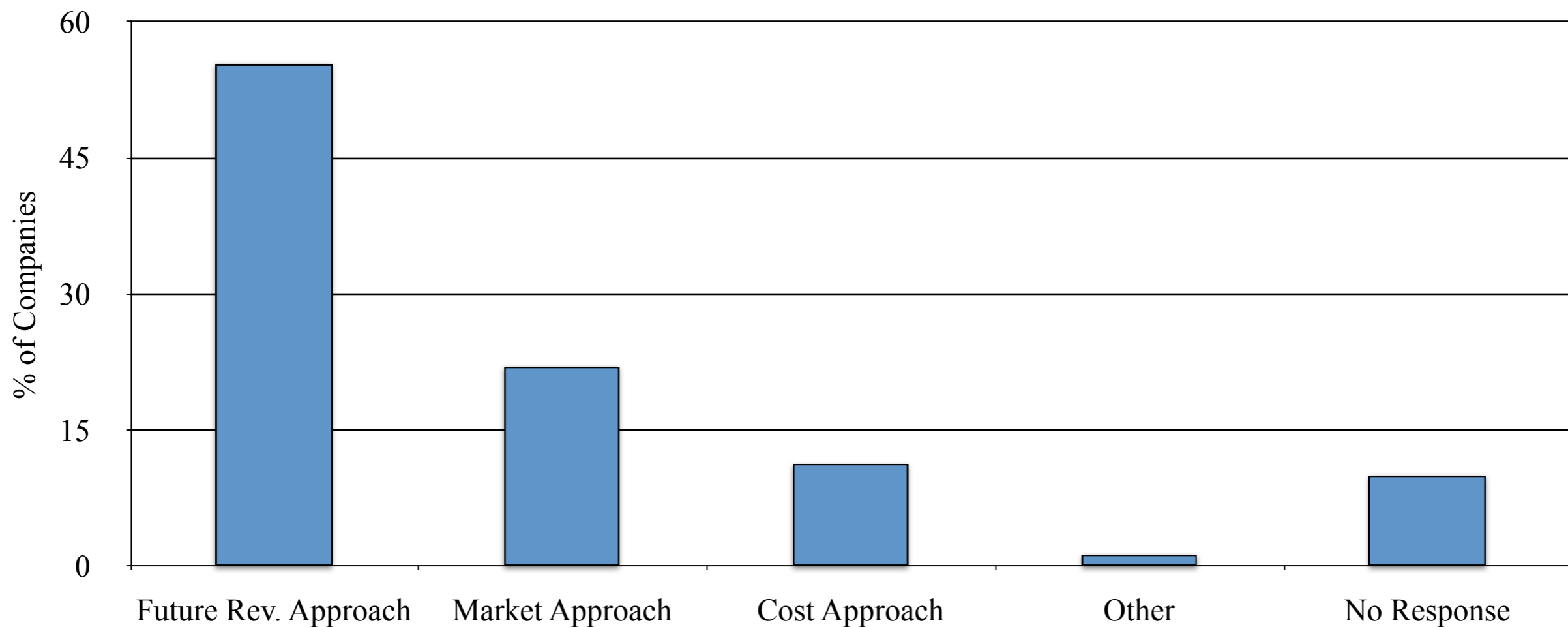


37% of companies stated confidentiality and publications were the easiest part of the negotiations followed by patents (13%).



# Biotech In-Licensing Negotiations

**Metric Your Company Typically Uses to Calculate Value of In-Licensing Opportunity**



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.

# Biotech In-Licensing Payment Structures

## Running Royalties On Product

**73% Stated Over 1/2 of Licenses Include Running Royalties**

## Upfront Payments

**64% Stated Over 1/2 of Licenses Include Upfront Payment**

## Milestone Payments

**66% Stated Over 1/2 of Licenses Include Milestone Payments**



90% of companies have running royalties provisions.

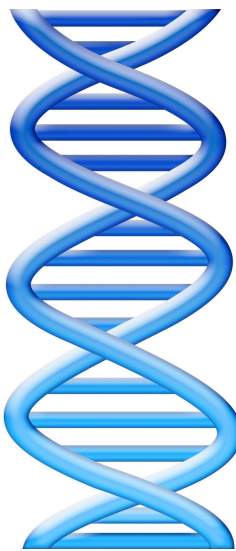
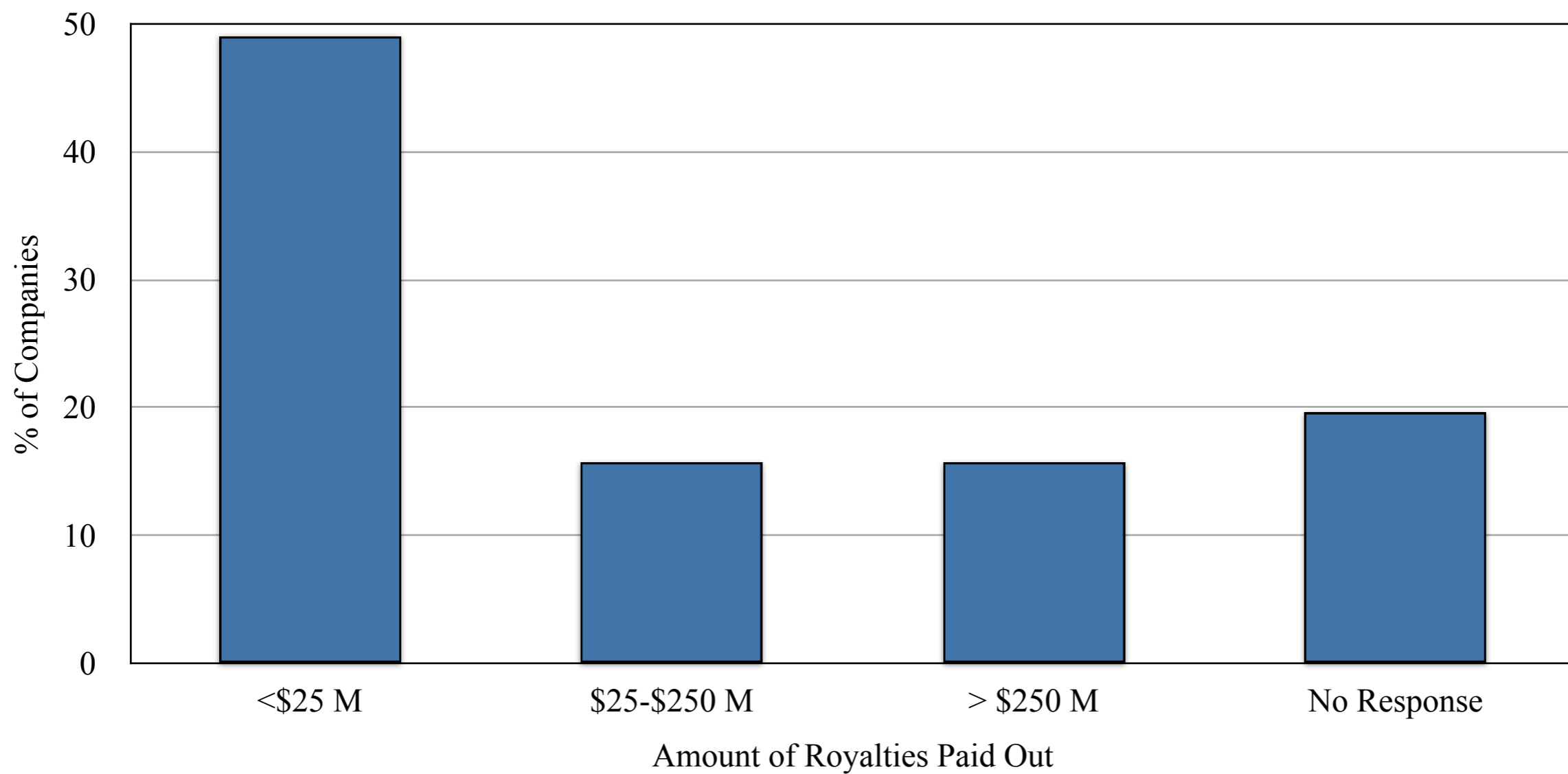
73% stated over 1/2 of their licenses and 62% stated over 3/4 of their licenses include running royalties.

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.

# Biotech In-Licensing Payments

## How Much Has Your Company Paid Out on Royalty 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.)

# Biotech In-License Agreements



- **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.

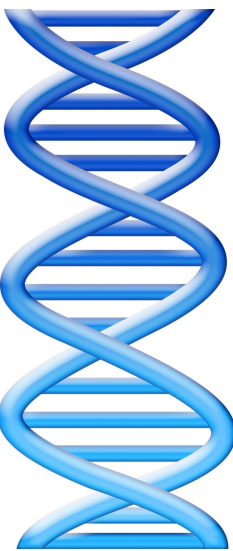
# Biotech In-License Agreements

- **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



# Biotech In-Licensing With Universities

**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.**



# Biotech In-Licensing With Universities

**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%)



# Oversight of Biotech In-Licensing

**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.

# Biotech In-Licensing With Universities

- **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 w/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

