

BIO 2009 MEMBER SURVEY
TECHNOLOGY TRANSFER AND THE BIOTECHNOLOGY INDUSTRY

The purpose of this survey was to examine the extent and importance of technology transfer and licensing activity involving biotechnology companies. The survey contains information on the types of licensing partners, the structure and characteristics of in-license agreements, and the impact of technology transfer on the industry. This survey was designed to help the biotechnology industry; federal, state and local governments; and universities have a productive dialogue on how best to preserve and enhance effective technology transfer in the United States.

Profile of Survey Participants

The survey consists of responses from 150 biotechnology companies in the therapeutic and diagnostic healthcare industry. Like the membership of the Biotechnology Industry Organization (BIO), most of these companies were small (fewer than 100 employees), with no approved product on the market and still several years away from successful commercialization. The respondents were roughly evenly split between public and private companies.

Data on Biotechnology In-Licenses

Survey responses show that in-licensing activity generally occurs very early in the product development lifecycle. The majority of companies (61%) stated they generally in-license products/projects that are in the pre-clinical or Phase I stage of development, and thus still require substantial R&D investment and commercialization risk by the licensee. In fact, a substantial majority (77%) of respondents without approved products indicated that they expect to spend 5-15 years developing the in-licensed technology into a commercially-available product.

Survey responses also show that university-industry and industry-industry partnerships are flourishing, while licensing between industry and the federal government is remarkably low. The vast majority of biotechnology companies' in-license agreements are with universities (76%) and pharmaceutical/biotechnology companies (77%). In stark contrast, the vast majority of those companies surveyed (69%) stated they do *not* have any license agreements with the federal government. Notably, 71% of respondents indicated that they have more than half of their in-license agreements with U.S.-based entities, reflecting U.S. leadership in technology transfer and biotechnology innovation.

Additionally, the survey responses show the need for flexible licensing opportunities, including the ability to obtain exclusive licenses where necessary. A large majority of companies (79%) stated that the ability to obtain an exclusive license where appropriate is critical to their ability to research, develop, and commercialize a product.

Impact of Technology Transfer on Biotech Start-Ups

Survey responses demonstrate the importance of technology transfer to the creation of biotechnology start-ups and local economic development efforts. Half of the companies surveyed stated they were founded on the basis of obtaining an in-license agreement. Additionally, just two to five years after obtaining their first in-license agreement, the companies reported significant job growth.

- Prior to obtaining an in-license agreement, 58% of the companies had less than 10 employees
- 2-5 years after obtaining the first in-license agreement, the number of companies with less than 10 employees dropped to 19%, and 42% had 10-100 employees

Structure and Oversight of Biotechnology Industry In-License Agreements with Universities

Survey responses demonstrate that university-industry license agreements are structured in a way to ensure progress is made towards commercialization without negatively impacting future research or the licensing of the same technology for other potential purposes. The majority of these in-license agreements include development and commercialization milestones, and non-commercial research and particular field of use provisions.

- 57% of respondents stated that their exclusive in-license agreements with universities include non-commercial research provisions (46% stated that more than 50% of their in-licenses with universities contain such provisions)
- 53% of respondents stated that their exclusive in-license agreements with universities include limited field of use provisions (42% stated that more than 50% of in-licenses with universities contain such provisions)
- 68% of respondents stated that their exclusive in-license agreements with universities include milestone clauses with penalties/revocation provisions (59% stated that more than 50% of in-license agreements with universities contain such provisions)

The survey data also shows that universities are actively monitoring and engaging with licensees to ensure compliance with milestone provisions. Roughly 31% of respondents indicated that they had a university licensor revoke, restrict or renegotiate a license or impose a financial penalty.

This data supports the conclusion that the vast majority of biotech licensees are effectively carrying out their obligations with respect to R&D and commercialization efforts.