

## Revenue Recognition for Collaborative Arrangements in the Biotechnology Industry

### Executive summary

At a fundamental level, the biotechnology industry is engaging in the commercialization of cutting edge science. As scientific progress is a serendipitous endeavor, biotechnology companies will collaborate with one another to pursue their research and development objectives. Furthermore, collaborative arrangements provide an opportunity for specialization so that small biotechnology companies may focus on scientific innovation while a larger company may have greater expertise in downstream clinical trial management. These agreements involve financial arrangements often with the combination of upfront payments, payments for achieved milestones, or reimbursements for research and development undertaken. These agreements are pervasive throughout the industry with duration ranging from several years to indefinite.

Due to the capital intensive nature of bringing a new therapy to market, collaborative agreements for the biotechnology industry are a highly popular mechanism to finance the development of new therapeutics. Collaborations, in which a small biotechnology company and a larger company typically agree to share technology, research costs, and resulting profits, are a common way to access additional funding and commercialization networks. Biotechnology research and development has a long and arduous road. Biotechnology companies are often lacking funds for research and development of early stage products. It takes an estimated 8 to 12 years to bring a biotechnology therapy to market and costs between \$800 million and \$1.2 billion.<sup>1</sup>

Indeed, the number of collaborative agreements that are over \$100 million has substantially increased over the last several years providing financing for the development of new therapeutics.<sup>2</sup> Accordingly, the revenue recognition of collaborations substantially impacts valuation for these companies and its investors. Thus, biotechnology companies are concerned that the current revenue recognition rules on collaborative agreements do not accurately reflect the underlying economics of these agreements. Furthermore, the lack of guidance by accounting standard setters increases the likelihood of the occurrence of restatements which can often shake investor confidence and increase costs to the company.

This study analyzes the impact of current accounting rules on collaborative agreements for 25 representative biotechnology companies followed by recommendations to accounting standard setters. Also, the study provides recommendations on how biotechnology companies could navigate revenue recognition of collaborations under the current rules.

<sup>1</sup>Tufts Center for the Study of Drug Development, *Impact Report*; Volume 8, Number 6, November/December 2006.

<sup>2</sup>Recombinant Capital (RECAP), *The Latest Trends in Biotech Business*, May 7, 2008.



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## State of current accounting

Revenue recognition is the most difficult area of accounting to do accurately. Glass Lewis' data on restatements show revenue recognition errors to be a leading cause of restatements year after year. Revenue recognition accounting is even more difficult for smaller biotechnology companies whose complex research contracts must be paired with equally complex accounting rules. Factor in the limited accounting resources of these companies and the task becomes troublesome indeed.

At the core of the accounting complexity are the varying rules for determining each aspect of a collaborative arrangement. To muddy matters further, the legal contract may call for varying types of payments for which the timing and amount cannot be determined when the contract is executed. Nonetheless, accounting rules for collaborative arrangements require the multiple elements of a contract to be evaluated individually. It is not as simple as assuming a nonrefundable payment received from a R&D partner should be recorded as revenue when the cash is first received. Nor is it as simple as spreading the revenue evenly over the term of the collaboration agreement. Often, specific contract terms or durations are open-ended and the descriptions of the services or deliverables to be provided are nebulous at best.

With the lack of any overarching accounting rules, companies resort to a hodgepodge of guidelines, many of which were not written with the biotechnology industry in mind. The SEC has issued piecemeal accounting guidance and recommendations, often taking the form of comment letters to specific companies or speeches at annual American Institute of Certified Public Accountants (AICPA) conferences. Although the Financial Accounting Standards Board (FASB) recently issued some much needed guidance, it remains unclear as to whether such guidance is sufficiently helpful.

The state of revenue recognition accounting for biotechnology companies' collaborative agreements is still much like throwing a dart in the dark -- hope for a bulls-eye, but be satisfied with just hitting the board. Miss the dart board with incorrect accounting, and a company could end up with a SEC inquiry or a restatement. Revenue-related restatements shake investor confidence in the reliability of the financial disclosures and also consume huge amounts of management time while diverting company attention away from research activities. Affymax Inc. and Curis Inc. are just two examples of companies running into problems because of revenue recognition. Affymax's initial public offering was delayed while the company evaluated its revenue recognition for joint steering committees. Curis restated its financials based on SEC comment letters regarding its revenue recognition.



## Key findings

In a sample of 25 biotechnology companies,<sup>3</sup> the study found 60 active revenue-related collaborations. Despite collaborations being common practice among biotechnology companies, the study found:

- Different accounting methods were used to account for similar aspects of collaborations. The differences caused wide variations in the timing of revenue being recognized in the income statement. Such diversity could be attributed both to contract nuances and differences in management’s judgment.
- The majority of companies deferred recognition for partnering payments and recognized the revenue over the life of the collaboration.
- The timing of revenue recognition varies widely. Most companies in the sample wait to recognize, or defer, revenue until after cash has been received. Companies chose different periods over which to defer and amortize revenue based on their evaluation of the collaborative efforts they are required to perform. The amortization period in the sample ranged from 18 months to more than 18 years.

Determining the required tasks, or revenue deliverables, has prompted numerous restatements and continues to be a sticking point between companies and the Securities and Exchange Commission (SEC). The SEC has been looking at revenue recognition at biotechnology companies and causing some companies to rethink their previous accounting.

- In 2007, the biotechnology and drug industry ranked third, out of 15 industry groupings, for the highest number of restatements.<sup>4</sup> Even though biotechnology investors primarily focus on research progress and available cash, revenue-related restatements still shake confidence in the reliability of the financial statements. Most importantly, a restatement diverts management’s focus away from the primary task at hand – new research and development.
- The SEC is actively looking at milestone revenue recognition for biotechnology companies, large and small. Specifically, the SEC is scrutinizing a company’s determination of “substantive vs. non-substantive” milestones and the corresponding impact to revenue recognition for up-front and/or milestone payments.

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<sup>3</sup> The Biotechnology Industry Organization (BIO) selected 25 representative biotechnology companies for the Glass Lewis & Co. (Glass Lewis) study.

<sup>4</sup> Glass Lewis & Co. LLC 2008 Trend Alert on restatements: *Out of Sight, Out of Mind*.



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## **Recommendations to accounting standard-setters**

The SEC and Financial Accounting Standards Board (FASB) are deliberating more rules and guidance for recognizing revenue from collaborations. Convergence with international accounting rules bears monitoring as well since these standards are based more on principles than specific guidance particularly for revenue recognition. Glass Lewis recommends the accounting rule-makers consider the following:

- Reconsider whether Joint Steering Committee (JSC) participation is a material or substantive component to revenue recognition criteria. To improve the accounting for JSCs, participation in a JSC should only be considered a substantive deliverable if a company is incentivized to participate either through payment for services or detriments for nonparticipation.
- Reinterpret the relevant accounting rules. The SEC's interpretation of revenue recognition in the biotechnology industry is prompting modifications to contractual language in order to avoid the JSC issue. Additional contract language can change the accounting outcome without changing the collaboration, but the debate about a JSC's role continues to be an issue for existing collaborations.
- Given the wide range of duties a JSC will undertake as well as the vast array of collaborations, any attempt to assign a fair value to a JSC is unrealistic.
- Require companies to provide enhanced financial disclosures detailing a company's obligations, cash receipts, research progress, and future expectations, including risks that would change expectations.
- Provide additional guidance for recognizing revenue when contracts include multiple revenue-generating elements.

Revenue accounting should reflect the economics of a transaction. Waiting to recognize revenue until the end of a collaboration is not the best answer. Parsing over technical accounting minutiae regarding JSC participation has little impact on the economics of collaboration for investors.

## **Recommendations for biotechnology companies**

Until the accounting rules either change or the rule-makers provide more guidance, biotechnology companies could prevent errors in their financial statements by:

- Define an end date to the collaboration.
- Use a JSC opt-out clause in the agreement, if appropriate and substantive.



- If the nature of a JSC is determined to be substantive, assume there is a single unit of accounting and apply the appropriate accounting.
- Document the rationale and assumptions used to determine the accounting treatment.
- Evaluate the nature of each milestone to determine if it is substantive. This is especially critical if revenue is linked to individual milestones.
- Provide investors with enhanced financial statement disclosures about ongoing collaborative agreements.
- Ensure auditors review the collaborative contract prior to finalization and obtain their concurrence on the proper revenue recognition treatment.



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## Biotechnology industry background

Due to the high-risk nature of the industry, biotechnology companies are continually faced with challenges in obtaining sufficient capital to fund research and development for novel high-risk products. Promising biotechnology research has a long and arduous road. It is estimated to take between 8 and 12 years to bring a biotechnology therapy to market and costs between \$800 million and \$1.2 billion.<sup>5</sup>

In order to further advance research and development, the biotechnology industry commonly employs collaborative arrangements between smaller companies that have innovative technologies and larger companies that have the capital necessary for more research or the commercialization and marketing expertise to bring a product to market. Collaborations typically entail two or more companies agreeing to share technology, research costs and resulting profits.

How a company accounts for the collaboration's activities in its financial statements is defined by the legalities of the arrangement. A company, for instance, that receives \$100 million for research does not necessarily record \$100 million in revenue when it gets the check. Current accounting rules require that a company determine what services or activities the \$100 million will fund – say, rights to the technology – and how long it expects to perform those activities. The company then allocates revenue to each service and books it when the service is performed. The revenue may come in many forms from the company's collaboration partner. Common payments include upfront cash in exchange for technology rights, bonuses connected to achievement of specific milestones and royalties on sales.

The current accounting rules that link pieces of revenue to various parts of the collaboration agreement complicate the accounting process. Also, the duration of collaborations sometimes is not defined explicitly so deciding when revenue will be earned can be difficult.

Other attributes of collaborations also impact accounting. For example, a joint steering committee comprised of participants from each party oversees many collaborations. If each party's committee participation is required, it is sometimes assigned a portion of the revenue. If the company cannot determine how long its participation will last, it may have to wait to record any revenue at all. This is called deferred revenue and is recorded on the balance sheet as a liability instead of on the income statement.<sup>6</sup>

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<sup>5</sup>Tufts Center for the Study of Drug Development, *Impact Report*; volume 8, number 6, November/December 2006.

<sup>6</sup> Deferred revenue is recorded as a liability because the obligations in the earnings process are not complete even though cash may have already been received.



## Cash is king but revenue recognition still matters

Investors typically value biotechnology companies on their potential drug pipeline and ability to fund research. Therefore, cash flow and financing metrics are most important particularly for emerging companies. Revenue and earnings are less important for drug-development stage companies, which may not have any revenue and only report losses. Nonetheless, any financial restatement can shake investors' confidence in a company's ability to report accurately its results.

When a company is forced to restate its financial statements for revenue-related reasons, the market typically reacts negatively. Company share prices dropped more than 5 percent on average after announcing a revenue-related restatement, according to an April 2008 study by the U.S. Department of Treasury.

Restatements do more than shrink share price. They may result in shareholder class-action litigation.<sup>7,8</sup> The ensuing loss of market confidence may cause the cost of capital to increase. To potentially make matters worse, bank covenants<sup>9</sup> on existing debt may be broken. Also, restatements will most likely lead to delayed filings, which create the possibility of delisting. Restatements have forced companies to delay public stock offerings. Additionally, there are internal administrative costs associated with the accounting cleanup. Most importantly, the restatement diverts management's focus away from the primary task at hand – new drug research and development.

## Restatements and late filings statistics

Glass Lewis' analysis of restatements indicates that not getting the accounting correct the first time is a persistent issue in the biotechnology and drug industry. As shown in Chart 1, the biotechnology and drug industry had the third-highest number of restatements in 2007, trailing only the software and oil and gas industries, which are also burdened with complex and vague accounting rules. The number of restatements for biotechnology and drug companies did,

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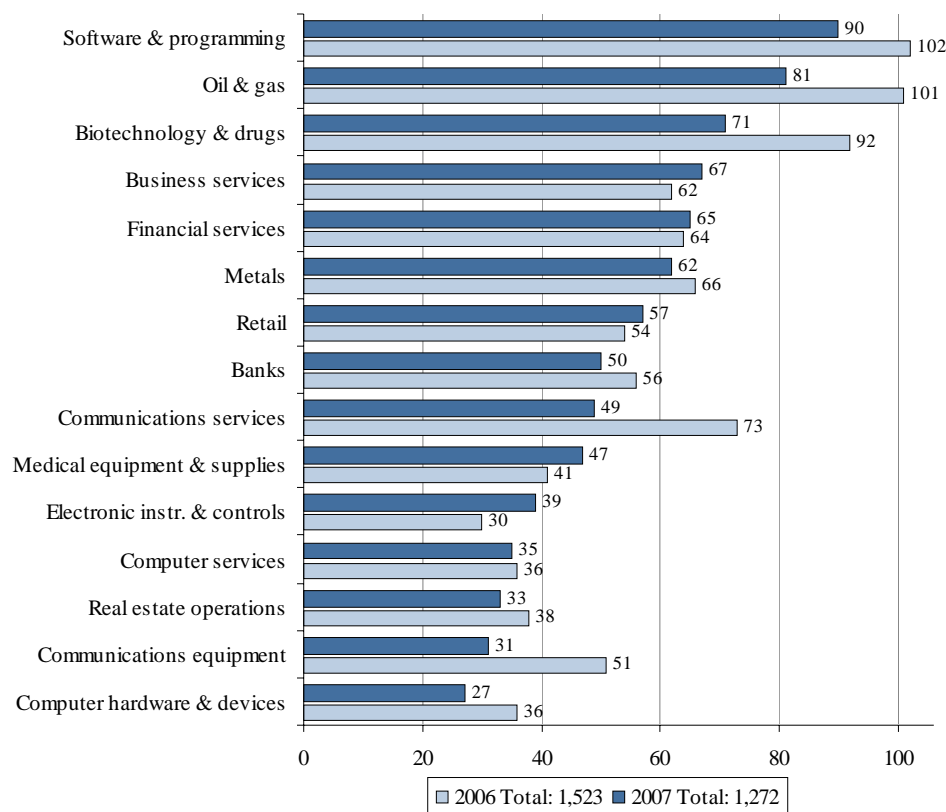
<sup>7</sup> In 2004, drug-maker Bristol-Myers Squibb paid nearly \$800 million to settle civil and criminal litigation arising out of revenue-related accounting improprieties which ultimately led to a restatement. The following year, pharmaceutical distributor McKesson agreed to settle a class action suit for \$960 million which also related to revenue-related accounting issues which led to a restatement.

<sup>8</sup> In a 2004 article, *Class Action Lawsuits Fall, Though Targets Get Bigger*, Todd Gordinier, a corporate legal expert, said, "Earnings restatements are still by far and away the biggest litigation trigger." In the same article Bill Grenner, a corporate-law partner at Gates & Ellis added that "Revenue recognition is a common catalyst for securities litigation."

<sup>9</sup> A bank covenant is an agreement between a borrower and lender requiring the borrower to comply with specific terms (e.g. minimum financial ratios) in order to maintain a loan. If the borrower fails to comply, the loan will be "in default" and the lender may have the right to demand repayment of the loan.

however, drop 22 percent from 92 percent in 2006 to 71 percent in 2007.<sup>10</sup> In general, there was a precipitous drop in 2007 restatements across most industries. Glass Lewis research indicates industries which have overly complex accounting rules have a higher restatement rate than those industries which do not.

Chart 1: Number of restatements, by industry



Source: Glass Lewis, Reuters, company filings. Note: Includes industries with more than 25 restatements.

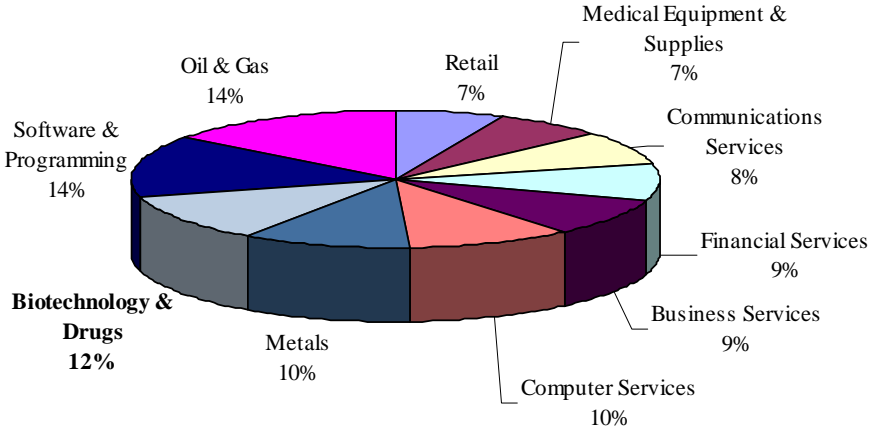
Companies that have material weaknesses in internal controls appear more likely to report restatements in the future than companies with no material weaknesses.<sup>11</sup> The primary purpose of maintaining a strong system of internal controls over financial reporting is to ensure the preparation of accurate and reliable financial statements. The existence of a material weakness indicates there is more than a remote likelihood that the weakness will ultimately lead to a material misstatement in the financial statements. Maintaining a strong system of internal controls is problematic for smaller biotechnology companies who may have limited accounting expertise to deal with the complex and vague accounting rules associated with collaboration agreements.

<sup>10</sup> Glass Lewis & Co. LLC 2008 report on restatements: *Out of Sight, Out of Mind*.

<sup>11</sup> Glass Lewis & Co. Year-end Trend Alert – The Tide is Turning, published Jan. 16, 2008.

As with restatements, it appears a similar trend exists in the percentage of late filings by industry. Late filings happen for a variety of reasons. For example, if a company is restating its financial statements, it must refile the older financials before filing its current reports. Therefore, the delay creates a domino effect and causes more missed filing deadlines. As shown in Chart 2, in 2007, the biotechnology and drug industry had 12 percent of the combined late filings for the top 10 industries with the highest number of late filings. This represents the third-highest percentage of late filings, below only the software and oil and gas industries.<sup>12</sup>

Chart 2: Percentage of late filings in 2007, by industry



Source: Glass Lewis, Reuters, company filings. Note: Includes top 10 industries with highest number of late filings.

<sup>12</sup> Glass, Lewis & Co. LLC Trend Report: 2007 Annual Late Filings.



## Study methodology

The universe for this study consists of 25 companies.<sup>13</sup> Glass Lewis examined each company's annual report and disclosures on revenue recognition related to collaborative revenue arrangements. The SEC requires companies to disclose how they record revenue. This information was usually found in Management's Discussion and Analysis (MD&A) and the notes to the financial statements describing the company's accounting policies. The collaboration contract filed as an exhibit to each company's SEC filings were also examined. The 25 companies in the sample are:

Table 1: Biotechnology company sample

Acorda Therapeutics Inc. (ACOR)	Cadence Pharmaceuticals, Inc.(CADX)	Incyte Corp. (INCY)
Adolor Corp.(ADLR)	Cell Genesys, Inc.(CEGE)	Kosan Biosciences Inc. (KOSN)
Alexion Pharmaceuticals, Inc. (ALXN)	Cytokinetics, Inc. (CYTK)	Medicure Inc.(MCU)
Alynham Pharmaceuticals, Inc.(ALNY)	EntreMed, Inc.(ENMD)	Pharmacopeia, Inc. (PCOP)
Altus Pharmaceuticals Inc.(ALTU)	Gen Vec, Inc.(GNVC)	Regeneron Pharmaceuticals, Inc.(REGN)
Amicus Therapeutics, Inc.(FOLD)	Idenix Pharmaceuticals, Inc.(IDIX)	Seattle Genetics, Inc. (SGEN)
Antigenics, Inc. (AGEN)	Idera Pharmaceuticals, Inc.(IDRA)	Telik, Inc. (TELK)
Avigen, Inc.(AVGN)	ImmunoGen, Inc. (IMGN)	Tercica, Inc. (TRCA)
		ZymoGenetics, Inc.(ZGEN)

Source: Biotechnology Industry Organization (BIO).

Using Form 10-K disclosures, available collaboration contracts and discussions with management, Glass Lewis found 60 active collaborations as of Dec 31, 2007. The collaborations had the following partnering payments and attributes:

- *Up-front payments*: Fees paid at the beginning of the collaboration.
- *Milestone payments*: Fees paid upon achievement of a specific goal or accomplishment.
- *Joint steering committees*: Representatives from both partners provide guidance to the collaboration and oversee its activities.
- *Joint research and development (R&D) payments/cost-sharing provisions*: Expense sharing through cost-plus reimbursements or dividing the cost among the partners.
- *Equity purchase from collaboration partner*: Stock or warrant purchase by partner.
- *Loan from collaboration partner*: Payments required to be repaid in the future, with or without interest.

<sup>13</sup> The Biotechnology Industry Organization (BIO) selected 25 representative biotechnology companies for the Glass Lewis & Co. (Glass Lewis) study.



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- *Retained rights to co-promote or manufacture product:* Company's right to participate in manufacturing and/or selling products resulting from the collaboration.
  - *Opt-in rights to purchase a greater share of the arrangement:* Either party's right to participate in a larger share of profits or manufacturing in exchange for additional consideration.

For this study, a revenue-related collaborative arrangement was defined as a pact that specifies a company receive payment or consideration for services or intellectual property. Forms of consideration could include up-front payments, rights to milestone payments and future royalties. For example, a smaller biotechnology company has a patent for a compound or technology process with potential as a pharmaceutical product. In order to finance the development and create a marketable product, the company enters into a collaborative arrangement with a larger company. In many cases, without the agreement the product development would slow or cease altogether. The smaller company contributes rights to the compound or technology, its development expertise, and agrees not to allow another company to use that compound for the same purpose. In exchange, the larger company pays cash, agrees to finance development costs and contributes its manufacturing and commercialization expertise.

The study's findings include this type of arrangement (sometimes called an out-license agreement) and development-services-only agreements in which companies recognize revenue for performing specified research tasks. The study excluded expense arrangements which do not have any revenue-related terms, such as in-license agreements, where companies pay other parties for rights to technology, but do not recognize any revenue other than product sales.

### **Selected statistics for study sample**

The companies in the sample are all small to mid-sized public and most have no product on the market. Most are developing pharmaceutical compounds. Three companies recorded no revenue in 2007. Table 2 shows the sample's selected financial characteristics as of Dec. 31, 2007.<sup>14</sup>

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<sup>14</sup> BIO selected the sample from the population of small to mid-sized public biotechnology companies within a range of market capitalizations and number of employees. In the population, the average market capitalization for a public biotechnology company was \$370.7 million in 2007 (E&Y's Beyond Borders Global Biotechnology report 2008). Market capitalization fluctuates based on stock price changes. Smaller biotechnology companies in the population typically have fewer than 350 employees. The study sample includes three companies that have more than 350 employees (Appendix 1).

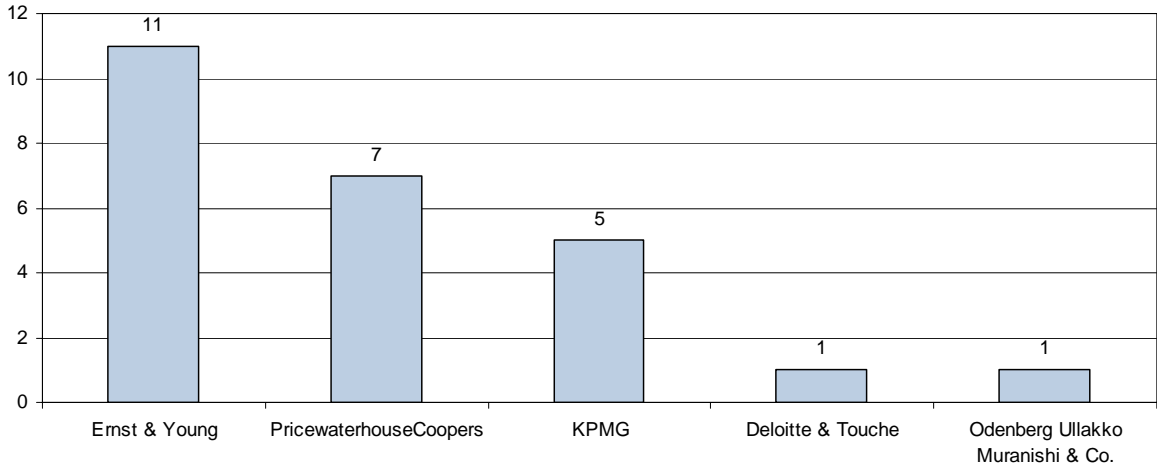
Table 2: Sample’s financial statistics

<i>\$ in millions</i>	Study Sample		
	Low	High	Average
Market capitalization	\$9.0	\$2,698.2	\$480.8
Employees	36	682	180
Deferred revenue	\$0.0	\$263.3	\$39.3
Total assets	\$26.1	\$936.3	\$185.7
Revenue	\$0.0	\$125.0	\$28.3
Net income / (loss)	(\$148.1)	(\$13.2)	(\$56.6)
Operating cash flow	(\$139.6)	\$196.5	(\$24.6)
Investing cash flow	(\$127.3)	\$234.4	\$9.4
Financing cash flow	(\$0.9)	\$319.4	\$52.3

Source: FactSet, GLC.

As of Dec. 31, 2007, Ernst & Young audited 11 of the 25 sample companies.  
PricewaterhouseCoopers audited seven.

Chart 3: Audit firms of sample companies



Source: FactSet, GLC. Auditor information as of Dec. 31, 2007.

## Analysis of sample findings

The study found 60 active revenue collaborations among the 25 sample companies as of Dec. 31, 2007. Active collaborations mean research is ongoing. The study will discuss the types of partnering payments in the active collaborations and the accounting methods disclosed by the companies.

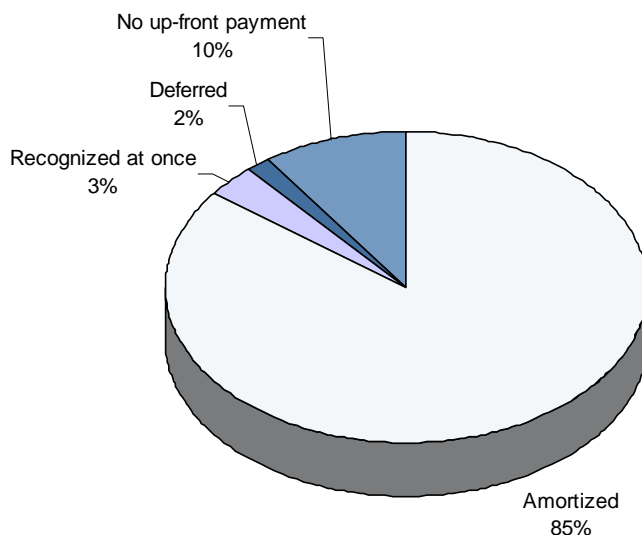
### Up-front payments

Up-front payments were the most common type of revenue received from the collaborations. Fifty-four of the 60 agreements contained up-front payments in which the smaller biotechnology company receives cash upon signing. Current accounting rules provide three ways to recognize up-front payments:

1. Record 100 percent when the cash is received, or “recognized at once.”
2. Record portions of the payment as revenue over the life of the agreement, or “amortized.”
3. Wait to recognize any revenue until other terms are certain, or “deferred.”

The most common accounting for up-front payments in the sample was amortization (Chart 4).

Chart 4: Up-front payment accounting choices



Source: Company reports, GLC.

Most companies amortized the up-front fees using proportional performance or ratable methods. Under proportional performance, a company estimates the cost of the activities it will



perform for the collaboration, then records revenue in proportion to the costs incurred to date. Ratable amortization recognizes the up-front payment evenly over the length of the collaboration.

The amortization period in the study sample ranged from 18 months to more than 18 years. Some contracts have an indefinite life so determining how long to amortize an up-front payment requires professional judgment. The study notes four main amortization periods:

1. Contractual research and development period as outlined in the contract if the biotechnology company has no other performance obligations after the research is performed.
2. Clinical timeline, if research activities have been planned in advance.
3. End of a last-to-expire patent.
4. Average length of a company's contracts if no time can be determined.

All companies considered up-fronts payments to be nonrefundable and did not believe they would have to repay any portion if the collaboration ended early. While four contracts were terminated early, none of the companies repaid any up-front fees.

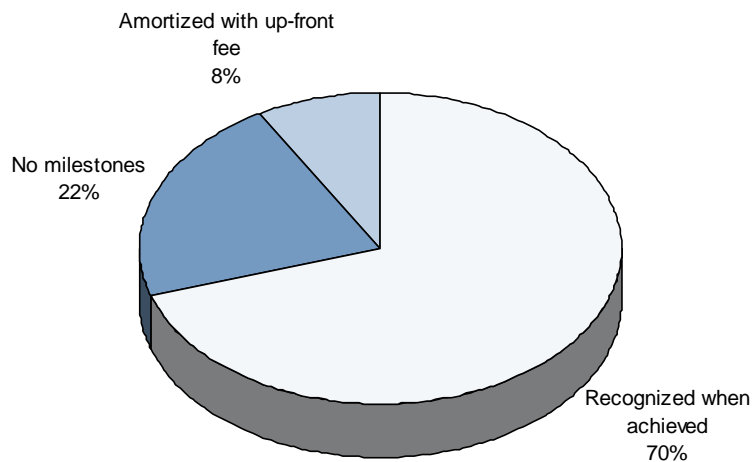
## Milestones

Forty-seven of the 60 collaboration agreements included milestone payments. In most, the milestones have not yet been met so companies have not recognized any revenue. For example, a company eligible for a bonus if its compound reaches Phase III clinical trials should not record any revenue related to this milestone if the compound is still in Phase II trials. Recording milestone payment revenue usually falls into two categories:

1. Recording revenue when the target is achieved and collection is assured, or “recognized when achieved” or
2. Recognizing the milestone payment over the life of the contract or “amortized.”

Most companies, 70 percent, planned to recognize the milestone payment when the goal is met and collectability of the payment is assured (Chart 5).

Chart 5: Milestone payment accounting methods



Source: Company reports, GLC.

Current rules allow both accounting methods. Choosing which to use depends on the specifics of the milestone. If the milestone is not considered substantive, meaning there is a risk it might not be achieved, amortizing the milestone revenue along with any up-front payments is the preferred method. In other words, if the company is assured of meeting the milestone, it may not be considered at risk. For example, a milestone payment for beginning initial trials that is paid two weeks after the collaborative agreement is negotiated may never have been in doubt.

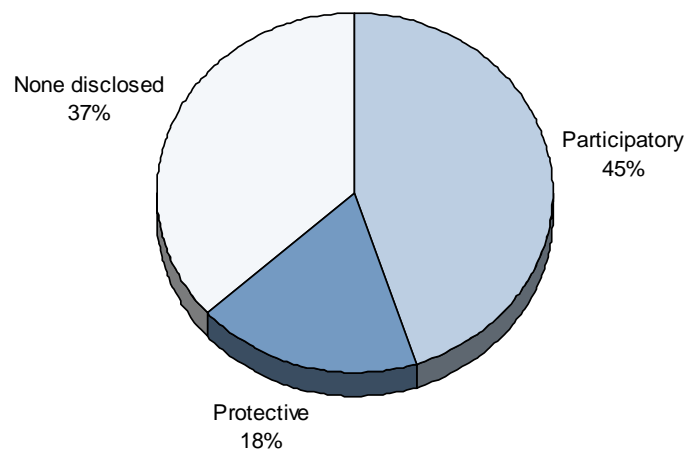
Most companies disclose the maximum value of all potential milestones in the contract, but typically redact specific goals and payments for confidentiality reasons. Payments and targets are often negotiated, and revealing details could place a company at a disadvantage in future negotiations.

### Joint steering committees

Thirty-eight of the 60 collaboration agreements provided for joint steering committees, which operated under various names including joint marketing committee, joint commercialization committee and joint research committee. The remaining 22 agreements did not disclose what, if any, oversight responsibility existed for the collaboration. All types of committee involvement can translate into an ongoing commitment that precludes revenue recognition. For example, if a company cannot determine when its committee participation will end, it may not be able to record any revenue until the collaboration terminates.

The study found that the Form 10-K disclosures did not always discuss participation in committees even though the contract called for one.

Chart 6: Joint steering committees



Source: Company reports, GLC.

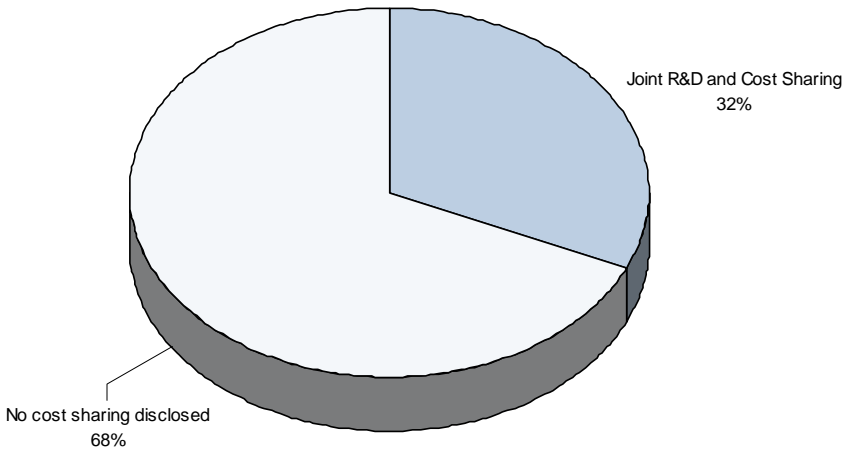
Companies with older contracts often designated their committee involvement as either participatory or protective based more on interpretation than on the contract's legalese. The arbitrariness is baked into these contracts because they were written before the current

accounting interpretation that considers committee participation to be a revenue deliverable. Recent arrangements specifically designate committee involvement as protective.

**Joint R&D funding payments**

Nineteen of the 60 collaborations had joint R&D and cost sharing arrangements. Sometimes the type of cost sharing arrangement also dictated future profit sharing. For example, a biotechnology company and larger pharmaceutical company may agree that the larger company will reimburse the biotechnology company for all research expenses. Collaborations calling for reimbursement of actual costs more often included a royalty on future sales. Arrangements with 50/50 cost sharing often called for 50/50 profit sharing instead of royalties.

Chart 7: Joint R&D and cost sharing payments



Source: Company reports, GLC.

Most companies recognize reimbursed costs for Joint R&D payments gross. In other words, the reimbursed cost appears on both revenue and expense line items in the income statement rather than being offset against each other and reported on one line item.

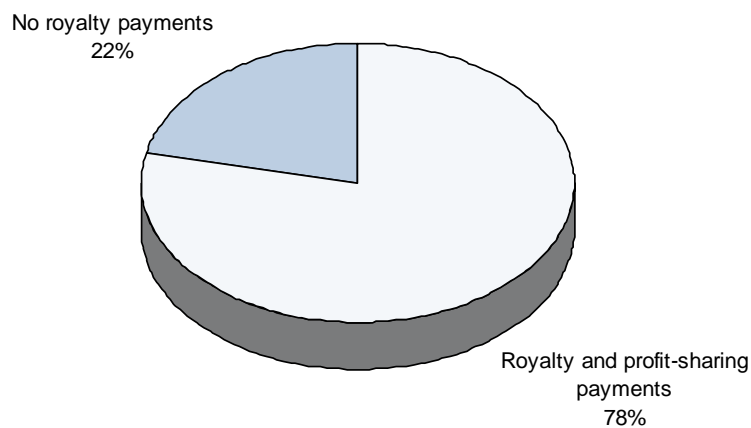
**Royalties and profit-sharing payments**

Royalties allow biotechnology companies to share in profits if a product is successfully commercialized with no drawback for failure. For example, the collaboration may state a biotechnology company will provide all research and the larger pharmaceutical company will commercialize and market the resulting drug. If the biotechnology company receives royalties, it could be entitled to collect a percentage of product sales from the large company without

regard to whether the sales are profitable. On the other hand, if the arrangement calls for profit-sharing, the biotechnology company would be eligible to receive a percentage of any profits.

Forty-seven of the 60 collaborations contained terms for royalty and profit-sharing payments. Royalties come in different forms. Typically, royalties are calculated based on product sales and are payable until the product's patent expires. Royalty terms were kept confidential in many contracts. However, few of the companies have royalty revenue since they do not yet have a product available for sale. As such, revenue recognition methods are not yet applicable.

Chart 8: Percent of contracts which contained royalty and profit-sharing payment terms

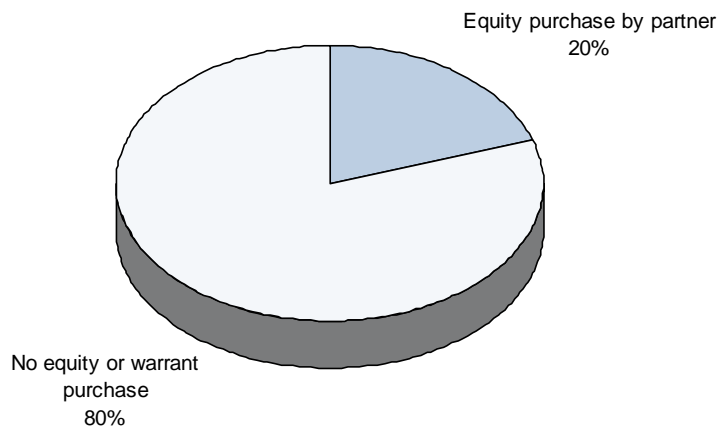


Source: Company reports, GLC.

## Equity purchase from partner

Equity purchases are another way collaboration partners can provide capital to finance biotechnology companies. Only 12 of the 60 collaborations included equity purchase provisions. All the equity purchases were made when the collaboration initiated, thus providing immediate cash for the biotechnology company to spend on operations.

Chart 9: Equity or warrant purchase by partner



Source: Company reports, GLC.

Equity purchases can impact revenue recognition if the equity is purchased at anything other than fair value. Some companies disclosed additional consideration being recorded as revenue when their equity was priced above fair value. The excess purchase price was recognized ratably over the life of the agreements or amortized similar to the way the company recognized up-front payments.

Equity purchases are typically negotiated with the original contract. The initial purchase may be completed when the contract is entered into with provisions for the collaboration partner to maintain its ownership percentage in the event of future share issuances.

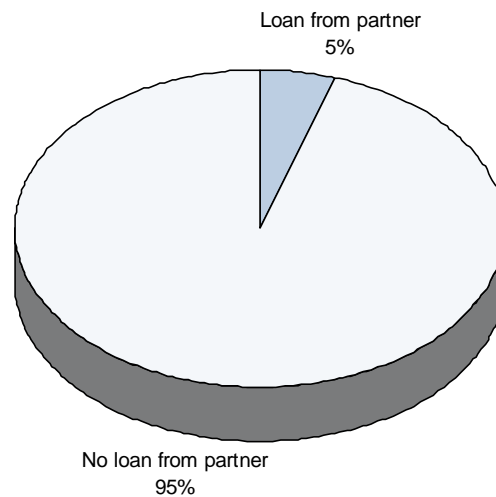
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## Loans from partner

Loans were not common. Only three collaborations reported loans from the collaboration partner and all loans were completed before the collaboration began. One loan was considered an advance against a future milestone payment. If the milestone is not achieved, the company is not required to repay the loan. Another loan was interest free. Accounting rules require the company assign an interest rate to the loan anyway. This imputed interest was added to deferred revenue and recognized ratably over the development period.

Chart 10: Loans from partners

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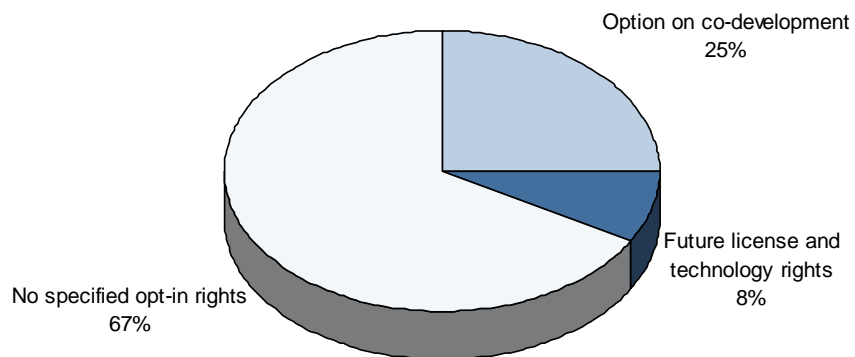
Source: Company reports, GLC.

## Opt-in rights

Opt-in rights include the ability of either party to exercise a greater share of the economics of a collaboration. In the study sample, 15 collaborations had rights to co-develop the compounds and five had rights to license future technology. No revenue is recognized for these rights.

For example, one company granted its collaborator the option to participate in the development and commercialization of additional compounds. If that option is exercised, the partner company would reimburse the biotechnology company for certain development costs. Afterwards, it would participate in profits.

Chart 11: Opt-in rights

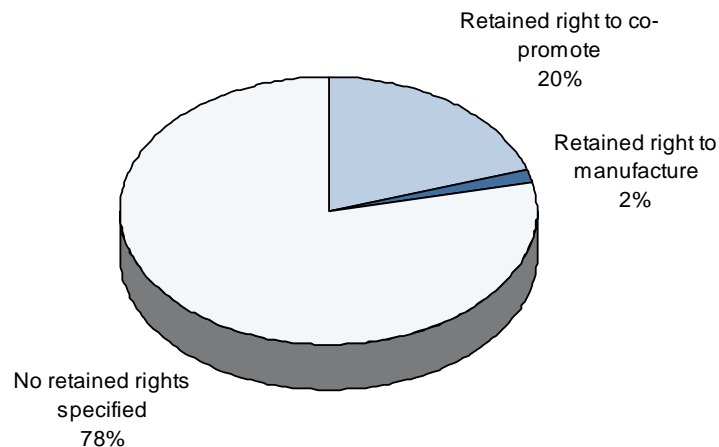


Source: Company reports, GLC.

## Retained rights

Twelve collaborations retained rights to co-promote any successful compounds. One retained the right to manufacture their compounds. Some of these rights pertained to specific geographic regions. For example, one company retained the rights to market any successful drugs in North America while granting its collaborator the right to market the same drug in other regions. No disclosures mentioned any influence on revenue recognition due to retained rights.

Chart 12: Retained rights



Source: Company reports, GLC.

## Accounting for terminated agreements

Terminated collaborations were not included in the 60 active collaborations at Dec. 31, 2007. The study found four collaborations that were terminated but are still being disclosed in Form 10-Ks due to revenue comparison in the MD&A. Upon termination, all of these companies recognized all revenue from up-front payments that had been deferred previously. These collaborations were terminated due to the parties deciding not to pursue further research of a compound after reviewing clinical trial results.

Prior to termination, the up-front payments were being amortized over the collaboration's estimated life. Recognizing all of the remaining deferred up-front payment upon termination is an acceptable accounting method.



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## Current state of accounting for collaborative agreements

Revenue recognition is the most difficult area of accounting to do accurately. Glass Lewis' data on restatements show revenue recognition errors to be a leading cause of restatements year after year. Revenue recognition accounting is even more difficult for smaller biotechnology companies whose complex research contracts must be paired with equally complex accounting rules. Factor in the limited accounting resources of these companies and the task becomes troublesome indeed.

At the core of the accounting complexity are the varying rules for determining each aspect of a collaborative arrangement. To muddy matters further, the legal contract may call for varying types of payments for which the timing and amount cannot be determined when the contract is executed. Nonetheless, accounting rules for collaborative arrangements require the multiple elements of a contract to be evaluated individually. It is not as simple as assuming a nonrefundable payment received from a R&D partner should be recorded as revenue when the cash is first received. Nor is it as simple as spreading the revenue evenly over the term of the collaboration agreement. Often, specific contract terms or durations are open-ended and the descriptions of the services or deliverables to be provided are nebulous at best.

With the lack of any overarching accounting rules, companies resort to a hodgepodge of guidelines, many of which were not written with the biotechnology industry in mind. The SEC has issued piecemeal accounting guidance and recommendations, often taking the form of comment letters to specific companies or speeches at annual American Institute of Certified Public Accountants (AICPA) conferences. Although the Financial Accounting Standards Board (FASB) recently issued some much needed guidance, it remains unclear as to whether such guidance is sufficiently helpful.

The state of revenue recognition accounting for biotechnology companies' collaborative agreements is still much like throwing a dart in the dark -- hope for a bulls-eye, but be satisfied with just hitting the board. Miss the dart board with incorrect accounting, and a company could end up with a SEC inquiry or a restatement. Revenue-related restatements shake investor confidence in the reliability of the financial disclosures and also consume huge amounts of management time while diverting company attention away from research activities. Affymax Inc. and Curis Inc. are just two examples of companies running into problems because of revenue recognition. Affymax's initial public offering was delayed while the company evaluated its revenue recognition for joint steering committees. Curis has to restate its financials based on SEC comment letters regarding its revenue recognition.



## **International accounting rules even foggier than GAAP**

The study sample included only U.S.-based companies following Generally Accepted Accounting Principles in the U.S. (GAAP).<sup>15</sup> However, non-U.S. companies may be using a different set of accounting rules called International Financial Reporting Standards (IFRSs). IFRSs are generally considered to be more principles-based with fewer specific exceptions. The accounting world, including the U.S., is moving towards the adoption of IFRSs as the one comprehensive set of accounting rules to be adhered to by all public companies worldwide.

Deloitte & Touche provided the following thoughts on the impact of IFRSs in a 2008 survey:

*“With the use of IFRSs, companies, auditors, regulators, and users will need to adapt to an accounting and financial reporting framework that requires greater professional judgment and less reliance on detailed rules and bright lines. This will require a change in behavior by all market participants and more of a focus on understanding the substance underlying a transaction or event and how it aligns with base principles and objectives. The challenge is to ensure that although different outcomes may result from the application of IFRSs, such outcomes are within the conceptual parameters of the standards.”*<sup>16</sup>

Until the SEC allows companies to report financial statements using IFRSs, U.S. GAAP will be the standard for U.S.-based companies. At this time, IFRS does not include specific rules regarding the appropriate accounting for the various parts of a collaborative arrangement.

## **Collaborative agreement revenue recognition accounting rules**

Because collaborations are typically the sole source of revenue for biotechnology startups, getting the revenue recognition accounting correct is critical. These accounting rules are the most applicable to collaborative agreements:

- SEC Staff Accounting Bulletin (SAB) 104, *Revenue Recognition*.
- FASB Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*.
- AICPA Statement of Position (SOP) 81-1, *Accounting for Performance of Construction/Production Contracts*.
- FASB EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* which will become effective for active collaborations presented in fiscal years after Dec. 15, 2008.

<sup>15</sup> Generally Accepted Accounting Principles (GAAP) is the body of accounting rules and conventions used to record transactions in company’s financial statements. The Financial Accounting Standards Board issued, Financial Accounting Standard No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, May 2008. Currently GAAP is defined in the auditing standards by Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*.

<sup>16</sup> Deloitte and Touche *2008 IFRSs Survey: Where are we now?*, May 2008.



SAB 104 stipulates that revenue can be recognized only when four criteria are met:

- There is a contractual right to receive such payment;
- The contract price is fixed or determinable;
- The collection of the resulting receivable is reasonably assured; and
- There are no further performance obligations under the license agreement.

In simple terms, if a company has finished the work or delivered the product and is going to get paid, then recognize the revenue. That seems straightforward enough, but toss in the complexities of a collaboration where the amount and timing of payments are not known, and revenue recognition very quickly becomes very complicated.

Depending on specific facts and circumstance, a company has four acceptable ways to recognize revenue from collaborative agreements:

1. Record all the revenue up-front when the cash is received;
2. Defer, or wait to record, the entire payment until the end of the agreement;
3. Record portions of the payment as the services are performed over the term of the arrangement or the expected period of performance; or
4. Record portions of the payment when substantive milestones or deliverables are completed.

First, a company must decide if a collaboration has multiple revenue generating activities. If so, revenue is attributed to each activity. For example, transferring rights to technology and performing research experiments could be considered separate revenue-generating activities. With so many possible sources of revenue, determining how the fees are to be recognized as revenue is highly subjective and requires a sizeable amount of judgment.

#### ***All or nothing revenue recognition rarely seen***

The first revenue recognition accounting scenario records all the revenue up front when the cash is received. Up-front revenue recognition should be the exception rather than the rule because it is the most aggressive treatment and will certainly draw the attention of the auditors and quite possibly the SEC. In the study sample, only one of the collaborations accounted for revenue up front. Since the payment was in exchange for rights assigned to intellectual property and no more payments were received under the agreement, the treatment seemed reasonable.

Waiting to record any revenue until the end of the agreement, considered the most conservative accounting treatment, is even rarer. None of our companies accounted for revenue in this way.



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***Partial revenue recognition methods – more common and more complex***

If the treatment can be justified, accounting for the first two revenue recognition methods is straightforward. The same can not be said for methods three and four. Both require a significant amount of management judgment and expertise.

The third method stipulates that portions of the payment are recorded as revenue as the services are performed over the term of the arrangement or expected period of performance. In other words, the fees are recognized as revenue systematically (ratably) over the length or expected length of the agreement or some other substantiated time frame.

Under this scenario, there are two ways to calculate the amount of revenue to recognize – the proportional performance method and the ratable method.

The proportional performance method estimates the total cost of the activities a company will perform for the collaboration. It then records revenue in proportion to the costs incurred to date in relation to the total costs.

The ratable amortization method recognizes the payment evenly over either: 1) the length of the collaboration or if the contract is open-ended, 2) the end of the related patent life, 3) clinical timeline, 4) product life cycle or 5) an estimated duration if all else fails. Once again, if the duration of a contract is not stipulated in the agreement, a sizeable amount of management judgment is required to determine an appropriate amortization period.

***Milestone payments - substantive deliverable?***

Under the fourth method, a company records portions of the payment as revenue when it completes a substantive (at risk) milestone or deliverable. In this situation, the collaboration contains specific milestones or deliverables that may also have associated milestone payments.

If a milestone is determined to be non-substantive, the revenue must be deferred and recognized using the ratable method. For example, a milestone payment for beginning initial trials that is paid two weeks after the collaborative agreement is negotiated may never have been in doubt and would be recognized over the life of the agreement.

On the other hand, if a milestone is deemed to be substantive and is linked to a payment, a company needs to justify an alternatively used revenue recognition method. This is the situation that recently resulted in an SEC inquiry at Noven Pharmaceuticals. Noven delayed filing its 2007 annual report in order to address:

*“An open accounting matter relating to revenue recognition raised in an SEC comment letter. The open matter relates to Noven’s accounting policy of deferring revenue recognition of non-refundable milestone payments and recognizing them as revenues over the estimated life of*



*their related licensed products. In an SEC comment letter received in December 2007, and in a follow-up comment letter received in February 2008 following Noven's response to the first letter, the SEC staff has asked Noven to clarify its basis for deferring the recognition of such milestone payments, including the approval and sales milestones that Noven has received from Shire in connection with the license of Noven's Daytrana™ product. Noven has responded to the SEC comment letters and is continuing to work with the SEC staff to resolve this open matter.*

*Noven's actual results for 2007 would be materially different than the preliminary unaudited information discussed in this press release if Noven were required to change its revenue recognition accounting policy for upfront milestone payments. Such a change in accounting policy would also likely result in a restatement of Noven's financial results for 2006 and/or other periods."*

On March 27, 2008, Noven disclosed it had received written confirmation that the SEC completed its inquiry into the revenue recognition practice and concluded the deferral of revenue was indeed acceptable. However, it remains unclear whether the SEC would have been so quick to accept the accounting treatment had revenue been accelerated rather than deferred.<sup>17</sup>

Although the SEC ultimately accepted Noven's accounting, there is an important takeaway from the inquiry - **the SEC is actively looking at milestone revenue recognition for biotechnology companies, large and small.** Specifically, the Staff is scrutinizing a company's determination of "substantive vs. non-substantive" milestones and the corresponding impact to revenue recognition for up-front and/or milestone payments.

Given these developments, it is important for biotechnology companies to understand what constitutes a substantive milestone. Although there is not any authoritative accounting guidance, several SEC comment letters reviewed presented the following definition:

A milestone is deemed to be "substantive" after considering all of the following conditions:

- The milestone or up-front payment is non-refundable.
- The achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement.
- A substantial effort is involved in achieving the milestone.
- The amount of any milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone.
- A reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

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<sup>17</sup> Our phone calls to request more information about Noven's inquiry were not returned.



Once again, the determination as to whether a milestone meets these conditions involves a significant amount of management judgment.

***Partial revenue recognition method complexity: Multiple element arrangements***

Since collaborative agreements typically encompass providing a variety of services, revenue recognition accounting scenarios three and four fall under the realm of “multiple element arrangements (MEA).” Simply put, a MEA is a revenue-related arrangement involving the delivery of multiple products and/or services (elements) over a period of time.

U.S. GAAP requires that, if possible, each substantive element or deliverable be separated and revenue be recognized individually as the specific deliverable is completed. If the separation of the elements is not possible, revenue may need to be spread evenly over the performance of all deliverables or perhaps even deferred completely until all elements have been delivered.

Typical substantive deliverables in a biotechnology collaborative agreement include:

1. Technology licenses
2. Marketing rights
3. Research and development services
4. Selling services
5. Manufacturing services
6. Participatory joint steering committees

Specifically, the FASB’s EITF 00-21 requires that MEA’s must be evaluated in order to determine the fair value of each deliverable. If not, the arrangement is deemed to be a single unit of accounting. In that case, the company must recognize the entire fee using partial revenue recognition methods. The penalty to a company for a single unit of accounting – revenue recognition is based upon the last deliverable. In other words, no revenue can be recognized until all work is completed under the agreement.

If the fair value of each deliverable is determinable, revenue would be recognized separately also using partial revenue recognition methods. Although this results in a more accelerated recognition of revenue, there are some additional complexities.

For example, how does a company determine the fair value of each substantive deliverable? More importantly, how does a company justify and document the fair value in order to withstand the rigors of an SEC inquiry? Each license agreement is unique and the deliverables and terms are oftentimes vague. Given this, the determination of fair value is more often than not, grey and subject to a significant amount of management judgment.



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***Joint steering committees - substantive deliverable or not?***

Joint steering committees (JSC) have been a source of uncertainty for biotechnology companies. Companies with JSCs are faced with the following: (1) Does the mere existence of a JSC in a collaboration create a substantive deliverable? (2) If so, how does one place a fair value on it? (3) Does the JSC have a stated duration in the contract? These are three questions that should be at the forefront for any company engaged in a collaboration.

The SEC admitted that lack of authoritative guidance makes it difficult for registrants to determine the substantive nature of a JSC. The SEC recently did try to clarify matters. In a December 2007 speech at the AICPA National Conference, Mark Barrysmith, an accounting fellow in the SEC's Office of the Chief Accountant, acknowledged the confusion:

*"We have received a number of questions concerning the accounting, or lack thereof, for participation on a joint steering committee that is established through a collaborative research and development arrangement in the biotechnology industry."*

Mr. Barrysmith specified the following criteria in determining whether a company's participation on a JSC constitutes a substantive deliverable.

1. Does the agreement contractually require the company to participate on the JSC?
2. If the company does not actively participate, would the other parties to the agreement contend the company is meeting its full performance obligations?
3. Does a company's committee participation affect the arrangement fee or payments?
4. Is there a contractual financial penalty to a company for not participating on the JSC?
5. In management's judgment, is participation on the committee considered inconsequential or perfunctory?

In concluding his statements, Mr. Barrysmith made the following important point:

*"If the obligation to sit on the steering committee is for an indefinite period of time, the vendor must estimate the expected term over which to recognize the related revenue. If a vendor cannot estimate the expected term, it must defer revenue recognition."*

As follow up, Glass-Lewis contacted Mr. Barrysmith to inquire whether a company may be required to defer 100 percent of revenue until it can estimate a term for the JSC.<sup>18</sup> He said he knew of a couple of companies where they had. He added, *"That was the penalty a company would have to pay"* if the company was unable to estimate a JSC term and the company was obligated to participate on the committee.

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<sup>18</sup> Glass Lewis phone conversation with Mr. Barrysmith took place on May 16, 2008.



When asked how difficult it is to determine a fair value for JSC participation, he told Glass Lewis *“it’s not impossible”* and *“the SEC would consider any reasonable estimates made by a registrant.”* Remember, if a company wants to avoid a single unit of accounting and it has a participatory JSC, it must determine a fair value for the JSC services.

Based upon review of the collaborative agreements of the study sample companies, it appears the JSC role varies significantly. In some cases, the JSC role indeed appears substantive or participatory while in others the role appears to be protective and therefore non-substantive. A protective role is one where participation on a JSC is to essentially “protect” the rights of a company, but not actively participate in any collaborative decision making.

Since financial disclosures rarely divulge the assessed role played by the JSC, Glass Lewis cannot evaluate management’s judgment. None of the companies included any financial disclosures regarding a JSC duration or fair value.

Two companies in the study sample received SEC comment letters questioning their participation in JSCs. In one case, the company stated the role of the JSC was protective: *“We participate in these committees as a means to govern or protect our interests.”* Since the related drug had been commercialized, the company supported its opinion by effectively saying – we develop drugs, our collaborator commercializes drugs. *“Accordingly, we believe our [JSC] obligation post-commercialization is inconsequential.”* The SEC agreed.

The second SEC comment letter involved a company that said its JSC was protective because it met only twice annually during product development. Since the JSC was not actively involved in the collaboration, the SEC agreed with the assessment.

### **Curis and Affymax: JSC revenue recognition accounting gone bad**

Curis Inc. is the poster child for what can go wrong if the SEC concludes JSC assumptions and revenue recognition are not reasonable. Curis found itself in SEC inquiry purgatory that is documented by the exchange of 12 written letters between the two parties in addition to numerous phone conversations.

In June 2005, the SEC inquired about a 2003 collaboration in which Curis received up-front payments of \$7.5 million from Genentech for license and maintenance fees. From 2003 through 2005, Curis recognized \$2.2 million of revenue from those payments. The primary problem was Curis could not reasonably estimate when its contractual steering committee obligations would end. Under the agreement, the term of the committee obligations was indefinite. Therefore, Curis decided to defer all revenue until it was able to reasonably estimate when its committee obligations would either cease or become inconsequential.



In the fourth quarter of 2007, Curis recognized all of the revenue it had been previously forced to defer as “the company concluded that its joint steering committee performance obligation had become inconsequential to the agreement.”

The SEC correspondence indicates that Curis’ decision to defer all of the revenue did not come easily. In a Sept. 28, 2005 letter, the company stated it would recognize the revenue from the payments ratably through June 2011, the estimated date for regulatory approval for the products under collaboration.

In a Nov. 18, 2005 comment letter, the SEC continued to question the company’s revenue recognition treatment for the payments and also added:

*“We note you plan to revise your accounting in future periods. From our telephone conversations, we understood that the correction of this accounting policy had no impact on historical periods. Please tell us if our understanding is correct.”*

Based upon the comment, it appears to us the SEC thought that Curis was trying to avoid a restatement. It did not work. After several additional exchanges between the parties in which Curis reasserted its claim the change in accounting would not require a restatement, the company finally succumbed.

In a March 21, 2006 letter, the company informed the SEC it would indeed restate due to its incorrect assumption that:

*“its participation on the steering committees would become inconsequential after the first product was approved in each of the two programs covered under this collaboration, and would therefore no longer represent a performance obligation.”*

The company also said “the contractual term of the Company’s steering committee obligations is indefinite and the Company expects that **it will not record any revenue related to these payments** for at least several years.” (emphasis added) On April 19, 2006, the SEC completed its review.

Since Curis had already told the SEC it could not estimate reasonably when its contractual steering committee obligations would cease, it decided to defer 100 percent of the revenue. Why did the company not continue amortizing the revenue over a term when it knew the JSC would no longer exist, such as the end of the patent life?<sup>19</sup>

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<sup>19</sup> In a discussion with BIO staff, Curis’ chief operating and chief financial officer Michael Gray said the company chose not to amortize revenue over the life of the patent because, in theory, the patent life would never end. With the development of new compounds, back-up compounds, and new classes of compounds, the life of the patent would be unclear.



Although not resulting in a formal restatement, Affymax Inc. was required to revise its revenue recognition policy for collaborative agreements in conjunction with a SEC review of its initial public offering S-1 document. The existence of a participatory JSC was once again the driving force behind the change.

In its review of the S-1, the SEC asked Affymax: “*Why it is appropriate to defer revenue recognition of your up-front payment until final delivery of the clinical trial results?*” The question was being asked in reference to a joint collaboration with Takeda.

Affymax responded: “*The Company originally determined that it will defer the commencement of revenue recognition for this single unit of accounting until the final delivery of the clinical trial results which is expected to occur during the second half of fiscal 2007.*”

The SEC thought differently as Affymax ultimately changed its view when it said in an Oct. 2, 2006, response to SEC comments:

*“Upon further analysis and informal discussions with Takeda about the Company's required participation on the joint steering committee obligation, the Company determined that the term of the Company's **joint steering committee obligation extends for as long as products subject to the collaboration with Takeda are being sold under both agreements by either of the parties.** As a result, it is no longer possible to reasonably and reliably estimate the expected performance period for this obligation which was initially assessed to be twenty years from the agreement effective date. Accordingly, the expected performance period of the Company's steering committee obligations is currently indefinite. Therefore, the Company will now defer the commencement of revenue recognition for this single unit of accounting until the earlier of either (i) the expected performance period of the Company's joint steering committee obligations can be reasonably and reliably estimated or (ii) the Company is no longer contractually obligated to perform all joint steering committee duties.*

*This change in the Company's assessment **moves the trigger for revenue recognition from the final delivery of clinical results to a later date that cannot be determined at this time.***  
(emphasis added)

This indefinite deferral of revenue was particularly difficult for Affymax as it was deemed to apply not only to milestone and upfront payments but also to product sales revenues. The SEC's decision could have resulted in perpetual losses for the company.

### **Avoiding the JSC revenue recognition problem contractually**

From an accounting perspective, the true substance or form of a transaction will usually outweigh the legal form. Glass Lewis' view is that no amount of legalese is going to transform a participatory JSC into a protective JSC. Nonetheless, companies are modifying JSC language in new agreements or amending JSC language in existing agreements.



In the study's 25-company sample, 29 of the 60 collaborations commenced after March 20, 2006 -- the date Curis announced its restatement. Of the 29, only three had new JSC language that either included a JSC "opt-out" provision or provided an end date for JSC participation.

Glass Lewis obtained examples of JSC "opt-out" and termination boilerplate language being incorporated into collaboration agreements from a non-sample company.

- *"Withdrawal from Committees. At any time during the Term and for any reason, Company A shall have the right to withdraw from participation in the Committees upon written notice to Company B, which notice shall be effective immediately upon receipt ("Withdrawal Notice")."*
- *"DISSOLUTION OF JSC. The JSC shall be dissolved at the end of the collaboration Term; provided that Company A's participation in the JSC after the fifth (5th) anniversary of the Effective Date will be at Company B's sole option."*
- *"The JDC shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the JDC or (b) Company A providing to Company B written notice of its intention to disband and no longer participate in the JDC following the end of the Development Period."*

### **New FASB rule for collaborative agreements**

In December 2007, the FASB adopted a new accounting rule, EITF 07-01 "Accounting for Collaborative Arrangements." Glass Lewis foresees little impact from the rule on the bulk of the biotechnology industry, particularly smaller firms. Glass Lewis' view has been initially confirmed by several recent biotechnology companies' filings.

While the rule name "Accounting for Collaborative Arrangements" showed promise for those hoping to see much needed clarification, the substance of the rule is negligible. Chances are most firms are already following the guidance although the FASB was compelled to provide additional accounting guidance in the areas of:

- Definition of a collaborative agreement
- Income statement presentation and classification
- Disclosures relating to collaborative arrangements

In the 25 company sample, there was a general lack of adequate disclosures relating to the collaborative agreements. In this regard, EITF 07-01 provided guidance as to what minimum disclosures should be provided for each collaborative agreement. Specifically, each participant in a collaboration should disclose:



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*“The nature and purpose of its collaborative arrangements, its rights and obligations under the arrangement, the accounting policy in accordance with Opinion 22,<sup>20</sup> and the income statement classification and amounts attributable to transactions with partners.”*

Another new FASB issue, EITF 08-1, *“Revenue Recognition for a Single Unit of Accounting,”* may provide some revenue recognition relief for biotechnology companies. In its March 12, 2008 meeting, the FASB discussed the issue and recommended its staff perform more research for future EITF consideration. A summary of the specific issue to be addressed is as follows:

*“Companies often enter into arrangements that provide for multiple payment streams for a single deliverable or a single unit of accounting (that is, multiple deliverables that cannot be separated for revenue recognition purposes). To recognize revenue in these arrangements, a company needs to determine how to attribute the multiple payment streams (customer consideration) to the single deliverable or unit of accounting (assuming multiple deliverables cannot be separated under EITF Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables”). The issues are (a) whether it is acceptable to use multiple methods to attribute multiple payment streams to a single deliverable, and (b) depending on the facts and circumstances of an arrangement, whether it is acceptable to use multiple methods to attribute multiple payment streams to a single unit of accounting (multiple deliverables that cannot be separated), as determined under Issue 00-21.”*

The impact of EITF 08-01 on biotechnology companies remains uncertain since the FASB has provided little information at this time.

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<sup>20</sup>APB Opinion #22 (paragraphs 12 and 13): Disclosure of accounting policies should identify and describe the accounting principles followed by the reporting entity and the methods of applying those principles that materially affect the determination of financial position, changes in financial position, or results of operations. In general, the disclosure should encompass important judgments as to appropriateness of principles relating to recognition of revenue and allocation of asset costs to current and future periods; in particular, it should encompass those accounting principles and methods that involve any of the following: a) A selection from existing acceptable alternatives; b) Principles and methods peculiar to the industry in which the reporting entity operates, even if such principles and methods are predominantly followed in that industry; c) Unusual or innovative applications of generally accepted accounting principles (and, as applicable, of principles and methods peculiar to the industry in which the reporting entity operates). Examples of disclosures by a business entity commonly required with respect to accounting policies would include, among others, those relating to basis of consolidation, depreciation methods, amortization of intangibles, inventory pricing, accounting for research and development costs (including basis for amortization), translation of foreign currencies, recognition of profit on long-term construction-type contracts, and recognition of revenue from franchising and leasing operations. This list of examples is not all-inclusive.



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## Collaboration revenue recognition accounting recommendations

There is still hope that revenue recognition accounting rules can and will improve. In general, the accounting rules for revenue recognition are difficult for the biotechnology industry to follow since some of the guidelines were written for other industries. While collaborations often have multiple elements that should merit accounting scrutiny, certain accounting issues just are not that important. Heading our list of irrelevant accounting issues for biotechnology companies is the requirement to evaluate whether a JSC constitutes a substantive deliverable.

**A suggestion to improve the accounting in this area is simple: JSC participation should only be considered a substantive deliverable if a company is incentivized to participate either through payment for services or detriments for nonparticipation.** Identifying a JSC as a deliverable would, in most cases, substantially distance the accounting of the collaborative arrangement from the actual economics and intent of the transaction between the two parties.

A JSC's primary function is to provide high-level consultative input. Another key function is to provide project management that keeps the collaboration on track. In several cases, the JSC had no decision-making authority. Even if a JSC did not exist for a particular collaboration, these oversight functions would be necessary to protect a company's interests.

Assigning a fair value to a JSC complicates things even more. **Given the wide range of duties a JSC will undertake as well as the vast array of collaborations, any attempt to assign a fair value is unrealistic.** Accordingly, unless a company receives payment to participate on a JSC or gives up consideration not to participate, a JSC's activities should not be considered a defined deliverable.

If the SEC continues to classify a JSC as a deliverable, many public biotechnology companies face the prospect of restating their financial statements. If they were forced to restate, this would take away valuable resources from research and development. Lastly, the SEC's interpretation of EITF 00-21 is prompting modifications to contract language of collaborations in order to avoid the issue. If additional contract language can change the accounting outcome without changing the collaboration, then why is the debate about a JSC's role even happening?

The accounting rule-setters could provide much needed guidance for the biotechnology industry. Given the complexity surrounding the proper accounting for revenue-related transactions combined with limited accounting resources, small biotechnology companies will continue to struggle implementing the rules.



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## What biotechnology companies can do now

Until the accounting rules either change or the rule-makers provide more guidance, biotechnology companies could protect themselves against the possibility of a restatement. Here are some suggestions about how to do that:

1. Put an end date for JSC activities in each collaboration agreement, if practical.
2. If appropriate and substantive, use a JSC opt-out clause in the agreement.
3. Do not amend existing agreements in order to avoid current accounting rules. Rather, review the terms of each material agreement in order to understand any existing accounting issues.
4. Ensure auditors review the collaborative contract prior to finalization and obtain their concurrence on the proper revenue recognition treatment.
5. Adequately document the rationale and assumptions used to determine the accounting treatment.
6. If the nature of a JSC is determined to be substantive, assume there is a single unit of accounting and apply the appropriate accounting.
7. Evaluate the nature of each milestone to determine if it is substantive. This is especially critical if revenue is linked to individual milestones.
8. Provide investors with enhanced financial statement disclosures about ongoing collaborative agreements. Disclosures should include the nature and purpose of the agreement as well as a company's obligations, cash receipts, research progress, and future project expectations (including risks that would change expectations).
9. In order to comply with EITF 08-01, a company should enhance footnote disclosures regarding accounting policies and practices for collaborative agreements. These disclosures should include appropriate income statement classification and all amounts attributable to transactions with key partners. A discussion of the following is required:
  - A selection from existing acceptable alternatives;
  - Principles and methods unique to the industry in which the reporting entity operates, even if such principles and methods are predominantly followed in that industry;
  - Unusual or innovative applications of GAAP (and, if applicable, principles and methods peculiar to the industry in which the reporting entity operates).

## Appendix

### 1: Selected Financial Statistics

Ticker	Company Name	Mkt Cap (MM)	Employees	Total deferred revenue	Total assets	Sales (LTM)	Net income (LTM)	Operating cash flow (LTM)	Investing cash flow (LTM)	Financing cash flow (LTM)
ACOR	Acorda Therapeutics Inc.	\$623	144.0	\$21.8	\$127.3	\$39.5	(\$38.0)	(\$25.7)	(\$50.7)	\$75.1
ADLR	Adolor Corporation	\$213	108.0	\$58.7	\$178.7	\$9.1	(\$48.4)	(\$18.0)	\$30.3	\$0.1
AGEN	Antigenics, Inc.	\$137	100.0	\$4.5	\$44.5	\$5.6	(\$36.8)	(\$26.7)	\$13.2	\$3.8
ALNY	Alnylam Pharmaceuticals, Inc.	\$1,016	129.0	\$263.3	\$493.8	\$50.9	(\$85.5)	\$196.5	(\$277.4)	\$58.6
ALTU	Altus Pharmaceuticals Inc.	\$150	160.0	\$2.1	\$154.1	\$28.5	(\$63.2)	(\$39.2)	(\$6.3)	\$97.7
ALXN	Alexion Pharmaceuticals, Inc.	\$2,325	434.0	\$0.0	\$334.4	\$72.0	(\$92.3)	(\$139.6)	\$3.1	\$64.8
AVGN	Avigen, Inc.	\$82	38.0	\$0.0	\$81.1	\$0.0	(\$25.2)	(\$21.1)	(\$8.4)	\$28.1
CADX	Cadence Pharmaceuticals, Inc.	\$227	47.0	\$1.2	\$64.6	\$0.0	(\$51.7)	(\$40.7)	(\$3.4)	\$12.6
CEGE	Cell Genesys, Inc.	\$243	302.0	\$12.0	\$273.4	\$1.4	(\$99.3)	(\$89.7)	\$4.6	\$85.0
CYTK	Cytokinetics, Inc.	\$172	161.0	\$36.6	\$155.4	\$13.6	(\$48.9)	(\$3.0)	\$45.5	\$34.7
ENMD	EntreMed, Inc.	\$59	57.0	\$0.0	\$53.0	\$7.4	(\$22.4)	(\$23.5)	\$12.6	\$19.7
FOLD	Amicus Therapeutics, Inc.	\$258	91.0	\$50.6	\$167.1	\$1.8	(\$41.2)	\$15.2	(\$75.0)	\$91.9
GNVC	GenVec, Inc.	\$137	119.0	\$1.9	\$28.3	\$14.0	(\$18.7)	(\$15.0)	\$6.9	\$3.6
IDIX	Idenix Pharmaceuticals, Inc.	\$340	219.0	\$54.5	\$160.5	\$68.0	(\$82.5)	(\$70.7)	\$63.0	\$0.2
IDRA	Idera Pharmaceuticals, Inc.	\$242	38.0	\$15.8	\$27.7	\$8.0	(\$13.2)	(\$15.8)	\$0.9	\$2.9
IMGN	ImmunoGen, Inc.	\$154	213.0	\$13.1	\$79.8	\$39.5	(\$16.9)	(\$14.7)	\$19.1	\$2.9
INCY	Incyte Corporation	\$929	196.0	\$0.6	\$275.7	\$34.4	(\$86.9)	(\$92.7)	\$170.4	\$12.3
KOSN	Kosan Biosciences Incorporated	\$80	80.0	\$3.3	\$77.9	\$22.7	(\$28.7)	(\$34.7)	\$3.4	\$42.6
MCU	Medicure Inc. (USA)	\$9	36.0	\$0.0	\$62.8	\$5.0	(\$54.6)	(\$42.8)	(\$1.5)	\$61.6
PCOP	Pharmacopeia, Inc.	\$108	169.0	\$47.2	\$90.4	\$21.4	(\$47.9)	(\$11.1)	(\$43.7)	\$41.9
REGN	Regeneron Pharmaceuticals, Inc.	\$1,540	682.0	\$236.8	\$936.3	\$125.0	(\$105.6)	\$27.4	(\$85.7)	\$319.4
SGEN	Seattle Genetics, Inc.	\$760	189.0	\$83.7	\$148.5	\$22.4	(\$48.9)	\$39.8	\$4.1	\$6.6
TELK	Telik, Inc.	\$132	95.0	\$0.0	\$98.5	\$0.0	(\$55.2)	(\$48.4)	\$11.4	\$0.8
TRCA	Tercica, Inc.	\$313	126.0	\$11.6	\$176.7	\$31.0	(\$40.5)	(\$34.3)	\$2.1	\$64.2
ZGEN	ZymoGenetics, Inc.	\$683	570.0	\$40.9	\$263.1	\$38.5	(\$148.1)	(\$87.5)	\$106.1	\$5.0

Source: FactSet, GLC.

## 2: Revenue Collaboration Detail

Ticker	Company Name	Active Revenue Collaborations	Up-front Payments	Milestone Payments	Joint Steering Committees	Joint R&D / Cost Sharing	Royalty Payments	Equity Purchase	Loan from Partner	Future Rights	Retained Rights
ACOR	Acorda Therapeutics Inc.	0	0	0	0	0	0	0	0	0	0
ADLR	Adolor Corp.	2	2	2	2	2	2	0	0	1	2
ALXN	Alexion Pharmaceuticals Inc.	0	0	0	0	0	0	0	0	0	0
ALNY	Alnylam Pharmaceuticals Inc.	5	3	3	5	0	4	2	0	2	1
ALTU	Altus Pharmaceuticals Inc.	1	0	1	1	1	1	1	1	0	0
FOLD	Amicus Therapeutics Inc.	1	1	1	1	1	1	0	0	0	0
AGEN	Antigenics Inc.	3	3	3	1	0	2	0	0	0	0
AVGN	Avigen Inc.	1	1	1	0	0	1	0	0	1	0
CADX	Cadence Pharmaceuticals Inc.	0	0	0	0	0	0	0	0	0	0
CEGE	Cell Genesys Inc.	3	2	1	1	1	2	1	0	1	0
CYTK	Cytokinetics Inc.	2	2	2	2	1	2	2	0	2	2
ENMD	EntreMed Inc.	2	2	2	0	0	2	0	0	0	0
GNVC	GenVec Inc.	5	5	1	0	0	0	0	0	0	0
IDIX	Idenix Pharmaceuticals Inc.	1	1	1	1	1	1	1	0	1	1
IDRA	Idera Pharmaceuticals Inc.	4	4	3	4	1	3	1	0	2	0
IMGN	Immunogen Inc.	7	7	7	7	2	7	1	0	2	1
INCY	Incyte Corp.	1	1	1	1	0	1	0	1	0	0
KOSN	Kosan Biosciences Inc.	2	2	2	1	2	2	0	0	0	1
MCU	Medicure Inc.	0	0	0	0	0	0	0	0	0	0
PCOP	Pharmacopeia Inc.	4	4	4	3	0	3	1	0	2	1
REGN	Regeneron Pharmaceuticals Inc.	5	5	2	2	2	3	0	0	1	1
SGEN	Seattle Genetics Inc.	6	6	6	2	2	5	0	0	2	1
TELK	Telik Inc.	0	0	0	0	0	0	0	0	0	0
TRCA	Tercica Inc.	1	1	1	1	1	1	1	1	1	0
ZGEN	ZymoGenetics Inc.	4	2	3	3	2	4	1	0	2	2
	Total	60	54	47	38	19	47	12	3	20	13

Source: Company reports, GLC.

### **Disclosure Information**

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