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Co-Commercialization Deals in Life Science Collaborations

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The life sciences industry is witnessing an explosion in the use of co-commercialization arrangements in collaboration arrangements.

Ropes & Gray conducted a sample survey of life science collaboration agreements and observed over a four-fold increase in the use of co-commercialization arrangements from 2017 to 2019.

This trend appears to be driven, at least in part, by skyrocketing biotechnology valuations and increased competition among pharmaceutical companies to partner with biotechnology companies to license key technology. In this environment, biotechnology companies are increasingly gaining the leverage to demand co-commercialization arrangements.

This commentary provides background on co-commercialization provisions generally and highlights some of the creative ways negotiators tailor the scope of these terms in collaboration agreements to win deals.

This analysis also provides data, based on a survey of 35 agreements from 2015 to 2019, on market trends for co-commercialization terms in the industry. While our survey showed that there are some common trends, we found that there is an abundance of diverse approaches taken by companies, with no "one size fits all" approach.

Co-Commercialization

Under the traditional collaboration agreement model, a biotechnology company exclusively licenses a product or technology, perhaps in specific fields or geographies, to a pharmaceutical company that, in exchange, commercializes the respective product and pays milestone payments and royalties to the biotechnology company for the license. Co-commercialization arrangements typically change this traditional relationship in two ways.

First, co-commercialization arrangements often allow the biotechnology company to participate directly, along with the pharmaceutical company, in the promotion of a product under a single brand name. This is sometimes known as "co-promotion" or "co-detailing."

For example, a biotechnology company might be responsible for a certain percentage of overall detailing activities—such as visits by sales representatives with a health-care provider to discuss approved uses or effectiveness of a product, thereby increasing prescriptions and sales.

Second, in a co-commercialization arrangement, the biotechnology company often shares in the profit and loss of a co-commercialized product and, in many cases, the development costs as well. The biotechnology company typically foregoes receipt of milestone payments and royalties, whether in part or in whole, in exchange for sharing of profit/loss and development costs.

Typically, a biotechnology company has an option to opt into a co-commercialization arrangement. However, some collaboration agreements make co-commercialization the default scenario, with the biotechnology company having the right to opt-out.

Co-commercialization arrangements are distinguishable from co-marketing arrangements, where two companies promote the same product but each under a different brand name.

Business Rationales

Biotechnology companies, which initially lack the internal resources and experience to commercialize products on their own, often favor co-commercialization arrangements.

Co-detailing provides a mechanism for biotechnology companies to build up their internal sales force infrastructure under the guidance of an established pharma company. Many biotechnology companies seek to co-detail in the U.S. in particular, given that it is the largest pharmaceutical market in the world.

In addition, co-commercialization arrangements are often financially attractive to biotechnology companies, as profit sharing may offer more financial upside than receiving milestone payments and royalties. A co-commercialization option can demonstrate accumulation of value and positively signal to Wall Street and other investors the company's future value.

However, large pharmaceutical companies often disfavor co-commercialization arrangements due to associated administrative burdens and reduced control over commercialization.

For example, pharma companies must coordinate with (and sometimes train) the biotechnology company's personnel, which can divert resources, and a pharma company may have questions about the biotechnology company's ability to effectively co-commercialize and co-detail given resource constraints. Considerable time may need to be expended to coordinate joint commercialization plans and strategies, and disputes can arise if the collaborators have different visions.

Of course, co-commercialization provisions come with their own risks for biotechnology companies.

Financially strapped biotechnology companies could find themselves on the hook for reimbursement of significant development costs prior to commercial launch of a product. These costs could be unexpected if a biotechnology company makes erroneous assumptions in its financial modeling and forecasting or the development plan of a product.

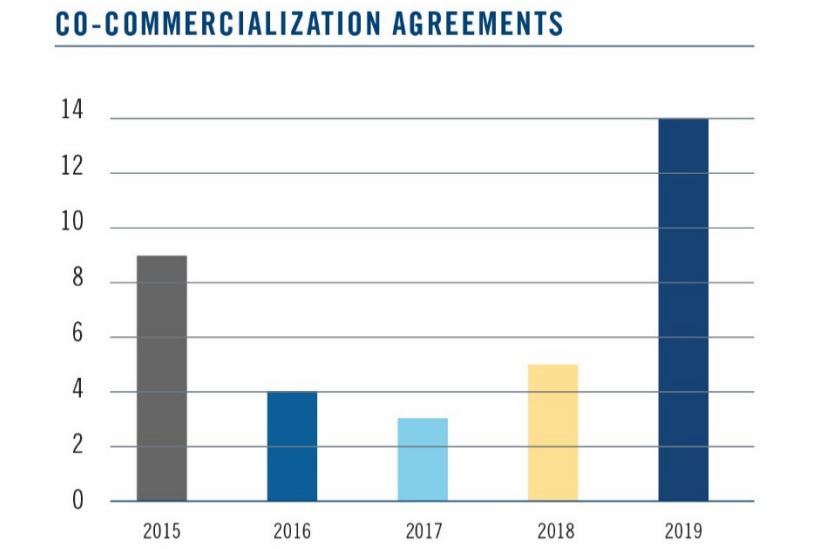
Some co-commercialization arrangements attempt to address this risk by allowing the biotechnology company to defer payment of development costs. A biotechnology company may, for example, defer payments until after first commercial sale of a product, or allow the pharma company to offset such costs against other payments (e.g., a milestone payment or profit splits).

A biotechnology company could also elect to "opt down" its share of development costs, along with its profit share percentage.

Recent Market Trends

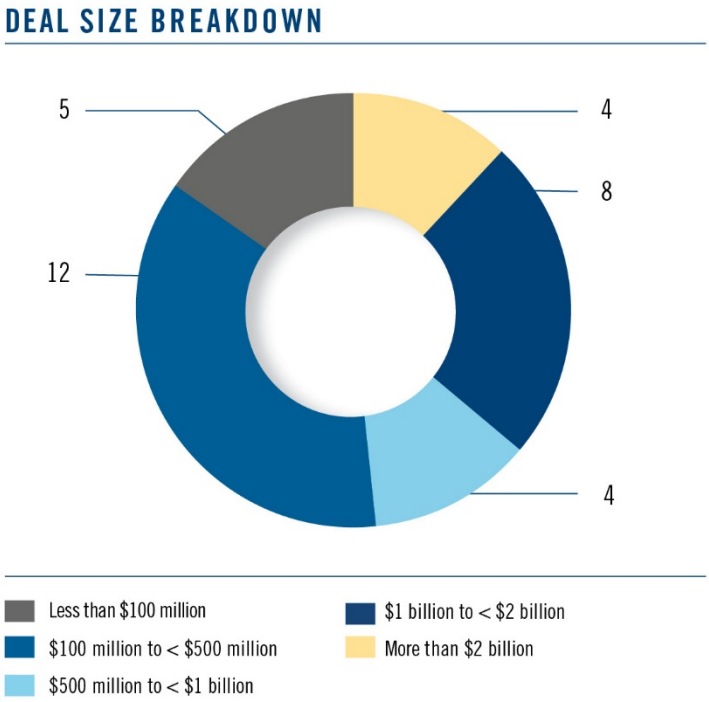
In analyzing recent market trends, we reviewed all agreements dating from Jan. 1, 2015 until Dec. 1, 2019 that were publicly available in redacted form via filings with the U.S. Securities and Exchange Commission or otherwise confidentially available to our firm. From that process, we identified 35 agreements containing co-commercialization arrangements.

Figure 1 illustrates the sharp growth in the use of co-commercialization arrangements over that period. We identified nine agreements containing co-commercialization terms in 2015, which fell to three in 2017 and later swelled to 14 in 2019.



*Number of commercialization agreements for 2015 to 2019 shown above.

We also reviewed related press releases for these deals. We calculated that the average deal value size, where such information was available, was approximately $840 million, taking into account upfront payments, milestone payments and other equity investments. Figure 2 breaks down the deal value sizes of the surveyed agreements.



*Deals without a press release and with redacted financials omitted from this chart.

While the smallest deal was approximately $15 million, the largest deal surpassed $2.5 billion. A dozen agreements, which mostly came from very recent years, topped over $1 billion.

More than three-quarters of surveyed agreements involved pre-clinical stage assets, with the remainder covering clinical-stage assets.

While the agreements we surveyed covered a variety of diseases and disorders, close to half were for cancer therapies. This was followed by agreements for treatments of central nervous system disorders or cognitive degeneration.

Almost all of these agreements provided the biotechnology companies with the right to opt into co-commercialization arrangements.

The timing for opting in varied widely, from immediately after execution of the collaboration agreement to two years following commercial product launch. Popular opt-in times were anchored around the filing of an investigational new drug application, completion of Phase I clinical trials and the filing of regulatory or marketing approval of a product.

Only two agreements we surveyed hard-wired the biotechnology company's co-commercialization and co-detail rights from the outset.

The vast majority of the surveyed agreements limited co-commercialization and co-detail rights to the U.S. However, we observed a handful of agreements where the biotechnology company could also co-commercialize and co-detail in Canada, certain European countries (most commonly Germany, France, Spain, Italy, and the U.K.) or China.

Although our sample size was limited, our survey echoes observations shared to us by industry insiders—co-commercialization arrangements are hot.

Competition for collaboration relationships is fierce given that promising biotechnology companies are limited in number. Biotechnology valuations are therefore skyrocketing, and biotechnology companies (many times advised by bankers, venture capitalists or other consultants) are pushing for terms that are favorable to them.

As a result, we have seen a shift, with biotechnology companies increasingly asking for co-commercialization arrangements in collaboration deals and gaining greater leverage in negotiating for them.

While in the past pharmaceutical companies may have been able to reject co-commercialization proposals outright, such companies are now under mounting pressure to identify creative solutions to win and close deals, including agreeing to co-commercialization terms.

In fact, in our practice, we have seen pharma companies lose competitive deals due to lack of familiarity with effective ways of drafting co-commercialization terms. In short, co-commercialization terms are becoming deal makers or deal killers.

Negotiation Considerations

While our survey revealed that there are some common trends in co-commercialization arrangements, we also found that there is a plethora of unique approaches taken by companies, with no one-size-fits-all solution.

Negotiators have a number of tools to limit or expand the scope or effect of a co-commercialization right, some of which we highlight here.

Basic Co-Commercialization Terms

First, parties can consider appropriately tailoring the fundamental terms of a co-commercialization arrangement, including geography, products, and duration.

For example, the geographic territory of a co-commercialization arrangement can be narrow (e.g., U.S.) rather than broad (e.g., worldwide). A co-commercialization arrangement could also be limited to a set number of products, with the pharma company having a set number of veto rights with respect to option exercise.

A pharma company can also narrow the time period in which any option may be exercised. We have also seen "use it or lose it" terms – that is, if the biotechnology company does not exercise its co-commercialization option for the first product, it cannot do so for any subsequent product.

Criteria for Opt-In

One new, creative approach employed by pharma companies to limit the effectiveness of co-detailing options is a requirement that biotechnology companies meet certain threshold criteria before they can opt into co-detailing activities.

These criteria can be specific and objective (e.g., requirement to have a sales force of a certain size in place by a certain date) or more general and subjective (e.g., requirement to have sufficient capability, in the pharma company's reasonable discretion, to be an effective co-detailing partner).

We have also seen agreements that only permit the biotechnology company to opt-in if net sales of a product are below a certain dollar threshold by the end of the year, or where the biotechnology company must pay an option fee to the pharma company before it can co-detail.

Profit/Loss Share

Negotiators should give careful consideration to the economics of any co-commercialization arrangement.

Under a traditional co-commercialization scheme, the pharma and biotechnology companies will equally split the profit and loss of the co-commercialized product. However, we have sometimes seen other ratios such as 80-20, with pharma companies receiving most of the profits. We have also seen cases where profits were equally split, but commercialization costs were not.

Parties should always confer closely with their finance teams in determining what type of commercialization costs will be shared.

Negotiators may also wish to consider approaches other than strict profit sharing, though biotechnology companies may be less amenable to such approaches as they may have less upside potential.

For example, we have seen deals that involved a biotechnology company assisting in the detailing of a product but receiving a set amount of compensation per detail or reimbursement of commercialization costs up to a certain cap.

Another approach may include a royalty "buy up" scheme. Instead of sharing profits and losses upon opt-in, the biotechnology company could instead receive higher royalty payments.

Development Costs

Parties should also consider whether, and to what extent, development costs will be shared.

While development costs are typically split 50-50, it is not unusual to see other ratios such as 70-30, with pharma companies bearing the higher share of development costs.

Negotiators should contemplate whether the biotechnology company will reimburse the pharma company for any past development costs incurred by the pharma company prior to opt-in. Our survey showed that in most cases, past development costs were not reimbursed.

Other questions to consider include whether worldwide development costs will be shared, or only those that are allocable to a specific territory.

Governance

Governance is one of the most important issues in a co-commercialization arrangement.

Co-commercialization arrangements typically call for the creation of plans that govern detailing activities. While the pharma company typically wants to maintain as much control over these decisions as possible, the biotechnology company would generally prefer that these decisions run through joint committees.

Certain categories of decisions (e.g., regulatory decisions and key commercial decisions such as initiating product recalls) usually are not delegated to the joint committees. However, other decisions at the level of the implementation of detailing plans may be delegated to committees.

As such, parties need to determine which issues joint committees will oversee. For example, does the pharma company create the joint commercialization plan or does the joint committee do that? Does the pharma company set product pricing or does it recommend pricing to the joint committee?

In addition, parties must determine how disputes will be resolved at the committee level. From our survey, the majority of collaboration agreements gave final decision-making authority to the pharma company. However, some collaboration agreements provided that disputes escalate to arbitration.

Even if a party is generally given final decision making authority, negotiators can decide whether specific issues will require mutual agreement (e.g., increasing a development budget beyond 10%).

Commercialization Activities

Parties must also iron out specifics with respect to coordination of co-commercialization activities.

For example, who will book sales of products? Who is responsible for training?

Even if co-detailing is in a shared territory, should the parties have the right to designate some countries, states or types of medical practices within that territory to be the sole domain of one party?

What percentage of sales force efforts will each party provide? What happens if a party provides less than its share? Can a party make up for its shortfall going forward?

These are but a few of the types of practical questions that parties must consider as they negotiate co-commercialization arrangements.

Opt-Out Rights

Parties should also consider whether the biotechnology company has the right to opt-out of co-commercialization.

A slight majority of the agreements we surveyed gave biotechnology companies such an opt-out right.

Parties can consider whether to limit such opt-out exercise to a specific time period, or let the biotechnology company opt-out at any time. Our survey showed that most agreements did not time bar any such opt-out rights.

The economic consequences of opt-out is also an important topic. While opt-out exercise often triggers reversion to the economics that were in place prior to opt-in (e.g., milestones and royalties), we have seen other unusual approaches, such as penalty fees for opt-out.

Change of Control

One tool that appears to be under-utilized in co-commercialization arrangements relates to change of control transactions.

To protect itself in the event that a biotechnology company is acquired by a competitor of the pharma company, a pharma company could consider including a change of control trigger, allowing the pharma company to terminate the biotechnology company's co-commercialization activities, disband joint commercialization committees, cease co-detailing activities and limit information sharing to just high-level financial information (rather than detailed commercialization strategies).

Parties should decide whether such a right triggers upon any change of control or just a change of control involving a competitor.

Conclusion

Co-commercialization arrangements are valuable tools that allow life science companies to share in the financial risks and rewards associated with the development and commercialization of a drug product. In the current environment, it is increasingly important that life science companies familiarize themselves with different approaches to negotiating co-commercialization terms to effectively close favorable deals. This article provides some food for thought for legal and business development professionals as they think about how to structure co-commercialization deals.