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as seen in ***Law360***

April 1, 2024

Negotiating Milestones in Pharma Licenses Requires Care

By Edward Angelini and Lori Waldron

With an ever-expanding landscape of novel pharmaceutical and biotech products, license agreements serve as a mechanism to foster research and development, continued collaboration and market access.

Companies are able to leverage each other's innovation and resources to bring products to market more efficiently. One of the key components of any license agreement is the economic blueprint between the parties.

This article focuses on milestone payments and various strategies and nuances that each of the parties might consider, with an eye toward either increasing the likelihood and amount of milestone payments received as the licensor, or ensuring milestone payments are carefully and closely tied to events that truly drive value as the licensee.

A fundamental concept behind determining milestone payments is that, as the product progresses through the various stages of R&D and commercialization, the risks associated with obtaining a viable product decrease and, thus, the value of the licensed technology increases.

Typical milestone triggers for a pharmaceutical or biotech product are associated with (1) clinical trials and related outcomes, (2) regulatory filings or approvals, and (3) product launch and achievement of specified sales targets. Each item described below can be quite complex, and this list is illustrative and intended only to spark ideas without including all the fine print.

Some Important Considerations Based on Milestone Type

Clinical-stage milestone payment obligations should correlate directly to events that reduce risk and increase the value of the product.

When occurrence of a milestone event is tied to one or more of the various clinical developmental stages of a product, again, milestone payments should correlate closely with events that reduce product risk and increase value.

Rather than tying payments to completion of a particular clinical stage, a licensee could consider linking payments to the commencement of the next stage to avoid payments that are not tied to true clinical advancement.

For example, it is quite possible that the licensee would complete its Phase II clinical trial, but not be satisfied with the results. Instead of moving forward to a Phase III trial, the licensee may opt to conduct another Phase II trial or, perhaps, end its R&D with respect to the product entirely.

In either of these scenarios, it would be unfortunate for the licensee to be contractually required to pay a milestone payment to the licensor for completing the Phase II trial.

An alternative approach for the licensee would be to tie the occurrence of the milestone event to completion of the Phase II clinical trial, but to provide that specific successful trial results must be obtained in order for the milestone payment obligation to be triggered, such as achievement of primary endpoints as set forth in the study protocol.

Regulatory milestone payments should be specific and correlate to regulatory success.

Submission of regulatory filings and receipt of regulatory approvals are also frequently included as milestone payment triggers. Typically, earlier stage submissions will be associated with lower payments, since a product at the preclinical stage still carries with it significant risk.

Thus, milestone payments for the submission of an investigational new drug will typically be lower than payments based on submission of a new drug application or biologics license application.

With respect to paying milestones for submission of regulatory filings, a note of caution is warranted. Not all submissions are created equal, and a prudent licensee will want to avoid being required to pay a milestone payment for a substandard submission by the licensor that was hastily submitted for the sake of achieving a milestone, with the knowledge that the submission will have to be improved and reworked in order to be accepted by the U.S. Food and Drug Administration.

One way to address this issue is to tie payment to the actual acceptance of the submission by the FDA, i.e., the submission has met the FDA's filing requirements.

Similarly, with respect to milestones that are paid upon FDA approval, it is worth noting that not all approvals are created equal. Ideally, based on the nature of the product, the licensee will want to limit payment for approval milestones to final, nonconditional approvals with no post-approval commitments — for example, a Phase IV, pediatric or other study.

A required post-approval study may cost millions of dollars to complete and may materially diminish the true value of the approval.

Commercialization milestones should tightly define launch, sales and other relevant targets.

Once a product has been approved by the FDA for commercialization, the parties will frequently attach additional milestone value to launch and commercialization of the product.

For launch, key performance metrics to consider are security and continuity of supply, including delivery of commercial launch quantities of product.

Timing of launch is also a critically important factor. In order for a launch milestone to be earned, ideally, launch should occur within a relatively short period of time following FDA approval, and could be further qualified based on the number of competing products on the market at the time of launch.

Of course, commercialization milestones also often include payments attached to the achievement of certain net sales thresholds. Licensees will want these milestone triggers to be carefully drawn based on a definition of "net sales" that includes appropriately negotiated deductions.

In addition, licensees will want to define with sufficient clarity the time periods for which net sales thresholds will be measured. Annual net sales is probably the most common time period that is used, but frequently there will also be milestones based on total cumulative net sales.

Additional Frequent Issues

Consider flexibility of milestone payments.

The dollar amount of every milestone payment does not need to be predetermined at the time that the parties execute the license agreement.

For instance, keeping in mind the original premise that milestone payments should be tied to a decrease in risk and an increase in value, the actual amount of the payment owed could fluctuate based on the date that a particular event is achieved, the complexity of regulatory hurdles, whether or not patent protection has been granted, or the number of competing products on the market at a specified time.

Intellectual property protection is often critical.

With respect to intellectual property protection for a product, often additional patent applications are being prepared or are pending during development.

The additional patents, once issued, may secure market exclusivity for a product in a way that warrants contribution of additional value from the licensee in the form of a milestone payment.

These milestones should be carefully crafted to correlate payment to issuance of patents that are truly innovative, advance the therapeutic or diagnostic benefits of the product, and contain the specific claim or claims that are most likely to confer additional market exclusivity or other significant value.

Creditability is an option.

Milestone payments could be creditable, in whole or in part, against other payments owed under the license agreement. The credit is often applied to — and reduces — another payment owed under the license agreement that correlates to the same underlying facts.

For example, a milestone payment that is owed when an agreed upon net sales target is achieved could be creditable against a royalty or profit share payment that is owed based on the same net sales.

Credibility could be further fine-tuned. For instance, perhaps a credit could only be applied against a royalty payment to reduce the royalty payment by a maximum of 50%, with unused credits to be carried-forward for a specified time period.

Refunds can also come into play.

Milestone payments could also be refundable. When a party breaches an agreement, the other party typically has legal remedies such as a termination right and the right to seek monetary damages.

The license agreement could also include a liquidated damages provision providing that, in the event that the licensor materially breaches the license agreement, one or more previously paid milestone payments would be refunded.

Refund provisions could also be based on nonbreach scenarios such as the occurrence of a third-party infringement claim or the failure to obtain regulatory approval by a certain date.

Sometimes licensees may want to seek a refund of an FDA approval milestone payment if the licensor is also responsible for supply of the product to the licensee, but fails to deliver. The licensor is likely to resist refunds of milestones, in general, on the grounds that refundability may delay recognition of milestone revenue.

Detecting and avoiding problems is essential.

Licensors are encouraged to include robust systems for tracking and documenting achievement by the licensee of individual milestone targets to ensure accurate and timely payments.

This could include, for example, a requirement that the licensee provides, in addition to prompt notice of its achievement of any milestone target, regular reports regarding the status of ongoing activities related to milestone targets.

With respect to sales based milestone targets, e.g., a milestone payment being owed when a particular net sales threshold is achieved, the licensor could include a right to audit the licensee's books and records.

Typically, the licensor would bear the costs and expenses of its audit activities, unless the audit revealed an underpayment by the licensee that is above an agreed-upon threshold, in which case the licensee could be required to bear the costs and expenses.

Sometimes "most favored licensee" protection is relevant.

From the licensee's perspective, in the event of a nonexclusive license, a most-favored-licensee provision could be beneficial. Such a provision often provides that, notwithstanding the terms described in the license agreement, in the event that the licensor grants a license for the same inventions or technology to a third party on more favorable terms, the milestone payments — and perhaps other financial and nonfinancial material terms — of the license agreement would be reduced or otherwise adjusted to conform to the more favorable terms.

Conclusion

Each of the strategies described above can be used individually or can be combined with these and other strategies to affect the amount and timing of milestone payments. Although the interrelation of these various provisions could be complex, by understanding the unique issues and concerns that arise when analyzing and negotiating milestone provisions, each party is better able to advocate for itself and its stake in the relationship.

Edward G. Angelini *is the vice president and associate general counsel for M&A and business transactions at Amneal Pharmaceuticals.*

Lori M. Waldron *is co-chair of the life sciences practice group at Sills Cummis & Gross P.C.*