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February 2022

2022 - A Collaborative Year?

Overview

"Scorpion Therapeutics enters into Agreement with AstraZeneca to discover, develop and commercialize novel cancer treatments[i]…"

"Amgen swings another deal, this time with RNA drugging player Arrakis for several billion[ii]…"

"Codex DNA signs early access Collaboration and Licensing Agreement with Pfizer to Further Develop Codex DNA's Novel Enzymatic DNA Synthesis Technology[iii]…"

"Dren Bio announces Research Collaboration and License Agreement with Pfizer to Discover and Advance Multiple Therapeutic Antibodies[iv]…"

If the headlines we have seen during the first month and a half of 2022 are any indication, the sector is in for another busy year of collaboration and licensing arrangements, as life science entities look to partner with one another to develop and/or commercialize certain drug candidates or medical products.

What Are Collaboration Agreements?

Life science companies frequently enter into collaborative arrangements to share resources and risks associated with developing future products. These agreements are mutually beneficial agreements in which two entities contract to collaborate in a defined research and development or commercialization effort. Collaborative arrangements frequently involve activities such as R&D, regulatory actions, manufacturing, distribution, sales and marketing activities, and general and administrative tasks. One party may license out its intellectual property and perform research and development activities, while the other party is responsible for regulatory and commercial efforts. In some agreements, one party may be required to pay an up-front payment, reimburse the other party for research and development activities, and payout developmental and commercial milestones and royalties. In return, they will gain access to

the other party's intellectual property, clinical results, and expertise needed to develop and eventually commercialize a product.

Typically, a governance structure (e.g., a joint steering committee) is established to facilitate decision-making during the terms of the endeavor.

In collaborations, the parties may allocate responsibility for individual activities to each other or share the responsibility for one or more activities under a joint operating arrangement. Joint operating activities may involve the joint development and ultimate commercialization of intellectual property related to a potential new drug candidate, R&D, marketing (including promotional activities and physician detailing), general and administrative activities, manufacturing, and distribution activities.

Based on contractually defined terms, the participants may share the profits or losses associated with these joint activities. Such arrangements are often complex and can vary significantly in scope, terms, conditions, and risk mitigation objectives.

Accounting Implications

When an entity enters into a collaboration agreement, careful consideration must be made to determine if the contract meets the U.S. GAAP definition of a collaborative arrangement and, thus, is subject to the requirements of ASC 808. The legal characterization of a collaboration does not always mean the arrangement qualifies as a collaborative arrangement under U.S. GAAP.

Under ASC 808-10-20, a collaborative arrangement is a "contractual arrangement that involves a joint operating activity" and involves two (or more) parties that are both of the following:

- "Active participants in the activity."
- "Exposed to significant risks and rewards dependent on the commercial success of the activity."

Only concluding that the arrangement meets both of these criteria, will lead to ASC 808 guidance applied to the arrangement.

Another critical assessment the entity must make is if the Company has an obligation to repay the funding party or is under a contract to perform R&D services. If a determination is made at the onset of the arrangement that successful completion of the R&D is probable, it may be more appropriate to treat the arrangement as the sale of future revenues under ASC 470-10-25. If this guidance does not apply, the Company should next evaluate ASC 730-20 to determine whether the arrangement represents an obligation to repay the funding party or a contract to perform services. Under ASC 730-20-35-3, "if the entity is obligated to repay any of the funds provided by the other parties regardless of the outcome of the research and development, the entity shall estimate and recognize that liability. The requirement applies whether the entity may settle the liability by paying cash, issuing securities, or by some other means."

If the arrangement does not meet ASC 808, ASC 470, or ASC 730, management must determine if the arrangement is within the scope of ASC 606. Under the ASC 606 5-Step Model, the entity must then assess the following:

- Identify the contract with a customer;
- Identify the performance obligations in the contract;
- Determine the transaction price;
- Allocation of the transaction price;
- Recognize revenue when or as the entity satisfies a performance obligation.

Concluding whether revenue is recorded up-front or over-time could result in a drastically different P&L and balance sheet presentation. Future development and commercial milestones, as well as commercial royalties that are contingent upon a future event, must also be analyzed, documented, and properly disclosed.

How Centri Can Help

You may have heard that collaboration arrangements are like snowflakes in that there are no two agreements that are exactly alike. This is why experience matters. We'll help you answer questions that may come to mind like these:

- Which guidance does your agreement fall under?
- How (and when) do you recognize the up-front payment?
- What if there is an equity component?
- Do you have a funded R&D contract?
- What if the other party is reimbursing us for R&D costs?
- Once the product is commercialized, how are the milestone payments, options, or royalties accounted for?

Our Life Sciences Team can help you with these questions and more. We offer customized life sciences accounting services designed to meet the demands of your company as they emerge and evolve. Our experts provide guidance for biotechnology, medical device manufacturers, and pharmaceutical companies throughout their lifecycle.

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[i] AstraZeneca and Scorpion Therapeutics Enter Agreement to Discover, Develop and Commercialize Novel Cancer Treatments Against 'Undruggable' Targets

[ii] Busy Amgen Swings Another Deal, This Time with RNA Drugging Player Arrakis for 'Several Sillion' – Endpoints News (endpts.com)

[iii] Codex DNA Signs Early Access Collaboration and Licensing (globenewswire.com)

[iv] Dren Bio Announces Research Collaboration and License Agreement with Pfizer to Discover and Advance Multiple Therapeutic Antibodies - BioSpace