PhaseBio – A Drug Development Financing (Almost) Tested in Bankruptcy

January 9, 2023, *Covington Alert*

As 2022 drew to a close, a Delaware bankruptcy court approved a settlement between PhaseBio Pharmaceuticals and SFJ Pharmaceuticals over their ill-fated drug development financing partnership. This court approval ended a legal saga that began two years ago, when PhaseBio, a public biopharmaceutical company developing a novel drug to control bleeding in certain patients, entered into an agreement with SFJ, a company that finances and supports drug development, to fund up to $120 million to advance PhaseBio's pivotal Phase III trial for the drug. The dispute and settlement highlight some risks inherent in these deals, and how their structure may be treated in a bankruptcy proceeding.

Drug development financing deals have been around for a number of years. But until now, the deals had eluded any notable challenge in bankruptcy court.

Drug Development Financings in Brief

Drug development financings are one of the sources of capital available to biotechs and established pharmaceutical companies to help fund the time consuming and expensive clinical trial process necessary for the regulatory approval and launch of promising new medicines. In these deals, investors agree to provide capital for drug development in exchange for milestone and/or royalty payments that are earned in the event the drugs are ultimately approved for sale. These are primarily financial arrangements, as compared to licensing and collaboration agreements, common in the life sciences industry, where intellectual property necessary for drug development is an integral part of the transactions. Given the risk taken in these deals for products still in clinical trials, the returns earned by investors for successful drugs generally range from two to five times, or more, of invested capital.

Background of the PhaseBio Dispute

In the PhaseBio case, SFJ provided $120 million of capital to PhaseBio in exchange for up to $600 million, payable in tranches once PhaseBio obtained approval to sell its product in relevant markets. This significant potential return on investment for SFJ suggests a high level of risk in the deal. To secure its promise to make the agreed milestone

unique for a transaction of this type, involved an obligation on the part of PhaseBio to transfer to SFJ the product and related assets upon SFJ's request if PhaseBio included a "going concern" footnote in its quarterly or annual financial statements or otherwise became unable to meet its obligations as they became due within the next 12 months, in each case subject to a 180-day cure period. In addition, the agreement provided that the data resulting from the clinical trial was to be owned by SFJ and transferred to PhaseBio only upon regulatory approval and the making of a milestone payment by PhaseBio.

This transfer right became effective as a result of an uncured going concern qualification issued when PhaseBio filed its 10-K on March 24, 2022. The parties attempted to negotiate a consensual transfer of the drug development program to SFJ when it became clear that the transfer right would be triggered. But PhaseBio appears to have sought terms different from those specified in the development agreement. When SFJ and PhaseBio could not come to an agreement, SFJ sent a demand to PhaseBio to transfer the program pursuant to the terms of their agreement, and then sued PhaseBio on October 7, 2022 in federal district court to enforce that demand. PhaseBio consequently filed for bankruptcy protection, with a plan to sell the drug under development (PhaseBio's principal asset) in a Section 363 sale, with a stalking horse bidder lined up to pay $40 million up-front with $60 million in potential milestone payments.

To facilitate this sale, PhaseBio commenced litigation**[1]** on an expedited schedule in the bankruptcy court seeking to recharacterize the drug development financing as an equity investment, and to declare SFJ's ownership of the trial data package invalid as a legal fiction. To support the recharacterization claim, PhaseBio pointed to the pure risk-capital nature of the investment, highlighting the five-times return SFJ could receive and the fact that SFJ would get *nothing* if the product was never approved. PhaseBio also noted the "never-before-tested" nature of this drug development structure in bankruptcy. For its part, SFJ argued**[2]** that the agreement between SFJ and PhaseBio was an arms-length, industry-standard pharmaceutical development agreement that gave certain bargained for rights to SFJ, secured by a perfected first priority security interest over substantially all of PhaseBio's assets. But, as compared to pharmaceutical licensing and collaboration agreements that include a license of intellectual property, the SFJ arrangement was primarily a financial accommodation, which made it more susceptible to challenge under applicable bankruptcy law.

Order Approving Settlement

On the last day of 2022, and after a court arranged mediation, the bankruptcy court issued an order**[3]** approving a settlement of the dispute between PhaseBio and SFJ on the following terms, pursuant to which SFJ obtained the assets it was seeking, but at a financial cost:

- The transfer of the drug under development and other program assets to SFJ, free and clear of all liens,
- The ownership by SFJ of the trial data package,
- Payment by SFJ of $32.9 million in cash, which will be used to pay the expense reimbursement of the stalking horse bidder, certain vendor payments and the costs necessary to wind down the chapter 11 estate, including the repayment of DIP facility entered into to finance the bankruptcy case,
- Payment by SFJ of up to $8.3 million in cash for certain other expenses, and

Lessons Learned

Companies considering product development financing, and investors in those deals, can take-away a few lessons from the PhaseBio dispute and its ultimate resolution in bankruptcy:

- *Be Mindful of Financial and Other Covenants*. Careful attention should be given to any liquidity, financial or similar covenants, and other legal terms, that may be included in these deals. These terms can have significant consequences - in this case the going concern transfer right seems to have been a precipitating factor in the bankruptcy filing.
- *Consider the Importance of Perfected Security Interests*. Security interests over intellectual property and other product assets can be an important protection for investors. In this case, perfected security gave SFJ significant leverage in its fight to ultimately obtain control over the principal asset of the company.
- *Downside Often Plays Out in Bankruptcy Court*. The bankruptcy treatment of important legal terms needs to be considered. For example, unless the underlying contracts are assumed in the bankruptcy proceeding, material contractual rights (such as the right, in this case, of SFJ to a transfer of the program assets) will likely not be specifically enforced in bankruptcy.
- *Structure Matters*. There are a number of ways to raise capital, including equity, secured and unsecured debt, true royalty monetizations and synthetic royalty or drug development deals. A true royalty monetization, where there is an incoming future royalty stream from a creditworthy payor, can often be structured in a way to insulate the royalty purchaser from the risk of the development company's bankruptcy proceeding. The other structures, however, usually remain subject to significant bankruptcy risk, which can result in uncertain and expensive litigation for all parties, even those with first priority security interests over valuable assets. SFJ walked away with the asset that it believed it had a right to, but at a significant additional cost as compared to that specified in its drug development deal with PhaseBio.

With equity valuations down and fundraising for biotech companies a more difficult proposition than it has been for a number of years, we are seeing and expect to continue to see creative biotech financing structures in the coming year, and more biotech companies with structured deals who may be facing financial distress.

If you have any questions concerning the material discussed in this client alert, please contact members of our finance and bankruptcy practices.

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[1] Phase Bio Complaint.

[2] SFJ Counterclaim and Answer.

[3] Bankruptcy Court Order Approving Settlement.

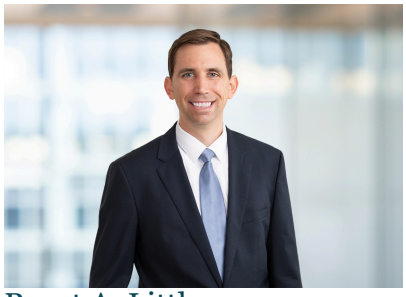
Related Professionals

Peter A. Schwartz

Partner

Martin E. Beeler

Of Counsel

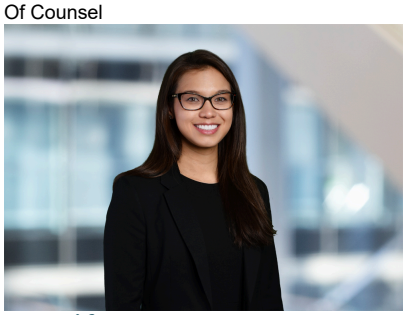


Brent A. Little

Of Counsel

Julian Wright

Special Counsel



Jennifer Uren

Partner

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As we previously reported in Royalty Rights as Unsecured Claims: The Relevance of Mallinckrodt to M&A, Revenue or Royalty Interest Financings, and Other Transactions Involving Future Payment Streams, a decision arising out of the Mallinckrodt plc...

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Financing Study

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