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An Overview of Debt and Royalty Financing Structures for Life Sciences Businesses

As a supplement to equity capital and licensing and collaboration revenues, there is an increasingly broad array of evolving methods for life sciences companies to raise money to fund their drug development and commercialisation activities. These include venture lending, growth lending, synthetic royalties, drug development financings and royalty monetisations. Each of these are available to life sciences companies in different stages of development, have unique structures, involve varying degrees of contractual restrictions, and provide different risk/return profiles for investors. In this article the authors consider these key methods for raising non-dilutive financing.

Key Points

- The five key methods for raising non-dilutive financing for life sciences businesses vary in deal size, company features, structure and economic terms, and covenants and collateral terms.
- Where life sciences businesses are entering into or have completed pivotal clinical trials (after which data is or will be available to support regulatory approval), they can access drug development finance and synthetic royalty finance, respectively.
- Recent court decisions in the US have caused most synthetic royalty and drug development financings to require security over IP and other product assets.
- Many royalty monetisations remain unsecured.

Introduction

Life sciences companies require ever-growing resources to discover, develop, obtain regulatory approval for, and bring to market new life-saving drugs. As global populations age and both medical expenditures and the pace of healthcare innovation increase, these expenditures are likely to continue to increase. In fact, notwithstanding advances in technology, as drug discovery, development and regulatory approval have become more complex, the expenses for these efforts have multiplied. Researchers at Sanford C Bernstein (now part of AllianceBernstein) coined the term “Eroom’s Law” – the inverse of Moore’s Law – to describe this phenomenon. Over the 60-year period studied, the inflation-adjusted cost of developing new drugs broadly doubled every nine years. In this environment of ever-expanding costs, the valuations of many public and private biotech and pharma companies continue to remain at levels that make equity raising a

less attractive source of funding. For those life sciences companies that are not of sufficient scale to tap traditional debt markets, or have valuations that cannot support meaningful equity financings, the need to find ways to support the capital intensive needs to produce a viable product has become imperative. As a result, in recent years, debt and royalty-focused investors have stepped into that funding void. This article explores five of the key methods used by life sciences companies to raise non-dilutive financing from these investors:

i. venture lending;
ii. growth lending;
iii. synthetic royalties;
iv. drug development financings; and
v. royalty monetisations.

These types of financings are often referred to as "non-dilutive" because they do not require the company to give up a significant ownership interest in exchange for the investment and thereby "dilute" the equity interests of other investors. Instead, investors earn their returns primarily from interest, fees, royalties and other cash payments. In this overview of the key features of these non-dilutive financing alternatives, we reference elements of both English and New York law, as these tend to be the most common governing laws for such transactions.

Venture Lending

Typical deal size

$5m to $25m (or equivalent).

Company features

Companies that raise venture debt financing typically do not yet have a revenue stream, but have the potential for significant growth in the short- to medium-term. Lenders often base their principal lending criteria on the scope and potential value of key company assets, often focused on patents and other intellectual property (IP). As such, venture debt lending is well suited to the life sciences industry, where businesses often have valuable IP, but do not have positive cashflow (or often any revenue at all). In addition, given that companies that raise venture debt often require equity finance as part of their business plans, lenders will need to be comfortable that existing investors are credible suppliers of this future equity investment. As a result, venture debt will generally not be suitable for businesses until they have done one or more significant rounds of equity financing.

Structure and economic terms

Venture debt is typically structured as a term loan, with a three- to four-year maturity (with an agreed amortisation schedule), sometimes with the ability to draw additional tranches over time. Interest is typically charged at a floating rate, tied to a relevant market benchmark. Interest-free periods (during which interest accrues and is added to principal (PIK interest) for a defined period of time) or interest-only periods (during which no capital repayments are required) can be negotiated to give the borrower more flexibility to grow its business in the early life cycle of the loan. Such periods are generally in the region of 3-18 months depending on the overall terms of the transaction. The loans will often also have upfront, prepayment and/or exit fees. In addition to cash fees, venture debt lenders commonly require a modest amount of warrants to purchase shares of stock in the borrower, thereby giving the lender some economic upside in the event of the borrower's subsequent growth. Occasionally, some portion of the debt is convertible into equity of the borrower, although the secured loan package supplemented with an "equity kicker" in the form of the warrant instrument is the more common structure.

Covenants and collateral

Venture debt financings do not have financial covenants, but will frequently include a requirement that the company maintain a significant amount of cash liquidity (given their lack of revenue to fund the business). Venture debt is invariably secured over substantially all assets of the borrower's business, although in some circumstances certain assets may be excluded from the security package (eg particular parts of the IP, if there are good commercial reasons for it to remain unencumbered).

As with most secured debt financings, venture debt will also include a significant series of representations and covenants that, among other things, will restrict the amount of further debt that can be drawn, material asset sales (including out-licences which grant another organisation the right to use the company's product), material acquisitions (including in-licences where the company acquires the rights to a product from another organisation), and dividends and other payments to shareholders and junior creditors.

Growth Lending

Typical deal size

$25m to $500m (or equivalent).

Company features

These types of loans are for a larger quantum than venture debt loans, and suitable for borrowers that have marketed products, or at the very least have later-stage products in development that expect to be marketed during the term of the loan. These companies may have recurring revenue streams, but typically still have negative cash-flow. Like venture loans, in these arrangements, lenders are generally focused on asset value – ie in a down-side scenario they believe the assets of the company could be sold for a value that is in excess of the amount owed on the loan. Sometimes this type of financing is planned or expected to bridge the company to a future period when they expect to be cash-flow positive.

Structure and economic terms

Like venture debt, growth lending is typically structured as a term loan, but the term is normally longer, often up to five years, and sometimes has a bullet maturity rather than a fixed amortisation schedule. These loans are also often offered with delayed draw tranches, and interest is charged at a floating rate, tied to a relevant market benchmark. Interest-free and interest-only periods are sometimes included, and the loans will often also have upfront, prepayment and/or exit fees. Sometimes there is also warrant coverage or convertible loans, as in the venture loan arena. And these loans also sometimes include a small, and capped, participation in revenue or product sales.

Covenants and collateral

Growth loans have a similar set of representations and covenants as are found in venture debt documents, but sometimes they also have revenuebased financial covenants. Transactions are typically secured against all assets of the business, and this will usually include all material IP.

Synthetic Royalty Financings

Typical deal size

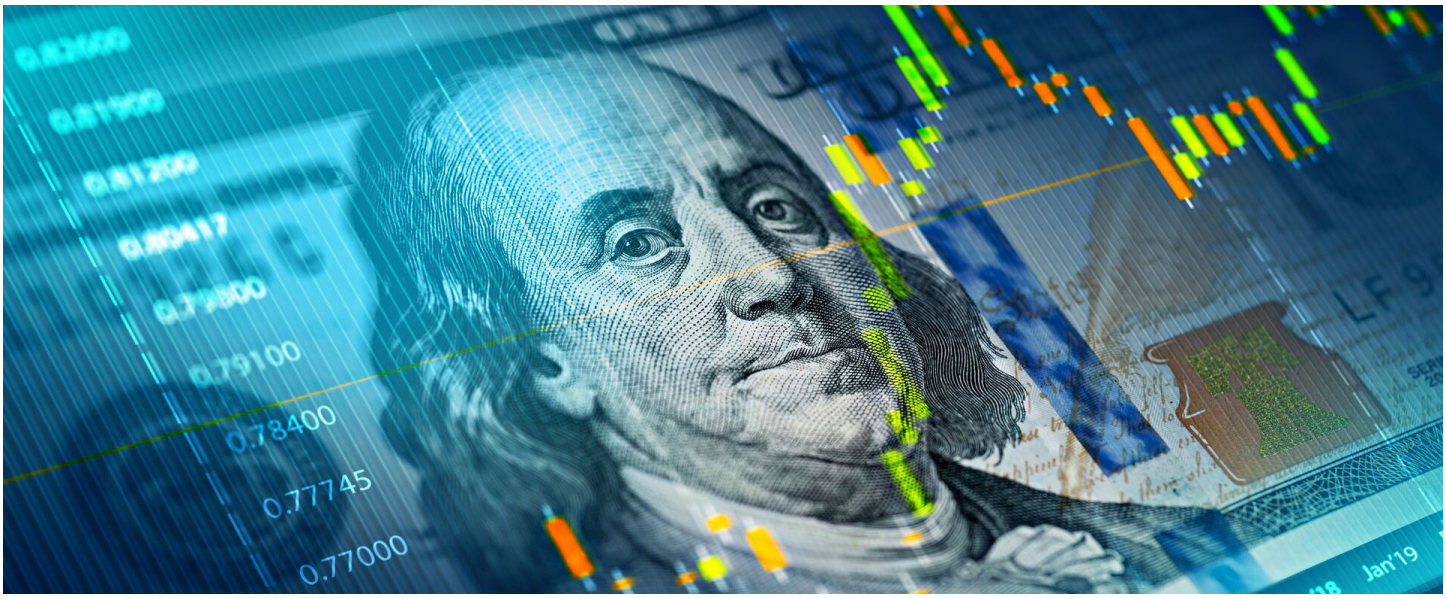
$10m to $500m (or equivalent).

Company features

Synthetic royalty financings are available to companies that have marketed products or have completed pivotal clinical trials and are awaiting regulatory approval.

Structure and economic terms

A synthetic royalty financing transaction involves the purchase of the right to receive a "synthetic royalty" on net sales of a product owned by the synthetic royalty seller. The investor will pay an upfront purchase price (akin to the principal amount of a loan) in exchange for



periodic future payments equal to a percentage of the seller's net sales of a specific product in the applicable period. As opposed to "drug development" financings, discussed below, synthetic royalty financings are typically only funded once a drug has received regulatory approval. However, it is not uncommon for a company to enter into a synthetic royalty financing after pivotal clinical trials are complete but prior to regulatory approval, with a condition to closing and funding that the regulatory approval be received. A synthetic royalty differs from traditional debt finance in a number of ways:

- the synthetic royalty will have variable payments over time (which are based on a percentage of fluctuating net sales of the product in question), rather than on a fixed interest rate as with a loan;
- there may or may not be an obligation to repay the principal amount (ie the original purchase price) and/or some premium representing a fixed return for the investor;
- credit support is frequently limited to just the IP and assets relating to the product and not all assets of the seller; and
- financial and operating covenants upon the seller are much more variable and can be less restrictive and onerous than would be the case with a typical loan arrangement, particularly in cases where the synthetic royalty is expected to be outstanding for a longer period of time than a term loan.

Most synthetic royalty financings have a cap on the total returns available to the investor. Typically, the median return cap for such transactions is in the region of 2x the initial purchase price, although the cap can be significantly lower or higher, depending on the time period expected to be required for the investor to receive the return on its investment, and the risk borne by the investor in the particular transaction. A significant number of such transactions include a requirement that the seller repay at least the original purchase price by a designated catchup payment date (although others do not require any payment in excess of the amount of royalties received). The royalty rates themselves can be quite variable depending on the product in question and may have different rates if a distinction is drawn between direct sales and revenue generated from licensing transactions.

Covenants and collateral

Recent case law in the US has had an impact on the structure of synthetic royalty financings and similar transactions both in the US and across Europe. Where a transaction similar to a synthetic royalty transaction was structured on an unsecured basis, a US bankruptcy proceeding, *Sanofi-Aventis U.S. LLC v Mallinckrodt plc (in re Mallinckrodt),* 646 F. Supp. 3d 565 (D. Del.2022) *(Mallinckrodt)*, treated the outstanding royalty payments due to the recipient, Sanofi-Aventis, as an unsecured claim in the debtor-payor bankruptcy that was discharged when the bankruptcy court approved the debtor-payor Chapter 11 plan, rather than a "true sale" of the future revenue stream (which would have given Sanofi a proprietary interest that was protected in the debtor-payor bankruptcy).

So, while historically some synthetic royalty transactions were done on an unsecured basis (sometimes in

circumstances where one or more of the parties was seeking to obtain "true-sale" treatment), given the ruling in *Mallinckrodt* in the US, and the inherent difficulty in structuring a transaction as a true-sale in jurisdictions outside of the US, the trend since 2023 is for transactions with less than investment-grade companies to always be secured. Such security is typically over the IP and assets relating to the product that is the subject of the synthetic royalty. The covenants in these transactions are often (but not always) more limited than those in debt financings. Likewise, financial covenants are exceedingly rare. Unlike venture and growth lending transactions, synthetic royalty deals do not normally include additional warrant or similar equity participation for the purchaser.

Drug Development Financings

Typical deal size

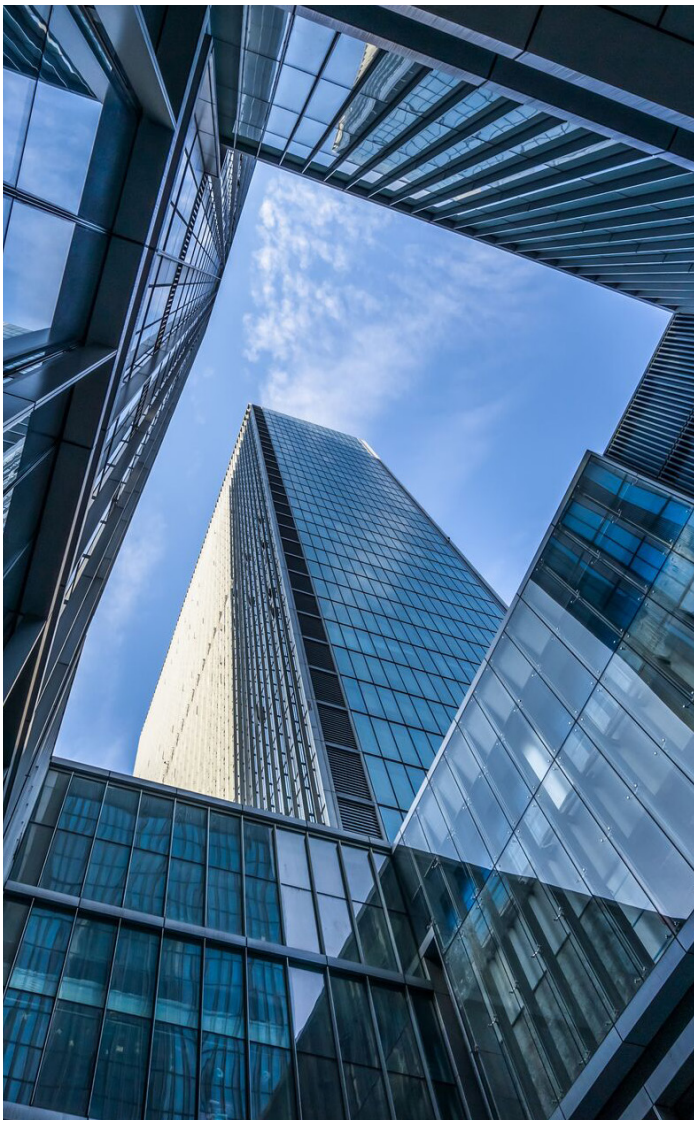
$150m to $500m (or equivalent).

Company features

Drug development financings are most readily available to companies that have drugs entering pivotal clinical trials (ie clinical trials after which data could be available to support regulatory approval), although some drug development financings are done with earlier-stage products. Drug development financings are utilised by both biotech and big pharma companies. When big pharma companies enter into drug development financings, it is often critical for them to get acceptable (often off-balance sheet) accounting treatment. The accounting treatment is beyond the scope of this article, but it is important to align on the proper accounting for these deals up front, and it can make or break the viability of a deal.

Structure and economic terms

These transactions are generally structured in a similar manner to synthetic royalty financings, although the compensation provided to the investor can often include milestone payments (related to product approval and/or sales) in addition to royalty payments. As opposed to synthetic royalty financings, drug development financings rarely guarantee payment of principal or any fixed return to the investor – instead, investors typically take the risk that if the product is not approved for sale, they will not receive their money back or any return on their investment. As a result, although the returns for drug development financings are often capped, the caps are closer to 4x (or higher) the initial purchase price, rather than the 2x typical for a synthetic royalty.



Covenants and collateral

The approach to covenants and collateral in drug development financings is similar to that for synthetic royalties, but the covenant package has fewer debt-like covenants. In their place are covenants surrounding the drug development process. For instance, there is often a joint development committee set up to oversee the drug development efforts.

Typically, though, the company will have ultimate control and decisionmaking authority over the drug development process. But some investors will offer to take over significant portions of clinical trial management, or share their expertise in the process.

Royalty Monetisations

Typical deal size

$10m to $1bn+ (or equivalent).

Company features

Royalty monetisations are available to companies that have contractual rights to future payments under existing licence or partnering agreements and are not normally an option for companies at an earlier stage of growth. For example, royalty monetisations may be an attractive source of finance to a biotech company that has developed and out-licensed innovative technology but is seeking a way to accelerate those future payments in order to invest further in its business now.

Structure and economic terms

In a royalty monetisation transaction, an investor purchases the right to receive a future stream of payments pursuant to an existing third-party agreement. As with a life sciences debt financing transaction, the investor expects to earn a return by providing funding up front in exchange for the right to receive these future payments. A royalty monetisation differs from a straight debt financing transaction in that the seller is not typically responsible for the investor's payments; instead, the investor looks primarily to the product that underpins the royalty stream. Such transactions permit sellers to raise capital while retaining ownership and control of their businesses without the restrictive covenants that might typically be seen in debt financing transactions or the equity dilution inherent in raising capital from equity-based financing. Some royalty monetisation transactions are structured so that the investor purchases the entire amount of the royalty stream for a given product without a cap, while others provide that the royalty stream reverts back to the seller once a particular return cap has been reached. In the context of those deals with return caps, typically these caps for royalty monetisations involving approved drugs are in the 2x range (similar to synthetic royalty financings), although the caps can vary significantly from case to case.

Covenants and collateral

Unlike more traditional debt financing transactions, royalty monetisations tend not to have any liquidity covenants or other financial covenants. They are also often unsecured arrangements, although there can be some bankruptcy risks in this structure, which need to be closely analysed on a caseby- case basis. They also do not usually have covenants precluding the incurrence of additional debt, asset sales, or the creation of security on

behalf of the seller, save as in respect of the assets that form the product underling the monetisation. It is also not customary for there to be any additional warrant or similar equity incentive for the purchaser as there would be in venture or growth debt financings of the type noted above.

Conclusion

The foregoing methods are certainly not the only forms of finance available to life sciences businesses. Many companies will no doubt be of sufficient scale that they can make use of more traditional financing or have equity values that support equity rather than nondilutive financing alternatives. However, with venture and growth debt, and various flavours of royalty financing, there is a broad menu of options for a chief financial officer to consider as they look to fund the insatiable capital needs of life sciences companies.

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