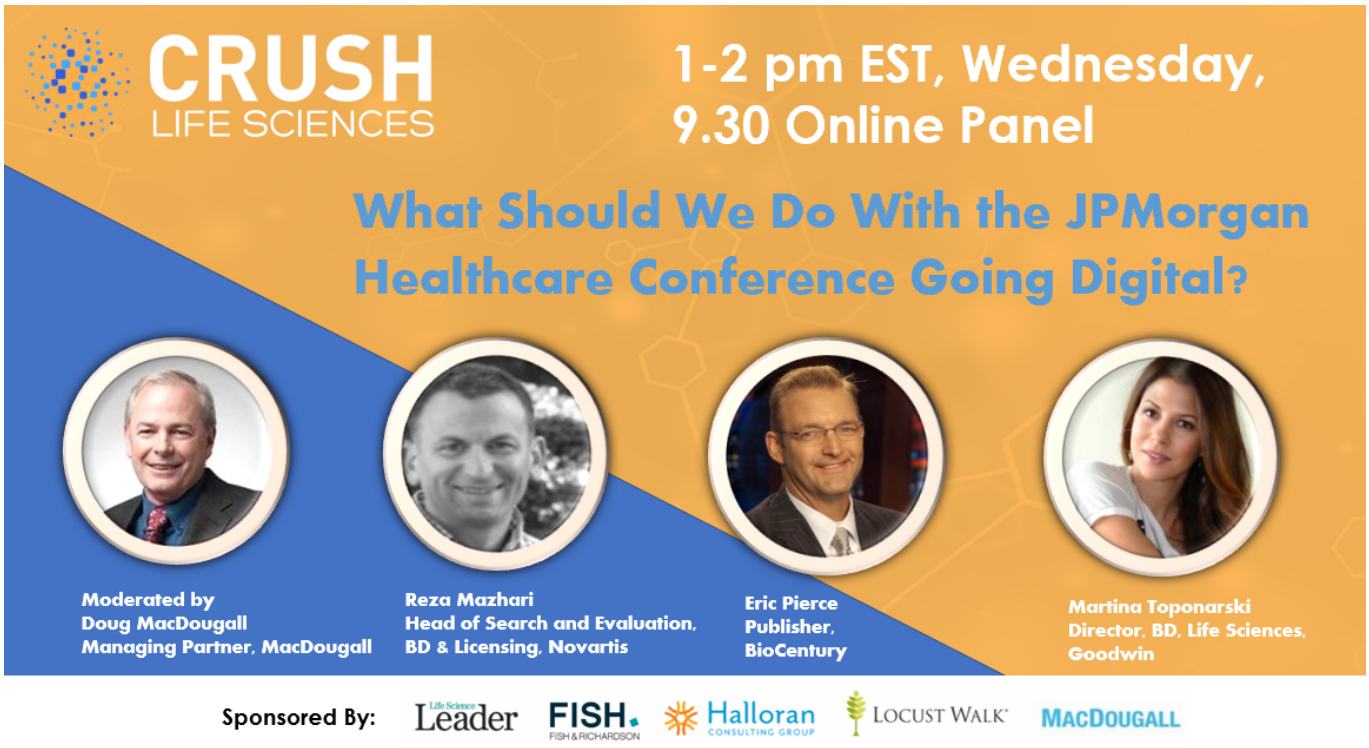
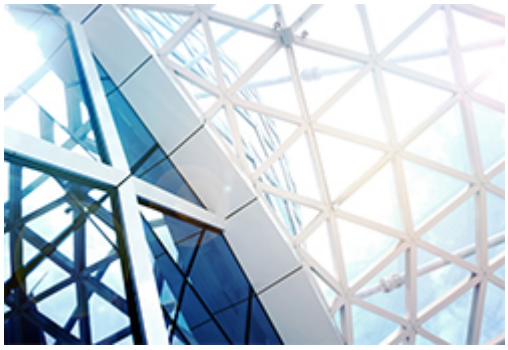
What Should We Do With The JPMorgan Healthcare Conference Going Digital?



Join Goodwin's Director of Business Development for Life Sciences, **Martina Toponarski**, as she speaks on a panel of industry experts to discuss how to make the most of JPMorgan 2021 when the conference has gone fully virtual!

For more information and to register for this timely panel, click **here**.

Review of Joint Ventures in Life Sciences Real Estate Deals



> The convergence of life sciences companies and traditional real estate developers has led to the emergence of an alternative real estate asset class known increasingly as "**PropSci**".

In this blog, we review:

1. features of the PropSci sector that make the joint venture ("JV") model attractive for market players; and
2. key terms that parties may wish to consider before embarking on a PropSci JV.

Why pursue a JV model?

Cost and scale

The high cost of building PropSci space (usually large-scale, mixed-use schemes sometimes including residential, retail and social spaces) means the ability to pool capital with partners in a JV is appealing.

Shortage of expertise

PropSci requires a marriage of capital and expertise with each party having a particular role in the transaction/project, e.g., funding, asset management, market creation, etc. and there is a relative scarcity of recognized specialist real estate operators in this space.

Public/private partnerships

There are numerous opportunities for private-sector players to partner with government and public sector bodies via public/private JVs as this is a key area of focus for government and public sector bodies (in the U.S., U.K. and E.U.).

Which standard JV terms require a more nuanced approach for PropSci JVs?

Transfer rights

In PropSci JVs, the operator's identity is critical to investors so the investor may wish to restrict any change of control/ownership of the operator or its exit from the venture. This may be further bolstered with "key person" protections. Conversely, the operator may wish to resist 100% ownership requirements and transfer prohibitions to give itself some flexibility.

Control

In investor and operator PropSci JVs, operational control of the assets typically rests with the specialist operator with certain key decisions requiring unanimity.

Default remedies

Removal of a PropSci operator mid-stream (as a default remedy) may not be possible/desirable as the investor may not have the expertise to handle the PropSci operations. Accordingly, alternative default remedies should be considered. The Operator may also wish to consider default remedies in the event of a material default by the investor (e.g. a funding default).

Exit

The parties to PropSci JVs may have different expectations on hold periods for the underlying real estate and, accordingly, the JV arrangements between such parties will need to provide for exit mechanisms.

Exclusivity

In investor and operator PropSci JVs, the investor may desire exclusive access to the operator's PropSci investment pipeline. Conversely, the operator may push for freedom to pursue opportunities independent of the investor provided the relevant key persons are devoting sufficient business time to the JV and there being no conflicts of interest.

The features of the PropSci market lend themselves to JVs, which are familiar to most commercial real estate market players. However, it is worth noting the particular quirks of PropSci and considering the useful tools available to parties to address these nuances and align JV participants.

Three Key Leasing Models in Life Sciences

The real estate needs of life sciences companies can be fluid and complex, with early stage companies typically needing smaller flexible space and later stage companies typically requiring larger build-to-suit space. With an equally diverse group of life sciences landlords and business terms on the table, there are many variations of leasing models and terms to be negotiated between the parties.

However, perhaps as a result of a natural life cycle of a life sciences company, there are currently three major types of leases emerging in the U.S. for companies seeking space for research and development and laboratory uses:

Flexible License Model

Often used by early stage and pre-Series A companies, this model is often described as an "incubator," "accelerator" or the "WeWork" model of life sciences. Characteristics include functioning as a license, versus a full-fledged lease, and full-service amenities, including everything a company needs to immediately start performing their science.

Shorter-Term Lease Model

Sometimes referred to as "incubator-lite", this second model is often times attractive to companies seeking their Series A financing round that in its pre-clinical or discovery phase. The underlying agreement is generally in the form of a lease (versus a license), and is often for a two or three year period. Services can vary, but generally include those services that are capital intensive, such as conference facilities, common lab support areas and equipment.

Longer-Term Lease Model

The final model is more in line with other asset-classes and takes the form of a seven-ten+ year lease, largely with little to no landlord-provided services. Though for buildings with multiple tenants there can be shared services for things like a backup life safety generator and pH neutralization system, the landlord tends to take on very little responsibility for these shared systems. These long-term leases are often capital intensive for both the landlord and the tenant, with large improvement allowances, but the maximum flexibility for a user in terms of being able to program the space to best fit its needs. By the time a company gets to its Series B or C fundraising rounds and gets to a clinical phase of development, it has grown to the point where it needs to invest in its own space. Companies at this stage of life often need to weigh their financial situation, including their burn rates and pipelines, in order to ensure they are right-sizing their capital commitments for long term leases.

From the short-term license to the long-term lease, as life science companies move through their life cycle, their needs with respect to physical space will evolve along with the science. With many new owners and investors potentially pivoting towards this asset class alongside industry veterans, it seems like the sky is the limit as to innovation and growth both for and in partnership with life science companies.

Learn more about **Goodwin's PropSci Practice**.

The Continuing Saga of Lab Developed Tests, Including for COVID-19 Testing

In August, the U.S. Department of Health & Human Services (HHS) **announced** that the FDA will not require premarket review of laboratory developed tests (LDTs), whether COVID-19 related or not, absent notice-and-comment rulemaking. Labs may voluntarily seek a premarket approval, 510(k) clearance, or an emergency use authorization (EUA) for their LDTs. Importantly, labs that do not obtain such FDA approval, clearance, or authorization would not be eligible for **PREP Act** coverage.

This announcement may have come as a surprise to FDA, which historically has asserted its medical device regulatory authority over LDTs while often subjecting them to enforcement discretion. Despite this HHS announcement, FDA's May 11, 2020 **Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency** remains in effect and has not been revised since the announcement. Importantly, this guidance offers two pathways for COVID-19 related LDTs – an EUA

submission to FDA and the development of an LDT under the authorities of the State in which the laboratory resides, where the State takes responsibility for COVID-19 testing by labs in its State.

For FDA's latest statements on COVID-19 testing, see the **opinion piece** authored by CDRH Director Dr. Jeffrey Shuren and Dr. Timothy Stenzel, Director of the Office of Health Technology 7, In Vitro Diagnostics and Radiological Health, in the Hill.

Life Sciences Crowdfunding Considerations

In recent years, equity (or investment-based) crowdfunding has been growing as an alternative source of funding for early stage biotech companies. This is due to the increasing availability of capital and willingness of the general public to invest in innovative companies, the potential speed and efficiency gains for companies compared to other sources of funding and the positive marketing and media exposure associated with a successful crowdfunding campaign, which can then generate more follow-on funding for companies.

Although early stage biotech companies will often need many millions before a product can be launched to the market, equity crowdfunding can be (and has been for some) an important source of capital at the start of that journey, when venture capital or other institutional investors may otherwise be less inclined to participate in that stage of funding.

According to a recent report tracking equity crowdfunding campaigns in the UK, whilst there was a slight decline in the number of campaigns and amount raised during Q2 2020 (with the market uncertainty resulting from Covid-19 likely having an impact), more investors are backing crowdfunding campaigns than in previous quarters, the crowdfunding market remains strong and there is an expectation that investors and companies will continue to utilise this source of funding. In addition, an interesting market trend is the growing number of purpose-driven companies, including those that qualify as "Certified B Corps" and actively commit to balancing profit with social and environmental impacts. Such companies can generate additional public interest, and this can be particularly relevant for life sciences companies which are often engaged in activities that have the potential to benefit the public in general.

This article explores 5 key considerations relevant to any equity crowdfunding campaign, including those in the life sciences sector.

Size of the crowd

Equity crowdfunding involves a high number of individual 'crowd investors' investing into a company through an online platform, such as Crowdcube or Seedrs, which continue to dominate the overall

equity crowdfunding market – according to a recent report, during Q2 2020, approximately 95% of all campaigns took place, and money was raised, on Crowdcube and Seedrs. There are also specialist life sciences equity crowdfunding platforms, such as Capital Cell, which was the first of its kind in Europe and launched in Barcelona, Spain and Cambridge, UK.

There can be hundreds or thousands of crowd investors (and potentially more if multiple campaigns are completed over time). Individually, each crowd investor will hold a very small proportion of the company's share capital, but together, the crowd investors may hold a more meaningful proportion. As a result, companies should consider how the crowd investors will align with its existing shareholder base and, if necessary, what protective wording needs to be included in the company's equity documents (including those set out below).

Transactions on crowdfunding platforms are also generally structured for compliance with UK financial promotion regulations. Companies should ensure, and potentially seek confirmations from the platform, that all necessary financial promotion regulations have been complied with by the platform in respect of the offer to the new crowd investors.

Nominee structure

Crowdfunding platforms often use a nominee structure, whereby the nominee holds the legal title (including the right to vote) and the underlying crowd investors hold the beneficial title (the economic interest) to the crowd shares. This can provide enhanced protection to investors, simplify the administrative burden on the company and make it easier to manage the equity going forward on both sides.

Crowd investor rights

Deal terms will vary but, generally, although crowd investors will receive the same economic rights as other investors that hold the same class of shares, the non-economic rights afforded to crowd investors will not be the same as those typically given to institutional investors in the company. For example, it is normally the case that crowd investors do not: (a) conduct extensive due diligence into the company; (b) receive business warranties or extensive information rights from the company; or (c) participate in consent matters or receive other contractual rights, such as the benefit of restrictive covenants from the founders of companies. Companies should evaluate if, and to what extent, crowd investors should receive pre-emption rights on new issues of shares, rights of first refusal over transfers of existing shares and / or co-sale rights. Crowd investors and the nominee will also not typically become a party to a company's shareholders' agreement and so their rights will be set out in the company's articles of association.

Decision-making

Companies should consider how decisions in respect of the shares are made by the crowd investors and/or the nominee and reflect this in the investor terms and conditions that will apply between them and the company's articles of association. In some cases, a decision is effective if approved by the majority of the crowd investors that respond to a request from the nominee. In other cases, the nominee can act in its discretion (without any vote), so long as it acts in the best interests of the crowd investors. Given the number of crowd investors, companies should try to avoid having to obtain consent from each crowd investor.

The articles of association should also clarify how shareholder offers, notices and communications are shared with crowd investors. It is customary to allow them to be sent to the nominee only, to avoid the company having to also distribute the same to each crowd investor.

Share transfers and exits

Companies may consider restricting the ability of the nominee and each crowd investor to transfer the legal or beneficial title (respectively) in shares to limited scenarios, such as permitted transfers, board approved transfers, tag-along transfers and compulsory transfers. These restrictions would be set out in the articles of association and referenced in the investor terms and conditions entered into between the nominee and the crowd investors. This will help avoid a secondary market in the shares, given the size of the crowd and the known split in the legal and beneficial title to the shares. It is important that, wherever beneficial ownership is transferred, the nominee remains the legal owner of the shares.

It is also important that companies understand how an exit can be implemented in respect of the crowd shares. Companies will want to avoid relying on the consent of each crowd investor to implement the exit, given how many there may be. This can be achieved by relying instead on nominee consent (subject to various protections) and ensuring the nominee and the crowd investors are capable of being 'dragged' with other shareholders under the drag-along provision in the articles of association.

Conclusion

Equity crowdfunding is distinct from other forms of crowdfunding, such as reward-based crowdfunding on Kickstarter, donation crowdfunding on Crowdfunder or loan-based crowdfunding on Funding Circle. It is also distinct from other sources of capital from angel investors, venture capital funds, corporate venture companies or sovereign wealth funds. It presents a unique set of issues and challenges that should be evaluated to facilitate the effective management of the crowdfunding investment, beyond the initial campaign. It can, however, provide an important source of capital for life sciences startups, particularly at the start of their journey.

Down Rounds 101

Private life sciences companies looking to raise funds in the current environment might face the prospect of a "down-round" – a financing round at a lower pre-money valuation than the post-money valuation in prior round(s). "Down-rounds" raise various risks and considerations for both companies and investors.

"Down-rounds" affect both ownership percentage and value of shares, and typically trigger antidilution protections, which would increase the conversion price/ratio such that existing investors would receive more Common Stock for each share of Preferred Stock, based on the formula in the company's Certificate of Incorporation.[1] Companies should carefully calculate and evaluate the

effects of “down-rounds” on their capitalization and related thresholds for various requisite approvals. Following “down-round” financing, the conversion prices should be reset to reflect any adjustments.

Companies can encourage existing investors to participate (and, potentially, avoid “down-round”) by offering senior preference (ahead of prior liquidation preferences), adding a multiple liquidation preference (e.g. 2x instead of 1x), and/or introducing mechanics that would further dilute non-participating investors or even convert Preferred Stock of such investors to Common Stock, such as pay-to-play, cram down (by stock splits or conversion ratio modifications) or pull up (by converting the outstanding preferred stock of participating investors to the new preferred stock).

Careful consideration should be given to fiduciary duties of controlling stockholders and of directors, in particular those representing existing investors who participate in a “down-round,” since “Interested party” transactions are not afforded the benefit of the business judgment rule, and may face liability for such financings under the “entire fairness” standard. Due process matters, and adopting practices (to the extent possible) can mitigate potential risks. Customary and advisable practices include a board committee of disinterested directors, consent of a super-majority of the stockholders, offering all stockholders the right to participate in the financing through a rights offering, soliciting outside investors and obtaining a third-party valuation or fairness opinion.[2]

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[1] Customary protections include: (i) full ratchet, which resets the conversion price to the price of new securities and is unfavorable to founders and, consequently, is rare; (ii) narrow based weighted average, which takes into account the share price and number of the new securities, the original issue price of existing shares and the number of outstanding shares, and counts fewer shares as outstanding; and (iii) broad based weighted average, which is the same as narrow based weighted average, but counts more shares as outstanding and is therefore less favorable to investors and results a smaller increase in conversion rates.

[2] For an overview of good practices see client alert **https://www.goodwinlaw.com/publications/2020/04/04_28-dilutive-down-round-financings-in-the-us**.

The Purple Book and The Orange Book – When do Patents Expire and Regulatory Exclusivities end for FDA Approved Products?

The Food and Drug Administration (FDA) maintains two searchable online databases for approved products: the **Purple Book** (approved licensed biological products) and the **Orange Book** (approved drug products). The Orange Book provides details about an approved drug product, including the patents covering the approved drug product and the expiration dates of the patents and regulatory exclusivities, leaving investors, competitors, and the public in the dark as to when an approved biological product falls into the public domain.

For example, Sunosi® (solriamfetol hydrochloride) is a small molecule drug developed by Jazz Pharmaceuticals and was approved by the FDA on June 17, 2019 for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea. The NDA (new drug application) number, patents covering the product, the expiration dates of the patents, and regulatory exclusivity data are provided in the Orange Book.

Contrast this with Evenity® (romosozumab-aqqg), Amgen's monoclonal antibody approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture. The Purple Book provides the approval date, proprietary name and generic name, BLA (biologics license application) number and type, date of first licensure, and a link to the product label. However, the Purple Book does not list the patents covering the product or regulatory exclusivity information. Thus, unlike patent litigation involving generic approvals for small molecule drugs, where the patents that will be involved are predictable based on the Orange Book listings, the patents that will be involved in litigation over a biosimilar approval are typically revealed for the first time during the litigation itself.