LIFE SCIENCES SNAPSHOT

A Quarterly Report on Financing Trends

LEVERAGING NON-DILUTIVE FINANCING FOR DRUG DEVELOPMENT AND FAVORABLY LICENSING DEVELOPED PRODUCTS AS A GLOBAL HEALTH MODEL Q4 2022

orrick

Data provided by

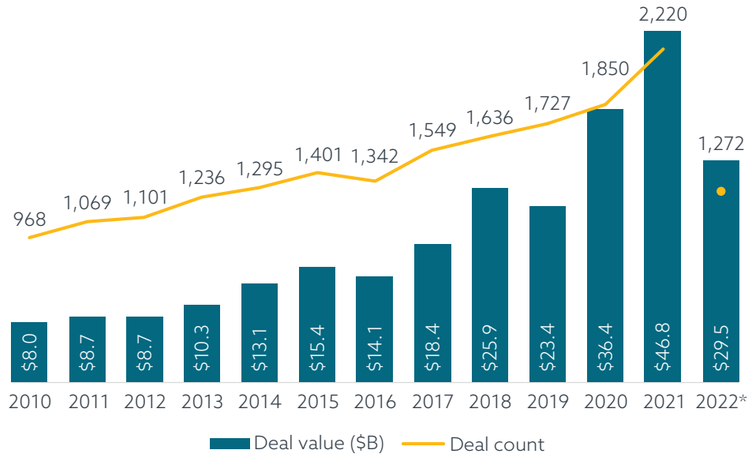
PitchBook

Key Takeaways

This report series examines quarterly trends in life sciences venture investment. Key findings for Q3 2022 include:

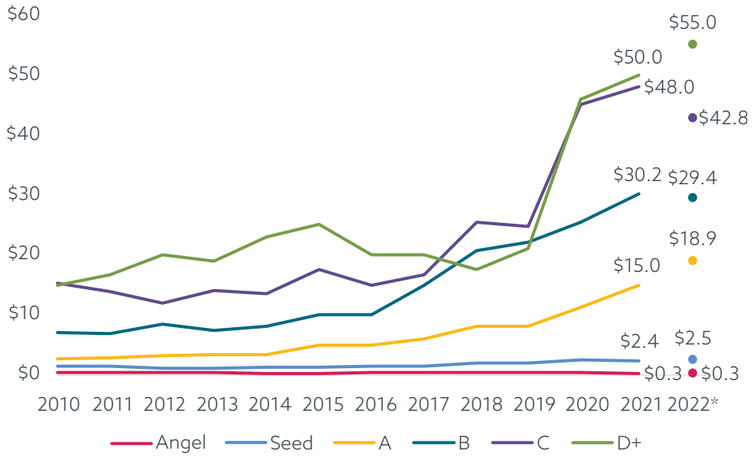
- The industry generated $6.2 billion in deal value across 352 deals in Q3, exhibiting further quarterly declines as punishing macroeconomic conditions continued. YTD deal value, however, remains higher than before the onset of the pandemic.
- Deal volume has continued to decline, with Q3 deal volume returning to prepandemic levels.
- Median deal sizes for Series A and Series D or later companies experienced material growth, but some other stages saw declines. Median pre-money valuations rose for both angel, seed and early-stage venture-backed companies but declined slightly for late-stage deals.
- Exit prospects remain unfavorable, with just $463.6 million generated across nine deals in Q3. In contrast to deal value, YTD exit value of $13.8 billion lags far behind the annual totals of previous years, including before the pandemic. Public market volatility continues to impact IPO candidates, and many have adopted a wait-and-see approach.

Life sciences VC deal activity



Source: PitchBook | Geography: US
*As of September 30, 2022

Median life sciences VC deal value ($M) by series



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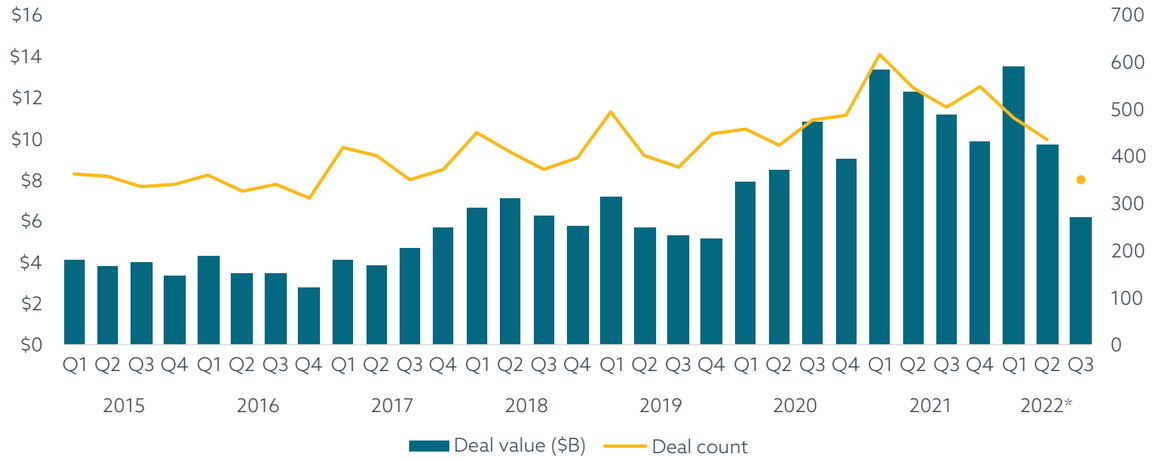
Market Analysis

Life sciences VC deal activity by quarter



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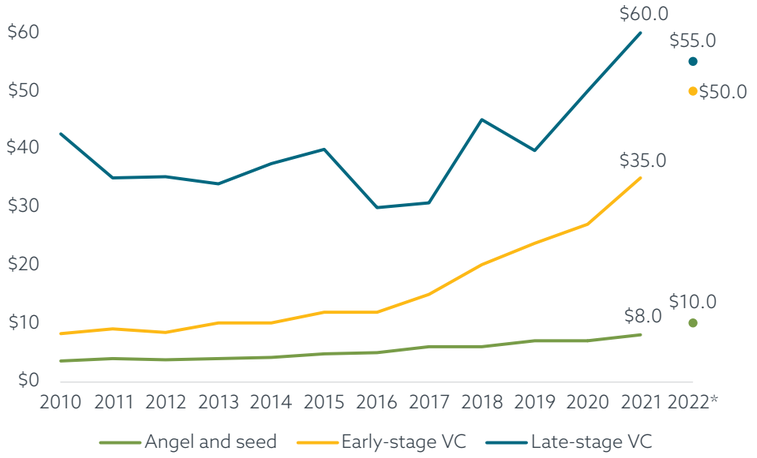
2022 presented significant challenges for the venture industry, and life sciences companies were not immune to dealmaking disruptions. Inflation remains top-of-mind for broader markets as the Federal Reserve continues raising interest rates to bring down prices. Policy changes and higher lending costs have taken a toll on consumer and investor confidence, and life sciences venture dealmaking has lost momentum as difficult conditions persist. The decline in public equity prices for life sciences companies is also no doubt taking a toll on private market activity. Deal activity has declined each quarter this year, and Q3 deal value represents less than half that of Q1 with a notable drop in deal count. YTD deal value totaled $29.5 billion, compared to $36.9 billion in the same period of 2021 and $27.3 billion in 2020. The macroeconomic environment has taken a toll on the industry, but deal activity has sustained the rise in activity that emerged during the pandemic. YTD deal value exceeds the annual totals generated each year prior to 2020.

Median life sciences pre-money valuations ($M) by stage



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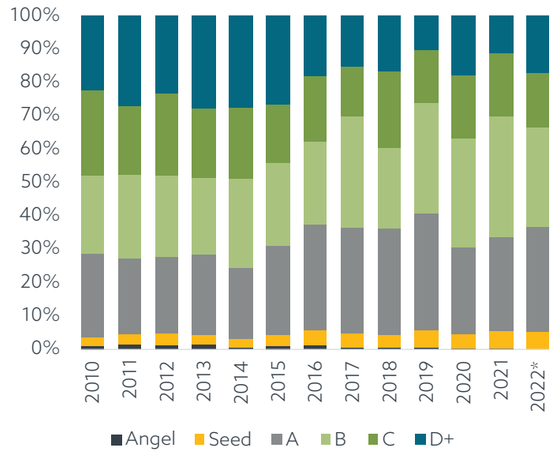
Share of life sciences VC deal value by series



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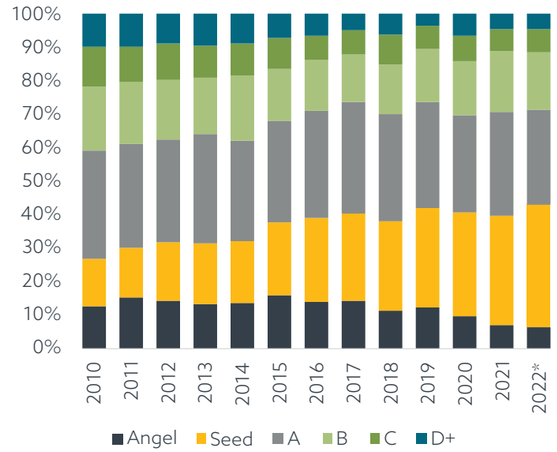
Share of life sciences VC deal count by series



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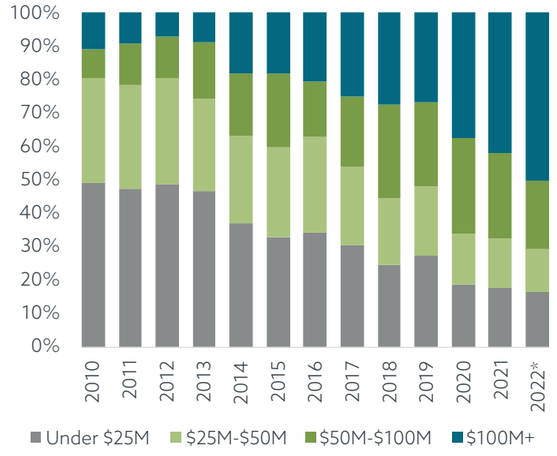
Share of life sciences VC deal value by size



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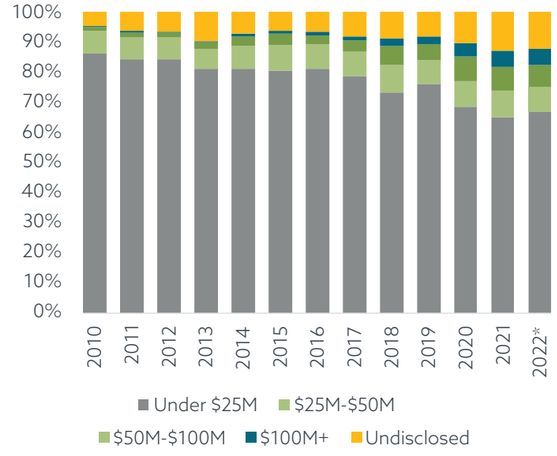
Share of life sciences VC deal count by size



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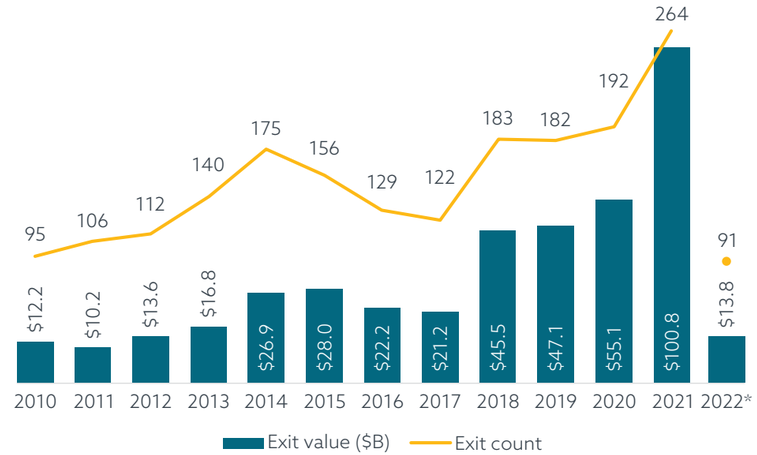
Market Analysis

Median deal sizes have seen mixed movement this year. The median deal size grew 25.9% for Series A companies and 10.0% for Series D and later, but declined 10.8% for Series C. Despite varied changes, deal sizes for late-stage companies are still elevated on a historical basis after skyrocketing in 2020. Deals over $100 million represent a larger share of total deal value this year at 50.1%. More mature companies with the strongest prospects in this difficult macroeconomic environment are still able to secure significant rounds. The median pre-money valuation, on the other hand, declined 8.3% for late-stage venture-backed companies. By contrast, the median valuation for early-stage companies grew 42.9%. Late-stage companies approaching exits are more likely to be impacted by the decline in public market conditions, contributing to valuation declines. While the smaller population of deals YTD can account for some skew, early-stage company valuations appear to indirectly benefit from difficult IPO and SPAC conditions by becoming more enticing acquisition targets for the industry's largest players looking for a competitive edge.

Acquisitions account for more than half of total exit value YTD. IPOs represent the second largest exit type, although the YTD IPO total pales in comparison to totals from prior years. Overall exit value reached $13.8 billion YTD, demonstrating that exit activity slowed down significantly this year and remains low compared to exit activity from the past several years, even prior to COVID-19. Exit value came down off a near-record high in Q4 2021 and has declined further each quarter this year. Q3's total reached $463.6 million, representing the slowest quarter since 2017.

Life sciences VC exit activity



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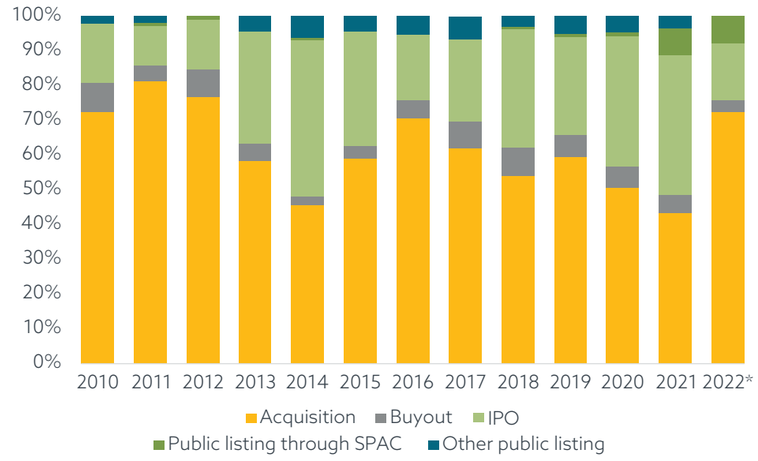
Share of life sciences VC exit count by type



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Roundtable

Participants

Dennis Cho
SVP, General Counsel & Chief Ethics & Compliance Officer at Twist Bioscience

Robert Mittendorff, MD
General Partner and Head of Healthcare at B Capital Group

Thora Johnson
Partner and Co-Chair of Life Sciences Group, Orrick

Gargi Talukder
Partner, Orrick

Neel Lilani
Global Head of Tech Clients, Orrick

INTRODUCTION

Thora Johnson: *As the market is softening, non-dilutive financing may be a viable and valuable option for early-stage life sciences companies. While non-dilutive financing can take the form of a traditional loan, it can also consist of a government grant such as from the NIH (National Institute of Health) and from programs such as the Small Business Technology Transfer or Small Business Innovation Research—as well as from private foundations. More established life sciences companies are also investing in startups with innovative and promising technologies. Their non-dilutive financing can consist of a revenue royalty financing arrangement or the take back of certain IP rights.*

We have seen non-dilutive financing have a profound effect on propelling vaccine and therapy development in recent years. In this roundtable discussion, our panelists discuss this alternative to equity investment and the various forms non-dilutive financing can take, their experiences with it, and thoughts on the opportunities it can provide startups amid this time of macroeconomic uncertainty.

ROUNDTABLE SUMMARY

Neel Lilani: Welcome, everyone. We're excited to have this conversation today! In the current macroeconomic climate, we are seeing increased interest in alternative funding models. Let's begin by sharing some general thoughts on using grant funding as a strategic option for growing life sciences companies.

Dennis Cho: I would say giving capital in a non-dilutive way can have some great benefits, especially for early-stage companies. There is always going to be some level of strings attached—whether that's government reporting, or, depending on the institution, there may be financial or IP obligations. But, generally speaking, I think it's an excellent early-stage option. And more broadly, depending on the magnitude of the funding, this can be helpful in later stages of development too.

Robert Mittendorff MD: Grant funding or federal funding can also be a good opportunity for companies to leverage smaller amounts of capital for moving science to projects that are more translatable. Whether it's through SBIR (Small Business Innovation Research), the NIH, or other grant organizations, it's incredibly important to get the details right–because the goal of that funding should be to retire risk while creating a space within which institutional risk capital can be deployed to those translational efforts.

Neel: Robert, from the investor's perspective, at what point in a company's life cycle is the best time to consider grant funding? How does that relate to a stage of financing, or for therapeutics, to an FDA-approval stage?

Robert: Typically, I've seen this type of grant funding happen earlier. At that stage, the dollars required to reduce risk are lower, and therefore it's easier to map to the activities of a company that is in the preclinical stage. COVID has changed that a bit in some sectors, but unless you are branching off from the core attributes of the company, it's more challenging to take this grant money at a later stage, in many situations. Also, at later stages, you might run into additional terms that may reduce the attractiveness of this grant funding to venture capitalists. For example, under the NIH's definitions you're no longer considered a startup if you raise more than $5M and have been around for more than five years—this makes the focus for these dollars earlier in the Company's development. I think the sweet spot is retiring research risk earlier and moving it into the translational realm. We saw some opportunities in the COVID-era where grants can be useful later, but, frankly, if venture funding is not available to a company, I see that as a message in itself with respect to the quality of the idea, science, or team. There are billions of dollars sitting on the sidelines for innovative biotech companies that are available for attractive projects.

Neel: Dennis, from your perspective, when have you seen the grant funding most effectively utilized?

Dennis: Here at Twist, we did a Series B financing round of $25M back in 2014. Associated with that, we also had a $5.1M award from DARPA (Defense Advanced Research Projects Agency). There are other companies, and a lot of startups, that specialize in getting some of these grants. For example, at Trevarx Biomedical, an early-seed-round company, the principals have a lot of experience in the academic world of applying for grant funding. Currently, they are taking a PARP inhibitor diagnostic into multicenter phase two trials primarily through non-dilutive grant funding. And to Robert's point, sometimes companies are not eligible for some of this funding if they're at a certain level of development, so finding a sweet spot can really depend on the company and management's level of experience in applying for these grants. Also, in my prior experience at Celgene, we pioneered different types of non-dilutive funding to other startup biotech companies. That's a different focus than grants, but it is an example of what can happen in private enterprise. This is less common in today's environment, but we still see models such as build-to-buy, where you invest in an early-stage company and have an option to acquire the company at a later date, often at a valuation to be determined, or a collaboration agreement with an up-front and an option to license certain products or targets.

Robert: We've all seen relationships with larger bio pharmaceutical enterprises where R&D is done jointly, typical biobucks deals, which is another type of non-dilutive financing that's common in the industry. We often see that biotech companies will license or do deals on their noncore assets; typically, this happens when they're selling off part of the portfolio to fund the more valuable, core near-term assets. I think we'll see a lot more of that in the next few years. The recently passed Inflation Reduction Act will further accelerate this narrowing of project focus, in my opinion.

Neel: Do you see this flowing from economic pressure pushing companies to shift out noncore assets to raise capital?

Robert: I think it's for three reasons. The first is that most boards right now are looking at the programs that are in development and saying, "Okay, we're working on four things. If we have to pick two, what will they be?" They then either slow down the other two, or they consider partnering them off. These are important negotiations because you don't want to give anything away and you want a fair deal, and because there is currently so much macroeconomic uncertainty. The second reason is that some valuations require that companies grow into them over a longer period of time. As the XBI index has come down, some companies might be sitting at a valuation where they need more on the milestone-side to justify the up-round. In this case, they'd need to run the company longer with existing capital or take capital via a structure that they don't find favorable—so the other option is to rationalize or partner off some of the assets. The third reason is that many more companies are now thinking of themselves as a platform with a group of therapeutics—this provides a lot of option value and gives them a number of shots on goal. However, it also provides assets that a small company may not be able to work on simultaneously. We're a big proponent

of this platform plus therapeutics idea for companies that have many potential therapeutic assets in play.

Dennis: I totally agree, especially if there is an area of the platform that can be applied to a hot target. In a situation like that, they might be able to offer exclusive rights to that target, and in return the company might hear, "Here's a chunk of non-dilutive cash," or "Here's an option to co-commercialize on preset terms that will give this early-stage company access to sales and marketing expertise with an established partner that has already commercialized many products." Meanwhile, the platform company can still retain other targets for its own use, benefit, and development.

Gargi Talukder: If a platform company has an asset that's particularly risky, or is just at such an early stage that they don't have resources, then would this type of financing be a particularly good fit? Not necessarily whether there's a known endgame for licensing out the platform or any IP, but just in regard to the science being unknown, yet promising.

Robert: In the case of a venture-backed biotech that has identified IP that is adjacent to what they're doing, but not core to what they're doing, then I would say yes. There would probably be a healthy debate with management and the board as to whether it's worth the hassle, depending on the size of the grant funding. And I think that's a worthy debate, because once you have momentum on the core programs and platform, adding a couple million dollars of private capital is a little bit easier, where grant funding may have different processes. But, again, I think this is dependent on the details of what exactly the requirements would be. These grants all include unique publication requirements, patenting requirements, and licensing processes.

Dennis: We saw quite a bit of this during the COVID-era, as an example, in terms of the government funding that was available. It was a riskier play, but government assistance allowed companies to take a shot. The actual financial entanglements and commitments were quite manageable, but there can be a lot of red tape. If a company can deal with jumping through those hoops, then many investors would find the financial terms with government funding quite reasonable. There are also consultants that can help with this process.

Robert: In my work diligencing some of these grant-based deals, I've noticed that the skills used to secure the grants versus managing the grant requirements over time are only modestly overlapping with the skill set of raising venture money or doing deals with larger bio pharma companies. They're complementary skill sets, but they're different skills, so business development professionals may need some education to navigate these processes efficiently if they want to fully engage in SBIR or associated grant programs.

Gargi: And for private foundations that are providing this kind of funding, how do their licensing and patenting requirements compare to government sources? Would you say they're more or less onerous?

Robert: In my experience as an HHMI (Howard Hughes Medical Institute) fellow, I think they are largely liberal in the sense that they allow the host institutions to manage many of those IP efforts. However, they have requirements regarding publications' research and requisite research licenses for any IP developed by their grants. We often see Gates Foundation grants as well, and I think it's a reasonably approachable system. I would say the NIH definitely has more of a structured process than some of the other private institutions.

Dennis: Another area worth mentioning is state investment funds. Sometimes they'll come in alongside an existing equity round as investors, but occasionally there are other types of non-dilutive funds available that might offer, "If you establish your headquarters in our state, then we'll give you this forgivable loan."

Robert: Also notable in terms of the size of support, the military branches have billions of dollars in grant funding for life sciences projects. There's AFWERX, DARPA, and ARPA-H (Advanced Research Projects Agency for Health), which was just created. We've seen a number of companies with grants from those institutions, and they tend to be fairly permissive in the early stages of work. They often include a dual-use mandate for the research; this is generally pretty broad, but that can create some challenges in making sure your research is applicable to not only the military realm but also the commercial realm.

Gargi: Are there sources from academia that you've seen involved with this type of funding?

Robert: Yes, some. Dana Farber has a number of pools of capital that are from donors that are targeting specific diseases, and we've also seen this with disease-based foundations. Those grants are typically small enough that they fit well with an early-stage company—and they provide even more validity, given the number of eyes that you have on it in a particular space. Typically, societies or patient groups that are focused on a certain disease tend to be very liberal with licenses for developed IP, and they're not typically as interested in generating royalties off of them as they are in promoting new therapies. The royalties' revenue streams in university spaces are incredibly skewed to just a couple of licenses–far more skewed than venture returns are, for example, in my analysis.

Dennis: In my past work at Celgene, we did a deal with M2Gen, a for-profit subsidiary of the Moffitt Cancer Center. Their focus is on informatics and clinical data relating to cancer. We saw a number of these cancer centers become very interested in data analysis in specific indications. But this is a phenomenon that I don't see as often as some of these other funding routes.

Neel: Do you think that there is validation that's presented to the market when a company receives a non-dilutive financing from one of these organizations, be it governmental or private?

Robert: I think there's signaling, but it's nuanced. It shows that they have organized processes and can conduct research at a level that a federal authority or other grant body finds satisfactory. I have seen a number of companies that have CRDAs (Cooperative and Research Development Agreements) in place, or have done co-development work and have patents that are licensed to them as a result of research, but they still don't fit the criteria in terms of the market they're focused on, or they're hitting a target that has seventy competitors. Things like that are still relevant. So it can be a good signal, but only in the context of the broader set of attributes for the project being conducted.

Dennis: I think sophisticated investors in a company that's getting grant funding will appreciate the additional capital, but I'm not sure they would view government funding as an automatic validation of the actual project.

Robert: Personally, I'm not a big fan of government venture capital. For a variety of reasons, I don't think it's something that can be done well, frankly, even with the right people in place. As a venture capitalist and seeing the complexity and the number of stakeholders that one needs to manage in helping these companies get to what we define as success, I think government-based venture capital, in general, is a bad use of tax dollars.

Neel: By definition, venture capital is money in exchange for equity; and non-dilutive financing is something a little bit different than that. Do you consider grant non-dilutive funding to be in the same category?

Dennis: I wouldn't necessarily lump them together. Sometimes governments can allocate non-dilutive funding to specific target areas of interest, such as during the COVID era. Those efforts can potentially be helpful and accelerate development. But I agree with Robert's point that when you have a government-backed venture capital arm trying to invest in specific companies, sometimes those decisions may be driven by other types of motivations and analyses, and they may not be very efficient.

Robert: Operation Warp Speed was a good example of government allocated non-dilutive funding. Putting a prize out there for the first one to get approval or to meet certain specs–I think that's a better way. It allows the risk capital to manage the high-risk technology selection of teams, et cetera. In the case of the pandemic, it worked well as a key distribution incentive. But, in contrast, when the government picks a particular company, like in the case of Solyndra, it can be a big mistake. So whether it's a grant, or it's a loan targeted at specific companies, it can end up looking like a loan that doesn't have to be repaid. It gets very tricky. Government can set procurement standards and general requirements for grants and funding—this is nuanced—but shouldn't be trying to pick market winners.

Neel: What restrictions and obligations have you seen tied to non-diluted financing? And as a result, what implications might there be from a public health perspective?

Robert: There are a number of reports you have to provide over time. And patenting typically involves a discussion with the funding body. Also, often a number of the source code assets are required to be published. For certain companies, these requirements may be unattractive. Another deal term might be that if you're not able to advance the science, or if the science isn't translatable in numerous experiences, the license needs to revert. As a venture capitalist, that term is not in my self-interest, but for the public good, I think a timeline needs to be applied for this. For example, if you invest in a technology and you hit a wall that is going to require $500M of capital, but you were expecting to spend $50M - $100M, then it's not fair to the public to hold on to that. It might be better to revert it and then let the funding body decide if there's another player that can do something better with that IP.

Dennis: I agree that it makes sense to increase the number of reversion-type clauses in these agreements. Currently, if you can show any kind of progress whatsoever in an annual status report, then you often don't have to give it back, or if the licensor wants to get it back, they have to fight you for it. And that often results in the technology languishing. On the broader topic of restrictions, companies sometimes need to grapple with the Bayh-Dole Act, which comes up when government funding goes to a nonprofit or academic institution, and being able to navigate those restrictions is important. We're actually noticing a lot of innovative technology coming from academic institutions; in particular, Stanford has done a great job of monetizing and commercializing some of their academic innovations.

Gargi: Some of these funding organizations will put geographic restrictions on patent estates for the public good. For example, they want to be collaborative in an emerging environment or geography where they don't have enforcement rights, and the initial goal is to serve the public good in the developing world, but then they find an opportunity to monetize and capitalize in jurisdictions with a higher price point for a therapeutic or licensing out of specific jurisdictions where the patent estates are available. Does that feel like an onerous restriction to either of you? Or does that seem to be a reasonable way to approach this type of division of license rights to enforce certain parts of the patent estate?

Robert: Personally, I think that's a good idea. The U.S. consumer pays for the majority of pharmaceutical innovation globally, and I'm glad that the IRA (Inflation Reduction Act) didn't go farther than it did around creating a most favored nation pricing status. At its core, the IRA has the real potential to lower some costs today by reducing the number of patients seeing new therapies tomorrow. The IRA trades savings today for lives saved tomorrow. I think that a most favored nation pricing approach would potentially decimate innovation and biotech over the next decades, which would be sad for all of us as potential patients. For particular diseases where it's applicable to a geographic population, I do think that that kind of license makes sense. That being said, we've seen the complexity of implementing that during COVID, with developing the RNA-based and other vaccines through early federally-funded research. Overall, I think it's a good idea, but it is complicated to implement.

Dennis: Another practical issue is that the great majority of both research and investment dollars, as well as the potential financial return, are coming from the U.S., followed by the E.U., and then other countries such as Japan and China. These are the major markets that any company is going to try to exploit to make a return. So the real challenge for much of the developing world is that a lot of medicines and therapeutics are not even available, sadly, as a lot of companies don't see these geographies as economically feasible. And to the extent that it could become economically feasible, they have to deal with issues such as trans-shipment and export controls and things of that nature. As someone who cares about the public good and the global community, I think that even if it's tricky, it's an idea that is well worth developing and exploring.

Robert: There are also many examples of government intervention that have been positive drivers of innovation: patent law in the U.S. Constitution, the Orphan Drug Act. And then there's the shadow cost in the newly passed IRA to restricting innovation: controlled pricing for seven years for small molecules at eleven, that will have a deleterious effect on risk-adjusted NPVs, which will have a deleterious effect on company valuations, which will have an effect on the amount of capital a company can raise and the number of drugs they can try to pursue. The other implication here is if we start giving away markets, we need to be very careful about which ones, because that's another part of a risk-adjusted NPV. For example, we wouldn't give away Japan, because it's a developed country. But if we were to start talking about countries in Latin America, it could be a bigger debate. I think we have to be very careful with how we start chipping away at the value that these drugs bring, because it will have an effect on the amount of innovation that we will see over decades in the space.

Dennis: And that pipeline may not be immediately reduced. If people are not paying attention to the long-term effects of it, there could be a lot of unintended consequences down the road.

Gargi: Do those unintended consequences and potential effect on innovation come about because a particular jurisdiction has been given away for a certain amount of time?

Robert: With the example of the Inflation Reduction Act, and to paint a picture of how that structure could unfold: starting with the assumption that the IRA says by 2026, ten of the top Medicare drugs will have pricing examined, then that pricing will largely be determined by the U.S. government; then later another 15 drugs are added, etc.; by 2031, we'll see a hundred or so drugs whose prices will be determined this way. About two hundred to three hundred drugs drive a majority of the Medicare Part-D budget, so quickly we'll get to a point in the mid 2030s where pricing is controlled in many ways by the federal government. At that point, when we build an economic model for a drug, the price starts to drop at year seven or nine rather than year twelve–so that drug is worth less today as an investor. In turn, when I sum up the portfolio for a company and see that the company's worth thirty percent less, they'll probably raise thirty percent less capital–and therefore execute on thirty percent fewer projects. This model would require a sophisticated analysis, but that's the gist. And as a society, we should be okay with this trade-off: we're robbing Peter, who's a patient in 2050, to pay Paul today. We just have to hope that we're not robbing five Peters in 2050 to pay for one Paul today. So when we give away geographies, or we start talking about ideas of giving most-favored nations status pricing, then we're talking about massive reductions in commercial profits and, in my opinion, reductions in innovation that fuel future medicines.

Gargi: Are there particular therapeutics or diagnostics that might be better suited for this kind of model? Or certain technologies would not have been developed, but within this type of model that technology might be very valuable as either a companion diagnostic or for something like detecting certain types of diseases?

Robert: The Orphan Drug Act is a government intervention that largely created the orphan drug industry. These are drugs that are only applicable to a handful of patients, and without the economic incentives, they would not be developed. That's one example of government intervention working the other way as well. Similarly, we just won't know what the shadow costs of the IRA will be for a little bit—perhaps the trade-off is reductions in innovation for mega blockbuster drugs. These drugs have to be one percent or more Medicare, which means they have to be a billion dollars or more. Last year Medicare spent over $100B on Part D, so they've got to be big—but not enormous.

Neel: Akin to patents, is there a model where a favorable licensing term for a developing market would not kick in until, perhaps, year five of a drug's development, so that the innovation has time to be recouped by the company that initially developed the therapy?

Robert: I think the challenge is the human component: the treatment is available today, but it's not available to you for five more years. That's a hard message, but that's the quid pro quo with patents, and investment is continual innovation.

Dennis: I see this as a question of trying to figure out a good balance in the financial modeling. In many cases, we want to make sure the innovator companies are able to make a return on their investment before various parts of it are chipped away. Ultimately, I think it's important for anyone who is seeking to make a policy decision to be mindful of this dynamic.

Neel: Any last thoughts or concepts that you would like to raise?

Robert: The recent governmental fiscal efforts over the last two years created a lot of additional funding outside of the NIH budget. ARPA-H and other supplemental funds might offer good grant potential for companies. I don't think most entrepreneurs are tracking the legislation. And there are billions of dollars that have been allocated above and beyond the forty-ish billion that went to the NIH each year for other areas in biomedicine.

Dennis: In general, I think there is a very strong and proper focus on human advancement, human progress, and helping patients. When we balance that with incentivizing investment in R&D, we want to make sure that, as a whole, these goals are all being advanced. As we mentioned at various points today, this is a complicated and nuanced topic, so I think it's important for policymakers to take care. In some instances, they might think that they're trying to help, but it could have a very unintended impact, especially in the long term.

Gargi: Thank you for this interesting discussion on granting mechanisms in the public health space. It's exciting to know that these options are available, given the fluctuations we're seeing in the market, to continue advancements for innovative technologies.

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