MARWOOD GROUP®

Life Sciences Investment in the Era of COVID-19
Part 1 of 3: Venture Capital and Private Equity

EXECUTIVE SUMMARY AND OUTLINE

While the life sciences industry has demonstrated its resilience in prior recessionary periods, the COVID-19 pandemic has brought challenges at each stage of the development and investment process. In this first installment of a 3-part series, Marwood opens by addressing the challenges faced by life science companies in moving treatments into and through human testing, an essential component to reaching milestones crucial in attracting new investors, strategic partners, and acquirers. We then turn to examine the state of the life science venture capital and private equity space, from the perspective of available capital and transactions. Subsequent whitepapers in this series will address crossover investors and the IPO landscape as well as M&A considerations of end manufacturers in biopharma and medtech. The information in part 1 is broken down into the following sections:

I. Introduction

The economic ramifications of COVID-19 on the life sciences industry may be more muted than the overall market basket – given the long-term nature of these investments, the often-essential nature of the end product, and the public/private mix of payors in the US and globally. To this point, the industry has demonstrated its resilience in prior recessionary periods.[1] For example, in 1991, life sciences deal volume grew an estimated 54%, while deal volume for all other sectors combined declined by 2.4%. In 2001, life sciences deal volume is grew an estimated 18% while deal volume for all other sectors declined by 32%. Finally, in 2008, while life sciences deal volume experienced an estimated decline of 25%, it was still better than the 30% decline in deal activity for all other sectors. Although constrained by capital, during none of these recessionary periods was research & development, constrained by pandemic.

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[1] Based on EY estimates

acquirers. We then turn to examine the state of the life science venture capital and private equity space, from the perspective of available capital and transactions. Despite market uncertainties, public and private biopharma companies appear to have had limited difficulty raising capital when viewed across the last 12 months. As private companies continue to generate record amounts of capital, with 459 companies raising $17.2B since June 2019, a slight uptick from the year before **(Figure 1)**. In context, the industry has raised ~$80B across 1,249 transactions in the last year alone. Buoyed by trends leading up to the full effects of the COVID-19 pandemic, this is 36% greater than the comparable period from 2018-2019. In this same period, 59 new molecular entities have been approved by the FDA topping the 55 in the parallel 2018-2019 period. Given these trends, we will examine how COVID-19 has impacted crossover investors and the IPO landscape as well as M&A considerations of end manufacturers in biopharma and medtech, in subsequent installments of this 3-part whitepaper series.

June-May	IPO		Follow-ons		Public/other		Private		Total	
2017-2018	$6,176	*60*	$37,834	*249*	$9,121	*355*	$15,203	*385*	$68,334	*1,049*
2018-2019	$11,143	*83*	$20,177	*217*	$10,257	*360*	$16,991	*401*	$58,569	*1,061*
2019-2020	$9,655	*58*	$35,555	*274*	$17,391	*458*	$17,217	*459*	$79,819	*1,249*

Figure 1: *Biopharma capital raised, ($M) and number of financings.*[2]

II. Clinical Trials – The Development Bottleneck

To attract new investors, strategic partners, and acquirers, clinical-stage companies need to reach milestones, such as moving treatments into and through human testing. By late May, ~100 drug companies reported impacts to ~240 trials **(Figure 2).** Small biotechs were disproportionally impacted, and with them, earlier stage trials.[3]

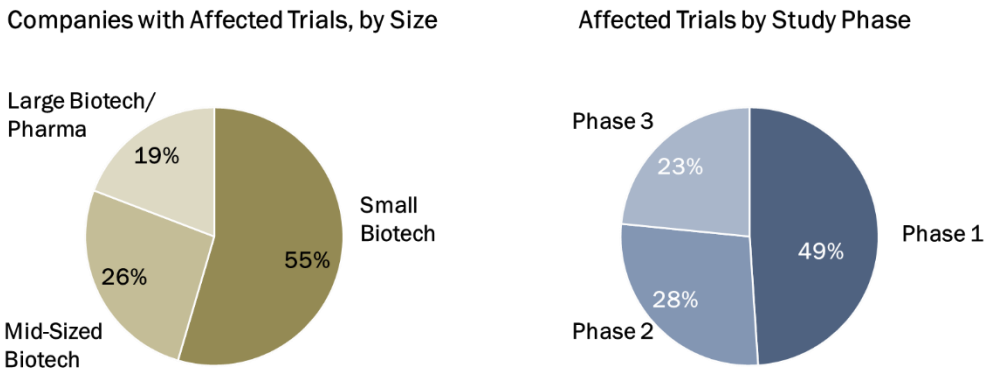

Figure 2*: Companies with affected trials and affected trials by study phase; expressed as a percentage of affected (n=~100 drug companies; ~240 trials).*[3]

[2] Based on estimates from the Biotechnology Innovation Organization BIO as of May 2020
[3] Based on Biopharmadive estimates as of May 15, 2020: https://www.biopharmadive.com/news/coronavirus-clinical-trial-disruption-biotech-pharma/574609/

Marwood believes that active trials will remain active as sponsors arrange contingencies to prevent disruption that would result in a loss of sunk costs and disrupted treatment. Clinical research organizations/site management organizations (CROs/SMOs) are working to ensure ongoing trials can be completed. For example, Eli Lilly and Company has noted that, "for patients already enrolled in clinical trials, discontinuation would disrupt their treatment and potentially diminish the societal value of the research information to which they are contributing". As such, Lilly is maintaining ongoing studies, although evaluating the status of each trial individually. Similarly, Vertex plans to implement virtual visits and ship drugs to participants in its ongoing trials. These and other efforts are designed to enable participants in ongoing studies to continue without having to travel to trial sites.

Conversely, trials in the planning and recruitment stage will remain paused for the near future. CROs are seeing an abrupt slowdown in the timeline of existing project work. CRO/SMO revenue decline is expected to appear in second quarter results. Global CRO/SMOs expect a continued recovery in Asia, but anticipate difficult conditions in Europe and North America to persist through the end of Q2 at the earliest. Drawing from the previous examples, Lilly is slashing its clinical trial activities in response to the COVID-19 pandemic. With COVID-19 putting healthcare systems under tremendous strain, Lilly has decided to delay most trial starts and pause enrollment in most ongoing studies. Vertex is pausing enrollment and delaying initiation of trials. Marwood estimates that 60% of trial participation occurs via hospitals and academic medical centers. With hospitals across the country forced to devote many of their resources to helping patients with COVID-19, even many large drug makers have been forced to pare down or suspend some clinical development operations. This extends to even those trials on life-saving drugs. Multiple oncologists from major cancer centers interviewed during the recently-concluded virtual American Society of Clinical Oncology annual meeting reported that their CAR T-cell therapy development efforts have had to face some adjustments, given competition for healthcare resources diverted to COVID-19, including patient recruitment efforts. An exception to these rules, COVID-19 trials have an open, expedited runway. For example, an official from Northwell Health noted trials of Gilead and Regeneron drugs were able to get up and running in four days rather than taking months to start, in part because clinical trials in other disease areas have been put on hold.

The FDA is attempting to help sponsors navigate the challenges to clinical trial execution that now exist. The agency has recently released guidance on the conduct of clinical trials during the COVID-19 pandemic. Regulators recognize the need for sponsors to make modifications to the conduct of their trials, since "business as usual" is no longer the norm. These modifications include adjustments to accommodate the safety and needs of patients under lockdown, as well as virtual trial technologies and updates to standard operating procedures to avoid unnecessary site visits. In addition, virtual inspections and audits will substitute for on-site audits to protect trial participants, verify the accuracy and reliability of clinical data, and to assess study compliance. In the next section, we address how investors in clinical-stage companies have initially reacted to these challenges and regulatory guidance.

III. Venture Capital and the Larger Private Equity Space

Venture capital and private equity firms have three factors in their favor: record amounts of dry powder, accommodative fiscal policies from the federal government, and low interest rates. Despite the unprecedented nature of the crisis, the fundamentals underpinning investment in the life science industry remain in place - most notably, the barriers to competitor entry of clinical regulation and IP protection of an often-essential product paid for by a relatively consistent mix of private and

governmental payors. Here, Marwood provides a deeper look into the challenges and opportunities faced by private capital.

a. Venture Capital

When the financial crisis hit in 2008, healthcare-focused venture firms found it extremely difficult to raise money from their investors. Viewing life sciences as a risky bet, perception did not start to change until 2013. Biopharma acquisitions and initial public offerings, typically the two main ways venture firms receive returns, would hit record highs in the following years, giving these firms and their backers confidence to keep putting in money. Polaris Partners, 5AM Ventures, Third Rock Ventures, and Versant Ventures (among others) each secured hundreds of millions of dollars across 2018 and 2019, while Flagship, Arch Venture Partners, and VenBio closed new funds this spring worth almost $3B combined. Deerfield, a "crossover" investing in both private and publicly traded companies, raised $840M to put into healthcare companies, including the life sciences. Despite this inertia, even into Q1 2020, COVID-19 is likely to have a prolonged impact on both fundraising and investment.

i. *Dry Powder (VC)*

US venture funding for the life sciences sector reached a peak of $5.5B in the first three months of 2020, according to data from PitchBook **(Figure 3)**. Notably, much of that record money was raised in March, after the United States and much of Western Europe had entered lockdown, in the midst of huge public market volatility. Experts note that a well-functioning capital market existed even as the stock market was thrown into excessive turmoil. However, as investors take defensive measures, first-time funds may have difficulty raising cash this year. Firms with existing networks of investor relationships may be able to pull off follow-on funds, but they would likely take longer to complete.

Fundraiser	Amount Raised (M)	Date Announced
Frazier Healthcare	$617	January 16
Andreessen Horowitz	$750	February 4
New Enterprise Associates	$3,600*	March 11
Flagship Pioneering	$1,100	April 2
Arch Venture	$1,460**	April 2
VenBio	$394	April 3
Gilde Healthcare	$450	April 3
Deerfield	$840	April 6
Qiming Venture	$1,100	April 9

**Technology and healthcare*

***Total across two funds targeting early-stage biotechs*

***Figure 3**: New Life Sciences Venture Capital Funds, US and Global, Q1 2020*

ii. Transactions (VC)

While money has been plentiful, the economic disruption caused by COVID-19 raises concerns over the rate of deal flow. At the surface, data compiled by the Biotechnology Innovation Organization, Bio,[Error! Bookmark not defined.] reveals private deals in the year ending in May 2020 to be up slightly from the year before ($17.2B across 459 transactions in 2019-2020 vs $16.9B over 401 transactions in 2018-2019). However, based on data compiled by PitchBook, the pace of biopharma venture deals appears to be lagging, with 228 deals between early February and mid-May this year, down ~16% from the 271 seen in a similar timeframe in 2019.

In this environment, venture capital firms have adopted a number of strategies – taking a page from prior recessions while taking stock of critical bottlenecks in clinical trial operations. Compared to the tech sector, the life sciences sector has avoided the exorbitant valuations that have been common among companies. In addition, by nature of the duration of the clinical development cycle, the long game may mitigate short-term impacts of the pandemic. Companies at the earliest stages of research may benefit. Investors assume that, by the time these companies reach human trials, some of the challenges and uncertainties surrounding COVID-19 will have been ironed out. Some investors note little apprehension investing in life sciences developers that will be working on pre-clinical research for the next 12-18 months, while observing how other investors on the later-stage side work through new guidance on clinical trials. Relatively quarantined from COVID-19 effects on clinical trials, these investors are content as long as the developers can accomplish standard concerns of having enough capital to get through preclinical data collection in a timely manner.

However, if a slowdown persists, a new crop of developers seeking initial rounds could find it difficult to close their next rounds of financing. VCs may find themselves having to make decisions on whether to back companies whose executives they have never met in person, with social distancing, self-quarantining and travel restriction still a factor – at least in the near term, and possibly in the coming months if a second wave of the pandemic is to develop.

b. Private Equity

Private equity is more known for investments into businesses, such as hospitals and medical device manufacturing, that produce steady cash flows, which can be used to pay off the debt used for acquisitions. However, in recent years, private equity has become a major investor in life sciences and big pharma. For example, KKR has built in-house expertise, investing $300M of its own money and funding six deals from this pool of capital. Subsequently, it raised a $1.4B life sciences fund, in which KKR remains the biggest investor. In 2016, Bain Capital established Bain Capital Life Sciences to focus on a wide variety of investment opportunities in the life sciences space, from early-stage venture capital investment to large private equity buyouts. Blackstone acquired Clarus, a life sciences investment firm that takes promising drugs that are being developed by big pharma groups and guides them through the approval process, taking a share of the profits for those drugs that are successful. As private equity groups build their life sciences business, they are moving closer to the earliest stage financing model of venture capital firms, such as Sequoia, or those such as General Atlantic, a private equity firm with a history of providing growth equity to the sector as a minority investor. A number of factors place private equity in a favorable position heading into the COVID-19 pandemic.

i. Dry Powder (PE)

As of September 2019, the US PE market held about $683B in unspent capital, up from $655B in 2018. The abundance of dry powder is fortunate timing for an industry that will need to put a lot of money to work in a variety of ways. The downturn is creating a need for equity contributions for companies that don't intend to cede control to new owners. Similarly, general private equity debt is near all-time highs ($170B), which bodes well for a broader array of funds to deploy strategies, such as direct lending to companies that were formerly investment grade, but have temporarily become stressed.

Using the 2009 downturn as a precedent, a slowdown in overall fundraising is expected. A recovery in public equities would help resuscitate the market to a degree, but the number will be smaller going forward. It will take more time for funds to close, adding to a slowdown in deal activity; and the funds that do close will likely have smaller "step-up" multiples compared to their predecessors. Managers are also getting creative with fee and incentive structures, depending where they are in the fundraising cycle.

ii. Transactions (PE)

Of particular interest in the COVID-19 era, private equity is identifying novel roles at the intersection of large biotech and government support. For example, on June 17, Carlyle Group Inc-backed Ortho Clinical Diagnostics announced that its COVID-19 antibody testing program received a grant from the U.S. Biomedical Advanced Research and Development Authority (BARDA). BARDA has invested billions in the development of testing kits, vaccines, and treatments against COVID-19, as well as industrial infrastructure, such as generics manufacturers that can provide active pharmaceutical ingredient (API) support for COVID-19 drug manufacturing.

In this unparalleled environment of government support, understanding the timing and release of state and federal COVID-19 relief programs – and the terms that a company plans to or has already accepted – plays a key role in fully appreciating the risks associated with transactions in the life sciences. The "affiliates" rule in CARES Act stimulus legislation precludes some private equity portfolio companies from loan eligibility. For private equity sponsors excluded from the PPP, the Main Street Lending Program may offer another lifeline for portfolio companies impacted by the COVID-19 pandemic. Established by the US Treasury and launched by the Federal Reserve on June 15, 2020, Main Street loans are not forgivable, unlike loans guaranteed by the Small Business Administration (SBA) under the Paycheck Protection Program (PPP). However, in deciding whether to participate, sponsors should be mindful of the program eligibility requirements (including affiliation rules), the restrictions imposed on borrowers and implications of planned public disclosures regarding Main Street loans.

About the Author

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Marwood Group is a healthcare advisory firm offering strategic consulting services, with expertise advising healthcare investors in conducting market diligence, strategizing market access and managing product life cycles leveraging direct insight into federal and state policy as well as intra-institutional dynamics.

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