

# Part 2

**CRO/CDMO prospects: funding  
overhang to drive growth?**

**CPHI Frankfurt 2022**





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## Predictions on the Health of the CRO/CDMO Sector in Uncertain Economic Times: When – or Will – the Bubble Burst?

### Introduction

Public and private funding into the biotech and emerging pharma sector has created unprecedented demand for outsourced pharma services over the last several years, as the number of compounds in development has skyrocketed. Considering the current disruptions in public markets, global geopolitical concerns, and other economically impactful factors, important questions remain to be answered:

Can the CRO/CDMO sector expect a slowdown? And if so, when, and to what degree?

These are difficult questions to answer definitively, so we will explore the macro factors affecting the sector in order to provide our prognostications on the health of the pharma services space over the new few years.

### Current VC Funding Into Biotech & Emerging Pharma

Demand for pharma services increased sharply in the wake of COVID-19, as some resources were globally focused on getting vaccines to the public, and others were focused on keeping up with demand for non-COVID therapeutic development and manufacturing. During this period, total biotech funding spiked from a little under \$20B (~\$70B TTM) in Q1 of 2020 to approximately \$40B (~\$140B TTM) in Q1 of 2021 (Figures 1 & 2). Despite a decline since Q2 of 2021, funding and the sector itself remain strong.

**TTM Biotech Industry Funding, 2007 to Present**

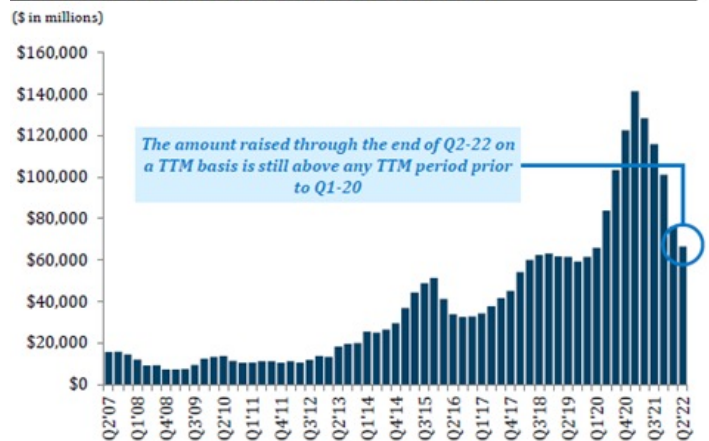


Figure 1. William Blair Equity Research. August 2022.

Putting pandemic-related factors aside, a significant portion of the heightened demand for CRO/CDMO services has been driven by VC-backed pharma and biopharma companies. While Q2 2022 follow-on and IPO funding have receded to Q2 2019 levels, post-pandemic VC funding remains above that of Q2 2019, even though we have seen a significant decline from its peak (Figure 2). The VC contribution to total funding places the current overall level essentially even with Q2 2019, though these comparisons are restricted to private funding, not public. The situation in public markets is dicey, to say the least. A model released by BlackRock on June 30, 2022, indicated that more than 80% of asset returns are attributable to macro risk factors – levels similar to those of 2008 and 2020.

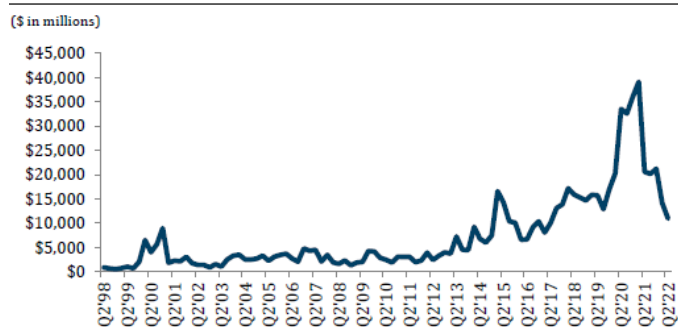
Focusing on VC biotech funding levels, we can see that the growth from 2010 to today has been strong and relatively consistent (Figure 2). The increase in VC funding just from 2016 to 2021 was 161%, topping the overall growth rate of 116%. So, while biotech

R&D spending is certainly lower than in 2021, the “decline” is mainly driven by the historical spike surrounding the global COVID-19 response. This appears to make for an unfavorable comparison, but only if we limit ourselves to a very short view.

## While Biotech Funding Has Declined From Prior Levels...

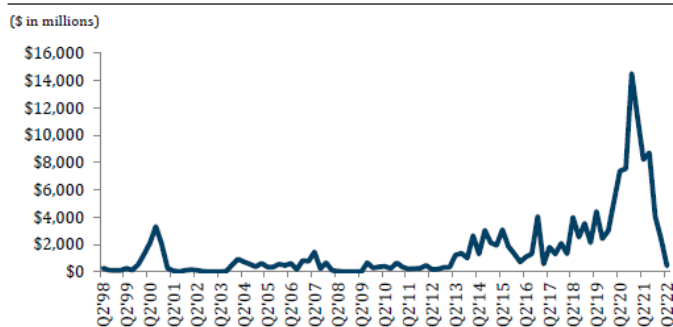
*Historic strong growth in biotech funding given investor appetite to support product development has significantly declined over the past several quarters*

### Total Biotech Industry Funding



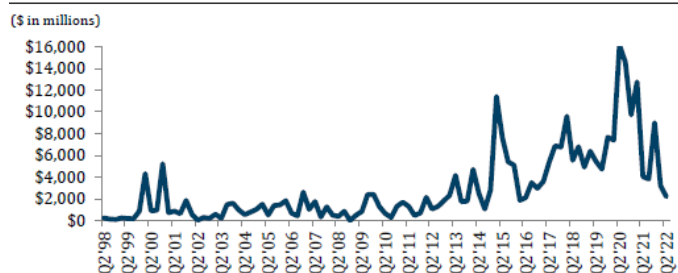
*Q2-22 funding was the fifth consecutive quarter in which funding declined YoY - while the percentage decline in the past two quarters seems stark (-64% in Q1-22 and -47% in Q2-22), funding on a dollar basis has only slightly dipped below the “normal” trendline one would expect*

### IPO Funding



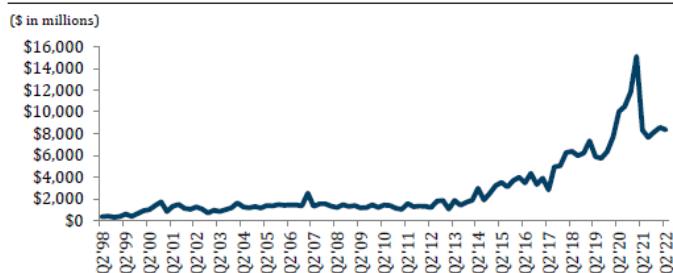
*Total IPO dollars in the second quarter were just over \$400 million (down 95% year-over-year and 83% sequentially), the weakest IPO quarter since late 2013*

### Follow-On Funding



*Follow-on funding in Q2-22 is down 46% from Q1-21 and 32% sequentially*

### Venture Funding



*Venture / private funding has remained robust, once again exceeding \$7.5 billion for the fifth consecutive quarter and well above any level observed pre-pandemic*

Figure 2. William Blair Equity Research. August 2022.

There is more than enough capital available to continue fueling innovation. Let us take a closer look at the numbers:

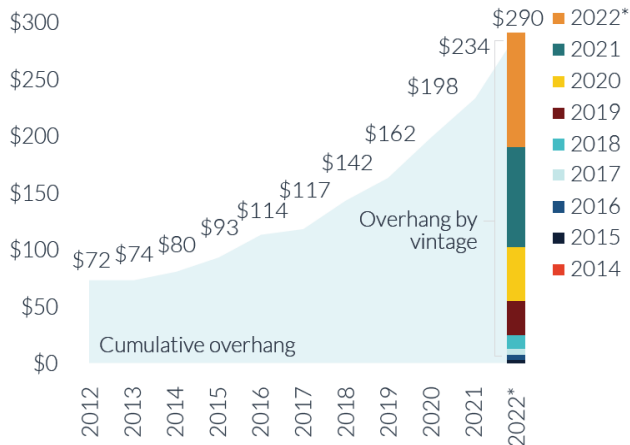
- **Q2 2022** — \$6B+ invested
  - Less than Q2 in 2021, nearly equal to 2020, but more than in any Q2 prior to 2020 (on record)
  - More VC funding than the entire year of 2013, which is viewed as a “boom” year for biotech backing
- **June 2022** — Biggest month of Q2
  - ~\$2.5B, more than any Q2 from 2019 or before
  - Occurred 18 months after the public market peaked (disentangled dynamics)

All of this funding into biotech and emerging pharma has created a turbocharged demand for pharma services, and the CRO/CDMO sector has seen almost no pullback in demand even during the current market disruptions. This is due, in part, to the VC-funded biotechs sitting on 2-3 years of cash reserves; critical programs remain funded. Further, biotech funding that has been raised over the last couple of years is likely to be deployed relatively soon because these closed-end investment vehicles must be used in deals within 4-5 years; VCs cannot sit on cash like hedge funds. The amount of dry powder set to be ignited in VC-backed biotech is enormous (Figure 3).

Figure 3. PitchBook-NVCA Venture Monitor. As of June 30, 2022.

## Dry powder continues to climb to new heights on the back of record fundraising

US VC capital overhang



So, is it time for cautious optimism? Can biotech M&As take the place of private and public funding since those have slowed? Can M&As act as a lever to keep biotech growth and need for CRO/CDMO services growing?

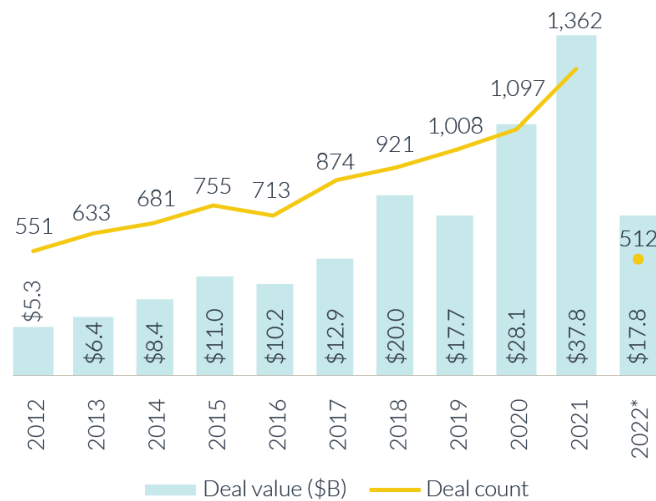
We can see that the total value of VC deals for 1H of 2022 already exceeds the value for all of 2019, and there has been a growing focus on late-stage deals over that same period (Figure 4).

Additionally, the average U.S. biotech VC deal size has grown by over 25% from 2021 to 2022 (from \$30 to \$40.4 million), and average pre-money valuations are at an all-time high (from \$114.6 to \$169.4 million as of June 30, 2022) (Figure 5). This data suggest that new VC investment, for now, is skewed toward later phase and less risky assets.

Figure 4. Pitchbook-NVCA Venture Monitor. As of June 30, 2022.

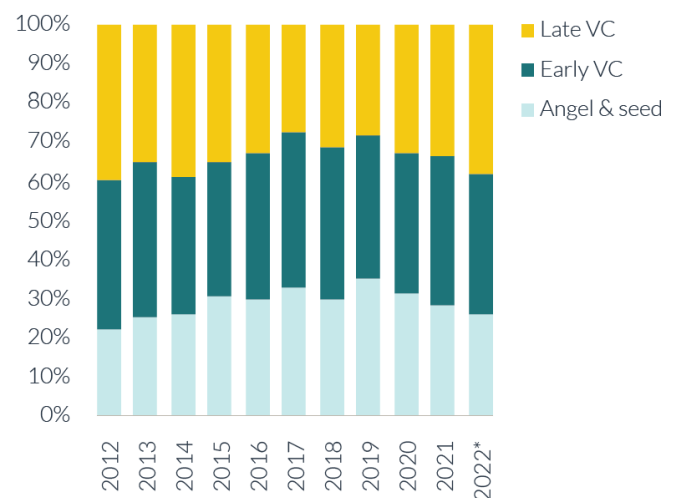
## H1 deal value exceeds pre-pandemic full year levels

US biotech & pharma VC deal activity



## Investor focus on late-stage deals persists

Share of US biotech & pharma VC deal count by stage



## Strong VC & PE Funding = Strong CRO/CDMO Sector

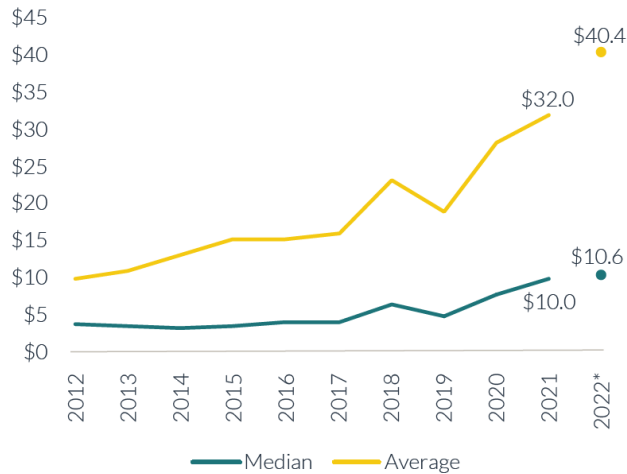
Due to their virtual nature, biotech and emerging pharma work almost exclusively with pharma services companies. Overall, VC cash flows through biotech companies and into CROs/CDMOs, which has bolstered demand for pharma services. The unprecedented level of biotech funding has spawned an unprecedented number of new therapeutics in development (Figure 6).

The thousands of new compounds in development are translating into new opportunities for pharma service providers. The pattern is very interesting in that the steepest growth is for compounds in early development. This is where most of the emerging pharma companies reside. These companies generally prefer to work with smaller CROs (Figure 7). The advantages of outsourcing to smaller, more "boutique" CROs that provide specialized expertise, speed, and high-touch relationships play well with the innovative nature of emerging companies.

Figure 5. Pitchbook-NVCA Venture Monitor. As of June 30, 2022.

### Average deal size grew more than 25% over prior year

Median and average US biotech & pharma VC deal sizes (\$M)



### H1 valuations reach record highs

Median and average US biotech & pharma VC pre-money valuations (\$M)

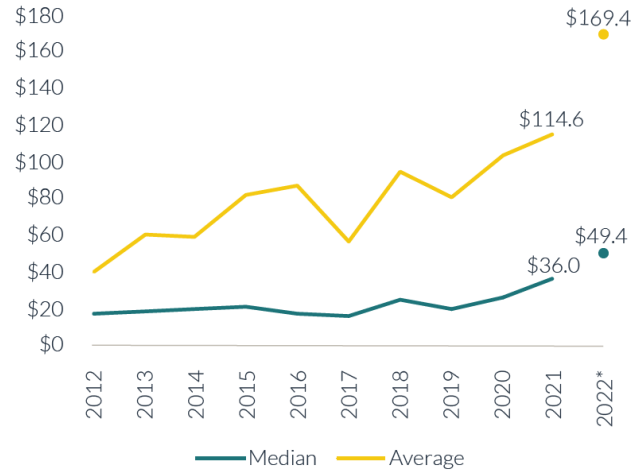


Figure 6. William Blair Equity Research. August 2022.

### Drug Pipeline, 2009 to Present

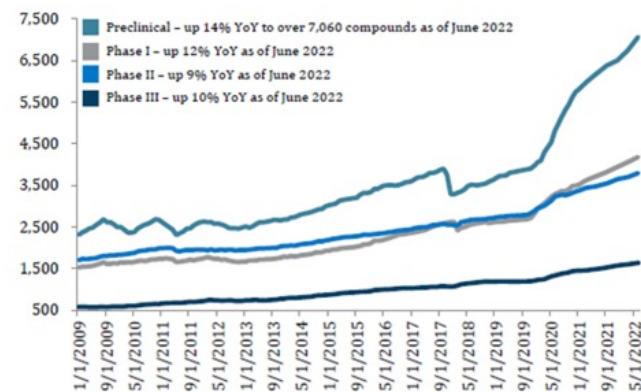


Figure 7. Credit Suisse Research.

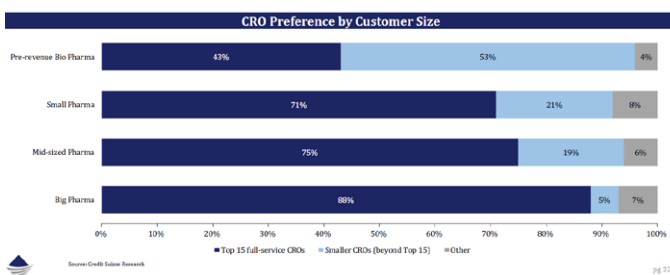
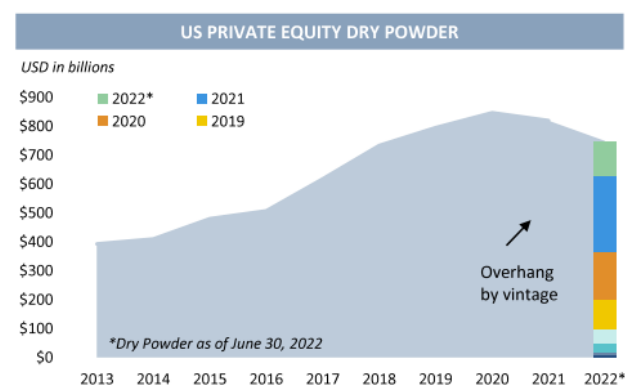


Figure 8. Bourne Partners. Pharma Services Snapshot (1H). As of June 30, 2022.



As compounds move further along in clinical phases and toward commercialization, emerging pharma companies grow into larger entities or are acquired by big pharma. At this point, the demand pattern shifts toward more integrated CRO's/CDMOs as the outsourced provider preference.

The key takeaway is that pipelines are extremely full across all phases of development, and growth has only accelerated. Smaller pharma service companies tend to match up well with bigger players in early phases of development, whereas the larger integrated CROs/CDMOs dominate in mid and later stages. Regardless of how biotech funding modulates or ebbs and flows between earlier and later stage investments, the large number of compounds already in pipelines are effectively "queued" up for further development as funding levels resume.

In addition to funding levels into biotech, an especially strong indicator for the health of the pharma services sector is the amount of dry powder that remains to be utilized in private equity. In June of 2022, the U.S. private equity capital overhang was about \$749 billion, and even though fund deployment has decreased the amount of dry powder compared to Q4 2021, private equity groups are on pace to raise record funding in 2022 (Figure 8).

The \$749 billion total overhang in private equity, the need to deploy capital, and the limited supply of actionable CDMO/CRO M&A mean that PE-funded pharma services company valuations are likely to remain elevated relative to historical



values. It should be noted that based on numerous discussions we have had with investment banks and private business owners, private CRO/CDMO valuations seem to have modulated (maybe 3-4 turns of EBITDA) in the past 6-9 months, so that a

“high teens” multiple might be more in the “mid-teens,” though still at historically high levels. Public CRO/CDMO company valuations have seen a more pronounced decline (Figure 9).

Figure 9: William Blair Equity Research. August 2022.

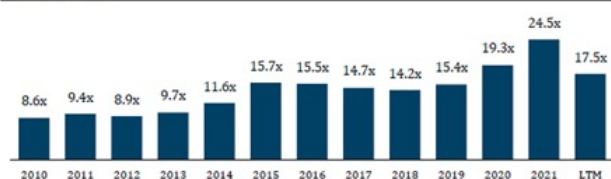
Public company valuations have experienced volatility and decline from record levels.

### Equity Performance

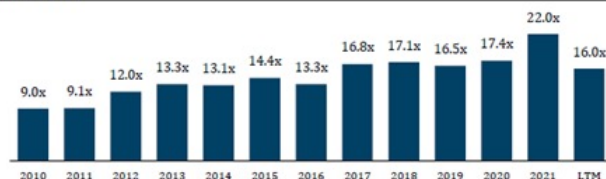
Companies	Market Cap (\$M)	YTD Price Performance	2022E Revenue	2022E EBITDA	21-22' Revenue Growth	2022E Gross Margin	2022E EBITDA Margin	EV / LTM EBITDA	EV / 2022E EBITDA
<b>CDMOs</b>									
AVID BIOSERVICES	\$1,215	(29.1%)	\$134	\$26	40.0%	32.0%	19.4%	NMF	44.4x
Catalent	20,269	(9.2%)	5,040	1,334	12.4%	34.2%	26.5%	19.0x	17.1x
Lonza	44,916	(23.1%)	6,185	1,967	14.3%	41.1%	31.8%	29.5x	20.7x
SOCIETAL	51	(47.7%)	91	15	9.7%	24.9%	16.6%	7.8x	8.2x
Siegfried	3,106	(20.2%)	1,228	254	11.4%	22.8%	20.7%	13.9x	12.8x
<b>Median</b>	<b>\$3,106</b>	<b>(23.1%)</b>	<b>\$1,228</b>	<b>\$254</b>	<b>12.4%</b>	<b>32.0%</b>	<b>20.7%</b>	<b>16.4x</b>	<b>17.1x</b>
<b>Mean</b>	<b>\$13,911</b>	<b>(25.9%)</b>	<b>\$2,536</b>	<b>\$719</b>	<b>17.6%</b>	<b>31.0%</b>	<b>23.0%</b>	<b>17.5x</b>	<b>20.6x</b>
<b>CROs</b>									
charles river	\$12,734	(30.8%)	\$4,006	\$1,030	11.8%	37.7%	25.7%	15.4x	14.7x
ICON	19,668	(18.5%)	7,838	1,708	5.0%	27.9%	21.8%	16.2x	13.7x
IQVIA	44,835	(12.2%)	14,539	3,357	4.8%	35.1%	23.1%	19.0x	16.1x
labcorp	24,346	(12.1%)	15,316	3,029	(5.6%)	29.8%	19.8%	6.5x	9.5x
MEDPACE	5,255	(20.9%)	1,395	263	22.1%	62.2%	18.9%	24.1x	21.5x
SynGene	8,118	(20.4%)	5,661	845	8.6%	23.9%	14.9%	14.4x	13.1x
<b>Median</b>	<b>\$16,201</b>	<b>(19.4%)</b>	<b>\$6,750</b>	<b>\$1,369</b>	<b>6.8%</b>	<b>32.5%</b>	<b>20.8%</b>	<b>15.8x</b>	<b>14.2x</b>
<b>Mean</b>	<b>\$19,159</b>	<b>(19.1%)</b>	<b>\$8,126</b>	<b>\$1,705</b>	<b>7.8%</b>	<b>36.1%</b>	<b>20.7%</b>	<b>16.0x</b>	<b>13.9x</b>

### EV / LTM EBITDA Multiples Over Time

#### CDMO Sector



#### CRO Sector



Despite the public markets cooling off, and valuations modulating a bit, transaction volume is strong in the CRO/CDMO sector. Specifically, 1H of 2021 saw 29 transactions for CDMOs and 36 for CROs, while 1H of 2022 saw 25 and 35, respectively (Figure 10). The number of deals remains high, and even though total value has dropped, this is in part due to mega-sized deals that happened in 2021, skewing the numbers. Some examples:

- **Icon acquisition of PRA Health** = \$12 billion
- **Thermo Fisher acquisition of PPD** = \$17.4 billion
- Total = ~\$30 billion

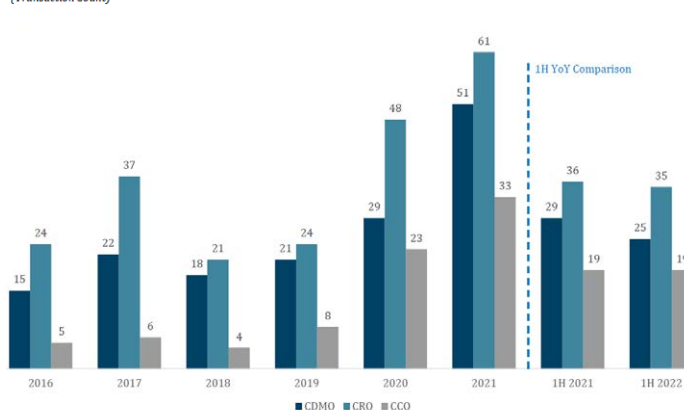
In short, the number of M&A deals is on par with 2021 and activity looks very healthy through the first half of 2022. The appetite for CRO/CDMO M&As is strong, indicating that the sector outlook is still very strong.

Based on the positive macro trends, analysts continue to be bullish on the longer-term growth prospects in the pharma services sector.

Figure 10: William Blair. Pharma Services Market Trends. August 2022.

### Transaction Volume by Segment

(Transaction Count)



The global CRO market is predicted to grow from \$58B in 2021 to \$76B in 2025 (~7.2% CAGR) due to increased R&D spending and outsourcing. Similarly, the CDMO market is predicted to expand from \$177.2B to \$246B (~8.5% CAGR) over the same period due to growth in drug development and outsourcing (Figure 11).

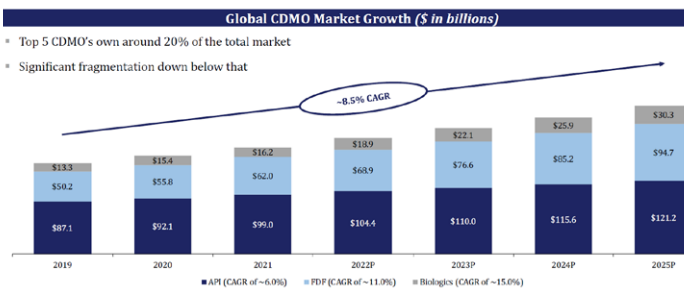
Figure 11. Top: Piper Sandler. Bottom: Edgemont Capital, Piper Sandler, William Blair.

The CRO market is expected to exhibit strong growth trends due to increasing R&D spend and outsourcing.



Source: Piper Sandler

CDMO market is expected to exhibit similar growth trends to the CRO market due to drug development growth and outsourcing dynamics.



Source: Edgemont Capital, William Blair, Piper Sandler

### Will CROs/CDMOs See Any Slowdown in the Next 24 Months?

Many have asked, “when can we expect the economic slowdown to actually hit the CRO/CDMO space?” It is not clear that it will in any meaningful way, though a variety of issues must be considered.

#### Factors affecting the demand and valuation in the pharma services space:

**VC and PE:** We have explored at length the relationship between VC/PE and the CRO/CDMO sector in this article. All signs are generally positive for continued strength in demand for pharma services and continued healthy CRO/CDMO valuations due to the amount of PE dry powder and more limited inventory of pharma service assets. However there is some negative pressure on pharma service valuations due to a more difficult leverage environment.

**Public Markets:** The IPO environment is currently not great; market volatility is high and stock values are down. This has dampened VC exits in later-stage biotechs. We are starting to see signs that some VC-funded biotechs (particularly later stage) are

beginning to stretch out CRO/CDMO programs where possible to slow the cash burn. This is putting negative pressure on the pharma services outlook.

**Big Pharma M&A:** With all the dry powder in big pharma coffers and a sub-optimal IPO environment, M&A activity should pick up in this area as they shop around for good strategic assets. This should be an overall positive for the pharma services sector, but the advantage will be skewed toward the larger integrated CDMOs because they have more strategic relationships with big pharma companies.

**Supply Chain and Re-Shoring:** The re-shoring phenomenon is real, and the momentum it gained during the pandemic is continuing due to ongoing global geopolitical concerns. The Russian/Ukraine conflict, EU energy concerns, and U.S.-China and Taiwan-China tensions are all causing uncertainty about materials moving around the globe. In addition, Kearney’s 2021 Reshoring Index shows that an increasing number of U.S. companies are returning offshore sourcing, production, and assembly to the States. In the same report, Kearney also disclosed the following information from U.S. executives:

- 92% express positive sentiments toward re-shoring
- 79% of those with offshore manufacturing operations have either already moved a portion of operations back to the U.S., or they plan do so within 3 years
  - o An additional 15% are considering

#### Other anecdotal factors:

In addition to the macro items described above, it should be noted that several of the discussions we have had with CDMOs and investment banks have pointed to some interesting issues impacting on the overall health of the pharma services market going forward:

- **Turnover within the FDA:** The agency has lost numerous reviewers due to turnover, which could be contributing to the significantly lower number of approvals in 2022 YTD. This could impact commercial launch of many drugs awaiting approval over the near/midterm.

- *Book-to-bill ratios at public CROs:* While most have maintained greater than 1.0, there are a few CROs where this has dipped below 1.0. This may start to impact revenue growth in Q4 of this year (and beyond?).
- *Slowing cash burn at late stage biotechs:* This is impacting CDMO contracts. Our discussions with a number of CDMO BD staff have indicated biotech CFOs are getting more involved in the proposal process to keep a closer eye on cash burn. In addition, average proposal values are starting to drop, owing to some biotechs chopping programs into smaller pieces to slow down cash burn.
- *PE Investment Committee Pushback:* we are hearing more broadly about more pushback from PE investment committees on valuations and deal structures in the current environment, as compared to the past couple of years.

### Summary of the Health of CRO/CDMO Sector

While it is true that private funding is down in the short term versus the past couple of years, and many factors are contributing to negativity and fear in public markets, there are also many reasons for optimism in the CRO/CDMO sector. Both PE (pharma services) and VC (emerging pharma) funding are historically high, demand for services is strong, dry powder is massive, and VC funds will – and must – be used. There is also movement among U.S.- and EU-based companies to re-shore manufacturing operations in the next few years, which should somewhat modulate the impact of uncontrollable global factors in these regions. For these reasons and others discussed above, the current and future health of the sector appear relatively strong, though not at the levels we have seen the past few years. Time will tell, but barring any major escalation in geopolitical events, there is more than sufficient cause for cautious optimism over the next 1-2 years.

## CPHI Additional Q&A Insights

**CPHI: Figure 6 on the make-up of CRO/CDMO preference by customer's size. Coupled with smaller companies mostly being earlier in development. Does this imply small and medium CROs/CDMOs will do very well in the next two years (out of the early-stage pipeline). With perhaps some using this pipeline to become medium CROs. But then in two years' time and onwards, this pipeline is going to secure massive revenues to large CROs.**

**BS:** *"Some of the small CRO/CDMO's will begin to invest in more scale to enable "continuity of supply". One example here, is where a smaller chemistry house doing small scale custom synthesis of API's to support medchem through GLP tox lots invest in some small scale GMP capability to allow them to produce from preclinical through first-in-human GMP lots."*

**CPHI: Or is the patten of late phase growth for large CDMOs already set. I.e. they are doing exceptionally well now from late phase projects (please put aside the benefits of Covid projects which we have to assume will gradually reduce) and will just continue to do well or better.**

**BS:** *"I think the pattern for growth for the larger CDMO's is largely set. As the increasing number of compounds make their way into later phases of development (and commercialize in some cases), the larger, more integrated CDMO's will dominate. Not in all cases, but I'd say the majority of later phase programs. In order to "feed the beast", the larger, integrated CDMO's have traditionally bought the smaller players to enable more pipeline of programs."*

**CPHI: What can we read into this statement for the next 2-5 years? 'the advantage will be skewed toward the larger integrated CDMOs because they have more strategic relationships with big pharma companies'?**

**BS:** *"It's not really significant as a blanket statement. All I mean by that statement is that the advantage for later stages of development goes to the large CDMO's because these require more integrated resources and scale to support later phases of development and commercial launch. The advantage for the earlier phases of development, generally speaking, is with the smaller CRO/CDMO's who, by virtue of their size/culture, match up well with the emerging pharma companies."*





**CPHI: ‘the dry powder overhang’ as this has to be spent soon; do we think this has been accounted for in growth projections for CRO/CDMOs or could we see growth over and above the 7.2% and 8.5%? (figure 11).**

**BS:** “I don’t believe the dry powder overhang has been accounted for in CRO/CDMO growth, but keep in mind the dry powder overhang for PE’s is different than the overhang for VC’s. The PE overhang will more drive both valuations (supply of cash against more limited CRO/CDMO targets) and capacity expansions to support market demand. The VC overhang/spending will support the demand side (i.e. funding more compounds in development)”

**CPHI: Does this mean for example that we might see lots of drugs funded to go much further into development and more approvals in the next 2-3 years? (granted I also noted that the FDA may be under resourced).**

**BS:** “VC funding overhang (supply of cash) may push funding into later phases of development. However, this should be tempered by the geo-political/inflation/public market headwinds.”

**CPHI: do you have any view on whether the big CROs/CDMOs might become too big and over the next 2-5 years (seems they look set to get the best of the growth) and it might be counter production for biotechs in the future – or do you think we will see an emergence of a mid-sized class of CRO/CDMO to work with biotech’s.**

**BS:** “I believe the market moves in cycles. The big become bigger by consolidating the available mid-sized players. This, in-turn creates a void between the big and small players (we see this today). Next, some percentage of the small players will themselves grow into mid-sized CRO/CDMO’s, then the cycle of consolidations come back again. Finally, there is no shortage of supply of small CRO’s/CDMO’s. Some of these desire to grow into mid-sized, others remain small as “lifestyle” businesses for the owners.”

**CPHI: looking at the table appears the bulk of future growth is in biologics and finished dose. Where would you invest CRO/CDMO resources with most certainly (mRNA, finished dosages, biologics, advanced therapies, HP etc etc)?**

**BS:** “Candidly, I’d invest in any pharma services company that is differentiated, has a proven track record of technical expertise and delivery, and can tackle challenges of today’s advanced therapeutics. When I say “advanced therapeutics”, I’m not only talking about large molecules. Could be large or small molecule.”

**CPHI: The US has a tremendous biotech growth engine (with perhaps not enough local CDMOs), China a quickly growing one, Europe relatively steady. Do you have any thoughts on the prospects for CDMOs in the USA, Europe, India and China. Are they all winners? (are there bigger winners among them – or is simply size is the main driver of the big winners?)**

**BS:** “Each region has its advantages, and the industry is starting to get serious about a more balanced approach in terms of supply chain balance given both Covid and now the geopolitical challenges the world faces. I think the prospects are strong in the regions you mentioned because the world is not a static place. China and India have both build formidable pharma services infrastructures, and we have been seeing companies in both countries invest in global strategies to ensure a multi-continent approach; ensuring facilities are strategically located across the globe. Much like the US and EU companies did over the past 25 years in those regions. The US has a unique challenge because it is still the largest pharmaceutical marketplace in the world, and still the largest hub of pharmaceutical innovation. Yet, there are relatively fewer pharma services companies on the continent. This has set up the supply/demand imbalance we are seeing in North America right now.”