Updated Insights into a Volatile Biopharma Marketplace

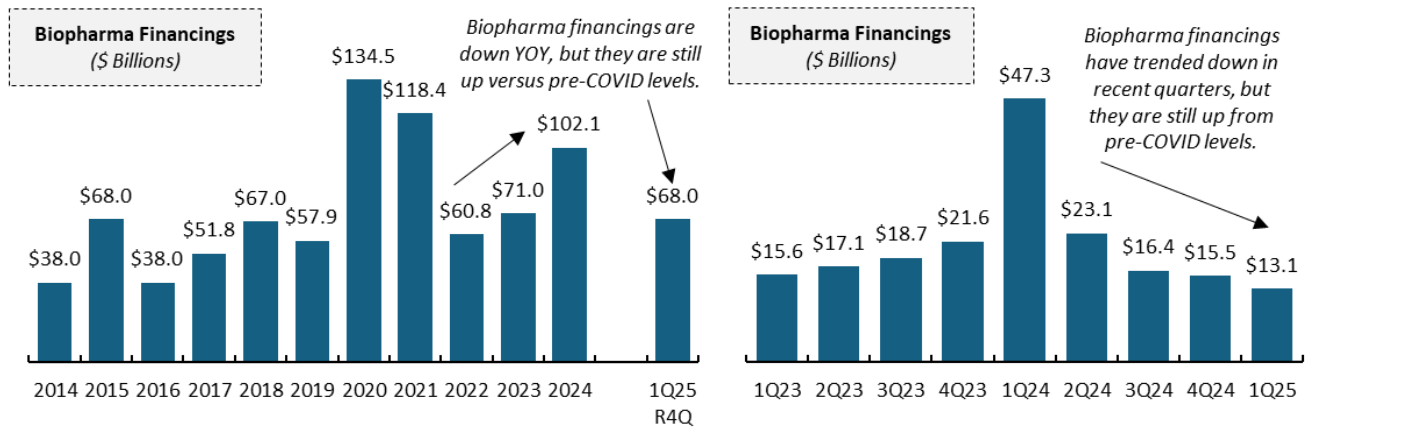
Key Thoughts and Insights Coming Out of the 2025 CPHI Americas Conference

The Bourne Partners team attended the 2025 CPHI Americas Conference in Philadelphia, Pennsylvania last week to hear from biopharma industry executives about marketplace dynamics and trends impacting their businesses. Panel discussions at the CPHI Conference highlighted the need for executives to think "differently" about their businesses in the face of a more challenging capital raising environment and an increasing focus on specialized precision medicines. For biopharma firms, this could include the greater use of non-dilutive funding such as revenue interest financings (RIFs), royalty monetizations, venture credits, and the monetization of future priority review vouchers. For outsourcing services providers, this could lead to more integration of R&D and manufacturing activities as well as the adoption and use of artificial intelligence software applications, among other things.

Also, **there was a general consensus view that biopharma sponsors and pharma services companies need to prioritize being operationally flexible** given a volatile pharma supply chain and trade policy environment. While pharma products were excluded from the initial wave of tariff announcements by the Trump administration, the anticipation of future pharma-related tariffs has led to a series of major announcements of new domestic pharma manufacturing capacity expansions. This, in turn, raises questions about the availability of a domestic labor force to support this new capacity. *For more discussion on the contract development and manufacturing organization (CDMO) space, refer to our recent deep-dive industry report: **CDMOs and Precision Medicines** (March 27, 2025).*

The 2025 CPHI Americas Conference consisted of a variety of topical panel discussions relevant to our coverage of pharma and pharma services, and we had the opportunity to catch up with several dozen executives on a one-on-one basis. Key topics at the conference included the biopharma funding environment, challenges in the pharma supply chain, the impact of tariffs and trade policy, new use cases for artificial intelligence, and applications of information technology in clinical trials, among other topics. In total, this year's CPHI Conference hosted over 4,000 individual attendees and over 300 companies.

Figure 1: Navigating a Volatile Biopharma Funding Environment



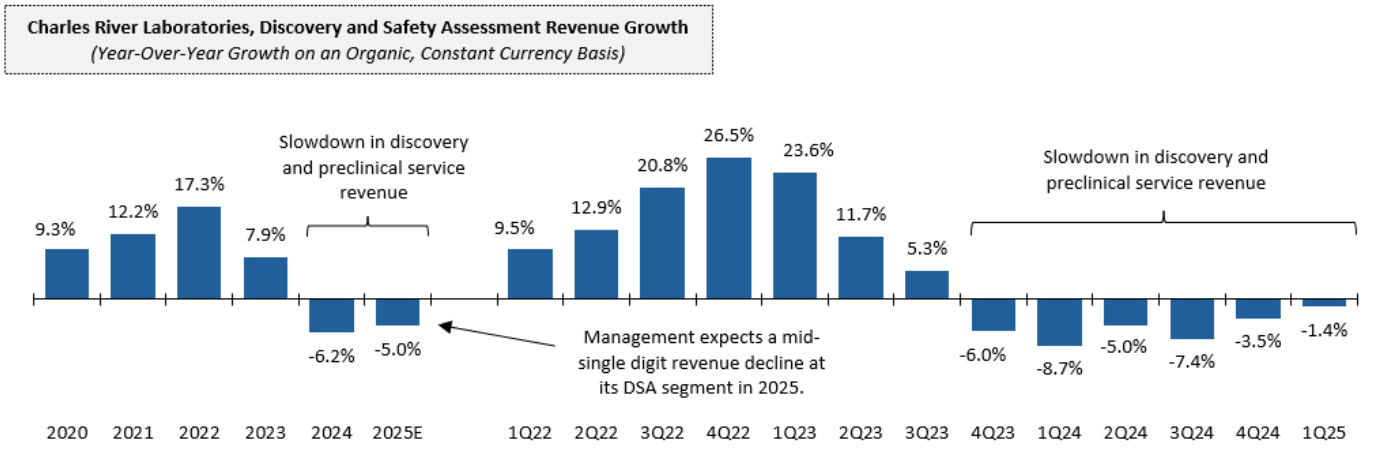
Source: BioWorld and Bourne Partners

In particular, **our one-on-one executive meetings highlighted continued very strong demand in the sterile CDMO space** (i.e., the production of sterile injectable pharma products such as vaccines and injectables). This is being driven by the increasing mix of biologic drugs that require intravenous, subcutaneous, and/or intramuscular injections. These CDMOs are also benefiting from the acquisition of Catalent by Novo Holdings late last year since this is expected to take considerable competitive sterile fill-finish manufacturing capacity off the market. Also, everyone seems to be in a "wait-and-see" mode with respect to the recent tariff announcements by the Trump administration. There has been an uptick of RFPs from foreign companies in response to the tariffs, but they mainly seem to be "price checking" exercises at this point (versus truly making the decision to on-shore production).

1) All Eyes on the Biopharma Funding Environment

There were a lot of discussions at the CPHI Americas Conference about the biopharma funding environment, and its downstream impact on pharma services companies. Our take-away is that, while access to funding is down materially from the 2020 and 2021 "bubble" levels, it is still reasonably healthy, on an absolute dollar basis, and well above pre-COVID levels. What we think *has* changed is that, while in the past capital was more ubiquitously available, there is now much more of a disparity in funding between "winners" and "losers." Investors in the biopharma space are demanding much more clearly articulated investment cases, including explicit pathways to Investigational New Drug (IND) approval and commercialization. This could include an openness to things like 505(b)(2) approvals to accelerate time-to-market. Also, multiple panel discussions at the conference emphasized the importance of alternative sources of funding, such as special investment vehicles, social media capital raising, family offices, and state-run pension plans. Several discussions referenced non-dilutive financing solutions as well. In fact, at Bourne Partners, we have seen growing interest in non-dilutive financing solutions such as revenue interest financings (RIFs), royalty monetizations, venture credits, and the monetization of future priority review vouchers. Refer to Figure 1 (previous page).

Figure 2: Soft Financial Results at Charles River Laboratories Highlights Slowing Preclinical Research Activity



Source: Charles River Laboratories and Bourne Partners

Essentially, **many contract development manufacturing organizations (CDMOs) and contract research organizations (CROs) reported seeing shrinking customer bases and volumes.** Multiple CPHI Conference panelists appeared concerned that this trend may continue for some time given proposed cutbacks in federal government research funding for the *National Institutes of Health (NIH)* and weak demand for discovery and preclinical research. This is

evidenced by financial results from public companies like Charles River Laboratories (NYSE-CRL), Evotec (NASDAQ-EVO), and Schrödinger (NASDAQ-SDGR). Weak demand for discovery and preclinical research could have lagging implications for clinical development activity in future years. Refer to Figure 2.

2) Innovative Pharma Services Business Models

In the face of funding pressures, **a number of panel discussions at the Conference highlighted the need for pharma services companies (e.g., CDMOs and CROs) to think "differently"** about their businesses. This echoes the theme of our recent deep-dive CDMO industry report: the increasing need for specialization as a competitive necessity. For years, we have seen the benefits of economies of scale with larger CDMOs acquiring smaller CDMOs to create integrated, end-to-end capabilities for their pharma and biotech customers. However, going forward, we expect to see more strategic consolidation around specific categories of precision medicine, each of which requires specialized expertise, equipment, and production infrastructure.

In our view, **one of the most interesting innovations in the CDMO space is the concept of an integrated CRO-CDMO business model.** In our CDMO report, we called out the recent announcement by Thermo Fisher Scientific (NYSE-TMO) of its new services offering that integrates its CRO (i.e., PPD) and CDMO (i.e., Patheon) businesses into a "single outsourcing solution." We highlighted this as something worth watching since it is the first major attempt to bring together a clinical-phase CRO and a global-scale CDMO under one roof. Also, we highlighted specialty CDMOs like Abzena. Key to Abzena's success, as a CDMO, has been its research capabilities which essentially function as an extension of the development teams of its customers. Traditionally, research and manufacturing services have been procured separately -- likely because people like to focus on things where they have most control ("within function capabilities"). However, this has led to coordination and communication breakdowns and data silos due to disparate systems. With the rising focus on complex precision medicines, such as antibody drug conjugates, the management teams at Thermo Fisher and Abzena hope that their integrated manufacturing and research capabilities will allow them to offer more streamlined execution for their respective customers.

Figure 3: New Research Highlights the Value of Integrated CDMO and CRO Business Models

	Large Molecule Drug		Small Molecule Drug	
($ in Thousands)	NPV Delta	ROI Multiple	NPV Delta	ROI Multiple
Phase I Only	$1,451	5.9x	$45	0.2x
Phase II Only	3,141	5.8x	1,548	2.9x
Phase III Only	62,932	113.1x	25,072	46.9x
Phase II + Phase III	16,359	24.9x	6,801	10.6x
Phase I + Phase II + Phase III	9,109	16.5x	2,999	5.8x

Source: Tufts Center for the Study of Drug Development and Bourne Partners

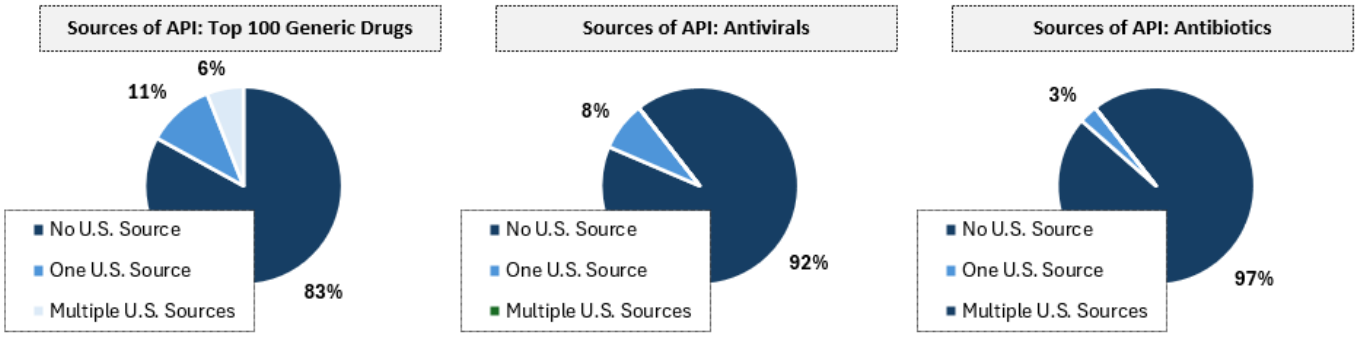
On this topic, **one highlight at the CPHI Americas Conference was a panel discussion that featured a research study by the *Tufts Center for the Study of Drug Development* on the economic value of an integrated CDMO-CRO model.** This study is now in peer review, and it is expected to be officially released in an academic journal soon. The study showed that the integration of CDMO and CRO services leads to both financial improvements and time savings in virtually all scenarios for the development of both large molecule and small molecule drugs. For example, when used consistently across *Phase I*, *Phase II*, and *Phase III* clinical trials, this model yielded $9.1 million of positive net present value (and a 16.5x return-on-investment) for large molecule oncology drugs and $3.0 million of positive net

present value (and a 5.8x return-on-investment) for traditional small molecule drugs. Also, the Tufts study showed that the use of an integrated CDMO-CRO model resulted in a 14.5-month average reduction in clinical trial timelines for large molecule oncology drugs and a 9.2-month average reduction in clinical trial timelines for traditional small molecule drugs. Refer to Figure 3.

3) Pharma Supply Chains, Tariffs, and Trade Policy

Another major theme of the CPHI Conference was the pharma supply chain and the need for pharma companies to diversify their sources of raw material. A panel discussion led by the *API Innovation Center* highlighted the need for the United States to maintain good international trading relationships; however, this should be balanced with a healthy level of domestic manufacturing of "priority" active pharmaceutical ingredients (APIs) and finished drug products. From a federal policy standpoint, this requires a clear definition of what is "made in America" -- along with a list of "priority" APIs and pharma products. Unfortunately, pharma supply chains have evolved over the years based on cost and capacity with little regard for resiliency. This has led to the pharma supply chain becoming very concentrated, and the COVID-19 pandemic exposed this as a vulnerability, particularly for foreign API. This dependence has worsened over time. From 2010 to 2020, the U.S. shuttered 60% of its API manufacturing capacity, while API manufacturing increased materially in both India and China. Today, of the top 100 generic drugs, 83% have no U.S. source of API and only 6% have multiple sources of domestic API. Refer to Figure 4.

Figure 4: Over Reliance by the United States on Foreign Raw Materials (Active Pharmaceutical Ingredients)



Source: Sardella A., "The US Active Pharmaceutical Ingredient Infrastructure: The Current State and Consideration to Increase US Healthcare Security." Center for Analytics and Business Insights, Washington University, August 2023, CPHI Americas Conference, and Bourne Partners

On a related matter, **the CPHI Conference featured panel discussions on the potential impact of tariffs and trade restrictions**. President Trump has made rebuilding domestic manufacturing in the United States a priority of his administration. This has resulted in dozens of tariff related announcements in recent months. To date, pharma related products have been explicitly excluded. Still, panelists were quick to point out that these tariffs are indirectly impacting domestic pharma manufacturing insofar as they are increasing the costs of imported consumables, processing equipment, and components used in pharma manufacturing. This could make domestic capital investment more difficult, particularly for smaller CDMOs. The *U.S. Department of Health and Human Services* is currently going through a Section 232 investigation on how the United States's dependence on pharma imports could be a national security issue. Nobody knows for sure how this is going to play out, but it is feared that this could lead to "sectoral" tariffs. In our view, there was a consensus view at the Conference that more domestic manufacturing is a good thing. However, most conference participants seemed to prefer other ways to accomplish this goal, such as streamlining domestic regulations and/or offering tax incentives.

4) Concerns About Future Access to Domestic Skilled Labor

One topic at the CPHI Americas Conference that surprised us a bit was that there was some concern about future shortages of skilled labor for CDMOs in the United States. Since the Trump administration started introducing tariffs, there have been a number of splashy press releases by major pharma companies about significant capital investments in domestic manufacturing infrastructure. On a few panels we heard concerns that there may not be enough of a trained domestic workforce in place in the United States to support these manufacturing capacity expansions. Pharma companies have deep pockets, and this could result in talent being bid away from the CDMO space in the coming years (assuming these capital expansion announcements do, in fact, occur). In fact, only one of the major pharma company media announcements that we are aware of included investments in domestic CDMO capacity (i.e., Fujifilm Diosynth Biotechnologies).

Figure 5: Artificial Intelligence (AI) Use Cases in the Biopharma Space

Drug Discovery	Analyzing vast datasets of biological and chemical information to identify potential drug candidates Predicting molecular interactions and the efficacy and toxicity of drug compounds Designing novel drug molecules with desired properties
Clinical Trials	Identifying suitable patient candidates for clinical trials, optimizing trial designs and protocols Predicting trial outcomes and patient responses and treatments Improving the efficiency and accuracy of clinical trials
Pharmaceutical Manufacturing	Monitoring and optimizing production processes in real time Predicting equipment failures and reducing downtime through predictive maintenance Automating quality control checks and ensuring regulatory compliance
Personalized Medicine	Analyzing individual patient data, including genetic profiles, lifesyle, and medical history Tailoring treatments and drug dosages to specific patient needs Developing personalized nanomedicines for targeted drug delivery
Supply Chain Optimization	Forecasting drug demand accurately Managing inventory levels efficiently to prevent shortages or overstock Optimizing production scheduling and logistics
Pharmacovigilence	Monitoring real-world data to identify adverse drug reactions Automating the reporting of adverse events and ensuring safety compliance Assessing associated with drug interactions and side effects
Regulatory Compliance	Automating the tracking and interpretation of regulatory changes Streamlining the preparation of compliance reports and submission documents Ensuring adherence to data privacy regulations like HIPAA and GDPR
Market Analysis and Strategy	Analyzing market trends and forecasting demand Conducting competitive intelligence analysis Optimizing marketing strategies and communication with healthcare professionals

Source: Improzo and Bourne Partners

We did not hear any convincing "solution" to any potential future CDMO-related skilled labor shortage. A number of CDMO panelists commented on the importance of partnering with academic organizations and setting up apprenticeships in order to ensure a stable inflow of skilled labor over time. Other CDMOs talked about the need to become more aggressive with in-house training programs, particularly in emerging modalities. Still others talked about the greater use of "fractional" (gig) hiring in which CDMOs use pools of independent freelancers and consultants, as a shared service, to temporarily fill vacant scientific, technical, and project management positions. (These fractional roles could ultimately lead to full-time employment down the road as well).

Finally, **there were a number of panel discussions on opportunities to use artificial intelligence (AI) for pharma manufacturing efficiencies.** The use of AI in pharma manufacturing is very nascent, in our view -- probably with adoption rates in the low/mid-single digits. So, most of the conversations were very high-level and conceptual in nature. AI was seen to help in various ways from speeding production times, lowering costs, enhancing quality

control, and improving regulatory compliance. As one representative example, at the recent AWS Summit in late 2024, Pfizer (NYSE-PFE) disclosed that AI has increased product yield by 10% and accelerated throughput by 20% by detecting anomalies and recommending actions to operators in real time. Also, using AI, Pfizer found that it could search and collate data and scientific content in a fraction of the time it previously took manually. Notable advice from panelists (including AI vendors) was that, when deploying AI in drug manufacturing, users should ensure they have sufficient data (warehouse) infrastructure in place in order to be able to normalize and manage large quantities of data. Also, there should be visibility and explainability to AI models with regular validation reviews for real-world accuracy. Finally, effective change management is absolutely essential to ensure that the AI is actually integrated into the drug manufacturing workflows. Refer to Figure 5 (prior page).

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