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Private Company Spotlight

Wheeler Bio

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Wheeler Bio

Company Snapshot

Closed series A round of $31M in April 2023

35,000 ft² GMP drug substance manufacturing facility in Oklahoma City

Comprehensive offerings including QC testing lab and Portable CMC Services platform

New bookings of >$15M in first quarter 2024

Nominated for ISPE Facility of the Year Award

Select Customers

DEKA Biosciences

BITT

Aakha Biologics

Our Q&A With Jesse McCool,

CEO and Founder

Company Overview

Wheeler Bio is a biomanufacturing pioneer, founded by a team of industry experts and strategic investors who believe a different CDMO model is needed to help innovators reach their clinical milestones faster. Wheeler Bio's novel hub-and-spoke operational model, centered in the biomanufacturing metro of Oklahoma City and integrated with discovery CROs, could revolutionize the speed of drug development. Wheeler Bio's technology platform, Portable CMC®, simplifies the path between drug discovery and clinical manufacturing by providing a new bridge for translating discoveries to first-in-human trials. Innovators benefit from increased momentum during technology transfer, shorter timelines, reduced risk, and lower costs.

1. Can you first describe the problem that Wheeler is trying to solve?

Venture-backed biotech companies account for an outsized portion of the investigational drug pipeline (80%) but only need a tiny portion of installed bioreactor capacity for their supply chains. In contrast to commercial supply chains (with a global demand of >40,000 kg/year bulk product), the average amount of clinical materials required to support a Phase 1 trial is around 250 g. With a typical process yield of 3 g/L, a single 500 L batch would yield more than five times the necessary amount. Therefore, the scarcity of clinical-scale bioreactors and CDMOs focused on clinical supply is an issue for biotech companies.

So, in 2021, Wheeler Bio was founded with a clear mission: to solve this scarcity in the biopharma CDMO sector. Our focus is on offering on-demand development and right-batch size, phase-appropriate Good Manufacturing Practice (GMP) services to biotech firms, aimed at enhancing the translational process for investigational new drugs (INDs). We are confident that our dedicated team, strategic partnerships, cutting-edge platform, digitalized infrastructure, and advantageous geographical location will pave the way for a new era within the United States that lowers the cost of early development.

2. Can you provide some background for those new to the pharma services industry?

The biopharma CDMO market has experienced substantial growth in recent years, driven by various factors such as the growing complexity of biologic drugs, the prohibitive cost of constructing and maintaining in-house production facilities, and the desire to mitigate risk and enhance flexibility in drug development and manufacturing processes. However, despite this growth, the market remains highly fragmented, with numerous players operating at different stages of the value chain. Key participants include CDMOs (contract development and manufacturing organizations), CROs (contract research organizations), and CMOs (contract manufacturing organizations).

CROs offer drug discovery services to aid clients in multiple steps of the process, including antigen design, hit generation, lead selection, lead optimization, and lead characterization. Fully integrated CROs may also provide pharmacology (in vitro/in vivo), biomarker development, and safety assessments.

CDMOs provide comprehensive services for biologic drug

development and manufacturing, encompassing process development, manufacturing, and analytical testing. Leading CDMOs in the market include Lonza, WuXi Biologics, Fujifilm, and Samsung Biologics. These companies tout a fully integrated clinical-commercial offering.

CMOs offer large-scale commercial manufacturing services. Major players in this sector include the same four mentioned in the CDMO category as they account for nearly 4 million liters of bioreactor capacity (representing approximately 50% of global bioreactor capacity in 2024).

Despite touting integrated clinical-commercial capabilities, the proportion of available capacity in large providers aligned with the needs of biotech firms (i.e., comprising clinical-scale bioreactors geared to supply early-stage clinical needs) is negligible. Large providers prioritize capacity utilization as a business imperative, often directing their focus toward larger customers with broader scopes, budgets, and program requirements. Moreover, large providers often "upsell or upscale" client needs to "fit" the facility (certainly for 1,000 L and 2,000 L); as an aside, if 2 x 500 L batches could be competitive to 1 x 1000 L, there's intrinsic value-add to product and manufacturing experiences, density of datasets, and practical process knowledge.

3. How are you trying to make a difference in the industry?

We crafted our novel business model with meticulous intent and embarked on the start-up journey by intricately crafting our novel business model, infrastructure plans, and technology development roadmap right from the outset with the founding 6 team members. Today, with a growing team exceeding 50, Wheeler Bio proudly offers on-demand access to a next-generation biomanufacturing platform for antibodies at a competitive price point comparable to offshore providers while ensuring regulatory compliance at the level required for first-in-human (FIH) trials.

Our success stems from a customized implementation of GMPs and RightSource℠ (Charles River Laboratories), assuring stringent controls of manufactured materials while streamlining costs related to systems validation and managing in-house analytical GMP testing. While Charles River Laboratories continues to invest in laboratory facilities, equipment, and digital infrastructure to maintain compliance and efficiency, Wheeler Bio remains steadfastly focused on our core strengths: bioprocess development, manufacturing, and customer service.

Moreover, we've pioneered a robust, scalable, high-yielding process for drug substance manufacture, which we've generously made open source (Portable CMC®). This process integrates Leap-In Transposase® (ATUM) and a machine-learned predictive bioprocess model and facilitates an accelerated parallel CMC development approach without incurring additional expenses and time.

Wheeler Bio is dedicated to delivering unparalleled value to its customers by harnessing the efficiencies of process development integrated with phase-appropriate GMP and clinical-scale operations. We further enhance our offerings through strategic partnerships that seamlessly connect drug discovery with drug development. This holistic approach ensures that we not only meet but exceed the expectations of our clients, delivering innovative solutions and exceptional outcomes.

4. How does bioreactor scale factor into your plans?

We see that the global CDMO industry has grown disproportionately large for biotech firms seeking only one or two batches of a high-titer/high-yielding process to supply their Phase 1 trials. To illustrate, the estimated bioreactor volume required to supply Phase 1 trial materials for four representative antibody drugs (vedolizumab [Entyvio®], ixekizumab [Taltz®], olaratumab [Lartruvo®], and durvalumab [Imfinzi®] would have been less than that of a single 500 L bioreactor utilizing Wheeler Bio's Portable CMC platform.

The oversizing trend is largely driven by the growth of the biologics end-market, leading CDMOs to rush in adding large-scale facilities. China has taken a significant lead in building such large-scale facilities, offering attractive pricing for biotech CEOs despite the scale mismatch. However, with the looming BIOSECURE Act, we are witnessing shifts in industry dynamics. Recent announcements, such as Lonza's closure of their clinical drug substance site in Hayward, CA (6,000 L), and the concomitant acquisition of the Vacaville, CA, commercial site (330,000 L), signals a strategy for CDMO incumbents to establish more large-scale capacity in the United States. As part of the Vacaville deal, Lonza intends to invest an additional CHF 500 million to upgrade the facility.

However, as the biologics pipeline is ever expanding, there is scarcity in clinical-scale bioreactors supporting early development and with the potential for renewed onshoring, Wheeler Bio seizes the opportunity by establishing a high-quality biologics development center of excellence in Oklahoma City. As previously mentioned, we recently inaugurated a cutting-edge GMP facility, equipped with 50 L and 500 L scale bioreactors.

This strategic location offers cost advantages comparable to those of offshore biomanufacturing hubs, buoyed by a burgeoning local biomanufacturing workforce. The presence of several established pharmaceutical companies in the region, coupled with recent federal grants for biomanufacturing workforce training, bolsters the skilled labor pool and sustains the cost advantage.

Wheeler Bio remains committed to its focus on right-batch size manufacturing and has devised a brick-and-mortar strategy (with Convergence OKC) to swiftly augment the center with additional clinical capacity. Furthermore, Wheeler Bio's cost-effective operational model is further fortified by its on-demand CMC development platform and RightSource™ integration. This comprehensive approach positions Wheeler Bio as a pioneer in delivering rapid, efficient, and top-quality CDMO services to venture-backed biotech companies, finely attuned to the evolving demands of the biopharmaceutical industry.

5. Talk about your market opportunity and key market tailwinds expected to drive growth in the future.
The biologics CDMO market provides a long runway for future revenue growth enhanced by tailwinds that should bolster Wheeler's market-leading position in the early development sector.

Many biotech firms face a significant funding hurdle when attempting to progress their drug candidates into clinical trials, a challenge often dubbed the "valley of death" due to the struggle in securing adequate funding. This difficulty stems from the inherent technical risks involved in navigating preclinical testing, designing clinical trials, and planning the CMC development and material supply strategy. Compounded by the substantial capital required for these activities, program momentum frequently stalls throughout the translational process until sufficient supporting datasets such as CMC data are available to potential investors. However, therein lies a catch-22: How can CMC data become available without proper funding? This dilemma is one that many firms encounter while endeavoring to circumvent attrition.

Wheeler Bio's value proposition aims to address this challenge by enhancing the accessibility of CMC data through low-cost (on-demand platform), right-batch size, phase-appropriate GMP services provided from our clinical development center at an accessible price point. By offering these services, Wheeler Bio seeks to empower biotech firms with the necessary CMC data to attract funding and overcome the "valley of death," thereby accelerating their journey towards successful clinical development.

The tailwinds that should help drive our growth in the future:

- Healthcare investors are showing renewed interest in biopharma following the long, uncertain "pandemic biotech bubble."
- The expanding Inflation Reduction Act (IRA) is predicted to drive a larger investor wallet share in large molecule drugs because of the more favorable pricing protections relative to small molecule drugs.
- The existence of continued commercialization challenges in cell and gene therapy coupled with the increased adoption of accelerated regulatory pathways for protein therapeutics.
- The U.S. pharma industry (post-pandemic) is growing wary of offshore supply chains, which is driving a renewed interest in using domestic suppliers to support the development and manufacture of drug substance.
- The looming BIOSECURE Act is diverting U.S. biotech firms to select domestic CDMOs.
- Increased regulatory acceptance of compressed CMC development strategies is leading to deferral of major bottleneck steps until post-IND.

6. What is unique or attractive about your manufacturing platform, and how does it simplify the path between drug discovery and clinical manufacturing?
The most unique and attractive features of our manufacturing platform are Leap-In Transposase and Portable CMC and their proven performance in our next-generation facility.

Leap-In Transposase from ATUM is the industry-leading gene delivery system that delivers uniform and high-frequency target gene integration resulting in high productivity levels. There have been 32 INDs accepted that feature this technology as it is fast becoming the most widely adopted standardized transposon tool for enabling robust CMC development.

Portable CMC is Wheeler Bio's standard process for drug substance production and was developed from the ground up using machine learning and an array of technologically advanced scaled-down process models (250 ml, 10 L, and 40 L laboratory systems) that accurately capture the essential characteristics and behaviors of our 50 L and 500 L GMP DynaDrive™ bioreactors (Thermo Scientific).

Although Portable CMC and the knowledge of how to design, optimize,

and intensify bioprocesses represent Wheeler Bio's core intellectual property, the tangible components of Portable CMC are open source and customer owned:

- Process flow diagram with key operating parameters
- Process description and control strategy
- Integrated bioprocess model with supporting datasets
- Process batch records with sampling plan
- Bill of materials (BOM)

When implemented early through workflow parallelization at our discovery CRO partners, Portable CMC further simplifies the path between drug discovery and clinical manufacturing through a pools-based CMC strategy that is tailored to the most technologically advanced biologics production infrastructure available on the market today.

Finally, an additional intentionality of Wheeler that makes us quite unique is that we are the only CDMO in the world that operates inside of a venture capital firm. Echo Investment Capital, headquartered at the Zig in Oklahoma City (same building as Wheeler Bio's GMP), has been a strategic sponsor of our company's development and differentiation. Led by founding partner and CEO Christian Kanady, Echo has a core mission to revolutionize the drug development process for next-generation biopharmaceuticals. The firm envisions a transformative development paradigm that enables a faster translational process by aligning venture capital, service providers, workforce, and clinical research into one cohesive ecosystem inside a single, low-cost, geographic hub. Echo aims to enhance patient access to next-generation therapeutics in Oklahoma while improving healthcare outcomes for Oklahomans and de-risking investor returns. Wheeler Bio plays a pivotal role within this ecosystem as a cornerstone asset to de-risk CMC, supporting the broader Echo portfolio of therapeutics. By leveraging our expertise and resources, Echo aims to drive forward innovation in the biopharmaceutical sector and ultimately benefit patients worldwide.

We understand that biotech is intimately tied to venture funding, and our customers' workflow needs to accommodate their funding ebbs and flows. Guided by our own venture backers at Echo, we have developed a series of work packages that progress the project to value-infection points. We are the only CDMO in the world that has specifically designed our service offerings to meet the needs of our customers and their venture backers.

7. Who are your biggest competitors, and why have they failed at solving the translational challenges inherent in advancing from discovery to clinical manufacturing?

Wheeler Bio's strategic focus on early clinical phase manufacturing and its role as a crucial link between discovery and FIH supply sets it apart within the biopharmaceutical CDMO landscape. While maintaining a global database of 90 organizations offering CDMO services, Wheeler Bio stands out for its specific emphasis on this critical phase of drug development.

Within this database, Wheeler Bio has identified approximately 10 CDMOs equipped with at least one 500 L scale bioreactor. Notably, only five of these companies are based in the United States. This highlights the relatively limited pool of U.S.-based providers specializing in early clinical phase manufacturing.

Moreover, Wheeler Bio's analysis reveals that none of these identified CDMOs intentionally focus solely on providing services for the clinical stage without also advertising commercial capabilities. Many of these providers offer more comprehensive services, including drug product manufacturing and microbial production. While such comprehensive offerings may seem advantageous, they can also result in increased operating costs for these organizations and higher prices for clients.

In addition to being the only CDMO in the world set up inside of a venture capital firm, key differentiators that set Wheeler Bio apart from the few CDMOs with 500 L scale bioreactors include the distinction of being the only CDMO that offers:

a) Discovery integration with strategic CRO partners

b) RightSource™ integration (on-site outsourcing)

c) A well-characterized platform process that's open source (Portable CMC)

d) 100% focus on mammalian production of antibodies whereas others are focused on additional modalities such as gene therapy, small molecules, and microbial

e) Exclusively, Leap-In Transposase–based cell line development and a well-tested pools-based workflow for compressing the CMC development timeline

At the end of the day, it is high predictability and reduction of human intervention in bioprocessing that garner successful outcomes and happy customers. Customers will view their CDMO as being reliable and a good partner whenever the following three questions can be answered reliably:

- How long will it take to get my clinical materials?
- How much will it cost to get my clinical materials?
- How much clinical material will I get out of my batch?

8. Discuss the strategic benefits associated with your hub-and-spoke model centered in Oklahoma City, as well as the value of your agreements with leading discovery contract research organizations. Partnering with discovery CROs presents an invaluable opportunity for Wheeler Bio to gain insights into their drug discovery processes and identify optimal entry points for integrating Wheeler Bio's Portable CMC process. By collaborating closely with these CROs, Wheeler Bio can better understand the specific needs and challenges faced during late discovery stages.

For instance, many in vitro and in vivo efficacy and safety studies conducted by discovery CROs utilize preclinical materials generated from transient transfection systems like HEK293. However, this expression platform is not scalable and may not generate materials that are reliable, reproducible, and representative of IND-enabling materials or even early clinical materials. In contrast, Wheeler Bio employs transposons to generate stable pools of Chinese hamster ovary (CHO) cells to produce preclinical materials that more closely resemble the future manufactured materials. This distinction highlights the potential for Wheeler's Portable CMC process to offer superior materials to support late discovery, thereby enhancing the reliability and relevance of the preclinical data and reducing risks in tech transfer between discovery CROs and CDMOs.

Through our growing partnerships with discovery CROs (Charles River, Alloy Therapeutics, ATUM) and active engagement with their staff scientists, commercial team members, and clients, Wheeler aims to establish itself as a trusted partner and resource within the industry. By socializing Wheeler Bio's capabilities and expertise, the company can increase referrals through these "practical sales channels," effectively expanding its client base and market reach.

The benefits of collaborating with Wheeler Bio extend beyond mere transactional gains. Customers stand to gain significantly from reduced risk, accelerated timelines, and access to early CMC data, which can strengthen their fundraising efforts and enhance investor confidence. By mitigating risks associated with CMC development and offering timely access to critical data, Wheeler Bio empowers its clients to navigate the complexities of drug development more efficiently and effectively. This ultimately contributes to the overall success of their therapeutic programs and facilitates the advancement of innovative treatments to market.

9. What are your plans for further building out your offering over time? Are there any related markets that you view as particularly attractive? Wheeler Bio's strategic focus on adding value to the early clinical phase biologics market is evident in its commitment to enhancing development capabilities and scaling out clinical manufacturing bioreactor capacity. This targeted expansion approach aligns with the company's mission to serve a global biotech client base while maintaining excellence in biologics development and manufacture.

The company's headquarters in Oklahoma City, positioned within a vibrant ecosystem of clinical research, investors, academia, and service providers, underscores its strategic advantage. With a state-of-the-art development laboratory and CGMP manufacturing facility, Wheeler Bio ensures seamless access to cutting-edge tools and technologies for advancing antibody and biologics development.

The Convergence project, a $177 million development within the Oklahoma City Innovation District, serves as a testament to the city's commitment to fostering cross-sector collaboration, particularly in biotechnology and healthcare. By uniting academic and research centers with financial and venture institutions, Convergence will create an ecosystem conducive to entrepreneurism and translational science when it opens in January 2025.

Wheeler Bio's role as the anchor tenant at Convergence further solidifies its commitment to driving innovation and collaboration in Oklahoma City's biotechnology ecosystem. The new facility, boasting state-of-the-art development laboratories and manufacturing cleanroom space, will provide ample capacity for Wheeler Bio to expand its comprehensive suite of development and GMP manufacturing services.

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