Industry Report

PROPHASE LABS, INC. (NASDAQ: PRPH) SUBSIDIARY, PHARMALOZ MANUFACTURING - A HIGH-GROWTH, EXPERIENCED CDMO MANUFACTURER

DIAMOND EQUITY RESEARCH

ProPhase Labs, Inc. (NASDAQ: PRPH) subsidiary, Pharmaloz Manufacturing Inc. (PMI) -

PMI Undergoing Hyper-Growth with Near-Term and Long-Term Profitability

We hold the belief that Pharmaloz Manufacturing Inc.'s underlying value surpasses the entire current market valuation of Prophase Labs. Emerging as a promising contender in the Contract Development and Manufacturing Organization (CDMO) space, Pharmaloz Manufacturing has astutely established itself as a trusted and reputable CDMO partner, particularly within the Over-the-Counter (OTC) drug and dietary supplement market. As a wholly owned subsidiary of ProPhase Labs (NASDAQ: PRPH), Pharmaloz is currently experiencing accelerated growth rates in revenues, margins, and net profits. This growth is attributed to strong domestic and global supply demand variables, which signal a robust outlook for both the short term and long term. This report presents a thorough assessment of Pharmaloz Manufacturing's CDMO capabilities and expansion strategies, emphasizing its interconnectedness with the OTC market. Tailored for stakeholders, investors, and those engaged in the CDMO sector, the report provides valuable insights into the industry's evolution, while highlighting Pharmaloz Manufacturing's position within the industry.

Key Data PMI	
Sector	Healthcare
Type	Private
Founded	1984
Headquarters	Lebanon, PA
2024E Revenue	$20.0 million
2025E Revenue	$40.0 million

Pharmaloz Manufacturing, a subsidiary of ProPhase Labs, is a Contract Development and Manufacturing Organization (CDMO) specializing in pharmaceuticals, Over-the-Counter (OTC) drugs, and dietary supplements. Operating from a state-of-the-art, UL and FDA-compliant facility, Pharmaloz focuses on natural cough drops and lozenges, offering quality, organic, and non-GMO products. The company also owns, manufactures, and packages TK Supplements. Pharmaloz' robust manufacturing capabilities encompass lozenges, blistering, and packaging, all underpinned by stringent quality standards and regulatory compliance.

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Investment Highlights

- **Strong Growth Momentum Driven by Key Client Wins -** Pharmaloz Manufacturing Inc. (PMI) continues to exhibit strong growth momentum, underscored by a series of strategic moves that position the company favorably in the Contract Development and Manufacturing Organization (CDMO) market, particularly within the over-the-counter (OTC) segment:
    1. *The company has implemented* ***an average price increase of 15%*** *across its entire product line*, effective in Q1 2024. This development is a direct response to favorable market demands and limited competition, immediately enhancing revenues and profits.
    2. PMI *announced* ***two significant contract wins*** *in January 2024* with major lozenge brands, potentially boosting annual revenues by an additional $5 million and pre-tax profits by over $1.25 million. The company anticipates substantially more revenue as the capacity expands. The combination of recently implemented price increases and two new important customers is expected to elevate PMI to a $16 million revenue run rate entering the second quarter of 2024, with anticipated annualized net profits ranging between $3.2 million and $4 million, reflecting a net profit margin of 20-25%. It is imperative to highlight that these projections do not account for the revenues from TK supplements, which are on a run rate of approximately $2.5 to $3 million of profitable revenue.
    3. Business from existing customers, including the recently announced new customers, should continue to grow as PMI increases capacity.
    4. PMI is also in advanced discussions with two major global lozenge brands, *either one of which could potentially more than triple its revenue run rate by the end of 2024.*

- **Aggressive Expansion Plans to Satisfy Growing Demand -** Operational advancements, including the recent acquisition of state-of-the-art automation equipment, are set to increase production capacity by over 50%, elevating annual production capabilities from below $10 million to at least $16 million during Q2 2024. Looking ahead, the installation of the second production line and further automation during Q3 2024 are projected to further double the capacity to a $30-$35 million run rate goal, with strong profit margins. Additional enhancements are planned for the fourth quarter, with the introduction of more equipment, potentially boosting annual production values to $60-$80 million targeted between year-end 2024 and the first half of 2025. By expanding the workweek, the company could further increase capacity and potentially achieve $100 million in revenue, generating potentially $20-$25 million in net profit. The management's vision extends beyond immediate gains, aiming for a long-term goal of potentially expanding production capacity to $200 million in annual revenues over the next three plus years. These efforts by the company to capitalize on positive market reception and favorable OTC market trends indicate a strong growth pathway enabled by significant investments in expanding capabilities.

- **Positive Market Reception -** Retailers like Walgreens, Walmart, and CVS prioritize stocking popular products and ensuring constant shelf availability to maximize profits. Empty shelves result in lost revenue, making consistent product supply crucial. Due to supply chain issues in the global lozenges industry, Pharmaloz has attracted interest from major brands, some seeking the company to be their primary manufacturing partner, not only in the U.S. but also on a global scale. Aside from reliability in ensuring a timely supply of drugs, the credibility of Pharmaloz's CDMO services is reflected through its passing of FDA audits and inspections. Furthermore, with a decrease in industry-wide reliable manufacturing capacity for lozenges, companies like Pharmaloz are likely to benefit from addressing the growing need for a consistent and dependable lozenge manufacturer.

- **Underlying Industry Trends -** Pharmaloz Manufacturing focuses on the OTC drug and dietary supplement market, particularly in the natural cough drops and lozenges sub-segment. OTC drugs, available without prescriptions, play a vital role in treating common conditions, saving the U.S. healthcare system billions of dollars annually. The U.S. OTC drug and Vitamins, Minerals and Supplement (VMS) market is valued at over $100 billion, anticipated to grow at a steady rate over the next decade. Cough, cold, and flu products remain the dominant category, with throat lozenges gaining prominence due to their therapeutic and palatable attributes. Several drivers are steering the growth of the OTC drug market, including an aging population, the FDA's support for Rx-to-OTC switches, rising self-medication practices, and increased prevalence of minor health conditions. Moreover, the COVID-19 pandemic further heightened the demand for OTC products. With these industry dynamics at play, the OTC drug and dietary supplement market holds a promising future.

- **Carving out a Niche in an Expanding Market -** The CDMO market is a fragmented one, with the top five players accounting for less than 15% of the overall market. The market includes players that operate across one or more sub-segments of the pharmaceutical and nutraceutical domains. Pharmaloz has identified and is focusing on one such sub-segment known as OTC drug development, allowing the company to develop niche expertise in providing specialized services for OTC drug formulations, manufacturing, and regulatory compliance. By concentrating efforts on this specific area, Pharmaloz aims to distinguish itself within the broader pharmaceutical and nutraceutical CDMO landscape, offering tailored solutions and meeting the unique needs of clients seeking non-prescription medication to market efficiently and effectively.

The CDMO Value Proposition and the Evolving Landscape

Both nutraceuticals and pharmaceuticals involve complex and time-consuming processes in bringing a product from concept to market. It's not just about extensive research and discovering a patent molecule; it's about safety, optimizing the formulation, scaling up its production, and ensuring that every pill, vial, or syringe meets the highest standards of quality. Now, consider the immense capital, infrastructure, and expertise required to achieve this. Not every pharmaceutical company, especially small and emerging companies, has the resources to manage this colossal task in-house.

CDMOs bridge the gap, allowing nutraceutical and pharmaceutical companies to outsource parts or the entirety of the development and manufacturing process. CDMOs have proven themselves as a viable alternative to the in-house development and manufacturing units of bio-health companies over recent decades. They offer end-to-end solutions, allowing companies to focus on what they do best and innovate.

CDMOs allow nutraceutical and pharmaceutical companies to outsource parts or the entirety of the development and manufacturing process

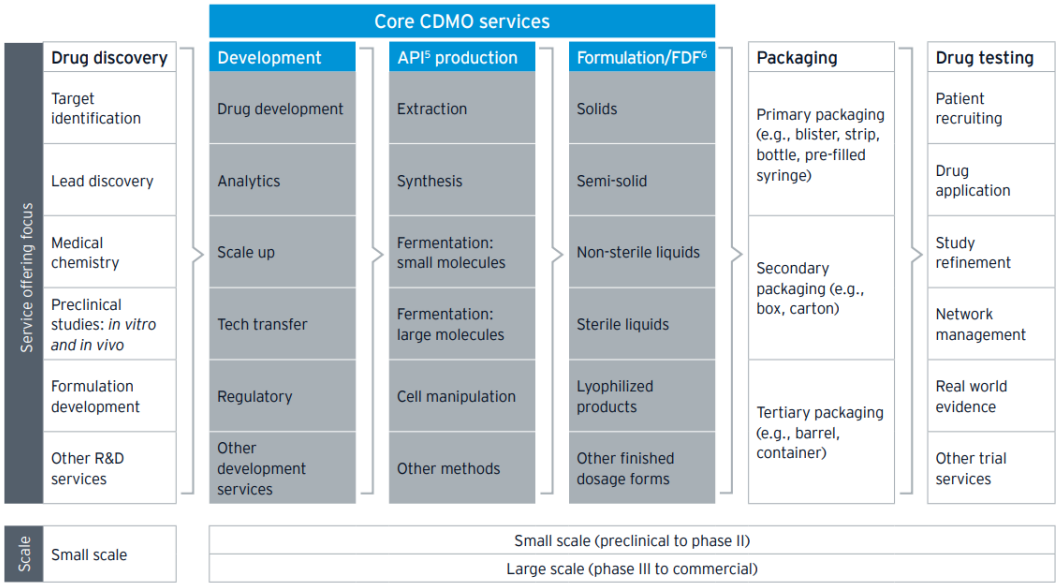


Exhibit 1: CDMO Value Chain Overview. Source: EY-Parthenon Analysis, Diamond Equity Research

Over the past three decades, the pharmaceutical landscape has undergone a drastic shift with the increasing prominence of CDMOs. The late 1990s and early 2000s gave rise to the CDMOs, with early players such as Lonza and Cardinal Health (now known as Catalent) positioning themselves as the leaders of today. Similarly, in 1996, companies like Custom Pharmaceuticals evolved into Patheon, initiating acquisitions in Europe. As the Pharmaceutical industry grappled with the complexities of drug development, increased regulatory scrutiny, and the rise of generic drugs, the value proposition of CDMOs became even more evident. Three pivotal factors spurred the industry's unabated growth in the first phase, which started in the late 1990s and lasted for the next ten years.

- **Excess Capacity Shedding and Patent Cliff:** The initial years were characterized by the patent expiry of several blockbuster drugs, leading to a surge in the generic drug market. As pharmaceutical giants faced revenue losses due to generic competition, there was a

strategic shift towards outsourcing to maintain profitability. CDMOs, with their flexible manufacturing capabilities, played a crucial role in helping companies pivot to this new market reality. Major pharmaceutical companies offloaded excess capacity, often selling facilities to emerging CDMOs.

- **Rise of Early-Stage Biotechnology Companies:** Emerging biotechnology enterprises capitalized on the momentum of internet firms to tap into venture capital and access the public financial markets. These companies, lacking manufacturing capabilities, became core CDMO clients.

- **Success of Clinical Research Organizations (CROs):** CROs like Quintiles and Covance validated outsourcing as an effective strategy, paving the way for CDMOs.

CDMOs have evolved from niche players in the late 1990s to pivotal partners, driven by factors such as patent expirations, biotechnology growth, and outsourcing

The early years of the next phase (2008 - 2017) coincided with the global financial crisis, having mixed effects on the CDMO industry. The next ten years paved the way for new opportunities and significant development that completely reshaped and transformed the landscape of the CDMO industry.

- **Challenges Post-Financial Crisis:** In the wake of the financial crisis, the CDMO industry grappled with a series of setbacks. Emerging biopharmaceutical companies, a primary clientele for CDMOs, faced a sharp decline in funding. Concurrently, mergers among major biopharmaceutical entities led to a slowdown in drug innovations. This challenging environment forced some CDMOs to cease operations while others had to restructure to stay afloat.

- **Entry of Private Equity Firms:** Despite these challenges, the downturn presented a silver lining in the form of investment opportunities for private equity firms. Attracted by the industry's undervalued assets and low-interest rates, these firms saw potential in the CDMO market's long-term growth. They not only infused capital but also introduced the "roll-up" strategy, which involves an initial acquisition followed by further acquisitions to expand capabilities. Investment firms such as Black Rock, KKR, and JLL Partners emerged as influential stakeholders, bringing with them experienced leaders from the pharmaceutical domain.

- **Resurgence of the CDMO Sector:** By 2013, the CDMO industry began to witness a revival. External funding for pharmaceutical startups resumed, leading to consistent revenue growth, especially in the small-molecule API segment. This segment, which had faced challenges in the late 2000s, benefitted from increased early-stage company funding, a shift in major pharmaceutical companies' outsourcing strategies, and growing concerns about regulatory compliance with emerging market API producers.

- **Mergers and Acquisitions Trend:** The positive momentum in the CDMO industry also sparked a surge in mergers and acquisitions. Between 2014 and 2016, an average of 35 deals were struck annually across various segments of this industry. This trend seemed to

intensify in 2017, with significant deals and consolidations marking the industry's landscape.

CDMOs have emerged as pivotal players, bridging gaps and offering specialized services to both established giants and nascent startups. A prolonged low-interest environment and ample liquidity coupled with robust industry growth allowed strategic as well as financial acquisitions, leading to consolidation within the industry. This was further supplemented by technological advancement, global events, and an increasing demand for intricate and specialized therapeutic solutions.

- **COVID-19 Supporting the Case for Domestic Manufacturing:** The pandemic brought to light the vulnerabilities of global supply chains, especially in the pharmaceutical and healthcare sectors. As countries went into lockdown and international trade faced disruptions, the reliance on overseas manufacturing hubs posed significant challenges. This situation underscored the importance of domestic manufacturing capabilities, and CDMOs were at the forefront of this realization. This shift ensures reliable drug delivery for the U.S. market and offers easier access for regulatory inspections, potentially accelerating approvals.

- **Technological Advancements:** The past few years also marked rapid technological advancements, allowing companies to streamline production while ensuring consistent quality. Embracing continuous manufacturing has improved efficiency and product consistency. Single-use systems have bolstered manufacturing flexibility, while the integration of AI and advanced analytics has refined operational processes in recent years. Moreover, a focus on cell and gene therapy technologies has equipped CDMOs to cater to the rising demand for personalized treatments.

- **Strategic Consolidation:** The drive to create a "one-stop-shop" has been a significant catalyst for consolidation. Larger CDMOs, aiming to offer comprehensive, end-to-end solutions, recognized the value of niche expertise held by smaller, specialized entities. To bridge gaps in their service portfolios and to cater to the diverse needs of the pharmaceutical and biotech sectors, these bigger players strategically acquired smaller companies with niche focuses to enter a particular segment or strengthen an already established position. For instance, in 2022, Catalent, a global CDMO leader, agreed to acquire Metrics Contract Services, a North Carolina-based CDMO specializing in oral dosage products, including high-potency products, for $475 million. Another prominent example was Lonza's acquisition of PharmCell, strengthening its position in cell and gene therapies. This M&A activity not only expanded the service offerings of the acquiring CDMOs but also integrated deep knowledge and specialized capabilities, further solidifying their position as "one-stop-shop" providers. Furthermore, it has been observed that small molecule transactions focused mostly on geographic and capacity expansion, while deals including biologics and novel modalities mostly included the acquisition of new capabilities. This consolidation trend, fueled by the desire for holistic service provision and the allure of niche expertise, has reshaped the industry, leading to the emergence of multifaceted, versatile CDMO giants.

In recent years, the CDMO industry has undergone transformation through technological advancements, strategic acquisitions, and an increased focus on domestic manufacturing

Market Size and Segmentation of the CDMO Market

The CDMO (Contract Development and Manufacturing Organization) market is expected to grow aggressively in the years ahead. According to estimations by Grand View Research, the market is projected to expand from $226.6 billion in 2022 to $392.3 billion in 2030 at a compound growth rate (CAGR) of 7.1%.[1] Several factors contribute to the growth of the CDMO market. One significant driver is the increasing demand for pharmaceuticals, fueled by a growing world population. This demand is further amplified by improved insurance coverage in developing nations and aging populations in industrialized countries. Another catalyst for the CDMO market's expansion is the growing trend among companies to outsource their drug development and manufacturing processes. Outsourcing allows these firms to accelerate time-to-market, reduce costs, streamline operations, and allocate resources more efficiently, leading to increased utilization of outsourcing services. Additional factors also play a role in the market's growth. The expiration of patent protections on biologic drugs creates opportunities for generic and biosimilar manufacturers to produce more affordable versions, thereby increasing demand for CDMO services. Furthermore, market drug shortages drive the need for rapid development and production of pharmaceutical products. CDMOs have the ability to quickly scale operations to address these shortages, providing both resources and expertise to expedite pharmaceutical production.

The CDMO market is poised for robust growth, with projections indicating an increase from $226.6B in 2022 to $392.3B by 2030, at a CAGR of 7.1%

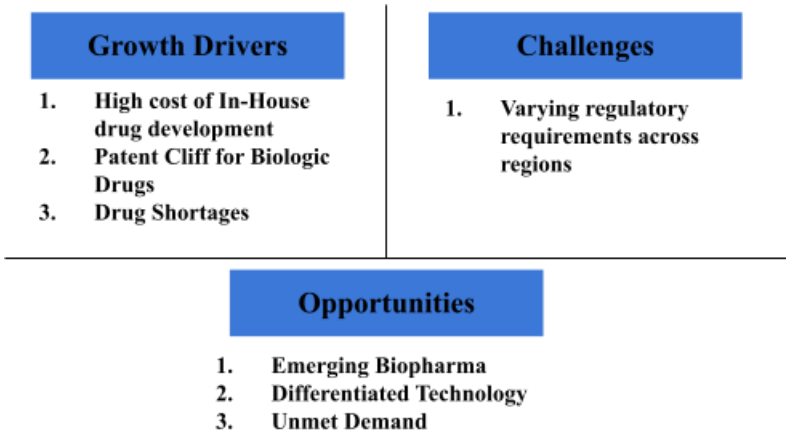


Exhibit 2: CDMO Market Growth, Opportunities, and Challenges. Source: Diamond Equity Research

In terms of market segmentation, the contract manufacturing segment holds a commanding position, accounting for over 66.20% of the revenue share in 2022.[1] This segment is further segmented into API/bulk drugs manufacturing, advanced drug delivery formulations, packaging, and finished dose formulations. The remaining market share is distributed among other sectors within the CDMO market, which include services such as target identification and evaluation, function validation and analysis, lead identification, candidate optimization, and preclinical development. The pharmaceutical contract manufacturing and research services market is quite competitive and fragmented, with multiple players operating in the industry. Unlike the contract research organization (CRO) space, where the top five companies dominate 70% of the market, the top five companies in the contract development and manufacturing organization (CDMO)

[1] https://www.grandviewresearch.com/industry-analysis/pharmaceutical-contract-manufacturing-market

sector collectively hold less than 15% of the total market share.[2] Some notable companies in this market include Catalent, Pharmaceutical Product Development LLC, AbbVie, Baxter BioPharma Solutions, Patheon, Grifols International, S.A., Dalton Pharma Services, Boehringer Ingelheim Biopharmaceuticals GmBh and Lonza AG.

While there is an optimistic outlook for the CDMO market, there are challenges that need to be addressed. One such challenge is dealing with varying requirements across different regions. Compliance with guidelines is significant in the pharmaceutical industry as noncompliance can severely affect businesses and brand reputation. CDMOs encounter difficulties when it comes to managing data and submissions related to formulations across multiple countries, thereby increasing risks associated with errors in regulatory filings. This complexity in regulatory compliance creates substantial entry barriers for new entrants in the CDMO market.

U.S. OTC Vitamins, Minerals and Supplement (VMS) Market

The US OTC supplement market is a significant industry, with a projected value of approximately $61 billion RSP (retail sales price) in 2022. This market is expected to continue growing due to various factors, including the increasing interest from the next generation of consumers, such as millennials and Gen Z, as well as product innovation. Historically, the U.S. OTC supplement market has experienced mid-single-digit annual growth. However, during the COVID-19 pandemic, sales of OTC supplements saw a substantial increase as consumers focused on their health and well-being. Even after the record growth in 2020, sales continued to grow in 2021. However, in 2022, the market normalized due to inflation and other economic concerns. Market participants anticipate that growth will return to pre-COVID projections by 2024.

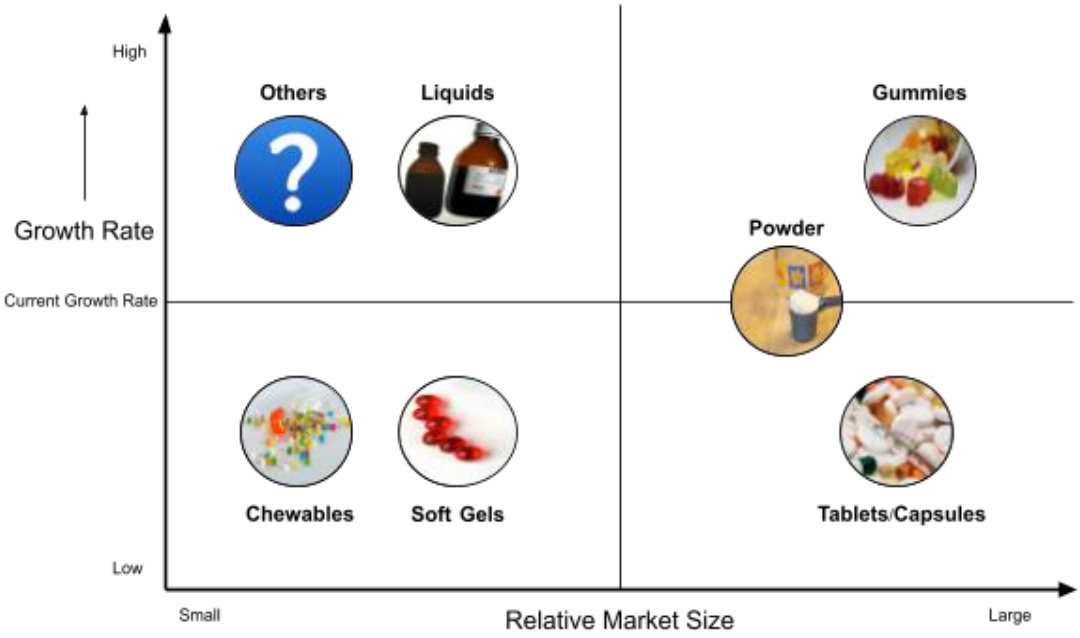
The US OTC VMS market was valued at approximately $61 billion RSP in 2022 and is expected to grow rapidly, fueled by increasing role of CDMOs

VMS Market Growth Trends

The aging U.S. population plays a significant role in the growth of the VMS (Vitamins, Minerals, and Supplements) market. Older consumers have the highest frequency of supplement usage, and with the aging population expected to grow at a rate of 1.1% per annum from 2020-30, they will continue to contribute to the VMS consumer base. Millennials, on the other hand, have the highest average annual VMS spend and have experienced faster median earnings growth compared to older generations. This makes them strong contributors to the growth of the VMS market. Additionally, Gen Z is increasingly entering the category due to the proliferation of digital-native brands and increased social media presence. The COVID-19 pandemic and the rising prevalence of chronic health conditions have resulted in a shifting consumer mindset toward prevention and, thus, the purchase of supplements. This has led to a 7-percentage point increase in the percentage of the population consuming dietary supplements from 2020-21. Digital native brands have been experiencing growth, with Amazon sales of VMS increasing at a rate of 25%[3] per annum from 2019-23. These brands have effectively utilized social media to engage potential consumers and increase awareness of the VMS category, particularly among younger generations.

[2] https://www.pharmamanufacturing.com/sector/contract-manufacturing/article/11301805/cdmo-trends-drug-development-and-industry-consolidation
[3] L.E.K Research

Consumers within the VMS market are increasingly seeking clean labels and other health attributes such as organic and non-GMO. Many are willing to pay a premium for these products, driving premiumization within the market. Product formats have also evolved, with consumers showing a preference for non-pill formats such as gummies, lozenges, liquids, and single-serve powders. These formats are easier to consume and provide a more enjoyable experience for consumers.



Consumer demand in the VMS market is leaning towards clean labels and health-conscious attributes, fueling premiumization. Non-pill formats such as lozenges and gummies are increasingly favored

Exhibit 3: OTC CDMO Market Growth Areas. Source: Diamond Equity Research
*Other includes formats such as lozenges, effervescent, candies, and lollipops.

Throughout the relevant time range, non-pill formats have outgrown overall market growth; the expansion of these segments has increased the dependency on CDMOs' manufacturing expertise. An increase in CDMO's manufacturing activities is directly related to organizations' propensity to outsource. It is directed by CDMO's following advantages:

- Reduces the regulatory restraint burden on an organization.
- Provides manufacturing guidance across all manufacturing segments.
- Reduces ineffective use of resources and enables organizations to focus on their competencies.
- Increase Speed to Market by faster WPI to Finished good process (Ex. testing, large scale manufacturing)
- Increases organization capacity permanently and production whenever it is required.

VMS CDMO Market Segment Based on Customer Dynamics

VMS CDMOs serve a variety of customer sectors, each with its own set of needs and preferences for outsourcing VMS development. Private labels are more likely to outsource most of their activity to a CDMO, followed by MLM and Specialty Brands. Integrated manufacturers are least likely to outsource to a CDMO.

Integrated Manufacturers	MLM & Specialty Brands	Private Labels
• Manufacture most of their own prodcuts	• Outsource most processes to CDMOs	• Private label owned by FMD/e-commerce retailers
• Uses CDMOs to supplement own competencies like capacity expansion	• Requires order flexibility, shorter lead time & high innovative capabilities from CDMO end	• Lack of manufacturing knowledge leads to total outsourcing of development and manufacturing

Exhibit 4: OTC CDMO Market by Segment. Source: Diamond Equity Research

Impact of Broader Market Trends on Brands' Propensity to Outsource to CDMOs

The landscape of pharmaceutical and healthcare manufacturing is undergoing significant transformation, driven by a myriad of market trends that are influencing brands' outsourcing strategies. One of the critical shifts is the increasing propensity of brands to engage Contract Development and Manufacturing Organizations (CDMOs) for their production needs. This trend is fueled by various factors, including regulatory challenges, the rise of digitally native brands, and evolving consumer preferences for new product formats.

The growing trend of outsourcing to CDMOs is a notable shift in the pharmaceutical manufacturing landscape. This is driven by factors such as regulatory challenges and evolving consumer preferences for new product formats

Incoming Higher Regulation Restraints

- The increasing VMS regulations imposed by regulatory agencies is one key trend that has influenced outsourcing proclivity.
- These regulatory bodies are establishing stringent approval requirements, including the requirement for independent lab testing separate from the CMO.
- International regulatory agencies have also imposed stricter standards on manufacturers, forcing them to adapt or face restrictions in certain global markets.

Implication: Brands are finding it more difficult to meet regulatory compliance, resulting in a higher rate of outsourcing to CDMOs with the expertise and personnel to effectively navigate these changes.

Increase in Digitally-Present Brands

- Digital VMS brands primarily sell to consumers directly (DTC) or through platforms such as Amazon.

Implication: Because of their emphasis on brand identity and marketing, digitally native brands frequently lack manufacturing capabilities and must rely on CDMOs for production.

Growth of New-format VMS

- Newer formats, such as gummies and liquids, have gained significant market share. Because of this shift in consumer preferences, brands now need to manufacture across modalities.

Implication: Brands are more likely to outsource manufacturing to CDMOs with the necessary capabilities across multiple modalities.

VMS CDMO Market Competitive Landscape

The VMS contract manufacturing space is highly fragmented, with numerous players offering a variety of services and modalities to customers. Consolidation has occurred in the industry, however, as contract manufacturers seek to gain scale and breadth in order to better serve customer needs.

1. Customer preferences for working with CDMOs that can produce products across multiple modalities have contributed to this consolidation. Smaller brands seek to reduce vendor management time and volume risk concerns, whereas larger brands prioritize capacity risk mitigation through a broader supply base. As a result, CDMOs that provide one-stop-shop solutions across multiple modalities have a competitive advantage in attracting and retaining customers.

2. As consumers' demand for sophisticated VMS products to support their health and wellness goals grows, so does the outsourcing landscape. Brands seek CDMOs with capabilities in the latest science, access to new ingredients, better delivery format technologies, and improved efficacy. Rather than being developed in-house, these capabilities are frequently acquired through collaboration with CDMOs with narrow and deep expertise. As a result, CDMOs that have strong R&D capabilities and access to innovative solutions have a competitive advantage in meeting consumer demands.

Investor interest in the VMS CDMO market is high, particularly targeting companies with unique product formats, in-house R&D, high-growth customer lists, or turnkey capabilities

VMS CDMO Investor Implications and the Future

Investors have shown a strong interest in the VMS CDMO market, with recent deals focusing on companies with format differentiation, in-house R&D, customer lists with high-growth brands, or turnkey capabilities. Prospective investors can consider several strategies to create value in this market. For starters, creating one-stop-shop solutions for customers across a wide range of modalities and service offerings can attract brands looking for all-inclusive manufacturing solutions. Second, in a volatile market where consumer preferences change rapidly, investing in sales infrastructure to acquire new customers is critical. Furthermore, a dedicated team can maximize gross margins by improving efficiencies, capacity utilization, and customer management. Furthermore, improving overall business performance by driving efficiencies through supply chain optimization and scaled back-office operations. Finally, the implementation of AI-powered solutions can help automate manual business processes such as quoting, sourcing, and quality assurance. The VMS industry is undergoing significant market dynamics shifts as a result of broader market trends. Increased VMS regulations, the growth of digitally native brands, and the expansion of innovative formats all influence brands' increased proclivity to outsource to CDMOs. Understanding these trends and how they affect customer dynamics is critical for brands and investors in the VMS CDMO market. CDMOs can position themselves as key players in this evolving industry by aligning with these trends and implementing value-creation strategies.

Mergers and Acquisitions in the CDMO Market

The CDMO industry has seen a significant surge in mergers and acquisitions in recent years, a trend that underscores the strategic importance of such transactions as a key growth lever. These M&A activities serve multiple objectives, from immediate scale advantages and portfolio diversification to technological synergies and financial leverage. The acquisitions often bring in complementary capabilities, thereby enhancing the competitive edge of the acquiring companies. Moreover, the financial strength gained through these transactions enables further investments in R&D and market expansion.

However, the M&A landscape isn't solely dominated by CDMOs; large life sciences corporations and private equity entities have also executed some of the sector's most significant deals. These acquirers often exhibit a willingness to pay high EBITDA multiples for their targets. For instance, in 2017, Thermo Fisher Scientific acquired Patheon at an EBITDA multiple of approximately 18.2x. Similarly, private equity firms The Carlyle Group and GTCR acquired AMRI at a 14.7x EBITDA multiple, and Lonza acquired Capsugel at a 15.1x EBITDA multiple in 2017.

The CDMO sector has seen a rise in M&A activity recently, serving as a key growth driver. These deals aim for scale, portfolio diversification, technological synergies, and financial leverage

The robust pace of M&A in the CDMO sector highlights the industry's favorable conditions for such strategic moves, positioning companies for accelerated growth and a strengthened competitive stance. The following table provides a snapshot of some of the major M&A transactions in the CDMO sector, further illustrating the industry's opportune environment for such strategic activities.

Year	Acquirer	Target	Acquisition Amount (USD)
2023	Biofarma Group	US Pharma Lab	Pending
2022	Charles River Laboratories	Vigene Biosciences	$292 million
2022	Charles River Laboratories	Cognate Bioservices	$875 million
2022	IFF	Health Wright	Pending
2022	Sirio	Best Formulations	Majority Stake (80%)
2022	Astorg	CordenPharma	Pending
2022	Recipharm	ArrantaBio	N/A
2022	PharmaZell	Novasep	N/A
2021	Catalent	Bettera Brands	$1 billion
2021	INW	Capstone Nutrition	N/A
2021	Wind Point Partners	Food Science	Pending
2019	Catalent	Paragon Bioservices	$1.2 billion
2018	Thermo Fisher Scientific	Brammer Bio	$1.7 billion
2018	Cambrex	Halo Pharma	$425 million
2018	Cambrex	Avista Pharma	$252 million
2018	Clinigen	CSM	$150 million
2017	Lonza	Capsugel	$5.5 billion
2017	Carlyle Group and GTCR	AMRI	$1.5 billion
2017	Thermo Fisher Scientific	Patheon	$7.2 billion

Exhibit 5: Select CDMO M&A Deals. Source: Diamond Equity Research

An M&A landscape analysis conducted by EY-Parthenon reveals a significant uptick in M&A activities in the CDMO sector between 2017 and 2021. Although the total deal volume has experienced fluctuations, largely influenced by major multibillion-dollar transactions in 2017 and

2021, the average deal size has seen a substantial increase. The mean total deal volume across these years stands at $7 billion. Furthermore, the average individual deal volume has seen a significant uptick, showing a more than six-fold increase from $131 million in 2017 to $811 million. Moreover, the number of deals per year has also shown a rising trend, with a low of 30 deals in 2018 and a high of 68 deals in 2021, which alone accounted for a total transaction volume of nearly $42.4 billion.

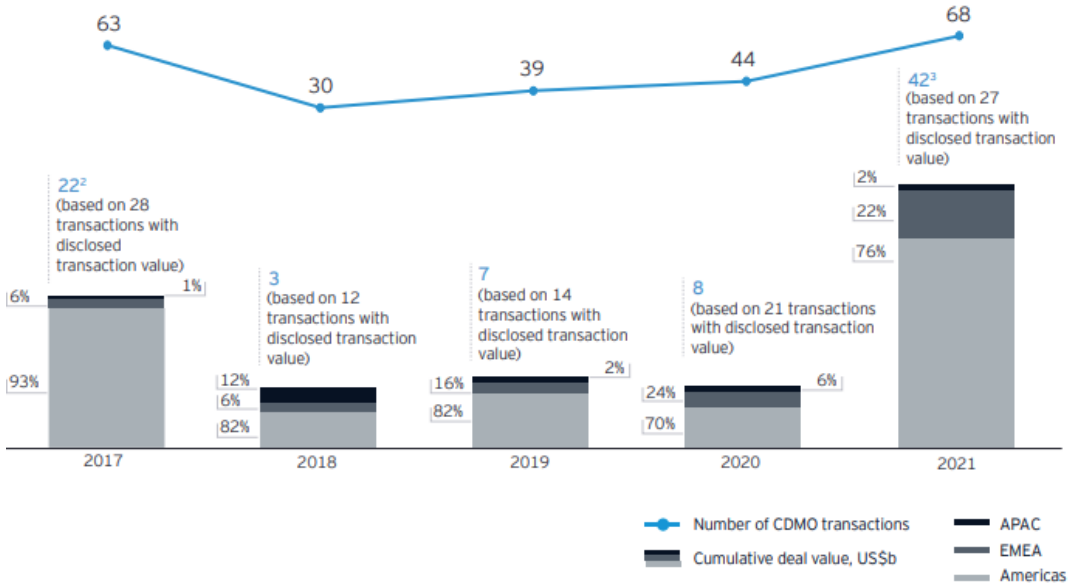


Exhibit 6: Overview of CDMO-related M&As (2017-2021). Source: EY

A supplementary analysis by EY-Parthenon examined the ownership types of companies involved in CDMO M&A transactions from 2017 to August 2022. The study found that while most targets were private companies, the buyers were more evenly split but still largely public strategic companies.

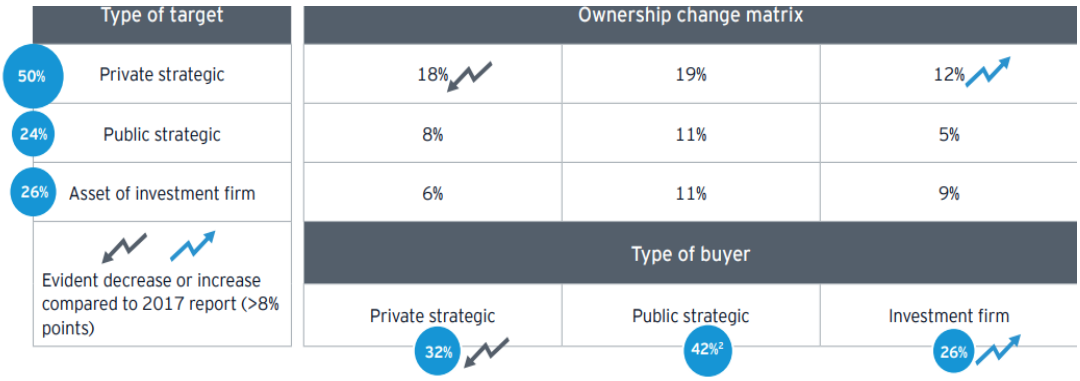


Exhibit 7: Ownership Change Matrix Based on CDMO-related M&A Deals (2017-2022). Source: EY

An updated target-buyer matrix revealed that investment firms are increasingly active, particularly in acquiring private companies. Although the number of deals involving private companies has decreased, the overall number of transactions with investment firms as buyers has risen. This suggests a growing role for investment firms in the CDMO M&A landscape, indicating heightened interest in this segment of the life sciences industry.

Digitization & Artificial Intelligence in CDMO Operations

The Contract Development and Manufacturing Organization (CDMO) sector is undergoing a transformative shift with the integration of digitization and Artificial Intelligence (AI). These technologies are becoming central to enhancing operational efficiencies, ensuring compliance, and driving innovation. The adoption of digital technologies is a critical factor in advancing the manufacturing process across industries. This digital transformation encompasses the integration of robotics, automation solutions, and computerization, which collectively contribute to cost reduction, enhanced efficiency, and increased adaptability to change. The pharmaceutical industry has, however, been resistant to digitalization, mainly due to fair experience and the complexity of the entailed development and manufacturing processes. The FDA's Task Force on Drug Shortages underscored the significant impact of quality on drug supply chain disruptions. Their findings revealed that between 2013 and 2017, nearly two-thirds of the 163 drugs that experienced shortages did so due to supply chain disruptions stemming from manufacturing or quality issues.

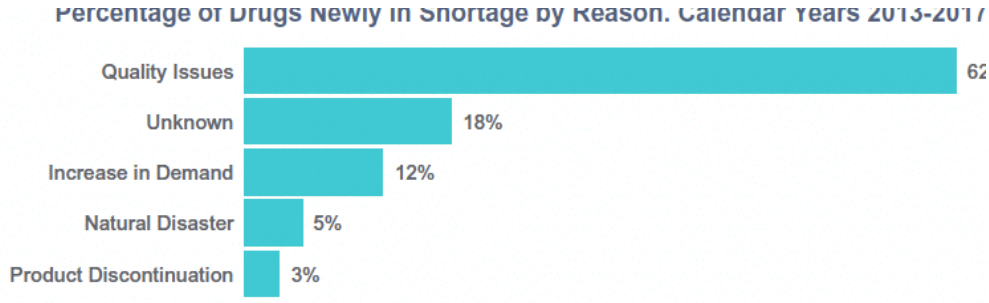


Exhibit 8: Percentage of Drug Shortage by Reason (2013-2017). Source: FDA

The COVID-19 pandemic has accelerated digital transformation in the CDMO industry, making it essential for operational and supply chain resilience

The COVID-19 pandemic has served as a turning point for the CDMO industry, pushing organizations to reevaluate their operational risk profiles. The disruption to global supply chains has compelled CDMOs to focus on digital transformation as a strategic imperative. Digitization is no longer an option but a necessity for ensuring operational resilience. It enables CDMOs to improve data integrity, streamline workflows, and ensure regulatory compliance. Advanced technologies like blockchain are being employed to enhance traceability and transparency in the supply chain, thereby reducing the risk of counterfeit drugs entering the market.

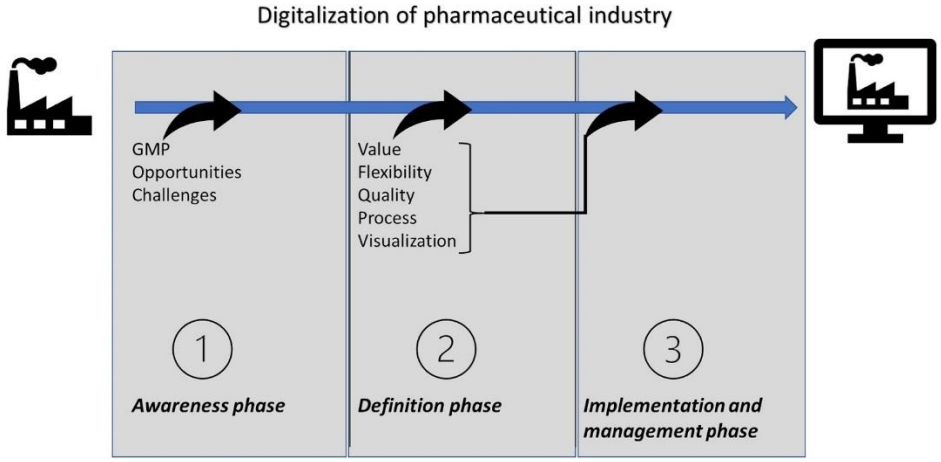


Exhibit 9: Digitalization in the Pharmaceutical Industry. Source: International Journal of Pharmaceutics

Data-Driven Decision-Making

Data analytics is becoming a cornerstone for operational excellence in CDMOs. Companies are utilizing data analytics for real-time monitoring and predictive maintenance, which significantly reduces downtime and enhances productivity. Beyond maintenance, data analytics is also being employed in process optimization. By analyzing historical data, CDMOs can identify bottlenecks and inefficiencies in their manufacturing processes, thereby implementing targeted improvements. This not only enhances productivity but also ensures that products meet stringent regulatory standards. Through the application of digitization and analytics to improve overall equipment effectiveness (OEE), pharmaceutical plants can potentially achieve a significant reduction in machine downtime—by an estimated 30 to 40 percent.

Artificial Intelligence in Supply Chain Management

AI is increasingly being used to optimize supply chain operations. From demand forecasting to inventory management, AI algorithms provide actionable insights that make the supply chain more efficient and cost-effective. Machine learning models can predict when a machine is likely to fail, allowing for preventive maintenance and reducing downtime. Similarly, AI can forecast demand spikes, enabling better inventory management, and reducing carrying costs.

The FDA highlights AI's role in pharmaceuticals for optimizing process design, enabling real-time controls, and enhancing monitoring and trend analysis

When integrated with other advanced manufacturing technologies, AI serves as a catalyst for adopting an Industry 4.0 framework (refers to the ongoing fourth industrial revolution, characterized by integrated, autonomous, and self-organizing production systems), leading to a highly coordinated, interconnected, and digitized pharmaceutical manufacturing ecosystem. Based on industry interactions and existing literature, the FDA has identified several promising applications of AI in pharmaceutical manufacturing, although this list is by no means exhaustive and is expected to evolve over time.

1. **Process Design and Scale-Up:** Utilizing machine learning models generated from process development data, AI can expedite the identification of optimal processing parameters. This not only shortens the development timeline but also minimizes waste during the scaling process.

2. **Advanced Process Control (APC):** APC enables real-time adjustments to the manufacturing process to achieve specific outcomes. AI techniques, when combined with real-time sensor data, can develop predictive process controls. Such APC methods, which integrate an understanding of the chemical, physical, and biological changes occurring during manufacturing, are gaining traction and have been implemented by multiple pharmaceutical manufacturers.

3. **Process Monitoring and Fault Detection:** AI algorithms can monitor equipment performance and identify deviations, thereby triggering timely maintenance activities and reducing operational downtime. Additionally, AI can oversee product quality, including packaging quality, through vision-based systems that quickly detect any deviations from established quality standards.

4. **Trend Monitoring:** AI can analyze large sets of consumer complaints and deviation reports to identify recurring issues and prioritize areas for continuous improvement. By integrating AI methods with metrics for process performance and capability, manufacturers can proactively monitor operations and predict when thresholds for corrective and preventive actions might be reached.

Understanding Regulatory and Compliance Nuances: A CDMO Perspective

The Contract Development and Manufacturing Organization (CDMO) industry is a critical component of the pharmaceutical and biotechnology sectors. Operating at the intersection of innovation and production, CDMOs are subject to various regulations and compliance standards that ensure the safety, efficacy, and quality of the products they help bring to market. The U.S. Food and Drug Administration (FDA) plays a pivotal role in ensuring the safety and efficacy of pharmaceutical products, and Contract Development and Manufacturing Organizations (CDMOs) are no exception to this regulatory oversight. The FDA conducts various types of inspections, including Pre-Approval Inspections (PAI), Routine GMP Inspections, Compliance Follow-up Inspections, and For-Cause Inspections, to assess compliance with Good Manufacturing Practices (GMP) and other regulatory standards.

CDMOs operate under stringent regulations, including FDA oversight, to ensure the safety, efficacy, and quality of pharmaceutical products they produce

Types of FDA Inspections

1. **Pre-Approval Inspections (PAI):** These inspections are conducted before the approval of a new drug application (NDA) or abbreviated new drug application (ANDA). The focus is on verifying the integrity of the data submitted and ensuring that the facility is capable of manufacturing the drug as specified.

2. **Routine GMP Inspections:** These are regular inspections to ensure ongoing compliance with Good Manufacturing Practices (GMP). They can be announced or unannounced and are typically conducted every two to three years for domestic facilities.

3. **Compliance Follow-Up Inspections:** These inspections review actions taken by a firm/manufacturer in response to a previous inspection that resulted in significant 483 observations or a Warning Letter.[4] A compliance follow-up is conducted to verify the adequate correction of previous violations, to document continuing violations, or to support future regulatory action.

4. **For-Cause Inspections:** These are triggered by specific events such as complaints, recalls, or issues identified during previous inspections. They are more in-depth and can result in severe consequences if non-compliance is found.

[4] A 483 observation is an FDA-issued document highlighting regulatory violations or deficiencies found during an inspection of a pharmaceutical or manufacturing facility.

The outcome of an FDA inspection can have a direct impact on a CDMO's relationship with its clients. Pharmaceutical companies are increasingly vigilant about the regulatory compliance of their partners. An adverse inspection outcome can not only tarnish a CDMO's reputation but also lead to the loss of business.

Also, CDMOs often serve clients that operate in multiple jurisdictions. As such, compliance with FDA regulations can facilitate easier market entry in other regions that have mutual recognition agreements with the United States. This makes FDA inspection outcomes a key consideration in global supply chain strategies.

Frequency and Trends

While specific numbers are not publicly disclosed, the frequency of FDA inspections has been subject to fluctuations based on various factors, such as changes in regulatory guidelines, public health crises, and advancements in manufacturing technologies. For instance, the FDA's focus on data integrity has led to an increase in inspections centered around electronic records and data management systems.

Stable domestic inspections suggest consistent U.S. oversight, while a peak in foreign inspections underscores the FDA's expanding global reach

From a CDMO standpoint, the FDA inspection data spanning fiscal years 2009 to 2023 offers critical insights into the evolving landscape of regulatory scrutiny. The general stability in domestic inspections, usually around the 13,000 to 14,000 mark, indicates a consistent level of oversight in the U.S. market. However, the upward trend in foreign inspections, peaking at 3,323 in 2019, signals the FDA's expanding global reach, which is particularly relevant for CDMOs with international operations or partnerships.

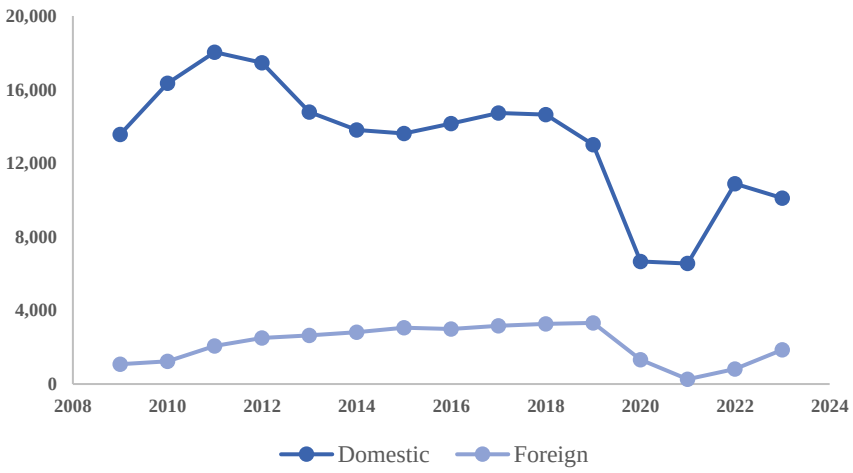


Exhibit 10: Total FDA Inspections (2008-2023). Source: FDA, Diamond Equity Research

The inspections are categorized into three main types: Voluntary Action Indicated (VAI), Official Action Indicated (OAI), and No Action Indicated (NAI). A notable trend across all sectors is the predominance of NAI outcomes, indicating a generally high level of compliance with FDA regulations. However, the Food/Cosmetics sector stands out with significantly higher numbers in all categories, reflecting the extensive scope of FDA oversight in this area.

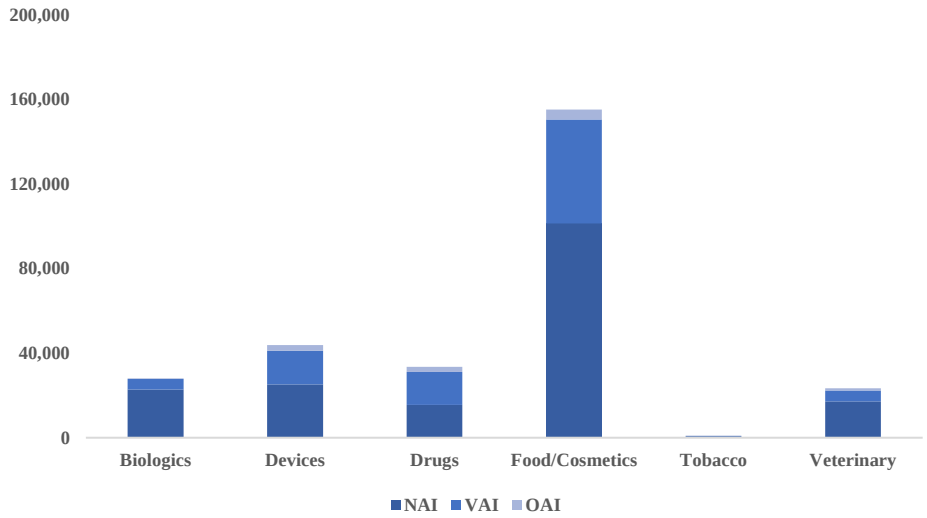


Exhibit 11: FDA Inspections by Product Type (2009-2024). Source: FDA, Diamond Equity Research

FDA inspections are crucial for CDMOs, affecting both compliance and reputation. Non-compliance risks include warnings, import bans, and criminal charges

Implications for CDMOs

For CDMOs, FDA inspections are a critical aspect of their operations, impacting not just regulatory compliance but also their reputation and business relationships. Non-compliance can result in warning letters, import bans, or even criminal charges, making it imperative for CDMOs to maintain an impeccable compliance record. In Europe, the European Medicines Agency (EMA) has its own set of guidelines, including EU Guidelines for Good Manufacturing Practice and Marketing Authorization Procedures. The Asia-Pacific region also has its regulatory bodies, such as the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and the China Food and Drug Administration (CFDA).

Quality management is another important aspect of the CDMO industry. Global standards like ISO 9001 are often considered the benchmark for quality management systems. Operational methodologies such as Six Sigma and Lean Manufacturing are integrated to enhance efficiency and quality. Intellectual property (IP) is another significant area of concern, often necessitating confidentiality agreements to protect sensitive information. Understanding the scope and limitations of patent licenses is crucial to avoid legal complications. Regulatory commitments and quality agreements between CDMOs and their clients are essential components of the compliance requirements.

Data integrity and security are governed by specific regulations. In the United States, the FDA's 21 CFR Part 11 sets the standards for electronic records and electronic signatures. In Europe, EU Annex 11 governs computerized systems used in clinical trials. Environmental, Health, and Safety (EHS) compliance is another critical area, with guidelines like OSHA in the United States and REACH and RoHS in Europe. Risk management is integral to CDMO operations. A structured approach like Failure Modes and Effects Analysis (FMEA) is often employed to identify and mitigate potential risks. The main goal for any drug company collaborating with a CDMO is

achieving a speedy path to market, which is often facilitated by robust regulatory support from the CDMO.

Regulatory compliance doesn't end once a product is in the market. CDMOs and their clients must engage in post-market surveillance to monitor the safety and efficacy of their products. Post-market surveillance (PMS) is an integral part of the regulatory compliance landscape for CDMOs. While much of the focus is often on pre-market activities like clinical trials and manufacturing, PMS is crucial for monitoring the safety and efficacy of pharmaceutical products once they are in the market. This involves a range of activities, including adverse event reporting, product recalls, and periodic safety update reports (PSURs).

The advent of Industry 4.0 technologies like IoT, blockchain, and AI is revolutionizing how CDMOs manage compliance. These technologies can automate traceability, improve data integrity, and even predict compliance risks, offering CDMOs a significant advantage.

Regulatory Considerations in Mergers and Acquisitions

The CDMO sector has seen significant M&A activity. Each merger or acquisition brings its own set of regulatory challenges, from due diligence to harmonizing compliance frameworks post-acquisition. Due diligence is a critical first step, where both the acquirer and the target must thoroughly assess each other's compliance records, pending litigations, and any potential regulatory risks. This process often involves a deep dive into quality management systems, FDA inspection records, and intellectual property portfolios. Post-acquisition, one of the most complex challenges is the harmonization of compliance frameworks. This involves aligning quality management systems, standard operating procedures, and even corporate cultures to ensure seamless regulatory compliance. Failure to effectively integrate can result in operational disruptions and increased scrutiny from regulatory agencies. M&A activities can have significant financial implications, including the cost of compliance harmonization and potential fines for non-compliance. On the strategic front, a successful M&A can offer competitive advantages like expanded capabilities and market reach, but this is contingent on effective integration.

Pharmaloz Manufacturing Inc. - An Emerging CDMO Player

Pharmaloz Manufacturing Inc. (PMI), is a wholly-owned subsidiary of ProPhase Labs, a publicly-traded biotech, genomics and diagnostics company headquartered in Garden City, NY. Specializing in the pharmaceutical, Over-The-Counter (OTC), and dietary supplement sectors, Pharmaloz has earned a reputation for delivering high-quality products with a focus on customer success. Primarily, Pharmaloz serves as a full-service contract manufacturer and private-label developer, specializing in non-GMO, organic, and natural-based cough drop lozenges, OTC drugs, and dietary supplements. Leveraging advanced technological capabilities and a team of highly-skilled professionals, the company adheres to stringent quality and regulatory standards. It operates a 60,000-square-foot, climate-controlled facility in compliance with strict FDA CFR 21CFR 210 & 211 guidelines. Strategically located near major transportation routes in Lebanon, PA, Pharmaloz ensures expedited distribution timelines.

Exhibit 12: Pharmaloz Manufacturing Inc. Source: Company

Cold-EEZE, once the company's flagship product, was sold to Mylan Pharma in 2017, generating liquidity of $50 million. Despite the sale, Pharmaloz Manufacturing Inc. (PMI) continues to contract-manufacture the lozenges at its facility. The subsequent manufacturing agreement with Mylan Consumer Healthcare Inc. and Mylan Inc., established post-sale in March 2017, serves as a critical component of the company's operations. Extended until March 2024, this agreement offers a stable revenue stream, with Mylan procuring products at market-competitive rates and an agreed-upon markup on costs. The contract includes provisions for renewal, ensuring the potential for sustained collaboration and revenue generation.

Pharmaloz functions as an all-inclusive contract manufacturer and private-label creator, with expertise in crafting non-GMO, organic, and natural lozenges, OTC pharmaceuticals, and nutritional supplements

Manufacturing Facility

Pharmaloz Manufacturing Inc. operates out of a state-of-the-art, 60,000-square-foot facility that is climate-controlled to ensure optimal conditions for product quality and stability. The facility adheres to stringent FDA CFR 21CFR 210 & 211 guidelines, reinforcing the company's commitment to regulatory compliance and quality assurance. The facility is strategically situated near key transportation arteries, facilitating efficient logistics and distribution. This advantageous location enables Pharmaloz to offer expedited distribution timelines, a critical factor in customer satisfaction and retention. The proximity to major transport routes also allows for cost-effective shipping, further enhancing the company's ability to compete on price without compromising on quality.

Exhibit 13: Pharmaloz Manufacturing Site. Source: Company

Pharmaloz Manufacturing Inc. has been strategically expanding its lozenge manufacturing operations. In 2022, the company introduced micro-testing for its customers in-house, leading to the production of more than 50 R&D sample runs. The addition of two new customers and the launch of seven new products in 2022 resulted in a production increase of over 5.25 million units. In 2023, Pharmaloz implemented multiple new pieces of equipment, effectively doubling its pouch packaging capacity. Additionally, the company installed a new capsule-filling machine capable of producing 400 capsules per minute. This addition is anticipated to enable the in-house production of ProPhase Biopharma's Equivir and the company's own supplement lines, TK Supplements—a $2.5 million yearly revenue business—thereby enhancing per-unit profitability and eliminating third-party manufacturing mark-ups. Further, Pharmaloz Manufacturing Inc. also plans to contract out capsule manufacturing to bolster its production capabilities.

In terms of product innovation, Pharmaloz is currently in the initial stages of developing new liquid-filled lozenges. The company has already placed orders for additional equipment and plans to integrate these into the existing production line by early 2024. Furthermore, Pharmaloz secured two significant contracts in January 2024 with major lozenge brands, which are expected to increase annual revenues by $5 million and boost pre-tax profits by over $1.25 million. Moreover, several leading lozenge brands are actively exploring the possibility of outsourcing their long-term manufacturing to Pharmaloz. Some have even expressed interest in having the company oversee their global production operations. These brands are willing to invest in both the products and the requisite equipment to expand capacity. Collectively, these strategic initiatives are expected to result in a multi-fold increase in the company’s overall capacity by 2024 compared to 2022. This enhanced capacity aligns well with the rising market demand for Pharmaloz’s offerings, creating opportunities for potential revenue growth. Building on this momentum, the company has set a manufacturing revenue target of $35 million for the year 2024 with 20-25% pre-tax net profits.

Manufacturing Capabilities

Pharmaloz demonstrates strong manufacturing capabilities in various areas, including lozenges, OTC drugs, and dietary supplements, with a focus on non-GMO and HFCS-

The company exhibits robust manufacturing capabilities across multiple domains, reflecting its strategic focus and operational efficacy. Starting with Lozenges, Pharmaloz specializes in the production of not only lozenges but also extends its expertise to OTC drug products, dietary supplements, and formulations made with non-GMO or high-fructose corn syrup (HFCS). Importantly, the company offers Gluten-Free Unit (GFU) options and has a variety of natural, organic, and herbal extracts. Furthermore, it provides certification services, including organic, non-GMO, and kosher, augmenting its market credibility. The company is also certified as dairy-free, gluten-free, nut-free, and other allergen free facility.

Turning to blistering, the company employs advanced blistering technologies that offer high efficiency and security in packaging. Within this segment, specialized lines exist for the production of capsules and caplets, optimized for OTC drug products, supplements, and even prescription-based (Rx) medicines. Additional manufacturing capabilities include the production of various forms of lozenges or hard candies, chewable tablets or melts, and gum-based products. The company is also expected to launch several lozenge products this year, taking full advantage of its extensive blister packaging capabilities.

The Packaging division complements the company's manufacturing prowess. Offering a comprehensive suite of solutions, the packaging capabilities range from the initial wrap stages to the final package. The firm employs multiple wrapping techniques, including twist wrap and flow wrap. Moreover, the company offers an array of final packaging options, such as cartons and specialized pouches, which include Fin Sealed, Resealable, and Gusseted pouches.

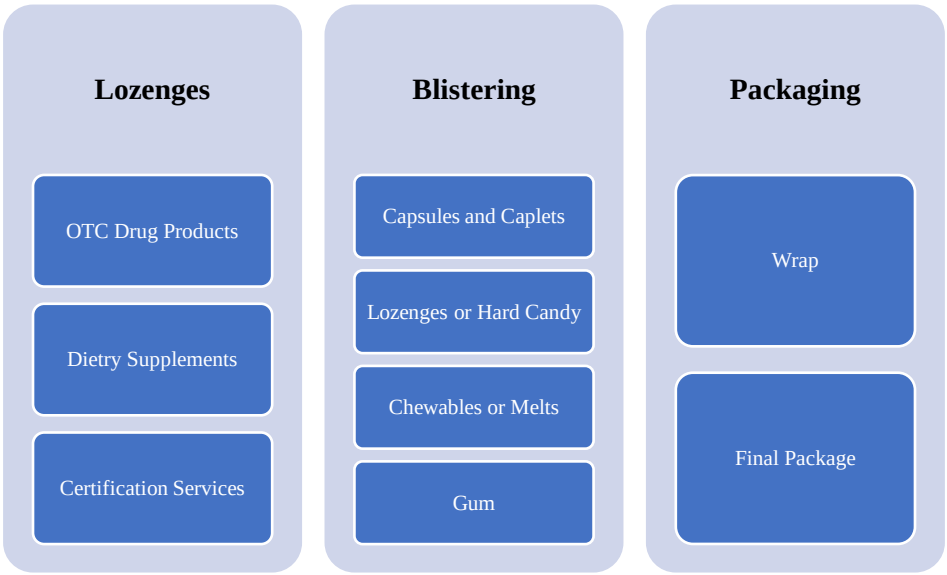


Exhibit 14: Pharmaloz Manufacturing Capabilities. Source: Company

The company's manufacturing capabilities are defined by a commitment to quality and regulatory compliance at every level, from product development to the finished product. This focus is demonstrated through batch record and vendor management, annual product reviews, and adherence to GMP certification and FDA regulations. The firm undergoes audits by regulatory

bodies and customers, promoting continuous improvement. Operational protocols include process, packaging, and cleaning validations, as well as rigorous testing and release procedures for both finished goods and incoming materials.

Advanced analytical methods like High-Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) analysis are utilized for quality assurance. These methods are complemented by moisture and pH level determination, as well as the identification of ingredients through Fourier-Transform Infrared Spectroscopy (FTIR). The company also conducts comprehensive quality reviews, which encompass stability studies and the development of robust testing methods. An emphasis on health and safety is consistently maintained, supported by structured product labeling and National Drug Code (NDC) submissions. Additionally, the firm offers specialized stability services, available in both accelerated and concurrent formats.

The Research & Development team at the company plays a critical role in ensuring product excellence. A diligent approach is adopted for ingredient selection and dose optimization to ensure both efficacy and safety. The team also specializes in flavor refinement, crafting innovative proprietary blends that differentiate the product offerings.

Pharmaloz's Evolving Market Focus

Pharmaloz Manufacturing has channeled its efforts and resources into building a competitive position within the Over-the-Counter (OTC) drug and dietary supplement market. Notably, the company currently focuses on natural cough drops and lozenges sub-segment of the OTC drug market. OTC drugs don't require prescriptions and can be purchased directly from grocery stores, drug stores, mass merchandisers, and convenience stores. As a vital component of the healthcare industry, OTC medicines are accessible, affordable, and trusted first line of defense for healthcare providers and consumers alike for commonly occurring conditions, including common cold, headaches, body pain, allergies, heartburn, GI issues, and fungal infections. OTC medications enable the healthcare system to allocate its resources more efficiently by concentrating on diagnosing and treating severe diseases that necessitate physician intervention. On average, every dollar spent by consumers on OTC medicines saves $6-$7 for the U.S. healthcare system as a whole.[5] This translates to approximately $94.8 billion in yearly clinical cost-saving and $51.6 billion in drug cost-saving.[6] Furthermore, OTC medications offer an additional $34 billion in productivity benefits by keeping the American workforce healthy and at work.[6]

OTC medications play a crucial role as a cost-effective initial healthcare option for common conditions, resulting in substantial savings in clinical and drug expenses

The global over-the-counter (OTC) drugs market was valued at $167.9 billion in 2022 and is expected to reach over $245.9 billion by 2030, expanding at a CAGR of 6.6% from 2022 to 2030.[7] The U.S. accounted for approximately one-fourth of the global OTC drug market, valued at $41.2 billion as of 2022, while the developed markets accounted for the majority share.[6] The broad category of OTC drugs can be further segmented into multiple other subcategories based on product type and its dedicated application. While Pharmaloz Manufacturing Inc. concentrates on

[5] Consumer Healthcare Products Association (CHPA), The Value of OTC Medicine to the United States, January 2012

[6] Consumer Healthcare Products Association (CHPA), https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics

[7] Data Bridge Market Research

cough, cold, and flu products, their specific emphasis within these segments is on the throat lozenges market, the global market value of which is estimated at $5.4 billion, and the U.S. market is valued at $1.3 billion in 2022.[8] Throat lozenges are small, medicated tablets intended to be dissolved in the mouth to soothe and lubricate irritated tissue of the throat. Often formulated with ingredients like menthol, honey, or herbal extracts, they provide relief from coughs, sore throats, and other related symptoms. In addition to their therapeutic benefits, many people appreciate them for their pleasant taste and the immediate comfort they offer, making them a popular choice for minor throat irritations.

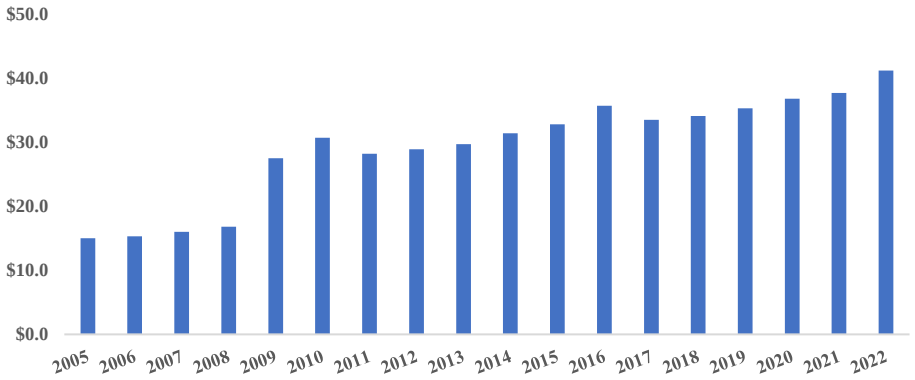


Exhibit 15: U.S. OTC Drug Sales (in $ billions). Source: Consumer Healthcare Products Association (CHPA), Diamond Equity Research

The over-the-counter (OTC) drug market has witnessed significant shifts and growth trends over the years, driven by various factors. Some of these trends and drivers are steering the trajectory of the OTC markets, offering insights into its current state and future potential.

- **Increase in Geriatric Population:** The aging population is a significant driver for the OTC drug market. As people age, they become more susceptible to minor health issues such as cough, colds, and joint pain, to name a few, thus leading to increased consumption of OTC medication. In 2022, about 17.3% of the U.S. population aged 65 years or over compared to just 12.4% in the year 2000.[9] This proportion is further expected to increase, reaching 20.6% by the year 2030. This demographic shift is expected to boost the demand for OTC drugs, especially those addressing age-related ailments.

- **Rx-to-OTC Switch:** The FDA has been actively facilitating the switch of certain prescription medications to OTC status. This trend has been gaining traction, supporting the growth of the OTC market. For example, when nicotine replacement therapies transitioned to OTC, their purchase and usage surged by 150 to 200% in the first-year post-switch.[10] Over the past 30 years, the FDA has approved the switch for more than 700 products, highlighting the evolving pharmaceutical landscape. Driven by the proven safety and efficacy of these drugs, this switch expands consumer access to medication, offering them more choices and convenience in

[8] https://www.factmr.com/report/throat-lozenges-market
[9] https://www.statista.com/statistics/457822/share-of-old-age-population-in-the-total-us-population/
[10] https://www.chpa.org/our-issues/otc-medicines/rx-otc-switch

managing their health. As more drugs make this transition, it's anticipated that the demand for OTC drugs will continue to rise, further bolstering the growth of the OTC market.

- **Self-Medication Practices:** Self-Medication has been on the rise, especially in developed countries like the U.S.A. Data from the U.S. Consumer Healthcare Products Association (CHPA) reveals that a significant 81% of American adults turn to OTC drugs as their initial remedy to minor health concerns. Additionally, the number of allergy sufferers using OTC medications has increased from 66% in 2009 to 75% in 2015. The popularity of OTC medications stems from their easy accessibility, cost-effectiveness, and trusted efficacy. This trend highlights the increasing consumer preference for self-reliance in healthcare and the expanding role of the OTC market.

- **Rising Prevalence of Minor Health Conditions:** The U.S. has seen a rising prevalence of minor health conditions such as headaches, cold and flu symptoms, allergies, and digestive issues. This has led to a sustained demand for OTC medication catering to these ailments. The convenience and efficacy of OTC drugs in treating such conditions have contributed to their increased consumption.

- **COVID-19 Impact:** The COVID-19 pandemic had a varied impact on the OTC drug marker. Some products, especially those related to immunity-boosting, experienced a surge in demand. The pandemic heightened awareness about the importance of self-care, leading to accelerated growth in self-medication practices and consumption of vitamins, minerals, and dietary supplements.

The OTC drug market's ongoing growth is fueled by substantial economic savings and a multitude of favorable factors

The Over-the-Counter drug market is poised for continued growth over the next decade. The benefits of OTC drugs are immense, translating to savings of more than $150 billion to the U.S. economy. The benefits, coupled with multiple drivers, such as the aging population, increasing consumer preference for self-medication, and a favorable regulatory environment promoting Rx-to-OTC switches, will support the market's expansion. Additionally, the rise in the prevalence of minor health conditions and lasting behavioral impacts of the COVID-19 pandemic further underscore the market's promising future prospects.

Expansion Plans

The company has demonstrated strong growth in the past financial year and secured favorable market reception of its CDMO services not only across the U.S. but also from global lozenge brands. The company's reputation within the space is a testament to its reliability in delivering quality products on time, which is vital for brand owners to maintain and maximize shelf space and profitability. This has remained a significant growth driver in the wake of the COVID-19 impact and the resulting supply chain disruptions, positioning it as a reliable partner. Moreover, in the last 12-18 months, Pharmaloz has witnessed customer expansion, with its existing customer base reporting increased sales. The positive feedback and growing demand for its products and services have prompted the company to expand its manufacturing capabilities, setting the stage for sustained high and steady growth for the next five years.

Pharmaloz's reliable CDMO services have fueled strong growth and positive market reception, prompting the need for aggressive expansion of production capacity

Expansion Strategy

In the earlier part of 2023, the company made an announcement indicating that it was operating at optimal capacity, concurrently receiving inquiries from multiple perspective clients interested in collaboration. In response to the escalating demand for its services, Pharmaloz Manufacturing Inc. had previously laid out a comprehensive expansion plan. This includes the acquisition of new equipment that would allow the company to double its pouch packaging capacity and simultaneously expand its lozenge manufacturing capabilities. Furthermore, the company is partnering with a top-tier engineering and consulting firm to potentially increase annual revenue capacity to $100-$200 million by the end of 2025, indicating a strategic effort to significantly elevate production capabilities.

Doubling Down on Growth Initiatives

Post the above expansion roadmap laid down in February this year; the company has now doubled down on its effort to be one of the prominent CDMOs in the United States. Sustaining its robust growth trajectory, contract manufacturing, excluding the legacy Cold-Eeze business, has achieved an impressive year-on-year growth rate of 100%. In response to the heightened interest in its services, with some of the biggest brands seeking to lock in long-term contracts, the company has formulated plans to amplify its lozenge production capacity, targeting an expansion of over four times its existing manufacturing facility. Additionally, the company has contracted the country's leading engineering firm to map a three-year 'master plan' to quadruple capacity by mid-2025. The developments that are expected to materialize sequentially include:

- The company recently announced the acquisition of state-of-the-art automation equipment, which is set to increase production capacity by over 50%, elevating annual production capabilities from below $10 million to over $15 million.

- The second line is already being manufactured, with delivery scheduled for the beginning of the second quarter of 2024 and full implementation expected in Q3 2024.

- Equipment for lines three and four have already been ordered and should be delivered by the end of the fourth quarter of 2024.

- Once the new lines are all installed, the Company intends to dedicate one of the lines to higher-margin organic lozenges.

- Further addition of new equipment by Q4 2024 is poised to expand the company's annual production value to $60-$80 million, based on a 3.5-day workweek, and is expected to be fully operational by 2025.

Reinforcing these advancements, the company also announced the passing of its multi-year FDA inspection and the completion of a pilot run for one of the world's largest lozenge manufacturers. With the three-year 'master plan' in motion, the company is not only meeting the current surge in demand but also strategically positioning itself for sustained long-term growth.

Valuation

Pharmaloz Manufacturing Inc. occupies a favourable position within the Contract Development and Manufacturing Organization (CDMO) space. It represents an optimal blend of sustainable robust growth, profitable performance, and clear visibility over cash flow generation. These attributes are further enhanced by prevailing industry trends, which continue to support the company's expansion efforts. ProPhase Labs has a current market capitalization of approximately $93 million and is comprised of multiple valuable businesses in addition to Pharmaloz. Given the considerations outlined in this report, we hold the belief that Pharmaloz Manufacturing Inc.'s underlying value surpasses the entire current market valuation of Prophase Labs. Moreover, it can be contended that the depressed market value of the parent company, ProPhase Labs, can be attributed to a major extent to various non company specific factors such as deteriorating global macroeconomic conditions and an elevated interest rate environment.

Our valuation assessment of the CDMO business, i.e., Pharmaloz Manufacturing Inc., has been derived using a blend of discounted cash flow (DCF) methodology and a comparable company analysis assigning a weightage of 70% and 30%, respectively. Our DCF assumptions include a discount rate of 12.0% and a terminal growth rate of 1.5%, which yielded a DCF value of $179.20 million. On the other hand, based on the median 2024e P/S of 2.7x and a median 2024e P/E of 30.8x, we have derived a GPCM (Public Company Comparable) valuation of $87.90 million. The combined approach resulted in a valuation of $151.82 million, contingent on successful execution by the company.

Approaches (in $ mm)	Value (USD)	Weight	Wtd. Value
DCF	$179.20	70%	$125.45
GPCM	$87.90	30%	$26.37
GTM	-	-	-
Wtd. Avg. Equity Value (USD)			**$151.82**

Company Name	Ticker	Price	Currency	Country	Mkt Cap.	P/S*	P/E*
WuXi AppTec Co., Ltd.	603259	74.00	CNY	CN	217,793	4.40	18.10
Lonza Group AG	LONN	381.40	CHF	CH	28,331	4.40	32.20
Catalent, Inc.	CTLT	49.66	USD	US	8,970	1.90	30.80
Syngene International Limited	SYNGENE	695.65	INR	IN	276,294	6.30	42.10
Siegfried Holding AG	SFZN	847.00	CHF	CH	3,597	2.70	23.70
Avid Bioservices	CDMO	6.60	USD	US	417	2.50	73.30
Fine Foods & Pharmaceuticals	FF	8.80	EUR	IT	215	0.80	22.56
Median						**2.7x**	**30.8x**
Average						**3.3x**	**34.7x**

Exhibit 16: Valuation Snapshot. Source: Diamond Equity Research
(Values in $mm except per share data or otherwise stated)
(*2024 multiple)

Risk Factors

- **Regulatory Changes and Compliance Risks -** The pharmaceutical and supplement industry is heavily regulated by various governmental bodies, including the FDA. Changes in regulations or failure to comply with existing laws can result in fines, legal actions, or the suspension of operations, thereby affecting profitability and reputation.

- **Supply Chain Vulnerabilities -** CDMOs are reliant on a network of suppliers for raw materials and components. Disruptions in the supply chain, whether due to geopolitical tensions, natural disasters, or supplier insolvency, can lead to production delays and increased costs.

- **Intellectual Property Risks -** As a CDMO, Pharmaloz may handle proprietary formulations and processes. The unauthorized disclosure or theft of intellectual property could result in legal ramifications and loss of client trust.

- **Competitive Pressures -** The CDMO and lozenge manufacturing sectors are highly competitive. New entrants or technological advancements by competitors could erode market share and put downward pressure on pricing.

- **Contractual Risks -** CDMOs often operate based on long-term contracts with clients. The loss of a major client or unfavorable contract terms can significantly impact revenue streams.

- **Quality Control and Product Recalls -** Failure to maintain stringent quality control measures can lead to product recalls, which are not only costly but can also damage the company's reputation and client relationships.

- **Technological Obsolescence -** The rapid pace of technological advancements in manufacturing processes poses a risk of current equipment and methods becoming obsolete, requiring further investment to stay competitive.

- **Environmental and Sustainability Risks -** Failure to adhere to environmental regulations or to meet sustainability goals can result in fines and reputational damage, and may also affect the company's ability to secure contracts from environmentally-conscious clients.

- **Geopolitical Risks -** Global operations expose the company to geopolitical uncertainties, including trade tariffs and restrictions, which could impact the cost structure and supply chain.

- **Talent Retention and Skilled Labor Risks -** The specialized nature of pharmaceutical manufacturing requires a skilled workforce. The inability to attract or retain talent could impact operational efficiency and quality.

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