



**BOURNE PARTNERS COMPOUNDING INDUSTRY UPDATE**  
**SUMMER 2024**



Bourne Partners is a leading healthcare-focused investment bank headquartered in Charlotte, NC. Since 2000, Bourne has been offering a unique perspective and unmatched expertise while remaining highly focused on fulfilling the needs of established middle market healthcare companies across the globe.

## OUR MISSION STATEMENT

*“We strive to enrich the lives and improve the health and well-being of our employees, partners, and patients across the globe by facilitating the efficient movement of capital through the global healthcare sector.”*

## HIGHLY-FOCUSED FIRM



PHARMA & LIFE SCIENCES



CONSUMER HEALTH



HEALTHCARE SERVICES



PHARMACY SERVICES



Healthcare... it's all we do

## BOURNE PARTNERS INVESTMENT BANK

Mergers & Acquisitions		Capital Raising	
Company & Product Focus	Sell-Side Assignments	Debt	Equity
Buy-Side Assignments	\$20M to \$1B+ Enterprise Value	Alternative Options	\$20M to \$1B+ Capital Raises
Business Development Services		Strategic Initiatives & Consulting	
Partnerships in US and Abroad	In and Out-Licensing	Strategy & Management	Sales/Marketing, Operations

## VALUE-ADD ADVISORS WITH A GLOBAL REACH

**\$10B+**  
Successful Transactions

**5**  
Continents

**20+**  
Year Track Record



Bourne Partners currently has multiple active transactions in the compounding / personalized medicine space. Over the past few years, Bourne Partners has closed several highly relevant transactions and has become the established, leading “compounding” M&A advisor.

\*indicates signed pending close 

## RELEVANT CURRENT ENGAGEMENTS

 <p><b>PROJECT NIRVANA</b></p> <p>operator of California-based sterile 503B outsourcing facility</p>  <p><i>Sell-Side Advisory</i></p>	<p><b>PROJECT PACER</b></p> <p>hospital focused unit dose non-sterile liquids pharma company</p>  <p><i>Sell-Side Advisory</i></p>	<p><b>PROJECT ALCHEMY</b></p> <p>major 503A platform serving various therapeutic categories</p>  <p><i>Sell-Side Advisory</i></p>
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## BOURNE'S VALUE ADD

-  Unmatched industry expertise and strong relationships with counterparties
-  Expert-level attention from senior bankers throughout the process
-  Bespoke process strategy and comprehensive outcome evaluation
-  Negotiating favorable deal terms and economics on a swift timeline

## REPRESENTATIVE COMPLETED TRANSACTIONS

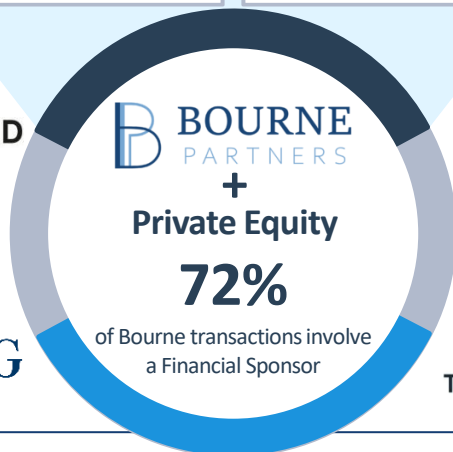
 <p>has received financing from</p>  <p><i>Capital Raise Advisory</i></p>	<p><i>MEDQUEST PHARMACY</i></p> <p>a subsidiary of</p>  <p>has been acquired by</p>  <p><i>Sell-Side Advisory</i></p>	 <p>has divested its CDMO franchise to</p>  <p><i>Sell-Side Advisory</i></p>	<p><i>American njectables</i></p> <p>has received financing from</p>  <p><i>Capital Raise Advisory</i></p>	<p><i>LINCARE</i> A Linde company</p> <p>sold home infusion assets to</p>  <p>a portfolio company of</p>  <p><i>Sell-Side Advisory</i></p>	 <p>recapitalization and fund-to-fund transfer of</p>  <p><i>Sell-Side Advisory</i></p>
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As an advisor, counterparty, or investment partner, PE has long valued Bourne's industry and transaction expertise. Our deep relationships will assist in reaching the right buyer and maximizing value.

## REPRESENTATIVE COMPLETED TRANSACTIONS

 has been acquired by  a portfolio company of  M&A Advisory	 has been acquired by  M&A Advisory	 a portfolio company of  has been acquired by  M&A Advisory	 has been acquired by  a portfolio company of  M&A Advisory	 has been acquired by  M&A Advisory	 has been advised by  on an undisclosed investment in a major healthcare platform M&A Advisory
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## ENTRUSTED TO PARTNER WITH...



## ...THE TOP NAMES IN PRIVATE EQUITY

*"On the back of their extensive knowledge and first-hand experience of transacting in the pharma space, Bourne Partners were able to help provide significant guidance as we prepared for our exit process... We received great engagement from the full team and thank Banks, Minor and Jeremy for their insightful input."*

**Cinven**  
Supraj Rajagopalan  
Partner  
Cinven

**CARLYLE**  
Steve Wise  
Head of Global Healthcare  
The Carlyle Group

*"Bourne Partners has deep relationships and significant transaction experience across the industry. Formalizing the relationship with Bourne is a reflection of our belief that our venture can add significant value in the space, as well as our positive outlook for investing capital in the Pharmaceutical industry going forward."*

Investment in the space is still in the early innings. The current landscape represents significant consolidation opportunity, with a vast majority of 503A pharmacies still being owned by local providers (~7,500 503As in US).

Value Driver	Platform EBITDA Multiple Range		Buyer Priority	Commentary
	Lower	Higher		
<b>National Footprint and Licensure at Scale</b>	<i>Regional / emerging player</i>	<i>National / established player</i>	Medium	<ul style="list-style-type: none"> <li>▶ Compounding is highly fragmented; a current scarcity of scaled platforms plays a large role in premium valuations</li> <li>▶ National presence with ability to sell into major population hubs drives valuation</li> </ul>
<b>Pristine Quality Record</b>	<i>Spotty / short dated</i>	<i>Clean / long quality history</i>	High	<ul style="list-style-type: none"> <li>▶ Clean inspection record / licensing history and a strong system in place to maintain quality are must-haves</li> <li>▶ Robust quality and regulatory function is highly valued alongside reputation of going above and beyond to ensure pharma grade quality</li> </ul>
<b>Organic Growth and Revenue Visibility</b>	<i>Little line of sight</i>	<i>Strong growth rate and revenue visibility</i>	High	<ul style="list-style-type: none"> <li>▶ Stickiness of prescriber base, long standing prescriber relationships, and refill rates are highly valued and prove durability of revenue</li> <li>▶ Proof of organic revenue growth to supplement M&amp;A activity shows health of underlying business</li> </ul>
<b>Attractive Therapeutic Areas</b>	<i>Slow growing / temporary TAs</i>	<i>Fast growing; benefiting from mega-trends</i>	Medium	<ul style="list-style-type: none"> <li>▶ Serving therapeutic areas with sticky patient / prescriber populations, large addressable markets, and strong underlying growth dynamics</li> <li>▶ Expansion into new therapeutic categories to take advantage of near-term opportunities or realize cross-selling opportunities is a value add</li> </ul>
<b>M&amp;A Sophistication</b>	<i>Limited – lack of ability to integrate</i>	<i>Proven ability to execute / integrate</i>	High	<ul style="list-style-type: none"> <li>▶ A demonstrated ability to source, execute, and integrate M&amp;A targets enhances value by reducing required sponsor involvement</li> <li>▶ Proven track-record of post-acquisition integration and performance creates confidence in forecasting and an outsized growth story</li> </ul>
<b>Quality Expertise and Management Strength</b>	<i>Outdated technology and inexperienced team</i>	<i>Strong, integrated team and systems</i>	High	<ul style="list-style-type: none"> <li>▶ Strong management team, systems, and capability set across multiple facilities to support growth and quality management</li> <li>▶ Large roster of pharmacists with duplicate state licenses across the business eliminates key man risk / ensures continuity of licensure</li> </ul>

**Investors prioritize compounders delivering critical, medically necessary treatments and will pay a premium for businesses that bridge essential healthcare gaps and safeguard patient populations from significant health risks**

**FDA has further clarified its stance on regulations controlling the distribution of compounded drugs. Guidelines are aimed at ensuring compounded drugs, which don't go through an approval process, are distributed via tightly controlled channels to protect patient safety.**

## FDA'S 503B CLARIFICATION: PERMITTED VS. PROHIBITED DISTRIBUTION CHANNELS<sup>1</sup>

### "PROHIBITED" CHANNELS / SCENARIOS<sup>2</sup>

#### 503Bs distributing products to repackagers

*If compounded drugs are distributed by repackagers, there's a risk they could be sold or transferred inappropriately, potentially leading to misuse or distribution of drugs not intended for specific patient needs*

#### 503Bs transferring products to a non-commonly owned 503B

*Because the non-commonly owned 503B does not administer the compounded drug or dispense pursuant to a prescription, the sale or transfer is prohibited to maintain the integrity of the compounding process*

#### Third parties offering access to 503B products

*Offering bundled services or indirect compensation to physician offices doesn't change the fundamental nature of the transaction; the third party is selling a drug via unauthorized channels (e.g., telemedicine platforms)*

### "NOT PROHIBITED" CHANNELS / SCENARIOS<sup>2</sup>

#### 503Bs moving a drug to another location that is part of the same outsourcing facility

*The drug has not been sold or transferred by an entity other than the outsourcing facility that compounded it. Therefore, because the transfer was solely within the 503B facility, there is no prohibition on this movement*

#### 503Bs distributing drug to pharmacies (including 503As) for dispensing

*So long as the state-licensed pharmacy, federal facility, or licensed physician dispenses the drug pursuant to a prescription, the sale or transfer involved is included in the exception to the prohibition on wholesaling*

#### 503Bs distributing drug to healthcare professional without prescription

*Because the sale or transfer by the healthcare professional takes place as part of administering the drug in a healthcare setting, the transfer or sale is not prohibited*

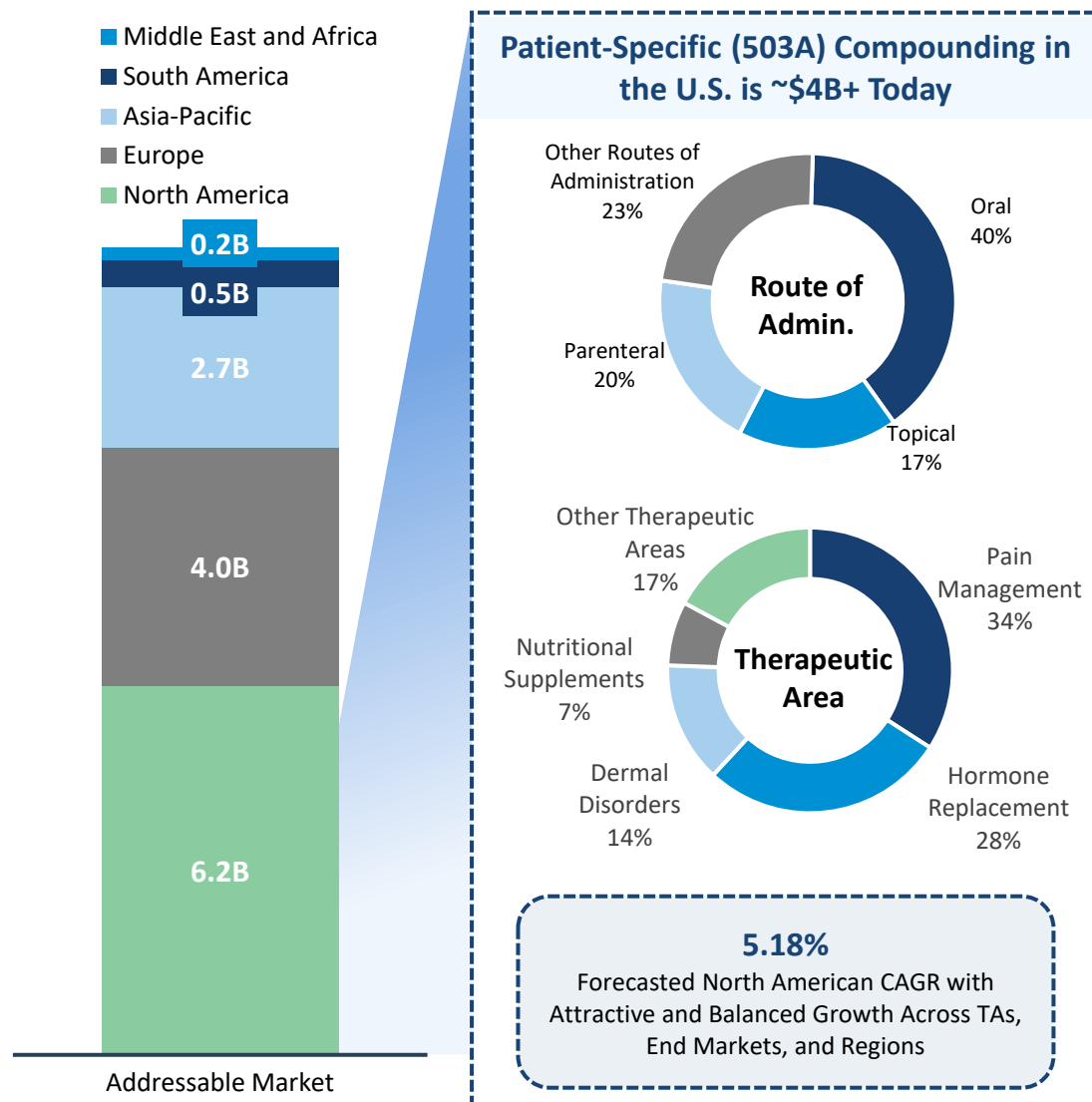
## NEW REGULATIONS MAXIMIZE MANUFACTURING POWER AND EFFICIENCY FOR VERTICALLY INTEGRATED COMPOUNDERS

In June 2023, FDA released guidance clarifying the permitted relationship between 503A and 503B entities; notably 503Bs were given the green light to sell directly to 503A compounding pharmacies, so long as the 503A dispenses the product for a patient specific script

Type	503A	503B	New Regulatory Guidance
Overview	<ul style="list-style-type: none"> <li>▶ Patient specific compounding based on a physician prescription specifying dose and formulation</li> </ul>	<ul style="list-style-type: none"> <li>▶ Non-patient specific compounding occurring prior to a prescription being written</li> </ul>	<ul style="list-style-type: none"> <li>▶ New federal guidance significantly expands the capabilities of 503B outsourcing facilities, clarifying that a 503B distributing to state-licensed pharmacies is <u>not</u> prohibited</li> <li>▶ Those that stand to benefit are entities equipped with both a 503A and 503B facility, where there is opportunity for significant vertical integration</li> </ul>
Regulatory Oversight	For cause FDA inspections only	Subject to random FDA inspections	503A & 503B Integrated Platform
	Facility registration dependent on state	Must register with BOP, DEA, and FDA	
	Subject to USP Chapters	Must comply with 21CFR Part 210 and 211	
Abbreviated Landscape			

**Resilient and recession resistant market growth driving demand in a highly fragmented market ripe for consolidation.**

## THE 503A COMPOUNDING MARKET<sup>1</sup> IS ATTRACTIVE AND SIZABLE...



## ...WITH STRONG GROWTH DRIVERS

TAILWINDS	IMPACT
<p><b>Increasing Elderly Population Enables Growing Demand</b> Age group has high drug-prescribing patterns and increasing chronic diseases and disorders</p>	<p><b>Greater Need for Custom Rx</b></p>
<p><b>Increased Acceptance of Provider Community / Concierge Medicine</b> Continued focus on personalized care and improving patient outcomes by tailoring formulations and treatment plans specifically to each patient</p>	<p><b>More Outcome Focused Treatments</b></p>
<p><b>Growing Emphasis on Integrative Health and Wellness</b> Focus on preventative care, alternative therapies, and personalized medicine are key focuses of integrative medicine</p>	<p><b>Tailor-Made, Prescription Care</b></p>
<p><b>Increased Utilization of Telemedicine Services</b> Advances in and growing popularity of telemedicine platforms increasingly utilize compounders to fill their prescriptions</p>	<p><b>Greater Access to Custom Medications</b></p>
<p><b>Drug Price Inflation and Increased Out-of-Pocket Costs for Patients on Commercial Products</b> With coverage gaps, patients may face higher co-pays or find certain medications not covered by insurance</p>	<p><b>Increased Value Prop. for Compounding</b></p>



Compounding is governed by three chapters which provide standards primarily related to contaminants and drug handling. New USP chapters with more stringent requirements, specifically for 797 and 800, went into effect last year.

## DESCRIPTION AND COMMENTARY OF RELEVANT USP GENERAL CHAPTERS

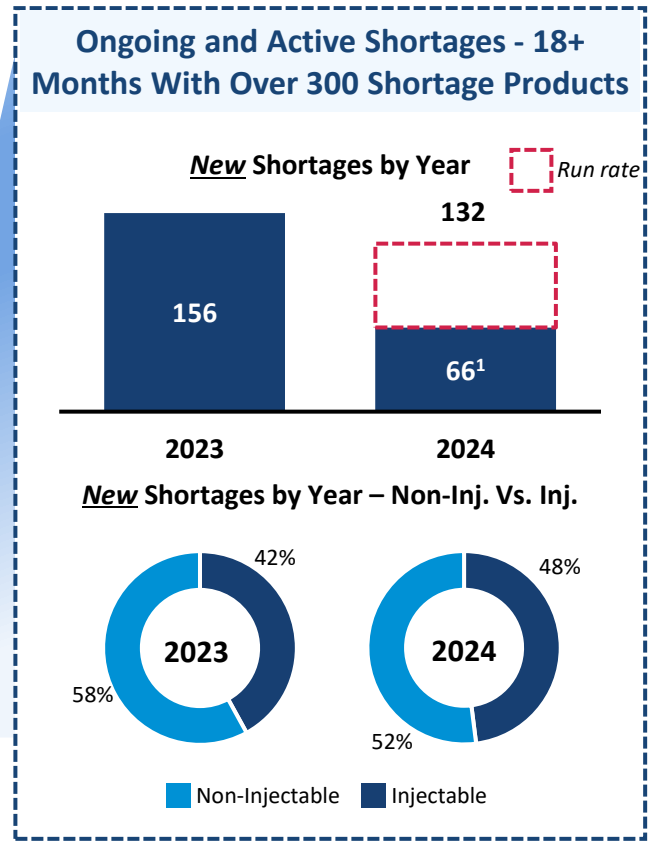
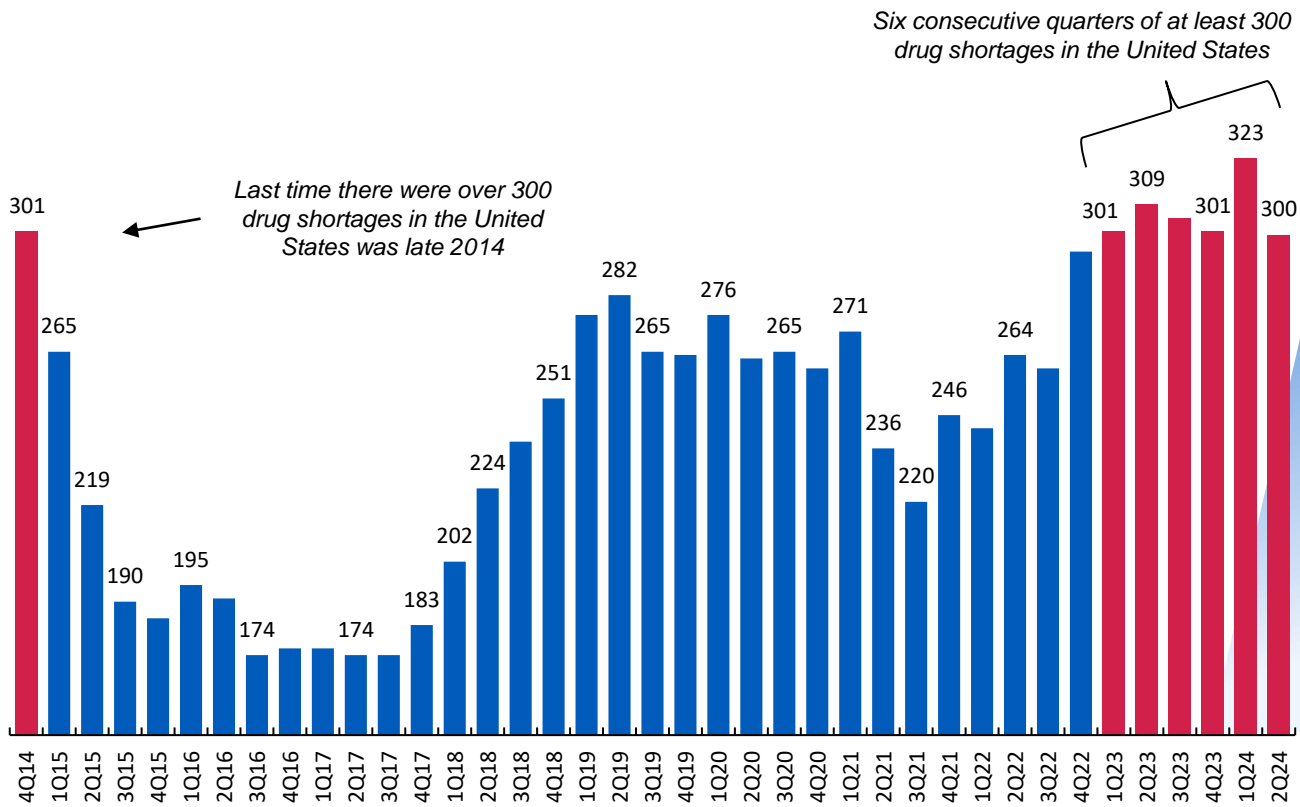
USP* General Chapters	Description	Commentary
USP <795>	<ul style="list-style-type: none"> <li>▶ Outlines standards for non-sterile compounding, including clean, but not aseptic facility conditions</li> <li>▶ Regulations focus on staff training, quality tests, and compounding records, including raw material sources</li> </ul>	<ul style="list-style-type: none"> <li>▶ Updates to USP&lt;795&gt; contain more specific guidelines and requirements for the compounding process that external compound suppliers and hospitals must meet                             <ul style="list-style-type: none"> <li>▶ Strict personal hygiene as well as cleaning and sanitizing schedules (surfaces cleared at the start &amp; end of a shift)</li> <li>▶ Establishes maximum beyond the use dates (BUDs)</li> </ul> </li> </ul>
USP <797>	<ul style="list-style-type: none"> <li>▶ Set rules to ensure sterile compound drugs are free from contaminants and contain the right concentrations of active ingredients                             <ul style="list-style-type: none"> <li>▶ Necessitates separate storage space for hazardous and non-hazardous products to prevent potential contamination</li> <li>▶ Requires equipment to test airflow and balance at the site of compounding</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▶ Changes to USP &lt;797&gt; have made it harder for hospitals to make compounds in-house, as requirements for maintaining sterility have become stricter</li> <li>▶ Shelf life of compounds made in-house is also significantly impacted under USP&lt;797&gt;, at times limited to 48h at room temperature (outsourced compounded products from a 503B facility; by contrast, can have a shelf life up to 180 days at room temperature)</li> <li>▶ Smaller compounders have increasingly looked towards exit strategies as opposed to investing in costly facility and process upgrades due to the change in &lt;797&gt; requirements</li> </ul>
USP <800>	<ul style="list-style-type: none"> <li>▶ Provides additional standards for the handling of hazardous drugs, (e.g. oxytocin, chemotherapies, etc.)</li> <li>▶ Sets requirements for additional protective equipment and training for staff, facility and engineering controls, and policies for waste disposal</li> <li>▶ Requires multiple spaces designated for specific steps of hazardous drug handling, and specifies additional lab equipment to ensure safety</li> </ul>	<ul style="list-style-type: none"> <li>▶ USP&lt;800&gt; standards build on the &lt;797&gt; regulations to create even stricter guidelines for both external compound suppliers and hospitals requiring significant investment in HVAC / engineering controls</li> <li>▶ Focus on quality has pushed many hospital pharmacies externally to meet compounding needs for hazardous substances</li> </ul>

Non-sterile

Sterile

Hospitals that in-source their compounds are governed by the USP general chapters, the State Board of Pharmacy, and the Joint Commission, but unlike 503Bs, they are not governed by the cGMP or FDA 503B regulations\*\*

## RAPIDLY INCREASING DRUG SHORTAGES



## LEADING CONTRIBUTORS TO INCREASING DRUG SHORTAGES

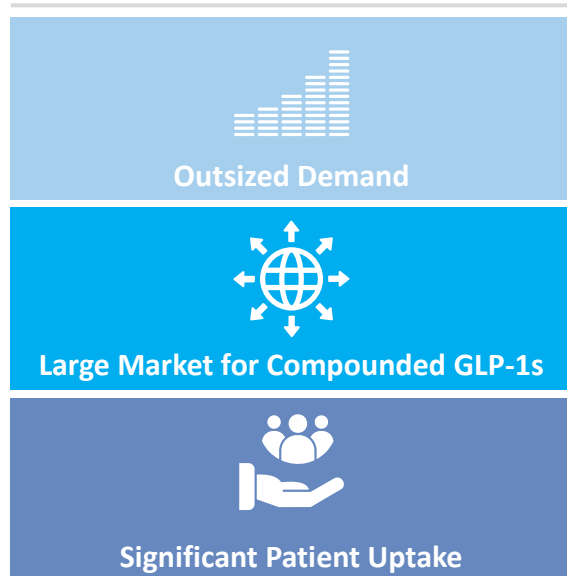


While 503B compounding facilities are positioned to be vital solution providers in the pharmaceutical supply chain and shortage drug market, many have yet to fully capitalize on this opportunity. FDA survey reveals that fewer than 20 facilities derive 20% or more of their total volume from products on the drug shortage list. This underutilization represents a significant growth opportunity for the 503B industry, not only in addressing current high-profile shortages like GLP-1s but also in expanding to tackle the broader spectrum of drug scarcities

10 Notes: 1) 66 is the number through June. ASHP numbers being shown above; official FDA shortage list is distinct from ASHP list. FDA survey mentioned above was taken prior to major GLP-1 tailwinds

The GLP-1 market is growing rapidly, driven by favorable macro trends: increasing health proactivity from consumers, rising demand for personalized healthcare solutions, and the expanding utilization of alternative therapies and treatments to help manage comorbid conditions.

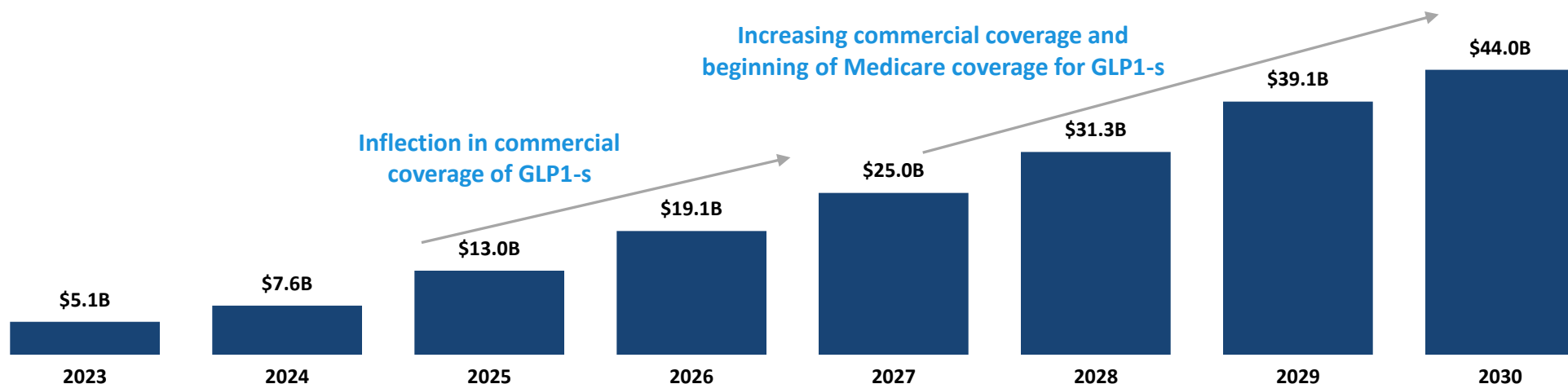
## GROWTH TRAJECTORY



## COMMENTARY

- ▶ GLP-1s are witnessing unprecedented levels of demand and uptake from patients seeking an effective solution for weight loss
- ▶ Quickly after launch, GLP-1 drugs from Eli Lilly and Novo Nordisk went into supply shortage and have remained on the FDA’s Drug Shortage List since late 2022, opening the door to compounders
- ▶ Recently, the supply squeeze for Eli Lilly’s tirzepatide and Novo Nordisk’s semaglutide has shown early signs of lifting; FDA now lists the drugs as available, though they currently remain on the official shortage list<sup>1</sup>
- ▶ Compounders in the U.S. are estimated to produce ~\$1B worth of compounded GLP-1s in 2024<sup>2</sup>
- ▶ Compounded GLP-1s are often cash pay products and significantly cheaper than the branded commercial medication
- ▶ The ultimate scale and sustainability of the compounded GLP-1 market is largely dependent on 1.) evolving reimbursement policies from government and commercial payers 2.) in-process GLP-1 manufacturing supply coming online for Eli Lilly and Novo Nordisk 3.) emerging landscape and future approvals of other GLP-1 products

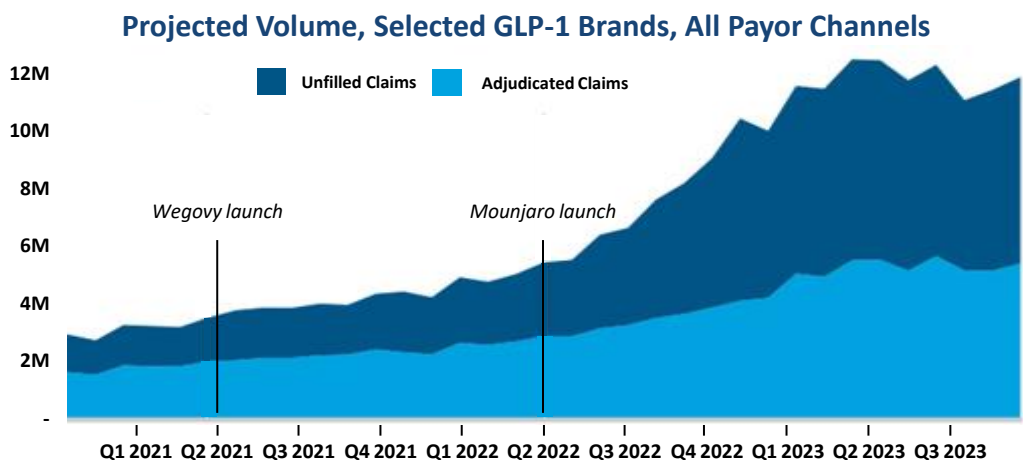
## U.S. OBESITY MARKET IS EXPANDING RAPIDLY RESULTING IN A GROWING APPETITE FOR GLP-1s<sup>3</sup>



11 Source(s): 1) As of: 8/12/2024. All presentations are listed as “available” but for one Semaglutide presentation 2) Bloomberg: Unsafe Ozempic Knockoffs Are Flooding the Market, 6/22/2024; 3) J.P. Morgan: The Increase in Appetite for Obesity Drugs, 2/2/2024

Despite rapid growth, the GLP-1 market faces significant challenges. These include stringent regulatory hurdles, high treatment costs, patient adherence issues, and rising lawsuits related to safety concerns.

## INCREASED DEMAND FOLLOWING BRAND NAME LAUNCHES<sup>1</sup>



- ▶ Wegovy's launch as a weight-loss variant of Ozempic led to a modest 3% monthly growth in GLP-1 prescriptions from June 2021 to May 2022. However, Mounjaro's introduction caused an 8% surge in prescriptions from July 2022, doubling adjudicated GLP-1 prescriptions across all payers
- ▶ Although more GLP-1 prescriptions were written, the rejection rate from payors increased from 30% pre-Wegovy to 41% post-Mounjaro, reflecting changes in patient access. Despite some transitional assistance, nearly 60% of written GLP-1 prescriptions remained unfilled in the first half of 2023 due to rejection from payors to be reimbursed

## COMMENTARY

- ▶ Navigating stringent regulatory requirements from bodies like the FDA and EMA can be complex and time-consuming. State-level prescribing standards and telehealth regulations add layers of complexity, requiring adherence to specific requirements for obesity medication and compounding practices
- ▶ The high cost of GLP-1s limits patient access and obtaining favorable reimbursement from insurers remains a challenging aspect. For instance, achieving a 1% weight loss can cost up to \$1,845 with semaglutide, and annual Medicare costs could reach \$26.8 billion if 10% of the U.S. population used semaglutide<sup>2</sup>
- ▶ Research shows over 85% of users discontinue use after two years due to high costs, availability issues, and side effects. Only 14.8% of patients remained on the medication after two years<sup>3</sup>
- ▶ Increasing lawsuits related to safety concerns of GLP-1 drugs, such as gastrointestinal issues, can potentially erode trust in these treatments. The high demand for these medications has led to significant supply shortages, placing them on the FDA Drug Shortages List and allowing compounding pharmacies to produce them under specific conditions. However, once shortages are resolved, access to compounded GLP-1s will likely diminish
- ▶ Many compounders have benefited from the GLP-1 shortage, but at the expense of criticism within the public sphere. Many pundits are quick to forget scenarios in which compounders have provided necessary and life saving products to large sets of patient populations (e.g., recent amoxicillin shortage, Covid's impact on hospital's access to drugs)

## KEY CHALLENGES

Regulatory Hurdles

Cost and Reimbursement

Patient Adherence

Rising Lawsuits

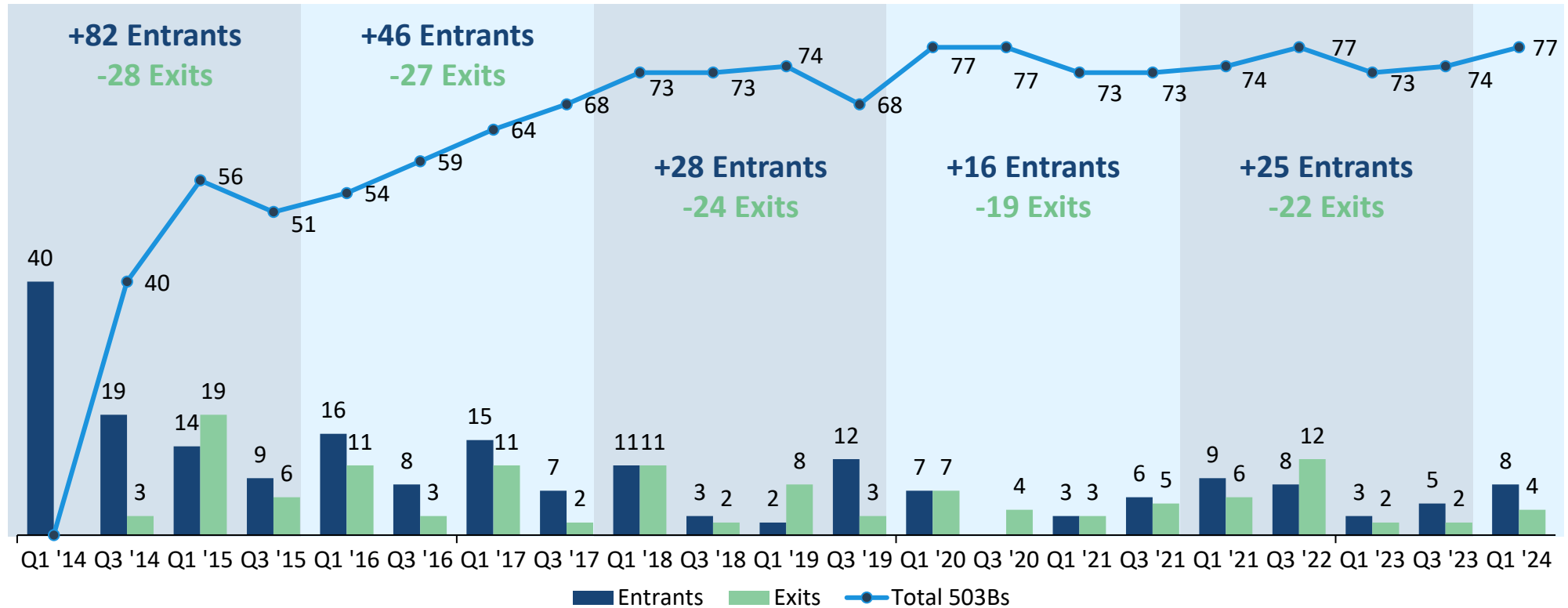
Drug Shortages

**Compounding facilities will continue to play an important role in the pharmaceutical supply chain. Despite regulatory scrutiny, the 503B model is a cost efficient, scalable, and profitable approach to satisfying pharmaceutical demand.**

- ▶ Nearly 50% of FDA registered 503Bs currently have an outstanding 483 report, meaning these facilities have been flagged for a condition that may constitute violations of the Food Drug and Cosmetic Act and related Acts<sup>1</sup>. Alongside growth in M&A activity, we expect continued focus on / investment in quality and regulatory compliance as quality systems become an ever-increasing differentiator for buyers and a critical factor in vendor selection
- ▶ cGMP compliance is costly, but noncompliance is far more costly – outsourcing facilities that understand this will benefit as low-quality providers lose out on their quality record alone
- ▶ Several private equity backed 503B platforms are likely to trade within the next 12-24 months, which will highlight investor sentiment on the space in the wake of the trends outlined below



The 503B industry’s relative youth has resulted in a dynamic landscape, with only a handful of players establishing long-term success and stability. Quality across the industry is improving and the total number of outsourcing facilities has leveled off in recent years.



## MAIN CHALLENGES THAT LEAD TO MARKET EXITS

- ▶ **Compliance Issues:** Compliance with cGMP is complex. As a newly regulated industry, there is significant “policy flux” compared to more established industries. Additionally, varying regulatory models from state to state make compliance challenging. Some groups have struggled to properly master the FDA’s policies, leading to exits from the market. Despite stories highlighting quality issues with major players, there has been a general flight to quality in the industry. This is evident in the declining number of 503Bs with outstanding 483s. In 2018, all but two 503Bs had open 483s; today, about 60% of facilities do
- ▶ **Outsourcing Facility Operations Not Primary Business Model:** Diversified players, whether it be pharma companies, hospital systems, or specialty pharmacy chains that get into the space oftentimes end up leaving because 503B is non-core to their business model and proves difficult to master (typically also quality related)
- ▶ **API Availability:** The availability of APIs and drug inputs is another factor contributing to exits in 503B facilities. Many 503B players are not large-volume purchasers and have difficulty consistently sourcing quality, affordable APIs

Bourne possesses unparalleled depth and breadth in compounding, having achieved superior results across the space.

Bourne led transaction

Date	Type	Target	Buyer	Commentary
Aug 2024	503B	<b>Blinded</b>	<b>hims &amp; hers</b>	Hims & Hers has agreed to acquire an outsourcing facility, one of the few CA approved 503Bs in the wellness space. The deal will allow Hims & Hers to make compounded versions of weight-loss drugs and other medicines
Jul 2024	503A			The latest acquisitions in Revelation Pharma's (Osceola Capital backed compounding platform) roll-up strategy across the 503A and 503B space. Platform currently has 16 member pharmacies
Jan 2024	503B			Biote acquired 503B manufacturer of compounded bioidentical hormones. Asteria was a longtime provider to Biote-certified practitioners and a Biote-partnered clinics across the US
Jun 2023	503B			1315 invested in Medivant, a sterile injectables focused 503B outsourcing facility providing injectables to hospitals and healthcare providers in 47 states
May 2023	503A			MedQuest is a 503A compounding pharmacy and leader within Bio-Identical Hormone Replacement Therapy as well as a leader in CME accredited education
Jan 2022	503A Infusion			BHI is an operator of in-house compounding pharmacies and provider of home-based care for patients requiring intrathecal pump
Jan 2022	503A Infusion			AleraCare is a provider of infusion treatments and pharmacy services for high-need and medically complex populations; compounding pharmacy services are focused on men's / women's health, fertility, and veterinary
Nov 2021	503B			503B outsourcing facility serving hospitals, ASCs, and physician and ophthalmic practices in all 50 states. Capability portfolio includes: PFS, vials, bag, and other injectable compounds
Jan 2021	503B		 	503B outsourcing facility providing RTU, sterile compounded products to hospitals and health systems nationwide



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