

Outsourced Pharmaceutical Commercialization

Fall 2024



A scientist wearing a white lab coat, a light blue surgical mask, and blue nitrile gloves is working in a laboratory. They are using a pink and white pipette to transfer a liquid into a small blue vial. In the background, there are various laboratory equipment, including a flask with blue liquid, a petri dish, and other glassware. The scene is brightly lit, suggesting a clean and professional environment.

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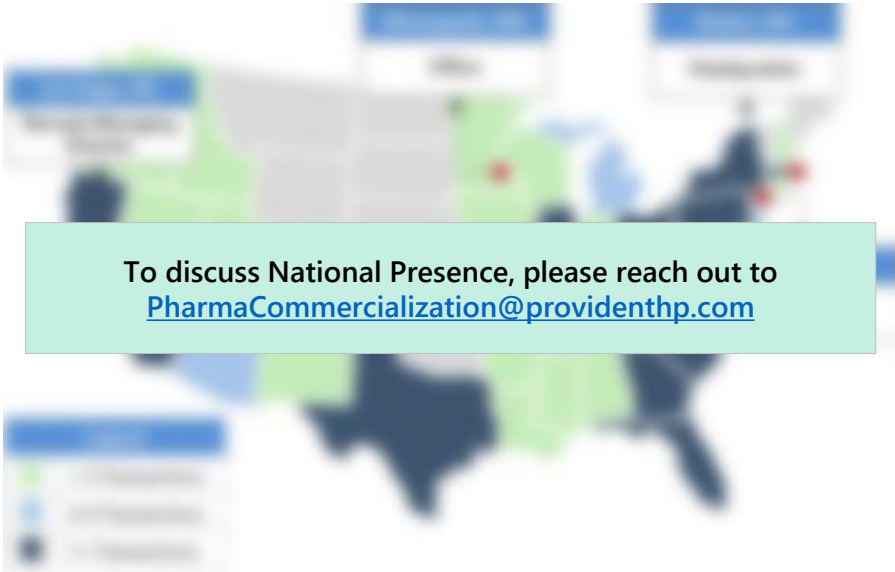
- a. Introduction to Provident Healthcare Partners
- b. Outsourced Pharmaceutical Services
- c. Outsourced Pharmaceutical Commercialization

Provident Overview: Introduction to Provident Healthcare Partners

Areas of Expertise and Coverage

1 Mergers & Acquisitions		2 Recapitalizations & Growth Capital		3 Debt Raises		4 Strategic & Shareholder Advisory			
Pharma Services		Pharmacy		Provider Services		Post-Acute Care		Behavioral Health	
<div>Commercialization</div> <div>CROs</div> <div>Clinical Research Sites & SMOs</div>		<div>503B Pharmacy</div> <div>Infusion Therapy</div> <div>Specialty & LTC Pharmacy</div>		<div>ASC & Surgical Facilities</div> <div>Multi-Specialty</div> <div>Primary Care</div> <div>Single Specialty</div>		<div>Home Health</div> <div>Hospice & Palliative Care</div> <div>Physical Therapy</div> <div>Senior Living</div>		<div>Autism Services</div> <div>I/DD Services & Support</div> <div>Substance Use Disorder</div> <div>Mental Health</div>	

National Presence



To discuss National Presence, please reach out to PharmaCommercialization@providenthp.com

Key Statistics

To discuss Key Statistics, please reach out to PharmaCommercialization@providenthp.com

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Provident Overview: Why Provident is the Most Qualified Advisor

To discuss Provident Qualifications, please reach out to
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Provident Overview: Select Provident Transaction Experience

To discuss Transaction Experience, please reach out to
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A background image of a laboratory setting. A scientist wearing a white lab coat, a light blue surgical mask, and blue nitrile gloves is using a pink pipette to transfer liquid into a clear conical flask. The flask already contains some blue liquid. In the background, there are other laboratory equipment like beakers and test tubes, some containing blue liquid. The overall scene is brightly lit and clean.

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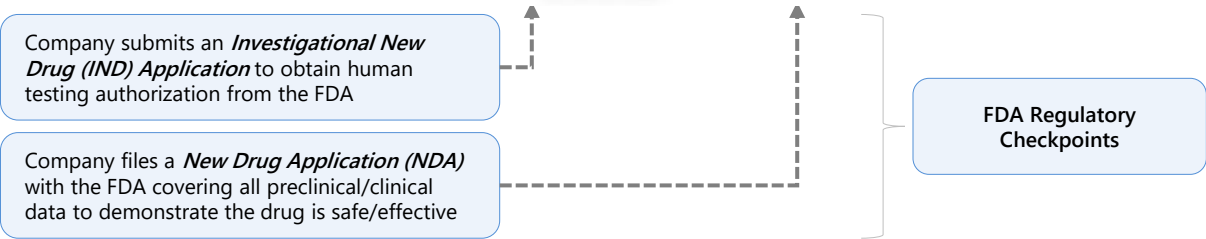
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Outsourced Pharma Services: Drug Development Lifecycle

The drug development life cycle is a multifaceted and multi-year process that spans from the initial discovery of a potential therapeutic compound to its FDA approval and post-market surveillance.

Discovery & Preclinical Research		Clinical Research	Manufacturing & Supply Chain		Commercialization	
Discovery	Preclinical Research	Clinical Trials	Manufacturing	Packaging & Distribution	Sales & Marketing	Post-Market Surveillance
10,000+ Compounds	250 Compounds	5 Compounds	1 FDA Approved Drug			
3 to 6 Years		6 to 7 Years	6 to 24 Months		Ongoing	

To discuss Drug Development Lifecycle, please reach out to PharmaCommercialization@providenthp.com



Outsourced Pharma Services: Outsourcing Across the Value Chain

Due to the costs and complexities derived from the drug development life cycle, pharmaceutical and biotechnology companies increasingly look to outsource development activities to reduce costs and increase a drug’s likelihood of commercial success.

Discovery & Preclinical Research		Clinical Research	Manufacturing & Supply Chain		Commercialization	
Discovery	Preclinical Research	Clinical Trials	Manufacturing	Packaging & Distribution	Sales & Marketing	Post-Market Surveillance

To discuss Outsourcing Across the Value Chain, please reach out to PharmaCommercialization@providenthp.com

CROs	Research Sites & SMOs	CMOs & CDMOs	CCOs
<ul style="list-style-type: none">Contract Research Organizations (CRO) provide a wide range of research and development offerings related to discovery, preclinical research, clinical research, and post-market surveillance	<ul style="list-style-type: none">Research Sites are the facilities in which research studies/trials are conducted; locations include hospitals, academic institutions, clinics, or dedicated facilitiesSite Management Organizations (SMO) provide operational, administrative, and management related services to preclinical and clinical trial sites	<ul style="list-style-type: none">Contract Manufacturing Organizations (CMO) specialize in the manufacturing aspects of drug productionContract Development & Manufacturing Organizations (CDMO) provide end-to-end, fully-integrated drug development and manufacturing services	<ul style="list-style-type: none">Contract Commercialization Organizations (CCO) provide a range of services (ex. market access, RWE/HEOR, patient support, and regulatory affairs) to ensure pharma products reach providers and patients efficiently and effectively

To discuss Key Players, please reach out to PharmaCommercialization@providenthp.com

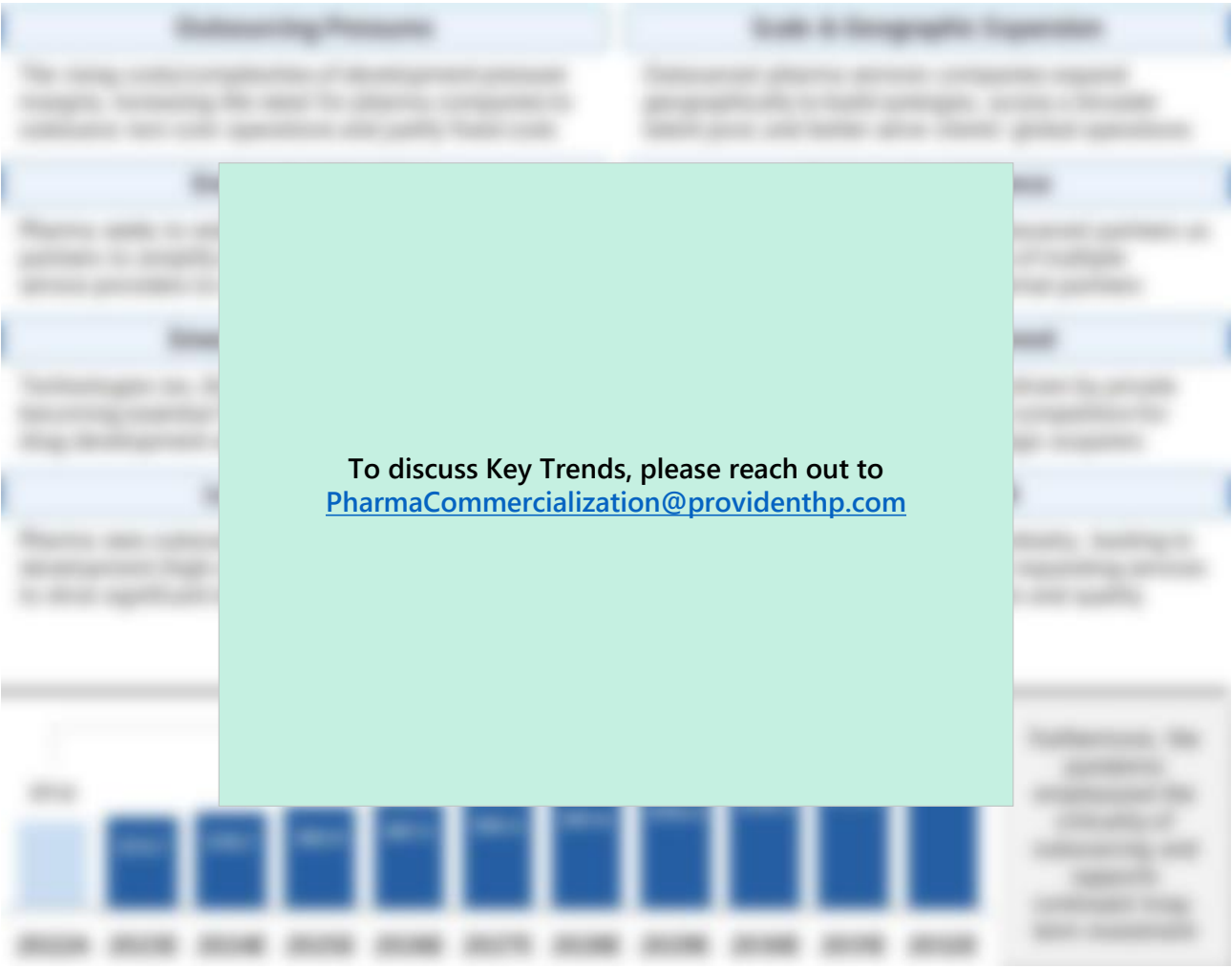
Outsourced Pharma Services: Investment Thesis

The investment thesis in outsourced pharmaceutical services is primarily supported by an increasingly complex and expensive drug development life cycle, driving sponsors to rely on outsourced service providers for more efficient and effective processes.

General Overview

- Historically, pharmaceutical companies targeted therapeutic areas with large patient populations, ensuring significant market share and payor support
- Increased market saturation and traditional therapeutic area coverage has driven a shift in focus to specialized therapies, which are more costly; *specialty drugs have grown from 15% to 44% of pharmacy revenues (2010-2020)*
- Specialized therapeutics are more expensive due to (i) smaller patient populations, (ii) complex diseases, (iii) challenges in finding effective compounds, and (iv) constrained patient recruitment for clinical trials
- Furthermore, twenty-year patents start during the R&D phase of drug discovery, leaving only ~5-10 years post-R&D to recoup costs
- Post-FDA approval, commercialization introduces further expenses as manufacturers must demonstrate efficacy and cost-effectiveness, leading to additional clinical trials and higher costs due to payor and provider demands for supplemental data
- Given these dynamics, pharmaceutical companies increasingly rely on outsourcing to enhance efficiency and effectiveness in drug development, reducing launch timelines and boosting commercial success

Key Trends



Outsourced Pharma Services: Market Trends

Outsourcing growth can be characterized by an increase in pharma R&D spend, new FDA approvals, and a shift from traditional to specialty drugs, resulting in a greater need for outsourced service providers to drive efficiencies and cost reductions.

To discuss Market Trends, please reach out to
PharmaCommercialization@providenthp.com

A background image of a laboratory setting. A scientist wearing a white lab coat, a light blue surgical mask, and blue nitrile gloves is using a pink pipette to transfer liquid into a clear conical flask. The flask already contains some blue liquid. In the background, there are other laboratory equipment like beakers and a white container, all slightly out of focus. A semi-transparent blue overlay covers the right side of the image, where the text is located.

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Commercialization: Types of Commercialization Companies

Outsourced commercialization organizations offer a comprehensive suite of services designed to ensure the successful market launch and sustained growth of a pharmaceutical product.

To discuss Types of Commercialization Companies, please reach out to
PharmaCommercialization@providenthp.com

Commercialization: Sample Service Offerings

To discuss Sample Service Offerings, please reach out to PharmaCommercialization@providenthp.com

To discuss Market Trends, please reach out to PharmaCommercialization@providenthp.com

Commercialization: Regulatory Landscape

1

Inflation Reduction Act ("IRA")

- Enacted in 2022, the IRA will be adopted over the next six years and introduces significant change to the manufacturing and commercialization landscape, primarily through the Medicare Drug Price Negotiation Program
- **Current Proposal:** Manufacturer must pay a rebate if a drug product's price rises faster than inflation
- **Potential Impact:** Higher launch price of new drugs due to restrictions on post-launch increases; delayed product launches to gather more evidence to justify higher prices, resulting in delayed patient access

While the full impact of the IRA remains uncertain, market access and commercialization strategies will change as manufacturers look to optimize financial outcomes.

2

Standardized Global Pharmaceutical Regulations

- The ongoing effort to standardize global pharmaceutical regulations aims to harmonize drug development, approval, and manufacturing processes to ensure patient safety and improve patient access
- **The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"):** To align regulations, major regulatory agencies (ex. FDA/EMA) adopt technical guidelines and standards developed by the ICH
- **World Health Organization ("WHO") Prequalification Program:** Established to (i) ensure medicines meet global standards for safety and (ii) streamline the global approval process by creating common benchmarks

3

Benefit-Risk Assessment for New Drug & Biological Products

- Released by the FDA in 2023, the Benefit-Risk Assessment for New Drug & Biological Products (the "Assessment") is a framework used to evaluate the approval of new drugs and biologics
- The Assessment changes the criteria for certain pre-market and post-market regulatory decisions that the FDA makes about New Drug Applications ("NDA") and Biologic License Applications ("BLA")
- Asserts that the FDA will place increased scrutiny on evidence generation while reviewing NDAs and will heavily weight "real world data" in their reviews

Outsourced services providers, particularly market research and analytics firms, will see increased demand as pharmaceutical companies require increased evidence generation.

4

Orphan Cures Act ("OCA")

- The OCA is a current legislative proposal which may alter the way orphan drugs are treated under the IRA
- **Medicare Price Negotiation Exemption:** The OCA looks to expand exemptions, ensuring orphan drugs are protected from U.S. government price negotiations
- **Market Exclusivity:** Under the OCA, orphan drugs would retain longer market exclusivity periods without being subject to pricing pressures
- **Orphan Drug Definition:** The OCA seeks to refine the definition of orphan drugs to ensure that only true orphan drugs qualify for exemptions and associated benefits

Commercialization: Competitive Landscape

To discuss Competitive Landscape, please reach out to
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Commercialization: Sub-Sector Specific Market Trends



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Commercialization: Sub-Sector Specific Market Trends *(Continued)*



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Commercialization: Transaction Activity & Key Themes

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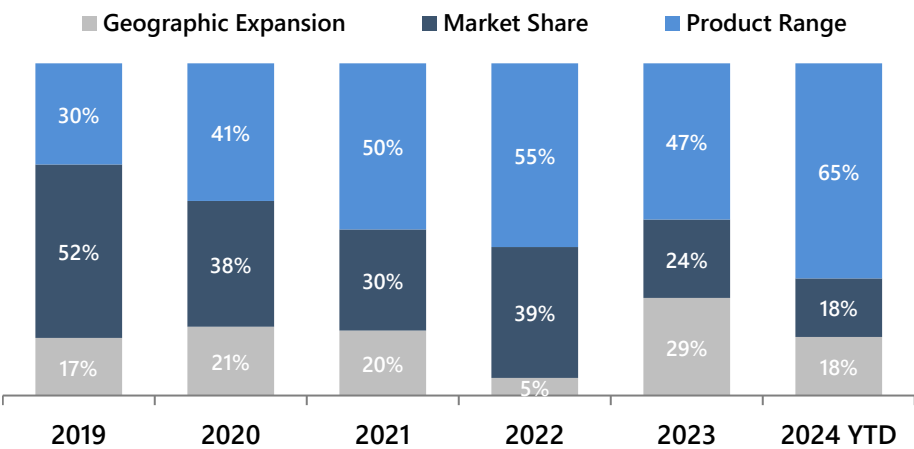
Key Themes & Industry Outlook

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Commercialization: Buyer Growth Strategies

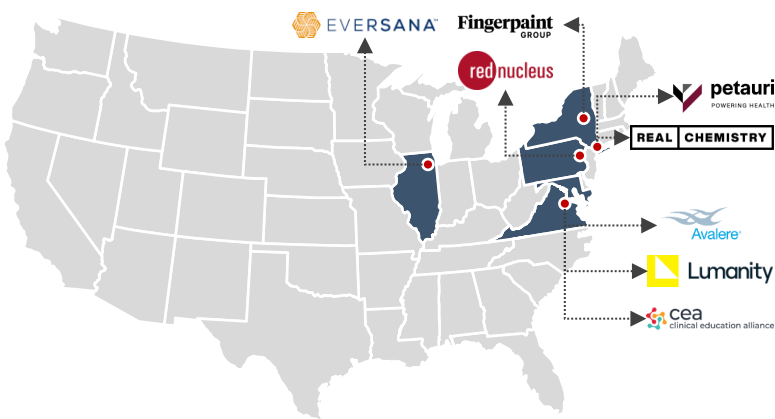
As the primary growth strategy for outsourced commercialization businesses, acquisitions are predominantly led by PE-backed platforms looking to increase market share and expand service offerings to become a “one-stop-shop” for pharma companies.

Add-Ons by Growth Strategy



- Geographic Expansion:** While geographic expansion is less common due to the sector's reliance on outsourcing, some companies pursue globalization, particularly in cross-border acquisitions between the U.S. and U.K.
- Market Share:** Established firms with broad service offerings or strong market positions are acquiring industry peers to expand market share, as seen with platforms like Citrus Health Group and Avalere Health
- Product Range:** PE-backed firms are aggressively acquiring to build full-service commercialization platforms, with 47% of deals in 2023 and 65% in 2024 YTD aimed at expanding their product range to become "one-stop-shops"

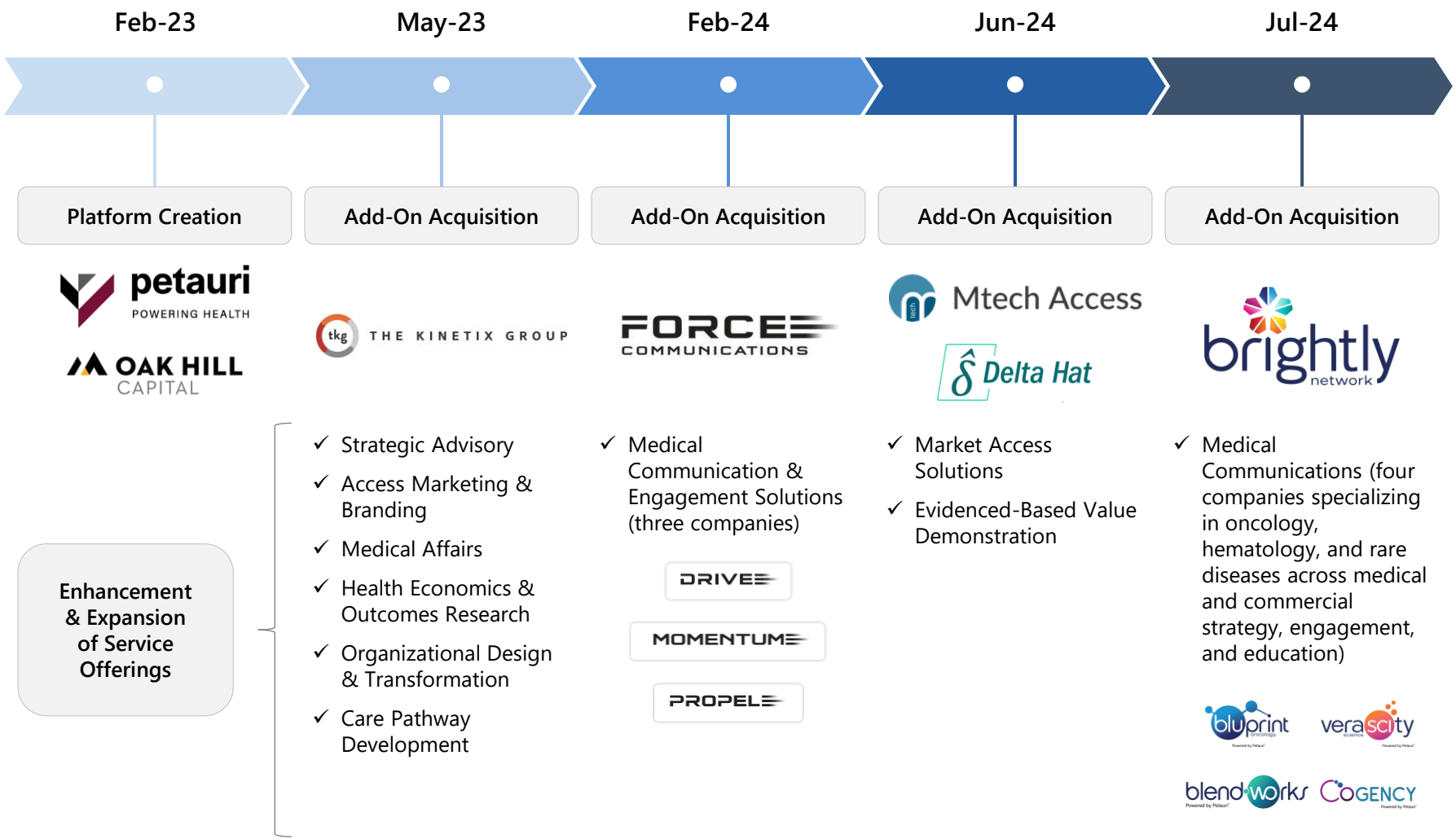
Active Consolidators



Company	HQ	Financial Sponsor	Add-Ons
 Avalere	Langhorne, PA	 Bridgepoint	19
 cea clinical education alliance	Reston, VA	 Riverside	7
 EVERESANA	Chicago, IL	Several Investors	14
 Fingerprint GROUP	Sarasota Spring, FL	 KNOX-LANE	11
 Lumanity	Bethesda, MD	 Arsenal Capital Partners	8
 petauri POWERING HEALTH	New York, NY	 OAK HILL CAPITAL PARTNERS	5
 REAL CHEMISTRY	New York, NY	 NMC NEW MOUNTAIN CAPITAL LLC	14
 red nucleus	Yardley, PA	 Riverside	7














Commercialization: Platform Spotlight (Petauri Health)

In 2023, Oak Hill Capital formed Petauri Health ("Petauri"), and subsequently acquired five companies in less than two years, demonstrating the organization's commitment to establish a full-service commercialization platform.



Commercialization: Acquisition Strategies in Action

Commercialization platforms are frequently evaluating M&A opportunities to more quickly develop full-service models. The featured transactions below showcase recent deals aimed towards broadening existing product lines.

		Transaction Example	
Expertise & Specialization	Therapeutic Area Expertise Specialization in specific, high-spend therapeutic areas (ex. oncology, rare diseases) allows companies to provide tailored solutions to enhance the commercialization process. Specialization can command greater fees and solidify niche market positioning, driving outside investor interest.		<div>Acquired</div> 
	Regulatory Knowledge Companies that offer expertise in navigating complex regulatory environments offer pharma a smoother post-FDA approval process and reduce the risk of non-compliant activities. Regulatory know-how helps investors ensure smoother market entry, sustained product lifespan, and enhanced profitability.		<div>Acquired</div> 
Technology & Innovation	Advanced Analytic Capabilities Advanced analytics and real-world evidence deliver valuable insights for market access, product optimization, and patient outcomes. Rising investor interest as analytics drive more precise services, leading to stronger customer retention.		<div>Acquired</div>  
	Digital Health Solutions Digital tools and platforms help to streamline patient engagement, remote patient monitoring, and virtual care. Digital solutions signal diversified revenue streams as well as innovation/scalability to investors, therefore attracting premium valuations and greater overall interest.		<div>Acquired</div> 
Stakeholder Engagement	Patient Adherence & Support With increased complexity, patient target populations decrease, thus raising the demand for companies engaged with and supportive of patient populations. Increased investor interest for groups offering comprehensive patient adherence/support programs that improve product uptake and patient outcomes.		<div>Acquired</div> 
	Physician Engagement Companies with high HCP engagement offer smoother access channels and bring specialized knowledge which helps drive the commercialization process. Rising investor interest in such companies as HCPs are increasingly averse to in office sales rep visits.		<div>Acquired</div> 

(1) PHP Transaction

Commercialization: Select 2023 & 2024 Transaction Activity

To discuss Transaction Activity, please reach out to PharmaCommercialization@providenthp.com

Commercialization: Select 2023 & 2024 Transaction Activity (Continued)

To discuss Transaction Activity, please reach out to PharmaCommercialization@providenthp.com

Commercialization: Select 2023 & 2024 Transaction Activity (Continued)

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Partners In Value

Provident is the leading investment bank offering mergers and acquisition advisory services for high growth, middle market companies in the healthcare industry.

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