



Houlihan Lokey

# PHARMA COMMERCIALIZATION

A Deep Dive in Market Access

Summer 2023

# No. 1 M&A Advisor

## Global Transactions Under \$1 Billion

### 2022 M&A Advisory Rankings Global Transactions Under \$1 Billion

Advisor	Deals
<b>1 Houlihan Lokey</b>	<b>381</b>
2 Rothschild	369
3 JP Morgan	217
4 Lazard	206
5 Goldman Sachs	203

Source: Refinitiv. Excludes accounting firms and brokers.

### 2022 M&A Advisory Rankings All Global Business Services Transactions

Advisor	Deals
<b>1 Houlihan Lokey</b>	<b>69</b>
2 Rothschild	50
3 Lincoln International	37
4 Goldman Sachs	34
5 GCG	26

Source: Refinitiv. Excludes accounting firms and brokers.

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### Americas

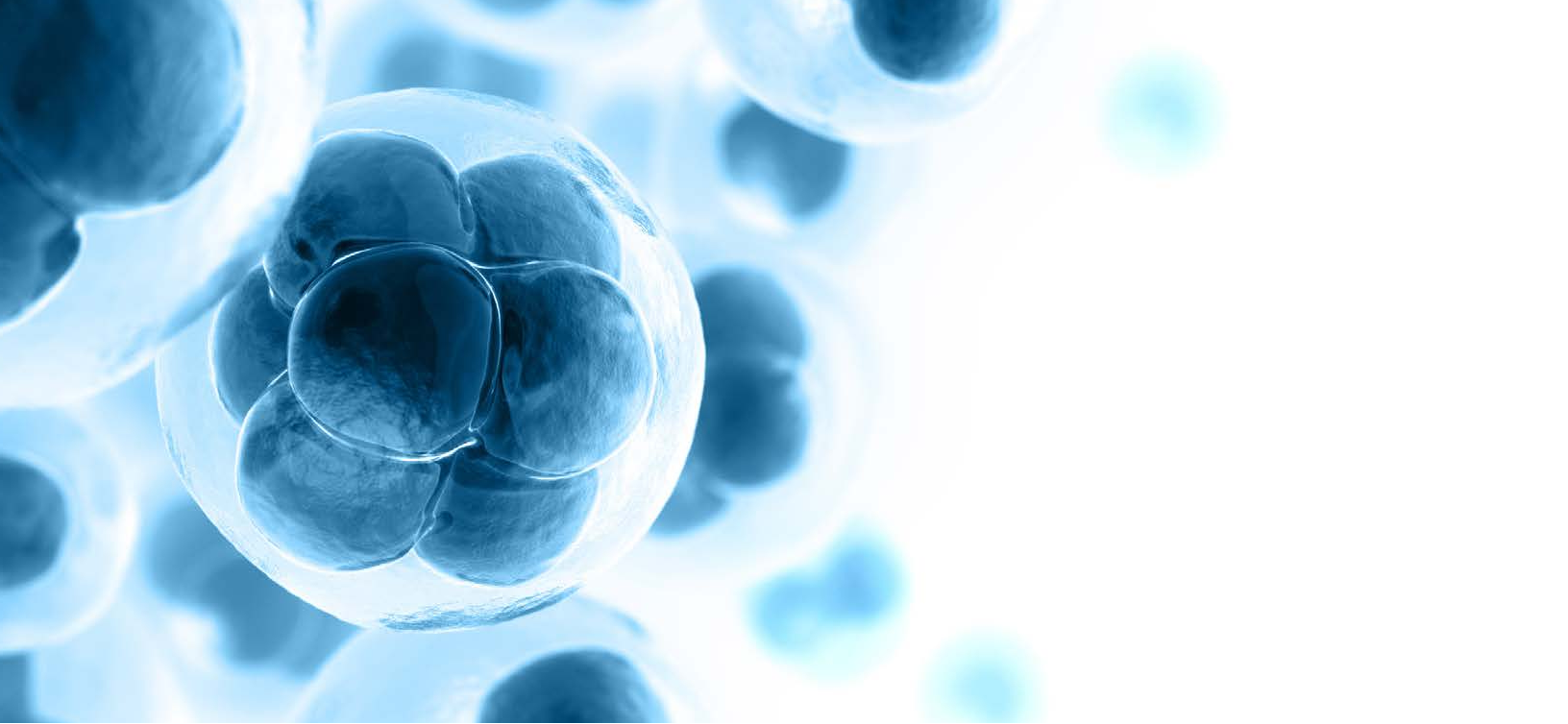
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# Pharma Commercialization: A Deep Dive in Market Access

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The increasing complexity of novel therapeutics has created a tailwind for pharmaceutical research and development spend, buoying the number novel drug approvals and increasing the demand for sophisticated, outsourced commercialization capabilities. In this white paper, we take an in-depth look at market access in the United States, one of the most sought-after subsegments of pharma commercialization. We'll focus on why market access is increasingly important across all stages of the drug development lifecycle, what affects drug pricing and reimbursement decisions, the impact of the Inflation Reduction Act, and other recent trends across the segment.

Houlihan Lokey is a global M&A market leader with dedicated coverage within the pharma commercialization sector, giving us a unique vantage point into key trends across the industry. We are happy to share the insights we've garnered from 22 closed commercialization deals since 2019, and we hope this white paper will provide you with a helpful perspective on market access.

# What Is Market Access?



**As pharmaceutical and biotechnology manufacturers continue to invest heavily in the research and development of novel therapeutics, the life sciences industry has realized a rapid increase in the number of drugs that have been brought to market over the past decade.** The trended increase in approvals has largely been driven by the industry's focus on specialty medicines that address rare diseases and niche patient populations. These novel molecules are increasingly complex, which has placed a premium on successful stakeholder communications that cover a variety of topics across the commercialization continuum. One critical area is the communication of a drug's value to key healthcare stakeholders, in an effort to expand patient access to therapies at equitable prices. In the life sciences community, the process is referred to as market access.

*"The communication of value for complex products, combined with the extremely nuanced healthcare marketplace, emphasizes the essential nature of market access specialists."*

**The primary goal of market access is to ensure patients receive timely, consistent, and affordable access to care at prices that reflect comprehensive negotiations between payors and biopharma manufacturers.** These negotiations on price are rooted in the fact that the value of a drug is not intrinsic but rather determined by the inherent importance of acting in the best interest of the patient, ensuring that they receive access to the best treatments and ultimately lead to improved outcomes. Furthermore, the target is not one singular buyer—as is typical in traditional markets—but rather a group of key stakeholders made up of the healthcare professionals (HCPs) who prescribe the product, the patients who receive the treatment, and the payors who reimburse the patients' claims. The introduction of a new drug can change the course of a patient's disease, resulting in both direct and indirect economic impacts that, when well communicated, can have a great effect on gaining improved reimbursement from payors.

**Market access enables pharmaceutical and biotechnology manufacturers to negotiate reimbursement with payors for specialized products, achieving a favorable market position with an equitable financial profile.** The process seeks to balance the need for optimal pricing and reimbursement, with access to target patient populations. It also outlines funding and prescription procedures required for a drug to be sustainable from a business perspective, while still achieving healthcare's ultimate goal of treating diseases and improving patient outcomes. Achieving the correct balance between all stakeholders encourages continued future growth and catalyzes the research and development of novel, complex therapies.

**The process of negotiating pricing between manufacturers and payors is driven by the appropriate shaping and communication of a product's value.** Before the clinical stage, payor negotiations rely on the development of value stories and analyses that help shape the payors' perception of a product before launch. Throughout the clinical stage, this process transitions to leverage evidence generated by clinical trials, which is increasingly more critical as rare disease treatments (e.g., cell/gene therapy, RNA-based therapeutics, bispecific antibodies, etc.) address smaller, targeted patient populations with little to no previously recorded treatment data. Post-approval, additional evidence is gathered from claims data, patient records, and other real-world data sources that are leveraged to continually inform

stakeholders. Ultimately, the more evidence that manufacturers can provide that corroborates the value of a product to the patient treatment journey, the more likely it becomes that payors provide a positive coverage decision at an optimal price point. The high-value proposition associated with evidence generation further pushes manufacturers to seek market access consultancies that specialize in evidence communication. This trend will continue to increase in prevalence as the market embraces the impact of the Inflation Reduction Act.

Overall, market access is a critical piece of the pharma commercialization process that involves navigating nuanced challenges and barriers to ensure the latest and most effective products are approved, reimbursed, and accessible to target patient populations.

## What Are the Key Aspects of the Market Access Process?

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Market access' overarching purpose is to navigate pricing challenges with payors to ensure a drug is priced at an equitable level that maximizes market potential, balances affordability and access for patients, and ensures sustainability for manufacturers. To achieve this goal, there are several interconnected components of the market access process. We've highlighted a few below:

- **Market Analysis and Launch Strategy:** Provides a comprehensive understanding of the target market (e.g., landscape analysis, patient need analysis, regulatory environment understanding, competitive outlook, etc.), enabling the development of a tailored market access strategy that outlines the most effective pricing, reimbursement, and market entry options.
- **Value Shaping and Demonstration:** Develops and articulates the value story that shapes how payors understand and perceive novel therapeutics. The process includes the creation of comprehensive value stories that shape payor perspectives early in the product's lifecycle. Post-launch, additional evidence is gathered to further supplement initial communications.
- **Pricing and Reimbursement:** Creates a well-defined pricing strategy combined with successful reimbursement negotiating that ensures a product is priced competitively. Accurate pricing balances the need for manufacturer sustainability and affordability for patients and ultimately enhances the overall market potential and product adoption.
- **Stakeholder Engagement:** Builds relationships and establishes collaborations with healthcare professionals, patient advocacy groups, and patients by communicating the product's value proposition, addressing stakeholder concerns, and holding evidence-based discussions. These efforts contribute to a deeper understanding of the target market, enhance support for the product, increase the likelihood of expanded market access, and provide additional backing for payors.
- **Payor Communication:** Distills complex datasets, conveys key product benefits, highlights stakeholder support, and outlines the overall value proposition of the product to payors through effective, engaging communication channels that lead to seamless payor and manufacturer negotiations.
- **Market Entry and Execution:** Implements the market access strategy once regulatory approval has been granted, enabling the availability and adoption of the product within the market. The execution of this plan is done through the selection of distribution channels, management of the supply chain, execution of pricing and reimbursement strategies, and development of patient access programs. Effective market entry and execution will facilitate patient access and optimize market penetration.
- **Monitoring and Adaptation:** Updates the market access strategy as the landscape continuously evolves through the tracking of market data, evaluation of pricing and reimbursement impacts, review of regulatory changes, and implementation of necessary adjustments to the market access approach based on these developments.



## What Are Recent Trends Within Market Access?

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### Increased Pharma R&D Spending on Specialty Medicine That Addresses Rare Diseases for Niche Patient Populations Has Led to Complex Market Access and Pricing Challenges

Pharma manufacturers have increasingly turned their focus to addressing rare diseases with smaller patient populations that have unmet healthcare needs. The increasing complexity of novel therapeutics has led to several market access challenges regarding pricing and reimbursement. The manufacturing of specialty medicines often has higher development costs, evidenced by rising R&D budgets across the life sciences industry, posing a challenge in the balance of patient access and acceptable financial outcomes for manufacturers. These cost challenges often result in higher scrutiny from payors and drive the need for rigorous, evidenced-based analysis that highlights the long-term value of the product compared to alternative treatment options, supporting coverage and reimbursement decisions.

The Orphan Drug Act<sup>(1)</sup> defines rare disease as a condition that affects less than 200,000 people in the United States. This limited patient pool presents unique challenges for market access, with the smaller population making it more difficult to collect supportive data points for payor negotiations and higher price requirements for manufacturer feasibility. Patient population challenges make it crucial for innovative pricing and access solutions (such as value-based pricing) that enhance patient access while mitigating financial risk for payors and manufacturers.

### Demand for Value-Based Pricing Has Risen Exponentially Among Payors and Patients, and Manufacturers Have Embraced This Trend

Value-based pricing is an approach that determines the price of a product based on the value it delivers through clinical effectiveness, patient outcomes, and overall health system benefits. It seeks to align the price of a product with the demonstrated value of the treatment, ensuring it reflects the true worth, while considering cost-effectiveness. With payors and patients demanding that the price of healthcare interventions be aligned with their value and outcomes, manufacturers have needed to adopt a value-based pricing approach to enhance their value propositions.

By aligning the price of products with their proven effectiveness on the patient treatment journey, manufacturers can showcase the value of their products to the market through improved health outcomes, reduced hospitalizations, prescription uplift, and positive clinical data to increase the likelihood of favorable reimbursement decisions and patient access. By accepting patient and payor demands for value-based pricing, products can also achieve greater long-term market sustainability, with manufacturers ensuring that investment in R&D is justified through stronger reimbursement commitments and proven market differentiation for niche products with small patient populations.

(1) GARD, <https://rarediseases.info.nih.gov/about>.

## Increasing Importance of Real-World Evidence (RWE) That Provides Deeper Insights Into Treatment Effectiveness, Improved Patient Outcomes, Speed to Market, and Total Market Access

A goal of all stakeholders throughout the drug manufacturing and commercialization process is to find methods that accelerate drug development and bring advanced, effective treatments to market. One of the keys to achieving this acceleration is providing an abundance of evidence that shows the benefits a product has to the market. Payors are increasingly scrutinizing a product's value as medical treatment costs continue to rise and products become focused on smaller patient populations. RWE is increasingly called upon to understand the clinical and economic value of treatments.

Historically, clinical data has been the key input for evidence generation, but in recent years, RWE has begun to supplement market access communications both pre-launch (through analyses that identify unmet needs, highlight the limitation of other therapies, and evaluate the economic costs of solving those needs) and post-launch, by providing real-time insights into the impact of a product on the patient population through electronic health records, patient data, claims data, and other sources that highlight the product's commercial performance. Across all phases, RWE is increasingly necessary to achieve a successful, optimized market access strategy that garners support from payors.

## Patients Have Shifted From Passive Recipients to Crucial Engagement Targets as Payors and Regulators Look for Patient Perspectives and Patient-Reported Outcomes to Inform Decision-Making

There is a growing recognition within market access of the importance of patient perspectives and their role in the decision-making processes across the healthcare landscape. Patient advocacy groups have seen an increase in influence and are now active stakeholders in the market access process, encouraging improved access to effective treatments, fair pricing for patients, and greater consideration for patient perspectives in pricing and reimbursement discussions. By actively engaging patients in the market access process, manufacturers gain a powerful voice of support in pricing and reimbursement negotiations through valuable insights into the practical challenges patients face in accessing affordable treatments.

Patients are also critical for ensuring accurate evidence collection that supports market access functions. With the rise of digital health, patient reporting is critical to demonstrate the effectiveness, safety, and value of healthcare interventions across treatment journeys. This data provides essential insights into the long-term benefits of a product, helping inform access and decisions in price negotiations. Properly engaging patients is essential in gathering this data, as empowering patients with the proper information on how a potential treatment could impact their health will make them more likely to actively support beneficial market access initiatives.

## The Inflation Reduction Act (IRA) Could Lead to More Pricing Volatility, Specifically at Launch, in Response to Mandatory Rebates

The Inflation Reduction Act of 2022<sup>(2)</sup> alters many crucial aspects of the drug manufacturing and commercialization process, specifically within the Medicare Drug Price Negotiation Program. While the legislation will be phased in over the next six years, and there are still several unknowns with the legislation continuously receiving scrutiny from pharma manufacturers and lawmakers, the IRA has the potential to greatly impact the current drug pricing approach.

(2) KFF, <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>.

With the IRA demanding manufacturers pay rebates if they raise prices faster than inflation, the Congressional Budget Office projects an “increase in launch prices for drugs that are not yet on the market relative to what such prices would be otherwise.” If this is correct, it will fundamentally change market access, as manufacturers may look to gather more evidence and garner more support before launching a drug. This additional time will focus on achieving a higher launch price, given the restrictions on post-launch price increases, ultimately delaying product launches and patient access to treatments.

Overall, the unknowns around how price negotiations will be approached by different government administrations, the potential for legal challenges between now and the implementation of the legislation, and how controls will affect commercial prices mean that the full impact of the law may not be realized in the near term.







## Market Access Landscape

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As the specialization of medicine continues, the requirement for outsourced consultancies with market access expertise has become an essential tool for brand teams. The outsourced market access landscape consists of both full-service pharma commercialization platforms that maintain market access capabilities and specialized consultancies with market access expertise. Below we provide insights into a select few scaled commercialization and market access platforms across the industry:

- **ADVI:** Global consulting firm with a team of technical experts, data scientists, clinicians, product innovators, and payor advisors focused on advancing patient access, accelerating time to reimbursement, and providing business and strategic advice to life science and healthcare innovators, established companies, those that provide care on their behalf, and those that fund them. ADVI is backed by private equity firm Sheridan Capital Partners.
- **Amplify Health:** Deliverer of tailored medical and commercial solutions that scale throughout the drug lifecycle. The company's capabilities include clinical and medical outsourced teams; clinical and medical capability development; companion diagnostic and precision medicine solutions; medical communications; expert engagement; remote and field solutions for patients, payors, and physicians; and strategic and access consulting. Amplify Health is backed by the private equity firm Altamont Capital Partners.
- **BGB Group:** Strategic partner for the healthcare industry, merging science and creativity to deliver specialized services including healthcare advertising, medical education, strategic consulting, and payor marketing. BGB Group seamlessly integrates medical expertise into each piece of business, bringing insight, perspective, and scientific sophistication to every assignment. BGB Group is backed by private equity firm TPG.
- **Clearview Healthcare Partners:** Global strategy consulting firm focused on the life sciences, providing high-value guidance to clients in connection with (i) key decision points in the development and commercialization process and (ii) the management of growth and innovation across clients' entire clinical and commercial portfolios. The company's clients encompass a wide range of enterprises throughout the Big Pharma, biopharma, diagnostics, and medtech sectors. Clearview Healthcare Partners is backed by private equity firm GHQ Capital.
- **Costello Medical:** Global consulting firm that supports the healthcare sector in the analysis, interpretation, and communication of clinical and health economic data. Services include evidence development, value and access, medical communications, health policy and public affairs, medtech, rare diseases, and gene therapy.
- **Envision Pharma:** Global technology-enabled strategic solutions partner for the life sciences industry, working with more than 200 pharma and biotech companies, including 18 of the top 20 pharmaceutical companies.

The company supports clients across the product lifecycle through a comprehensive suite of services and technology solutions, including evidence-based scientific communications and engagement; commercialization and integrated medical consultancy; and Health Economics and Outcomes Research (HEOR)/market access and data analytics capabilities. Envision Pharma is backed by private equity firm GHO Capital.

- **EVERSANA:** Provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver value for patients, prescribers, channel partners, and payors. The company serves more than 500 organizations, including innovative startups and established pharmaceutical companies. EVERSANA is backed by private equity firms Water Street Healthcare Partners and JLL Partners.
- **Fingerpaint Group:** Integrated collective of healthcare companies that offer commercialization solutions spanning the full product lifecycle. The company is composed of marketing services, including Fingerpaint, Fingerpaint Multicultural, and Engage, and specialty services such as Fingerpaint Market Access, Leaderboard Branding, MedThink Communications, MedThink SciCom, Parsons Medical Communications, Fingerpaint Medical Communications, and The MYND Group. Fingerpaint Group is backed by private equity firm Knox Lane.
- **Fishawack:** Global commercialization partner for the biopharmaceutical, medical technology, and wellness industries. Established in 2001, the company's 1,300+ healthcare experts combine their knowledge and expertise across four core disciplines: medical; marketing; policy, value, evidence, and access; and consulting. Fishawack is backed by private equity firm Bridgepoint.
- **Genesis Research:** International HEOR and RWE research organization that supports the life sciences industry through value and access services. As a leader in evidence strategy, generation, and communication, the company also supports pharmaceutical and biotech clients with tech-enabled, dedicated partnerships delivered via an engagement model that enables life sciences companies to address complex needs quickly and comprehensively with timeliness and quality. Genesis Research is backed by private equity firm GHO Capital.
- **Inizio:** Strategic partner for companies in health and life sciences. Connecting a full suite of advisory, medical, marketing, communications, and patient and stakeholder engagement services across the lifecycle of a drug, the company supports its partners from initial assessment to loss of exclusivity. Inizio is backed by private equity firm Clayton Dubilier & Rice.
- **Lockwood:** Scientifically focused firm that communicates clinical and therapeutic advances to every type of medical expert, healthcare practitioner, and decision-maker. For the ultimate benefit of patients, Lockwood helps clients advance their objectives in a world of new regulations, business models, payment approaches, technologies, roles, and work practices. Lockwood maintains extensive experience in oncology, rare diseases, and all major therapeutic areas, along with highly specialized knowledge in biologics, devices, and diagnostics. Lockwood is backed by private equity firm Ares Management.
- **Lumaniy:** Transformative commercialization company that seeks to cut through complex situations and deliver healthcare outcomes that accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, the company transforms data and information into real-world insights and evidence that support the commercialization lifecycle. Lumaniy is backed by private equity firm Arsenal Capital Partners.
- **OPEN Health:** Provider of evidence generation and data communication services that leverage the company's scientific knowledge. Its evidence-based approach delivers best-in-class scientific communications, HEOR, and market access services to an ever-increasing audience, with OPEN Health serving more than 170 life sciences customers, including 48 of the top 50 pharmaceutical companies. OPEN Health is backed by private equity firm Astorg.

- **Oxford PharmaGenesis:** Independent, global health science consultancy providing communications services to the healthcare industry, professional societies, and patient groups. Founded in 1998, Oxford PharmaGenesis is a preferred supplier to eight of the top 10 global pharmaceutical companies and has a staff of more than 500 individuals across offices in the U.K., U.S., and Australia.
- **Petauri Health:** Full-service hybrid agency-consultancy that empowers life science companies to effectively engage with health system and payor customers. With market access expertise, deep relationships, and connections that span the healthcare ecosystem, the company is positioned to understand its clients' customers and design impactful market access solutions. Petauri Health is backed by private equity firm Oak Hill Capital.
- **Precision Value & Health:** Platform that brings specialized expertise to all phases of the commercialization process. With teams utilizing data-driven evidence and leveraging real-world experience, Precision Value & Health partners with life sciences companies to establish and communicate the clinical, economic, and humanistic value of innovative therapies through global pricing and market access strategy, investor relations and ESG solutions, healthcare communications and marketing, evidence generation and strategy, medical and scientific communications, managed-markets marketing, and data-driven analytics and insights. Precision Value & Health is part of Precision Medicine Group, backed by private equity firm Blackstone.
- **Prime Global:** Global medical communications and market access group that provides the world's leading biotech, pharmaceutical, and healthcare businesses with full-service professional communications, including healthcare strategy and consultancy, scientific and medical communications, consumer health, patient-integrated science, and market access. Prime Global employs more than 250 people and has offices in the U.K., the U.S., Germany, and New Zealand. Prime Global is backed by private equity firm Levine Leichtman Capital Partners.
- **Red Nucleus:** Scientifically focused commercialization platform to the life sciences industry with an ability to solve complex challenges from molecule to market. The company offers key capabilities across four distinct business units: scientific services and advisory, market access and commercialization services, medical communications, and learning and development. Red Nucleus is backed by private equity firm The Riverside Company.
- **Syneos Health:** Fully integrated biopharmaceutical solutions organization built to accelerate customer success through clinical, medical affairs, and commercial insights. With offices across more than 110 countries, the company provides a deep understanding of patient and HCP behaviors as well as market dynamics. Syneos Health is currently publicly traded on Nasdaq, but has agreed to be acquired by a private investment consortium of Elliott Investment Management, Patient Square Capital, and Veritas Capital. The transaction is expected to close in the second half of 2023, subject to shareholder and regulatory approvals.
- **Trinity Life Sciences:** Strategic commercialization partner, providing evidence-based solutions for life sciences. The company provides powerful tools and data-driven insights that enhance the commercialization process. The company's range of products and solutions includes evidence, access, and pricing; sales and marketing benchmarking; strategic advisory; advanced analytics; and market insights. Trinity Life Sciences is backed by private equity firm Kohlberg & Company.



# Contacts

Please reach out to the Houlihan Lokey Pharma Commercialization Services team to discuss the comprehensive market access landscape, including market access specialists as well as precedent transactions in the market access segment.



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## Selected Transaction Experience

 a portfolio company of <b>OAK HILL CAPITAL</b> has acquired  Buyside Advisor	 has made a strategic investment in  Buyside Advisor	 has received an investment from <b>KNOX-LANE</b> Sellside Advisor	 a portfolio company of <b>astorg</b> has acquired  Buyside Advisor	 has received an investment from  Sellside Advisor	 a portfolio company of  has acquired  a subsidiary of <b>inovation</b> Buyside Advisor	 a portfolio company of <b>GraphiteCapital</b> has been acquired by <b>Lockwood</b> a portfolio company of <b>ARES</b> Sellside Advisor	 a portfolio company of <b>AMULET CAPITAL</b> has been acquired by <b>astorg</b> Sellside Advisor
 has acquired <b>medicalknowledgeGROUP</b> a portfolio company of  Buyside Advisor	 has been acquired by <b>EVERSANA</b> a portfolio company of  or <b>WATER STREET</b> Sellside Advisor	 has received an investment from <b>ARES</b> Sellside Advisor	 a portfolio company of <b>RIH Equity Partners</b> has received an investment from  Sellside Advisor	 has received an investment from <b>TPG</b> Sellside Advisor	 has received an investment from <b>KNOX-LANE</b> Sellside Advisor	 has acquired <b>HUNTSMITH</b> 1875 Million Buyside Advisor	 a portfolio company of <b>MOUNTAINGATE</b> has been acquired by <b>NIMC</b> NEW MOUNTAIN CAPITAL LLC Sellside Advisor

Tombstones included herein represent transactions closed from 2020 forward.

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