

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the [REDACTED], the [REDACTED], [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

SOURCES OF INFORMATION

We commissioned Frost & Sullivan, an independent consulting firm, to conduct a detailed research on the ADC and broader bioconjugate markets and the outsourcing services industry. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries. We have agreed to pay a fee of RMB550,000 to Frost & Sullivan in connection with the preparation of the Frost & Sullivan Report. We have extracted certain information from the Frost & Sullivan Report in this section, as well as in the sections headed “Summary,” “Risk Factors,” “Business,” “Financial Information” and elsewhere in this document to provide our potential [REDACTED] with a more comprehensive presentation of the industry in which we operate.

During the preparation of the Frost & Sullivan Report, Frost & Sullivan performed both primary and secondary research, and obtained knowledge, statistics, information and industry insights on the industry trends of the global ADC and broader bioconjugate markets and the global ADC outsourcing services market, as well as major players in the ADC outsourcing services industry. Primary research involved discussing the status of the industry with leading industry participants and industry experts. Secondary research involved reviewing annual reports of public companies, independent research reports and Frost & Sullivan’s proprietary databases. The Frost & Sullivan Report was compiled based on the assumptions that (i) the global economies, in particular, the United States and China, are likely to maintain a steady rate of growth in the next decade; (ii) the key growth drivers mentioned in this section are likely to drive the growth of the global ADC and broader bioconjugate markets and the ADC outsourcing market from 2022 to 2030, and (iii) there is no force majeure or industry regulation that affects any of such markets dramatically or fundamentally. For the avoidance of doubt, the impacts of COVID-19 have been considered when compiling information in the Frost & Sullivan Report. In this section, Frost & Sullivan presents historical market information for five years (i.e., from 2018 to 2022) which is longer than the Track Record Period and, we believe, is a more accurate reflection of the trends that affect our markets.

Our Directors confirmed that, after taking reasonable care, as of the Latest Practicable Date, there had been no adverse change in the market information set forth herein since the date on which the Frost & Sullivan Report was issued.

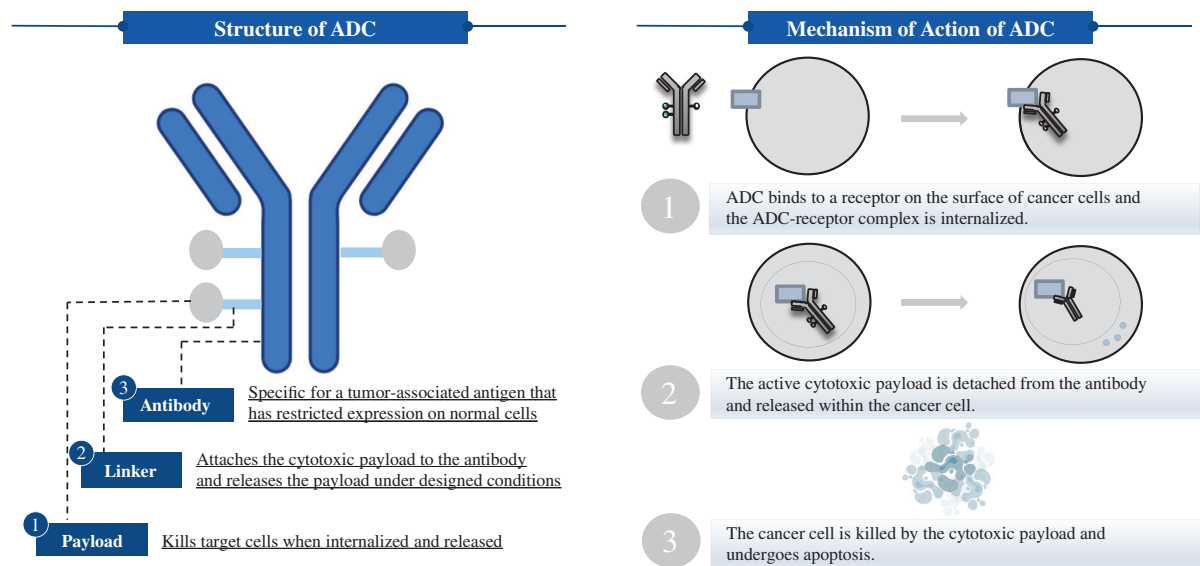
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OVERVIEW OF ADC AND BROADER BIOCONJUGATE MARKETS

Antibody Drug Conjugates (“ADCs”)

ADC is an innovative biologics drug modality composed of a biologic component (i.e., the antibody) attached to a small molecule drug (i.e., the cytotoxic payload) via a specifically designed linker. A traditional ADC drug utilizes the antibody to bind to the tumor-specific antigen, delivers the payload to the target cancer cell, and then releases the payload to cause cancer cell death. An ADC combines the target selective antibody and highly active cell-killing toxic drug, and has demonstrated the potential of significantly improving therapeutic window, which is the dose range of a drug that provides safe and effective therapy, compared to current standard-of-care therapies.

The following diagram illustrates an ADC’s structure and its mechanism of action (“MoA”).



Source: Frost & Sullivan Analysis

Two categories of payloads are frequently utilized among the marketed ADCs: (1) tubulin inhibitors, and (2) DNA damaging agents. With respect to antibodies, the IgG antibody stands as the most widely utilized antibody. When it comes to conjugation methods, there are typically two options commonly used: (i) leveraging stochastic conjugation by targeting existing lysine or cysteine residues through suitable coupling reactions, and (ii) employing site-specific conjugation strategies.

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Overview of Global ADC Market

Following the FDA’s approval of the first ADC, Mylotarg® (gemtuzumab ozogamicin), in 2000, both academic and industrial sectors have dedicated decades of effort towards the development of ADC therapies. In recent years, there have been significant advancements in ADC drug development, such as the emergence of new conjugation technology, optimization of drug-to-antibody ratios (DARs), and improved linker design. Consequently, the field has seen an acceleration in development, leading to an era of explosive growth. For the period from 2019 to 2022, ADCs represent approximately 15.4% of biologics approved by the FDA, according to Frost & Sullivan.

As of June 30, 2023, 15 ADC drugs had received approval worldwide, out of which 11 had been approved since 2018 and 4 have been approved since 2021. Several of these drugs have shown promising clinical benefits and have the potential to become blockbusters. For instance, Enhertu, a groundbreaking treatment for HER2+ cancers, generated revenue exceeding US\$200 million in 2020, its first year on the market after its commercial launch in December 2019. In 2022, three third-generation ADCs generated significant annual sales. Enhertu sales surpassed US\$1.2 billion, Padcev sales reached over US\$750 million, and Trodelvy sales amounted to approximately US\$680 million. These impressive sales figures were achieved in their third year after launch. In addition, 15 to 57 ADC drug candidates have entered clinical trials annually since 2018. As of June, 2023, there were over 500 ongoing clinical trials globally, involving 231 ADC drug candidates, among which, 134, 79 and 18 are currently undergoing phases I, II and III clinical trials, respectively. The flourishing clinical development of ADC drugs has led to the publication of over 100 abstracts related to ADCs at the 2023 American Society of Clinical Oncology (“ASCO”) Annual Meeting.

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Details of 15 Approved ADC Drugs Globally As of June 30, 2023

First Approval Year	Commercial Name	Developer	Indications	Target
2011 (FDA)	Adcetris	Seagen/Takeda	Classical Hodgkin Lymphoma, Systemic Anaplastic Large Cell Lymphoma, Primary Cutaneous Anaplastic Large Cell Lymphoma, Mycosis Fungoides, Peripheral T-Cell Lymphoma,	CD30
2013 (FDA)	Kadcyla	Roche	HER2-Positive Breast Cancer	HER2
2017 (FDA)*	Mylotarg	Pfizer	Acute Myeloid Leukemia	CD33
2017 (FDA)	Besponsa	Pfizer	B-Cell Acute Lymphoblastic Leukemia	CD22
2018 (FDA)	Lumoxiti	AstraZeneca	Hairy Cell Leukemia	CD22
2019 (FDA)	Polivy	Roche	Diffuse Large B-Cell Lymphoma, Large B-Cell Lymphoma	CD79B
2019 (FDA)	Padcev	Seagen/Astellas	Urothelial Carcinoma	NECTIN-4
2019 (FDA)	Enhertu	Daiichi Sankyo/AstraZeneca	HER2-Positive Breast Cancer, HER2 Low Expression Breast Cancer, Gastric Cancer, Non-Small Cell Lung Cancer, Gastroesophageal Junction Cancer	HER2
2020 (FDA)	Trodelyv	Gilead	Triple-Negative Breast Cancer, Urothelial Carcinoma, HR-Positive, HER2-Negative Breast Cancer	TROP-2
2020 (FDA)	Blenrep	GlaxoSmithKline	Multiple Myeloma	BCMA
2020 (PMDA)	Akalux	Rakuten Medical	Head And Neck Cancer	EGFR
2021 (FDA)	Zynlonta	ADC Therapeutics	Diffuse Large B-Cell Lymphoma	CD19
2021 (NMPA)	Aidexi	RemeGen	Urothelial Carcinoma, Gastric Cancer, Gastroesophageal Junction Carcinoma	HER2
2021 (FDA)	Tivdak	Genmab/Seagen	Cervical Cancer	TF
2022 (FDA)	Elahere	ImmunoGen/Huadong Medicine	Ovarian Cancer, Fallopian Tube Cancer And Peritoneal Cancer	FR-A

Source: FDA, NMPA, PMDA, Frost & Sullivan Analysis

Note:

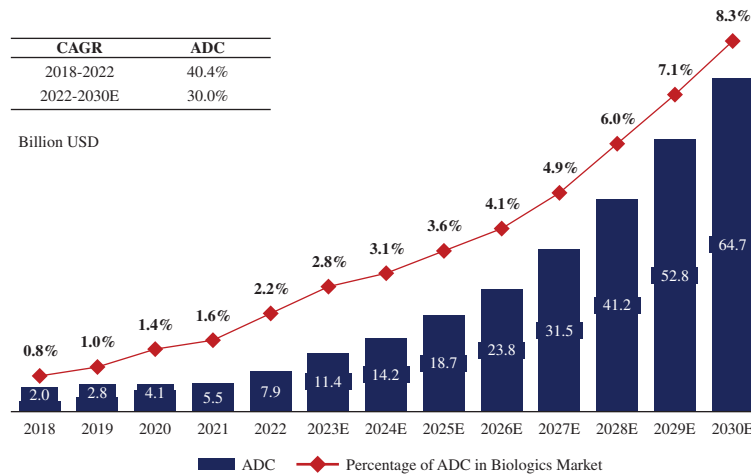
* The Mylotarg from Pfizer was initially approved in 2000, which was subsequently withdrawn from the market in 2010 voluntarily, and was re-approved in 2017.

Global ADC market is poised for substantial growth over the next decade. The global ADC market in 2022 has grown to US\$7.9 billion with a CAGR of 40.4% between 2018 and 2022, and is expected to further grow to US\$64.7 billion in 2030 at a CAGR of 30.0% between 2022 and 2030, according to Frost & Sullivan. The share of ADC drugs in the overall biologics market is expected to increase from 2.2% in 2022 to 8.3% in 2030, according to the same source.

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The following chart sets forth global market size of ADC and its percentage of overall biologics for the period between 2018 and 2030:

Global Market Size of ADC Between 2018 and 2030E

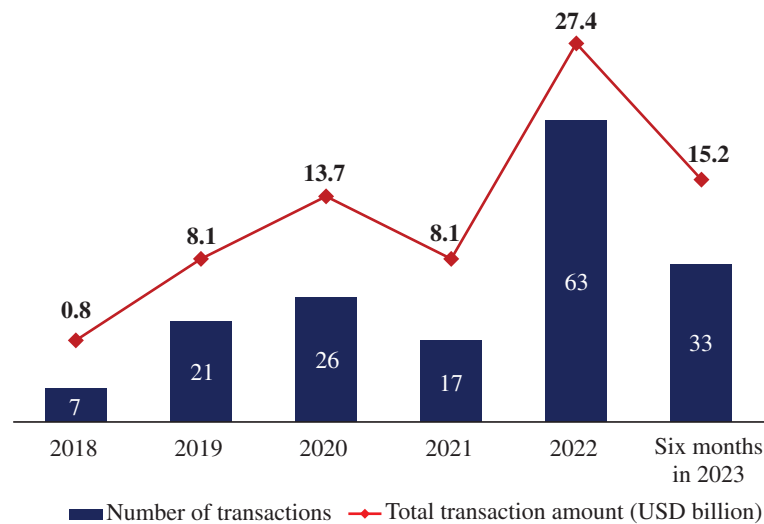


Source: Frost & Sullivan Analysis and Companies' Annual Reports

Furthermore, the commercial potential of ADCs and other bioconjugate drugs has been evidenced by significant acquisition and licensing activities globally. According to Frost & Sullivan, over 100 deals involving ADCs have taken place since 2022. These include the recent acquisition of Seagen, a leading biotech company specializing in developing ADCs for cancer treatment, by Pfizer, for a total consideration of approximately US\$43 billion. The surge in licensing deals for ADCs is driven by the technological developments in ADC, in particular, improvements in ADC platforms, linker technologies and new applications such as combination approaches with immunotherapy and chemotherapy to treat cancer, and profit potential, according to Frost & Sullivan. In 2022, there were a total of 63 ADC licensing deals worldwide, representing a 270% increase compared to the previous year. The reasons of the high transaction amount in 2022 include (1) the signing of a number of mega deals, for instance, Merck and Kelun-Biotech announcing an exclusive license and collaboration agreement for seven investigational ADC candidates in December 2022, where the upfront payment and milestone payments totaling up to US\$9.5 billion, accounting for 35% of the 2022 full year transaction amount; and (2) the sales performance and commercial potential of approved ADC drugs, especially some ADCs with breakthrough designation, drives up the number of deals and transaction amount in 2022. Indeed, the global ADC market increased by 43.6% in 2022 compared to 2021. Enhertu alone generated sales of US\$1,229 million in 2022, representing an 155% increase from the previous year. The chart below illustrates the number of global ADC licensing deals over the past five years. The decrease in the number of transactions and total transaction amount of global ADC licensing deals in 2021 was likely due to the COVID-19 pandemic impacted decision-making on licensing transactions.

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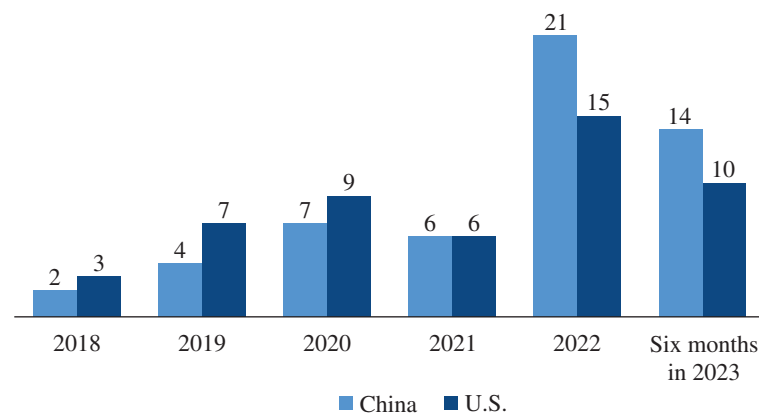
Global ADC Licensing Deals from 2018 to 6M2023



Source: Frost & Sullivan Analysis and Respective Companies’ Public Disclosures

China has emerged as the frontrunner in ADC development, occupying a prominent position in the global market. According to Frost & Sullivan, China has been the primary contributor to ADC out-licensing deals in recent years, with 35 deals between 2022 and June 2023, whereas the United States has contributed 25 deals in the same period. The chart below illustrates the number of ADC out-licensing deals from China and the U.S. over the past five years.

ADC Out-Licensing Deals from China and the U.S. from 2018 to 6M2023



Source: Frost & Sullivan Analysis and Respective Companies’ Public Disclosures

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According to Frost & Sullivan, since 2022 and as of June 30, 2023, there had been 10 China pharmaceutical and biotechnology companies that reached 14 ADC out-licensing deals with overseas partners, totaling US\$22.0 billion. Of these 10 China companies, eight of them are clients of our Company. The following table sets forth out-licensed ADC deals by China-based biotechnology companies with overseas partners since 2022 and as of June 30, 2023.

China Out-licensing ADC Deals with Overseas Partners since 2022

Number	Licensor	Licensee	Asset	Transaction Amount (billion USD)	Date
1	Kelun Biotech	MSD	7 ADCs	9.5	2022.12
2	Bliss Bio	Eisai	BB-1701	2.0	2023.5
3	Duality Biologics	BioNTech	2 ADCs	1.7	2023.4
4	Kelun Biotech	MSD	SKB-264	1.4	2022.5
5	CSPC Megalith Biopharmaceutical	Elevation Oncology	SYSA1801	1.2	2022.7
6	KYM Biosciences	AstraZeneca	CMG901	1.2	2023.2
7	LaNova Medicines	Turning Point	LM-302	1.0	2022.5
8	GeneQuantum	Pyramid Biosciences	GQ1010	1.0	2023.4
9	Kelun Biotech	MSD	SKB-315	0.9	2022.7
10	Evopoint Biosciences	AmMax	AMB-05X	0.9	2023.1
11	CSPC	Corbus	Nectin-4 ADC	0.7	2023.2
12	LaNova Medicines	AstraZeneca	LM-305	0.6	2023.5
13	Multitude Therapeutics	OnCusp Therapeutics	Highly differentiated ADC targeting CDH6	NA	2022.6
14	Biocytogen	ADC therapeutics	3 mAb/BsAb molecules against tumor targets for ADC development	NA	2022.11
Total Transaction Amount (billion USD)				22.1	

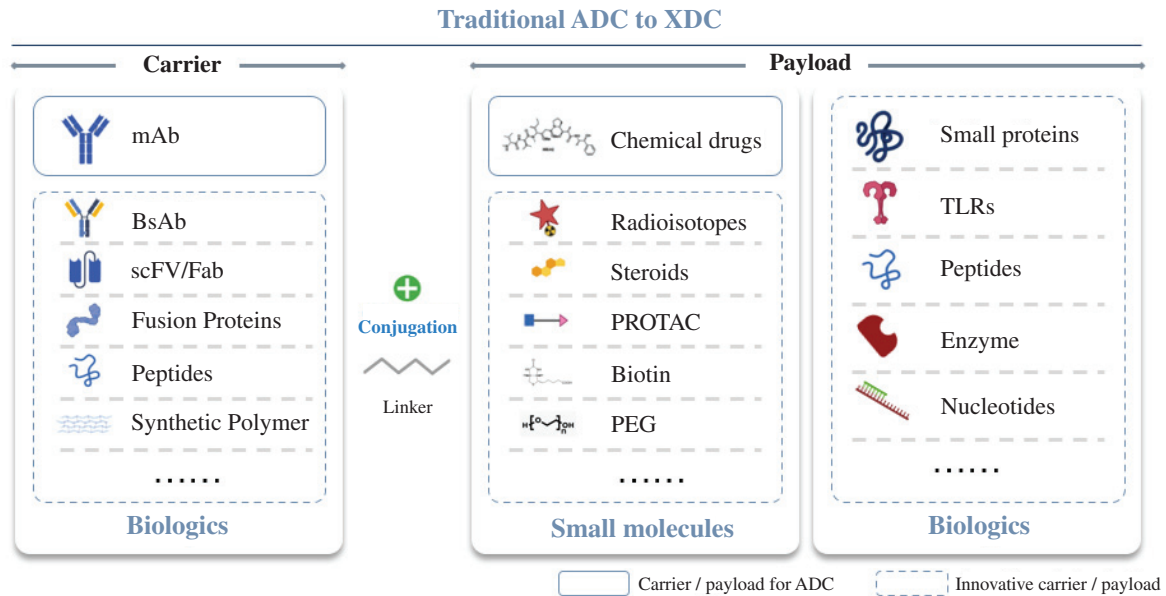
Source: Frost & Sullivan Analysis and Respective Companies' Public Disclosures

Broader bioconjugates — from ADCs to XDCs

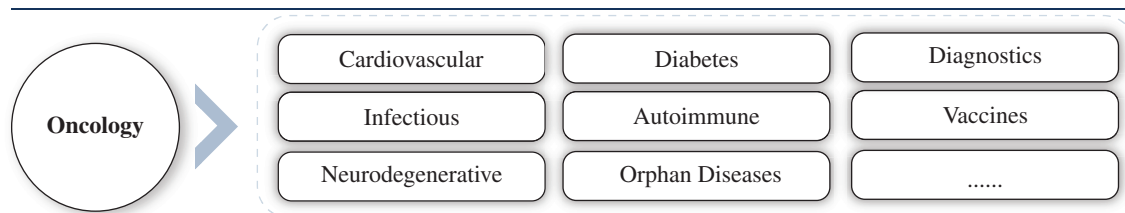
Ongoing research and development endeavors continually explore novel variations in payloads, linkers, antibodies (or alternative carrier categories), and conjugation methods. These efforts have generated a wide range of potential bioconjugates, providing diversified treatment options for various therapeutic applications.

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Bioconjugates are extending beyond ADC by first conjugating various payloads other than chemical drugs with antibody, and then further to conjugate various carriers other than antibody with various payloads (“XDC”). The following chart illustrates transition from traditional ADCs to broader bioconjugates and application expansion. It is worth noting, however, that the development of XDC beyond ADC is still at a preliminary stage, facing uncertainties to progress from traditional ADCs to broader bioconjugates and application expansion in terms of timing, market acceptance and likelihood of obtaining approval.



Indications Beyond Oncology



Source: Literature Review, Frost & Sullivan Analysis

Beyond the traditional cytotoxins, more than seven different types of payloads with novel mechanisms are currently being incorporated into ADC designs. Notably, radionuclide drug conjugates (“RDC”), or radioligand therapy, utilize radioisotopes to emit therapeutic radiation, causing damage to cells, while the target ligand selectively binds to specific markers on target cells. RDCs have demonstrated notable advantages in targeting specificity across various indications and a number of RDCs have achieved strong commercial performance. Novartis has made significant investments in RDC space, with two approved therapeutic RDCs. Pluvicto was approved in 2022 and achieved sales of US\$271 million in its first year of launch. Novartis has invested over US\$7 billion in RDCs since 2017, including the acquisition of Advanced Accelerator Applications (“AAA”) for Lutathera and NetSpot of US\$3.9 billion and Endocyte for Pluvicto of US\$2.1 billion. In March 2023, Novartis further invested US\$1.7 billion in Bicycle for collaboration in novel RDC candidates, further emphasizing the significance of RDCs in the pharmaceutical industry.

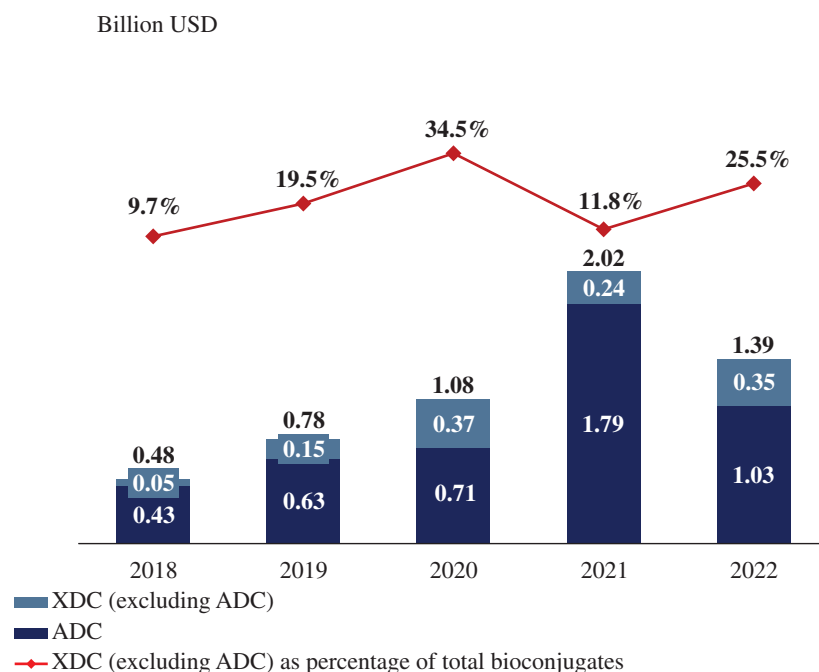
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The IgG antibody stands as the most widely utilized antibody, although researchers are actively working on reducing its size by eliminating the Fc segment. The advancement of bispecific antibody technology has opened up new possibilities for innovation in ADCs. In addition to antibodies, alternative molecules such as peptides, fusion proteins, and synthetic polymers are being investigated as potential carriers. Peptide-drug conjugates (“PDCs”) have emerged as the next generation of targeted therapeutics following ADCs, offering enhanced cell permeability, improved efficacy and reduced off-target toxicity. Compared with antibodies, peptides have the advantages of smaller molecular weight, which leads to enhanced cell permeability and higher feasibility to synthesize and purify, resulting in lower production cost of PDCs. As of June 30, 2023, there were three approved PDCs globally and over 10 PDCs in clinical stage, including two in the Phase III stage. Lutathera, the peptide conjugated to a radioisotope developed by Novartis, received FDA approval in 2018 and achieved sales of US\$471 million in 2022.

PEGylated recombinant protein is also an active ingredient that is increasingly used in XDC. PEGylation of recombinant protein allows for an increased stability of the bioconjugate drug and a prolonged circulation time in the body, therefore potentially contributes to an enhanced overall efficacy.

With the continuous advancements in technology development, XDCs including PDC, RDC, antibody-oligonucleotide conjugates (“AOC”), antiviral Fc conjugates and nanoparticle conjugates, etc. have seen increasing investment in global R&D activities. The following chart shows the global private market financings for XDCs in addition to ADCs in recent years. The decrease in the global private market financings for XDC (excluding ADC) as a percentage of total bioconjugates in 2021 was primarily due to a significant increase in the financing for ADCs. The absolute amount of financings for XDC remained relatively stable, and such a fluctuation in the private market financing for emerging modalities, such as XDC, is not uncommon.

Global Private Market Financings for ADCs and XDCs Between 2018 and 2022



Source: Frost & Sullivan Analysis and Respective Companies’ Public Disclosures

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As conjugation technologies continue to advance, there is also a growing exploration of carriers beyond mAb and payloads beyond small molecular drugs. These broader drug conjugates have the potential to target various aspects of treatment of cancer as well as other therapeutic areas. This diversification further enhances the market potential and contributes to the sustained growth of the industry.

As of June 30, 2023, there are 135 XDC products (excluding ADCs) undergoing clinical trials worldwide. Among them, 65 are in Phase II, while 56 are in Phase I and 14 are in Phase III, including 12 RDC candidates in Phase III, according to Frost & Sullivan. As of the same date, there are 98 RDC projects and 17 PDC projects in clinical stage, as well as three FDA-approved therapeutic RDCs. A significant number of XDC products in clinical development are focused on emerging targets, showcasing the considerable potential of XDCs in offering expanded treatment options. It is anticipated that 17 XDCs (excluding ADCs) will receive approval within the next five years, according to Frost & Sullivan. Although we have witnessed ongoing research and development endeavors continually explore broader bioconjugates, ADCs still form a substantial portion of the overall XDC market. There are very limited number of XDCs (other than ADC) approved globally and no XDCs (other than ADC) approved in China, according to Frost & Sullivan. As noted previously, over majority of XDC products (other than ADC) are still in pre-clinical and clinical stages.

Major trends and growth driver of global ADC market

ADC technology has evolved significantly since the development of the first-generation ADCs. The introduction of site-specific conjugation technology has contributed significantly to the third generation of ADCs. This advancement has allowed the production of homogenous ADCs with well-defined DARs. As a result, these ADCs exhibit the desired cytotoxicity and reduce off-target toxicity. Furthermore, the use of fully humanized antibodies, as opposed to chimeric antibodies, in the third generation helps mitigate immunogenicity concerns. This switch to fully humanized antibodies enhances the overall safety and effectiveness of ADCs. Highly potent payloads are adopted in the third generation ADCs, which further improve efficacy. Additionally, ADCs with homogenous DARs offer improved pharmacokinetics, ensuring optimal drug delivery and distribution throughout the body.

The global ADC market will continue to advance driven by the following factors:

- ***Advances in ADC design and conjugation strategies*** — Continued research in ADC technology and cancer biology is anticipated to fuel the exploration of innovative targets, payload molecules, linker designs, and conjugation strategies. This pursuit holds the potential to develop new ADC designs that enhance therapeutic efficacy and address toxicity concerns associated with existing ADCs available in the market.
- ***Expansion of applications and treatment lines*** — The progress in ADC technologies is projected to lead to a wider array of potential targets and applications, extending beyond oncology to include other therapeutic areas. It is anticipated that around 30 ADCs will receive approval within the next five years globally, covering applications such as cancers, autoimmune diseases, diabetes, cardiovascular diseases, and genetic diseases. ADCs are also expected to enter earlier treatment lines and expand into the early stages of cancers.

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- ***Combination with other treatment modalities*** — The mechanisms of action of ADCs have the potential to synergize with other treatment modalities, resulting in enhanced tumor cell eradication. Therefore, ADC is being actively studied in preclinical activities and clinical trials in combination with other anticancer agents including chemotherapy, molecularly targeted drugs, and immunotherapy in recent years. With the extensive efforts currently underway, it is believed that the ADC-based combination therapy holds promising prospects in the future. For example, the combination of ADC and immunotherapy has the potential to become the primary approach in immunotherapy. Nearly half of the current combination therapies involving immunotherapy and chemotherapy could be replaced by immunotherapy combined with ADC, according to Frost & Sullivan.

Challenges in ADC Discovery and Development Process

The discovery, development and manufacturing of ADC require an interdisciplinary expertise in both biologics and small molecule compounds, as well as a deep understanding of complex supply chain management.

Key challenges in ADC discovery, development, and manufacturing process involve but not limited to following and oftentimes are intertwined:

- ***Challenging ADC design and discovery conjugation scenarios*** — Achieving success in discovering and generating stable antibodies and payload-linkers of high purity demands interdisciplinary expertise. When venturing into conjugation discovery, it becomes crucial to extensively explore different conjugation methods, especially when working with less stable antibodies or highly hydrophobic payload-linkers. Additionally, a considerable level of expertise is required to align specific desired profiles, such as the desired DAR and drug load distribution. Furthermore, versatile analytical characterization methods are essential due to the involvement of diverse molecule types in each study.
- ***Developability assessment for seamless transition to CMC*** — When considering novel biologics as a modality, it becomes crucial to conduct a developability assessment to validate the selection of a lead candidate for subsequent preclinical studies. Before progressing to the CMC process, a substantial amount of time and resources may be required to verify the conjugability and stability of the lead molecule through thorough physicochemical and developability assessments.
- ***Complexity on conjugation process optimization and formulation development*** — Parameters such as DAR and heterogeneity (drug load distribution) are key in the conjugation process development, as they directly influence the stability and quality of the bioconjugates. The formulation development process becomes intricate as it involves the formulation of both the antibody intermediate and ADC drug substance and drug products. This necessitates the adoption of complex analytical method development and product characterization, which often requires double the effort compared to working solely with antibodies. Achieving proficiency in process development, formulation development, and analytical method development demands a high level of expertise. Ensuring process efficiency and consistency is also of utmost importance in this context.
- ***Handling of high potent compounds*** — The requirement for specialized facilities, experienced staff, and substantial investments in environmental health and safety (“EHS”) compliance in handling highly potent compounds during the development and manufacturing process result in high outsourcing demand, because few companies possess these capabilities in-house.

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- **Complex supply chain management** — To produce various components of ADCs and manage the manufacturing of ADC drug substances and final drug products, multiple manufacturing facilities for both biologics and small molecule drugs are typically required. The complexity of the supply chain management requires in-depth execution expertise and all-rounded facilities. The geographical proximity of these facilities becomes a significant distinguishing factor, as it enables better quality assurance and cost efficiency by minimizing logistical challenges.
- **Multiple outsourcing service providers required and fragmented supplier network** — Considering all the challenges in each discovery and development steps of ADC development, outsourcing has become a natural strategy for pharmaceutical and biotechnology companies. Despite strong outsourcing demands, most outsourcing service providers are only capable of handling specific segments of the process due to the interdisciplinary nature of antibody and payload-linker discovery, complex transition to CMC and multiple facilities required for development and manufacturing. Consequently, completing the full discovery and development process usually entails engaging multiple outsourcing service providers, which resulted in long development life cycle, potential delays and disruptions in the supply chain and potential loss of accountability when transitioning between outsourcing service providers.

For a typical ADC project, antibody, payload-linker, conjugation process development and formulation are moving forward in parallel, and highly dependent on each other. As ADCs are complex molecules, which require clean room biologic and high containment cytotoxic facilities for safe handling, most companies may find it challenging and even economically unviable to manage every aspect of the entire ADC development process. Hence, outsourcing has emerged as a preferred business strategy in this domain.

OVERVIEW OF GLOBAL ADC OUTSOURCING SERVICES MARKET

Overview of key process and value chain of ADC outsourcing services market

ADC outsourcing services cover every stage of the ADC development process, starting from discovery and extending to commercial manufacturing. The intricate and highly technical nature of ADC development has led the majority of pharmaceutical and biotech companies to rely on outsourcing partners for ADC development.

- **Discovery** — The process of ADC discovery, leading to the identification of a preclinical ADC drug candidate with desired properties, involves six crucial steps. These steps encompass: (1) target selection, (2) discovery of antibody intermediate for bioconjugate, (3) payload-linker discovery chemistry, (4) conjugation discovery, (5) physicochemical characterization and developability discovery, (6) *in vitro* and *in vivo* bio-function activity studies.
- **Development** — During the development phase, various activities are undertaken to optimize ADC's production to ensure manufacturing consistency and successful scale-up. This includes optimizing the antibody expression conditions and purification processes, conducting payload-linker medicinal chemistry analysis and optimization, developing the payload-linker synthesis process, optimizing the conjugation process, formulating and developing the drug product (“DP”), non-GMP manufacturing, conducting IND-enabling toxicity studies, preparing the CMC dossier, and providing regulatory support until the drug candidate receives approval from regulatory authorities.

Due to the complex nature of the development process and the stringent quality control requirements, it is uncommon to switch outsourcing service providers after this stage, if the chosen outsourcing service provider offers a comprehensive range of services spanning development and manufacturing.

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- Manufacturing** — Manufacturing services encompass the production of all components necessary for ADCs, including manufacturing antibody intermediates specifically tailored for ADCs. This also entails manufacturing payload-linkers, ADC drug substances, and ADC drug products in various scales and forms to meet the clinical and commercialization needs of customers, which needs to comply with requirements of FDA, the NMPA, the EMA and other regulatory agencies.

According to Frost & Sullivan, the global outsourcing rate for ADC discovery, development and manufacturing has reached approximately 70%, surpassing the 34% outsourcing rate observed for overall biologics by the end of 2022.

It is noteworthy that out of the 15 globally approved ADC drugs, 13 have been manufactured by outsourcing service providers, with the majority of them being outsourced to multiple outsourcing service providers. The following table illustrates an overview of global approved ADC outsourcing manufacturing:

Approved ADC Globally and Outsourcing Status

Drug Name	Company	Outsourcing Status	Whether Outsourced to Multiple Suppliers
Mylotarg	Pfizer	N	–
Adcetris	Seagen/Takeda	Y	Y
Kadcyla	Roche	Y	Y
Besponsa	Pfizer	N	–
Lumoxiti	AstraZeneca	Y	Y
Polivy	Roche	Y	N
Padcev	Seagen/Astellas	Y	Y
Enhertu	Daiichi Sankyo/ AstraZeneca	Y	Y
Trodelvy	Gilead	Y	Y
Blenrep	GlaxoSmithKline	Y	Y
Akalux	Rakuten Medical	Y	NA
Zynlonta	ADC Therapeutics	Y	Y
Disitamab vedotin	RemeGen	Y	NA
Tivdak	Genmab/Seagen	Y	N
Elahere	ImmunoGen/ Huadong Medicine	Y	NA

Source: Frost & Sullivan Analysis, European Medicines Agency (“EMA”)

Note: “NA” means information not publicly available.

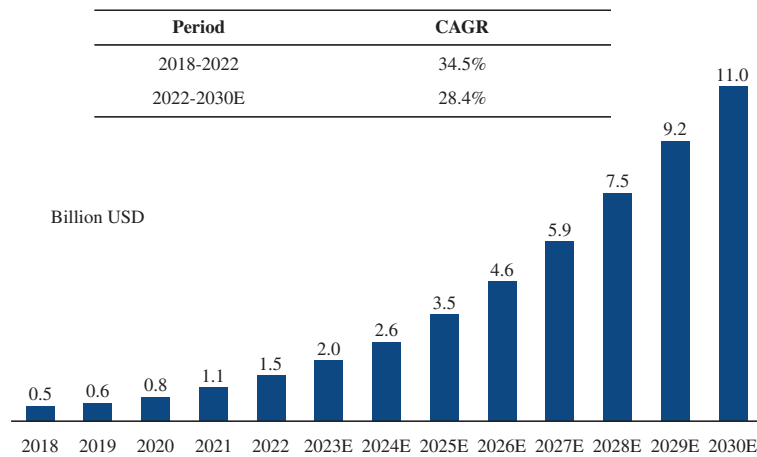
Global ADC outsourcing services market

The global market for ADC outsourcing services reached a value of US\$1.5 billion in 2022, exhibiting a CAGR of 34.5% between 2018 and 2022. This growth outpaced the overall biologics outsourcing services market, which had a CAGR of 21.8% during the same period. It is expected that the global ADC outsourcing services market will expand significantly to reach US\$11.0 billion by 2030, with a CAGR of 28.4% from 2022 to 2030.

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The following chart sets forth global ADC outsourcing services market size between 2018 and 2030.

Global ADC Outsourcing Services Market Size Between 2018 and 2030E



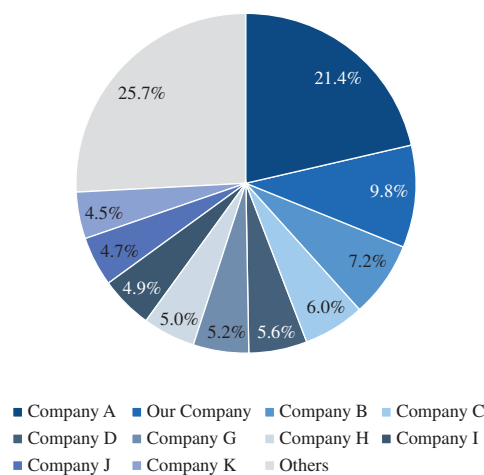
Source: Frost & Sullivan Analysis and Company Annual Reports

Competitive landscape of Global ADC outsourcing services market

The global market for ADC outsourcing services exhibits a relatively concentrated landscape, with the top 5 and top 10 players collectively holding a market share of 50.0% and 74.3% in 2022 in terms of revenue, respectively.

In terms of revenue in 2022, our Company ranked the second in the global ADC outsourcing service market with a market share of approximately 9.8%, according to Frost & Sullivan. The largest player has approximately 21.4% market share measured by revenue in 2022. The following pie chart shows the market shares of top players in the global ADC outsourcing service market in terms of revenue in 2022:

Global Competitive Landscape (by Revenue) in 2022



Source: Frost & Sullivan Analysis and Company Annual Reports

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The following table sets forth further details of top ten players in the global ADC outsourcing service market in terms of revenue in 2022.

Certain Details of Top 10 Global ADC Outsourcing Service Players

Company	Geographical presence			Revenue, million USD	Market share
	mAb	Payload-Linker	Conjugation		
Company A	Tuas (Singapore) / Slough (UK)	Visp (Switzerland)	Visp (Switzerland)	319.0	21.4%
 XDC The ADC Conjugation Leader	Shanghai (China), Wuxi (China)	Changzhou (China) (Wuxi (China) under construction, to commence operation by 2023)	Wuxi (China)	146.0	9.8%
Company B	Martillac (France)	Madison, Wisconsin (US)	St. Louis, Missouri (US)	107.5	7.2%
Company C	N/A	France	France	89.5	6.0%
Company D	Worcester (US)	Ireland, Chicago (US)	Chicago (US), Worcester (US)	83.0	5.6%
Company G	Latina (Italy)	Latina (Italy)	Latina (Italy)	78.0	5.2%
Company H	Wisconsin (US)	N/A	California (US)	75.0	5.0%
Company I	N/A	India and US	Grangemouth (UK)	72.3	4.9%
Company J	Teesside (UK)/ North Carolina (USA)	N/A	N/A	70.0	4.7%
Company K*	N/A	N/A	N/A	67.3	4.5%

Notes:

- All services performed by our Company are conducted in facilities located within 1-2 hours of driving distance.
- Company A is a multinational CDMO company that offers development and manufacturing services for fine chemicals, advanced intermediates, active pharmaceutical ingredients (“APIs”), biologics and functional ingredients. Company A is a public company with decades of operations and headquartered in Switzerland.
- Company B is the life science business unit of a global science and technology company. It has CDMO expertise in the development and manufacturing of highly potent APIs, linkers and monoclonal antibodies for both clinical and commercial use. The parent company of Company B is a public company with decades of operations and is headquartered in Germany. Company B is a private company established less than ten years ago and headquartered in the United States.
- Company C is a multinational company specialized in the development and upscaling of complex API production processes, as well as in the production of small molecule APIs for generic industry. Company C was a private company formed recently and headquartered in Germany.
- Company D is a multinational biopharmaceutical company with a business unit focusing on CDMO services. Its capabilities includes development and manufacture of biologics and small molecule APIs as well as drug product services. Company D is a public company established ten years ago and headquartered in the United States.


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6. Company G is a CDMO service provider focusing on the development and manufacturing of oncology drugs with high potency and cytotoxic characteristics for the pharmaceuticals industry. Company G is a private company with decades of operations and headquartered in Italy.
7. Company H is a CDMO service provider with expertise in development sciences, delivery technologies, and multi-modality manufacturing for the pharmaceutical industry. Company H is a public company with decades of operations and headquartered in the United States.
8. Company I is a multinational CDMO service provider offering services including drug discovery solutions, process & pharmaceutical development services, clinical trial supplies, commercial supply of APIs, and finished dosage forms. Company I is a public company with decades of operations and headquartered in India.
9. Company J is a CDMO service provider providing process development and cGMP production in cell culture, microbial fermentation and gene therapies for pharmaceutical companies. Company J is a private company formed more than ten years ago and headquartered in the United States. The parent company of Company J is a public company.
10. *Company K only provides drug product services for ADC products. Company K is a global CDMO service provider providing scientific expertise, sterile contract manufacturing solutions, parenteral delivery systems, and customized support services for pharmaceutical companies. Company K is a public company with more than ninety years of operations and headquartered in the United States.

Source: Frost & Sullivan Analysis; Respective Companies’ Public Filings/Disclosures

The following table sets forth further details of top three players in the China ADC outsourcing service market in terms of revenue in 2022.

Certain Details of Top 3 China ADC Outsourcing Service Players

Company	ADC dedicated Process			Full spectrum of ADC production facilities located within 1-2 hours driving	Revenue, million RMB	Market share in China
	R	D	M			
 XDC	Y	Y	Y	Y	982.6	69.5%
Company E	N	Y	Y	Y ¹	117.8	8.3%
Company F	N	Y	Y	Y ²	32.1	2.3%

Notes:


1. ADC production facilities locate in Yantai, China.
2. ADC production facilities locate in Suzhou, China. R: Research; D: Development, M: Manufacture.
3. Company E is a China-based company that provides CDMO services primarily for biologics including antibodies and antibody-drug conjugates. Company E is a private company established ten years ago and headquartered in China.
4. Company F is a China-based biopharmaceutical company that is dedicated to developing and commercializing oncology drugs. It also provides innovative drug CDMO services for pharmaceuticals. Company F is a public company with more than a decade of operations and headquartered in China.

Source: Companies’ Official Websites and Disclosures, Annual Reports, Frost & Sullivan Analysis

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In addition, our Company stands out as the sole global player offering dedicated full-spectrum capabilities throughout the entire discovery, development, and manufacturing process of ADCs. The following table sets forth a comprehensive comparison of capabilities of top global ADC outsourcing service players as of June 30, 2023.

Comparison of Capabilities of Top Global ADC Outsourcing Service Players

Company	Capabilities				ADC Dedicated Process			Full spectrum of ADC production facilities located within 1-2 hours driving
	mAb	Payload-linker	Conjugation	DP (Drug product)	R	D	M	
 XDC	√	√	√	√	√	√	√	Yes
Company A	√	√	√	√		√	√	No
Company B	√	√	√			√	√	No
Company C		√	√			√	√	No
Company D	√	√	√	√		√	√	No
Company G	√	√	√	√		√	√	Yes
Company H	√		√	√		√	√	No
Company I		√	√	√	√	√	√	No
Company J	√			√		√	√	No
Company K				√		√	√	No

Source: Frost & Sullivan Analysis; Respective Companies’ Public Filings/Disclosures

Following the global trend of high demand of ADC outsourcing services, China ADC outsourcing services market will continue its upward trajectory, reaching an estimated value of RMB\$16.5 billion by 2030, with a CAGR of 35.9% from 2022 to 2030. Our Company holds the No.1 position in China’s ADC

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outsourcing services market in both revenue and the number of integrated projects for ADCs and other bioconjugates in 2022. Our Company’s market leading position is highlighted by a significant market share of approximately 69.5% by revenue for 2022 in the China market.

It is likely that as the ADC industry continues to grow, CRDMO companies currently providing payloads/payload-linkers components or antibody components for ADC would expand their capabilities to provide full spectrum ADC CRDMO services and compete with the Company. However, as discussed in greater detail below, new players looking to tap into the full-spectrum ADC outsourcing services market would need to overcome the entry barriers and accumulate interdisciplinary know-how and capabilities that span across biologics, small molecules and conjugations. It takes great efforts for biologics focused outsourcing service providers to master chemical drugs capabilities and expertise for payload-linkers, and vice versa. In addition, with years of cultivation of client relationship and collaboration, market leading players such as our Company have established a solid and royal client base. Accordingly, CRDMO companies currently focusing on providing only payload-linkers components or antibody components for ADC would need to re-establish their credentials and expertises to persuade the client to change their services provider.

Entry barriers and key success factors in the ADC outsourcing services market

The following factors present entry barriers and key success factors that contribute to the dynamic and competitive ADC outsourcing services market.

- ***Research, development and manufacturing expertise across modalities*** — The development of ADCs requires interdisciplinary capabilities and expertise in both biologics and small molecules, which requires seamless coordination among different steps of development. To advance an ADC project from DNA synthesis to IND, the industry timeline typically ranges from 24 to 30 months involving different outsourcing service providers. Companies with integrated comprehensive capabilities dedicated for ADC development enjoy unparalleled advantages by saving time and costs while ensuring superior quality control.
- ***Facilities with integrated capabilities*** — As ADC development and manufacturing requires specialized facilities for different components and conjugation process, suppliers with integrated capabilities in both biologics and small molecules, across the supply chain from discovery to manufacturing are key in ADC outsourcing services. Companies operating facilities with integrated capabilities can effectively reduce logistical challenges, shorten ADC production time with assured quality and reduced cost. In addition, as a matter of practice, there is a trend of domestic regulations that strongly favor centralized manufacturing of biologics drugs, which in term is enabled by proximately located facilities with integrated capabilities.
- ***Comprehensive technical capabilities and capacity to support diversified needs*** — Players with integrated and comprehensive technology toolbox, characterized by extensive experience in a myriad of bioconjugates and their components, conjugation technologies, as well as scale-up capabilities can effectively deliver quality results efficiently for the discovery and development process. Moreover, world-class laboratories and GMP manufacturing facilities are necessary to handle highly toxic compounds safely, including but not limited to the facilities designed to handle Occupational Exposure Band 5 (“**OEB 5**”) substances, ranging from milligrams to kilograms.

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- ***Highly regulated process requiring proven quality track record*** — The strict and complex quality assurance standards mandated by regulatory bodies, coupled with the protracted approval process, have elevated barriers to entry for new entrants in the market. Customers, especially global leading pharmaceutical companies, would prefer to partner with outsourcing players that possess GMP quality track records and advanced quality control systems. Only the most exceptional players are able to achieve a proven track record in meeting customer specifications and applicable regulatory standards, and as a result to secure long-term contracts with existing clients and attract new ones.

The R&D of ADCs requires extensive biological, chemical and manufacturing know-how and capabilities that span across biologics, small molecules and bioprocessing. The increasing development and manufacturing needs for ADCs are expected to demand more outsourcing services from ADC CRDMOs with fully integrated comprehensive capabilities that enable the rapid advancement of ADC candidates. Our Company stands out as a global ADC outsourcing service provider with full-spectrum capabilities, encompassing discovery, development, and manufacturing, as well as facilities conveniently located within a 1-2 hour driving distance.

Market trends and growth drivers of ADC outsourcing services market

With the rise in R&D investments of the global ADC market, the demand for outsourcing services for ADC and other bioconjugates development will continue to grow. Outsourcing service providers with integrated comprehensive capabilities that are able to accelerate development timelines and ensure high quality for clients have rapidly gained market share in the past three years and are expected to continue to lead the outsourcing services market growth. As ADC-focused biotech companies in China continue to seek global partners, they are expected to partner with leading CRDMOs with stringent quality standard and global reputation. Capacities are expected to increase globally for discovery, development, and manufacturing of ADC and other bioconjugate drugs.

The following is a summary of the key growth drivers that are expected to further contribute to the global ADC outsourcing services market.

- ***Continuous innovation and increasing R&D spending in ADC and broader bioconjugates*** — The continuous innovation in conjugation technology and ADC drug development is expected to further drive the high demand for outsourcing services. Other than ADC, broader bioconjugate drugs with novel carriers and payload-linkers targeting expanding therapeutic areas require continuous support from outsourcing service providers, especially those with integrated comprehensive service capabilities that can provide efficient and reliable solutions.
- ***Increasing demand for efficient supply chain management*** — The complicated discovery, development and manufacturing process requires interdisciplinary expertise in both biologics and small molecule compounds. The ability to efficiently manage the complex supply chain to ensure smooth transition between steps with assured quality is increasingly important for pharmaceutical companies. Outsourcing service providers with strong capabilities in supply chain management, especially those with strategically located facilities within geographical proximity, are expected to benefit from the increasing demand.

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- ***Continuous technology improvement*** — As the industry evolves and expands from ADCs to broader bioconjugates, outsourcing service providers with innovative technologies focused on developing conjugation technology for novel linkers, new carriers and payloads would be in increasing demand. Leading players with cutting-edge technologies and proprietary conjugation platforms can provide customers with various choices in the fast-growing bioconjugates development process, which is critical for biopharmaceutical companies in its discovery and development process.