# An Outlook on Specialized Chemistry Outsourcing

One of the key opportunities for CRDMOs in the coming decade

April 2024





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#### **Executive Summary**



Complex therapeutics such as ADC and TIDES (pepTIDES and oligonucleoTIDES) are becoming an integral part of the biopharma portfolio

- Therapeutic market of ADC is was ~\$9B and expected to reach ~\$24 B by 2032, growing at a CAGR of 12%
- TIDES therapeutic market expected to witness significant growth in this decade Oligo is expected to become ~\$ 7B market by 2032 whereas peptide is expected to become ~\$ 70B market by 2032



CDMOs are becoming an integral part of the development and manufacturing of ADCs and TIDES therapeutics

- ~75% of ADC developers outsource their operations to CDMOs
- The global peptide CDMO market was \$2.5 B in 2022 and is expected to reach ~\$ 11 B by 2027, growing at a CAGR of 35%
- The global oligo CDMO market was \$2 B in 2022 and is expected to be ~\$ 7 B by 2027, growing at a CAGR of 28%



A few CDMOs are already adopting organic as well as inorganic strategies to capitalize on the opportunities offered by complex therapeutics

- Multi-million dollar investments to expand manufacturing facilities for ADC and TIDES
- In house development proprietary platforms for potent, stable, and safe ADC and TIDES candidates, yielding strategic biopharma collaborations
- Expanding the capabilities through M&A
- The market is expected to consolidate as CDMOs aim build a one-stop-shop solution for the development and manufacturing of complex therapeutics

MP Group with >30 years of biopharma experience can help catalyze your journey to expand into the specialized chemistry space





## Complex therapeutics will be an integral part of biopharma portfolio

	ADC	Oligonucleotides	Peptide	
Background	<ul> <li>Antibody–drug conjugate (ADC) is composed of mAbs covalently attached to a cytotoxic drug via a chemical linker.</li> </ul>	<ul> <li>Commonly referred to as "Oligos", are short sequences of nucleotides-building blocks of DNA and RNA</li> </ul>	Short chains of amino acids offering therapeutic potential due to their target selectivity, safety and tolerability	
Specialized chemistries	<ul><li>Bioconjugation</li><li>Linker chemistry</li><li>Payload chemistry</li><li>Antibody engineering</li></ul>	<ul><li>Solid-phase synthesis</li><li>Chemical modification</li><li>Conjugation</li></ul>	<ul> <li>Solid-phase peptide synthesis</li> <li>Chemical modification</li> </ul>	
Applications	<ul> <li>Oncology</li> <li>Combination therapies: chemotherapy, immunotherapy</li> <li>Immunomodulatory agents</li> </ul>	<ul> <li>Molecular biology: sequencing, gene expression</li> <li>Gene therapy: ASOs, CRISPR-Cas9 delivery</li> <li>Drug development: custom oligos for personalized medicine</li> <li>Diagnostics: probes</li> </ul>	<ul> <li>Antibody and protein production</li> <li>Peptide therapeutics</li> <li>Medical imaging</li> <li>Nutraceuticals and cosmetics</li> </ul>	
Therapeutic	2022: \$8.6 B	2022∙ \$1 B	2022: \$37 B	

Source: Company reports, Secondary Research, MP analysis

**CAGR - 12%** 

2032E: \$23.9 B



Market

**Opportunity** 



2022: \$37 B

2032E: \$72 B

**CAGR - 7%** 

2022: \$1 B

2032E: \$6.9 B

**CAGR - 24%** 

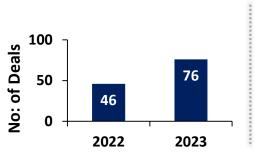
#### **ADC** and **TIDES** space is gaining momentum

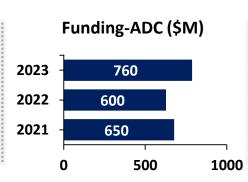
#### Investments and clinical activity have been steadily increasing

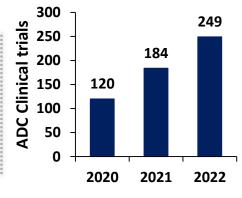


ADC

- 2023 witnessed a total of 76 deals in the ADC space; a ~65% increase from the number of deals in 2022
- Since 2019, the ADC initiatives have raised ~\$3.5 B
- ~400 ADC drug candidates in the pipeline 35% are in the various stages of clinical development









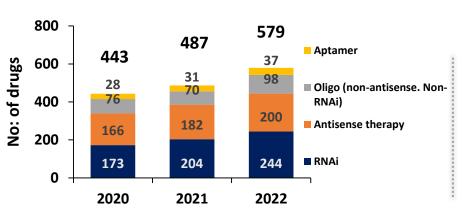
Oligo



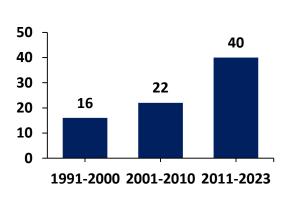
**Peptides** 

- Between 2022 and 2023, the FDA approvals for TIDES have almost doubled;
   9 TIDES (5 peptides and 4 oligos) in 2023 in comparison to 5 TIDES (4 peptides and 1 oligo) in 2022
- From ~ 450 drugs in 2020, the oligo pipeline has increased to ~600 in 2022
- There are ~1000 peptide drug (synthetic and recombinant) projects in development of which ~340 are in clinical development

#### Oligo-based drugs in pipeline



#### **Approved peptide therapeutics**







Source: Company reports, Secondary Research, MP analysis

<sup>\*</sup>This includes ribozymes, decoys, CpGs, and mismatched and immunostimulant oligonucleotides

## Biopharma is turning to outsourcing partners to optimize resources

CDMOs are becoming integral partners of Biopharma throughout the discovery and development of complex therapeutics



- ~75% of ADC developers outsource their operations to CDMOs
- Manufacturing agreements were the most common type among partnership models followed by product development and research agreements
- CDMOs are developing advanced conjugation technologies to overcome toxicity and improve therapeutic outcomes

#### **Collaborations/Partnerships**

Jan 2024: IntoCell (Biotech) partnered with Wuxi (CDMO) for bioconjugate platform and end-to-end CRDMO services

**Feb 2024:** Samsung Biologics (CDMO) will provide ADC development and drug substance manufacturing services to LegoChem (Biopharma) for its solid tumor program

**Dec 2022:** Aarvik Therapeutics (Biotech) partnered with NJ Bio (CDMO) for proprietary payloads, conjugation services and to manufacture materials for preclinical studies and clinical trials



Oligo



**Peptides** 

- The global peptide CDMO market was \$2.5 B in 2022 and is expected to be  $^{\sim}$ \$ 11 B in 2027 at a CAGR of 35%
- The global oligo CDMO market was \$2 B in 2022 and is expected to be ~\$ 7 B in 2027 at a CAGR of 28%
- Outsourcing services range from synthesizing peptides and oligonucleotides for research purposes to manufacturing drugs

**Jun 2023:** EUROAPI is currently working on 18 CDMO large molecule projects (including peptides, and oligonucleotides)

Jan 2023: Corden Pharma signed a multi-year deal, potentially valued at \$1 B, to manufacture large—volume peptides and support the launch of an innovative peptide molecule; the company's name was undisclosed due to confidentiality reasons

**Apr 2022:** Eli Lilly (Biopharma) entered into a strategic collaboration with Bachem (CDMO) for the manufacture of oligonucleotide-based drug substances. The annual order volume has the potential to achieve ~ \$100 M

Source: Secondary research, Company news, MP analysis





## CDMOs are building technical and manufacturing capabilities

CDMOs are investing in niche capabilities to strengthen their role in the development and manufacturing of complex therapeutics

	СОМО	Space	Strategic activities
	ALMAC	Peptide	<ul> <li>Mar 2024: Invested ~\$400 M in a GMP facility to double its peptide API manufacturing capacity</li> </ul>
Expansion	axplora  © Piramal	ADC	<ul> <li>Jan 2024: Axplora invested ~\$10 M to expand its ADC manufacturing capacity</li> <li>Dec 2023: Piramal Pharma invested ~\$60 M to develop a full-service ADC development and manufacturing facility in Scotland, thereby almost doubling its manufacturing capacity</li> </ul>
	Agilent	<b>MM</b> Oligo	Jan 2023: Invested \$725 M to double the manufacturing capacity of oligo-based therapeutics
Technology platforms	BSC Sciences®  Gest of Chemicals  Catalent  BIOLOGICS	ADC	BOC developed 2 proprietary technology platforms - a coupling technology platform and a systemic impurity detection system
			<ul> <li>Catalent developed the SMARTag® technology platform to develop ADCs and bioconjugates with optimized potency, toxicity, and stability characteristics</li> </ul>
	BIO•PHARMA S E R V I C E S	Peptide  Oligo	<ul> <li>AJIPHASE® technology platform is a hybrid of traditional solid phase and solution phase synthesis, for developing and manufacturing pure oligonucleotides and peptides</li> </ul>







success rate (much higher than the industrial average 75%)

Developed PepPower™, an advanced peptide synthesis platform, securing > 95% peptide synthesis

## CDMOs are unlocking value through M&A

CDMOs are undertaking inorganic strategic initiatives to build differentiated chemistry capabilities

Date	Acquirer (CDMO/CDO)	Territory	Acquiree	Territory	Space	Deal Value (\$ M)	Acquired for	
Nov 2023	EuroAPI	EU	BianoGMP	EU	Oligo	~ 11	Early-phase oligonucleotide expertise	
Sep 2023	Biosynth	EU	Pepceuticals	UK	Peptide	Undisclosed	Expertise in production of complex synthetic peptides with large scale GMP facilities	
Jun 2023	Lonza	EU	Synaffix	EU	ADC	107	Advanced payload and site-specific linker technologies	
Jan 2023	Lotte Biologics	Korea	Manufacturing plant from Bristol Myers Squibb	US	ADC	Undisclosed	ADC development and manufacturing services	
Apr 2021	Piramal Pharma	India	Hemmo Pharma	India	Peptide	105	Manufacturing of synthetic peptide API	
Apr 2021	Sterling	UK	ADC Bio	UK	ADC	Undisclosed	Bioconjugation and ADC development and manufacturing services	
Mar 2020	Biotage	EU	ATDBio	UK	Oligo	62	DNA and RNA oligonucleotide synthesis and purification expertise	

Source: Company reports, Secondary research, MP analysis





#### Key takeaways for CDMOs expanding into the niche chemistry space

CDMOs equipped with differentiated chemistry capabilities are poised to become critical partners to the biopharma industry



It is timely for the CDMOs to explore expansion opportunities to support complex modalities

- Biopharma companies are pursuing innovative and specialized drug modalities such as ADC, oligonucleotide, and peptide therapeutics, and turning to CDMOs for development and manufacturing support
- Multiple investments and an increase in the clinical pipeline indicates the increase in the momentum of ADC and TIDES



CDMOs are exploring opportunities to build capabilities in the complex chemistry space through strategic initiatives

- CDMOs are investing in technical platforms and manufacturing facilities to offer comprehensive solutions for the development of complex products
- CDMOs are also undertaking M&A activities to expand into differentiated offerings, thereby gaining a competitive advantage



Though the CDMO space offering specialized chemistry expertise is currently fragmented, consolidation is expected in the coming years

~60 CDMOs are offering ADC capabilities

- ~25 of them are public companies
- Of the remaining, ~35, the majority are based in the EU followed by US and APAC
  - Very few <10 are primarily focused on ADC while the others also have additional capabilities such as peptides

~120 CDMOs with TIDES offerings

- Majority of the companies ~40% are too large or public offering multiple capabilities along with TIDES
- Of the remaining, majority of the companies are based out of the EU and APAC region while the remaining are in the US

Source: MP analysis





## An indicative list of companies specializing in niche chemistry capabilities

Companies	HQ	Founded	ADC	Oligo	Peptide
NJ Bio	US	2019	✓	✓	✓
Bio-Synthesis Inc	US	1984		✓	✓
Biopeptek	US	2010			✓
BSP Pharmaceuticals	Italy	2006	✓	✓	✓
Symbiosis Pharmaceutical Services	Scotland	2011	✓		✓
Biospring	Germany	1997		$\checkmark$	
Biosynth	Switzerland	1965		$\checkmark$	$\checkmark$
Sennchem	Switzerland	1963		✓	✓

MP group tracks 100+ companies in the specialty chemistry space

Source: Secondary research, MP analysis





#### MP Group can catalyze your initiative

With over 3 decades of diverse experience and integrated perspective global BioPharma CDMO space, and a deep understanding of specialized chemistry, MP Group can support your strategic initiatives

MP Team will be happy to be an extension of the management team and support the following:

- Catalyze the growth and expansion strategy of your organization for long-term success
- Identify global opportunities with the key technologies in the chemistry space for enhanced development and manufacturing
- Leverage MP's global network to identify potential below-the-radar opportunities for partnering or investment, unique to the vision of the company
- Develop a robust opportunity assessment framework with the desired criteria for target CDMO selection and evaluate the relevant opportunities against the framework
- Technical due diligence of the target CDMOs and/or the associated technologies to investigate the technologies best suited for the need





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