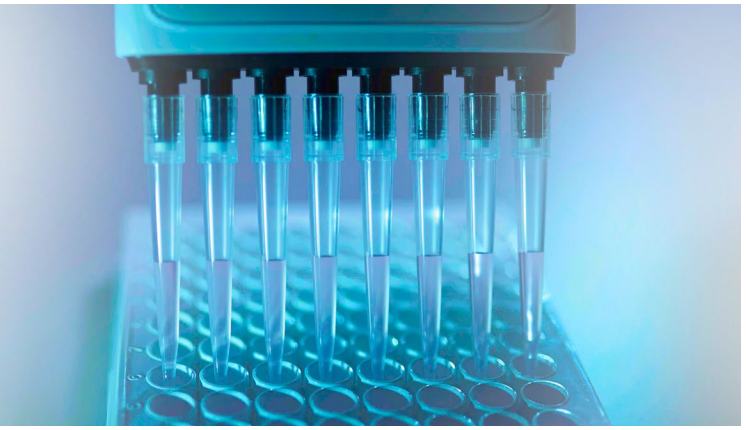

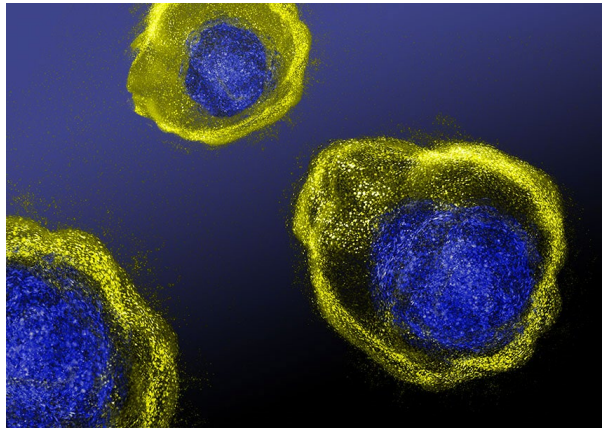

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CELL-BASED ASSAYS TRENDS, PIPELINE & INSIGHTS

Jessica Congiu
Global Product Manager Cell-based Solutions

2026-04-14

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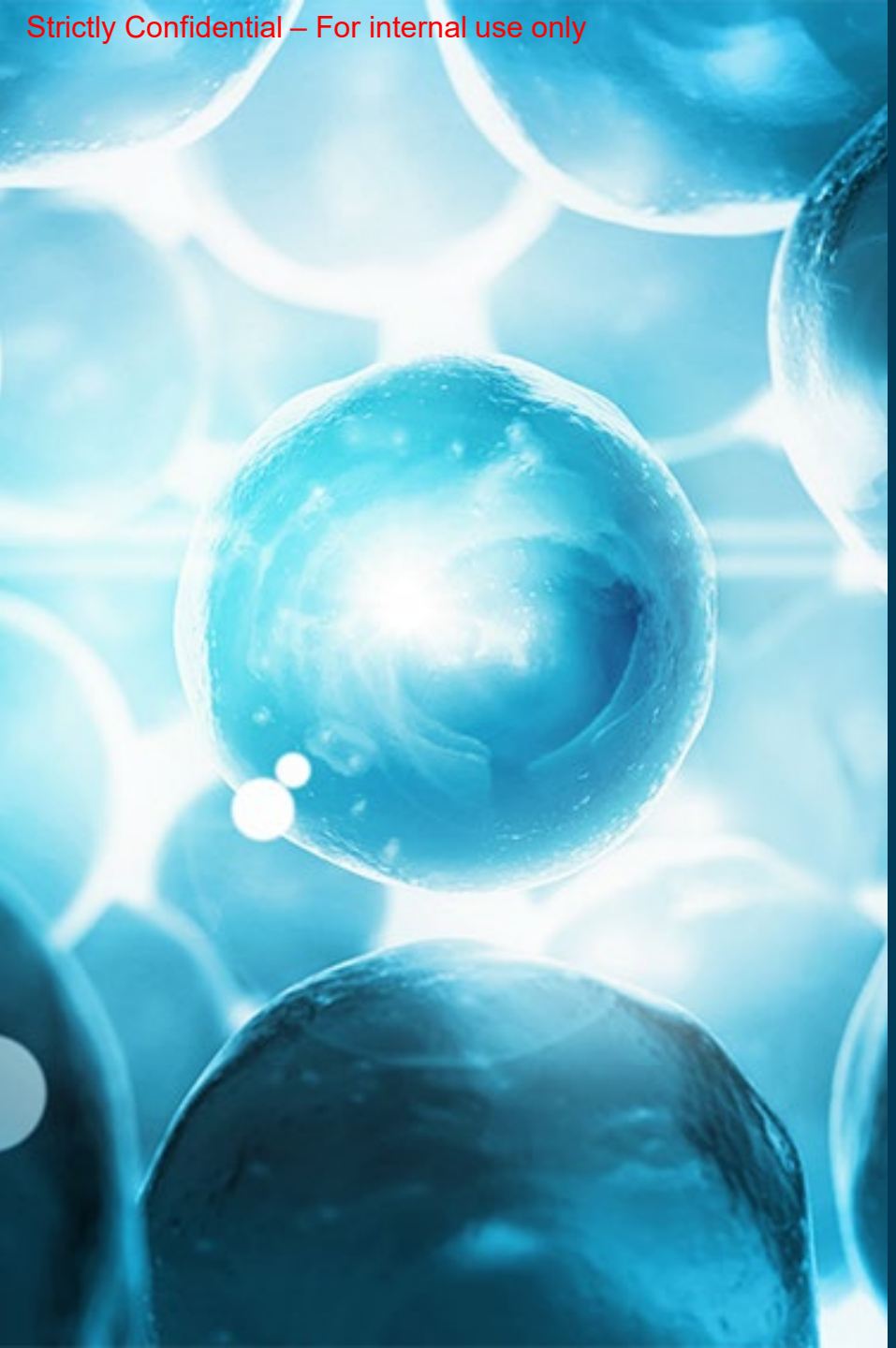


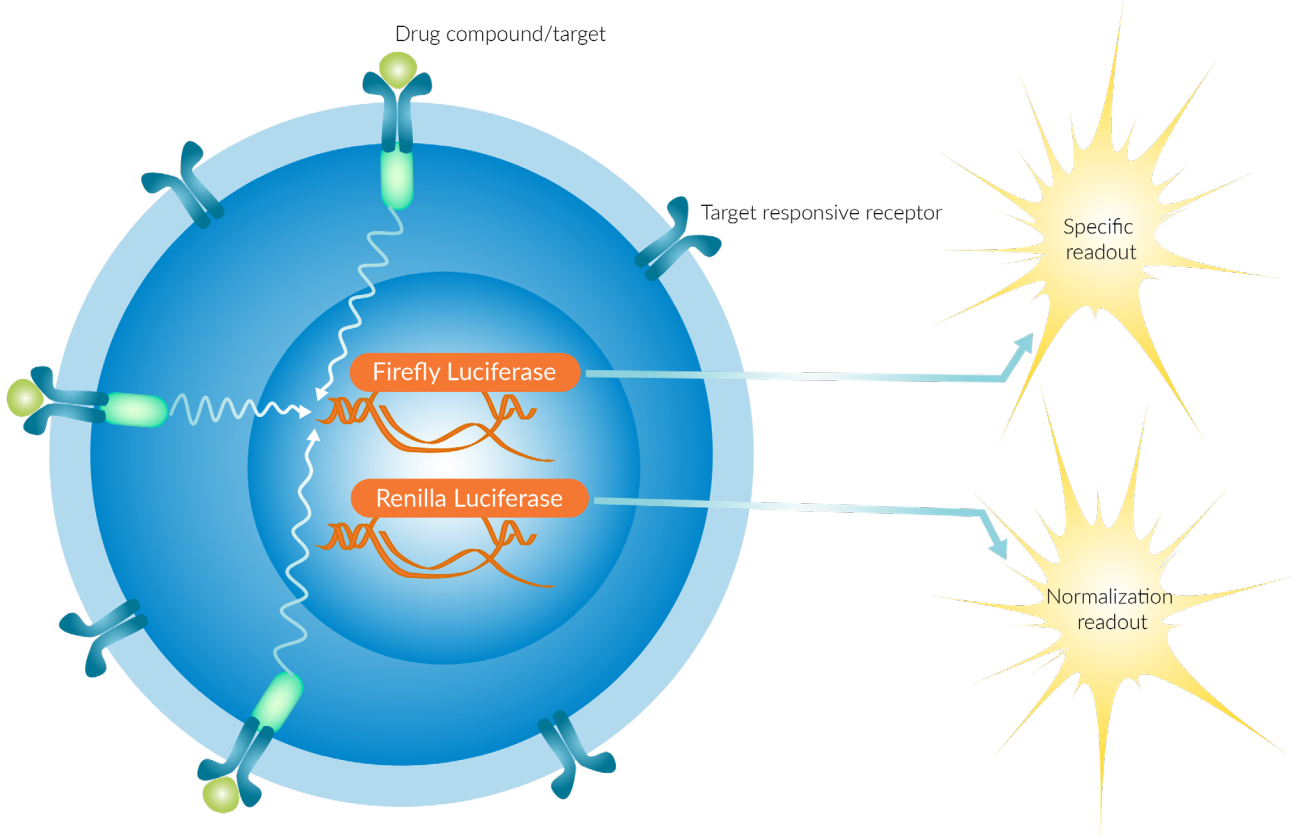
Agenda

1. **How *iLite* supports therapeutic development**
   Functional, MoA-reflective cell-based assays

2. **Key therapeutic application areas**
   Immuno-oncology • Complement • Obesity •
   Gene therapy • Biosimilars

3. **Portfolio strategy & what's coming next**

iLite® - Cell-Based Assays for Modern Biologics

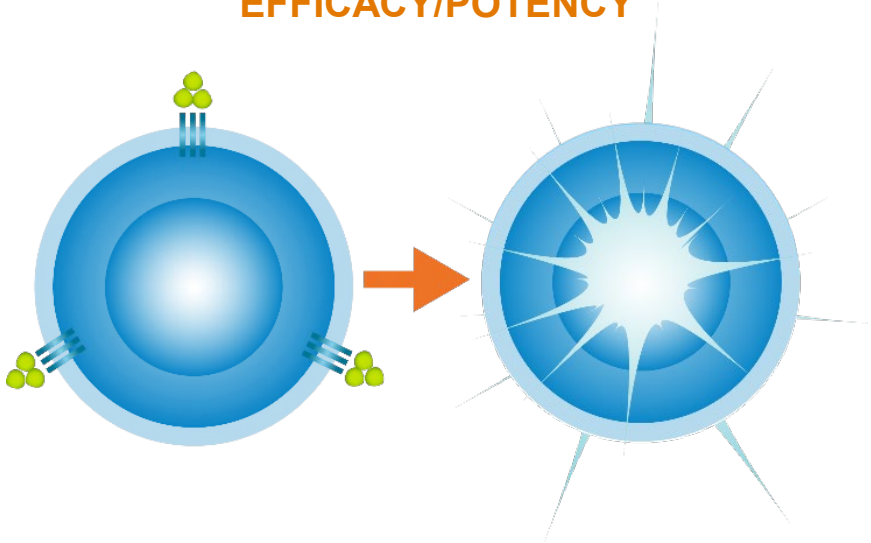


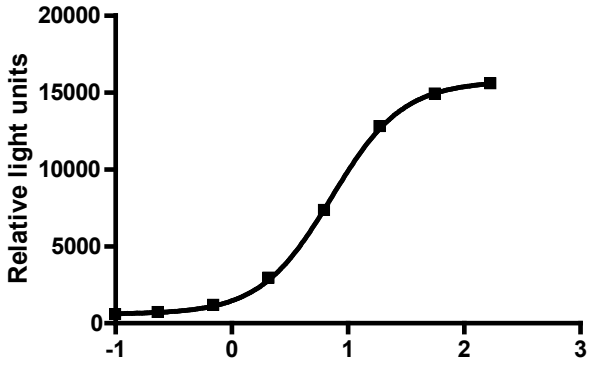
Connecting drug mechanism-of-action to meaningful biological function

iLite® Cell-Based Assays

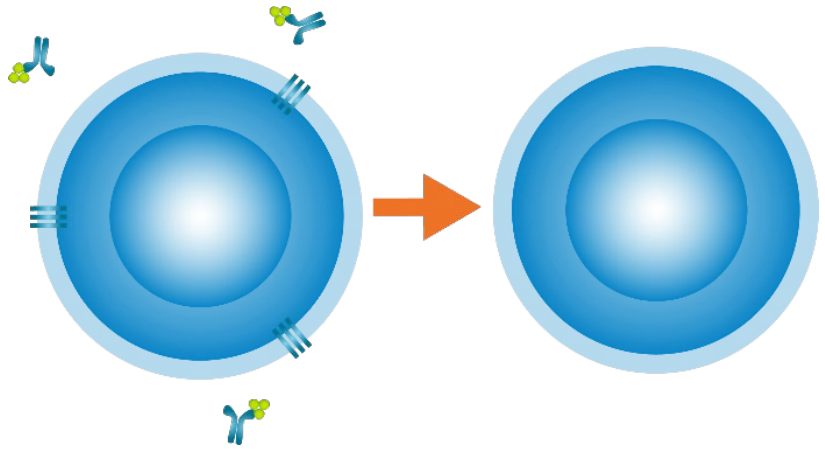
MAIN APPLICATIONS

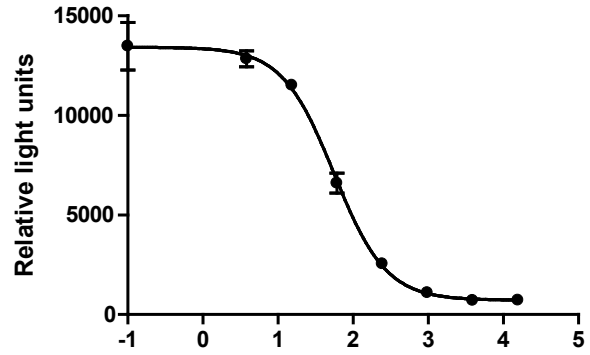
EFFICACY/POTENCY





IMMUNOGENICITY



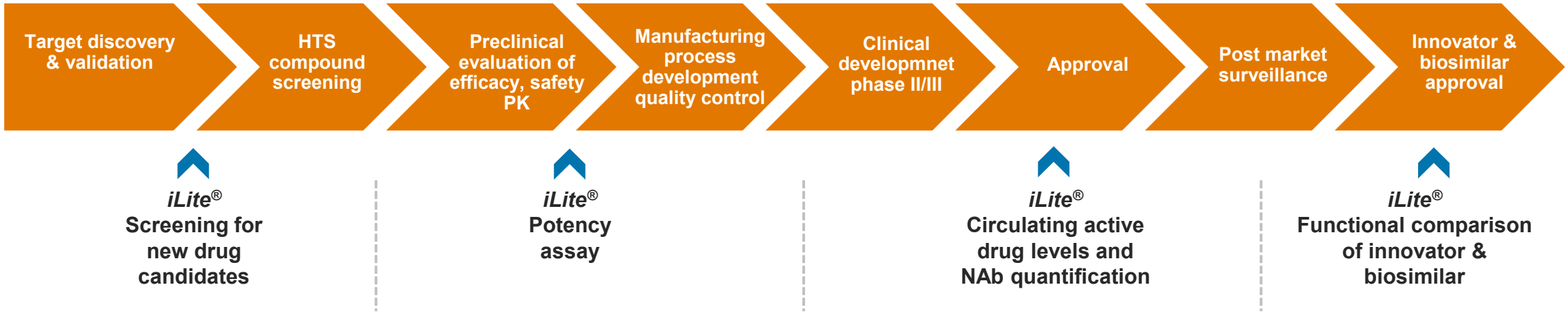


iLite® Cell-Based Assays

APPLICATIONS IN DRUG DEVELOPMENT

Examples of use of *iLite* cell lines

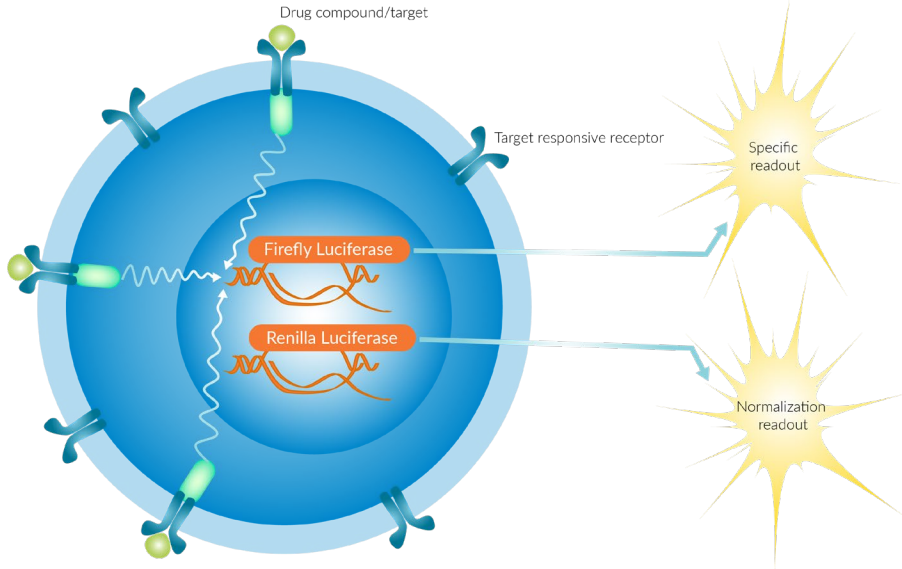
- Pathway activation assay during discovery
- Functional screening for a drug candidate
- Potency determination for Tox and PK studies and CMC
- Determination of drug levels and neutralizing antibodies in immunogenicity assessment
- Comparison between an innovator drug and a biosimilar

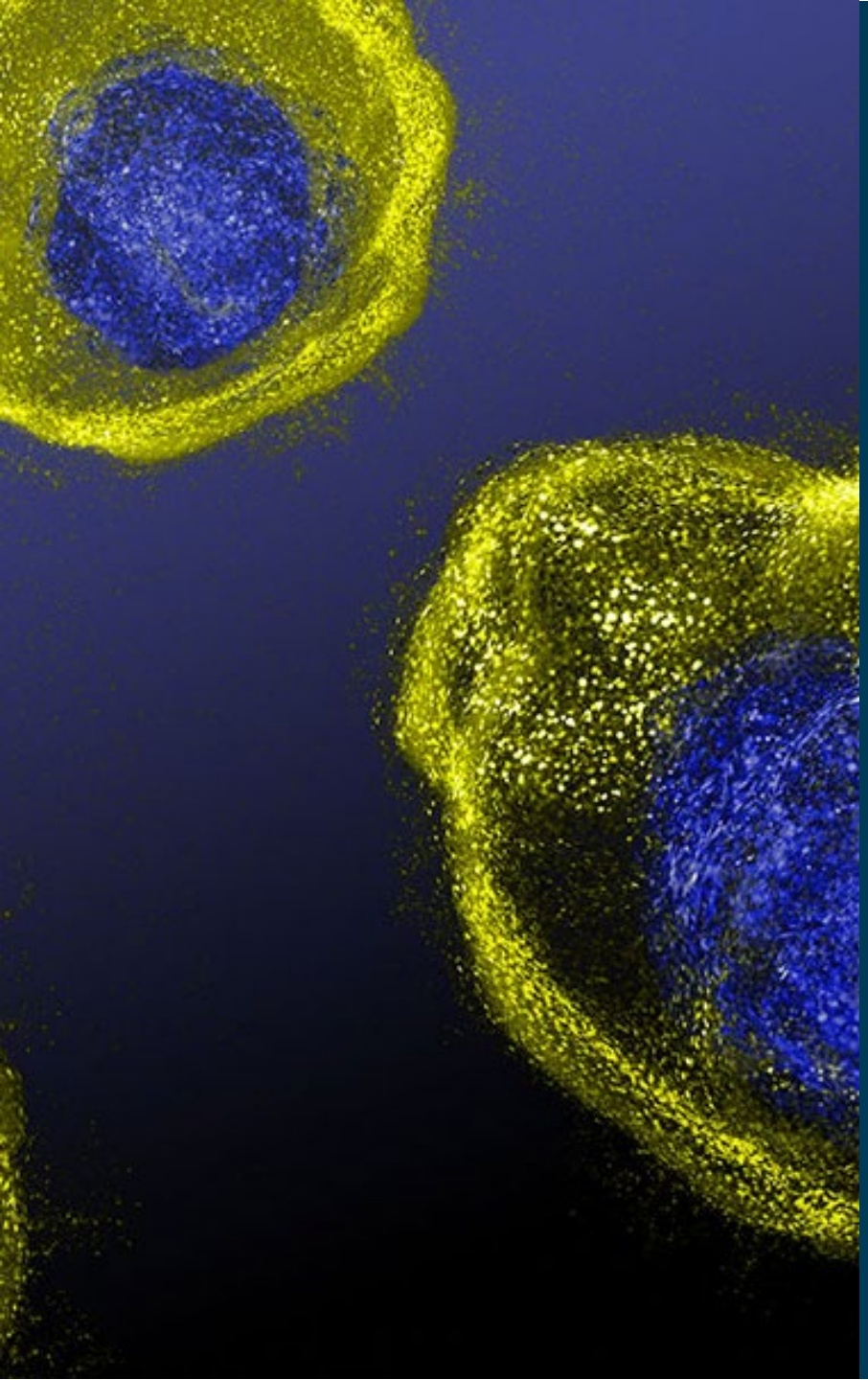


iLite® Cell-Based Assays

FEATURES & BENEFITS

- **Functionality** of the compound **can be determined**, not just binding interaction
- Reflects the **Mechanism of Action** (MoA) of a potential drug
- Can be designed & **customized for specific uses**
- Cells provided in an **Assay Ready Cell** format
  - **Decreasing timelines and workload**
  - Resulting in **superior performance**
  - **Reducing** assay variation





Functional assays are more relevant than ever before

- Shift toward more complex biologics & modalities
- MoA understanding is critical across entire development
- Increasing regulatory emphasis
- Competitive pressure makes function a differentiator

Regulators expect a potency strategy early on

Phase-appropriate Potency Assay Development

FDA

Pre-clinical	Early phase: phase 1 phase 2	Late phase: phase 3 (pivotal)	Marketing application
• Initial potency assay based on proposed MOA • Binding assay is generally acceptable • Broad acceptance criteria	• Knowledge build-up on MOA • Cell-based functional bioassay should be developed • Bridging of potency assays at different stages	• Validated cell-based functional bioassay • Defined acceptance criteria	

Expectations on potency assays for anti-body based novel modalities - a regulatory perspective

Key *iLite*® Application Areas

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Immuno-oncology

Therapies that utilize the immune system to fight cancer - clinical effect is driven by **immune function and signaling**

MARKET TRENDS

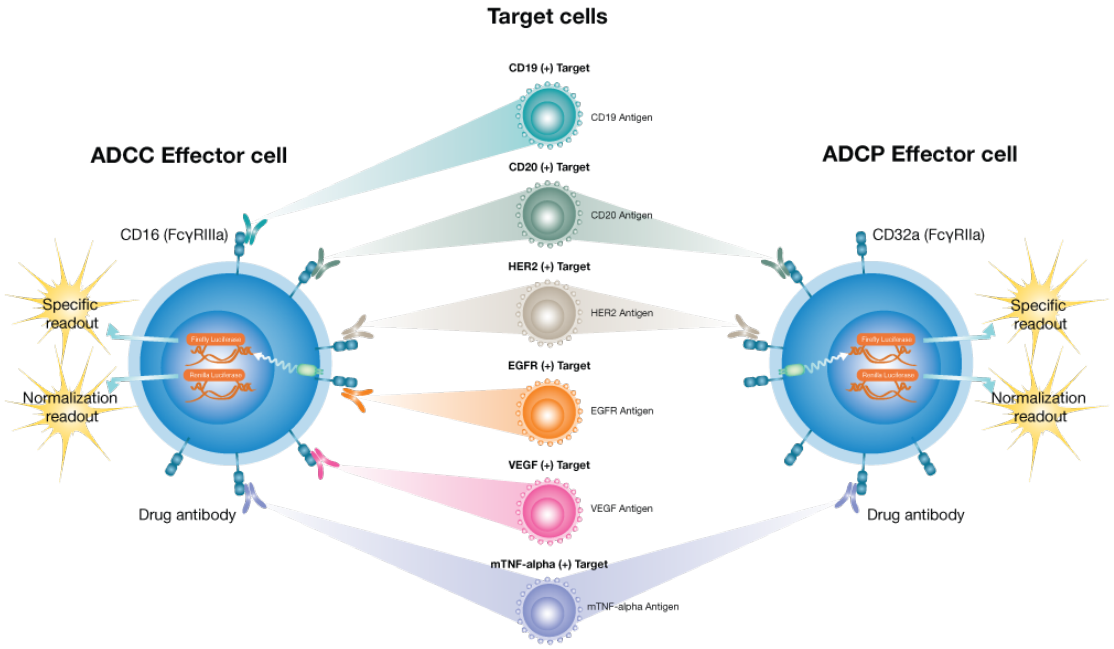
- Among the fastest growing therapeutic areas
- Dominated by biologic drugs with multiple MoAs (target antigen engagement, Fc effector modulation)
- Rapid growth of more complex modalities like bi-/multispecifics, ADCs
- Antibody engineering to improve drug design

Immuno-oncology

Therapies that utilize the immune system to fight cancer - clinical effect is driven by **immune function and signaling**

ILITE VALUE PROPOSITION

- Aligned with regulatory expectations for functional, MoA-reflective potency & immunogenicity assays
- Library of sensitive and robust assays covering common immuno-oncology targets & modalities
- Effector panel (ADCC, ADCP, CDC) supports antibody engineering evaluation
- Several new products in development

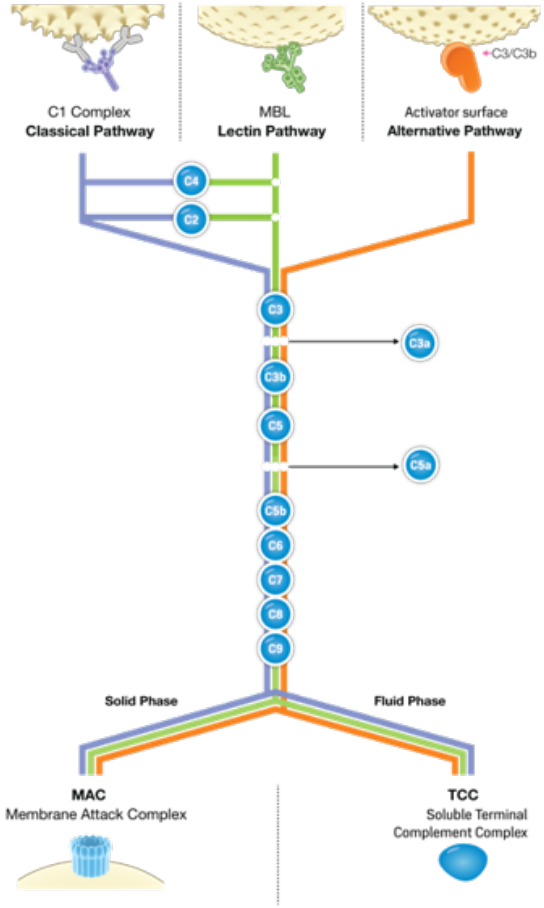


Complement

- The Complement System is part of the innate immune response, operating as an amplified biological cascade
- Complement inhibitors selectively block specific components or pathways to prevent disease-driven immune damage

MARKET TRENDS

- Complement inhibitors represent a multi-billion USD market today
- Chronic treatment meaning high requirements for consistent, functional potency
- Shift from terminal pathway (e.g. C5) to upstream and pathway-selective inhibition



Complement

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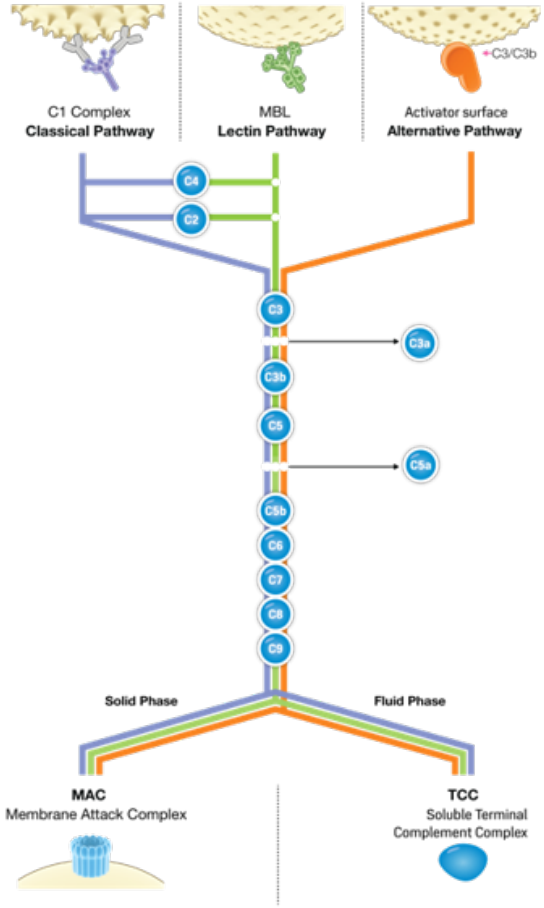
- Complement inhibitors selectively block specific components or pathways to prevent disease-driven immune damage

ILITE VALUE PROPOSITION

- Cell-based assays for functional assessment of complement pathway-modulating drugs
- Supporting potency and mechanistic studies of complement activity
- MoA-reflective measurement of complement-dependent cytotoxicity (CDC)



Obesity

- Obesity is a chronic metabolic disease driven by dysregulated appetite, energy balance, and glucose homeostasis
- Modern therapies are largely peptide and biologic drugs that act on metabolic hormone receptors

MARKET TRENDS

- One of the fastest-growing therapeutic markets in pharma (CAGR ~22%)
- Long-term, high-volume treatment
- Moving from GLP-1 to second-wave targets
- Growth of dual- and multi-agonists with increasingly complex MoAs
- Expanding into other indications

iLITE VALUE PROPOSITION

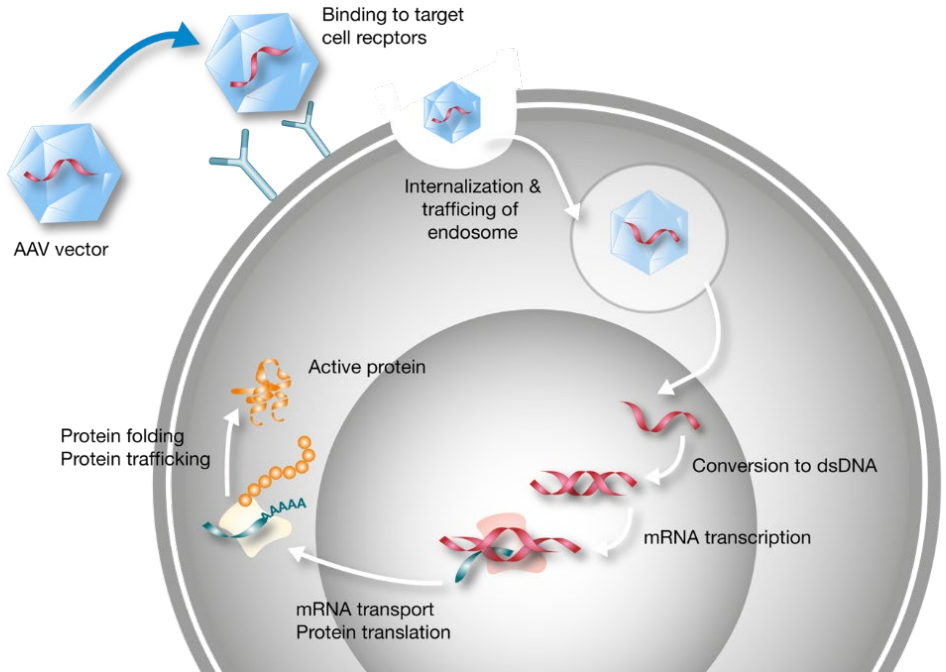
- Measures functional metabolic signaling
- Supports multiple metabolic pathways and emerging MoAs
  - New iLite product launches during 2026
- Robust and high-quality assays enable differentiation in a highly competitive market

Gene Therapy

- Gene therapy delivers genetic material into cells to restore, replace, or modulate biological function
- Therapeutic effect depends on successful cellular delivery and functional expression

MARKET TRENDS

- Market maturation & scale-up
- Growing pipeline targeting rare diseases and oncology
- Increasing vector and delivery complexity
- Immunogenicity as a central development challenge
- Evolving regulatory guidelines with strong focus on functional potency



Gene Therapy

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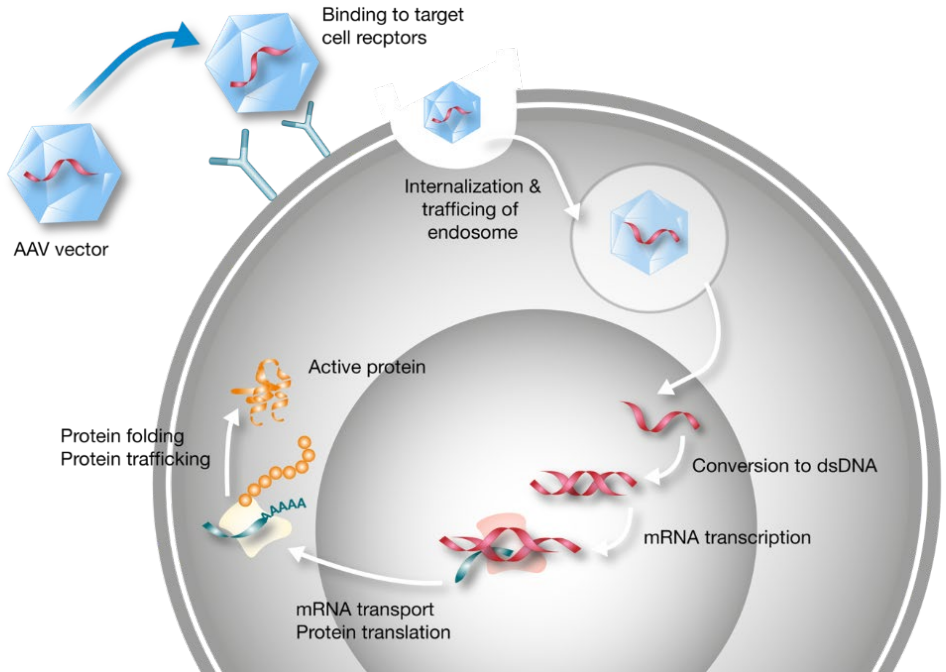
- Therapeutic effect depends on successful cellular delivery and functional expression

ILITE VALUE PROPOSITION

- Functional assessment of immunogenicity (NAb)
- Support across AAV serotypes and platforms
- Potency assays through Custom Cell Development service



Biosimilars

Biosimilars are biologic drugs developed to be highly similar to already approved reference products

MARKET TRENDS

- Major patent cliff is underway for blockbuster biologics across immunology, oncology and metabolics
- Patent expiry triggers:
  - Rapid entry of multiple biosimilar programs
  - Intense regulatory and commercial competition
- Increased focus on CAA (Comparability Analytical Assessment)

ILITE VALUE PROPOSITION

- Functional, MoA-reflective assays are an important pillar of the CAA
- Broad library of assays aligned with current and emerging biosimilar pipeline
  - Target-mediated signaling
  - Fc-effector functions

iLite® Off-the-shelf Products

IMMUNO-ONCOLOGY

Effector mechanisms

iLite® CD20 (+) Svar Luc Assay Ready Cells

ADCC Effector FcγRIIIa

ADCP Effector FcγRIIa

ADCP Effector (CD64) – in development

NK Effector – in development

CD3 Effector

CD19 (+) and (-) Targets

CD20 (+) and (-) Targets

EGFR (+) and (-) Target

HER2 (+) and (-) Targets

mTNF-alpha (+) and (-) Targets

mVEGF (+) and (-) Targets

Functional signaling

iLite® TNF-alpha Xcel Assay Ready Cells

iLite® Type I IFN FAST

iLite® RANKL

iLite® IL 2

iLite® IL 6

iLite® IL 12

iLite® IL 23

iLite® VEGF

iLite® GM CSF

iLite® G CSF

iLite® TLR4

iLite® TLR9

COMPLEMENT

iLite® CD20 (+) Svar Luc Assay Ready Cells

iLite® C5a

iLite® C3a

OBESITY/METABOLICS

iLite® hCG

iLite® Insulin

iLite® FGF 21

iLite® GIP – in development

iLite® GLP1 – in development

GENE THERAPY

iLite® AAV Responsive Reporter Assay Ready Cells

iLite® AAV2 Packaging Assay Ready Cells

iLite® AAV5 Packaging Assay Ready Cells

iLite® AAV6 Packaging Assay Ready Cells

iLite® AAV8 Packaging Assay Ready Cells

iLite® AAV9 Packaging Assay Ready Cells

What’s coming next?

Strategies for portfolio development

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Core principles for *iLite* portfolio development

Designed around MoA, future-proofed for regulatory expectations

1. FUNCTIONAL BIOASSAYS

- MoA-reflective by design
- Targeting drugs with complex or integrated mechanisms of action
- Focus on making biological function measurable, not just detectable

2. LEVERAGING THE REGULATORY PUSH FOR FUNCTIONAL POTENCY

- Strong regulatory tailwind toward MoA-reflective potency assays
- Portfolio development aligned with early-stage MoA understanding
- Supporting customers from early development through CMC and lifecycle management

Strategic focus areas for *iLite* portfolio expansion

OBESITY & METABOLIC DISEASE

- **Growth priority:** building dedicated functional assays for one of the fastest-growing biologics markets
- **2026 launches:** GLP-1 and GIP reporter cell lines + additional in the pipeline
- **Designed for differentiation:** measures functional receptor signaling (agonism/pathway response), not just binding

IMMUNO-ONCOLOGY

- **Core priority:** evolving the portfolio to match new IO modalities and customer needs
- **Strengthening Fc-effector toolkit (2026):** multiple launches across ADCC/ADCP workflows
    - CD64-mediated ADCP
    - Dual-readout NK effector cell – bridging the gap between primary killing and surrogate assays

THANK YOU!

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