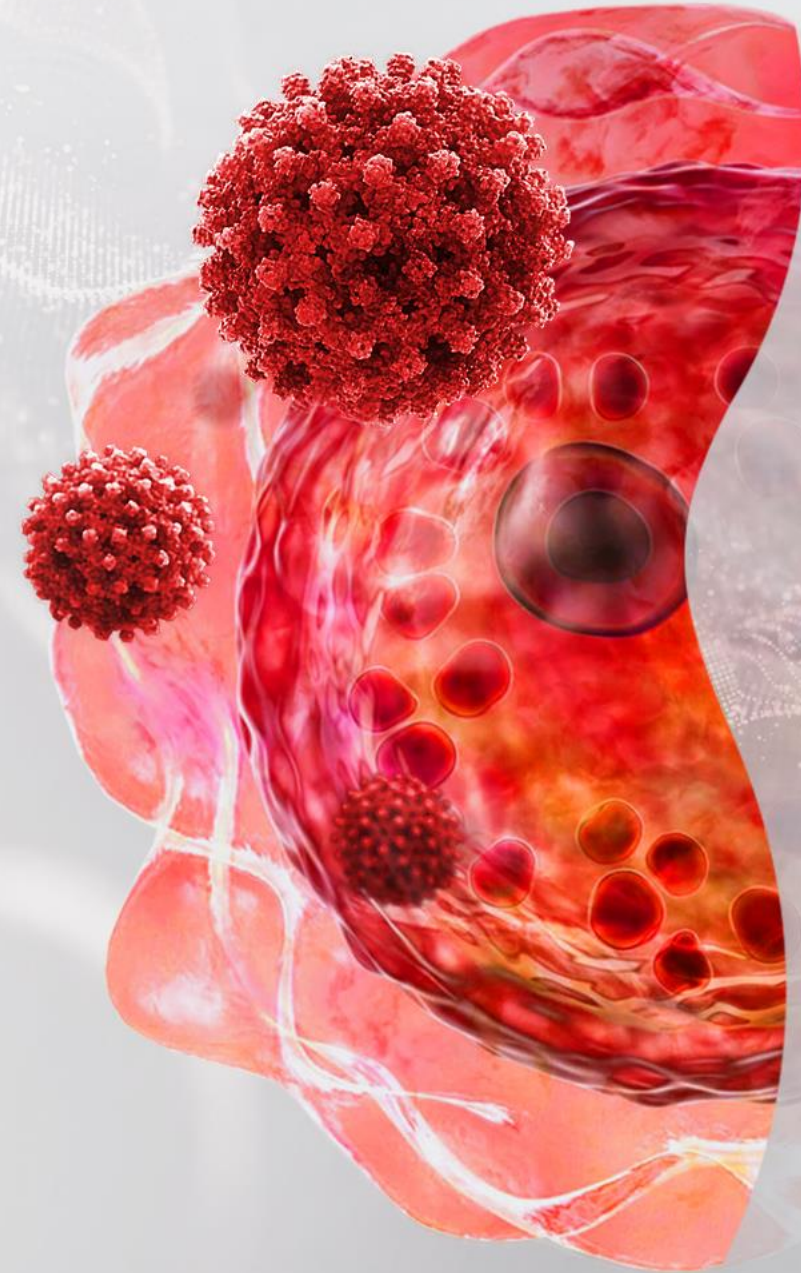


Cell and Gene Therapy - Dutch Life Science Conference

Willem Hoerée – Business Development Manager

December 2023

 The world leader in serving science



Agenda



Cell & Gene Therapy - Investments

Investment data globally and press release



Thermo Fisher Scientific supports cell and gene therapy development

Our total products and services capabilities and investments



Cell & Gene Therapy - Global Investment Data by Year

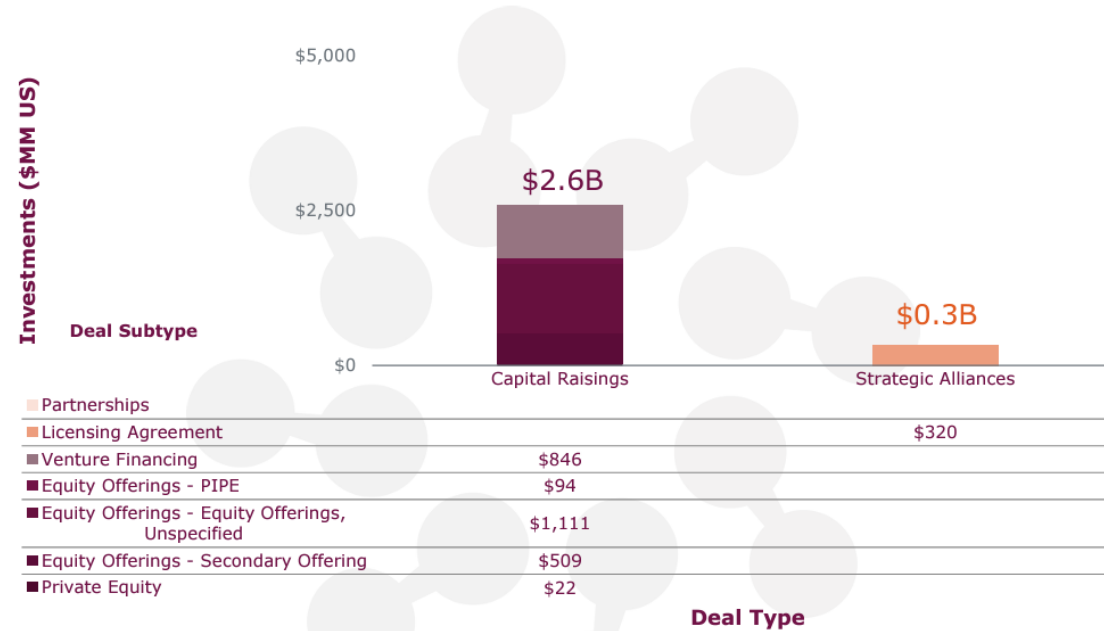
Investments by Year



Investment Data - 2023 Q2 | 1

Q2 2023 – Investments by Deal Type – North America

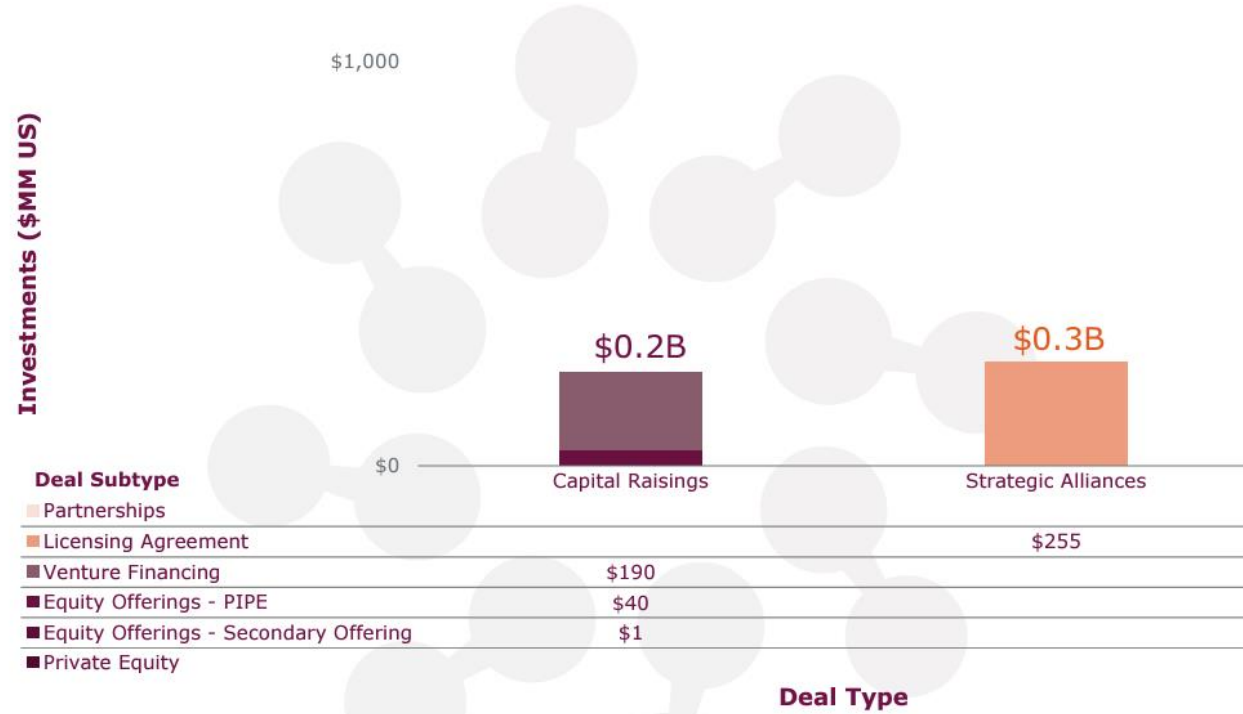
Investments by Deal Type for North America



Investment Data - 2023 Q2 | 3

Q2 2023 – Investments by Deal Type – Asia Pacific

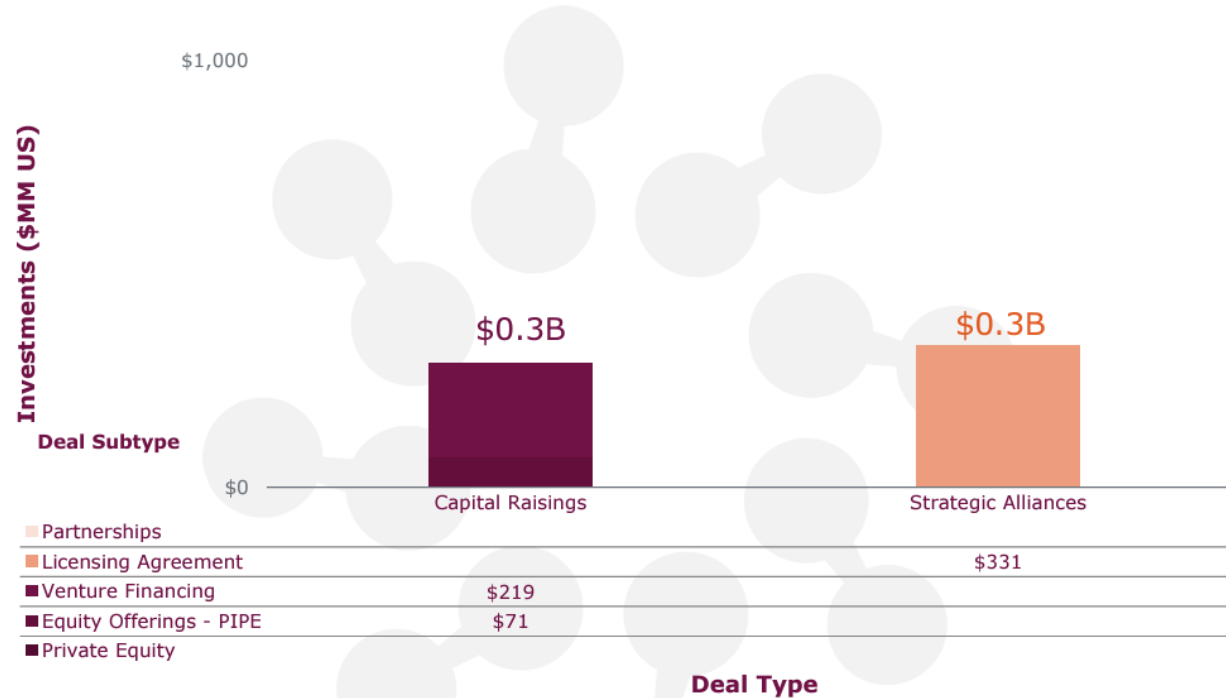
Investments by Deal Type for Asia Pacific



Investment Data - 2023 Q2 |

Q2 2023 – Investments by Deal Type – Europe

Investments by Deal Type for Europe






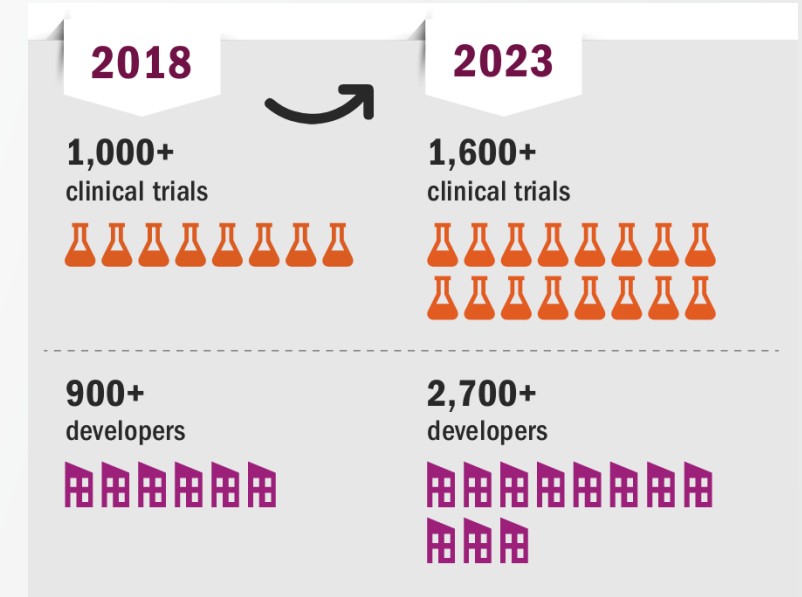
Investment Data - 2023 Q2 | 5

Q1 2023 Sector Data – Global Picture

Q1 2023 Sector Data

	Developers
	Clinical Trials
	Investment

	North America	Asia Pacific	Europe	Total
	1,235	888	543	2,760
	917	648	329	1,687
	\$2.4B	\$0.5B	\$0.2B	\$3.0B



PHARMA

Novo Nordisk Foundation pumps \$136M into new clinical cell therapy manufacturing 'hub' in Denmark

By Fraiser Kansteiner · Sep 21, 2023 9:30am

Novo Nordisk Cell & Gene Therapy cell therapy manufacturing Denmark



Dubbed the Cellerator, the facility will cater to public and private clients in academia, biotech and the pharmaceutical industry. Construction is due to kick off next summer, and the site is expected to be operational in 2027, the Novo Nordisk Foundation [said](#) in a release.

The group plans to support a range of cell therapy types, including those derived from embryonic stem cells, pluripotent stem cells and adult stem cells. The Cellerator's service offerings will run the gamut from process development and manufacturing to product release and regulatory support.

Mission:

To enable our customers to make the world healthier, cleaner and safer.

Focus on biotech:

We simplify the development path and accelerate your innovations to bring therapies to patients, faster.



>6,500

clinical trials supported annually



>300

large and small molecules manufactured in 2021



78%

customers in **clinical phase** are emerging biotech



>30

partnerships/sponsorship with Incubators

 The world leader in serving science

We offer targeted solutions across our portfolio for the right solutions at the right time

ThermoFisher
SCIENTIFIC

The world leader in
serving science



Your trusted partner in advancing cell and gene therapies from discovery to delivery

We help you simplify and accelerate time-to-market by offering trusted, **high-quality products and services** backed by **collaborative support** and our **robust global supply chain network**.



CGMP-quality products

Instruments and CGMP reagents like Gibco™ CTS™ formulations are designed to streamline the transition to commercial manufacturing.



Proven CRO and CDMO services

We are an experienced, full-service CRO and CDMO partner with scale, a broad range of services, and an extensive support network.



Scientific and regulatory support

We provide CRO/CDMO consultations and collaborative technical and regulatory product support, including traceability documentation, drug master files, and regulatory support files.



Robust global supply chain

Connect to a robust global supply chain network with targeted CGMP manufacturing investments.

Meeting the demand for qualified ancillary reagents

Cell Therapy Systems (CTS) reagents for cell and gene therapy manufacturing

Gibco™ CTS™ reagents are CGMP-manufactured products designed for cell and gene therapy applications, so you can transition your therapeutic to the clinic with confidence.

- ✓ Over 30 years of CGMP-compliant manufacturing experience
- ✓ Extensive safety testing panels and FDA drug master files
- ✓ Proven use in FDA-approved cell therapies and >200 clinical trials

CGMP manufacturing

Manufactured in conformance with GMPs for medical devices and 21 CFR Part 820; follow USP<1043> and Ph Eur 5.2.12

Manufacturing sites are FDA registered, ISO 13485 certified, and regularly audited

Testing and documentation

Traceable documentation—drug master files (DMFs) and/or regulatory support files (RSFs) as well as certificates of origin

We perform product safety testing for sterility, endotoxins, and mycoplasmas

Proven use

Used to manufacture FDA-approved and EMA-approved CAR T therapies [1,2] as well as the first FDA-approved therapeutic cancer vaccine [3]

Used in over 200 clinical trials

1. Tangying LL et al. (2016) A rapid cell expansion process for production of engineered autologous CAR-T cell therapies. *Hum Gene Ther Methods* 27(6):209-218.
 2. <http://thermofisher.mediaroom.com/2017-08-30-First-FDA-Approved-Cell-Therapy-for-Leukemia-Utilizes-Thermo-Fisher-Scientifics-CTS-Dynabeads-Technology>.
 3. Madan RA, Gulley JL (2011) Sipuleucel-T: harbinger of a new age of therapeutics for prostate cancer. *Expert Rev Vaccines* 10(2):141-150.

Product and service offerings for cell and gene therapy

Seamless transition to accelerate development

Leading product solutions



thermo
scientific

fisher
scientific

invitrogen

applied
biosystems

unity
lab services

gibco



- “Build” approach supported by leading product portfolio of reagents, instruments, consumables, and workflow solutions

Leading CRO and CDMO

PPD



patheon



- “Buy” approach supported by CDMO and CRO operations
- Translational early discovery, process development, clinical manufacturing, and commercial manufacturing

Investing to expand and meet future demands

Industry-leading solutions to support advanced therapies

**Critical raw material
manufacturing**

\$100 million

Investment to boost production of critical products like cell culture media



Gibco™ Dynabeads™ beads manufacturing
Vilnius, Lithuania

**CDMO drug product
manufacturing**

>\$3B

Investment in cell and gene therapy manufacturing capabilities since 2019

**Global site and facility
expansion to support
supply of CGT products**

**CRO capabilities for
clinical phase**

\$17.4B

Expanded cell and gene therapy clinical services

PPD

Thank you

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