Record Financing Drives Sector Growth



2020 has already exceeded full-year financing totals for all previous years and is now the best year on record for regenerative medicine & advanced therapy financing.

Raised in the First 3 Quarters of 2020 Up 115% Year-Over-Year Incl. **\$4.3B** in Q3 Up 76% Year-Over-Year

Gene Therapy

\$3.5B in Q3 2020 | Up 178% **\$12.0B** YTD 2020 | Up 114%

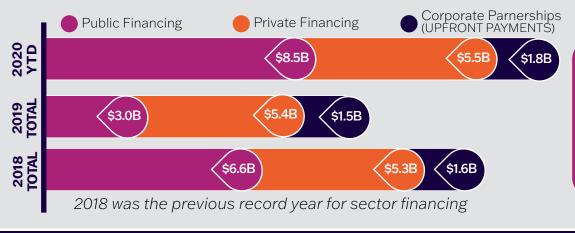
Cell Therapy

\$3.0B in Q3 2020 | Up 97% **\$11.0B** YTD 2020 | Up 242%

Tissue Based

\$226M in Q3 2020 | Up 11% **\$311M** YTD 2020 | Up 311%

Some companies utilize multiple technology types, and financings for those companies are included in each of the applicable categories.



Public financing is the main driver of increased financing in the sector, with both IPOs (\$2.8B YTD) & follow-on financings (\$5.7B YTD) surpassing previous years.

CLINICAL TRIALS ONGOING WORLDWIDE







The late-stage pipeline is robust, with 97 ongoing Phase 3 clinical trials & regulatory decisions expected on multiple product candidates in the coming months.



Anticipated near-term decisions from the **European Medicines Agency include:**

Relapsed or refractory large B-cell lymphoma

🎤 Eli-cel (bluebird bio) Cerebral adrenoleukodystrophy

GT-AADC (PTC Therapeutics) AADC deficiency

🎆 lde-cel (bluebird bio, Bristol Myer Squibb) Relapsed or refractory multiple myeloma

Libmeldy (Orchard Therapeutics) Early-onset metachromatic leukodystrophy

Leber hereditary optic neuropathy



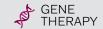
Anticipated near-term decisions from the US Food & Drug Administration include:

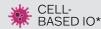
Relapsed or refractory large B-cell lymphoma

fide-cel (bluebird bio. Bristol Mver Squibb) Relapsed or refractory multiple myeloma

ళ StrataGraft (Mallinckrodt) Deep partial thickness thermal burns

> Already-approved products are also expected to receive approval in additional geographies and indications.







Cell-based immuno-oncology makes up a growing proportion of the pipeline, including more than half of Phase 1 trials.

373
GENE THERAPY

Ph 1: 111

Ph 2: 227 Ph 3: 35

694

trials ongoing in oncology

* IMMUNO-ONCOLOGY

492 CELL-BASED 10*

> Ph 1: 253 Ph 2: 223 Ph 3: 16

388

trials in prevalent diseases & cancers

② 202

CELL THERAPY

Ph 1: 50 Ph 2: 121 Ph 3: 31

186

trials ongoing in rare monogenetic diseases

42

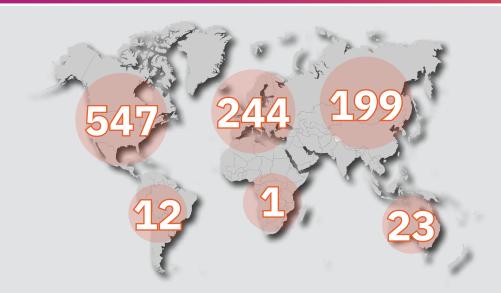
TISSUE-BASED

Ph 1: 4 Ph 2: 23 Ph 3: 15

16

trials ongoing in COVID-19 & complications

There are 1,026 regenerative medicine & advanced therapy developers active worldwide.



Gene Therapy: 536

© Cell Therapy: 641

₩ Tissue-Based: 135

Some companies included in multiple technology categories.

ARM's new Q1 & Q3 Trend Talk provides curated, up-to-date financial and clinical data, keeping stakeholders on top of the latest in the sector. Keep an eye out for our in-depth annual and H1 reports for a deeper dive on policy, scientific, and other trends!



The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization dedicated to realizing the promise of regenerative medicines and advanced therapies. ARM promotes legislative, regulatory and reimbursement initiatives to advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-based therapies. Early products to market have demonstrated profound, durable and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing regenerative medicines and advanced therapies. In its 11-year history, ARM has become the global voice of the sector, representing the interests of 370+ members worldwide, including small and large companies, academic research institutions, major medical centers and patient groups. To learn more about ARM or to become a member, visit http://www.alliancerm.org.

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