## ScaleReady's G-Rex® Grant Program

For the Advancement of CGT Development and Manufacturing





























**Bluecord** 





# G-Rex® Grant for the Advancement of CGT Development and Manufacturing

#### **Program Overview:**

The G-Rex® Grant Program is a \$30,000,000 initiative undertaken by ScaleReady, in collaboration with Wilson Wolf, Bio-Techne, and CellReady to benefit the cell and genemodified cell therapy community.

The G-Rex® Grant Program is unique and unlike any other grant program. G-Rex® Grant Recipients will not be burdened with inflexible timelines, bureaucratic constraints, micromanagement, or invasive oversight.

The G-Rex® Grant Program is intended to be simple, flexible, and easily accessible from initiation through completion. The G-Rex® Grant Program will be successful due to a partnership based on mutual trust, respect, and understanding.

The purpose of the G-Rex® Grant Program is to provide interested academic and commercial institutions engaged in pre-clinical research, process development, and/or cGMP manufacture of cell and gene-modified cell therapies (the "**Recipient**") with the devices, reagents, and operational know-how to:

- 1. Implement a highly efficient G-Rex® based cell manufacturing platform and/or
- 2. Optimize an existing G-Rex® based cell manufacturing platform quickly and at low cost.

#### **Key Features:**

The G-Rex® Grant will provide each Recipient between \$5,000 and \$300,000 worth of materials and services, along with free consulting support from ScaleReady G-Rex® Optimization Specialists, for up to 18-months\* (the "Collaboration Period") to any academic or commercial institution that meets the criteria outlined below.

• The duration of the Collaboration Period may be extended upon mutual agreement by the parties.

At the onset of the G-Rex® Grant Program:

- ScaleReady will work collaboratively with the Recipient during a series of discovery sessions to create a thorough understanding of the Recipient's goals.
- ScaleReady will interact with Wilson Wolf, Bio-Techne, CellReady and the Recipient to orchestrate a G-Rex® Grant Program Plan that aims to achieve the Recipient's goals.

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Under the G-Rex® Grant Program, ScaleReady will provide the most appropriate combination of devices, reagents, and consulting support as follows:

#### Wilson Wolf

- G-Rex® devices including G-Rex® well plates, G-Rex® bioreactors (including closed system models), and the GatheRex® Cell Harvest Pump
- G-Rex® ancillary products

#### Bio-Techne

- o RUO and GMP Reagents
- o RUO and GMP cell culture media
- TcBuster® transposon/transposase system

#### ScaleReady

- o G-Rex® Optimization Services
- Technical Application Support
- Marketing Support

#### CellReady

Process Development and Manufacturing Services and Consultation

During the Collaboration Period, the G-Rex® Grant Recipient and ScaleReady will work together to meet the Recipient's program goals, which will typically include creating a process and data package sufficient:

- To be included in the CMC section of an applicable IND(s), or
- Used to support further research or collaborative efforts in the Recipient institution.

To be eligible for the G-Rex® Grant Program, a Recipient must satisfy the following criteria:

- Be engaged in research and development of cell and gene-modified cell therapies based on or derived from T cells, NK cells, HSCs, or the like.
- Be working towards, or have, an existing Investigational New Drug (IND) application.
- Be interested in quickly establishing an optimized cGMP manufacturing process at low cost with minimal investment required.

#### **Inquiry Process:**

All interested parties should contact ScaleReady at <a href="info@scaleready.com">info@scaleready.com</a> with a brief description of how a G-Rex® Grant Program can be beneficial. A ScaleReady G-Rex® Optimization Specialist will quickly respond to every inquiry with the goal of advancing the inquiry to an actual application.

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#### The Application and Award Process:

The application process for a G-Rex® Grant is intended to be very easy and will be initiated by a simple form that will lead to a deeper dialogue with ScaleReady to help hone the application to a form suitable for receipt of a G-Rex® Grant.

G-Rex® Grants will be awarded to applicants that provide ScaleReady with:

- A compelling overview of why a G-Rex® Grant would be beneficial.
- A strong willingness to interact with ScaleReady to achieve program goals.
- Confidence that the recipient has wherewithal in program management.
- The collaborative nature of the applicant.
- Provision of a well understood set of G-Rex® Grant deliverables such as the following by way of example only:
  - o Data package to support the creation of IND enabling data
  - Data package to support an IND amendment
  - Pre-clinical data generation and publication
  - Data package to support a manufacturing change control to improve/simplify existing manufacturing processes
  - Data package to support switching cytokine or reagent suppliers
  - o Implementation of closed system G-Rex® manufacturing
  - o Data package to support the Adoption of G-Rex® "M" Series Models

#### Once a G-Rex® Grant is Approved:

Upon G-Rex® Grant approval, ScaleReady will provide a high-level Non-Binding Memorandum of Understanding to the Recipient indicating the loosely agreed upon goals, estimated timelines, deliverables, actions, and respective responsibilities that were identified in the discovery phase.

- Of importance, the Non-Binding Memorandum of Understanding is a guideline document only
- The relationship between a G-Rex® Grant Recipient and ScaleReady is based entirely on mutual trust and understanding that flexibility will be needed to reach the Recipient's program goals.
- During the Collaboration Period, the Recipient and ScaleReady will work openly and collaboratively to achieve the mutually agreed upon outcomes of the G-Rex® Grant.

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#### **G-Rex® Grant Partner Exclusive Offer Catalogue:**

ScaleReady has enlisted a legion of like-minded collaborators to bring additional value to help our G-Rex® Grant Recipients **save time and money**. All G-Rex® Grant Recipients will be provided a catalogue of exclusive offers from our official G-Rex® Grant Partners. The current list of Official G-Rex® Grant Partners and core contribution is listed below:

- Bio-Techne (R&D Systems) Discounted GMP reagents and GMP media
- Bio-Techne (Protein Simple) Discounted automated analytical equipment
- STEMCELL Technologies Discounted ImmunoCult™
- MaxCyte Discounted electroporators and consumables
- Thermo Fisher Discounted cleanroom-ready incubators (specifically designed for G-Rex®)
- Charles River Labs (Cell Solutions) Discounted RUO and GMP apheresis products
- Discovery Life Sciences (AllCells) Discounted RUO and GMP apheresis products
- VectorBioMed Discounted GMP lentivirus
- Applied Cells Discounted cell isolation technology
- Akadeum Life Sciences Discounted cell isolation technology

#### **G-Rex® Grant Program Impact:**

The array of expected impacts of the G-Rex® Grant Program typically includes:

- **Enhancing company valuation** by expediting and cost reducing the path to meaningful clinical data.
- **Quickly and inexpensively** implement an optimized G-Rex® centric manufacturing platform that is suitable for each stage of the path to commercial drug production.
- Establishing a seamless link, via G-Rex® platform continuity, between the research labs, process development labs, and the GMP manufacturing center to enable **faster** translation of new therapies into the clinic.
- Increasing patient access to cell and gene modified cell therapies by making significant reductions in process complexity.
- Increasing the value of academic institution's technology by allowing licensor's to save valuable time and money by inheriting an expeditious pathway to clinical inflection points.

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### **Contact Information:**

G-Rex® Grant inquiries can be submitted directly to <a href="info@scaleready.com">info@scaleready.com</a> or to your designated G-Rex® Optimization Specialist.

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