Rewriting Biopharma Business Model Through Disruptive Gene and T Cell Therapy Breakthrough Inventions

Advanced Science  |  Equitable Access  |  Healthier World
Tevogen Bio is a New Jersey based clinical-stage biotech pioneer, founded by prominent scientists and biopharmaceutical leaders in June of 2020.

Within 18 months of inception, the company has secured several US patents, moved its lead product from discovery to clinical trials, and earned recognition from industry analysts as one of the major immunotherapy innovators who will dominate the novel T cell market in the coming decades. This rapid progress is a testament to Tevogen’s advanced science and business prudence of leadership.

Tevogen’s current intellectual property portfolio includes several disruptive cell and gene therapy platforms which are internally invented and solely owned by the company. These breakthrough innovations open the vast and unprecedented potential of developing personalized immunotherapies for large patient populations impacted by common cancers and viral infections.

The company’s lead product, TVGN-489, consists of highly enriched allogeneic SARS-CoV-2 specific Cytotoxic T Lymphocytes (CTLs) and is currently in dose finding clinical trial for high-risk COVID-19 patients at Jefferson University Hospitals.
Platform Technologies

Tevogen’s investigational T cell immunotherapies harness nature’s approach to eradicating cancer and virus infected cells.

Tevogen leadership determined that CTL therapeutics can be developed from a single donor to treat hundreds of patients sharing the same human leukocyte antigen (HLA) type. Combining off-the-shelf convenience and safety eliminates the need for specialized medical facilities and patient specific products, such as CAR-T, making it possible to deliver safe T cell therapies with greater convenience, unprecedented speed, and at a much lower cost. This creates an opportunity to dramatically improve health outcomes for patients battling common life-threatening cancers and viral infections.

TVGN-489 was designed in anticipation of viral mutations and the investigational therapy is not impacted by Omicron or prior variants. The company’s patented off-the-shelf allogeneic SARS-CoV-2 specific CD8+ cytotoxic T lymphocytes manufacturing platform overcomes the primary barriers to the broad application of personalized T cell therapies: potency, purity, production-at-scale, and patient-pairing.

Potency and Safety: (COVID-19) TVGN-489 demonstrated strong activity toward viral targets in pre-clinical studies. In the ongoing dose finding study, the completed cohorts received single infusion of TVGN-489, with no dose limiting toxicities or treatment-related adverse events observed to date. All treated patients resolved their COVID-19 infections.

Purity: Rapid infusion delivers highly purified CD8+ CTLs within minutes.

Production-at-Scale: Tevogen’s 1st generation manufacturing leverages a highly efficient ratio of doses per donor (commercial scale ready); the 2nd generation, TCR-T process, is expected to further increase both the product’s potency and the number of doses which can be produced from a donor.

Patient-Paring: Simple patient pairing via rapid HLA typing (like blood typing) enables off-the-shelf convenience.

Robust Research Pipeline

Tevogen is pioneering lifesaving innovations for viral infections and cancers for which there is a high unmet need.

Virology, Neurology

<table>
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<tr>
<th>Clinical Phase:</th>
<th>COVID-19 (TVGN-489)</th>
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<tr>
<td>Select Preclinical Targets:</td>
<td>Long Covid, Multiple Sclerosis, Hepatitis B and HIV</td>
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Oncology

| Select Preclinical Targets: | Hodgkin’s Lymphoma, Cervical Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer and Nasopharyngeal cancer |

Intellectual Property in Virology, Neurology & Oncology

Since its inception in June 2020, Tevogen has filed for eight patents with three already granted by USPTO. This IP protects the underlying technology which empowers the unique solutions Tevogen will bring to the market; it also allows broad range use of the platform and will help ensure a robust pipeline of products for years to follow.

COVID-19

Method of Manufacturing COVID-19 peptide specific T cells (U.S. Patent 11,219,684)
Target Tuning Platform to overcome potential immune escape of SARS-CoV-2 viral variants (Pending)

Oncology & Other Viruses

Targeted CTL therapy for other viral infections with high unmet need (Pending)
Targeted CTL therapy for solid and hematologic oncology indications (Pending)
Target Specific T Cell Receptor Engineered CD8+CTL (TCR-Ts) for treatment of Cancers and Viral Infections (Pending)
Technology to Bring Targets for Tevogen’s Allogeneic CD8+Cytotoxic T Lymphocytes to Cancer Cells being Marked for Elimination (Pending)

Strategic Collaboration to Support Operational Readiness

BioCentriq – Manufacturing: Scale-out and commercial manufacturing readiness of TVGN- 489

Jefferson Health – Clinical Development: Research, clinical trial batch manufacturing and POC clinical trial

Hogan Lovells – Legal: Corporate, IP, Regulatory, Reimbursement

Yale School of Public Health – Talent Development, Disease Modeling and Epidemiology, Global expertise in COVID-19 Pandemic

Tapestry Networks – Collaboration: Thought leadership on public-private partnership, cross-industry collaboration

Simon Kucher & Partners – Market Access: World class expertise in global market access, pricing, and reimbursement
Current COVID-19 Landscape and Challenges

LIMITATIONS WITH PREVENTION

Vaccine:

| Hesitancy: | a significant portion of the population are vaccine hesitant, and a growing number are avoiding “booster shots”. Vaccine hesitancy is expected to increase |
| Breakthrough Cases: | high rate of breakthrough cases and hospitalization among the elderly and patients with certain underlying health conditions |
  | Limited immune response in immune-suppressed and immune-compromised individuals |
  | Immune evasion of current and emerging variants |
  | Short duration of protection after booster |

LIMITATIONS WITH SUPPRESSION OF INFECTION

| Mask Compliance and Social Distancing: | lack of adherence and growing pandemic fatigue |

LIMITATIONS WITH THERAPEUTICS

Monoclonal Antibodies: Susceptible to mutations

| Prevalence of Omicron: | efficacy of most monoclonal antibodies is compromised |

Antivirals:

| Safety: | history of safety issues |
| Potential drug resistance, potential to trigger additional viral mutations |
| Short time window from onset of symptoms to dosing: | narrow timeframe for treatment to be effective |
| Drug Interactions and contraindication: | many “high risk” patients currently receiving treatment for other health conditions may not qualify |

The COVID-19 CTL therapy developed by Tevogen is designed to anticipate viral mutational trajectory and is not susceptible to spike mutations, as are current vaccines and monoclonal antibodies. The safety of CTL therapy is well established in stem cell transplant patients and strategic use can significantly reduce the emergence of future variants.

There is a significant unmet need for an effective outpatient therapy for the elderly and individuals with certain underlying health conditions. Breakthrough deaths are hitting older people the hardest, amplifying a well-worn pandemic pattern. The Wall Street Journal reported data from the Epic Health Research Network and the medical-record software company Epic Systems Corp., showing about 80% of breakthrough deaths among the vaccinated are in people ages 65 and older. The data included records for 19.5 million fully vaccinated people as of November. Among all Covid-19 deaths in 2021, that age group represents closer to 69%, according to the CDC1.

The following initiatives are underway to prepare the organization for commercialization:

**Outsourced Commercial Manufacturing** – Initiated discussions with major global contract manufacturing organizations

**Rapid HLA Typing Equipment** – Initiated discussion with the manufacturer of rapid HLA typing equipment

**In-house Capability Building**
- Strategic plan to expand R&D, manufacturing, warehousing, and corporate headquarters
- Initiated discussions with leading cleanroom manufacturers
- Identified potential acquisition targets including CDMOs, Protein Research lab, and GMP peptide manufacturing company

**Established Supply Chain**
- All necessary laboratory suppliers and national donor program

## Agile and Experienced Leadership

**Ryan Saadi, M.D., M.P.H.,** Founder and Chief Executive Officer

As a renowned innovator and author in the world of healthcare and a leading expert in global health policy, patient access, clinical development, and infectious disease epidemiology, Dr. Saadi spent nearly three decades in healthcare, in leadership roles within global biopharmaceuticals, hospital administration, and managed care. He served a nine-year term as a voting member of Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), which provides independent guidance and expert advice to CMS, and is currently a member of the Leadership Council of Yale University School of Public Health. He has been recognized multiple times for his unique leadership approach, including being named among the Most Inspiring Leaders in the Life Sciences Industry by PharmaVoice magazine. Dr. Saadi is a graduate of Yale School of Medicine, Dhaka Medical College, and Harvard Business School Executive Education Program.

**Neal Flomenberg, M.D.,** Chairman, Research & Development Advisory Board - T Cell Therapy Pioneer

Dr. Flomenberg is Professor and Chair of the Department of Medical Oncology and Deputy Director of Thomas Jefferson University’s Sidney Kimmel Cancer Center and a pioneer in T cell therapy. His career has focused on the care of patients with blood cancers, particularly those undergoing bone marrow or peripheral blood stem cell transplants. His laboratory and clinical research efforts have focused on improving our understanding of the challenges these patients face and developing innovative solutions to these problems. He has authored more than 175 peer reviewed publications. Among others, his most significant scientific accomplishments include: The first in human administration of Interleukin-2; initial descriptions of immunologic recovery after allogeneic BMT, including the first description of the spectratyping technique to assess T cell receptor diversity; and establishment of a reproducible platform for haploidentical transplantation, which allowed T cell and stem cell dose to be consistently controlled and manipulated for therapeutic advantage.
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