Alloplex Biotherapeutics

EXECUTIVE SUMMARY

Retraining the immune system to conquer cancer

A novel cell therapy based on a de-risked immune cell training platform with broad applications across oncology, autoimmunity and inflammatory indications.

PREPARED

July 2026

Alloplex™ is a clinical-stage biotechnology company developing an innovative and differentiated approach to cellular immunotherapy. This approach employs an ex vivo immune cell training platform called **ENLYST™** which avoids the need for genetic engineering. The lead program derived from this platform is called **SUPLEXA™** and is manufactured from a small amount of patient blood in a two-week manufacturing process. SUPLEXA cells comprise highly activated innate lymphoid cells of the NK and type II NKT lineages. These are tissue-resident cells with cytolytic and antigen-presenting properties that display a unique and previously unrecognized activation profile.

Alloplex Investment Thesis

- **Emerging Field of Cellular Therapy:** Cellular therapy is an emerging and innovative field with proven efficacy in oncology and is now being developed for autoimmune indications. There are currently ten approved cell therapies (seven CAR-T, one TCR-T, one TIL, and one DC) in oncology —all autologous—with many allogeneic cell therapies in development for autoimmunity. Alloplex harnesses innate immune cells and their functional plasticity as a more holistic, multi-mechanistic approach to treating complex indications.

- **Uniquely Differentiated Platform Technology:** Alloplex has developed a versatile immune cell training platform, ENLYST, involving the use of proprietary cell lines to deliver an array of precise immunomodulatory signals through naturally expressed receptors on patient immune cells. The platform is simple to use, yielding reproducible results in a relatively quick process at highly favorable economics – all features well-suited to regional manufacturing.

- **De-risked Development Stage:** Alloplex has made significant progress in advancing SUPLEXA through a single-agent signal-seeking Phase 1 clinical study in end-stage solid cancer patients. All key clinical milestones have been achieved, including a robust and efficient manufacturing procedure and effective deployment under GMP conditions to deliver over 220 doses in a highly monitored setting. With a fixed cell dose and no treatment-related serious adverse events, these clinical data significantly de-risk further investment. This prepares the way for a first Phase 2 randomized clinical trial in our lead oncology indication: AML/MDS. Moreover, as these results were achieved with essentially no treatment-related adverse events and notable reported improvements in quality of life, Alloplex is positioned to rapidly test SUPLEXA in a number of indications involving fragile patients.

- **Prioritizing hematologic malignancies:** With the demonstrated ability to kill tumor cells on contact and a chemokine receptor profile that enables specific migration to the bone marrow, SUPLEXA cells possess significant potential for the treatment of malignancies that originate in the bone marrow, such as multiple myeloma (MM), myelodysplastic syndrome (MDS), acute myelogenous leukemia (AML), and chronic lymphocytic leukemia (CLL). In collaboration with premier institutions, preclinical experiments on patient blood samples have shown that the ENLYST immune cell training procedure works even with the most diseased samples to produce a product functionally comparable to that made from healthy volunteers.
- SUPLEXA cells employ multiple regulated mechanisms that are complementary and non-overlapping with the existing blockbuster class of immune checkpoint inhibitors: SUPLEXA cells possess the hallmark immunologic mechanisms expected to synergize with checkpoint inhibitors, a blockbuster class of drugs that has set the current standard for immunotherapies across multiple tumor types.
- **Optimized manufacturing with reduced Cost of Goods Sold (COGS) makes a strong pharmacoeconomic argument:** SUPLEXA cells are already expected to be less expensive than other cell therapies owing to their non-engineered nature, and current activities aim to reduce costs even further through a local manufacturing model, with the ultimate goal of making this individualized cell therapy priced comparable to monoclonal antibody treatment. If successful, it would allow for greater patient access and utilization in earlier stages of disease, where cell therapies are more likely to be most effective—especially those derived from the patient's own immune cells.

Financing

Alloplex has been highly capital-efficient, with over **$30 million USD** raised to date, predominantly from high-net-worth individuals. We are now seeking an additional **$25–$50M USD** to advance one or more clinical trials. The next clinical study could potentially be registration-quality should data emerge as expected, supporting an accelerated approval strategy.

Scientific background

The ENLYST immune cell training platform is versatile and can be applied to a variety of starting immune cells of either autologous or allogeneic origin. Alloplex, however, has focused on developing this platform from autologous, non-engineered PBMCs to create SUPLEXA therapeutic cells because of the ease of sample procurement and manufacturing efficiency. The platform can also be applied to TILs, isolated immune cell subsets, bone marrow, as well as iPSC-derived immune cells and cord blood for allogeneic, off-the-shelf approaches. While the initial embodiment is non-engineered, the methodology allows for integration with a variety of engineering approaches, thus seamlessly integrating with existing CAR, TCR, and cell armoring approaches.

Our lead program, SUPLEXA cells are non-engineered, autologous immune cells with the ability to:

- migrate to key immunologic sites including bone marrow, lymph nodes and tumor.
- kill tumor cells through cell-cell contact while avoiding harm to normal cells.
- acquire, process, and present released tumor antigen to educate and prime host T cells against the tumor.
- shift the host's peripheral immune repertoire toward one that favors a more sustained anti-tumor response.
- be manufactured through a commercially scalable proprietary process owing, in part, to the absence of cell selection and complex genetic engineering steps.

At the outset of this research program, we hypothesized that together, all these SUPLEXA activities would culminate in tangible clinical responses in end-stage metastatic cancer patients who had exhausted all other treatment options. SUPLEXA has now met all prespecified endpoints in a single-agent Phase 1 clinical proof-of-concept study and is poised to advance into select solid tumor indications.

- The **primary endpoint** demonstrated safety and tolerability.
- The **secondary endpoint** demonstrated single-agent clinical activity with RECIST responses in patients with specific solid cancer types.
- The **exploratory endpoint** demonstrated an early pharmacodynamic impact on the blood composition of treated patients within weeks of the first SUPLEXA dose. Based on numerous laboratory analyses, and extensive review of the literature concerning what is known of NK and NKT cell biology, Alloplex has delineated multiple SUPLEXA mechanisms that complement those of immune checkpoint inhibitors.

In addition to our effort in oncology, Alloplex has further developed our cell therapy platform to augment cell attributes deemed favorable for the treatment of autoimmune diseases. This recent effort opens an entirely new opportunity that leverages lessons and skills acquired during the development of our lead oncology product over the past 10+ years.

Regulatory and Commercial Background

Alloplex has recently submitted an IND for a solid tumor indication and has been granted Fast Track status, signifying very positive implications for future regulatory interactions. The FDA agreed with the proposed approach for development of SUPLEXA and provided clear guidance to further streamline manufacturing and clarify clinical trial designs.

Our cellular therapies take advantage of naturally occurring functionality, which is heightened through our proprietary immune cell training process. Alloplex is currently refining the immune cell training platform for indications as diverse as those involving chronic systemic inflammation and neuroinflammation, such as Autism Spectrum Disorder, Alzheimer's Disease, Parkinson's Disease, and Multiple Sclerosis. Alloplex is also prioritizing efforts in autoimmunity with inflammatory bowel disease indications.

Intellectual Property

The SUPLEXA program is fully owned and controlled by Alloplex with no third-party royalty obligations. The SUPLEXA intellectual property is protected by issued patents, filed patents, and closely held trade secrets. Due to the cellular nature of this treatment and its proprietary manufacturing process, SUPLEXA will also be afforded a level of exclusivity protection far beyond what composition-of-matter patents typically allow for small molecules or recombinant protein drugs.

Near-Term Company Goals

- Submit a full IND to the FDA for a hematologic malignancy.
- Select and perform a technology transfer to a US-based GMP cell manufacturing facility to support US-based clinical trials and eventual US commercial launch.
- Raise capital to develop manufacturing and clinical trial activities.

Exit Strategy

The evolving dataset should permit Alloplex to continue to raise sufficient capital to support advancement of the program. All options remain open, including a pharma strategic partnership, buy-out, or IPO. None of these preclude a go-it-alone strategy, given the streamlined development of the SUPLEXA asset.

Company History

Alloplex Biotherapeutics is a privately held company located in Boston, MA, founded in 2016 based on a novel technology invented by our CEO. The company is supported by our board of directors, scientific advisory board and a panel of seasoned business advisors. Extensive information is available on the website www.alloplexbio.com with additional information available under CDA.

Frank Borriello, MD, PhD
Founder and CEO
alloplexbio.com/contact