

## Executive Summary June 2024

**MISSION:** Bespoke is dedicated to engineering human B-cells into 1) immuno-oncology "living drugs" that can traffic to tumors, costimulate and activate T-cells, and locally secrete anticancer and immunomodulatory antibodies and cytokines, to eradicate high-risk locally advanced and metastatic solid tumor cancers, and 2) long-lasting safe and effective cellular gene therapies for adults and children with severe hemophilia A. Our breakthrough product candidates are intended to overcome obstacles to current pharmacologic immunotherapy (e.g., CAR-T) against cancer and rAAV-based, liver-targeted gene therapy for hemophilia A.

**BUSINESS:** Bespoke, founded in 2021, is an award winning, privately held biotechnology company focused on unlocking the vast potential of genome engineered B-cell therapeutics to address the clinical and emotional needs of persons with solid tumor cancers and those with severe hemophilia A. Bespoke is built upon the expertise and experience of its founders and core scientific advisers, B-cell genome engineering and synthetic biology innovations, and a robust B-cell engineering patent portfolio (14 granted to date). Bespoke is poised to expand internal and sponsored R&D as well as process development efforts to efficiently advance its lead solid tumor oncology and hemophilia A product candidates to IND and first-in-human, proof-of-concept, Phase I clinical trials.

## **LEADERSHIP:**



Steven R. Deitcher, MD Founder, CEO & Chairman Serial Biotech Builder Drug Dev Expert St. Jude CRH • Cleveland Clinic Nuvelo • Talon

Medeor • SandboxAQ

Branden Moriarity, PhD Co-founder & CSO U of Minnesota B-cell Genome Editing Expert B-MoGen Luminary Tx

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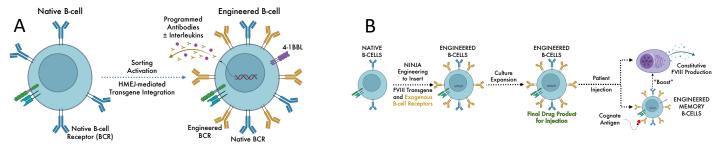


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**PLATFORMS:** Starting with venous whole blood collection, Bespoke combines the distinct protein production, antigen presentation, and immunologic memory functions of B-cells with cutting-edge non-viral B-cell genome engineering to impart <u>actuatable</u> (inducible) therapeutic antibody and cytokine expression, or coagulation protein secretion. Native B-cells are programmed into engineered B-cell therapeutics, using proprietary activation media and homology mediated end joining (HMEJ) to achieve T-cell co-stimulatory factor expression and site-specific large transgene (>5kb) cargo integration, as needed. B-cell receptors are engineered to detect specific cognate antigens, and when stimulated, actuate the production of programmed anticancer antibody +/- immuno-modulatory cytokines or coagulation factor VIII (Figures A & B). For solid tumor cancer treatment, engineered functions can be combined to detect and eliminate high-risk Stage II and Stage III (i.e., *Cancer Sentinels*) or treat Stage IV (i.e., *Cancer Rangers*) cancers.



PIPELINE: Bespoke's paradigm-changing engineered B-cell therapeutic product candidates include:

- BB-101: Autologous Cancer Sentinel product to prevent overt relapse of high-risk Stage II and Stage III HER2+ solid tumors.
- BB-ACT: Autologous engineered B-cell therapeutic designed to enhance native T-cell and CAR-T anti-cancer functions.
- **BB-2112**: Auto/Allo Cancer Ranger product to promote a multi-prong immune attack against metastatic solid tumor cancers.
- **BB-FVIII-BC:** Autologous "boostable" B-cell-mediated factor VIII replacement therapy and functional cure for hemophilia A.

**THE MARKET:** Bespoke engineered B-cell therapeutics will build and improve upon existing classes of anti-cancer and hemophilia A therapy, including cytokines, dendritic cell vaccines, antibody therapeutics, and hepatocyte-targeted gene therapy accounting for more than US\$60B in annual sales. Our oncology products are intended to be standalone drugs and synergize with immune checkpoint inhibitors as well as engineered T-cell products (i.e., CAR-T). Bespoke anticipates premium pricing and strong physician support.

**COMPETITION:** Others use viral-based, homologous recombination-mediated plasma cell product engineering using transgenes <5kb to treat congenital enzyme deficiencies. In contrast, Bespoke is focused on innovative **non-viral**, **HMEJ-mediated genome engineering of true B-cell products that require large (>5kb) transgenes** and build on our robust (14 granted) patent portfolio.

**OPERATIONS:** Bespoke is a JLabs Company housed at MBC BioLabs with discovery R&D and manufacturing process development activities centered in San Carlos, California and within the University of Minnesota's Masonic Cancer Research Center in Minneapolis.

**FUNDRAISING:** Bespoke seeks capital to 1) accelerate R&D activities; 2) build out its scientific team; and 3) generate additional proofof-concept data to support IND-enabling regulatory engagement, future fundraising efforts, and future Phase 1 clinical trials.