

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): June 7, 2019

**Precision BioSciences, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-38841  
(Commission  
File Number)

20-4206017  
(IRS Employer  
Identification No.)

302 East Pettigrew St., Suite A-100, Durham, North Carolina 27701  
(Address of principal executive offices) (Zip Code)

(919) 314-5512  
(Registrant's telephone number, include area code)

N/A  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

| Title of each class                          | Trading Symbol | Name of each exchange on which registered |
|--|----------------|---|
| Common stock, par value \$0.000005 per share | DTIL           | The Nasdaq Global Select Market           |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01. Regulation FD Disclosure.**

As previously announced, Precision BioSciences, Inc. (the "Company") will be participating in meetings with investors and analysts, and a copy of the Company's presentation materials being used at these meetings is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. These presentation materials are also available on the Investor Relations page of the Company's website at <https://investor.precisionbiosciences.com>.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u>  |
|--------------------|---|
| 99.1               | <a href="#">Precision BioSciences, Inc. Presentation, June 2019</a> |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PRECISION BIOSCIENCES, INC.

Date: June 7, 2019

By: /s/ Matthew Kane  
Matthew Kane  
President and Chief Executive Officer



Dedicated to Improving Life.

DTIL

Overcome cancer.  
Cure genetic disease.  
Feed the planet.



# Forward Looking Statements



This presentation (together with any other statements or information that we may make in connection herewith) may contain forward-looking statements. All statements other than statements of present and historical facts contained in this prospectus, including without limitation, statements regarding our future results of operations and financial position, business strategy, prospective products, planned preclinical or greenhouse studies and clinical or field trials, regulatory approvals, research and development costs, and timing and likelihood of success, as well as plans and objectives of management for future operations, may be forward-looking statements. Without limiting the foregoing, the words "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "may," "will," "would," "potential," the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements reflect various assumptions of Precision's management that may or may not prove to be correct. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding; our limited operating history; our ability to identify, develop and commercialize our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; our or our collaborators' ability to identify, develop and commercialize product candidates; our or our collaborators' ability to advance product candidates into, and successfully complete, clinical or field trials; our or our collaborators' ability to obtain and maintain regulatory approval of future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the regulatory landscape that will apply to our and our collaborators' development of product candidates; our ability to achieve our anticipated operating efficiencies as we commence manufacturing operations at our new facility; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; the success of our existing collaboration agreements; our ability to enter into new collaboration arrangements; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; potential manufacturing problems associated with any of our product candidates; potential liability lawsuits and penalties related to our technology, our product candidates and our current and future relationships with third parties; and other important factors discussed under the caption "Risk Factors" in our quarterly report on Form 10-Q filed with the SEC on April 29, 2019, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov)

All forward-looking statements speak only as of the date of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This presentation may also contain estimates, projections, and/or other information regarding our industry, our business and the markets for certain of our product candidates, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, clinical trials, studies and similar data prepared by market research firms and other third parties, from industry, medical and general publications, and from government data and similar sources. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

# Dedicated To Improving Life



Overcome Cancer.



Cure Genetic Disease.



Feed the Planet.





Proprietary **ARCUS genome editing platform** built for translation with full freedom to operate

Fully scaled and cell-optimized **allogeneic CAR T platform** in the clinic for R/R NHL and ALL



World class team of *Precisioneers* that includes the **pioneers** in genome editing



Industry leading **in vivo gene correction platform** first to publish in non-human primates



Wholly integrated **food editing platform** focused on human wellness and food security



# Our Near-Term Development Strategy







# ARCUS

## Nature's Genome Editing System





## Industry's Approach to Genome Editing

- ⊖ Ease of design
- ⊖ Speed of manufacture
- ⊖ Density of targeting
- ⊖ Open source

## Precision BioSciences' Approach to Genome Editing

- ✓ Safety
- ✓ Delivery
- ✓ Control of edits
- ✓ Proprietary

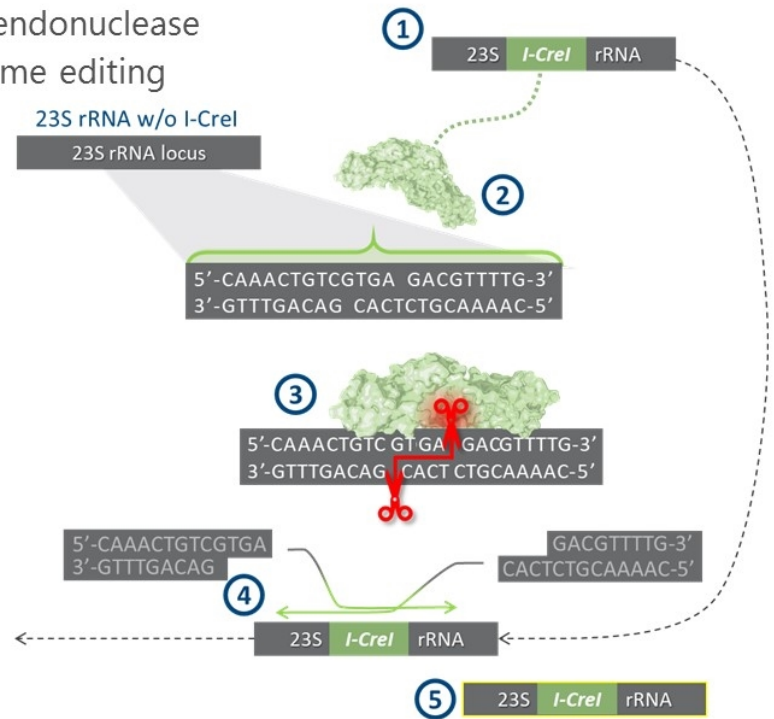
# ARCUS: Engineering Nature's Genome Editing System



ARCUS is derived from I-CreI, a homing endonuclease naturally evolved for highly precise genome editing

## Four Key Attributes

- 1. Safety:** Requires productive binding before cutting
- 2. Delivery:** Small size (364 amino acids) maximizes delivery
- 3. Control of edit:** "Sticky ends" enables all forms of edits
- 4. Proprietary:** Complete control of platform and freedom to operate





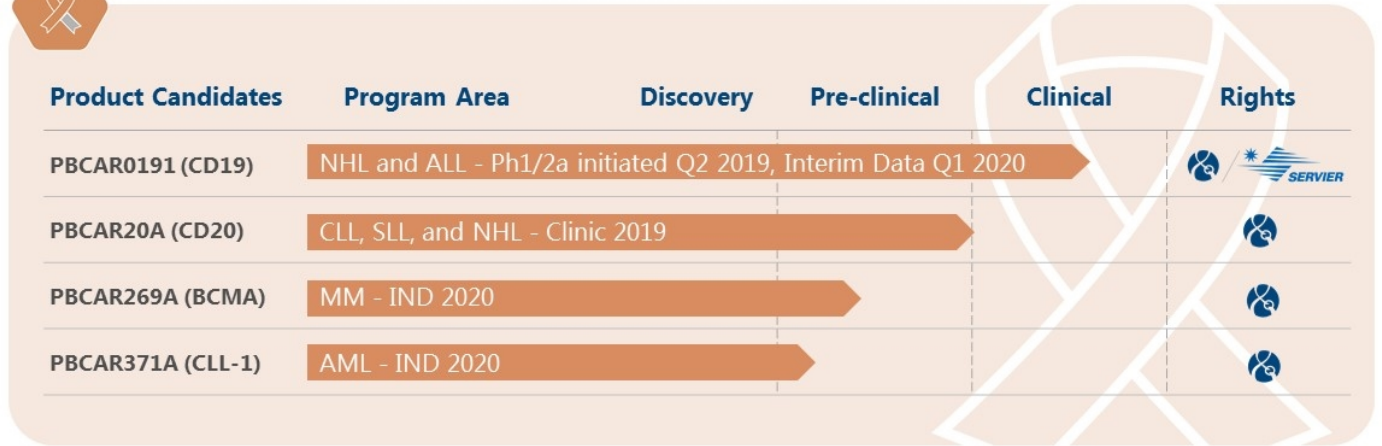


# Overcoming Cancer

Off-the-shelf CAR T



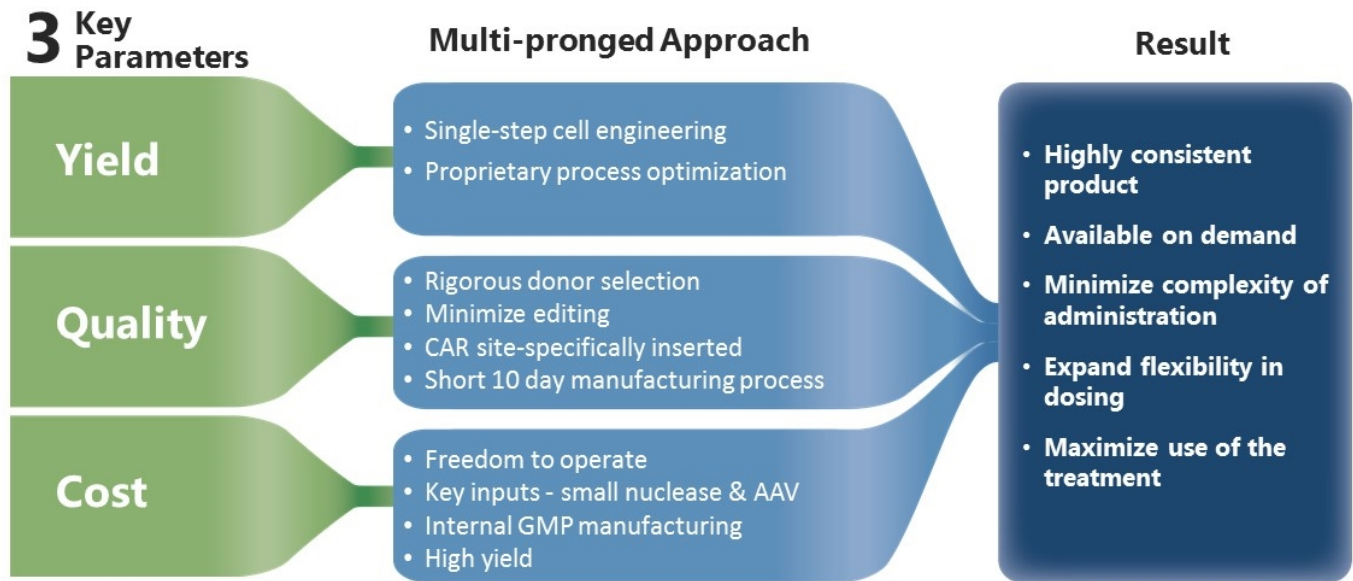
# Off-the-shelf CAR T Immunotherapy Pipeline

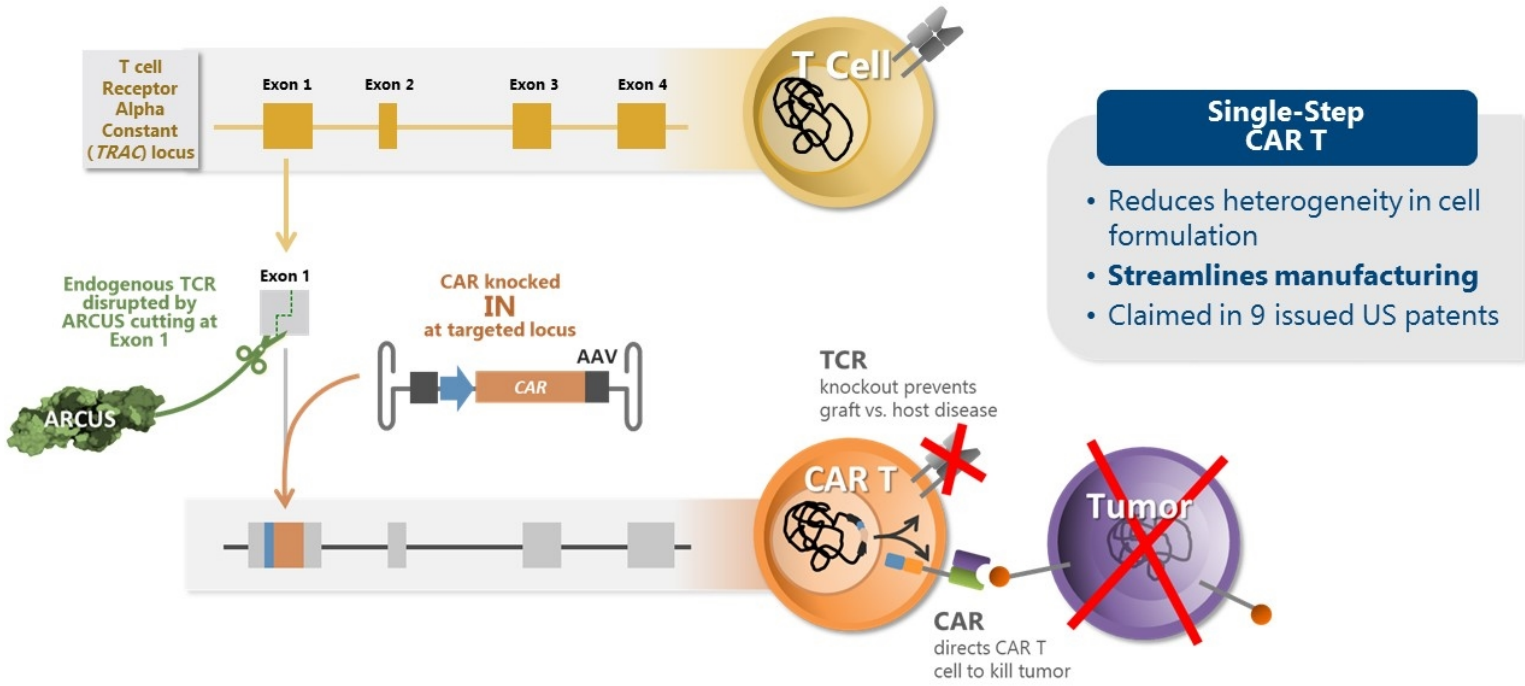


# An Allogeneic CAR T Platform Designed to Overcome Cancer

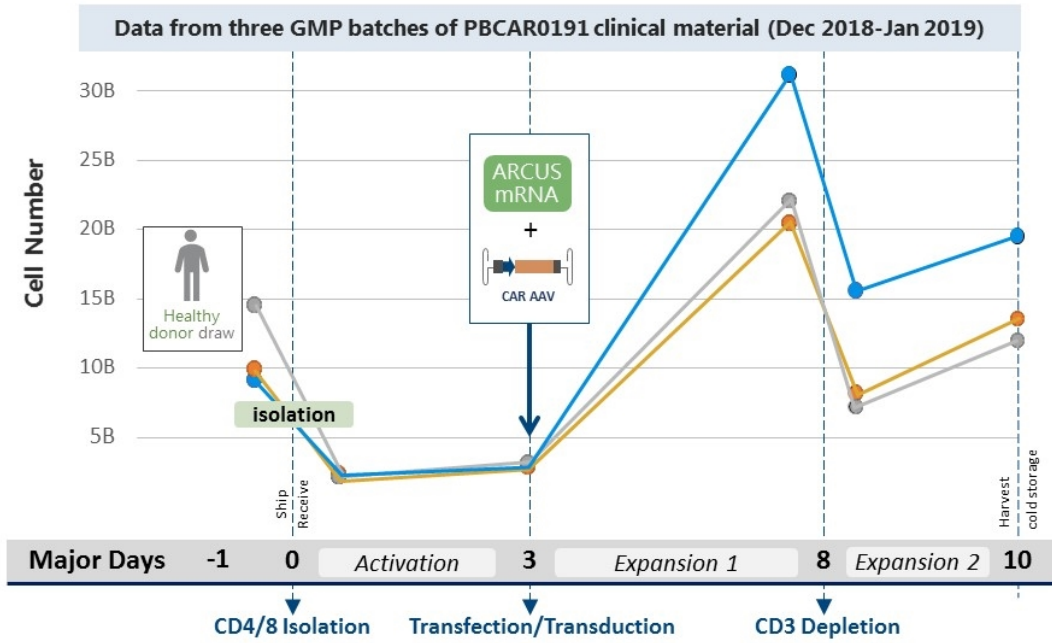


Allogeneic CAR T requires a traditional drug development approach to compete with traditional biologics





# Scaled CAR T Manufacturing: Optimizes Yield and Quality



**Final Yield  
CD19 Drug Product**  
(64M CAR T cells/vial)

| Batch | Vial Count |
|-------|------------|
| 1     | 130        |
| 2     | 114        |
| 3     | 100        |

CD3- >99%  
CAR+ 65% - 75%  
T<sub>N/SCM</sub> & T<sub>CM</sub> >50%  
1.25 CD4:1 CD8 (Batch2)

T<sub>N/SCM</sub> = Naïve; T<sub>CM</sub> = Central Memory

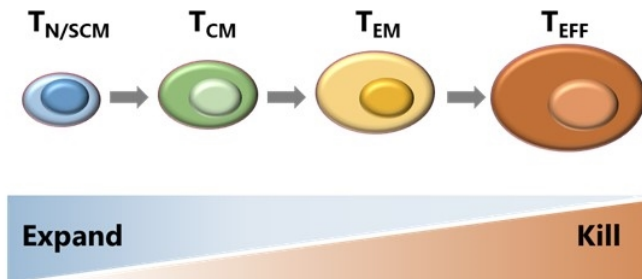
# CAR T Cell Phenotype Optimized for Robust Expansion



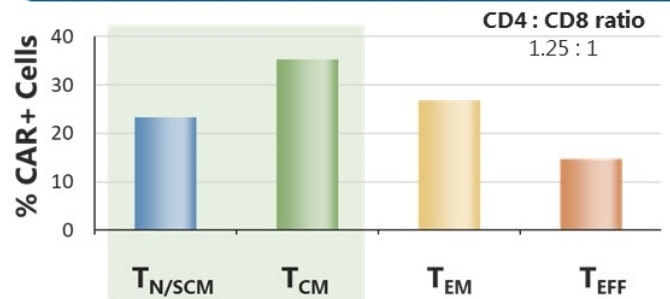
Donor selection and proprietary manufacturing designed to **maximize naïve and central memory T cells**

- Rapid *in vivo* expansion is correlated with high proportions of combined Naïve ( $T_{N/SCM}$ ) and Central Memory ( $T_{CM}$ ) CD4+ and CD8+ T cells. We believe that this is critical to the success of an allogeneic CAR T therapy.
- Lengthy and/or complex manufacturing processes result in primarily effector memory ( $T_{EM}$ ) and effector ( $T_{EFF}$ ) T cells.

Naïve and Central Memory CAR T cells are understood to be responsible for *in vivo* CAR T expansion.



PBCAR0191 has shown a high proportion of Naïve and Central Memory CAR T cells.

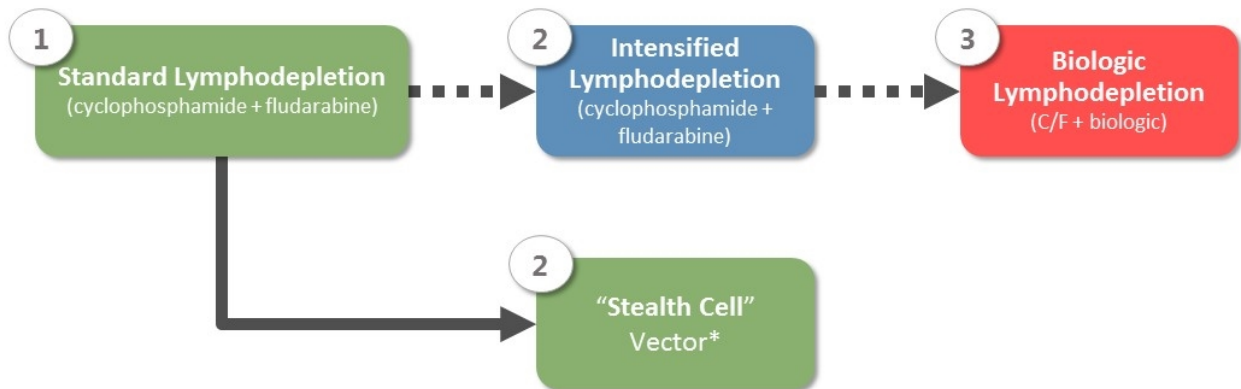


Actual data from PBCAR0191 clinical trial drug product (CTM2)

# Roadmap for Clinical Development



- Maximization of naïve and central memory T cells allows for initial exploration with standard cy/flu LD
- Clinical data will direct an expanded LD or the addition of a biologic *only if needed*
- The **“Stealth Cell”** vector will be explored upon completion of initial clinical studies



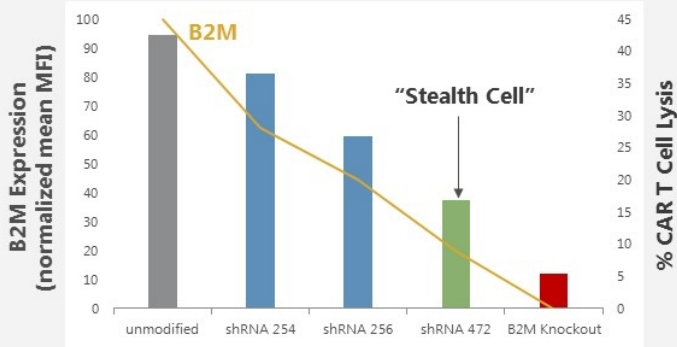
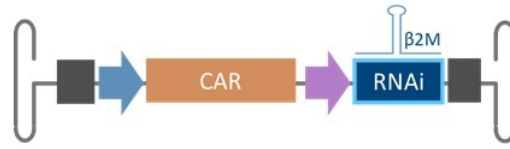
\*Novel cell masking strategy that does not require additional editing



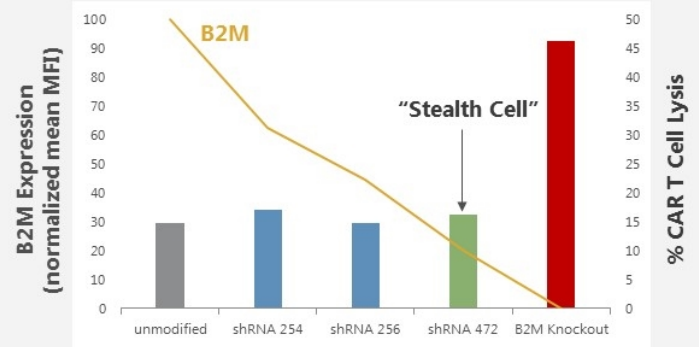
# "Stealth Cell" B2M Knockdown to Extend Cell Persistence



- Completely eliminating MHC-I (knocking out B2M) results in rapid cell killing by NK cells
- Reducing surface expression of MHC-I to ~10% of wild-type levels reduces cell lysis by T cells or NK



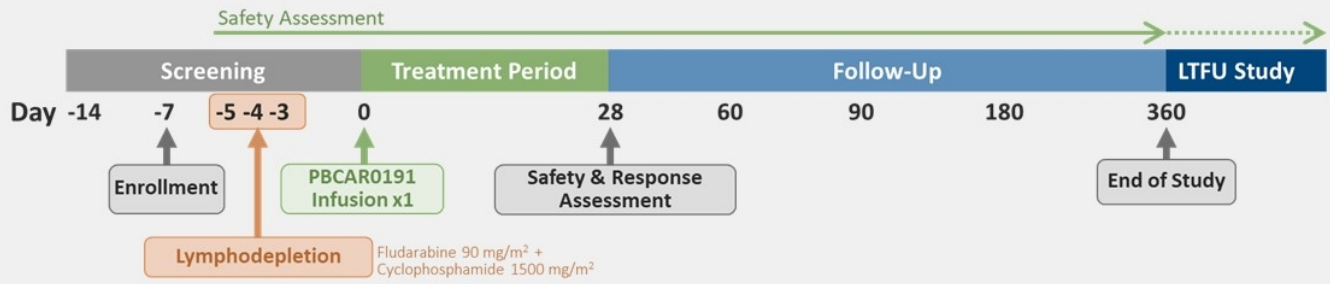
Rejection by T Cells



Rejection by NK Cells

\*B2M reduction reduces expression of MHC class 1 on cell surface. MHC-1 mismatch identifies the cell as non-self and triggers rejection by patient immune cells





**First patient dosed April 2019**

## Eligibility

- Adult patients with r/r B-NHL or r/r B-ALL

## Clinical Sites

- Moffitt (Bijal Shah)
- City of Hope (Anthony Stein / Alex Herrera)
- Dana Farber (Caron Jacobson)
- MD Anderson (Nitin Jain)

## Objectives

- Primary: safety and tolerability
- Secondary: anti-tumor activity
- Exploratory: expansion, trafficking, and persistence

## Dose Escalation

- DL1 = 3.0 x 10<sup>5</sup>/kg (~ 1.8 – 2.5 x 10<sup>7</sup> total cells) n=3
- DL2 = 1.0 x 10<sup>6</sup>/kg (~ 6.0 – 8.5 x 10<sup>7</sup> total cells) n=3
- DL3 = 3.0 x 10<sup>6</sup>/kg (~ 1.8 – 2.5 x 10<sup>8</sup> total cells) n=3

# First Allogeneic cGMP Manufacturing Facility in the U.S.



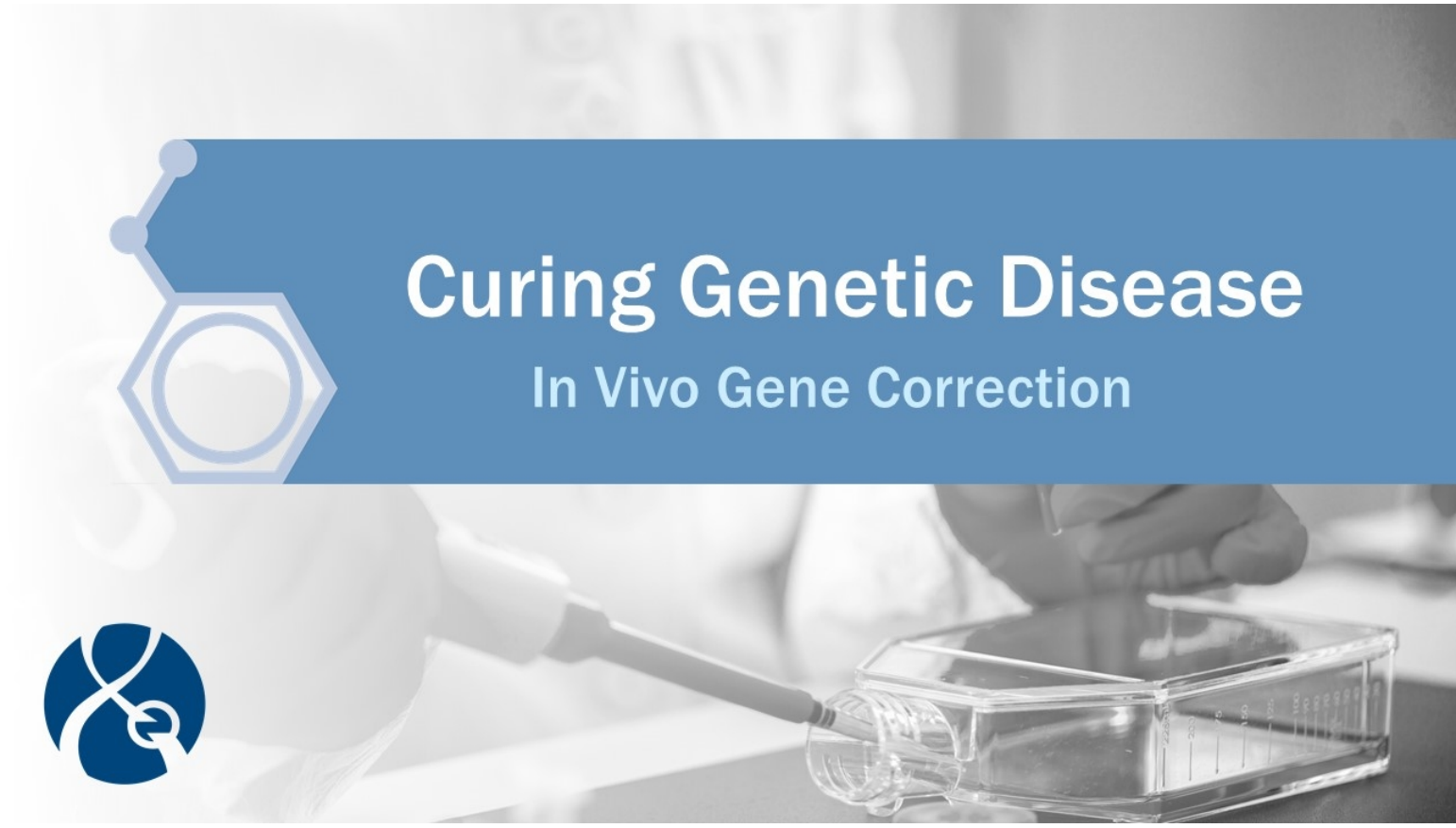
- 17,300 square foot cGMP clinical manufacturing expected to open in 2H 2019
- Allogeneic CAR T Cells, mRNA (10g scale) and rAAV (400L scale) vectors for *in-vivo* and *ex-vivo* uses
- Facility in close proximity to RDU airport and Precision R&D facility (<10 min)
- Second phase expansion for commercial (>10,000 CAR T doses / treatments per year)





# Curing Genetic Disease

In Vivo Gene Correction

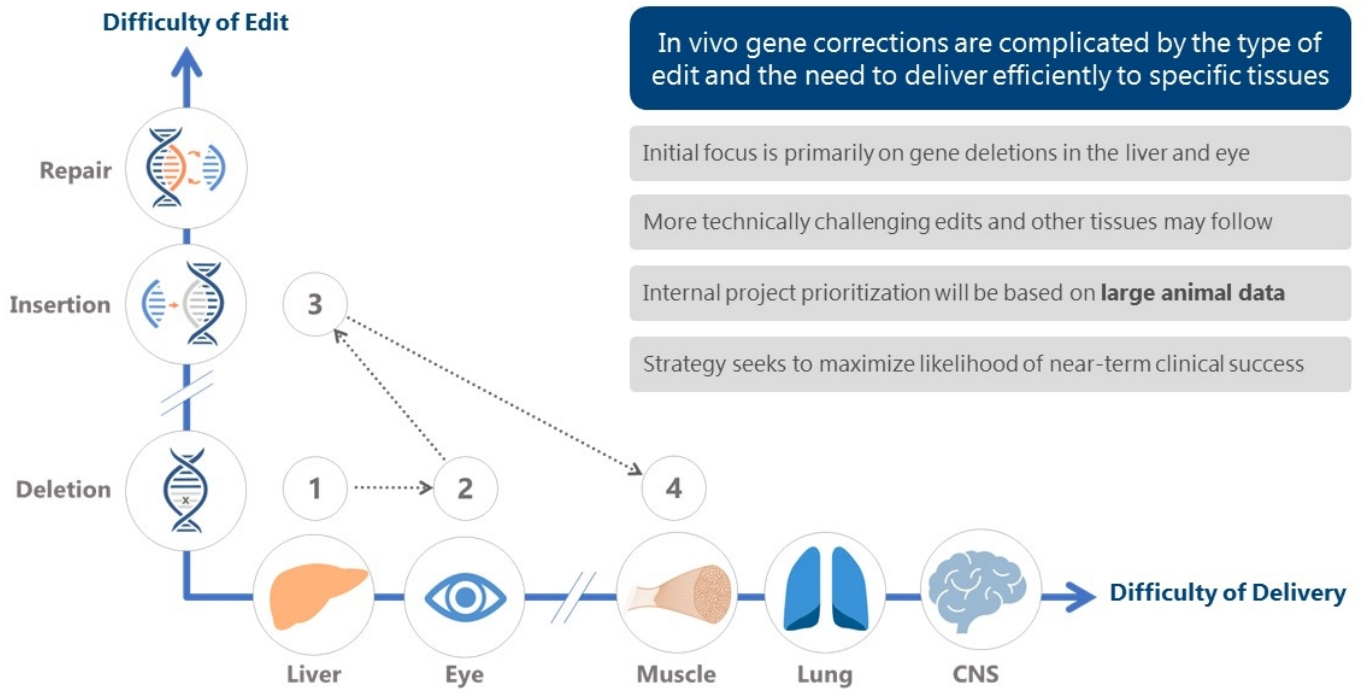


# In Vivo Gene Correction Pipeline



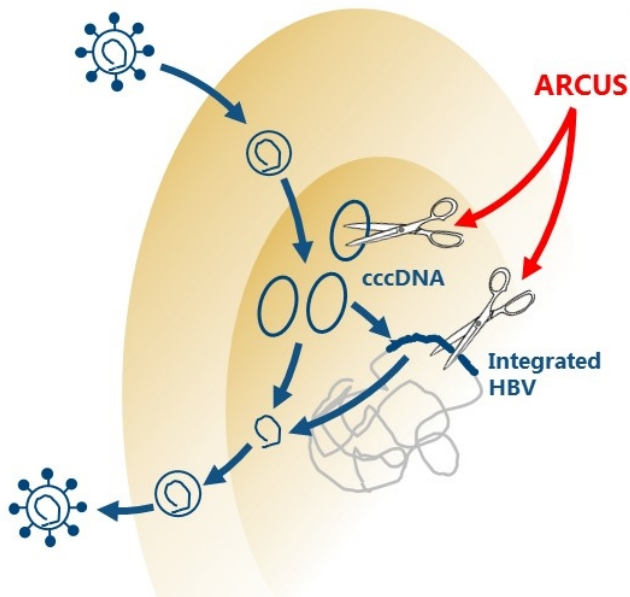
| Product Candidate           | Program Area                    | Discovery  | Pre-clinical | Clinical | Rights |
|-----------------------------|---------------------------------|--|--------------|----------|--------|
| HBV                         | Chronic Hepatitis B – IND 2020  |  |              |          | GILEAD |
| Transthyretin               | Familial amyloid polyneuropathy | <p>Candidate selection for lead gene correction (2H19)</p> |              |          |        |
| HAO1                        | Primary hyperoxaluria           |  |              |          |        |
| FVIII (Intron 22 inversion) | Hemophilia A                    |  |              |          |        |
| P23H RHO                    | Retinitis pigmentosa            |  |              |          |        |
| ApoC3                       | Lipoprotein lipase deficiency   |  |              |          |        |
| PCSK9                       | Familial hypercholesterolemia   |  |              |          |        |

# In Vivo Gene Correction Strategy

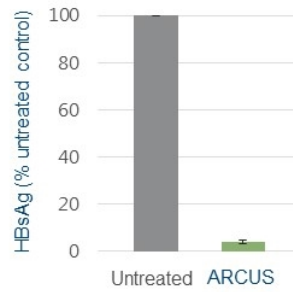


ARCUS can target and destroy HBV cccDNA to potentially cure chronic HBV

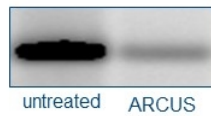
Development of a potential cure



A) ARCUS reduces HBV S-antigen in infected human hepatocytes



B) ARCUS reduces cccDNA in infected human hepatocytes



We are working with Gilead to develop a drug formulation for curing chronic HBV infection

- mRNA-based drug
- Lipid nanoparticle (LNP) delivery
- Large-scale in-house mRNA manufacturing process
- Preclinical data collection underway
- **IND expected in 2020**

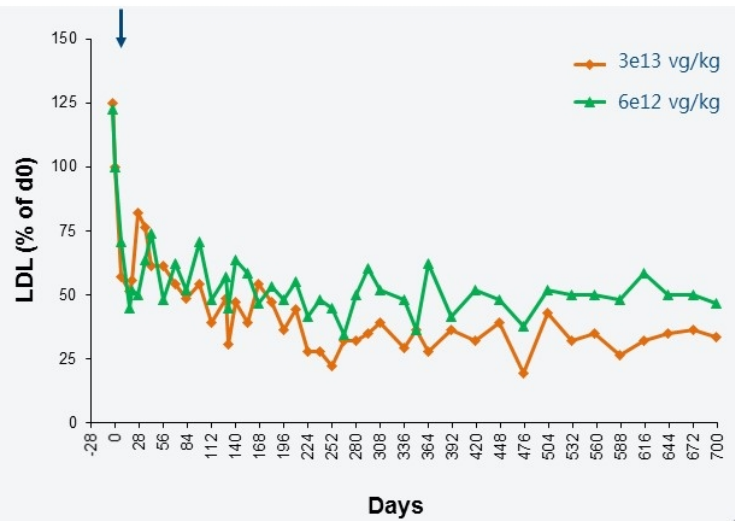
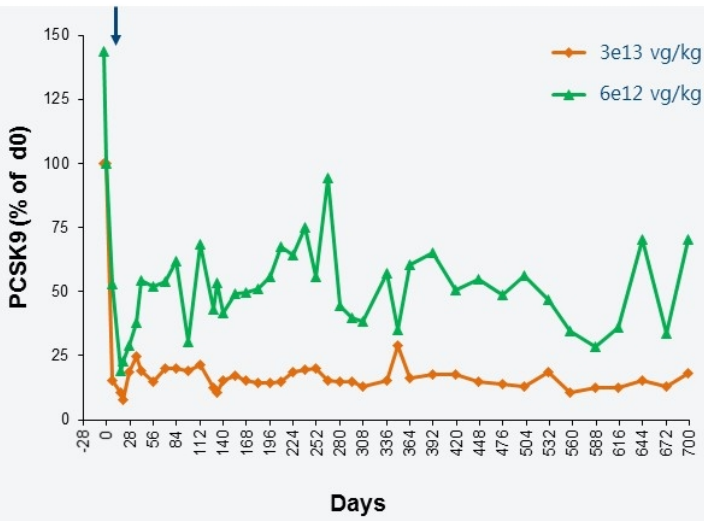


# Familial Hypercholesterolemia: Reduce 'Bad' Cholesterol



Rhesus macaques treated with ARCUS show sustained reductions in PCSK9 and LDL levels since 2017

- First peer-reviewed data demonstrating *in vivo* gene correction in a non-human primate model
- LDL levels are stably reduced by roughly 50% or more following one-time AAV delivery of an ARCUS nuclease
- Animals tolerated treatment, no obvious AEs and appear healthy two years after dosing
- Similar results obtained with 4 additional treated animals at 1 year+





ARCUS can be used to selectively eliminate the P23H *RHO* gene associated with adRP

>wild-type rhodopsin  
ACGGGTGTGGTACGCAGCCCT

← leave WT allele intact

>RHO C68A (P23H) mutant

← eliminate mutant allele

~~ACGGGTGTGGTACGCAGCCACT~~



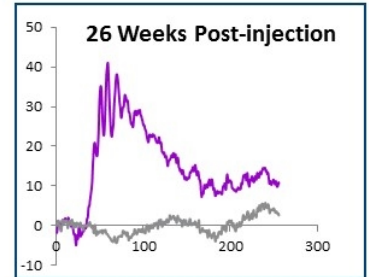
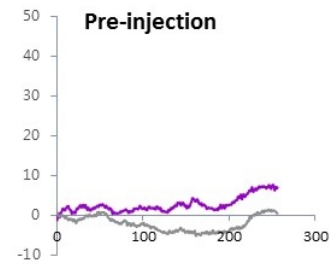
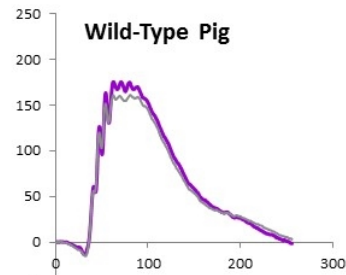
Inject P3-P7  
(one eye)



hP23H *RHO* Transgenic Pig

Electroretinogram (ERG)

ARCUS treatment restores vision in a humanized pig model of P23H adRP







# Feed the Planet

Elo Life Systems









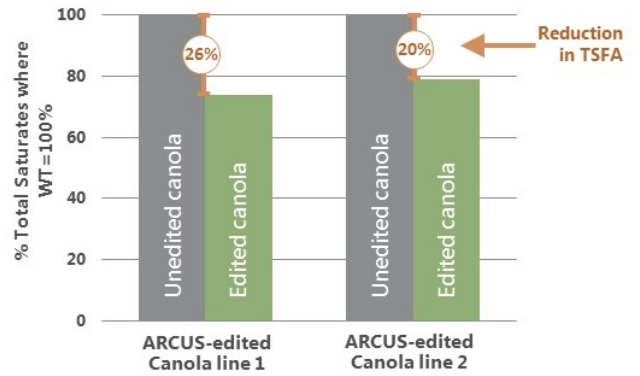
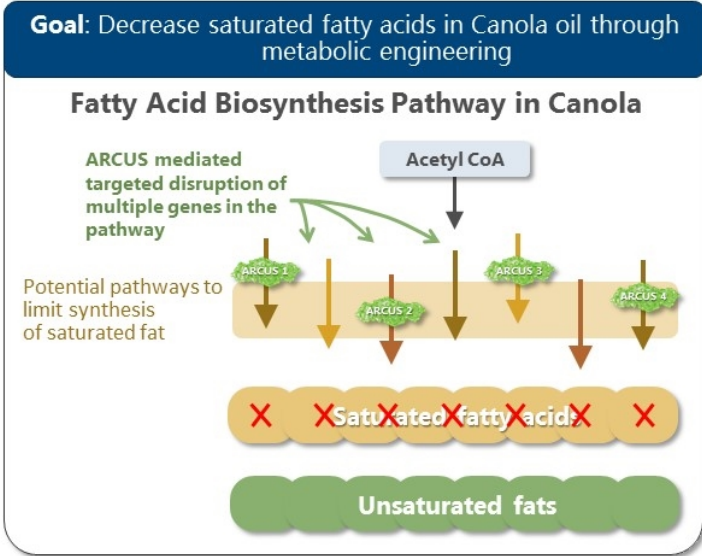
| Product                                   | Discovery | Greenhouse | Field | Program Lead |
|---|-----------|------------|-------|--------------|
| Ultra-low Saturate Canola Oil             |           |            |       |              |
| Scaled, Zero Calorie Watermelon Sweetener |           |            |       |              |
| Self-Breeding Stevia                      |           |            |       |              |
| High Protein Chickpea                     |           |            |       |              |

# Elo Seeks to Improve Human Health Through Food

Elo Life Systems is a food focused subsidiary of Precision BioSciences

-  Climate change is already having a dramatic impact on our food supply
-  Consumers are increasingly demanding healthier, sustainable sources of food
-  Elo has fully integrated ARCUS with key enabling and discovery technologies
-  Developed successful partner-driven model that minimizes internal capital use

**Cargill is one of the world's largest producers of cooking oil.** We are collaborating with Cargill to develop ultra-low saturate "heart healthy" canola oil



Edited canola plants produce significantly lower levels of saturated fat relative to current low-saturate canola lines

Source: US patent 2017/0034541 W; TSFA: C18:0/C20:0/C22:0/C24:0; TSFA = Total Saturated Fatty Acid

**Mogroside V is an all-natural zero calorie sweetener from Monk Fruit**

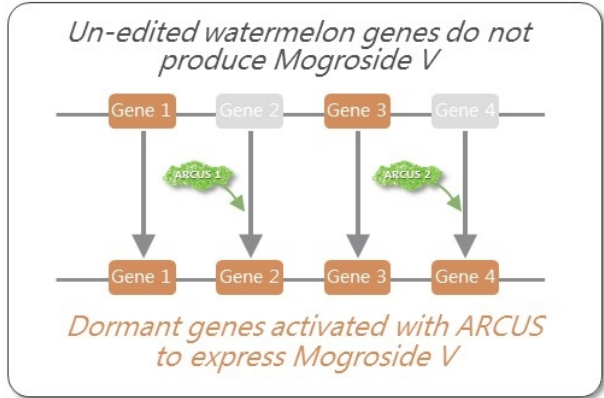
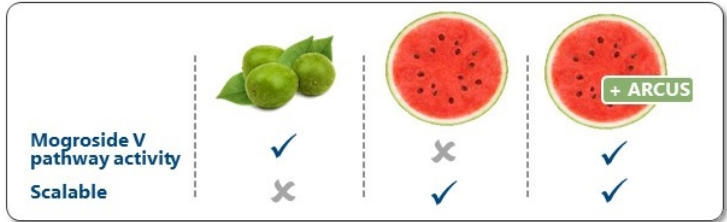
## Mogroside V is difficult to source because monk fruit is not scalable

- Grown regionally, long life cycle, small, difficult to cultivate and process

## Watermelon has all the genes to make mogroside V, but the pathway is dormant

## Elo is using ARCUS to re-activate the dormant mogroside V pathway genes in watermelon

- Watermelon production and processing is already highly optimized
- Production of mogroside V in watermelon would make harvesting this sweetener scalable
- Mogroside V could be produced locally and sustainably, for the global food, beverage and ingredient industry





- ✓ Initial Public Offering (Ticker: DTIL) - Q2 2019
- ✓ Clinical dosing of allogenic CD19 CAR T - Q2 2019
- Open cGMP manufacturing facility: mRNA, AAV, CAR T - 2H 2019
- Wholly-owned CD20 CAR T enters clinic Q4 2019
- Interim data from P1 CD19 CAR T - Q1 2020
- IND for wholly-owned BCMA CAR T - 2020
- IND for lead in vivo gene correction program - 2020

***Cash Runway Takes Us Into 2021***



# Key Takeaways



Highly experienced team of over 160 Precisioneers includes the pioneers in editing



Proprietary ARCUS genome editing platform with full freedom to operate



Independent cGMP manufacturing capabilities by YE 2019



Multiple CAR T programs will be in human clinical trials by YE 2019



Strong balance sheet and validating partnerships in each business area



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