

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 2, 2020

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, including 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 Act:

Title of each class	Trading Symbol(s)	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.

Item 7.01. Regulation FD Disclosure.

As previously announced, Precision BioSciences, Inc. (the “Company”) will be presenting at the Jefferies Virtual Healthcare Conference on June 3, 2020. A copy of the accompanying presentation materials that the Company will discuss in meetings with investors and analysts 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 Item 7.01 of 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

Exhibit No.	Description
99.1	Precision Biosciences, Inc. Presentation as of June 2, 2020

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 2, 2020

By: /s/ Dario Scimeca
Dario Scimeca
General Counsel



Dedicated to Improving Life.

June 2020

DTIL

Overcome cancer.
Cure genetic disease.
Feed the planet.



Forward Looking Statements



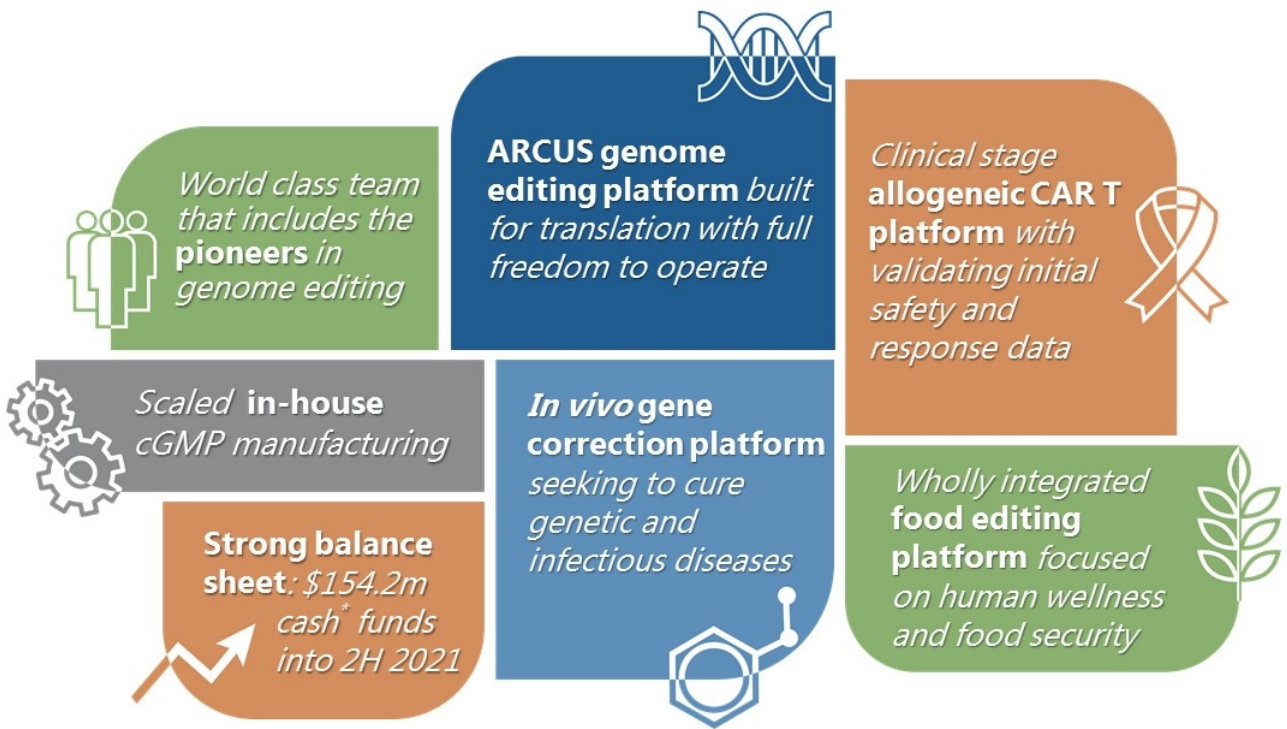
This presentation (together with any other statements or information that we may make in connection herewith) may contain forward-looking statements. All statements other than statements of present and historical facts contained in this prospectus, including without limitation, statements regarding our future results of operations and financial position, business strategy and approach, including related results, prospective products, planned preclinical or greenhouse studies and clinical or field trials, including expected release of data and dosage exploration, capabilities, including expected production levels and manufacturing timeframes, of our manufacturing facility, management's expectations regarding pipelines and milestones for product candidates and our food editing platform, 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 "aim", "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 and requirements under our current debt instruments; our limited operating history; the success of our programs and product candidates in which we expend our resources; 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 our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the laws and regulatory landscape applicable to our and our collaborators' development of product candidates; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in enrolling patients in clinical trials; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; if our product candidates do not work as intended or cause undesirable side effects the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; risks associated with applicable healthcare, data privacy and security regulations and our compliance therewith; the rate and degree of market acceptance of 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; pending and potential liability lawsuits and penalties related to our technology and our product candidates; our reliance on and current and future relationships with third parties; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key scientific and management personnel; effects of natural or manmade disasters; insurance expenses and exposure to uninsured liabilities; market and economic conditions; dilution and fluctuations in our stock price; and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as such factors may be updated from time to time in our other filings with the SEC, which filings are accessible on the SEC's website at www.sec.gov and the Investors & Media page of our website at investor.precisionbiosciences.com.

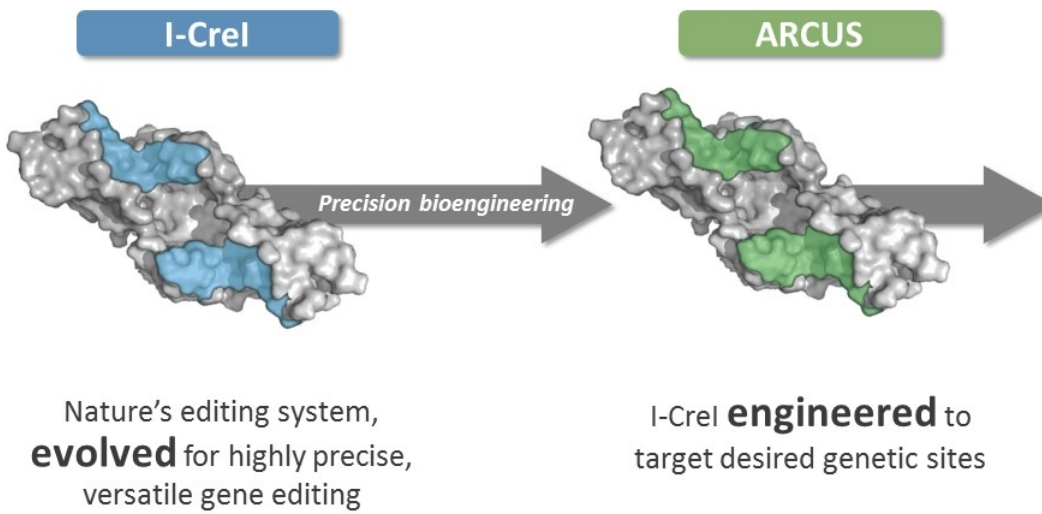
All forward-looking statements speak only as of the date of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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.

Delivering on the Promise of Genome Editing



* As of March 31, 2020



Key Advantages

- **Safety:**
*minimizes off-target editing;
natural "off switch"*
- **Ease of delivery:**
*small size permits both
LNP and AAV delivery*
- **Control of edits:**
*efficient knock in or
knock out*
- **Proprietary:**
*more than 50 issued US
and foreign patents*



Ability to produce **ARCUS-based CAR T** and *in vivo* therapies

MCAT: Manufacturing Center for Advanced Therapeutics



17,300 sq. ft.
facility in Durham, NC

Fully **cGMP** compliant

Operational **July 2019**

Currently producing clinical trial material
for **BCMA CAR T** program



Overcoming Cancer

Off-the-Shelf CAR T





Autologous CAR T

- High rates of efficacy in some cancers
- Can be effective where other options have failed



time



- High cost and challenging logistics leading to limited patient access
- Patient-to-patient product variability
- Safety considerations (CRS / neurotoxicity)

Allogeneic CAR T

- Early evidence of encouraging clinical efficacy



- Potentially widely available and lower cost
- Standardized product profile
- Potential for dose optimization like “traditional” drugs
- Potential for improved safety profile
- Opportunity to benefit many more patients

Four Key Requirements for Allogeneic CAR T Success



1 Scaled Manufacturing

- Efficiently deliver consistent, high quality cell product
- Reach all eligible patients
- Control costs

2 Optimal T Cell Phenotype

- Healthy cell product
- High percentage naïve and central memory T cell phenotypes
- Ability to employ more tolerable conditioning regimens

3 Improved Safety

- True off-the-shelf safety profile
- Supports ease of use / physician adoption
- Minimize CRS / neurotoxicity

4 Clinical Activity

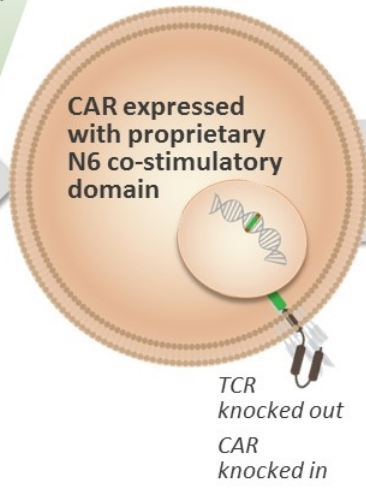
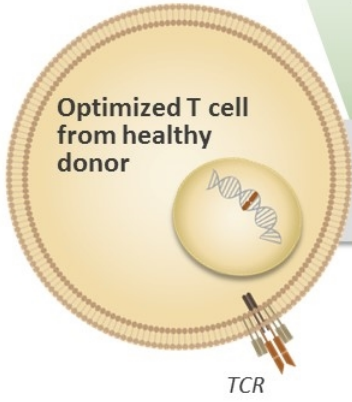
- Demonstrated efficacy
- Ability to optimize dosing

Key Features of Precision's Allogeneic CAR T Platform

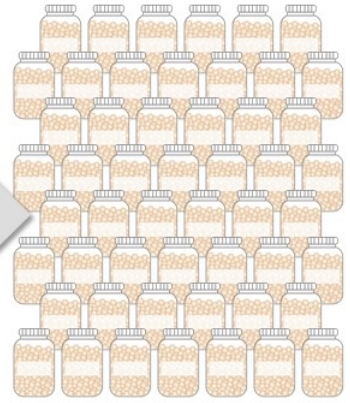


Single-step ARCUS editing

- minimizes off-targeting
- CAR directly inserted into TCR locus
- helps preserve phenotype



Short, 10-day manufacturing



Platform Is Delivering Against All Four Key Requirements



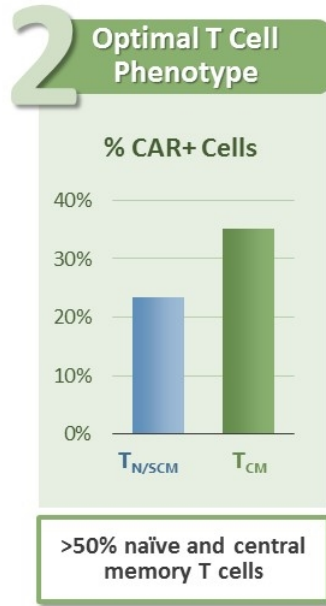
1 Scaled Manufacturing

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

Batch	Vial Count
1	130
2	114
3	100

CD3- >99%

Ability to manufacture consistent product at scale



3 Safety Profile

	NHL (n=6)	ALL (n=3)
GvHD		
DL1	0%	0%
DL2	0%	0%
CRS/ICANS ≥ Grade 3		
DL1	0%	0%
DL2	0%	0%
Infections		
DL1	0%	0%
DL2	0%	0%

Zero GvHD, severe CRS or neurotox; zero infections*

4 Clinical Activity

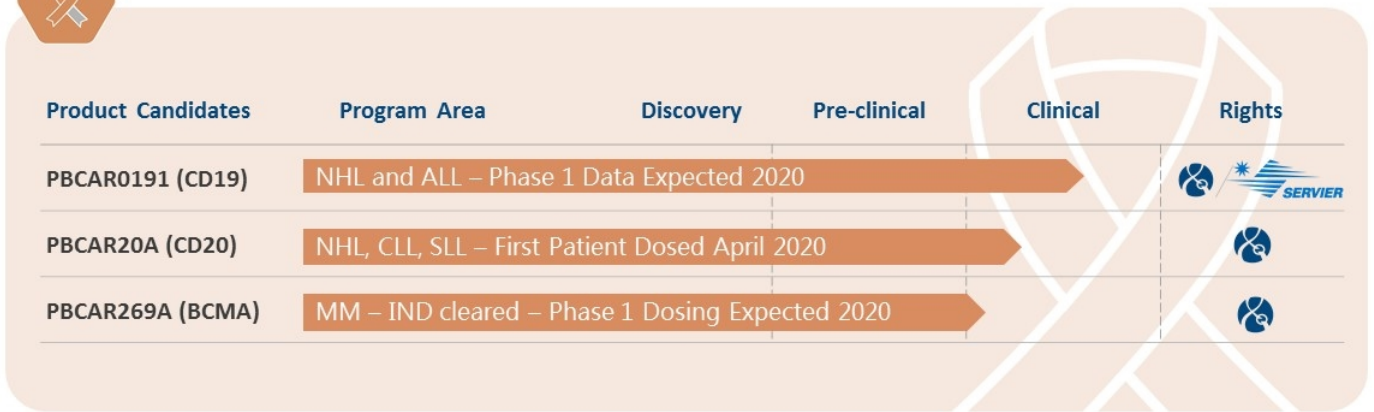
67% ORR
in NHL

2 CRs achieved
28+ days
1 NHL / 1 ALL

180 day
PFS observed at low dose

Encouraging early activity at low dose levels*

*Clinical data from PBCAR0191 DL1 & DL2 interim update presented in December 2019; n=6 NHL patients and n=3 ALL patients



Three allogeneic CAR T programs expected to be in clinical trials in 2020



	Population	Dose Escalation Range	Status
PBCAR0191 Targeting CD19	Adult patients with • R/R NHL (including MCL), or • R/R B-ALL	3.0×10^5 cells/kg - 9.0×10^6 cells/kg	<ul style="list-style-type: none"> • Actively enrolling in escalating doses • ODD granted for MCL
PBCAR20A Targeting CD20	Adult patients with • R/R NHL (including MCL), or • R/R CLL or SLL	1.0×10^6 cells/kg - 6.0×10^6 cells/kg*	<ul style="list-style-type: none"> • Phase 1/2a first patient dosed April 2020 • ODD granted for MCL
PBCAR269A Targeting BCMA	Adult patients with • R/R multiple myeloma	6.0×10^5 cells/kg - 6.0×10^6 cells/kg	<ul style="list-style-type: none"> • IND cleared January 2020 • Phase 1/2a expected to begin in 2020

Objectives

- **Primary:** safety and tolerability
- **Secondary:** clinical (anti-tumor) activity
- **Exploratory:** expansion, trafficking, and persistence

*FDA approved study to skip DL1 (3.0×10^5 cells/kg) and begin dosing at DL2 based on PBCAR0191 safety profile.

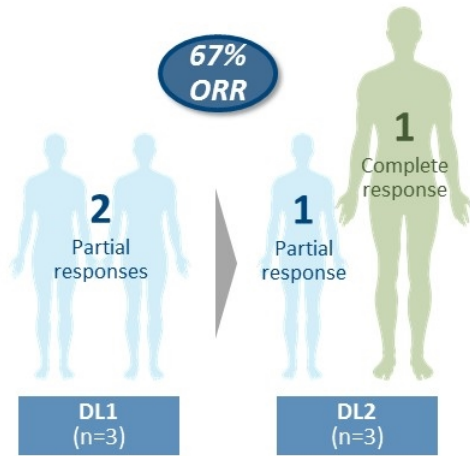
System Organ Class <i>Preferred Term, n(%)</i>	NHL (n=6)	B-ALL (n=3)
CRS (Cytokine Release Syndrome) – Grade 1 or Grade 2	2 (33%)	1 (33%)
ICANS (Immune Effector Cell Neurotoxicity) – Grade 1 or Grade 2	0 (0%)	1 (33%)
CRS Grade 3 or higher	0 (0%)	0 (0%)
ICANS Grade 3 or higher	0 (0%)	0 (0%)
GvHD (Graft versus Host Disease)	0 (0%)	0 (0%)
Infection	0 (0%)	0 (0%)

*Clinical data from PBCAR0191 D1 & DL2 interim update presented in December 2019; DL1 = 3.0 x 10⁵ cells/kg; DL2 = 1.0 x 10⁶ cells/kg.

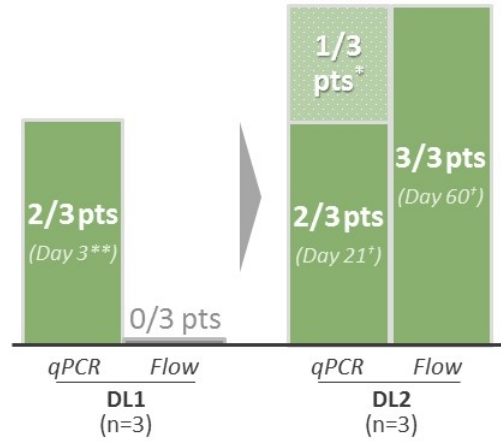


NHL Cohort Data

Best response day 28+
patients



CART cell expansion
patients with positive expansion
(maximum days positive)

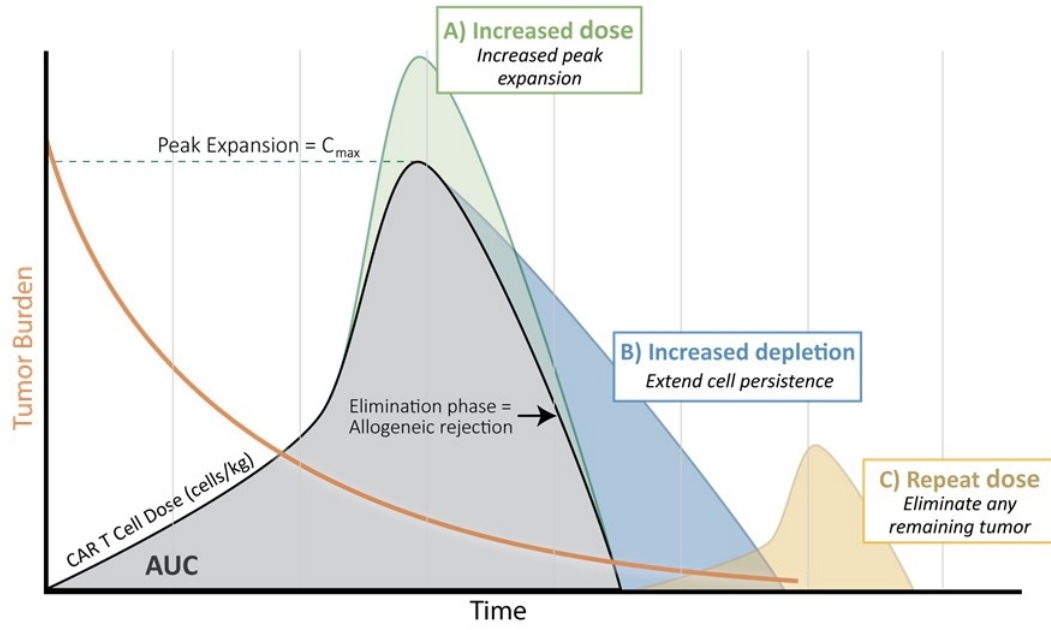


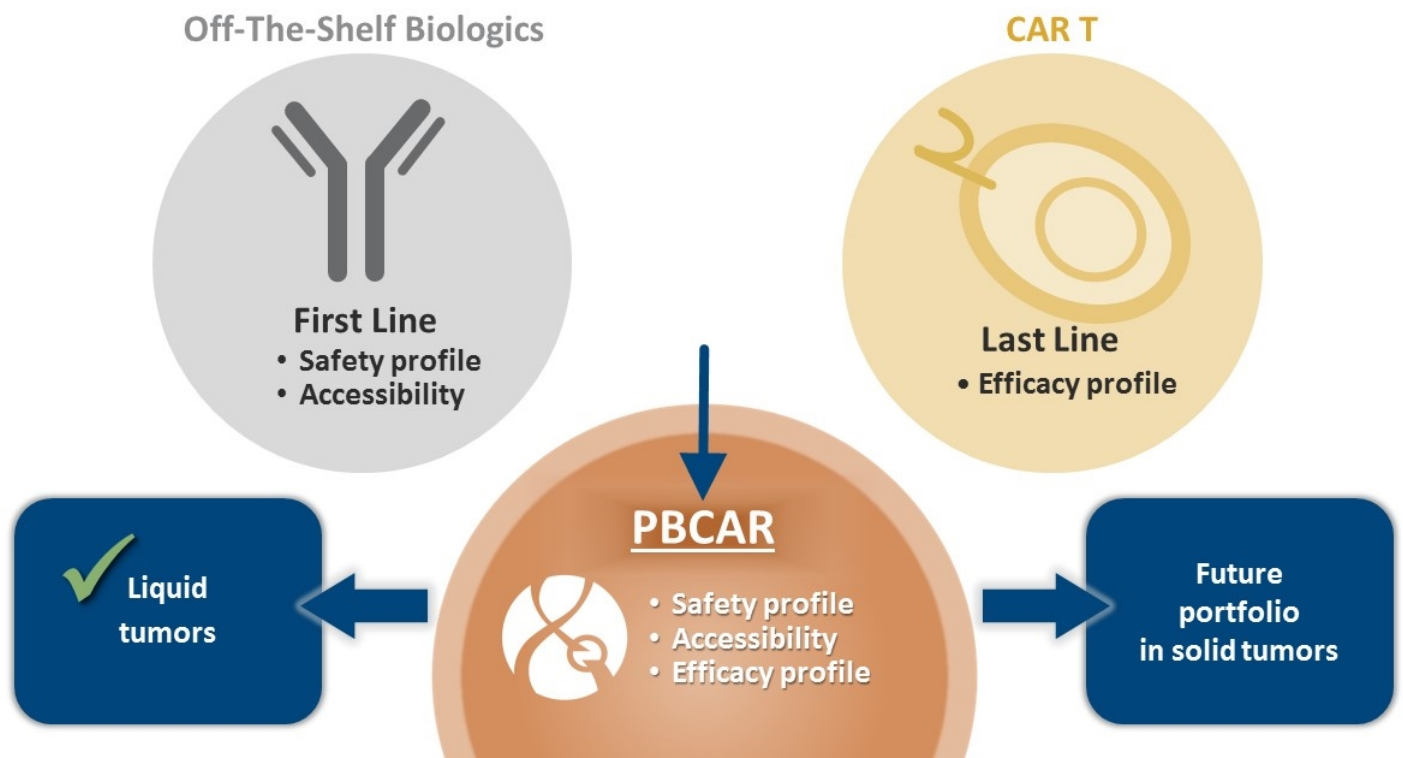
Notes: Clinical data from PBCAR0191 D1 & DL2 interim update presented in December 2019; DL1 = 3.0×10^5 cells/kg; DL2 = 1.0×10^6 cells/kg; ALL cohort data not illustrated. In ALL cohort (n=3, treated at DL2), best response observed at day 28+ of 1 patient with complete response and 2 patients with progressive disease

* Expansion formally reported as below lower limit of quantification by qPCR for this patient, but was detectable at day 7

** Ranged from day 1 to day 3

† Ranged from day 10 to day 21 by qPCR; day 1 to day 60 by flow



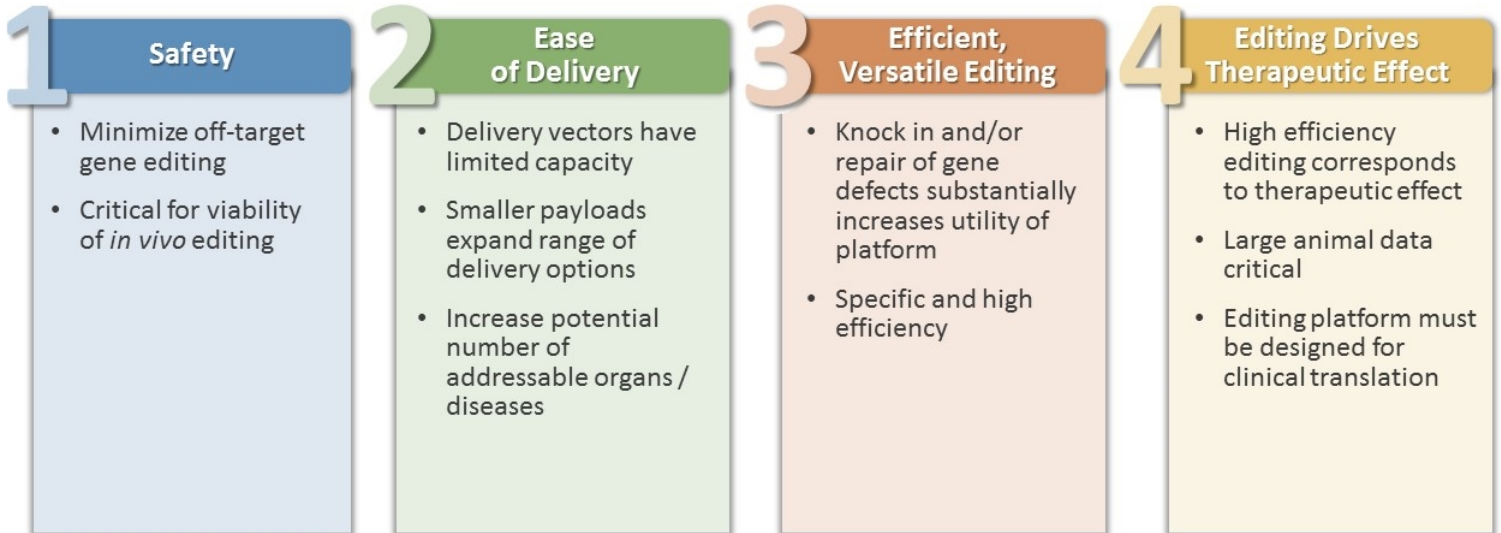




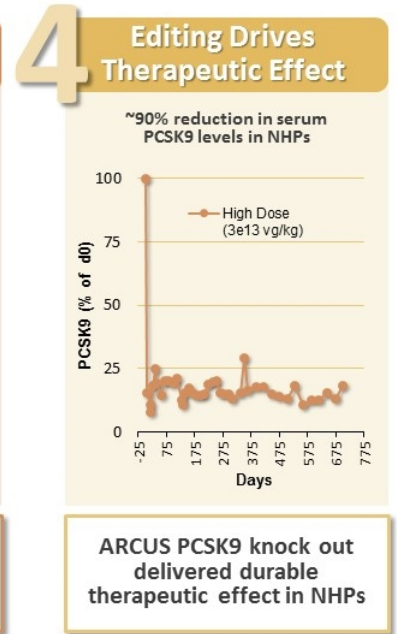
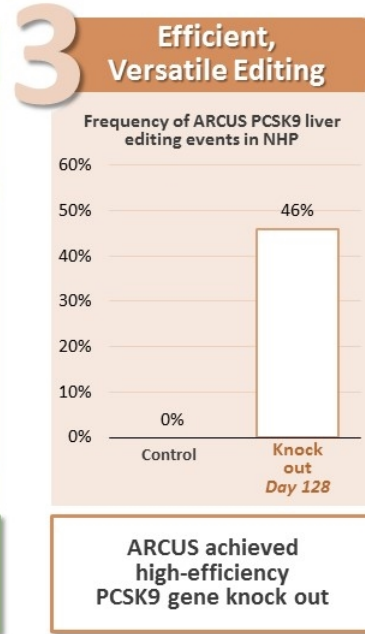
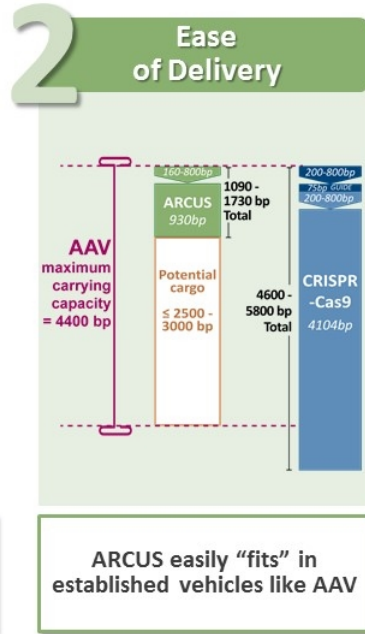
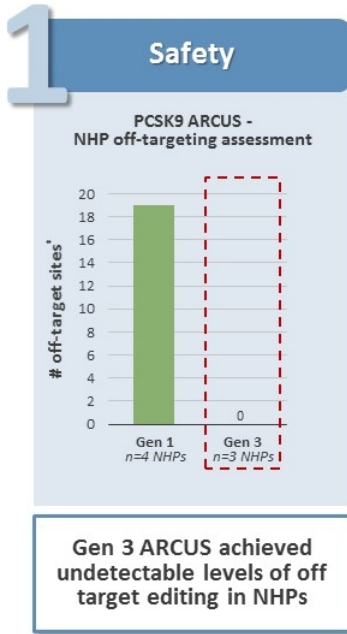
Curing Genetic Disease

In Vivo Gene Correction



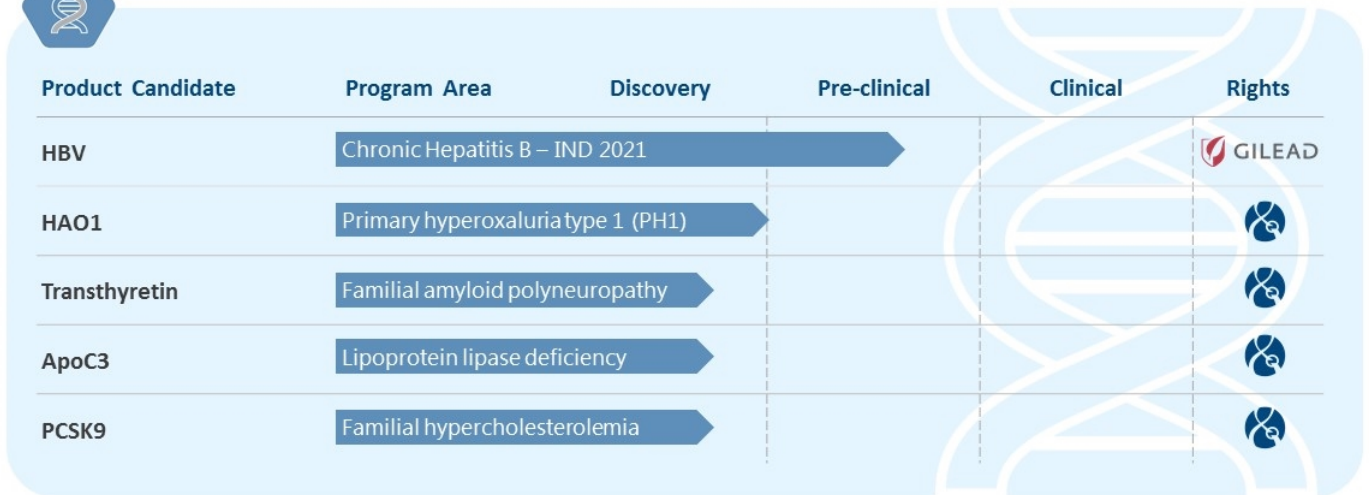


ARCUS Platform Delivers Against All Four Key Requirements



Full freedom-to-operate for ARCUS platform

* as assessed by oligo capture technique
PCSK9 data reported in part in Wang et al, Nature Biotechnology, 2018



PH1 selected as lead wholly-owned *in vivo* program



Primary Hyperoxaluria – key facts

Rare genetic disease characterized by accumulation of **calcium oxalate** in kidneys, which leads to painful kidney stones and ultimately **end-stage renal disease**

Prevalence of
1-3/1,000,000

~40%
patients have
end-stage renal
disease at the time
of diagnosis

Affects
adults
and young
children

Combined
**liver-kidney
transplant**
often required

Our Approach

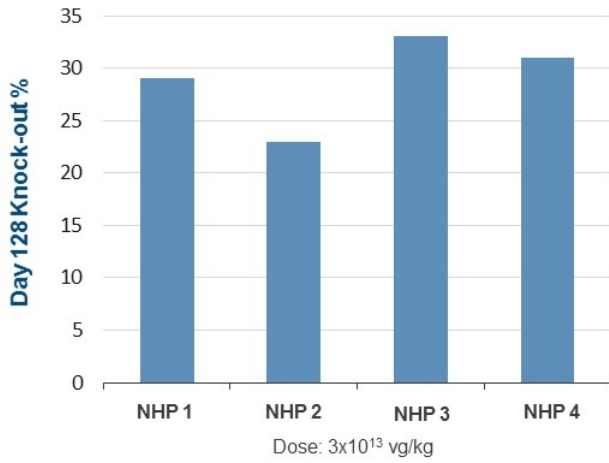
- ARCUS mediated **knockout of HAO1 gene** in liver
- Prevent buildup of oxalate
- Aim to develop a **one-time, permanent treatment**



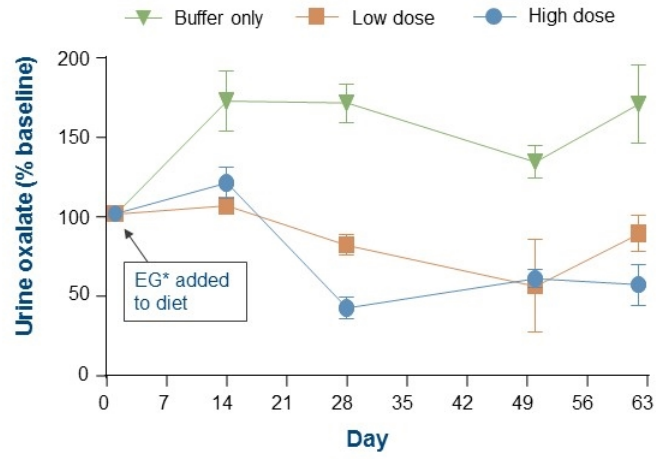
ARCUS efficiently knocked-out the *HAO1* gene in non-human primates following AAV8 delivery

ARCUS treatment resulted in ~70% reduction in urine oxalate in a PH1 mouse model

Non-human primate (whole liver)



Mouse model



*Ethylene glycol
Data on file



Feed the Planet

Elo Life Systems



A Human Health Opportunity

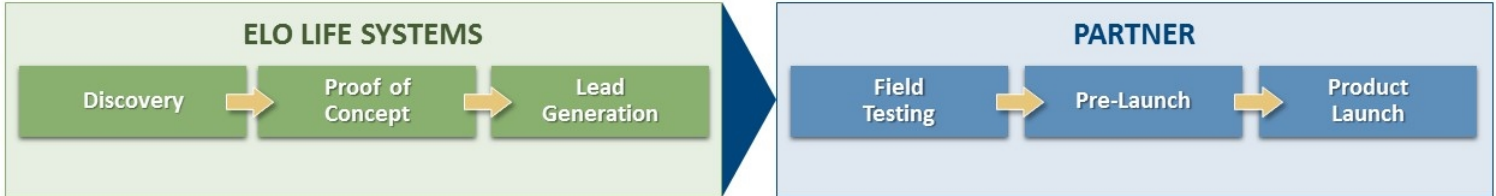
Food companies need new inputs to respond to:


- Climate change
- Consumer preference

Elo integrates ARCUS with enabling technologies to create greatly needed improvements to sources of food

- Partner driven
- Minimal capital investment

An Efficient Business Model





- IND accepted for BCMA CAR T
- Initiate dosing for CD20 CAR T
- Initiate dosing for BCMA CAR T
- PH1 candidate selection
- NHL (CD19) clinical data update
- ALL (CD19) clinical data update



Highly experienced team includes the pioneers in editing



Proprietary ARCUS editing platform confers fundamental advantages



Independent cGMP manufacturing capabilities



Early allogeneic CAR T clinical data validate core strategy



In vivo programs to address significant unmet medical needs



\$154.2m cash funds*, runway into 2H 2021; validating partnerships in all areas

* As of March 31, 2020



Overcome Cancer.



Cure Genetic Disease.



Feed the Planet.



Dedicated To Improving Life

