UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 15, 2020

Precision BioSciences, Inc.

(Exact name of registrant as specified in its charter)

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)

 $$\mathbf{N}/\mathbf{A}$$ (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)

Delaware (State or other jurisdiction of incorporation)

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 \boxtimes

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.

Explanatory Note

This Current Report on Form 8-K/A (the "Amendment") is being filed by Precision BioSciences, Inc. (the "Company") to amend its Current Report on Form 8-K (the "Prior 8-K") filed with the Securities and Exchange Commission on January 15, 2020 in order to include as Exhibit 99.1 the presentation materials referenced therein, which the Company will be discussing with investors and analysts.

Item 7.01 Regulation FD Disclosure.

As previously announced, the Company will be presenting at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California on January 15, 2020. A link to the live webcast is available <u>here</u> on the Investors & Media page of the Company's website at <u>https://investor.precisionbiosciences.com</u>. A copy of the accompanying presentation materials that the Company will be discussing during this webcast and in meetings with investors and analysts is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. Following the conference, a replay of the webcast will be archived for 30 days on the Investors & Media page of the Company's website.

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 January 15, 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.

By: /s/ Dario Scimeca Dario Scimeca General Counsel

Date: January 15, 2020



Dedicated to Improving Life.

38th Annual J.P. Morgan Healthcare Conference January 15, 2020

Overcome cancer. Cure genetic disease. Feed the planet. DTI

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, prospectus products, planned preclinical or greenhouse studies and clinical or field trials, capabilities, including expected production levels, 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 "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 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, into 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 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; and other imported restations or unexpected on form 10-Q for the quarterly period ended September 30, 2019, as such factors may be updated from time to time in our other filings

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



Delivering on the Promise of Genome Editing



World class team of ~200 Precisioneers that includes the **pioneers** in genome editing



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

Clinical stage allogeneic CAR T platform with validating initial safety and response data



Scaled in-house *cGMP manufacturing*

In vivo gene correction platform seeking to cure genetic and infectious diseases

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

4





ARCUS: Engineering Nature's Genome Editing System



6

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

Four Key Attributes

- 1. Safety: Evolved to avoid random off-targeting
- 2. Easy to Deliver: Small size compatible with existing gene delivery technologies
- 3. Control of Edits: Knock genes *in* or knock genes *out*
- 4. **Proprietary:** Complete control of platform and freedom to operate







- Manufacturing Center for Advanced Therapeutics (MCAT) is a 17,300 square foot cGMP clinical manufacturing facility
- Allogeneic CAR T cells, mRNA (10g scale) and rAAV (400L scale) vectors for *in vivo* and *ex vivo* uses
- Second phase expansion for commercial application (>10,000 CAR T doses / treatments per year)
- cGMP BCMA drug product will be produced at this facility





Senior Leadership

Includes recognized global pioneers in genome editing

Team

Over 200 Precisioneers including more than 85 PhD scientists and engineers

Core Competencies

Translational research, development, CAR T / AAV / mRNA manufacturing, clinical trial execution

Domain Expertise

Across genetics, biochemistry, protein engineering, immunology, clinical oncology, rare diseases, food & agriculture

Thought Leadership

Management supported by board of directors comprising experts in healthcare research, operations and investment; highly engaged Scientific Advisory Board of **global thought leaders in oncology, CAR T and genetics**

Curing Genetic Disease

In Vivo Gene Correction







In Vivo Gene Correction Pipeline



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Product Candidate	Program Area	Discovery	Pre-clinical	Clinical	Rights
HBV	Chronic Hepatitis B –	IND 2021			🖉 GILEAD
PCSK9	Familial hypercholes	terolemia	(~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Transthyretin	Familial amyloid poly	neuropathy			8
АроСЗ	Lipoprotein lipase de	ficiency			
HAO1	Primary hyperoxaluri	а			

A collaboration with Jim Wilson and the Penn Orphan Disease Center was initiated August, 2016 to develop *in vivo* gene editing in the liver

Scope

- Indications:
 - Familial hypercholesterolemia (PCSK9)
 - Transthyretin amyloidosis (TTR)
 - Lipoprotein lipase deficiency (ApoC3)
 - Primary hyperoxaluria type 1 (HAO1)
- 56 non-human primates treated
- 9 unique ARCUS nucleases evaluated
- Delivery: AAV and LNP/mRNA delivery

Parameters

- Editing efficiency and durability
- Toxicity both acute and long-term
- Immunogenicity pre-existing or acquired
- Off-target editing
- Persistence of ARCUS and vector

First published report of *in vivo* gene editing in a large animal (*Nature Biotechnology* 2018. 36(8):717-725)



In Vivo Gene Correction Pipeline



Product Candidate	Program Area	Discovery	Pre-clinical	Clinical	Rights
HBV	Chronic Hepatitis B –	IND 2021			GILEAD
HA01	Primary hyperoxalur	ia	(~
Transthyretin	Familial amyloid poly	neuropathy			R
АроС3	Lipoprotein lipase de	eficiency			
PCSK9	Familial hypercholes	terolemia			1

HAO1 nominated as lead wholly-owned in vivo program

Primary Hyperoxaluria Type 1 (PH1) – Disease Overview



14

1 Rare genetic disease caused by loss-of-function mutations in the AGXT gene

- Gene encodes an enzyme involved in glycine biosynthesis in the liver
 - Disease prevalence: 1-3/1,000,000



ARCUS Editing Effective in Pre-Clinical Models of PH1



ARCUS treatment resulted in ~70% reduction in urine oxalate in a PH1 mouse model • Prevented formation of renal CaOX crystals

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



15



Key Features of Precision's Allogeneic CAR T Platform



Starting material	Optimized donor cells	Proprietary markers and selection criteria	
ARCUS editing	Single-step editing avoids off-targeting	Product of 15+ years of research	
CAR insertion	CAR directly into TCR locus every time	Issued Precision IP	
Construct	Proprietary N6 co-stimulatory domain	Precision IP patent pending	
Length of process	Short, 10-day manufacturing	Optimizes expansile phenotype	
Quality	Consistent batch-to-batch performance	Proprietary platform,	
Product supply	High yield manufacturing process	development and scaling	

PBCAR0191 Phase 1/2a: NHL and B-ALL





Eligibility

· Adult patients with R/R B-NHL or R/R B-ALL

Clinical Sites

- Moffitt (Bijal Shah / Mike Jain)
- City of Hope (Anthony Stein / Alex Herrera)
- Dana Farber (Caron Jacobson / Dan DeAngelo)
- MD Anderson (Nitin Jain / Sattva Neelapu)
- +8-10 sites to be initiated

Objectives

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

Dose Escalation

- DL1 = 3.0 x 10⁵ cells/kg
- DL2 = 1.0 x 10⁶ cells/kg
- DL3 = 3.0 x 10⁶ cells/kg

Adverse Events Compare Favorably to Autologous CAR T



System Organ Class	NHL	B-ALL
Preferred Term, n(%)	(n=6)	(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%)

Dose Levels Compared to Autologous CAR T

Significantly below the dose ranges of approved autologous CAR T products





PBCAR0191 Summary: NHL Program

Patient ID	Baseline disease burden	Best Response Day ≥28		PFS (Days)*	CRS or ICANS (Mechanistic demonstration of cell expansion)	External PCR Expansion (Study Days +)	Internal Flow Expansion (Study Days +)	Auto CAR T benchmarks
1-NHL-DL1	Aggressive disease (Ki67 65%)	Partial Response		60	None	Positive (Day 3)	Negative##	
2-NHL-DL1	Bulky aggressive disease (SPD 2,337 / Ki67 90%)	Progressive Disease		N/A	None	Positive (Day 1)	Negative##	Y escarta – NHL (mostly DLBCL, Zuma-1) ¹ 54% CR rate / 82% ORR Grade 3/4 CRS 13%;
3-NHL-DL1	Progressed on Yescarta®	Partial Response	67%	180	CRS Grade 2	Negative [#]	Negative##	Gr 3/4 Neurotox 28% Yescarta – MCL (Zuma-2) ²
4-NHL-DL2	Bulky aggressive disease (SPD 3,693 / Ki67 40%)	Partial Response	ORR	60	None	Positive (Day 1-21)	Positive (Day 1-60)	5/% CR rate / 82% ORR; Grade 3/4 CRS 18%; Gr 3/4 Neurotox 46% Kymriah³ 40% CR rate / 52% ORR Grade 3/4 CRS 22%; Gr 3/4 Neurotox 12%
5-NHL-DL2	Aggressive disease (Ki67 85%)	Progressive Disease		N/A	Hypotension Grade 1; No Fever; ASCTC Gr = Not CRS	Positive (Day 1-10)	Positive (Day 1)	
6-NHL-DL2	Aggressive disease (Ki67 100%)	Complete Response		28+	CRS Grade 1	<llq; Detectable (Day 7)</llq; 	Positive (Days 1-3)	0.0, + 1.0000 1270

* Progression free survival is estimated at the time of study visit

1 Neelapu NEJM 2017 <u>https://www.neim.org/doi/full/10.1056/NEJMoa1707447</u> 2 Wang, et al., ASHPresentation, Zuma-2, December 2019 3 Schuster NEJM 2019 <u>https://www.neim.org/doi/full/10.1056/NEJMoa1804980</u>

qPCR performed on DNA extracted from isolated PBMC. Note: extremely low PBMC isolation in 6-NHL-DL2, 7-ALL-DL2, 8-ALL-DL2, and 9-ALL-DL2 yielded low DNA quantities, making interpretation of these results difficult. They are shown for completeness ## Lower limit for CAR+ cells wasset as 0.03% of lymphocytes. All positive have 20.03%, with highest detected at 0.43%

21



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Patient ID	Baseline disease burden	Best Response Day ≥28	PFS (Days)*	CRS or ICANS (Mechanistic demonstration of cell expansion)	External PCR Expansion (Study Days +)	Internal Flow Expansion (Study Days +)	Auto CAR T benchmarks	
7-ALL-DL2	95% marrow blasts Prior CNS disease	Progressive Disease	N/A	None	Negative [#]	Positive (Day 7)	Yescarta – adult ALL¹ 68% CR rate Durability – difficult to assess due to	
8-ALL-DL2	77% marrow blasts	Progressive Disease	N/A	None	Negative [#]	Negative##	transplant >50% pts in first 6 mos Gr 3/4 CRS 22%; Gr 3/4 Neurotox 22% Kvmriah	
9-ALL-DL2	19.8% marrow blasts	Complete Response	28+	CRS Grade 1; ICANS Grade 2	<llq; detectable<br="">(Day 1, 3, 10, 14)[#]</llq;>	Positive (Day 28)	60% CR rate (adult ALL) ² Grade 3/4 CRS 70% Grade 3/4 Neurotox 3.33%	

* Progression free survival is estimated at the time of study visit

qPCR performed on DNA extracted from isolated PBMC. Note: extremely low PBMC isolation in 6-NHL-DL2, 7-ALL-DL2, 8-ALL-DL2, and 9-ALL-DL2 yielded low DNA quantities, making interpretation of these results difficult. They are shown for completeness ## Lower limit for CAR+ cells wasset as 0.03% of lymphocytes. All positive have ≥0.03%, with highest detected at 0.43%

¹ Zuma-3 ASCO Presentation Shah et al., June 2019 ² https://www.clinicatrials.gov/ct2/show/results/NCT02030847?term=Tisagenlecleucel&cond=Acute+Lymphoid+Leukemia&draw=3&view=results



Key Protocol Amendments Recently Proposed to FDA

- ① Option to **re-dose** after a response and subsequent disease progression
- 2 Split dosing into a single lymphodepletion
- **Bigher** total doses
- Option to modify lymphodepletion (up or down)





Off-the-Shelf CAR T: The Best of Both Worlds



25

Off-the-Shelf CAR T Immunotherapy Pipeline

Product Candidates	Program Area	Discovery	Pre-clinical	Clinical	Rights
PBCAR0191 (CD19)	NHL and ALL – Phase	1 Data 2020			
PBCAR20A (CD20)	NHL, CLL, SLL – Phase	1 Dosing Q1 2020		\mathbf{X}	1
PBCAR269A (BCMA)	MM - IND cleared – P	hase 1 Dosing 2020		Y	K 🗞







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Trait stability

Regulatory

Field performance



A Human Health Opportunity

Food companies need new inputs to respond to:

- **Climate change**. Critical raw materials like citrus and banana are under existential threat
- Consumer preference. Consumers are demanding healthier diets

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

- **Partner driven**. Elo partners with end-users early in the life of each new program to ensure market uptake
- **Minimal capital investment**. Projects are primarily partnerfunded. Elo has its own facilities and an independent management team

An Efficient Business Model ELO LIFE SYSTEMS Discovery Proof of Concept Lead Generation ARCUS editing Greenhouse PARTNER Field Testing Pre-Launch Product Launch

Sales

Marketing

Distribution

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Bulk up

Pre-marketing

Supply chain

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Food Pipeline





*Partner funded in whole or in part

30

ZeroMelon[™]: A Zero Calorie Sugar Substitute



- Elo's ZeroMelon™ program leverages ARCUS to reactivate dormant genes in watermelon to produce natural, zero calorie sweetener mogroside V
- 250x sweeter than artificial sweeteners / sugar, tasting closer to cane sugar than alternatives
- Substantial opportunity global food sweetener market estimated at ~\$82bn by 2024*
- Ability to reactivate mogroside pathway with ARCUS already demonstrated validates approach

ZeroMelon[™] program highlights

- ✓ Non-GM watermelon that produces mogroside V at scale
- Completed ARCUS-mediated gene reactivation in publicly-available elite watermelon varieties
- ✓ ZeroMelon[™] product development in progress

* Source: Food Sweetener Market - Growth, Trends, forecast (2019-2024), April 2019, Mordor Intelligence

ARCUS-mediated reactivation of two latent mogroside V pathway genes in watermelon

Potentially rapid path to market

Major anticipated milestones:

\checkmark	2019 – activation of 2 mogroside V genes in watermelon using ARCUS
	2021 – greenhouse trials
	2022 – small scale field trial
	2023 – large scale, multi-site field trials
	Commercial product possible in 4-5 years

Upcoming Milestones Expected Across Portfolio





Key Takeaways









Dedicated To Improving Life