Intercepting autoimmunity to prevent chronic diseases

NOVEMBER 2020
Forward-looking statements

This presentation contains forward-looking statements including, but not limited to, the potential safety, efficacy, regulatory review or approval and commercial success of teplizumab and our other product candidates and those relating to the Company’s product development, clinical studies, clinical and regulatory milestones and timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. “Forward-looking statements” are statements that are not historical facts and involve a number of risks and uncertainties, which may cause actual results to be materially different from any future results expressed or implied in the forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “potential,” “predict,” “project,” “should,” “would,” and similar expressions and the negatives of those terms.

Forward-looking statements are based on the Company’s current expectations and assumptions. Forward-looking statements are subject to a number of risks, uncertainties, and other factors, many of which are beyond the Company’s control, including, but not limited to: our lack of operating history; our dependence on our product candidates, which are still in preclinical or various stages of clinical development; our dependence on third parties to manufacture our product candidates; our reliance on third-party vendors, such as contract research organizations and contract manufacturing organizations; the uncertainties inherent in clinical testing; our ability to complete required clinical trials for our product candidates and obtain approval from regulatory authorities for our product candidates; our ability to protect our intellectual property; the potential impact of COVID-19; the loss of any executive officers or key personnel and the other factors listed under “Risk Factors” in our annual report on Form 10-K for the year ending in December 31, 2019; and any subsequent filings with the Securities and Exchange Commission (SEC).

The Company cautions investors not to place undue reliance on any such forward-looking statements, which speak only as of the date of this presentation. The Company disclaims any obligation, except as specifically required by law and the rules of the SEC to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.
<table>
<thead>
<tr>
<th>Mission</th>
<th>Vision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seek out autoimmunity early to intercept and prevent debilitating and life-threatening diseases.</td>
<td>Change the world by unleashing the full potential of lives otherwise burdened or cut short by autoimmune disease.</td>
</tr>
</tbody>
</table>
Company Overview

The value of interception & prevention in autoimmunity

Intercept and prevent life-altering and life-threatening autoimmune diseases

• Focused on chronic autoimmune diseases with compelling biological and commercial rationale

• Advancing autoimmune investigational therapies in partnership with industry leaders
  • Amgen and Vactech

• Focused on the patient voice and committed to working with patient advocacy groups
  • JDRF and Beyond Type 1

Four programs with significant upside potential across multiple diseases

• PRV-031 (teplizumab), an investigational monoclonal antibody, for the delay or prevention of T1D in “at-risk” patients and the treatment of “newly diagnosed” patients

• PRV-3279, an investigational bispecific DART® targeting B-cell-driven disease such as systemic lupus erythematosus with multi-indication potential

• PRV-015, an investigational monoclonal antibody for nonresponsive celiac disease

• PRV-101, an investigational vaccine for the prevention of coxsackievirus B and potentially T1D and celiac disease

Fiscal strength to build a better future in autoimmunity

• $147.2 million in cash, cash equivalents, and marketable securities as of September 30, 2020
Company Overview

Intercept & prevent before it happens

Our goal is to intercept autoimmunity early to modify disease development and reduce chronic morbidity

- **Predisposition susceptibility**
  - Healthy individual (genetic risk)

- **Infection/Trigger**
  - Autoimmune phenomena
  - Autoantibodies
  - Biomarkers

- **Tissue inflammation**
  - Early onset
  - Evident tissue damage
  - Early symptoms

- **Prevent**
  - PRV-101*

- **Intercept**
  - PRV-031*
  - Teplizumab
  - PRV-3279*
  - PRV-015*

- **Treatment**
  - Conventional biopharma approach

* Product candidate under clinical investigation
# Company Overview

A diversified autoimmune pipeline

<table>
<thead>
<tr>
<th>Focus</th>
<th>Target Indication</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Regulatory</th>
<th>Next expected milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 diabetes (T1D) autoimmunity</td>
<td>Delay onset in at-risk patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Potential acceptance of BLA for review in Q1 2021</td>
</tr>
<tr>
<td></td>
<td>Newly diagnosed patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRV-031 (teplizumab)</td>
<td>Complete PROTECT enrollment*</td>
</tr>
<tr>
<td></td>
<td>Prevention</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRV-101</td>
<td>Initiate Phase 1 first-in-human trial Q4 2020</td>
</tr>
<tr>
<td>B-cell autoimmunity checkpoint</td>
<td>Systemic lupus erythematosus</td>
<td>PRV-3279</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initiate Phase 2a trial in H2 2021</td>
</tr>
<tr>
<td></td>
<td>Prevention of immunogenicity</td>
<td>PRV-3279</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preclinical data expected in Q4 2020</td>
</tr>
<tr>
<td>GI autoimmunity</td>
<td>Celiac disease</td>
<td>PRV-015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Complete enrollment in 2021; top-line data expected in 2022</td>
</tr>
</tbody>
</table>

*Enrollment in PROTECT was paused in March 2020 due to the COVID-19 outbreak; during Q2 2020, certain sites in certain countries resumed enrollment of patients.
Aiming to Intercept Type 1 Diabetes

T1D continuum leads to destruction of $\beta$ cells

Natural history of $\beta$-cell loss and T1D onset

Pre-stage 1: Autoantibodies
Stage 1: Dysglycemia and autoantibodies
Stage 2: Newly diagnosed symptomatic T1D

T1D Clinical Programs:
- Vaccination: PRV-031 (polyvalent coxsackievirus B vaccine)
- At-Risk study: PRV-031 (teplizumab)
- PROTECT study: PRV-031 (teplizumab)
Aiming to Intercept Type 1 Diabetes

T1D: high disease burden and unmet need in the US

Genetically predisposed autoimmune disease

- Newly diagnosed T1D is an orphan indication
- ~50% of newly diagnosed T1D patients present with a life-threatening condition called diabetic ketoacidosis (DKA)
- ~60% of cases associated with coxsackievirus B infection

Unmet need

- Currently no preventive or disease-modifying treatments
- Standard of care places considerable daily burden on patients
- >75% of people with T1D are poorly controlled (HbA1c >7%), leading to cardiovascular disease, kidney disease, retinopathy, and metabolic syndrome
- Life expectancy ~16 years shorter if diagnosed with T1D before the age of 10
Aiming to Intercept Type 1 Diabetes

Potential commercial opportunity for at-risk indication

Estimated US patient prevalence

- **300,000**
  - 2 or more autoantibodies

- **200,000**
  - 2 or more autoantibodies and dysglycemia

- **30,000**
  - Familial direct relatives of T1D patients
    (relatives represent ~15% of the pool of 200,000 patients with 2 autoantibodies and dysglycemia)

Up to 2.3 million people may be at risk of T1D globally

Broader population screening is expected to identify additional patients beyond familial direct relatives

Label expansion initiatives will potentially include multiple courses of treatment

"While technology (i.e., CGMs, insulin pumps) can help, they do not fully restore normalcy or confer total peace of mind."
- Pediatric endocrinologist
The T-cell approach to potentially intercept T1D and delay onset

Mechanism of action

- Humanized monoclonal antibody
- Binds to T-cell co-receptor CD3; acts as partial agonist
- Administered as a ~30-minute IV infusion over a 12-day or 14-day outpatient treatment

Supporting clinical data

- >800 patients dosed across multiple clinical studies
- Consistent slowdown of C-peptide decline\(^1\)
- “At-Risk” study results: significantly delayed T1D onset\(^2\)

1. See slide 15 for Newly Diagnosed and Sims 2020 for At Risk, \(p=0.02\)
2. “At-Risk” study results: significantly delayed T1D onset by a median of 3 years (hazard ratio 0.457, \(p=0.01\)) [Sims 2020]
PRV-031 (Teplizumab)

At-Risk study in T1D

Primary endpoint
- Time to development of T1D from randomization after single 14-day course of teplizumab by IV infusion

Population
- ≥8 years old, relative of a patient with T1D
- Abnormal glucose tolerance
- ≥2 T1D-related autoantibodies

Conducted by TrialNet
- Funded by the NIH and JDRF
**PRV-031 (Teplizumab)**

**At-Risk study:** clinical T1D delay = ~3 years

---

**Kaplan-Meier curve of time to T1D**

with number of subjects at risk

---

**Median time to clinical T1D diagnosis**

<table>
<thead>
<tr>
<th>Rx group</th>
<th>TID free</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teplizumab (N=44)</td>
<td>22/44 (50%)</td>
</tr>
<tr>
<td>Placebo (N=32)</td>
<td>7/32 (22%)</td>
</tr>
</tbody>
</table>

**Teplizumab:** 59.6 months

**Placebo:** 24.4 months

**Overall hazard ratio 0.457**

(\(p=0.01\), 2-sided, Cox model)

**Single 14-day course of PRV-031 significantly delayed the clinical onset of T1D by 35.2 months**

**One subject have yet to develop clinical diabetes >8.5 years from start of treatment**

---

Patient numbers on x-axis represent number of patients who have reached that time point.

Note: Chart above is as of May 2020; adapted from presentation 277-OR at ADA 2020 (Sims et al, June 15, 2020).
PRV-031 (Teplizumab)

At-Risk study: reversal of C-peptide decline

- C-peptide levels not only stabilized but reversed/increased ($p=.02$) upon teplizumab treatment, while placebo-treated subjects kept declining ($p=.002$ for teplizumab vs placebo)

- Improvement in C-peptide translated to:
  - Improved (higher) insulin secretion ($p=.004$)
  - Improved (lower) glucose levels ($p=.04$)
  - Correlated with induction of exhausted T cells ($p=.01$) and fewer inflammatory cytokines ($p<.0001$)

These data confirm preservation of β-cell function and suggest restoration of dysfunctional β-cell function.

Note: Adapted from presentation 277-OR at ADA 2020 (Sims et al, June 15, 2020).
**PRV-031 (Teplizumab)**

**At-Risk study: safety profile**

<table>
<thead>
<tr>
<th>Adverse effect category</th>
<th>PRV-031</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events occurring in ≥5% of subjects:</td>
<td>Number of events</td>
<td>Number of subjects (%)</td>
</tr>
<tr>
<td>Blood/bone marrow</td>
<td>45</td>
<td>33 (75.0)</td>
</tr>
<tr>
<td>Dermatology/skin</td>
<td>17</td>
<td>16 (36.4)</td>
</tr>
<tr>
<td>Pain</td>
<td>11</td>
<td>5 (11.4)</td>
</tr>
<tr>
<td>Infection</td>
<td>8</td>
<td>5 (11.4)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>5</td>
<td>4 (9.1)</td>
</tr>
<tr>
<td>Metabolic/laboratory</td>
<td>7</td>
<td>4 (9.1)</td>
</tr>
<tr>
<td>Pulmonary/upper respiratory</td>
<td>6</td>
<td>4 (9.1)</td>
</tr>
<tr>
<td>Endocrine</td>
<td>0</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total events and subjects</td>
<td>112</td>
<td>44 (100)</td>
</tr>
</tbody>
</table>

**Transient events as expected, due to drug mechanism:**

- Transient adhesion of lymphocytes and leukocytes to blood vessel walls due to partial activation (margination)
- Transient mild rash and neutropenia due to mild cytokine release

**No increased clinical Epstein-Barr virus (EBV) reactivations, no increased opportunistic infections**

Possibly Related Treatment-Emergent Adverse Events (TEAEs) by MedDRA High-Level Terms.
Events occurring in ≥5% of subjects.
PRV-031 (Teplizumab)

Regulatory approval strategy

**Received Breakthrough Therapy Designation Aug 2019 and PRIME Designation Oct 2019**
- Provides for greater dialogue with FDA and EMA
- Increases likelihood of Priority Review by FDA and Accelerated Assessment by EMA

**Rolling BLA submission completed in Q4 2020**
- Submitted nonclinical module Q2 2020
- Submitted clinical module Q3 2020
- Submitted CMC module and administrative modules in Q4 2020

**Anticipated timelines to potential approval in at-risk indication**
- US/FDA: Potential approval in mid-2021 (assumes priority review)
- EU/EMA: Potential approval in 2022
- EU commercialization with partner

**Planned BLA submission in 2023 for newly diagnosed indication if PROTECT study is successfully completed**
- PROTECT Phase 3 enrollment was resumed at certain sites in select countries during Q2 2020 after it was paused in March 2020 due to COVID-19
Teplizumab manufacturing

2019

Teplizumab 500L manufacturing process transferred from Eli Lilly to AGC

2020

Q1 2020
Completed GMP run; data added to IND

Q3 2020
Completed 3 PPQ batches (process performance qualification)

Q4 2020
Data from PPQ batches included in BLA module 3 and submitted

PRV-031 (Teplizumab)
Changing the future of T1D screening and care

We believe the prospect of a disease-modifying therapy receiving regulatory approval will increase screening, facilitate commercialization, and revolutionize T1D management

<table>
<thead>
<tr>
<th>Screening today</th>
<th>Expectations for screening tomorrow</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standard blood tests available</td>
<td></td>
</tr>
<tr>
<td>• &gt;1.5 million people screened</td>
<td>• Focus initially on screening direct relatives of T1D patients</td>
</tr>
<tr>
<td>• Identification rates for 2 autoantibodies:</td>
<td></td>
</tr>
<tr>
<td>• Family history ~1 : 100&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• Availability of treatment options may encourage broader population screening</td>
</tr>
<tr>
<td>• No family history ~1 : 1,000&lt;sup&gt;2&lt;/sup&gt;</td>
<td>• Early-stage diagnosis helps reduce disease morbidity:</td>
</tr>
<tr>
<td></td>
<td>• DKA reduced from ~50% to ~10%&lt;sup&gt;3,4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

"With that knowledge for hope, more would test."

- T1D patient

Taking steps today to get there tomorrow

Unbranded campaigns to increase awareness and educate patients and doctors on screening

PRV-031 (Teplizumab)

Securing payer access

Understanding payers’ baseline knowledge of T1D and current management is critical to developing our strategy.

Critical insights gained from payer advisory board and market research interviews:

- Attended by medical directors representing 73 million lives (Commercial and Medicaid)
- Majority of payer diabetes budget and management focused on type 2 diabetes
- Low awareness of the unmet need in T1D that exists today
- High enthusiasm for teplizumab data; expect strong coverage (to approved label) for potential novel T1D disease-modifying drug

PRVB Market Access Team direct payer engagements began in Q3

- To date: 5 major payer meetings representing > 12 million lives
- Discussions confirm the need for disease education, and reinforce enthusiasm for teplizumab

Critical HEOR work will anchor the teplizumab value story

- Real-world evidence study, building robust budget impact and cost-effectiveness models, and developing AMCP dossier
PRV-031 (Teplizumab)

Potential expansion strategy for teplizumab

T1D potential strategy

Repeat dosing
- At risk
- Newly diagnosed

Age expansion
- At risk (ages 2-8)
- Newly diagnosed (ages 2-8 and >18)

Combinations in T1D
- Antigens
- Metabolic drugs (e.g., GLP-1 agonist)
- Immune modulator (e.g., B-cell inhibitor PRV-3279)
- β-cell transplant

Subcutaneous formulation
- Improve on current IV dosing regimen by creating a subcutaneous formulation

Additional potential indications

Rheumatology
- Psoriatic arthritis
- Rheumatoid arthritis

GI immunology
- Crohn’s disease
- Celiac disease
- Autoimmune hepatitis
PRV-031 (Teplizumab)

PROTECT phase 3 study: newly diagnosed T1D

Objective
• Understand β-cell function preservation in T1D patients who are most responsive to teplizumab

Primary endpoint
• Difference in C-peptide at 18 months (detect a 40% difference with 90% power)

Secondary endpoints
• Insulin use
• HbA1c
• Hypoglycemic episodes
• Safety

Status
• Enrollment paused in March 2020 due to COVID-19
• Enrollment resumed at certain sites in certain countries during the second quarter of 2020

Trial design

- 0 months
- 6 months
- 18 months

PRV-031
- 12 days
- 300 participants
- Randomized 2:1 (teplizumab:placebo)
- Age range: 8-17 years
- Newly diagnosed: within 6 weeks of T1D diagnosis
  - Baseline C-peptide ≥0.2 pmol/mL
  - T1D-related autoantibodies

PRV-031
- 12 days

Baseline C-peptide >0.2 pmol/mL
T1D-related autoantibodies
**PRV-031 (Teplizumab)**

### Historical Data in Newly Diagnosed T1D Patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Phase 3: Protégé*</th>
<th>Protégé Subgroup</th>
<th>Phase 2: Study 1</th>
<th>Phase 2: AbATE</th>
<th>Phase 2: Delay**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Subjects</strong></td>
<td>513</td>
<td>89</td>
<td>40</td>
<td>77</td>
<td>58</td>
</tr>
<tr>
<td><strong>T1D diagnosis</strong></td>
<td>&lt; 12 weeks</td>
<td>&lt; 12 weeks</td>
<td>&lt; 6 weeks</td>
<td>&lt; 8 weeks</td>
<td>4 - 12 months</td>
</tr>
<tr>
<td><strong>Subject population</strong></td>
<td>Age 8-35 years Mean 18.4 years</td>
<td>Age 8-17 years and baseline C-peptide &gt; 0.2 pmol/mL</td>
<td>Age 8-30 years Mean 13 years</td>
<td>Age 8-30 years Mean 13 years</td>
<td>Age 8-30 years Mean 12.6 years</td>
</tr>
<tr>
<td><strong>Difference in C-peptide</strong></td>
<td>24%</td>
<td>43%</td>
<td>145%</td>
<td>92%</td>
<td>27%</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.027</td>
<td>0.026</td>
<td>0.02</td>
<td>0.002</td>
<td>0.03</td>
</tr>
</tbody>
</table>

**Consistent C-peptide benefit indicating preservation of beta cells**

* Full 9.0 mg/m²/course 14-Day regimen was explored in 205 treated patients and 98 placebos
** Delay study based on 12-month time-point. All other studies based on 24-month time-points
PRV-031 (Teplizumab)

Opportunity to intercept T1D in thousands of newly diagnosed patients

Estimated US patient prevalence

~64,000
new cases of T1D in the US per year

Ages 8-17
POTENTIAL FOR MARKET LAUNCH

26%

Large commercial market for potential newly diagnosed indication

Planned outreach to pediatric and adult endocrinologists to support identification of newly diagnosed type 1 diabetes patients

Future age groups expected to include 2- to 7-year-old and >18-year-old patients
Regulatory exclusivities provide additional market exclusivity beyond existing IP

PRV-031 (Teplizumab)

- US BLA approval provides 12 years of protection
- US Orphan indication provides 7 years of protection
- EU approval allows for 10 years of protection
- Method of use patents expire end of year
- Applications filed and planned that would extend IP
PRV-3279 B-Cell Autoimmunity Checkpoint Inducer Candidate

Bispecific DART® program with multi-indication potential

Mechanism of action
- Humanized, bispecific scaffold (DART®) targeting both CD32B and CD79B
- Designed to trigger inhibition of B-cell function, suppression of autoantibody production, and CD40 expression
- Designed to boost negative feedback loop regulating B cells without causing B-cell or platelet depletion

Established proof of mechanism
- Inhibition of the production of antibodies to hepatitis A vaccination in previously unvaccinated individuals
- Durable effect: 1-month B-cell inhibition after single dose

Multiple potential applications
- Intercept autoimmune diseases, such as lupus
- Prevent immunogenicity of a variety of therapeutic proteins and gene therapy vectors
PreVail phase 1b/2a study: systemic lupus erythematosus

PreVail phase 1b data study design
- Multiple-ascending dose (MAD) Phase 1b study in 16 healthy adult volunteers
- Randomized, double-blind, placebo-controlled

Positive PreVail phase 1b study results
- Well tolerated in subjects; no serious adverse events
- PK parameters were generally dose proportional
- Durable pharmacodynamic responses
- PreV-3279 durably inhibited the function of B cells without depletion

Status
- Expect to commence Phase 2a in lupus patients H2 2021

PreVail Phase 2a (lupus) trial design
- Phase 2a 24-week prevention of relapse proof-of-concept
- Lupus is a quintessential chronic autoimmune disorder driven by autoreactive B cells
- Polymorphisms in CD32B associated with lupus
*except very low-dose steroids and/or anti-malarial
PRV-3279 B-Cell Autoimmunity Checkpoint Inducer Candidate

PREVAIL Phase 1b Results

~90% of B cells engaged by PRV-3279

High levels of B-cell engagement resulted in durable pharmacodynamic responses

Durable inhibition of serum IgM by PRV-3279

PRV-3279 durably inhibited the function of B cells without depletion
PRV-015 GI Autoimmunity Candidate

Anti-IL-15 for gluten-free diet nonresponsive celiac disease

Poorly managed celiac disease is associated with deteriorating general health, multiple serious intestinal and extraintestinal medical complications, and increased morbidity and mortality.

The gluten-free diet is not effective in ~50% of patients, and flare-ups can occur after accidental exposure to gluten.

Fully-human anti-IL-15 monoclonal antibody

• 21-day half-life; subcutaneous administration every 2-4 weeks

Proof of concept (POC) established

• Well tolerated in 6 prior clinical trials with ~300 patients
• Achieved POC in Phase 2a studies in celiac disease and no known dose-limiting toxicity
• Also POC in refractory celiac disease Type II (in situ T-cell lymphoma)

Status

• Initiated Phase 2b trial in Q3 2020

Phase 2a data shown at 2018 DDW, published in The Lancet

Safety and efficacy of AMG 714 in adults with coeliac disease exposed to gluten challenge: a phase 2a, randomized, double-blind, placebo-controlled study.

PRV-015 GI Autoimmunity Candidate

PROACTIVE Phase 2b study: nonresponsive celiac disease

Objective

• Dose-finding Phase 2b study testing 3 dose levels of PRV-015 against placebo (1:1:1:1)

Primary endpoint

• Validated CeD-PRO (celiac disease patient-reported outcome) (GI symptoms)

Secondary endpoints

• Symptoms: BSFS Score
• Inflammation (IELs: intraepithelial lymphocytes)
• Histology
• Safety

Trial design

• ~220 adult celiac patients not responding to gluten-free diet
• Initiated Phase 2b trial in Q3 2020

Amgen has the right to reacquire PRV-015 for $150 million up front, milestones and royalties
Vaccine Candidate to prevent T1D and celiac disease

PRV-101 Candidate for Prevention Type 1 Diabetes

Vaccinating against coxsackievirus B (CVB)

PRV-101 is a polyvalent inactivated investigational vaccine designed to prevent acute CVB infection.

The role of CVB in T1D and celiac disease

CVB is a common, potentially serious infection:
• Damages insulin-producing cells and gut-lining cells, triggering a T-cell immune response

CVB is the only persistent infection significantly associated with development of T1D and celiac autoimmunity†:
• Found in the pancreas of ~60% of patients with T1D and in the gut of ~20% of patients with celiac disease
• 50% reduction in T1D was observed in the offspring of mothers with immunity to CVB during pregnancy

Phase 1 first-in-human study to begin H2 2020

Randomized, double-blind, placebo-controlled, dose-escalation study to evaluate the safety, tolerability, and immunogenicity of PRV-101 in healthy volunteers.

Two dose levels, each with a sentinel group. Three vaccine administrations, every 4 weeks.

First-in-human data expected in 2021

CVB vaccine has the potential to prevent acute coxsackie infection and to prevent up to ~50% of T1D and ~20% of celiac disease.

†TEDDY study of >400,000 children screened
Structured for success: Provention Bio financials

**Balance sheet**
- $147.2 million of cash, cash equivalents, and marketable securities as of September 30, 2020
- No debt

**Ownership and capital structure**
- 56.5 million shares outstanding
- 67.6 million shares fully diluted
- All directors and officers as a group own > 9%

**Nimble organizational structure**
- 44 full-time employees

**Operations**
- Net loss by quarter 2020:
  - Q1 20 $12.6 million
  - Q2 20 $22.1 million
  - Q3 20 $31.3 million
- Net loss for the nine months ended September 30, 2020 was $66.0 million
- Net cash-based operating expenses of $61.8 million in the first nine months of 2020
- Projecting $24-$28 million of cash-based operating expenses in the fourth quarter of 2020
Recent and near-term milestones to advancing autoimmune care

**2020**

- **PRV-3279**
  - Reported top-line results of Phase 1b study

- **PRV-031**
  - Reported ~3-year delay in clinical onset of T1D in at-risk patients

- **PRV-015**
  - Initiated Phase 2b trial in nonresponsive celiac disease patients

- **PRV-031**
  - Submitted BLA* for teplizumab in at-risk type 1 diabetes patients

**2021**

- **PRV-101**
  - File IND and initiate Phase 1 trial for coxsackievirus B vaccine in healthy subjects

  - Potential approval of teplizumab expected in the US via priority review in 2021
  - PRV-101 first in-human data expected H2 2021

---

*Commenced rolling submission in Q2 and completed BLA submission in Q4.
Corporate

Aligning science and experience to change the world

Ashleigh Palmer
CEO AND CO-FOUNDER
30+ years in Biopharma
Previously CEO of INO Therapeutics, bought by Ikaria, then by Mallinckrodt for $2.3B
At INO took inhaled NO for neonatal hypoxia through Phase 3 development, approval and launch, sales reached $250M in first 2 years
Executive Chairman and co-founder of Celimmune, focused on celiac disease and later sold to Amgen

Francisco Leon
CSO AND CO-FOUNDER
Basic and clinical immunologist by training
Drug developer at BMS, pre-AZ MedImmune, and Centocor/Janssen, with 20+ years experience, and 5 drugs on the market
Co-founded Celimmune, focused on celiac disease, as CEO and CMO and ran two Phase 2 trials for our anti-IL-15, later acquired by Amgen

Eleanor (Leni) Ramos
CMO
Transplant nephrologist
Drug developer at BMS and Roche, with 25+ years experience including 5 drugs currently on the market
CMO at both ZymoGenetics, acquired by BMS for $1B, and Global Blood Therapeutics
Previously ran all clinical trials for immune tolerance induction at ITN with Jeff Bluestone, including for teplizumab

Andrew Drechsler
CFO
23 years in Biotech
Previously CFO of Insmed from 2012-2017, took company from $100M to $1B, raised $400M in public markets, and built organization from 30 to 175 employees
Father of 3 children with T1D and personally involved with JDRF

Jason Hoitt
CCO
18 years in Biotech
Previously CCO of Dova, which was acquired by Sobi in Q4 2019
Commercial leadership roles at Insmed, Sarepta, Vertex, and Gilead
Launches include DOPTELET, Arikayce, Exondys 51, and Incivek

Heidy Abreu King-Jones
CLO
7 years in Biotech and 12 total years in legal roles
Previously SVP and GC of Axcella Health
Legal roles at Sarepta including head of Corporate Law Department, lead commercialization attorney for Exondys51
Started career at Ropes & Gray Securities & Public Company Practice Group
The value of interception & prevention in autoimmunity

Intercept and prevent life-altering and life-threatening autoimmune diseases

• Focused on chronic autoimmune diseases with compelling biological and commercial rationale
• Advancing autoimmune investigational therapies in partnership with industry leaders
  • Amgen and Vactech
• Focused on the patient voice and committed to working with patient advocacy groups
  • JDRF and Beyond Type 1

Four programs with significant upside potential across multiple diseases

• PRV-031 (teplizumab), an investigational monoclonal antibody, for the delay or prevention of T1D in “at-risk” patients and the treatment of “newly diagnosed” patients
• PRV-3279, an investigational bispecific DART® targeting B-cell-driven disease such as systemic lupus erythematosus with multi-indication potential
• PRV-015, an investigational monoclonal antibody for nonresponsive celiac disease
• PRV-101, an investigational vaccine for the prevention of coxsackievirus B and potentially T1D and celiac disease

Fiscal strength to build a better future in autoimmunity

• $147.2 million in cash, cash equivalents, and marketable securities as of September 30, 2020