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): August 10, 2020

PRECIGEN, INC.
(Exact name of registrant as specified in its charter)

Virginia	001-36042	26-0084895
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

20374 Seneca Meadows Parkway, Germantown, Maryland 20876
(Address of principal executive offices) (Zip Code)

(301) 556-9900
(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 (see General Instruction A.2. below):

☐ 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 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, No Par Value	**PGEN**	**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 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 2.02 Results of Operations and Financial Condition.

On August 10, 2020, Precigen, Inc. hosted a conference call and live webcast to discuss the second quarter and first half of 2020 financial results and provide a general business update. A copy of the transcript of the conference call and live webcast is furnished hereto as Exhibit 99.1 and incorporated by reference.

This information, including the Exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of the Conference Call and Webcast of Precigen, Inc. held on August 10, 2020
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

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.

Precigen, Inc.

By: /s/ Rick L. Sterling
Rick L. Sterling
Chief Financial Officer

Dated: August 14, 2020

Event Name: Precigen Second Quarter 2020 Financial Results Conference Call
Event Date: Monday, August 10, 2020, 4:30 PM Eastern Time

Presenters

Steven Harasym; Precigen, Inc.; Head of Investor Relations
Helen Sabzevari; Precigen, Inc.; President and Chief Executive Officer
Tom Samuelson; Precigen, Inc.; Head of Financial Strategy

Analysts

Roy Buchanan, JMP Securities

Presentation

Operator: Good afternoon. Welcome to the Precigen Second Quarter and First Half 2020 Financial Results and Business Update Conference Call.

(Operator Instructions)

I would now like turn the conference over to Steven Harasym. Go ahead.

Steven Harasym: Thank you, operator. I am pleased to be joined today by Dr. Helen Sabzevari, President and CEO of Precigen; as well as Tom Samuelson, Head of Financial Strategy.

Following our prepared remarks, we will open the call to Q&A.

Please turn to the next slide for our forward-looking statement. During today's call we will make various forward-looking statements. Investors are cautioned that our forward-looking statements are based on current expectations and are subject to risks and uncertainties that could cause actual results or outcomes to differ materially from those indicated by our forward-looking statements. Please read the safe harbor statement contained in this presentation, as well as the risk factors contained in Precigen's most recent SEC filings, for a more complete discussion of these risks and uncertainties.

I would now like to turn the call over to Dr. Sabzevari. Helen.

Helen Sabzevari: Thank you, Steve. I hope that this call finds all our listeners and their families safe and healthy as our nation continues to work through the COVID-19 pandemic. At Precigen, the health and safety of our employees is of the utmost importance. Our R&D staff have been back in the office full time and are getting tested on a regular basis. Employees are practicing appropriate safety measures, including social distancing, rigorous disinfection protocols and use of personal protective equipment while in our facility.

Despite these challenging times, our team has adjusted well to this new normal, and currently we remain on track to meet our previously stated clinical milestones and data readouts this year. This is meaningful for our team, as we are able to execute on our mission to deliver novel treatment options to patients with unmet medical needs.

Next slide, please. I would like to begin by giving a brief financial update highlighting our continued focus on fiscal and operational efficiency, all with the aim of increasing shareholder value.

In the second quarter of 2020, Precigen spending, which includes Segment-Adjusted EBITDA plus corporate costs, was approximately $13 million, versus $30 million in the first quarter of 2020. This decrease was primarily attributable to suspending operations at MBP Titan and streamlining our corporate functions to fit the narrower focus of the Company. We expect spend at MBP to continue to substantially reduce as we evaluate a strategic option for this platform.

Furthermore, our financial performance at both Trans Ova Genetics and Precigen Exemplar improved as a result of the efficiency measures we have implemented with both entities, who were contributors of cash through Q2. These measures and other efforts have positioned us to operate comfortably into the late 2021 without the need for additional cash. Tom will provide additional details later in the call.

Next slide, please. Turning now to our UltraCAR-T platform. When we began this journey at Precigen, our vision was to develop a non-viral, rapid, autologous T-cell therapy that can be scaled up in a cost-effective manner that is accessible to any cancer patient. We identified three major technical hurdles that we believed were essential to overcome in order for the non-viral Sleeping Beauty platform to cross the threshold of being commercially viable.

The first challenge was to be able to generate a homogeneous cell product that can expand *in vivo* and thus forego lengthy *ex vivo* expansion. We achieved this by optimizing the non-viral system to simultaneously express three genes: an antigen-specific CAR, membrane-bound IL-15 and a kill switch using our UltraVector platform, thus ensuring production of a homogeneous UltraCAR-T product, which we believe is an essential characteristic of a viable cell therapy. Membrane-bound IL-15 maintains “younger” UltraCAR-T phenotypes with superior *in vivo* expansion and persistence and allows for the elimination of *ex vivo* expansion, while the kill switch improves the safety profile. I want to emphasize that the intellectual property around the UltraVector platform and improvements to the non-viral system lie exclusively with the Precigen team.

The second challenge was to achieve feasibility of manufacturing UltraCAR-T using overnight gene transfer at medical centers. We accomplished this by developing an overnight decentralized manufacturing process without the need for CAR-T cell expansion outside the body, where we optimized the process to significantly improve the efficiency of non-viral gene transfer, UltraCAR-T-cell viability, and the quality-control testing to address dosing and regulatory requirements for overnight manufacturing. As a result of these innovations, we have progressed the UltraCAR-T platform through successful IND clearance and into the clinic with two first-in-class UltraCAR-T therapies.

Next slide, please. The third challenge was to develop a commercially viable process that can be scaled up to treat a large patient population across the globe. Today’s non-viral gene delivery approaches rely on commercially available electroporation devices, which have limitations due to the inverse relationship between system throughput and gene transfer efficiency. This results

in a labor-intensive process and a manual handling of samples that increase contamination risk and pose challenges for scale-up and eventual commercialization. As we advance toward initiating the expansion phases of our UltraCAR-T trials to investigate their efficacy in larger patient populations, the scalability of the process is of the utmost importance. I should emphasize that our ultimate goal is to develop and commercialize treatments based on the UltraCAR-T platform.

Next slide, please. In order to address this challenge, we have developed an exclusive electroporation device, UltraPorator, designed to scale up the manufacturing of our UltraCAR-T program at multiple medical centers. This is the third arm of our path toward developing a commercially viable UltraCAR-T manufacturing platform.

The UltraPorator is a high-throughput system with a custom hardware and software solution capable of handling the electroporation of billions of T cells in a matter of minutes, as compared to multiple hours of processing currently required. Furthermore, the semi-closed system minimizes handling requirements, significantly reduces contamination risk, and streamlines the overnight manufacturing process. The FDA has cleared the use of UltraPorator as a manufacturing device for our clinical trials, and we have initiated the manufacturing of cGMP-compliant systems. We are currently in the process of technology transfer to our clinical sites and expect to implement the system for the expansion phases of PRGN-3005, PRGN-3006 and the future UltraCAR-T clinical trials. Our progress so far with regulatory milestones and tech transfers under way is a testament to our team’s forward looking thinking, anticipating challenges and designing solutions in an aggressive timeline.

To take a step back and give you some perspective, we believe that these innovations represent a pivotal advance in the field of personalized medicine, allowing us to bring the drug manufacturing process as close as possible to patients in a commercially viable and expedient way. We will be updating you on additional milestones associated with the UltraPorator in the next several months.

Next slide, please. Turning to PRGN-3005, our Phase 1 clinical trial in ovarian cancer targeting the unshed portion of MUC16 on cancer cells. In June, we presented preclinical data of PRGN-3005 UltraCAR-T at the AACR virtual annual meeting. The preclinical data demonstrated that a single administration of PRGN-3005 was able to mount a durable antitumor response resulting in elimination of ovarian tumor burden for a second time after tumor re-challenge more than three months later. This study, designed to simulate tumor relapse, highlights the persistence and functional capability of PRGN-3005 to reactivate after long periods without antigen stimulation.

In the clinic, we are enrolling patients in the Dose Level 3 of the IP arm of this trial and remain on track for an initial data readout from this arm this year. Our confidence in our ability to successfully manufacture UltraCAR-T remains high, and we continue to have 100% manufacturing success as we are escalating to higher doses. We are very excited with the progress of PRGN-3005 UltraCAR-T in the clinic so far.

Next slide, please. Now moving to PRGN-3006, our first-in-class candidate for relapsed or refractory AML. This Phase 1/1b trial continues to enroll patients concurrently in both the lymphodepletion and non-lymphodepletion arms. We have completed dosing the third patient in the Dose Level 2 of the non-lymphodepletion arm. To date, we continue to have 100% manufacturing success and remain on track for an initial data readout this year. We are very excited with the progress of PRGN-3006 UltraCAR-T in the clinic so far.

Next slide, please. Turning to PRGN-2009. In April, we announced that the FDA had cleared an investigational new drug application to initiate a Phase 1/2 trial for PRGN-2009, our off-the-shelf investigational AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-positive solid tumors.

I would like to highlight that the design consideration differentiates PRGN-2009 from competing vaccines and TCR-T cell approaches for the treatment of HPV-associated cancers. PRGN-2009 incorporates a multi-epitope design including novel antigen epitopes to target both the HPV16 and HPV18 subtypes. Our approach is differentiated from other competitor HPV vaccines and TCR-T cell approaches. For example, TCR-T cells only target a single epitope within E6 or E7 regions of HPV and are restricted in their applicability to a small patient population due to HLA restriction. PRGN-2009, based on our gorilla adenovector, is an off-the-shelf therapy that can be administered repeatedly, unlike other viral-based vaccines, to activate polyclonal HPV-specific T cells *in vivo*. This is in contrast to TCR-T cells, which require lengthy and complex manufacturing process *ex vivo* prior to infusion and only target a single epitope of HPV.

PRGN-2009 is under development through a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, and NCI is currently recruiting patients for the open-label trial despite ongoing COVID-19 challenges. We believe PRGN-2009 has the potential to be an attractive treatment option for other HPV-associated malignancies, and we continue to evaluate the specific opportunities, including HPV-associated cervical cancer.

Next slide, please. AG019 is a first-in-class, disease-modifying, antigen-specific, investigational immunotherapy for the prevention, delay or reversal of type 1 diabetes, a disease with no approved disease-modifying treatment. AG019 is being evaluated as a monotherapy or in combination with anti-CD3 antibody, teplizumab, in a Phase 1b/2a study. In early spring, we implemented a voluntary COVID-19-related pause for the last remaining study cohort for the Phase 2a study, which is the combination arm in patients 12 to 17 years of age. The temporary pause has been lifted, and the trial is recruiting patients again.

Today, Precigen ActoBio announced positive top line results from the Phase 1b portion of the ongoing Phase 1b/2a study. Results from the Phase 1b portion, which is the AG019 monotherapy arm, indicated that the primary endpoint for the study was met, with no serious or any severe Treatment-Emergent Adverse Events. Moreover, preliminary analysis six months after treatment initiation showed an encouraging trend in insulin C-peptide levels, a common biomarker to measure pancreatic beta cell function. Furthermore, based on preliminary analysis, AG019 monotherapy shows an increase in the frequency of islet-specific Tregs, a potential mechanistic indicator of therapeutic activity. We are very encouraged by these preliminary data and look forward to reporting additional data in the near future.

Next slide, please. Another exciting asset in our portfolio is INXN-4001, a novel gene therapy for heart failure patients, which is being developed by our majority-owned Precigen Triple-Gene subsidiary. Last week, we announced six-month follow-up data from the ongoing Phase 1 study. We are encouraged that INXN-4001 was well tolerated, and the study successfully met the primary safety and feasibility endpoints with no product-related Adverse Events reported. Moreover, preliminary data showed an overall improvement in patient-reported outcome at six months post-treatment. We look forward to sharing the final study results at the 12-month follow-up interval. We are evaluating a strategic option to partner and finance the future development of this platform.

Finally, for an update for PRGN-5001, interest remains high in our multifunctional therapeutic candidate for solid tumors. We look forward to updating you in the near future.

With that, I will now turn the call over to Tom Samuelson to provide a financial update. Tom.

Tom Samuelson: Thank you, Helen, and good afternoon to our stakeholders on the call. Today we report progress in reducing our capital requirements and maximizing our cash runway.

In Q2, Precigen required $13.1 million, a reduction of $18.8 million, or 59%, versus Q2 ‘19 and a reduction of $16.6 million, or 56%, versus our previous quarter, Q1 ‘20. Unallocated corporate costs were $4.1 million, or 36%, lower than Q2 ‘19, due in large part to a 25% reduction in corporate employees and a decrease in professional fees as we streamlined our organization. Further savings were realized by our decision to suspend operations at MBP Titan and improve financial performance at operating subsidiaries Trans Ova Genetics and Precigen Exemplar.

At the beginning of this year, we identified a number of initiatives at Trans Ova aimed at increasing profitability, predominantly through growing out our high-margin service business and reducing various ancillary offerings and overhead costs. We are happy to report that despite ongoing economic challenges in the dairy and beef markets, H1 gross margins at Trans Ova expanded to $14.9 million, a $4.6-million or 45% increase over 2019, and Segment AEBITDA doubled.

We’re also encouraged by continued growth in both revenue and Segment AEBITDA at Precigen Exemplar, highlighting a growing market for predictive models of human diseases. Exemplar’s H1 revenue grew $1.2 million to $4.3 million and Segment AEBITDA expanded $2.7 million to $0.9 million, reflecting growth despite reductions in operating costs. Both Trans Ova and Exemplar contributed cash to Precigen, and we anticipate that both will continue to do so.

The present global economic conditions necessitate careful monitoring, and we will remain vigilant to developments that may occur in the industries in which we operate. While our net loss of $43.4 million, or $0.26 per basic share, exceeded that of Q2 ‘19, the majority of this loss, $31.7 million, was non-cash. We recorded $22 million in non-cash impairment charges in conjunction with the suspension of MBP Titan’s operations.

At June 30, we had cash, cash equivalents and short-term investments of approximately $133 million. Based on our present expectations, we anticipate these funds would be sufficient to fulfill our capital requirements into late 2021. We encourage you to read our 10-Q, which provides more information about all of the matters that I've discussed today. I would now like to turn the call back over to Helen.

Helen Sabzevari: Thank you, Tom. I'm extremely thankful to our team, which continues to advance our portfolio during these unprecedented times. In the second half, we have started to report a number of data sets and achieve milestones we set forth in early 2020.

At Precigen, we realize that only by efficiently translating research into therapies can we deliver benefits to patients with unmet medical needs, and in turn, create value for shareholders. For this reason, we are setting ambitious drug-development timelines for ourselves, as evidenced by our progress since the start of this year. We remain confident in our innovative and focused portfolio and look forward to providing you with updates in the coming weeks and months.

With that, we will now open the line for questions. Operator, please begin.

Questions & Answers

Operator: (Operator Instructions)

Our first question is from Jason Butler from JMP Securities.

Roy Buchanan: It's Roy in for Jason. Thank you for taking our questions. I guess the first couple on the UltraPorator. Maybe I missed it, but did you say what the total manufacturing time you think you can achieve with this new device? How much further do you think it can be improved? And what process improvements are you considering to get to that time?

Helen Sabzevari: Thank you for the question. Very good question. When we started actually advancing the UltraCAR-T and in our discussions even with the FDA, from the first moment, was not only achieving all the criteria that was necessary, but what does it take for this process of overnight to be scalable globally and reduce the handling and advance the technology to the point that we can go from hours of handling samples that is required for transfection and with the current electroporators, as you have seen in the slide, for instance. In order to process hundreds of millions, it takes many, many, many hours, which introduces a lot of issues with contamination, also, mistakes.

And we decided, in conjunction and discussions with the FDA, to — as we were advancing the platform — to come up with a device that can basically withstand the commercially viable production of the UltraCAR-T. And the result, was the UltraPorator. As you see in the slides — and by the way, obviously, these slides are shown in cartoon and to just get the point across, but currently the UltraPorators are being implemented at our clinical sites and especially as we are moving rapidly toward our expansion phases, which is quite exciting for us, it's being implemented and tech transfer is done. We are going and we are reducing the number of hours in handling and processing of hundreds of cuvettes which otherwise would have been handled in a matter of — to go from two to three hours to under 12 minute process.

This is how important this manufacturing device is, and it reduces the — basically, the processing and handling, which can lead to contamination and others, and failures of manufacturing. We anticipated this when we started this journey, and I am really proud of the team, that we have brought this forward in exact timelines that we had set and we had discussed with the FDA, and now we also have the FDA clearance for our clinical trial to implement today.

Roy Buchanan: Okay, great. And a question on PRGN-3005: You're at the third dose level. What's the initial data readout going to include? And could that include more than the first three doses?

Helen Sabzevari: Yes, so what we are currently doing, obviously, is the safety, and it will have the kinetics as we have discussed. And we will make a decision as we are enrolling other patients and move toward, perhaps, expansion, how we will communicate that.

Operator: (Operator Instructions)

Okay, at this time, we have no questions. We'll turn it back to Helen Sabzevari for closing remarks.

Helen Sabzevari: Thank you again for joining us on today's call. We are very excited with our progress and look forward to providing further updates in the near future. Thank you.

Operator: The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.