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): May 6, 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 May 6, 2020, Precigen, Inc. hosted a conference call and live webcast to discuss the first quarter 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 May 6, 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: May 11, 2020

MAY 06, 2020 / 8:15PM GMT, Q1 2020 Precigen Inc Earnings Call

CORPORATE PARTICIPANTS

Helen Sabzevari *Precigen, Inc. - President & CEO*
Steven Harasym *Precigen, Inc. - Head of Investor Relations*
Tom Samuelson *Precigen, Inc. - Head of Financial Strategy*

CONFERENCE CALL PARTICIPANTS

Jason Nicholas Butler *JMP Securities LLC, Research Division - MD and Senior Research Analyst*
Swayampakula Ramakanth *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

PRESENTATION

Operator

Good afternoon, and welcome to the Precigen First Quarter 2020 Business Update and Financial Results Conference Call. I will now turn the call over to Steve Harasym, Head of Investor Relations. Please go ahead.

Steven Harasym ***Precigen, Inc. - Head of Investor Relations***

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

Please turn to Slide 2 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 will now turn the call over to Dr. Sabzevari.

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Thank you, Steve. I hope that this call finds all our listeners and their families safe and healthy. Since we last spoke in March, so much has changed. We are living through an historic moment that has caused profound change from all perspectives: scientific, economic, sociologic and psychologic. Our nation and the world are making progress in working together to overcome the challenge of COVID-19. At Precigen, the health and safety of our employees is of the utmost importance. Our corporate employees have transitioned seamlessly to working remotely, and essential personnel, including research scientists, are in the lab and practicing all appropriate safety measures, social distancing, a staggered work time, and wearing of personal protective equipment. Despite these challenging times, we continue to advance our programs with the ultimate goal of benefiting patients.

Before I review the progress we made in the last quarter, I would like to reflect on the headway our team has made in bringing 3 first-in-class drugs from concept to clinic in the last 18 months. I am incredibly proud and privileged to lead such a passionate team. Even during these unprecedented times, what has not changed is our adherence to our core operating principles, as outlined on Slide 3.

I strongly believe that the most important way we can deliver value to our shareholders and our stakeholders is to advance toward important goals we laid out earlier this year because our company and our science must continue to evolve. As we work to become a key player in the gene and cell therapy market by realizing our mission of improving patient care through our innovative product portfolio, I'm pleased to report that at this point, we remain largely on track with our previously disclosed clinical timeline. I will provide a more detailed update on our clinical programs in just a moment.

Our team also wants to underscore that we are on track to achieve the 2020 goals we laid out on our last call, while preserving financial resources, which should allow us to continue to operate well into 2021. We have made considerable progress in streamlining the organization to focus on health. Key initiatives this quarter included: completing the sale of several of our non-health assets; improving operations at both Trans Ova Genetics and Exemplar, so they are net contributors of capital this year barring significant adverse impact from the COVID-19 pandemic; and substantially reducing cash burn at MBP Titan, which I will discuss in greater detail later in the call.

In the first quarter of 2020, Precigen spending, which includes segment AEBITDA plus unallocated corporate costs was approximately $30 million versus $39 million in the first quarter of 2019. This decrease was primarily attributable to significantly lower costs for corporate functions, which were streamlined to fit the narrower focus of the company. These numbers exclude the additional cost savings of $12 million, which resulted of the sale of certain of our non-core bioengineering assets, which closed in the first quarter.

Another top priority for us is to unify our health care businesses to become one Precigen, as you can see on Slide 4. We have made major strides here, allowing us to deploy resources, maximize collaboration and streamline workflows more efficiently. Specifically, we have taken steps to integrate our health businesses to achieve synergies at both the corporate and company level. We have also streamlined our infrastructure, eliminated redundancies, reduced corporate costs, and increased communication across our health businesses. In addition to Precigen, these include Precigen ActoBio, Precigen Exemplar and Precigen Triple-Gene. We have focused the efforts of our health subsidiaries on pipeline programs that we believe have the most potential value. Externally, this closer integration is evidenced through our recently updated website, precigen.com, which consolidates information on each of these respective programs in one place. We hope that you find it informative.

On Slide 5, you will note our strategy for our non-healthcare assets. I'm pleased to report that we are making progress in our overall objective to reduce our capital allocation to both businesses.

Consistent with our goal to allocate resources in a manner that best creates value, it is our commitment to reduce non-health spending. We continue to implement additional efficiency measures at MBP Titan while exploring the options to partner or sell the business.

The ongoing COVID-19 pandemic and the current state of the energy sector are especially challenging for the prospect and operation of this business. We expect that progressing this non-health platform will require significant capital and efforts to secure such capital have been hampered by world events. As a result, we have made the difficult but necessary decision to suspend operations in our MBP Titan facility and minimize the expense of the operation while continuing to maintain the potential value of the platform for a brighter economic situation. Specifically, we have taken steps to significantly reduce our MBP Titan workforce and to cut operating costs, while at the same time, prioritizing the preservation of intellectual property and technology. I also want to announce that by mutual agreement, David Witte, CEO of MBP Titan, is no longer with the company. I want to thank the entire MBP Titan team for their contribution in advancing our innovative Methane Bioconversion Platform. We will continue to evaluate options for this technology.

Another highlight this quarter was the upswing in financial performance at Trans Ova Genetics due to the combined impact of expanding the commercial dairy business and achieving operational efficiencies.

Turning now to update our health clinical programs on Slide 6, I am pleased to reaffirm that we remain on track to meet our previously announced goals for read-outs and other milestones in 2020.

Turning to Slide 7. On April 20th, we announced that the FDA has cleared the Investigational New Drug application to initiate a Phase I/II trial for PRGN-2009, a first-in-class, off-the-shelf investigational immunotherapy, utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive solid tumors. HPV-positive cancers represent a significant health burden in indications such as head and neck, cervical, vaginal and anal cancer. Globally, high-risk HPV infections cause nearly 5% of all cancers.

PRGN-2009 leverages Precigen UltraVector and AdenoVerse platforms, to optimize HPV antigen design in combination with its gorilla adenovector with a large payload capacity and the ability for repeat administration due to very low to nonexistent seroprevalence in the human population. Preclinical testing of PRGN-2009 has demonstrated robust HPV antigen-specific immune response and potent anti-tumor activity as a monotherapy and in combination in humanized mouse models of head and neck cancers. Please now turn to Slide 8.

The Phase I portion of the study will follow 3+3 dose escalation to evaluate the safety of PRGN-2009 administrated as a monotherapy and to determine the recommended Phase II dose followed by an evaluation of the safety of this combination of PRGN-2009 and

investigational bifunctional fusion protein M7824 in patients with recurrent or metastatic HPV-associated cancers. The Phase II portion of this study will evaluate PRGN-2009 as a monotherapy or in combination with M7824 in patients with newly diagnosed stage II or III HPV-16 positive oropharyngeal cancer.

PRGN-2009 is under development through a Cooperative Research and Development Agreement, or CRADA, within the laboratory of Dr. Jeffrey Schlom at the National Cancer Institute. This CRADA has allowed Precigen to rapidly and cost effectively advance PRGN-2009 to the clinic. The Phase I/II clinical trial will be conducted at the NCI and will be led by Dr. Julius Strauss and Dr. James Gulley.

Turning to Slide 9. We reaffirm that we are on track for initial data readouts from IP arm of our Phase I clinical trial of PRGN-3005 in ovarian cancer during the second half of this year. I am happy to announce that we have completed dosing of the dose level 2 of the IP arm of this trial. We are very encouraged by our ability to successfully manufacture UltraCAR-T, and to date, we continue to have 100% manufacturing success.

Fred Hutchinson Cancer Center has placed a temporary pause on non-COVID-19 Phase I clinical trials due to the medical center's prioritization of COVID-19 patients at the hospital. PRGN-3005 was part of this pause. It is important to note that it was neither related to safety issues nor any study related COVID-19 infections. Today, I'm pleased to announce that we are amongst the first trials to have the pause lifted and are actively recruiting again.

As seen on Slide 10, we believe this is in part due to the characteristics of our platform, decentralized manufacturing advantages and lack of lymphodepletion treatment to patients prior to UltraCAR-T administration. Unlike conventional CAR-T, UltraCAR-T cells do not use lentivirus and does not require long ex vivo expansion in large manufacturing facility. Instead, UltraCAR-T uses nonviral, rapid manufacturing at the hospital, allowing for the treatment of patients the day after gene transfer. We view this as an important competitive advantage in a post COVID-19 world.

Now moving to Slide 11. The PRGN-3006 trial continues to enroll and to date has not experienced any COVID-19 related interruption. The trial was initially structured to dose patients in the non-lymphodepletion arm followed by the lymphodepletion arm at the set dose level. The IND has been amended, and the FDA has allowed us to concurrently dose patients in both arms. We are currently enrolling patients in both lymphodepletion and non-lymphodepletion arms and are excited to compare them. And to date, we continue to have 100% manufacturing success. We remain on track for initial data readouts and look at the kinetics in the second half of 2020.

I will now go back to reviewing the rest of our portfolio on Slide 12.

I would like to move on to ActoBio AG013, which is partnered with Oragenics. Oragenics recently announced that early top-line results of the Phase II clinical trial of AG013 to prevent oral mucositis in the head and neck of cancer patients receiving chemo-radiation did not demonstrate a statistical significance on the primary endpoint of severe oral mucositis durations when compared to placebo. We look forward to hearing from the company as developments become available.

Turning now to AG019, as noted in earlier investor updates, Precigen ActoBio remains on track to announce interim data for the first cohort of Phase IB/IIA clinical study in the third quarter of 2020. AG019 is a first-in-class, disease-modifying, antigen-specific investigational immunotherapy for prevention, delay or reversal of type 1 diabetes, a disease with no approved disease-modifying treatment that is currently managed through lifestyle modification and diet combined with exogenous insulin.

We have implemented a temporary pause to randomization for the last remaining study cohort of the Phase IIA study, which is the combination of AG019 plus anti-CD3 antibody, teplizumab, in patients 12 to 17 years of age. This temporary pause is neither due to any study-related issue nor is based on any study-related COVID-19 infections. We decided to do this out of an abundance of caution given the immunosuppressive nature of teplizumab against the background of the evolving COVID-19 pandemic.

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. We expect to complete the Phase I trial and provide top line data by the end of 2020.

I will now turn the call over to Tom Samuelson to give a financial update.

Tom Samuelson ***Precigen, Inc. - Head of Financial Strategy***

Thank you, Helen, and good afternoon to everyone on the call.

As previously reported in our last quarterly conference call, we closed the sale of $65.2 million in legacy bioengineering assets and $35 million in our common stock. These transactions, not only provided Precigen with substantial additional capital, but also significantly reduced our 2020 requirements by an estimated $46 million, based on the aggregate expenditures incurred in 2019.

Please recall that segment AEBITDA, which is fully defined in our SEC filings, is generally the sum of net cash operating expenses and capital expenditures. Among continuing operations, our Q1 2020 and Q1 2019 segment AEBITDA losses plus corporate costs, which are not allocated to individual segments, totaled approximately $30 million and $39 million, respectively. A large component of this reduction of approximately $9 million or 23%, was a $7.8 million or 43% reduction in our unallocated corporate expenses, achieved largely by eliminating redundancies and decreasing professional fees.

Despite continued advancement on our multitude of clinical and preclinical programs in oncology and immunology, we maintained a comparable quarter-over-quarter segment AEBITDA therein as planned.

As Helen alluded to beforehand, we made the difficult decision to dramatically decrease expenditure towards MBP Titan, which required $36.7 million in 2019 and $8.8 million during the first quarter of 2020. In the second quarter, we are already significantly reducing these expenditures, ultimately to only those required to preserve the IP and technology.

At Trans Ova Genetics, revenues grew quarter-over-quarter by 12% to $16.8 million, while segment AEBITDA increased by approximately $1 million. Segment AEBITDA at Exemplar and ActoBio Therapeutics also improved by $0.9 million and $0.4 million, respectively, over the same quarter last year. On March 31, 2020, we had cash, cash equivalents and short-term investments of approximately $149 million and anticipate these funds to last well into 2021.

In closing, we enacted many of these operational improvements during the first quarter, and thus, we expect to see even greater impact in our Q2 results. I would also like to note that as is the case for every organization today, the effects of the ongoing COVID-19 pandemic will continue to impact our company. We advise you that further developments with respect to the pandemic may have an adverse effect on our operations.

I would now like to turn the call over to Helen for concluding remarks.

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Thank you, Tom. During 2020, we expect to report numerous data sets and achieve new milestones, as you can see on Slide 13.

In closing our call today, I want to confirm our confidence in Precigen's potential to transform the healthcare landscape with our innovative and focused portfolio. Despite the current challenges presented by COVID-19, we continue to deliver on our clinical plans and confirm our financial guidance for 2020.

We are committed to managing our company in a financially prudent, fiscally disciplined and transparent manner by reaching data-driven go/no-go decisions early in the development process to achieve our mission of bringing our potentially transformative treatment options to patients.

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

QUESTIONS AND ANSWERS

Operator

I would now like to turn the call back over to Steve Harasym.

Steven Harasym ***Precigen, Inc. - Head of Investor Relations***

Thank you, Kevin. Joining us today for our Q&A session will be Helen; Tom, who you just heard speak; and our CFO, Rick Sterling. I'd like to turn it back to our operator, who will assemble the queue now. Thank you.

Operator

(Operator Instructions) Our first question comes from Jason Butler from JMP Securities.

Jason Nicholas Butler ***JMP Securities LLC, Research Division - MD and Senior Research Analyst***

Thanks for taking the question. Congrats on all the progress. Maybe just starting off on 2009. Can you discuss what you've seen preclinically with the combination with bintrafusp alfa and how we should think about the potential for monotherapy efficacy or signals of efficacy in this study versus the combination? And how do you think about the combination for other potential combinations?

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Thank you very much, Jason. Excellent question. Actually, in collaboration with NCI and the studies that have been done at NCI, we evaluated the efficiency and efficacy of PRGN-2009 in a number of the humanized mouse models of head and neck and in HPV positive. And it has been actually quite encouraging data from the reduction or stabilization of the tumors that we have been in a number of different indications, HPV-positive ones, of course. And in combination, we have seen an enhancement also into the tumor -- reduction of the tumors as well as the activations of immune cells. The importance of the combinations that we currently have is with the bifunctional molecule that actually also targets the TGF-beta pathway, which in a number of indications that the basically checkpoint inhibitors are not functional. And the reason might be for TGF-beta, this will add additional actually effect. One of the very important designs of -- especially of off-the-shelf immunotherapy is the way that it's designed, we are using in the clinic in a window of opportunity between -- especially in the Phase II design, at the time that patients are not receiving any treatment. And I think this is going to be very exciting, and that's one of the excitements in the field. We believe that our PRGN-2009 in -- as we have seen in monotherapy, in indications that are HPV positive, but also in combination, not only with the current bifunctional molecule that may have a bit -- at NCI, but also with our -- some of our own portfolio molecules that exist. And we have done studies. And we believe that this would be a very exciting molecule to move forward. And it's very unique as it was mentioned because we used both our UltraVector, special antigen design and our gorilla AdenoVerse platform, which allows us to dose number of times as well as it gives us a larger payload. And this makes the PRGN-2009 a very unique drug product that is -- and we are looking forward to the study.

Jason Nicholas Butler ***JMP Securities LLC, Research Division - MD and Senior Research Analyst***

That's great, Helen. Thank you. My second question, just for both the 3005 and 3006 programs, you reiterated again that you're maintaining this 100% manufacturing success rate. Can you give us a sense of what this represents in total number of patients or manufacturing processes you've now successfully completed? Or I guess, maybe to put it different way, how far along the path are you to having confidence that a very high success rate is sustainable in a multicenter setting?

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Right. Excellent. First of all, PRGN-3005 is done at Fred Hutchinson for solid tumors and PRGN-3006 for liquid tumors, AML patients at Moffitt Cancer Center. This was very important for us that the manufacturing can be duplicated in a number of the centers. And this -- at this point, we have shown that and demonstrated that in either of these centers, they have achieved 100% manufacturing despite of the different sizes of the facilities. So we are very confident, and we have seen now both -- as we also reported in this call for PRGN-3005, we are really excited. We have finished the second dose cohort at this point. And we also have finished the first cohort in a lymphodepletion and in the second cohort of -- I'm sorry, in non-lymphodepletion. And as we mentioned, we have received the allowance, but now we can concurrently also do the lymphodepletion and do the comparison. So between all of this, there are a number of the patients, as you can imagine, these studies are 3+3. And so we have, up to this point, have dosed number of patients in either of the trials, and we have not had any manufacturing failures, which allows us for the confidence that we stress.

Jason Nicholas Butler ***JMP Securities LLC, Research Division - MD and Senior Research Analyst***

Okay, great. And then if I can just squeeze in a last one for Tom or Rick. I'm sorry if I missed this in Tom's comments before, but can you quantify the cost savings that you think you can capture from MBP Titan with the reductions you've put in place for 2020?

Tom Samuelson ***Precigen, Inc. - Head of Financial Strategy***

Yes. So thanks for the question, Jason. So we're not giving specific guidance on an exact number for 2020. What I can tell you is, reiterating just that the 2019 segment AEBITDA for MBP was $36 million. And the 2020 Q1 was approximately $9 million. So we would allow you to sort of draw the conclusions from there for now.

Helen Sabzevari ***Precigen, Inc. - President & CEO***

And maybe, Jason, one thing that I can stress, we have significantly reduced, basically the cost as the MBP Titan. So this would be reflected in the next Q as it comes.

Operator

Our next question comes from Swayampakula.

Swayampakula Ramakanth ***H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst***

This is RK from HCW. A couple of quick questions. The first one, you talked about some changes on the PRGN-3006 study. Can you tell us what additional changes have you -- are you proposing outside of the concurrent dosing of patients in both the arms?

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Got it. Thank you, RK. In regard to the PRGN-3006, the original IND that we had and was discussed with the FDA, we would start with the non-lymphodepleted arm to obviously look at the manufacturing ability as well as the safety. And after we were going to finish the non-lymphodepleted arm, then we will start the lymphodepletion arm. And as you can imagine, there's -- by that design, there would have been basically a long staggered time between the 2 arms. I'm really excited that with going through the first cohort with the non-lymphodepletion, and not only showing the manufacturing ability and 100% manufacturing success, but also the safety results that we have seen -- amendment was allowed by FDA. And now we can concurrently basically enroll patients, which obviously it allows us to, not only move more rapidly as well as get to the comparison between the arms of non-lymphodepletion and lymphodepletion.

Swayampakula Ramakanth ***H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst***

Okay. Thank you very much. There's going to be quite a bit of data coming up in the next couple of quarters across 4 of your programs. Trying to kind of focus a little bit on the diabetes program where you're expecting some interim data in the third quarter. Two questions. What sort of early data will we see? And also, will this kind of -- I'm trying to figure out how do you plan to take this program forward? Can you do it yourselves or you need some collaborators so that you can finish the program in terms of completing it to late-stage as well as trying to commercialize it?

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Sure. Thank you. So in regard to AG019, of course, there are 4 arms in main -- especially in a Phase IIa that compares the AG019, both in adult and adolescent, by itself as a monotherapy and then, of course, in combination with anti-CD3. And the first readout that we will be reporting on from a Phase Ia would be on the safety of the molecules and also some of the pharmacokinetics of the drug. And the interim data, obviously, we will further advance in the 6 months observations of the patients that they have received. As you know, this molecule, it basically delivers IL-10 and also for insulin in type 1 diabetes at the onset of the disease, which is very important. These patients don't have, really there's no therapy, except the diet as well as the insulin eventually. And I think this would be exciting, the readout from 6 months, and then eventually, there would be a readout on 12 months that we will be able -- allow us to see the platform as a monotherapy as well as in combination with the anti-CD3. And then based on that, the decisions will be made where we go.

As far as the strategy for the portfolio, I would address this in general. Our strategy is a continuous evaluation of our portfolio with the concept of efficiency in mind. And therefore, we look at all of our strategic possibilities in front of us. And of course, all these partnerships is a big part of that. So these things will be evaluated as we move on, and this is not really specific to one program, this is across our portfolio.

Operator

And I'm not showing any further questions at this time.

Helen Sabzevari ***Precigen, Inc. - President & CEO***

Great. Thank you.

Operator

Ladies and gentlemen, this does conclude today's presentation. You may now disconnect, and have a wonderful day.
