Event ID:
Event Name: Precigen Fourth Quarter and Year End 2019 Financial Results Conference Call
Event Date: Monday, February 2, 2020, 5:30 PM Eastern Time

Officers
Steven Harasym; Precigen, Inc.; Vice President, Investor Relations
Helen Sabzevari; Precigen, Inc.; President
Tom Samuelson; Precigen, Inc.; Vice President, Finance

Analysts
Jason Butler, JMP Securities
Swayampakula Ramakanth, H.C. Wainwright

Presentation

Operator: Good day, and welcome to the Precigen conference call.

(Operator Instructions)

Please note that this event is being recorded.

I would now like to turn the conference over to Steve Harasym. Please go ahead, sir.

Steven Harasym: Thank you, operator. Welcome to the Precigen Fourth Quarter and Full Year 2019 Business and Update Call. I'm Steve Harasym, Vice President of Investor Relations, and I'm pleased to be joined today by Dr. Helen Sabzevari, President and CEO of Precigen; and Tom Samuelson, Vice President of Finance.

During today's call, as seen on Slide 2, 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 in Precigen's most recent SEC filings, for a more complete discussion of these risks and uncertainties.

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

Helen Sabzevari: Thank you, Steve. Please go to Slide 3. I'm extremely pleased to be here today, as we have made great progress even since our last public presentation at J.P. Morgan Healthcare Conference in early January. We enter 2020 with renewed optimism about our ability to deliver on our aggressive goals and add value to shareholders.

Precigen's mission is to improve patient care through innovative gene- and cell-therapy-based approaches. I will review our carefully curated portfolio of unique solutions to unmet needs in health in greater detail. Our approaches are novel and designed to treat conditions that are both difficult to treat and have limited treatment options for patients.

Before we give a quick recap of the divestments and transactions that enabled us to advance toward our goal of becoming a dedicated healthcare company, I thought it would be useful to provide a recap of how far we have come in such a short time, as shown in Slide 3.

In Q4 of 2018, we started on the path to becoming a standalone healthcare company by reacquiring the rights to our oncology assets from our former partners. In just under a year, we advanced two programs from inception into the clinic and developed a pipeline of promising product candidates in immuno-oncology, autoimmunity and infectious diseases. We also took the necessary steps to expand on an already robust IP estate. Finally, we consolidated the majority of our operations in our Maryland headquarters and continued to bolster our scientific team here.

We believe the transactions that occurred over the last several months put us firmly on the path to being able to devote our resources to advance our healthcare assets and become a major player in the gene and cell therapy field. As you may recall, this included divesting the majority of Intrexon's non-healthcare assets, my appointment as the CEO, a name change from Intrexon to Precigen and associated stock ticker change to PGEN.

We also sold our position in AquaBounty for approximately $21.6 million, sold our 50% interest in EnviroFlight to our former partner Darling Ingredients for $12.2 million, completed the sale of several assets including our nonhealth subsidiaries Oxitec, Okanagan Specialty Fruits, AgBio and ILH Holdings for a combined $53 million plus certain contingent payment rights. These now divested nonhealth businesses accounted for $46 million in net cash operating expenses and capital expenditure in 2019 and raised $35 million in capital through the issuance of equity. Through the financial transaction, we achieved our previously stated cash position goal, allowing the company to deliver on several value-creating milestones in 2020.

Furthermore, we are happy to report that the going-concern qualifier has been removed from our financial statement. Based on combination of our cash position and reduced spending, we anticipate current capital on hand will allow us to operate well into 2021.

In light of our transition to a more health-focused company, we are evaluating all aspects of our operating structure and will provide updates in our next quarterly call. Concurrently, I want to acknowledge the contributions of General Bostick, COO and President of Intrexon Bioengineering, and Tom Reed, Founder and CSO of Intrexon, both of whom are no longer at the company. We thank them for their contribution and services.

Moving ahead, I want to share how we plan to manage Precigen going forward on the next slide. Slide 4, please. With our focus firmly on healthcare, we have aligned the entire company to operate in accordance with four key principles: First is adhering to strict fiscal responsibility. We will responsibly allocate capital to maximize value creation for stakeholders. Fiscal responsibility for us is not just about saving, maintaining cash and cutting cost. It is also about allocating resources to the right areas to create value. You will note that in 2019, we spent $43.7 million on our two most advanced healthcare subsidiaries, Precigen and ActoBio. Collectively, the health portfolio spent significantly lower than our nonhealth portfolio.

The second operating principle is actively managing our portfolio with strict adherence to data-driven go- and no-go decisions.

Third is focusing on rapid execution, moving our valuable portfolio of assets quickly into the clinic and advancing them into registration-enabling studies in accordance with the appropriate scientific, clinical and manufacturing standards.

And finally, forming strategic partnerships to advance or divest assets in our portfolio where appropriate, noting our fiduciary duty to operate in the best interest of shareholders.

Since January, we have aligned our portfolio, streamlined our operations and optimized our organizational structures to improve operational efficiency, especially at the corporate level. We will continue to take additional efficiency measures across the organization and will update you on our progress.

I strongly believe that the most important way we can deliver value to shareholders is to create value to patients through rapid development of novel therapeutics that are safe, effective and address unmet medical needs in a fiscally responsible manner.

Before moving on to a review of the anticipated 2020 milestones for Precigen, on the next slide, we want to discuss our strategy for the remaining nonhealth assets. Slide 5, please. Our subsidiary MBP Titan's technology platform has the potential to upgrade natural gas to higher-value carbon output through our methane bioconversion platform. As we prioritize our health portfolio, the Board of Directors and I are committed to significantly reducing our nonhealth spending, specifically for MBP. To this end, we have already implemented efficiency measures at MBP to achieve this goal and have already significantly reduced their capital requirements compared to last year. We will continue to evaluate further efficiency measures that support its ongoing operation while establishing clear fiscal guardrails on spending.

Our goal is to partner or ultimately sell this business. Whatever we do will be in the long-term interest of our stakeholders and adherence to our mission. We will continue to update you on our decisions when we have new information to share.

Another non-health business in our portfolio, Trans Ova, is the industry leader in advanced reproductive technologies for the cattle industry. We considered divestiture of this non-health business but ultimately elected to retain it because we believe it has more value than the offers we received. Nevertheless, we continue to strategically evaluate options for this business. In the meantime, however, we have implemented efficiency and cost reduction measures such that we will not contribute any additional capital toward Trans Ova and expect Trans Ova to return to being a net contributor of capital to Precigen this year.

Moving to the next slide, you can see the breadth of our healthcare organization. Slide 6, please. The new Precigen enters 2020 with a promising portfolio of investigational gene and cell therapy. Under the new One Precigen umbrella is our transformative UltraCAR-T, AdenoVerse Immunotherapy and ActoBiotics therapeutic platforms, which share a focus on developing

innovative therapies in immuno-oncology, infectious diseases and autoimmune disorders. We also are advancing an innovative approach from our subsidiary Triple-Gene in heart failure.

Slide 7, please. Moving to the next slide, we see the breadth and the value of our clinical portfolio, which includes our internal as well as partnered programs, including later-staged assets in Phase 2 and Phase 3 clinical trials.

Two important things to remember about our portfolio are that, first, we are advancing unique programs that represent substantial therapeutic class innovation, and second, we expect most of these programs to have important data readouts in 2020. Following the release of new data, we intend to assess and further prioritize our pipeline to optimize cash resources.

Beyond this clinical pipeline, we also have a portfolio of novel preclinical assets that will be assessed and funded according to a strict science- and data-driven analysis. Our most significant goal for preclinical assets for 2020 is to initiate a Phase 1 trial of PRGN-2009, our new off-the-shelf AdenoVerse Immunotherapy in HPV-positive cancers.

Slide 8, please. Before reviewing our many exciting milestones for 2020, I want to take a few moments on the next slide to provide an overview of one of our most promising therapeutic platforms, UltraCAR-T. We believe it holds the promise to revolutionize the CAR-T landscape and provide benefits to patients and the healthcare system at large for the following reasons.

First, unlike conventional CAR-T, UltraCAR-T cells do not require lentivirus and long ex vivo expansion in manufacturing facilities. Instead, UltraCAR-T uses non-viral, rapid, overnight manufacturing at hospitals. This overnight manufacturing brings the potential for repeat dosing of UltraCAR-T to patients as well. This manufacturing approach, we believe, brings the convenience of allogeneic CAR-T administration to autologous CAR-T treatment without the potential risk associated with the allogeneic CAR-T therapy.

Second, unlike conventional CAR-T, UltraCAR-T cells express membrane-bound IL-15, which provides higher potential to expand and persist in vivo and to maintain a younger, less differentiated state. Conventional CAR-T cells have limited potential for expansion after administration due to long manufacturing process that requires T-cell activation and expansion outside the body. Allogeneic CAR-T cells are even more limited in their persistence potential, since they are foreign and risk rejection by a patient's immune system and the occurrence of graft-versus-host disease. Furthermore, allogeneic CAR-T cells require severe lymphodepletion of patients, which also limits antigen-spreading potential. We believe membrane-bound IL-15 provides our UltraCAR-T cells with a higher potential for expansion and persistence in patients after administration than conventional CAR-T.

Third, we have built our UltraCAR-T platform such that all modified T-cells express a kill switch. This engineering provides us with an ability to selectively eliminate UltraCAR-T cells by administration of a kill switch activator in the event of toxicity, thus improving the safety profile.

With the potential to advance precision medicine and disrupt the current CAR-T landscape, our vision for the UltraCAR-T platform is to build and validate a library of UltraCAR vectors to

provide personalized, autologous CAR-T treatment for any cancer patient in a rapid and cost-conscious manner.

During 2020, we expect to report numerous data sets and achieve new milestones.

Slide 9, please. Looking at our advanced assets, 3005 is the first UltraCAR-T in solid tumors targeting ovarian cancer in Phase 1 clinical study. We currently are enrolling the second cohort for the IP arm. To date, we continue to have 100% manufacturing success, and the preliminary findings regarding UltraCAR-T kinetics, which includes expansion and persistence in patients treated in the lowest-dose cohort, are very encouraging. We know that everyone is eager to see these early data points, and we share their excitement. We will continue to evaluate the appropriate time to provide additional details. Presently, we expect to provide an initial readout from the IP arm in the second half of 2020. We are also planning to present preclinical data for 3005 at an upcoming medical meeting later this year.

Slide 10, please. 3006 is the first UltraCAR-T therapy to be evaluated in hematological cancers. We recently received orphan drug status from the FDA for this program. We are currently enrolling the second cohort for the non-lymphodepletion arm and the first cohort for the lymphodepletion arm. As with 3005, we continue to have 100% manufacturing success, and the preliminary findings regarding UltraCAR-T kinetics from the trial are very encouraging. We expect to provide an initial data readout in the second half of 2020.

We are very excited about the Phase 2 trial for AG013 for oral mucositis in head and neck cancer with our partner Oragenics, as we believe that it will further validate our ActoBiotics platform across multiple indications. Using our platform in partnership with Oragenics, we are targeting oral mucositis, a severe and painful side effect of chemo/radiation therapy, especially in patients with head and neck cancer. There are currently no drugs approved to prevent this condition in the cancer patient population. As a result, the FDA has given this program fast-track status, which validates the urgent need for a treatment.

AG013 is formulated as an oral rinse and used as a mouthwash to deliver the trefoil factor 1 gene, which prevents mucosal tissue damage and induces subsequent repair of the lining of the mouth. Based on the encouraging Phase 1 data, AG013 is currently in a Phase 2 trial. Enrollment in this study was completed in the fourth quarter of 2019, and we are looking forward to reporting interim data from the Phase 2 trial in the first half of 2020.

We also expect to report interim data from an ongoing clinical trial of AG019 in type 1 diabetes patients. AG019 is a first-in-class disease-modifying antigen-specific immunotherapy for the prevention, delay or reversal of type 1 diabetes, with encouraging results in preclinical studies. Currently, AG019 is in a Phase 1b/2a trial. The Phase 2a portion of the trial is now enrolling and interim data readout is expected in the third quarter of 2020.

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 Triple-Gene subsidiary. We expect to complete the trial by the end of 2020.

2009 is an off-the-shelf AdenoVerse Immunotherapy product candidate designed to activate the immune system to recognize and target HPV-positive solid tumors. This program is currently under development through a cooperative research and development agreement, or CRADA, with Dr. Jeffrey Schlom, a world-renowned investigator in immuno-oncology at the NCI. We expect the NCI to start dosing patients in 2020.

I'll now turn the call over to Tom Samuelson to provide a financial update.

Tom Samuelson: Thank you, Helen, and good evening, everyone. There are three key points that I would like to address today.

First, as Helen mentioned, we've made material progress in narrowing the company's focus to our core healthcare programs and reducing our other capital requirements. A critical component of this pivot was the divestiture of a number of our legacy bioengineering assets, including our shares in AquaBounty for $86.8 million plus certain contingent payments rights, and the sale of $35 million of common stock. The businesses sold in these recent transactions accounted for $46 million in 2019's segment-adjusted EBITDA losses -- capital that can be redeployed towards our healthcare assets in 2020.

Please recall that Segment AEBITDA, which is more fully defined in our 10-K, is generally the sum of net cash operating expenses and capital expenditures. The proceeds from these transactions, combined with the company's cash and short-term investments on hand, provide sufficient capital to remove the going-concern qualification from our 2019 financial statement. We've adjusted our 2019 and prior financial statements to reflect the effects of these businesses as discontinued operations.

Second, we reported fourth quarter and full year 2019 revenues of $17 million and $90.7 million in consolidated financial results from continuing operations, as we continued our shift from a business model focused on collaboration and licensing revenues to one wholly focused on our internal programs, primarily in human health. Despite pivoting away from a collaboration model, we continue to own the rights to certain legacy milestones and royalties. Any of these, if successful, could result in additional sources of capital for us without requiring any further obligations on our part.

Fourth quarter and full year Segment AEBITDA losses, including corporate costs, were $37.8 million and $144.4 million respectively. These annual losses included only $30.2 million at Precigen and $13.7 million at ActoBio. Among our retained bioengineering entities, MBP Titan and Trans Ova Genetics accounted for $36.7 million and $6.3 million respectively. As Helen mentioned, we are fully committed to reducing spend at these entities and have already implemented efficiencies that should substantially reduce their capital requirements going forward. I would further highlight that the aforementioned $46 million in Segment AEBITDA losses from transacted assets do not include an allocation of general corporate costs, which we do not allocate to particular segments. More details on segment information can be found in the financial discussion in our 10-K.

Third, the 2019 consolidated loss attributable to Precigen shareholders of $322.3 million, or $2.09 per share, includes $116.2 million, or $0.75 per share, associated with the discontinued operations. We further incurred a noncash impairment charge of $29.6 million for the write-down of goodwill associated with our Trans Ova Genetics subsidiary. As discussed, we've initiated efforts in 2020 to improve the financial performance of Trans Ova Genetics going forward.

In concluding the financial component of our call, I will again reiterate that Precigen is wholly committed to deploying our precious capital towards our highest-value healthcare assets in 2020 and beyond. We look forward to providing regular updates as our targeted value-generating milestones are achieved. I would now like to turn the call back to Helen for concluding remarks.

Helen Sabzevari: Thank you, Tom. In closing our call today, I want to confirm our optimism about Precigen's potential to transform the healthcare landscape with our innovative and focused portfolio. I think you will agree that there has never been a more exciting and promising time at Precigen. As Precigen's CEO, you have my commitment to manage our company in a financially prudent, fiscally disciplined and transparent manner, with the paramount goal of achieving our mission to bring novel treatment options to patients. If we do this, all of our stakeholders will benefit.

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

Questions & Answers

Operator: (Operator Instructions)

And our first question will come from Jason Butler of JMP Securities.

Jason Butler: Helen, first one, just on the UltraCAR-T trials. For both 3005 and 3006, can you frame for us how we should think about the readouts later this year in terms of patient numbers and maturity of data? And maybe if not specifically in terms of numbers, then in terms of how it could inform next steps or potentially progression to pivotal studies.

Helen Sabzevari: Thank you, Jason. Good evening. Actually, we are very excited for this upcoming interim data -- first of all, in regard to the ovarian cancer, the IP arm, and in regard to the AML that we have a non-lymphodepletion arm to report. As you might have seen in our slides, our trials currently are 3+3+3. There are three doses, and as we finish these doses, we obviously will be reporting on the safety and dose, which are the paramount aspects of the Phase 1, but at the same token, as we have always emphasized, what is the most important thing for us is also show that our manufacturing in vivo, directly in-patient, to show the persistence and also the expansion of T-cells. So we are looking forward to show some of the interim data by the second half of 2020, and it's quite exciting for us as we go through this journey and we continue to then expand these patients to Phase 1b.

Jason Butler: Great. And then I had a question on AG013 and the interim results upcoming. How should we think about the magnitude of treatment effect here in terms of what would be

clinically important to patients? And then in terms of the oral mucositis endpoint, can you still talk about subjectivity of the endpoint and how you're controlling for that, and any expectations for either reduction in analgesic use or a potential to prolong radiation dose?

Helen Sabzevari: Absolutely. Thank you. So our -- actually, the AG013 is a very exciting program for the platform of ActoBio. As you know, that ActoBio platform uses our *L. lactis* delivery mechanisms for delivering different proteins, specifically to the mucosal lining. In the case of the oral mucositis, this is a devastating disease. Especially after the treatment of head and neck cancer patients with chemo and radiation, there are tremendous ulcers in the mouth, which is quite painful, and currently there is really no treatment for this.

In the Phase 1 of the study that was done, we have designed *L. lactis* in such a way that it delivers a gene that protects and also stimulates the lining of -- the mucosal lining of the mouth, and we had very exciting results in the first Phase 1 showing reduction in the ulcers and actually the level of the pain, and now we have entered and actually finished enrollment of the patients in 2019 in a Phase 2 that is done in a randomized fashion, so there is a placebo arm versus the treatment arm, which is quite important.

And one aspect that is quite exciting, based on the Phase 1 data, FDA has given us a fast track for this indication currently. And this would be the first proof of this platform actually for ActoBio, which we also have an exciting trial ongoing in the T1D, type 1 diabetes, which we are anticipating to actually report on in second half of 2020 using a similar, actually, platform, but delivering a proinsulin, as well as IL-10, which suppresses the immune system, but actually it helps the onset of -- it reduces the onset of diabetes. And we had very encouraging preclinical data, the Phase 1 data, and now the Phase 2a will be reported in second half.

Jason Butler: Okay, great. That's helpful. And then just one last financial question, and sorry if I missed this in any of the prepared comments, but should we expect any further reorganization charges? And if so, how should we think about those in terms of cash versus noncash expense?

Helen Sabzevari: So currently, I think we are not expecting any further reorganization charges, and as we mentioned, by the end of January, all the assets will transfer to Third Security. And currently we do not expect anything in that.

Operator: (Operator Instructions)

Our next question will come from Swayampakula Ramakanth from H.C. Wainwright.

Swayampakula Ramakanth: This is RK from H.C. Wainwright. A couple of quick questions: For the non-oncology assets AG019 and INXN-4001, what do you plan for these assets in the long term? The reason for that question is, as you can imagine, as these assets get into late-stage development, they could become cash-intensive because of the large clinical trials that you would need to conduct. Would these be assets that can become currency in terms of out-licensing?

Helen Sabzevari: Thank you, RK. Great question. So we agree. We have a portfolio -- maybe I should just first give a few minutes on the reason that we have the portfolio that we have. The strength of our portfolio is that we are not a one-drug product company. It becomes very important because when you're a one-drug product company, basically, despite what the science might be or might not be, you are committed somehow. Whereas the way we have arranged our portfolio is that it's in such a manner that we prioritize and make go/no-go decision based on data, and we know the attrition of a portfolio, and therefore it's very, very important that we keep a fiscal responsibility with very, very laser-focused decision making to address our portfolio.

In regard to the assets that we have highlighted for this year, actually, this has been a principal factor behind it. We are looking at our data, we are evaluating the breadth of the data that comes in its totality, and then there will be decisions made that if these assets will go to the next levels of development or not.

However, what is very important, as the fourth pillar that I mentioned as part of our principles, is a strategic partnership, and this is very, very important for us in our portfolio. And to your point, obviously -- and I'm going to stress this over and over again -- we will not take every asset forward ourselves. We will also look into strategic partnerships that will bring the most value for our shareholders. And I think this is a pillar for us, that it would allow us to manage our portfolio accordingly and make the decisions with the right partners, with the right speed, and with the right cash to make these things and move them forward, and definitely, as you have mentioned, this is one of our strategic responsibilities and platforms that we have for these assets.

Swayampakula Ramakanth: One other question of a similar vein: The two non-health assets that you discussed about in your remarks, and though you did state that at some point it would get divested, is there a time point when you think you will divest, especially when they are currently giving you some revenues, which could help in your pipeline development? And so once the pipeline gets to a certain mature stage, would that time be the right point for the divestment of those two assets?

Helen Sabzevari: Right, absolutely. So for our MBP Titan subsidiary, currently we are obviously are not receiving revenues from this subsidiary. However, we are -- as mentioned, we are committed to make sure that we are fiscally managing this subsidiary, and the final endpoint for us is to partner or sell this asset. As far as time is concerned, as you know, last year we had David Witte with us, who is currently managing the strategy for this partnership, and in due time, we will be, actually, reporting on that aspect.

In regard to Trans Ova, you're absolutely correct. This is a subsidiary that, as we mentioned, we have already implemented sort of fiscal measures here that would allow us -- Trans Ova to bring capital back to Precigen this year, and this was one of the reasons that, as we basically raised our $175 million by January, we saw that there was no rush in divesting this asset any further at that moment, especially due to the, last year, challenges that the dairy market had, and by making it cash-positive, actually, you're absolutely correct; this can add value. But at the same token, we have our focus directly on health and expansion of our health assets, and what we will be doing is strategically looking at all of our options with having fiscal responsibility in regard to Trans Ova and ensuring that Trans Ova is cash-positive for the rest of Precigen.

Operator: (Operator Instructions)

This concludes our question-and-answer session. I would like to turn the conference back over to Helen Sabzevari for any closing remarks. Please go ahead, ma'am.

Helen Sabzevari: Thank you for taking the time to join us for our business and pipeline update. We look forward to providing you with updates in the coming months, and have a wonderful evening. Thank you again.

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