



PRECIGEN

Precigen Reports Fourth Quarter and Full Year 2020 Financial Results

March 1, 2021

- Company successfully accomplished anticipated 2020 clinical milestones despite challenges due to the ongoing pandemic -
- Strengthened balance sheet with successful public offering while streamlining operations and reducing operating costs -
- Initial data readouts from PRGN-3005 and PRGN-3006 UltraCAR-T® clinical trials demonstrated encouraging expansion, persistence and clinical activity -
- A PRGN-3006 UltraCAR-T patient achieved complete remission with incomplete hematologic recovery (CRi) per ELN criteria -
- Initiated first AdenoVerse™ immunotherapy clinical trial for PRGN-2009 in HPV-associated solid tumors -
- Interim data for AG019 ActoBiotics™ in T1D indicate encouraging trends in C-peptide levels and ability to induce antigen-specific immune modulation following only one treatment cycle of oral AG019 as monotherapy or combination -

GERMANTOWN, Md., March 1, 2021 /PRNewswire/ -- [Precigen, Inc.](#) (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today announced fourth quarter and full year 2020 financial results.



PRECIGEN

ADVANCING MEDICINE WITH PRECISION™

"2021 promises to be another transformative year for our company with important data readouts and trial initiations anticipated for our key programs," said Helen Sabzevari, PhD, President and CEO of Precigen. "Through a combination of fiscal discipline and our recent capital raise, we have sufficient cash on hand to support our capital needs into 2023. We will continue to work diligently to advance our pipeline of innovative therapies and technology platforms as quickly as possible and our entire team remains committed to achieving this goal on behalf of the patients that motivate us every day. We look forward to providing updates in the coming months."

Business Highlights:

Healthcare Transition

In January 2020, Precigen announced the change of the parent company's name to Precigen, Inc. from Intrexon Corporation to reflect the Company's tighter healthcare focus. The Company is now trading on Nasdaq under the stock symbol PGEN.

Public Offering

In January 2021, Precigen closed a public offering of 17,250,000 shares of common stock, which resulted in gross proceeds to Precigen of approximately \$129.4 million before deducting the underwriting discount and other offering expenses payable by Precigen.

PRGN-3005 UltraCAR-T®

PRGN-3005 UltraCAR-T is a first-in-class investigational therapy under evaluation in an ongoing Phase 1/1b clinical study for the treatment of advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer. Study subjects receive the PRGN-3005 infusion either via intraperitoneal (IP) (Arm A) or intravenous (IV) (Arm B) infusion (clinical trial identifier: [NCT03907527](#)). The study is being conducted in collaboration with the University of Washington and Fred Hutchinson Cancer Research Center.

- **Preliminary Clinical Data:** In December 2020, Precigen reported preliminary Phase 1 data for patients at dose level 1 (n=3) and dose level 2 (n=3) in the IP arm. Data showed a favorable safety profile with no dose-limiting toxicities (DLTs), neurotoxicity or cytokine release syndromes (CRS) reported. PRGN-3005 UltraCAR-T cells showed encouraging expansion

and persistence after low dose IP infusion without lymphodepletion. 50% (3 of 6) of patients experienced regression in total target tumor burden.

- **Enrollment Status:** The Phase 1 trial is enrolling patients in the dose escalation phase of both the IP and IV arms. The dose expansion phase for the IP arm is anticipated to start in the second half of 2021.

PRGN-3006 UltraCAR-T®

PRGN-3006 UltraCAR-T is a first-in-class investigational therapy currently under clinical evaluation in an ongoing Phase 1/1b trial for the treatment of patients with relapsed or refractory (r/r) acute myeloid leukemia (AML) or higher-risk myelodysplastic syndromes (MDS). Study subjects receive the PRGN-3006 infusion either without prior lymphodepletion (Cohort 1) or following lymphodepleting chemotherapy (Cohort 2) (clinical trial identifier: [NCT03927261](#)). The study is being conducted in collaboration with H. Lee Moffitt Cancer Center & Research Institute.

- **Orphan Drug Designation:** In January 2020, Precigen received US Food and Drug Administration (US FDA) Orphan Drug Designation for PRGN-3006 UltraCAR-T in patients with AML.
- **Preliminary Clinical Data:** In December 2020, Precigen reported preliminary Phase 1 data for patients at dose level 1 (n=3) and dose level 2 (n=3) without prior lymphodepletion and dose level 1 (n=3) with lymphodepletion. Data showed a favorable safety profile with no DLTs or neurotoxicity. Encouraging expansion and persistence of PRGN-3006 UltraCAR-T was observed in both lymphodepletion and non-lymphodepletion cohorts and across all dose levels. PRGN-3006 treatment indicated clinical activity as evidenced by reduction in AML tumor blast levels.
 - The potential strength of the UltraCAR-T platform was highlighted at the American Society of Hematology (ASH) 2020 annual meeting with a case study of a patient with multiple prior treatment failures. Data showed that UltraCAR-T cells persisted for more than seven months after a very low dose, only 24 million total UltraCAR-T cells in the infusion, without prior lymphodepletion. This patient had stable disease and data showed a decline in blast levels in blood and bone marrow concomitant with UltraCAR-T expansion and persistence.
 - One of the patients treated with PRGN-3006 at dose level 1 in the lymphodepletion cohort, with approximately nine million UltraCAR-T cells, had an objective response and achieved complete remission with incomplete hematologic recovery (CRI) per European Leukemia Net (ELN) criteria.
- **Enrollment Status:** The Phase 1 trial is enrolling patients in the dose escalation phase of both the lymphodepletion and non-lymphodepletion cohorts. A dose expansion phase is anticipated to start in the second half of 2021.

UltraPorator™

In 2020, Precigen announced its proprietary electroporation device, UltraPorator, designed to be a viable scale-up and commercialization solution for decentralized UltraCAR-T manufacturing. UltraPorator is a semi-closed, high-throughput system with a proprietary hardware and software solution and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk.

- **FDA Clearance:** In October 2020, Precigen announced that the US FDA cleared UltraPorator as a manufacturing device for its UltraCAR-T clinical trials.
- **First Patients Dosed with UltraCAR-T Cells Manufactured with UltraPorator:** In November 2020, Precigen announced dosing of the first patients with UltraCAR-T cells manufactured using the UltraPorator system in the ongoing PRGN-3005 and PRGN-3006 Phase 1 clinical trials.

AG019 ActoBiotics™

AG019 ActoBiotics is a novel investigational therapy designed to address the underlying cause of Type 1 diabetes (T1D) and is currently under clinical evaluation in an ongoing Phase 1b/2a clinical study for the treatment of early-onset T1D (clinical trial identifier: [NCT03751007](#); EudraCT 2017-002871-24).

- **Phase 1b AG019 Monotherapy Clinical Data:** In August 2020, Precigen ActoBio announced that the primary endpoint assessing safety and tolerability in the Phase 1b monotherapy portion of the study was met, and that preliminary results at six months after AG019 monotherapy treatment initiation showed an encouraging trend in the insulin C-peptide levels, a biomarker for T1D disease progression. Additional data announced in December 2020 showed that following a single 8-week treatment cycle of oral AG019, 58% (7 of 12) of the patients 17 years and older showed stabilization of C-peptide levels during the first 6 months and slower decline in C-peptide levels at 12 months compared to placebo. Results indicated the potential to preserve insulin production in early onset T1D through its capacity to induce antigen-specific immune modulation. The AG019 monotherapy treatment showed a favorable safety profile with no treatment discontinuations due to treatment emergent adverse events (TEAEs).
- **Interim Phase 2a Clinical Data:** In December 2020, Precigen ActoBio announced interim data from the Phase 2a portion of the study showing the combination of AG019 and teplizumab had a favorable safety profile. Data showed that following the treatment with the combination of AG019 and teplizumab, 70% of the adult patients (7 of 10) showed stabilization of C-peptide levels at six months post treatment initiation with a trend towards higher C-peptide levels as compared to baseline levels.
- **Enrollment Status:** Enrollment and dosing is complete in Phase 1b and Phase 2a portions of the study.

PRGN-2009 AdenoVerse™ Immunotherapy

PRGN-2009 is a first-in-class, off-the-shelf (OTS) investigational immunotherapy utilizing the AdenoVerse platform currently under clinical evaluation

in an ongoing Phase 1/2 clinical study designed to activate the immune system to recognize and target HPV+ solid tumors (clinical trial identifier: [NCT04432597](#)). The study is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI).

- **IND Clearance:** In April 2020, Precigen announced US FDA clearance of the IND to initiate the Phase 1/2 study.
- **First Patient Dosed:** In August 2020, Precigen announced that the first patient was dosed in the Phase 1/2 study.
- **Preliminary Clinical Data:** In January 2021, for the first time, Precigen provided preliminary Phase 1 data that showed that all patients (n=6) enrolled in the Phase 1 monotherapy arm have received multiple PRGN-2009 administrations and repeated administration of PRGN-2009 treatment has been well-tolerated with no DLTs. Preliminary correlative analysis from patients treated at dose level 1 (n=3) demonstrated an increase in HPV 16 and/or HPV 18-specific T-cell response post PRGN-2009 administration in 100% (3 of 3) of patients and an increase in the magnitude and breadth of immune response has been shown with respect to repeat administration of PRGN-2009.
- **Enrollment Status:** The Phase 1 monotherapy arm has completed enrollment and the Phase 1 combination arm, which combines PRGN-2009 with M7824, is enrolling patients. Phase 2 enrollment is anticipated to initiate in the second half of 2021.

PRGN-2012 AdenoVerse™ Immunotherapy

PRGN-2012 is a first-in-class, investigational OTS AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for treatment of recurrent respiratory papillomatosis (RRP).

- **IND Clearance:** In January 2021, Precigen announced the US FDA cleared the IND for the Phase 1 study (clinical trial identifier: [NCT04724980](#)) in adult patients with RRP. The study is being conducted under a CRADA with the Center for Cancer Research (CCR) at the NCI.
- **Preliminary Preclinical Data:** In January 2021, Precigen presented data from preclinical studies in which PRGN-2012 was shown to induce robust HPV 6 and HPV 11-specific T-cell response in RRP patient samples *in vitro*.

INXN-4001

INXN-4001 is a multigenic investigational therapy for heart failure that uses a non-viral plasmid designed to constitutively express human SDF-1 α , VEGF165, and S100A1 gene products to target the underlying molecular mechanisms of pathological myocardial remodelling. INXN-4001 is delivered to the ventricle via retrograde coronary sinus infusion (RCSI).

- **Interim Data at Six-Month Follow-up:** In August 2020, Precigen Triple-Gene announced encouraging six-month follow-up data from twelve chronic heart failure patients treated in the Phase 1 study (clinical trial identifier: [NCT03409627](#)). Data showed that the study met the primary endpoints to evaluate safety and feasibility for INXN-4001 and the infusions of INXN-4001 were overall well tolerated. Preliminary data suggest an overall improvement in patient reported outcomes in 50% of patients six months after treatment.
- **Interim Data at 12-Month Follow-up:** In January 2021, Precigen announced that the 12-month follow-up for Phase 1 clinical study is complete.

Fourth Quarter 2020 Financial Highlights:

- **Revenues:** Total revenues of \$19.3 million in 2020 compared to \$17.0 million in 2019;
- **Net Loss:** Net loss from continuing operations of \$39.7 million, or \$(0.22) per basic share, of which \$19.7 million was for non-cash charges in 2020 compared to net loss from continuing operations of \$64.2 million, or \$(0.41) per basic share, of which \$32.9 million was for non-cash charges in 2019; and
- **Cash, Cash Equivalents, and Short-term Investments:** Cash, cash equivalents, and short-term investments totaled \$100.1 million as of December 31, 2020.

Full Year 2020 Financial Highlights:

- **Revenues:** Total revenues of \$103.2 million in 2020 compared to \$90.7 million in 2019; and
- **Net Loss:** Net loss from continuing operations of \$103.8 million, or \$(0.62) per basic share, of which \$45.9 million was for non-cash charges in 2020 compared to net loss from continuing operations attributable to Precigen of \$168.7 million, or \$(1.09) per basic share, of which \$65.4 million was for non-cash charges in 2019.

Fourth Quarter 2020 Financial Results Compared to Prior Year Period

Total revenues increased \$2.3 million, or 14%, over the quarter ended December 31, 2019. Service revenues increased \$2.2 million due to increased customer demand at Trans Ova and Exemplar as well as the expansion of Trans Ova's commercial dairy business. Gross margin on services improved as a result of operational efficiencies gained through reductions in workforce earlier in the year and a reduction in third-party royalty rate obligations for certain licensed technologies.

Research and development expenses decreased \$2.8 million, or 21%, from the quarter ended December 31, 2019. Salaries, benefits, and other personnel costs decreased \$1.8 million due to reductions in headcount at Precigen and its ActoBio subsidiary as Precigen deprioritized certain internal programs at its ActoBio subsidiary in 2019. Selling, general, and administrative ("SG&A") expenses increased \$3.4 million, or 13%, and include a noncash \$11.4 million loss on the settlement agreement with Harvest Intrexon Enterprise Funds in the current year as well as increased noncash share-based compensation expenses attributable to equity grants made in the first quarter of 2020. These increased costs were partially offset by

decreases in fees payable to certain third-party vendors and a reduction in salaries, benefits, and other personnel costs following a 31% reduction in corporate headcount between the fourth quarter of 2019 and the fourth quarter of 2020 to support a more streamlined organization. There were also reductions in other corporate expenses as part of the streamlined organization and include the impact of the COVID-19 pandemic on travel.

Full Year 2020 Financial Results Compared to Prior Year Period

Total revenues increased \$12.5 million, or 14%, over the year ended December 31, 2019 primarily due to an increase in collaboration and licensing revenues as the Company accelerated the recognition of previously deferred revenue upon the mutual termination of two of its collaboration agreements in 2020. Product and service revenues generated by Trans Ova and Exemplar increased \$5.7 million due to an increase in services performed for new and existing customers and the expansion of Trans Ova's commercial dairy business. Gross margin on products and services improved as a result of operational efficiencies gained through reductions in workforce, improved inventory management, a reduction in third-party royalty rate obligations for certain licensed technologies, and a decrease in the cost of cows used in production.

Research and development expenses decreased \$25.0 million, or 38%, from the year ended December 31, 2019. Salaries, benefits, and other personnel costs decreased \$7.3 million and contract research organization costs and lab supplies decreased \$13.9 million as Precigen deprioritized certain internal programs at its ActoBio subsidiary and closed two of its operating divisions in 2019. SG&A expenses decreased \$6.9 million, or 7%, and include a net decrease in fees payable to certain third-party vendors and a reduction of 36% in corporate headcount to support a more streamlined organization. Other corporate expenses decreased \$2.6 million as part of the streamlined organization and include the impact of the COVID-19 pandemic on travel. These decreases were partially offset by increased share-based compensation expense attributable to equity grants made in the first quarter of 2020, one-time severance costs for terminated employees, and increased legal fees associated with litigation matters.

Conference Call and Webcast

Precigen will host a conference call today Monday, March 1st at 4:30 PM ET to discuss the financial results and provide a general business update. The conference call may be accessed by dialing 1-888-317-6003 (Domestic US), 1-866-284-3684 (Canada) or 1-412-317-6061 (International) and providing the number 9387943 to join the Precigen Conference Call. Participants are asked to dial in 10-15 minutes in advance of the scheduled call time to facilitate timely connection to the call. Participants may access the live webcast through Precigen's website in the Events & Presentations section at investors.precigen.com/events-presentations.

Precigen: Advancing Medicine with Precision™

Precigen (Nasdaq: PGEN) is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target the most urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. Our technologies enable us to find innovative solutions for affordable biotherapeutics in a controlled manner. Precigen operates as an innovation engine progressing a preclinical and clinical pipeline of well-differentiated unique therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on Twitter [@Precigen](https://twitter.com/Precigen) and [LinkedIn](https://www.linkedin.com/company/precigen).

Trademarks

Precigen, UltraPorator, UltraCAR-T, ActoBiotics, AdenoVerse and Advancing Medicine with Precision are trademarks of Precigen and/or its affiliates. Other names may be trademarks of their respective owners.

Cautionary Statement Regarding Forward-Looking Statements

Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon Precigen's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of Precigen's business, including the timing, pace and progress of preclinical studies, clinical trials, discovery programs and related milestones, and the promise of the Company's portfolio of therapies, and in particular its CAR-T therapies. Although management believes that the plans, objectives and results reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties, and actual future results may be materially different from the plans, objectives and expectations expressed. These risks and uncertainties include, but are not limited to, (i) the impact of the COVID-19 pandemic on our clinical trials, businesses, operating results, cash flows and/or financial condition, (ii) Precigen's strategy and overall approach to its health-focused business model; (iii) the ability to successfully enter new markets or develop additional products, including the expected timing and results of investigational studies and preclinical and clinical trials, including any delays or potential delays as a result of the COVID-19 pandemic, whether with its collaborators or independently; (iv) the ability to successfully enter into optimal strategic relationships with its subsidiaries and operating companies that it may form in the future; (v) the ability to hold or generate significant operating capital, including through partnering, asset sales and operating cost reductions; (vi) actual or anticipated variations in operating results; (vii) actual or anticipated fluctuations in competitors' or collaborators' operating results or changes in their respective growth rates; (viii) cash position; (ix) market conditions in Precigen's industry; (x) the volatility of Precigen's stock price; (xi) the ability, and the ability of collaborators, to protect Precigen's intellectual property and other proprietary rights and technologies; (xii) the ability, and the ability of collaborators, to adapt to changes in laws or regulations and policies, including federal, state, and local government responses to the COVID-19 pandemic; (xiii) outcomes of pending and future litigation; (xiv) the rate and degree of market acceptance of any products developed by Precigen, its subsidiaries, collaborations or joint ventures; (xv) the ability to retain and recruit key personnel; (xvi) expectations related to the use of proceeds from public offerings and other financing efforts; and (xvii) estimates regarding expenses, future revenue, capital requirements and needs for additional financing. For further information on potential risks and uncertainties, and other important factors, any of which could cause Precigen's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Precigen's most recent Annual Report on Form 10-K and subsequent reports filed with the Securities and Exchange Commission.

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(Amounts in thousands)	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 51,792	\$ 65,793
Short-term investments	48,325	9,260
Receivables		
Trade, net	16,487	20,650
Related parties, net	19	600
Notes	3,689	2,942
Other	232	2,030
Inventory	11,359	16,097
Prepaid expenses and other	7,192	5,827
Current assets held for sale or abandonment	9,853	111,444
Total current assets	148,948	234,643
Property, plant and equipment, net	34,924	43,952
Intangible assets, net	65,396	68,346
Goodwill	54,363	54,119
Investments in affiliates	—	1,461
Right-of-use assets	9,353	11,803
Other assets	1,603	1,349
Noncurrent assets held for sale or abandonment	—	40,090
Total assets	\$ 314,587	\$ 455,763

Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$ 4,598	\$ 5,528
Accrued compensation and benefits	8,097	13,198
Other accrued liabilities	9,549	11,674
Deferred revenue	2,800	5,697
Lines of credit	—	1,922
Current portion of long-term debt	360	31,670
Current portion of lease liabilities	2,657	2,634
Related party payables	19	51
Current liabilities held for sale or abandonment	14,047	50,538
Total current liabilities	42,127	122,912
Long-term debt, net of current portion	171,522	186,321
Deferred revenue, net of current portion	23,023	48,136
Lease liabilities, net of current portion	7,744	10,119
Deferred tax liabilities	2,897	2,834
Other long-term liabilities	100	—
Long-term liabilities held for sale or abandonment	—	13,730
Total liabilities	247,413	384,052
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,886,567	1,752,048
Accumulated deficit	(1,823,390)	(1,652,869)
Accumulated other comprehensive income (loss)	3,997	(27,468)
Total shareholders' equity	67,174	71,711
Total liabilities and shareholders' equity	\$ 314,587	\$ 455,763

Precigen, Inc. and Subsidiaries
Consolidated Statements of Operations
(Unaudited)

(Amounts in thousands, except share and per share data)	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Revenues				
Collaboration and licensing revenues	\$ 949	\$ (658)	\$ 21,208	\$ 14,059
Product revenues	3,952	5,297	24,349	23,780
Service revenues	14,284	12,096	56,899	51,803
Other revenues	148	267	722	1,080
Total revenues	19,333	17,002	103,178	90,722
Operating Expenses				
Cost of products	7,024	7,800	28,550	31,930
Cost of services	6,766	7,611	26,963	29,471
Research and development	10,671	13,485	41,644	66,666

Selling, general and administrative	30,039	26,646	91,704	98,634
Impairment of goodwill	—	29,642	—	29,820
Impairment of other noncurrent assets	—	542	920	990
Total operating expenses	54,500	85,726	189,781	257,511
Operating loss	(35,167)	(68,724)	(86,603)	(166,789)
Other Income (Expense), Net				
Unrealized and realized appreciation in fair value of equity securities and preferred stock, net	—	5,221	—	8,291
Interest expense	(4,570)	(4,542)	(18,400)	(17,666)
Interest and dividend income	426	603	2,451	3,871
Other income (expense), net	(310)	2,774	(165)	3,445
Total other income (expense), net	(4,454)	4,056	(16,114)	(2,059)
Equity in net loss of affiliates	(13)	(473)	(1,138)	(2,416)
Loss from continuing operations before income taxes	(39,634)	(65,141)	(103,855)	(171,264)
Income tax benefit	(48)	905	82	930
Loss from continuing operations	\$ (39,682)	\$ (64,236)	\$ (103,773)	\$ (170,334)
Loss from discontinued operations, net of income tax benefit	(1,979)	(104,979)	(66,748)	(153,582)
Net loss	\$ (41,661)	\$ (169,215)	\$ (170,521)	\$ (323,916)
Net loss attributable to the noncontrolling interests	—	—	—	1,592
Net loss attributable to Precigen	\$ (41,661)	\$ (169,215)	\$ (170,521)	\$ (322,324)
Amounts Attributable to Precigen				
Net loss from continuing operations attributable to Precigen	\$ (39,682)	\$ (64,236)	\$ (103,773)	\$ (168,742)
Net loss from discontinued operations attributable to Precigen	(1,979)	(104,979)	(66,748)	(153,582)
Net loss attributable to Precigen	\$ (41,661)	\$ (169,215)	\$ (170,521)	\$ (322,324)
Net Loss per Share				
Net loss from continuing operations attributable to Precigen per share, basic and diluted	\$ (0.22)	\$ (0.41)	\$ (0.62)	\$ (1.09)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	(0.01)	(0.68)	(0.40)	(1.00)
Net loss attributable to Precigen per share, basic and diluted	\$ (0.23)	\$ (1.09)	\$ (1.02)	\$ (2.09)
Weighted average shares outstanding, basic and diluted	178,225,571	155,230,741	167,065,539	154,138,774

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