



PRECIGEN

Precigen Reports Second Quarter and First Half 2020 Financial Results

August 10, 2020

- Announced proprietary electroporation device, UltraPorator™, designed to scale-up UltraCAR-T® manufacturing at multiple medical centers -

- Announced positive topline results from Phase 1b study of AG019 ActoBiotics™ for type 1 diabetes -

- Met primary endpoints of safety and feasibility in Phase I study of INXN-4001 for heart failure -

- Guidance maintained for clinical readouts in 2020 -

GERMANTOWN, Md., Aug. 10, 2020 /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 second quarter and first half financial results for 2020.



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ADVANCING MEDICINE WITH PRECISION™

Business Highlights:

- **UltraPorator™**: Precigen advanced the development of its proprietary electroporation device, UltraPorator™, including the initiation of both the manufacturing of a cGMP-compliant system and the process of technology transfer to its clinical sites. UltraPorator is a semi-closed, high-throughput system with a proprietary hardware and software solution designed to significantly reduce processing time and contamination risk, limitations of other electroporation devices and hurdles to the viable scale-up and commercialization of certain therapeutic programs. The Company expects to implement the system at multiple medical centers for the expansion phases of PRGN-3005, PRGN-3006 and the future UltraCAR-T clinical trials;
- **PRGN-3005 UltraCAR-T®**: Precigen initiated the dosing of patients in the third dose level of the intraperitoneal (IP) arm of the Phase 1 clinical trial of PRGN-3005 UltraCAR-T for treatment of advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (clinical trial identifier: [NCT03907527](#)). Preclinical data for PRGN-3005 UltraCAR-T presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting II demonstrated significantly superior expansion, persistence and preferred memory phenotype of UltraCAR-T *in vivo* and significantly superior efficacy in an ovarian cancer model compared to traditional CAR-T;
- **AG019 ActoBiotics™**: Precigen ActoBio, Inc., a wholly-owned subsidiary of Precigen, [announced](#) the Phase 1b monotherapy portion of the ongoing Phase 1b/2a clinical trial for investigational therapy AG019 ActoBiotics met the primary endpoint assessing safety and tolerability in patients with early-onset type 1 diabetes (T1D) (clinical trial identifier: [NCT03751007](#), EudraCT 2017-002871-24). The Phase 1b portion of the study evaluates safety and tolerability of 2 different doses of AG019 monotherapy, a capsule formulation composed of ActoBiotics delivering the autoantigen human proinsulin (hPINS) and the tolerance-enhancing cytokine human interleukin-10 (hIL-10). Preliminary results demonstrate an encouraging trend in C-peptide levels, a biomarker for T1D disease progression, as well as, an increase in the frequency of islet-specific Tregs, a potential mechanistic indicator of therapeutic activity; and

- **INXN-4001:** Precigen Triple-Gene, a majority-owned subsidiary of Precigen, [announced](#) six-month follow-up data from the Phase I trial of INXN-4001 (clinical trial identifier: [NCT03409627](#)), a multigenic, non-viral, plasmid-based investigational therapeutic candidate under evaluation for the treatment of heart failure. The study met the primary endpoints to evaluate safety and feasibility for INXN-4001. INXN-4001, delivered via retrograde coronary sinus infusion (RCSI), was well-tolerated. Preliminary data suggest an overall improvement in patient reported outcomes in 50% of patients six months after treatment;

Second Quarter 2020 Financial Highlights:

- Total revenues of \$30.4 million;
- Net loss of \$43.4 million, or \$(0.26) per basic share, of which \$31.7 million was for non-cash charges; and
- Cash, cash equivalents, and short-term investments totaled \$133.0 million at June 30, 2020.

First Half 2020 Financial Highlights:

- Total revenues of \$60.3 million;
- Net loss from continuing operations of \$73.3 million, or \$(0.45) per basic share, of which \$40.4 million was for non-cash charges.

"Precigen has continued this quarter to streamline operations and focus efforts on delivering value to stakeholders through forward progress on our programs," said Helen Sabzevari, PhD, President and CEO of Precigen. "In the clinic, we recently announced encouraging data from the AG019 Phase 1b monotherapy study in Type 1 diabetes and the INXN-4001 Phase I study of patients with chronic heart failure and expect additional results on these and other clinical programs in the coming months. Additionally, we are pleased to announce our proprietary UltraPorator manufacturing device, which we believe sets Precigen on the path to commercial viability for rapid decentralized manufacturing of UltraCAR-T at multiple medical centers."

Second Quarter 2020 Financial Results Compared to Prior Year Period

Total revenues declined \$2.4 million from the quarter ended June 30, 2019 primarily due to a decline in Precigen's collaboration and licensing revenues as the Company continues to transition from a collaboration business model to a model where the Company develops and advances its most valuable healthcare products on its own. While Trans Ova's revenues were comparable period over period, gross margins on their products and services increased \$1.3 million over the comparable prior quarter as a result of the implementation of operational efficiencies gained through improved inventory management, reduction in workforce, and lower royalty rates on certain licensed technologies.

Research and development expenses decreased \$14.0 million, or 50%, from the quarter ended June 30, 2019. Salaries, benefits, and other personnel costs decreased \$4.8 million as Precigen suspended the operations of its MBP Titan subsidiary in the second quarter. Precigen's research and development expenses for third-party vendors decreased \$7.8 million primarily as a result of the suspension of its MBP Titan operations and also deprioritized certain internal programs at its ActoBio subsidiary in the fourth quarter of 2019. Selling, general and administrative (SG&A) expenses decreased \$0.5 million and include a decrease of \$4.0 million in fees paid to third-party vendors as well as a reduction in salaries and benefits for corporate employees as Precigen reduced its corporate headcount by 25% from December 31, 2019 to June 30, 2020 as it scaled down the Company's corporate functions to support a more streamlined organization. These decreases were partially offset by an increase in compensation costs which primarily resulted from stock compensation expenses related to equity grants made in the first quarter of 2020 and one-time severance costs for terminated employees. In conjunction with the suspension of MBP Titan's operations in the second quarter of 2020, Precigen recorded \$22.0 million in non-cash impairment charges related to the write-down of goodwill and long-lived assets.

First Half 2020 Financial Results Compared to Prior Year Period

Total revenues increased \$4.8 million over the six months ended June 30, 2019 primarily due to an increase in Precigen's collaboration and licensing revenues as the Company accelerated the recognition of previously deferred revenue upon the mutual termination of one of its collaboration agreements in February 2020. This increase was partially offset by a decrease in collaboration revenues related to other programs as Precigen continues to transition from a collaboration business model to a model where it develops and advances its most valuable healthcare programs on its own. Trans Ova's revenues increased \$1.3 million over the six months ended June 30, 2019 primarily due to an increase in services performed and the expansion of its commercial dairy business. Gross margins on their products and services increased \$4.6 million over the comparable prior period as a result of the implementation of operational efficiencies gained through improved inventory management, reduction in workforce, and lower royalty rates on certain licensed technologies.

Research and development expenses decreased \$22.1 million, or 40%, from the six months ended June 30, 2019. Salaries, benefits, and other personnel costs decreased \$6.9 million as Precigen suspended the operations of its MBP Titan subsidiary in the second quarter. Precigen's research and development expenses for third-party vendors decreased \$12.8 million primarily as a result of the suspension of its MBP Titan operations and also deprioritized certain internal programs at its ActoBio subsidiary in the fourth quarter of 2019. SG&A expenses decreased \$8.5 million and include a decrease of \$7.9 million in fees paid to third-party vendors as well as a reduction in salaries and benefits for corporate employees as Precigen reduced its corporate headcount by 25% from December 31, 2019 to June 30, 2020 as it scaled down its corporate functions to support a more streamlined organization. These decreases were partially offset by an increase in compensation costs which primarily resulted from stock compensation expenses related to equity grants made in the first quarter of 2020 and one-time severance costs for terminated employees. In conjunction with the suspension of MBP Titan's operations in the second quarter of 2020, Precigen recorded \$22.0 million of noncash impairment charges related to the write-down of goodwill and long-lived assets.

Conference Call and Webcast

Precigen will host a conference call today, Monday, August 10th at 4:30 PM ET to discuss the 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 6003292 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 also access the live webcast through Precigen's website in the Events section at <https://investors.precigen.com/press-and-events>.

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 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 and LinkedIn.

Trademarks

Precigen, UltraPorator, UltraCAR-T, ActoBiotics, 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 and clinical trials and discovery programs, potential benefits of platforms and product candidates including in comparison to competitive platforms and products, and future plans for Precigen's remaining non-healthcare assets. 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 businesses, operating results, cash flows and/or financial condition; (ii) ongoing transition efforts following Precigen's recent divestment of several assets and businesses; (iii) Precigen's strategy and overall approach to its business model, its recent efforts to realign its business, and its ability to exercise more control and ownership over the development process and commercialization path; (iv) 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; (v) the ability to successfully enter into optimal strategic relationships with its subsidiaries and operating companies that it may form in the future; (vi) the ability to hold or generate significant operating capital, including through partnering, asset sales and operating cost reductions; (vii) actual or anticipated variations in operating results; (viii) actual or anticipated fluctuations in competitors' or collaborators' operating results or changes in their respective growth rates; (ix) cash position; (x) market conditions in Precigen's industry; (xi) the volatility of Precigen's stock price; (xii) the ability, and the ability of collaborators, to protect Precigen's intellectual property and other proprietary rights and technologies; (xiii) 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; (xiv) outcomes of pending and future litigation; (xv) the rate and degree of market acceptance of any products developed by Precigen, its subsidiaries, collaborations or joint ventures; (xvi) the ability to retain and recruit key personnel; (xvii) expectations related to the use of proceeds from public offerings and other financing efforts; (xviii) estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and (xix) the challenges inherent in leadership transitions. 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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Precigen, Inc. and Subsidiaries Consolidated Balance Sheets (Unaudited)

(Amounts in thousands)	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 46,713	\$ 65,793
Short-term investments	86,292	9,260
Receivables		
Trade, net	23,337	20,650
Related parties, net	294	600
Other	364	4,978
Inventory	12,729	16,097
Prepaid expenses and other	3,266	6,444
Current assets held for sale	—	110,821
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Total current assets	172,995	234,643
Property, plant and equipment, net	46,956	60,969

Intangible assets, net	64,759	68,346
Goodwill	54,122	63,754
Investments in affiliates	859	1,461
Right-of-use assets	20,683	25,228
Other assets	1,341	1,362
Total assets	\$ 361,715	\$ 455,763
Current liabilities		
Accounts payable	\$ 3,650	\$ 5,917
Accrued compensation and benefits	7,719	14,091
Other accrued liabilities	9,342	12,049
Deferred revenue	6,592	5,697
Lines of credit	—	1,922
Current portion of long-term debt	32,108	31,670
Current portion of lease liabilities	4,514	4,182
Related party payables	175	51
Current liabilities held for sale	—	47,333
Total current liabilities	64,100	122,912
Long-term debt, net of current portion	191,205	186,321
Deferred revenue, net of current portion	32,858	48,136
Lease liabilities, net of current portion	21,212	23,849
Deferred tax liabilities	2,698	2,834
Other long-term liabilities	100	—
Total liabilities	312,173	384,052
Commitments and contingencies		
Shareholders' equity		
Common stock	—	—
Additional paid-in capital	1,802,413	1,752,048
Accumulated deficit	(1,752,221)	(1,652,869)
Accumulated other comprehensive loss	(650)	(27,468)
Total shareholders' equity	49,542	71,711
Total liabilities and shareholders' equity	\$ 361,715	\$ 455,763

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

(Amounts in thousands, except share and per share data)	Three months ended		Six months ended	
	2020	June 30, 2019	2020	June 30, 2019
Revenues				
Collaboration and licensing revenues	\$ 4,315	\$ 6,450	\$ 15,036	\$ 12,421
Product revenues	8,540	7,800	13,501	12,637
Service revenues	17,381	18,400	31,327	29,783
Other revenues	188	186	398	580
Total revenues	30,424	32,836	60,262	55,421
Operating Expenses				
Cost of products	8,141	8,502	14,230	16,224
Cost of services	6,770	8,218	14,306	15,310
Research and development	14,208	28,239	33,099	55,177
Selling, general and administrative	18,739	19,250	41,757	50,299
Impairment of goodwill	9,635	—	9,635	—
Impairment of assets	12,406	—	12,406	—
Total operating expenses	69,899	64,209	125,433	137,010
Operating loss	(39,475)	(31,373)	(65,171)	(81,589)
Other Expense, Net				
Unrealized and realized appreciation in fair value of equity securities and preferred stock, net	—	5,760	—	6,209

Interest expense	(4,592)	(4,353)	(9,184)	(8,658)
Interest and dividend income	773	1,024	1,446	2,385
Other income (expense), net	71	(2,656)	135	(2,110)
Total other expense, net	(3,748)	(225)	(7,603)	(2,174)
Equity in net loss of affiliates	(251)	(716)	(602)	(1,464)
Loss from continuing operations before income taxes	(43,474)	(32,314)	(73,376)	(85,227)
Income tax benefit	120	9	80	22
Loss from continuing operations	\$ (43,354)	\$ (32,305)	\$ (73,296)	\$ (85,205)
Loss from discontinued operations, net of income taxes	—	(6,626)	(26,056)	(15,862)
Net loss	\$ (43,354)	\$ (38,931)	\$ (99,352)	\$ (101,067)
Net loss attributable to the noncontrolling interests	—	165	—	1,592
Net loss attributable to Precigen	\$ (43,354)	\$ (38,766)	\$ (99,352)	\$ (99,475)
Amounts Attributable to Precigen				
Net loss from continuing operations attributable to Precigen	\$ (43,354)	\$ (32,140)	\$ (73,296)	\$ (83,613)
Net loss from discontinued operations attributable to Precigen	—	(6,626)	(26,056)	(15,862)
Net loss attributable to Precigen	\$ (43,354)	\$ (38,766)	\$ (99,352)	\$ (99,475)
Net Loss per Share				
Net loss from continuing operations attributable to Precigen per share, basic and diluted	\$ (0.26)	\$ (0.21)	\$ (0.45)	\$ (0.55)
Net loss from discontinued operations attributable to Precigen per share, basic and diluted	—	(0.04)	(0.16)	(0.10)
Net loss attributable to Precigen per share, basic and diluted	\$ (0.26)	\$ (0.25)	\$ (0.61)	\$ (0.65)
Weighted average shares outstanding, basic and diluted	164,065,087	153,749,929	162,201,915	153,351,208

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