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Precigen Reports Full Year 2023 Financial Results and Business Updates

Mar 19, 2024

- Significant progress made in the development of the PRGN-2012 AdenoVerse immunotherapy for the treatment of RRP; Precigen plans to submit a BLA under an accelerated approval pathway in the second half of 2024; ramping up commercial readiness activities for a potential launch in 2025 –
 - Precigen's PRGN-2012 received the first Breakthrough Therapy Designation and accelerated approval pathway from the FDA for the treatment of RRP –
- Precigen received IND clearance for a randomized Phase 2 study of PRGN-2009 AdenoVerse immunotherapy in combination with pembrolizumab in HPV-associated recurrent/metastatic cervical cancer; study now active and recruiting patients –
 - Interim data from the ongoing Phase 1b study of PRGN-3006 UltraCAR-T in relapsed/refractory AML anticipated in the second half of 2024 –
- Preliminary data from the Phase 1 study of PRGN-3007 next generation UltraCAR-T in ROR1+ advanced cancers anticipated in the second half of 2024 –
 - Cash, cash equivalents, short-term and long-term investments totaled \$62.9 million as of December 31, 2023 –
- Continued focus on cost containment resulted in a reduction in SG&A costs of 16% for the twelve months ended December 31, 2023, compared to the prior year period –

GERMANTOWN, Md., March 19, 2024 /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 full year 2023 financial results and business updates.



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ADVANCING MEDICINE WITH PRECISION™

"2024 is poised to be a transformative year for Precigen, as we are on track to present pivotal Phase 2 data in the second quarter and submit a BLA for PRGN-2012 in the second half, a milestone bolstered by the Breakthrough Therapy Designation and accelerated approval pathway granted by the FDA," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are preparing our manufacturing facility and commercial operations in anticipation of the launch of PRGN-2012 in 2025. We are also looking forward to exciting updates from our UltraCAR-T programs, which offer a novel approach compared to traditional CAR-T therapies and have garnered significant interest from potential partners due to the safety, preliminary efficacy, and manufacturing advantages."

"With multiple value inflection points anticipated in 2024, we remain steadfastly committed to a strategy of sound financial management," said Harry Thomasian Jr., CFO of Precigen. "We are evaluating various financing opportunities to strengthen our balance sheet as we prepare our lead asset PRGN-2012 for potential commercial launch in 2025."

Key Program Highlights

AdenoVerse™ Immunotherapies

- **PRGN-2012 in RRP:** PRGN-2012 is an investigational off-the-shelf AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11 for the treatment of recurrent respiratory papillomatosis (RRP). PRGN-2012 has received [Breakthrough Therapy Designation](#) and [Orphan Drug Designation](#) from the US Food and Drug Administration (FDA) and [Orphan Drug Designation](#) from the European

Commission.

- PRGN-2012 is currently under investigation in a [Phase 1/2 pivotal single-arm study](#) in adult patients with RRP (clinical trial identifier: [NCT04724980](#)).
- PRGN-2012 demonstrated strong efficacy and a favorable safety profile in the Phase 1 portion of the study with [50% of patients \(N=12\) in durable and ongoing Complete Response](#) more than two years after PRGN-2012 treatment. Results of the Phase 1 portion of the Phase 1/2 study were published in the peer-reviewed journal, [Science Translational Medicine](#), a leading publication from the American Association for the Advancement of Science (AAAS).
- Enrollment and dosing in the Phase 2 portion of the study is complete and a Phase 2 data presentation is anticipated in the second quarter of 2024.
- The Company has received agreement from the FDA that PRGN-2012 is eligible for consideration of a rolling Biologics License Application (BLA) review. A planned BLA submission under an accelerated approval pathway is anticipated in the second half of 2024.
- Commercial readiness preparations are underway for a potential launch in 2025.
- **PRGN-2009 in OPSCC and Cervical Cancer:** PRGN-2009 is an investigational off-the-shelf AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-associated cancers.
 - The Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) is enrolling patients (clinical trial identifier: [NCT05996523](#)).
 - The Phase 2 randomized, open-label study of PRGN-2009 in combination with pembrolizumab in patients with HPV-associated recurrent/metastatic cervical cancer is active and recruiting patients (clinical trial identifier: [NCT06157151](#)).

UltraCAR-T® Cell Therapies

- **PRGN-3006 in AML/MDS:** PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a safety/kill switch. PRGN-3006 has been granted [Orphan Drug Designation](#) in patients with acute myeloid leukemia (AML) and [Fast Track Designation](#) in patients with relapsed/refractory (r/r) AML by the FDA.
 - PRGN-3006 is currently under investigation in a Phase 1b dose expansion clinical trial (clinical trial identifier: [NCT03927261](#)) for the treatment of patients with r/r AML or higher-risk myelodysplastic syndromes (MDS).
 - The first-in-human Phase 1 dose escalation study data show that PRGN-3006 was well-tolerated with no dose-limiting toxicities (DLTs) and a 27% objective response rate (ORR) in heavily pre-treated r/r AML patients infused following lymphodepletion.
 - An interim Phase 1b dose expansion data presentation is anticipated in the second half of 2024.
- **PRGN-3005 in Ovarian Cancer:** PRGN-3005 is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, mbIL15, and a safety/kill switch.
 - The Phase 1b dose expansion portion of the Phase 1/1b study is ongoing (clinical trial identifier: [NCT03907527](#)).
- **PRGN-3007 in Advanced ROR1+ Hematological and Solid Tumors:** PRGN-3007, based on the next generation UltraCAR-T platform, is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a safety/kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression.
 - The Phase 1 dose escalation portion of the Phase 1/1b study is ongoing (clinical trial identifier: [NCT05694364](#)).
 - A preliminary Phase 1 dose escalation data presentation is anticipated by the end of 2024.

Financial Highlights

- Cash, cash equivalents, short-term and long-term investments totaled \$62.9 million as of December 31, 2023.
- Selling, general, and administrative (SG&A) costs decreased versus the prior year, 16% for the twelve months ended December 31, 2023.

Full Year 2023 Financial Results Compared to Prior Year Period

Research and development expenses increased \$1.4 million, or 3.1%, compared to year ended December 31, 2022. Salaries, benefits, and other personnel costs increased \$2.8 million due to an increase in the hiring of employees to support the growth in the Company's development activities, and to a lesser extent, increases in salaries of our continuing employees. These increases were offset by less expenses incurred related to preclinical research programs for the comparable period.

SG&A expenses decreased \$7.6 million, or 15.8%, compared to the year ended December 31, 2022. This decrease was primarily driven by a reduction in professional fees of \$6.5 million, due to decreased legal fees associated with certain litigation matters, and \$0.7 million decreased insurance-related premiums.

Total revenues decreased \$20.7 million, or 76.9%, compared to the year ended December 31, 2022. Collaboration and licensing revenues decreased

or metastatic cervical cancer ([NCT06157151](#)), and a Phase 1/2 study of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis (RRP) ([NCT04724980](#)). PRGN-2012 has been granted [Orphan Drug Designation](#) and [Breakthrough Therapy Designation](#) in patients with RRP by the FDA and [Orphan Drug Designation](#) by the European Commission.

Trademarks

Precigen, UltraCAR-T, UltraPorator, AdenoVerse, UltraVector 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 the Company's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of the Company's business, including the timing and progress of preclinical studies, clinical trials, discovery programs and related milestones, the promise of the Company's portfolio of therapies, and in particular its CAR-T and AdenoVerse therapies. Although management believes that the plans and objectives 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 in this press release. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For further information on potential risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company'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)	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 7,578	\$ 4,858
Restricted cash	-	43,339
Short-term investments	55,277	51,092
Receivables		
Trade, net	902	978
Other	673	12,826
Prepaid expenses and other	4,325	5,066
Total current assets	68,755	118,159
Property, plant and equipment, net	7,111	7,329
Intangible assets, net	40,701	44,455
Goodwill	26,612	36,923
Right-of-use assets	7,097	8,086
Other assets	767	1,025
Total assets	\$ 151,043	\$ 215,977
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$ 1,726	\$ 4,068
Accrued compensation and benefits	8,250	6,377
Other accrued liabilities	6,223	4,997
Settlement and Indemnification Accrual	5,075	18,750
Deferred revenue	509	25
Current portion of long-term debt	-	43,219
Current portion of lease liabilities	1,202	1,209
Total current liabilities	22,985	78,645
Deferred revenue, net of current portion	1,818	1,818
Lease liabilities, net of current portion	5,895	6,992

Deferred tax liabilities	1,847	2,263
Total liabilities	32,545	89,718
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,084,916	1,998,314
Accumulated deficit	(1,964,471)	(1,868,567)
Accumulated other comprehensive loss	(1,947)	(3,488)
Total shareholders' equity	118,498	126,259
Total liabilities and shareholders' equity	\$ 151,043	\$ 215,977

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

(Amounts in thousands, except share and per share data)	Year ended	
	December 31, 2023	December 31, 2022
Revenues		
Collaboration and licensing revenues	\$ 75	\$ 14,661
Product revenues	840	1,903
Service revenues	5,301	10,094
Other revenues	9	251
Total revenues	6,225	26,909
Operating Expenses		
Cost of products and services	6,119	6,339
Research and development	48,614	47,170
Selling, general and administrative	40,415	48,006
Impairment of goodwill	10,390	482
Impairment of other noncurrent assets	445	638
Total operating expenses	105,983	102,635
Operating loss	(99,758)	(75,726)
Other Expense, Net		
Interest expense	(468)	(6,774)
Interest income	3,237	133
Other income, net	627	1,539
Total other income (expense), net	3,396	(5,102)
Equity in net loss of affiliates	-	862
Loss from continuing operations before income taxes	(96,362)	(79,966)
Income tax benefit	458	189
Loss from continuing operations	\$ (95,904)	\$ (79,777)
Income from discontinued operations, net of income taxes	-	108,094
Net loss	\$ (95,904)	\$ 28,317
Net Loss per share		
Net loss from continuing operations per share, basic and diluted	\$ (0.39)	\$ (0.40)
Net income from discontinued operations per share, basic and diluted	-	0.54
Net loss per share, basic and diluted	\$ (0.39)	\$ 0.14
Weighted average shares outstanding, basic and diluted	244,536,221	200,360,821

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