Precigen Reports First Quarter 2024 Financial Results and Business Updates

May 14, 2024

– *Pivotal Phase 2 study data of PRGN-2012 for the treatment of patients with recurrent respiratory papillomatosis to be presented at the 2024 ASCO Annual Meeting as a late-breaking oral presentation on June 3rd* –

– *Company to host a conference call on June 3rd following the PRGN-2012 ASCO presentation to discuss in detail the pivotal study results and provide business updates* –

– *PRGN-2012 rolling BLA submission, under an accelerated approval pathway, is anticipated in the second half of 2024; commercial readiness activities underway for a potential launch in 2025* –

– *Two trial-in-progress presentations for PRGN-2009 in combination with pembrolizumab for the treatment of recurrent/metastatic cervical cancer and oropharyngeal cancer to be presented at ASCO* –

– *Company and the Recurrent Respiratory Papillomatosis Foundation to co-sponsor the inaugural RRP Awareness Day on June 11th to raise awareness and bring together individuals living with RRP, caregivers, clinicians, and government officials* –

– *Cash, cash equivalents, and short-term investments totaled $44.8 million as of March 31, 2024* –

GERMANTOWN, Md., May 14, 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 first quarter 2024 financial results and business updates.

"We are excited to share the pivotal Phase 2 data for our PRGN-2012 study in patients with RRP at ASCO and look forward to providing additional details regarding the results at our planned conference call following the presentation. We remain on track for a PRGN-2012 rolling BLA submission in the second half of 2024 and we are actively moving ahead with our commercial readiness efforts in anticipation of a potential launch of PRGN-2012 in 2025," said Helen Sabzevari, PhD, President and CEO of Precigen. "Based on the competitive advantages of PRGN-2012, including a favorable route of administration, safety profile and the efficacy demonstrated in the clinical trial results so far, we believe PRGN-2012 has the potential to be the first-in-class and best-in-class treatment for RRP patients. We anticipate PRGN-2012 to overwhelmingly be the treatment of choice for RRP patients, if approved, as indicated by our commissioned research of healthcare providers and key opinion leaders which found PRGN-2012's competitive advantages highly compelling."

"With multiple milestones anticipated in 2024 and 2025, 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®

- **PRGN-2012 in RRP:** PRGN-2012 is an investigational off-the-shelf AdenoVerse gene therapy 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 was the first to receive Breakthrough Therapy Designation and an accelerated approval pathway for RRP from the FDA. PRGN-2012 received 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).
- Results from 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).
    - PRGN-2012 demonstrated overall safety and clinically meaningful benefit with 50% of patients (N=12) in Complete Response, which is defined as no surgeries needed during the 12-month period following PRGN-2012 treatment completion. All Complete Responses were durable and ongoing more than two years after PRGN-2012 treatment.
    - 83% of patients had a reduction in RRP surgeries in the 12-month period after PRGN-2012 treatment compared to 12 months pre-treatment.
    - Correlative data support expansion of peripheral HPV 6 and HPV 11–specific T cell immunological responses as the underlying mechanism of action for PRGN-2012.
- PRGN-2012 is built using the Company's differentiated gorilla adenovector that allows for repeat dosing. The redosing potential of AdenoVerse has been highlighted in clinical studies where repeat administrations of PRGN-2009 and PRGN-2012 gene therapies led to enhancement of antigen-specific T cell immune responses without generation of significant neutralizing antibodies in contrast to other viral vectors.
- Results from the pivotal Phase 2 study of PRGN-2012 for the treatment of RRP, including immunological responses, will be presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in a late-breaking oral presentation titled, "PRGN-2012, a novel gorilla adenovirus-based immunotherapy, provides the first treatment that leads to complete and durable responses in recurrent respiratory papillomatosis patients." Scott M. Norberg, DO, Associate Research Physician, Center for Immuno-Oncology, Center for Cancer Research, National Cancer Institute, will deliver the presentation on June 3, 2024 at 8:30 AM CT.
- The Company plans to host a conference call on June 3, 2024 to discuss in detail the PRGN-2012 pivotal study results presented and provide business updates.
- FDA confirmed that the ongoing Phase 1/2 single arm study will serve as pivotal and no additional randomized, placebo-controlled trial will be required to support submission of a Biologics License Application (BLA). A rolling BLA submission under an accelerated approval pathway is anticipated in the second half of 2024. Based on FDA guidance, the Company is on track to initiate a confirmatory study prior to submission of the BLA.
- Commercial readiness preparations are underway for a potential launch in 2025.
- The Company and the Recurrent Respiratory Papillomatosis Foundation will co-sponsor the inaugural RRP Awareness Day on June 11, 2024. The multi-stakeholder event will raise awareness and bring together individuals living with RRP, caregivers, clinicians, and government officials to encourage new connections and build community among those interested in and affected by RRP. The inaugural event will be hybrid with in-person participation at the National Press Club in Washington DC and a webcast for virtual participation.

- **PRGN-2009 in OPSCC and Cervical Cancer:** PRGN-2009 is an investigational off-the-shelf AdenoVerse gene therapy 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).
        - An abstract titled, "Phase II trial of immunotherapeutic HPV vaccine PRGN-2009 with pembrolizumab before standard treatment in subjects with newly diagnosed HPV-associated oropharyngeal cancer" will be presented as a trial-in-progress poster presentation on June 2, 2024 from 9:00 AM to 12:00 PM CT at ASCO.
    - 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).
        - An abstract titled, "A Phase 2 study to evaluate efficacy and safety of PRGN-2009, a novel gorilla adenovirus-based immunotherapy, in combination with pembrolizumab versus pembrolizumab monotherapy in patients with recurrent or metastatic cervical cancer" will be presented as a trial-in-progress poster presentation on June 3, 2024 from 9:00 AM to 12:00 PM CT at ASCO.

UltraCAR-T®

- **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).
    - 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, and short-term investments totaled $44.8 million as of March 31, 2024.
- Selling, general, and administrative (SG&A) costs decreased 13% compared to the three months ended March 31, 2023.
- Property, plant, and equipment, net, increased $5.5 million from December 31, 2023 primarily due to the build-out of our cGMP manufacturing facility.

First Quarter 2024 Financial Results Compared to Prior Year Period

Research and development expenses increased $2.1 million, or 17%, compared to the three months ended March 31, 2023. Salaries, benefits, and other personnel costs increased $1.5 million due to an increase in the hiring of employees throughout 2023 to support the growth in the Company's clinical development activities as well as increased fees paid to consultants and contract research organizations in the first quarter of 2024 compared to the same period in 2023.

SG&A expenses decreased $1.5 million, or 13%, compared to the three months ended March 31, 2023, primarily driven by a reduction in stock compensation and insurance expenses in the first quarter of 2024 compared to same period in 2023. In addition, the costs associated with PRGN-2012 commercial readiness increased compared to the same period in 2023.

Total revenues decreased $0.8 million, or 43%, compared to the three months ended March 31, 2023. This decrease was due to the reduction in products and services performed at Exemplar. Gross margin on product and services also declined in the current period primarily as a result of the decreased revenues at Exemplar.

Net Loss was $23.7 million, or $(0.10) per basic and diluted share, compared to net loss of $22.7 million, or $(0.10) per basic and diluted share, in period ended March 31, 2023.

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 therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on X @Precigen, LinkedIn or YouTube.

AdenoVerse®
Precigen's AdenoVerse platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse gene therapies have been shown to generate high-level and durable antigen-specific T-cell immune responses as well as an ability to boost these responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors leveraging UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

AdenoVerse® Clinical Programs
Precigen's AdenoVerse platform is currently under clinical investigation in a Phase 1/2 study of PRGN-2009 alone or in combination with an anti-PDL1/TGF-Beta Trap in patients with HPV-associated cancers (NCT04432597), a Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) (NCT05996523), a Phase 2 study of PRGN-2009 in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer (NCT06157151), and a Phase 1/2 study of PRGN-2012 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.

UltraCAR-T®
UltraCAR-T is a multigenic autologous CAR-T platform that utilizes Precigen's advanced non-viral *Sleeping Beauty* system to simultaneously express an antigen-specific CAR to specifically target tumor cells, mbIL15 for enhanced *in vivo* expansion and persistence, and a kill switch to conditionally eliminate CAR-T cells for a potentially improved safety profile. Precigen has advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. UltraCAR-T investigational therapies are manufactured via Precigen's overnight manufacturing process using the proprietary UltraPorator® electroporation system at the patient's medical center and administered to patients only one day following gene transfer. The overnight UltraCAR-T manufacturing process does not use viral vectors and does not require *ex vivo* activation and expansion of T cells, potentially addressing major limitations of current T cell therapies.

UltraCAR-T® Clinical Programs
Precigen's UltraCAR-T platform is currently under clinical investigation for hematological and solid tumors, including a Phase 1/1b study of PRGN-3005 in patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (NCT03907527), a Phase 1/1b study of PRGN-3006 in patients with relapsed or refractory acute myeloid leukemia (AML) or higher risk myelodysplastic syndrome (MDS) (NCT03927261) and a Phase 1/1b study of PRGN-3007 incorporating PD-1 checkpoint inhibition in patients with ROR1-positive ($ROR1^+$) chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL) and triple negative breast cancer (TNBC) (NCT05694364). PRGN-3006 has been granted Orphan Drug Designation and Fast Track Designation in patients with AML by the US Food and Drug Administration (FDA).

UltraCAR-T® Library Approach
Precigen's UltraCAR-T library approach is designed to transform the personalized cell therapy landscape for cancer patients. Precigen's goal is to develop and validate a library of non-viral plasmids to target tumor-associated antigens. Enabled by design and manufacturing advantages of UltraCAR-T, coupled with the capabilities of the UltraPorator® system, Precigen is working to empower medical centers to deliver personalized, autologous UltraCAR-T treatment with overnight manufacturing to any cancer patient. Based on the patient's cancer indication and biomarker profile, one or more non-viral plasmids would be selected from the library to build a personalized UltraCAR-T treatment. After initial treatment, this approach has the potential to allow for redosing of UltraCAR-T targeting the same or new tumor-associated antigen(s) based on the treatment response and the changes in antigen expression of the patient's tumor. Precigen believes that the combination of the advanced UltraVector® DNA construction platform and the ease of overnight manufacturing gives this library approach a proprietary advantage over traditional T-cell therapies.

UltraPorator®
The UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk. The UltraPorator device is a high-throughput, semi-closed electroporation system for modifying T cells using Precigen's proprietary non-viral gene transfer technology. UltraPorator is being utilized for clinical manufacturing of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices.

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)	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 17,478	$ 7,578
Short-term investments	27,280	55,277
Receivables		
Trade, net	872	902
Other	290	673
Prepaid expenses and other	3,626	4,325

Total current assets	49,546	68,755
Property, plant and equipment, net	12,620	7,111
Intangible assets, net	38,717	40,701
Goodwill	26,555	26,612
Right-of-use assets	6,658	7,097
Other assets	751	767
Total assets	$ 134,847	$ 151,043
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 4,716	$ 1,726
Accrued compensation and benefits	9,962	8,250
Other accrued liabilities	7,296	6,223
Settlement and Indemnification Accrual	5,075	5,075
Deferred revenue	407	509
Current portion of lease liabilities	1,318	1,202
Total current liabilities	28,774	22,985
Deferred revenue, net of current portion	1,888	1,818
Lease liabilities, net of current portion	5,387	5,895
Deferred tax liabilities	1,779	1,847
Total liabilities	37,828	32,545
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,088,025	2,084,916
Accumulated deficit	(1,988,209)	(1,964,471)
Accumulated other comprehensive loss	(2,797)	(1,947)
Total shareholders' equity	97,019	118,498
Total liabilities and shareholders' equity	$ 134,847	$ 151,043

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

	Three Months Ended	
(Amounts in thousands, except share and per share data)	**March 31, 2024**	**March 31, 2023**
Revenues		
Product revenues	$ 138	$ 324
Service revenues	919	1,527
Other revenues	8	-
Total revenues	1,065	1,851
Operating Expenses		
Cost of products and services	1,075	1,527
Research and development	14,249	12,163
Selling, general and administrative	10,151	11,639
Total operating expenses	25,475	25,329
Operating loss	(24,410)	(23,478)
Other Income (Expense), Net		
Interest expense	(2)	(324)
Interest income	608	633
Other income, net	37	380
Total other income, net	643	689
Loss before income taxes	(23,767)	(22,789)
Income tax benefit	29	55
Net loss	$ (23,738)	$ (22,734)
Net Loss per share		
Net loss per share, basic and diluted	$ (0.10)	$ (0.10)
Weighted average shares outstanding, basic and diluted	249,220,335	229,770,381

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