Precigen Reports First Quarter 2023 Financial Results and Business Updates

May 10, 2023

– Positive Phase 1 clinical data presented for PRGN-2012 AdenoVerse ™ immunotherapy in RRP demonstrated favorable safety profile and significant reduction in surgeries with 50% of the patients in Complete Response following treatment with PRGN-2012 –

– Enrollment completed in the Phase 2 study of PRGN-2012 in RRP –

– First patient dosed in Phase 1/1b dose escalation/dose expansion study of PRGN-3007, a next generation UltraCAR-T® incorporating PD-1 checkpoint inhibition, in advanced ROR1+ hematological and solid tumors –

– Regained exclusive rights to validated CAR-T targets, CD19 and BCMA, to enable unencumbered development and commercialization of UltraCAR-T® –

– Latest clinical advancements for PRGN-3005 UltraCAR-T® and PRGN-2009 off-the-shelf AdenoVerse ™ immunotherapy to be presented at the 2023 ASCO annual meeting in June –

– Significantly strengthened balance sheet, raising $72.8 million, net of offering costs via a public offering of common stock –

– Retired an additional $29.5 million of outstanding convertible notes, leaving $13.8 million maturing on July 1, 2023, which will be retired using the Company's restricted cash balance –

– Cash, cash equivalents, short-term and long-term investments and restricted cash totaled $125.4 million as of March 31, 2023 –

GERMANTOWN, Md., May 10, 2023 /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 2023 financial results and business updates.

"Precigen continues to execute on our strategy to maintain corporate strength while advancing our most promising programs. This quarter, we successfully closed a public offering and more recently announced that Precigen has regained rights to two validated targets (CD19 and BCMA) that will further bolster our already robust UltraCAR-T portfolio and provides an opportunity to advance potential best-in-class UltraCAR-T drug candidates. We continue to advance our vision to transform the personalized cell therapy landscape using Precigen's library approach to build the most comprehensive clinical and preclinical CAR-T portfolios with antigen-specific targets spanning both hematological and solid tumors where there is high unmet medical need for cancer patients, including CD33, MUC16, ROR1, CD19, BCMA and MSLN," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are pleased with the progress of our programs so far this year. We successfully dosed the first patient with PRGN-3007 and showcased preclinical data for our MSLN next generation UltraCAR-T at the 2023 AACR annual meeting. We also presented positive Phase 1 data for our PRGN-2012 AdenoVerse immunotherapy in RRP at our R&D day and completed enrollment in the Phase 2 study. Finally, we look forward to sharing additional data at the 2023 ASCO annual meeting for our PRGN-3005 UltraCAR-T and PRGN-2009 AdenoVerse immunotherapy."

"We remain focused on strengthening our financial footing while containing costs to support our business objectives," said Harry Thomasian Jr., CFO of Precigen. "Our program of financial discipline, combined with a public offering and early retirement of most of our debt, has provided a solid cash runway to support priorities into late 2024."

Program Highlights

Exclusive Rights to UltraCAR-T® Targets, CD19 and BCMA, and IL-12 Gene Therapy

- The Company amended its exclusive license agreement with Alaunos Therapeutics to bolster its portfolio and broaden strategic opportunities.
- The Company regained exclusive rights to CD19 and B-cell maturation antigen (BCMA) targets to enable unencumbered development and commercialization of two validated targets utilizing the UltraCAR-T® platform.
- The Company also regained exclusive rights to its interleukin (IL)-12 gene therapy, including application through the off-the-shelf AdenoVerse immunotherapy platform, paving the way for potential future treatments in oncology given the important role of IL-12 cytokines in targeting many types of tumors such as human papillomavirus (HPV)-associated cancers.

PRGN-2012 AdenoVerse™ Immunotherapy in RRP

- PRGN-2012 is an investigational off-the-shelf (OTS) AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for the treatment of RRP. The US Food and Drug Administration (FDA) granted orphan drug designation for PRGN-2012 for patients with recurrent respiratory papillomatosis (RRP).
- The Company announced positive Phase 1 dose escalation and expansion cohort data (N=15) in January 2023 at its R&D Day virtual event.
- The Company completed enrollment in the Phase 2 portion of the study (N=23) bringing the total number of enrolled patients to 35 at Dose Level 2. Patient follow up is ongoing.
- The Company plans to outline the regulatory strategy as FDA discussions advance.

PRGN 2009 AdenoVerse™ Immunotherapy in HPV-associated Cancers

- PRGN-2009 is an OTS investigational immunotherapy utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive (HPV^+) solid tumors.
- The Company completed enrollment in the Phase 1 monotherapy (N=6) and combination therapy (N=11) arms in patients with recurrent or metastatic HPV-associated cancers. An abstract for the clinical data of the PRGN-2009 Phase 1 study (Abstract # 2628) titled, "Phase I evaluation of PRGN-2009 alone and in combination with bintrafusp alfa in patients (pts) with recurrent/metastatic (R/M) HPV-associated cancers (HPV-C)" has been selected for presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on June 3, 2023 from 8:00 to 11:00 AM CT.
- Enrollment was completed in the Phase 2 monotherapy arm with 20 evaluable patients in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients. An interim clinical data presentation from the Phase 2 monotherapy arm is expected in the second half of 2023.

PRGN-3006 UltraCAR-T® in AML

- 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 kill switch. The FDA granted orphan drug designation and fast track designation for PRGN-3006 UltraCAR-T for patients with relapsed or refractory (r/r) acute myeloid leukemia (AML).
- The Company completed the Phase 1 dose escalation study and announced positive data at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. Subsequently, the Company initiated a multicenter Phase 1b dose expansion study of PRGN-3006. The Company received FDA clearance to incorporate repeat dosing in the Phase 1b trial. A Phase 1b clinical data presentation is expected in 2024.

PRGN-3005 UltraCAR-T® in Ovarian Cancer

- PRGN-3005 UltraCAR-T is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, mbIL15, and a kill switch.
- The Company completed enrollment in the Phase 1 dose escalation cohorts of the intraperitoneal (IP) and intravenous (IV) arms without lymphodepletion as well as in the lymphodepletion cohort in the IV arm. An abstract for the clinical data of the PRGN-3005 Phase 1 dose escalation study (Abstract # 5590) titled, "Phase 1/1b study of PRGN-3005 autologous UltraCAR-T cells manufactured overnight for infusion next day to advanced stage platinum resistant ovarian cancer patients" has been selected for presentation at the 2023 ASCO Annual Meeting on June 5, 2023 from 1:15 to 4:15 PM CT.
- The Company initiated a Phase 1b dose expansion trial of PRGN-3005. The Company received FDA clearance to incorporate repeat dosing in the Phase 1b study. A Phase 1b clinical data presentation is expected in 2024.

PRGN-3007 UltraCAR-T® in Advanced $ROR1^+$ Hematological and Solid Tumors

- PRGN-3007, based on the next generation of the 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 kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression.
- The Company announced dosing of the first patient in the Phase 1/1b dose escalation/dose expansion study of

PRGN-3007 in advanced ROR1-positive (ROR1^{+}) hematological and solid tumors. The target patient population for the Phase 1/1b study includes hematological cancers (chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), and diffuse large B-cell lymphoma (DLBCL)) and solid tumors (triple negative breast cancer (TNBC)).

Next Generation UltraCAR-T® Platform

- The Company showcased advances in the UltraCAR-T platform with a preclinical data presentation for the next generation UltraCAR-T platform utilizing mesothelin (MSLN) CAR from Precigen's library of non-viral plasmids at the American Association for Cancer Research (AACR) Annual Meeting 2023. Enhancement of efficacy due to incorporation of a novel mechanism for PD-1 blockade in MSLN UltraCAR-T in preclinical models was presented in the abstract titled, "Next Generation UltraCAR-T® Cells with Intrinsic Checkpoint Inhibition and Overnight Manufacturing Overcome Suppressive Tumor Microenvironment Leading to Sustained Antitumor Activity."

Financial Highlights

- In January 2023, the Company completed an underwritten public offering of approximately 44 million shares of common stock, including a partial exercise of the underwriters' option to purchase additional shares, at a price to the public of $1.75 per share, which resulted in net proceeds to the Company of $72.8 million (after deducting underwriting discounts, fees and other expenses).
- During the three months ended March 31, 2023, the Company successfully retired, through open market purchases, $29.5 million of outstanding convertible notes due in July 2023 at a discount to par bringing the total outstanding balance to $13.8 million. Any remaining outstanding convertible notes will be retired using the Company's restricted cash balance. Early retirements have saved the Company close to $7 million through retirements at discounts to par and reduced interest costs.
- Cash, cash equivalents, short-term and long-term investments and restricted cash totaled $125.4 million as of March 31, 2023.
- Selling, general and administrative (SG&A) costs decreased by 15% for the three months ended March 31, 2023 compared to the prior year period.

First Quarter 2023 Financial Results Compared to Prior Year Period

Research and development expenses increased $0.4 million, or 3%, from the three months ended March 31, 2022. This increase was primarily driven by a continued prioritization of clinical product candidates.

Total other income, net, increased $2.5 million over the three months ended March 31, 2022. This increase was primarily due to reduced interest expense associated with the Company's Convertible Notes as a significant portion of the original $200 million face value of the Convertible Notes has been retired. In addition, interest income increased due to higher interest rates on the Company's investments.

SG&A expenses decreased $2.1 million, or 15%, from the three months ended March 31, 2022. This decrease was primarily driven by a reduction in professional fees of $2 million, primarily due to decreased legal fees associated with certain litigation matters.

Total revenues decreased $3.7 million, or 66%, from the three months ended March 31, 2022. This decrease related to the recognition of revenue in the first quarter of 2022 related to agreements for which revenue was previously deferred that did not occur in the first quarter of 2023 of $1.0 million, as well as declines in services performed at Exemplar.

Loss from continuing operations was $22.7 million, or $(0.10) per basic and diluted share, compared to loss from continuing operations of $23.9 million, or $(0.12) per basic and diluted share, in Q1 2022.

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 Twitter @Precigen, LinkedIn or YouTube.

AdenoVerse ™ Immunotherapy

Precigen's AdenoVerse immunotherapy 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 immunotherapies have been shown to generate high-level and durable antigen-specific neutralizing antibodies and effector T cell immune responses as well as an ability to boost these antibody and T cell responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors combined with UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

AdenoVerse ™ Immunotherapy Clinical Program

Precigen's AdenoVerse Immunotherapy platform is currently under clinical investigation in a Phase 1/2 study of PRGN-2009 AdenoVerse immunotherapy alone or in combination with anti-PDL1/TGF-Beta Trap (M7824) in patients with HPV-associated cancers (NCT04432597) and a Phase 2 study of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis (NCT04724980). PRGN-2012 has

been granted Orphan Drug Designation in patients with RRP by the FDA.

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 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 Program
The UltraCAR-T platform has shifted the autologous CAR-T manufacturing paradigm using an advanced non-viral multigene delivery system and an overnight, decentralized manufacturing process for administration of autologous CAR-T cells one day after gene transfer to reduce vein-to-vein time. Precigen's UltraCAR-T platform is currently under clinical investigation for hematological and solid tumors, including a Phase 1/1b study of PRGN-3005 UltraCAR-T in patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (NCT03907527), a Phase 1/1b study of PRGN-3006 UltraCAR-T 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 UltraCAR-T incorporating PD-1 checkpoint inhibition in patients with ROR1-positive ($ROR1^+$) hematologic chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL) and solid tumor triple negative breast cancer (TNBC) malignancies (NCT05694364). PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation and East 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 cancer 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

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, including the possibility that the timeline for the Company's clinical trials might be impacted by the COVID-19 pandemic, 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.

Investor Contact:
Steven M. Harasym
Vice President, Investor Relations
Tel: +1 (301) 556-9850
investors@precigen.com

Media Contacts:
Donelle M. Gregory
press@precigen.com

Glenn Silver
Lazar-FINN Partners
glenn.silver@finnpartners.com

Precigen, Inc. and Subsidiaries

Consolidated Balance Sheets
(Unaudited)

(Amounts in thousands)	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 9,740	$ 4,858
Restricted cash	13,800	43,339
Short-term investments	94,351	51,092
Receivables		
Trade, net	1,771	978
Other	13,751	12,826
Prepaid expenses and other	4,330	5,066
Total current assets	137,743	118,159
Long-term in investments	7,460	-
Property, plant and equipment, net	6,908	7,329
Intangible assets, net	43,848	44,455
Goodwill	36,966	36,923
Right-of-use assets	7,617	8,086
Other assets	1,004	1,025
Total assets	$ 241,546	$ 215,977
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 3,809	$ 4,068
Accrued compensation and benefits	4,959	6,377
Other accrued liabilities	22,887	23,747
Deferred revenue	15	25
Current portion of long-term debt	13,819	43,219
Current portion of lease liabilities	1,244	1,209
Total current liabilities	46,733	78,645
Deferred revenue, net of current portion	1,818	1,818
Lease liabilities, net of current portion	6,623	6,992
Deferred tax liabilities	2,239	2,263
Total liabilities	57,413	89,718
Commitments and contingencies (Note 14)		
Shareholders' equity		
Common stock	-	-
Additional paid-in capital	2,078,133	1,998,314
Accumulated deficit	(1,891,301)	(1,868,567)
Accumulated other comprehensive loss	(2,699)	(3,488)
Total shareholders' equity	184,133	126,259
Total liabilities and shareholders' equity	$ 241,546	$ 215,977

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

	Three months ended	
(Amounts in thousands, except share and per share data)	**March 31, 2023**	**March 31, 2022**
Revenues		
Product revenues	$ 324	$ 492
Service revenues	1,527	4,933
Other revenues	-	88
Total revenues	1,851	5,513
Operating Expenses		
Cost of products and services	1,527	1,694
Research and development	12,163	11,801
Selling, general and administrative	11,639	13,689
Impairment of goodwill	-	482
Total operating expenses	25,329	27,666

Operating loss		(23,478)		(22,153)
Other Income (Expense), Net				
Interest expense		(324)		(2,038)
Interest income		633		38
Other income, net		380		198
Total other income (expense), net		689		(1,802)
Equity in net loss of affiliates		-		(1)
Loss from continuing operations before income taxes		(22,789)		(23,956)
Income tax benefit		55		58
Loss from continuing operations		(22,734)		(23,898)
Income from discontinued operations, net of income taxes		-		4,647
Net loss	$	(22,734)	$	(19,251)
Net Loss per share				
Net loss from continuing operations per share, basic and diluted	$	(0.10)	$	(0.12)
Net income from discontinued operations per share, basic and diluted		-		0.02
Net loss per share, basic and diluted	$	(0.10)	$	(0.10)
Weighted average shares outstanding, basic and diluted		229,770,381		199,629,218

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