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Precigen Reports Second Quarter and First Half 2024 Financial Results and Business Updates

Aug 14, 2024

- In June 2024, the Company announced groundbreaking pivotal study data for PRGN-2012 gene therapy at the 2024 ASCO annual meeting in which more than half of RRP patients achieved Complete Response –
- In July 2024, the Company appointed Phil Tennant as Chief Commercial Officer to spearhead potential PRGN-2012 commercial launch –
- In August 2024, the Company announced a strategic reprioritization of its pipeline to focus on advancement of its lead program, PRGN-2012 in RRP –
- PRGN-2012 rolling BLA submission, under an accelerated approval pathway, is anticipated in the second half of 2024; the Company has initiated enrollment in the confirmatory clinical trial of PRGN-2012 –
- In August 2024, the Company strengthened its cash position by raising approximately \$31.4 million via a public offering of common stock –

GERMANTOWN, Md., Aug. 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 second quarter and first half 2024 financial results and business updates.



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"We are all in on PRGN-2012 given the immense unmet need for RRP patients and our groundbreaking pivotal data supporting the potential of what we hope to be the first-ever FDA approved therapy to treat RRP," said Helen Sabzevari, PhD, President and CEO of Precigen. "By strategically focusing our portfolio, streamlining resources and recent public offering, we have optimized the company to rapidly prepare for submission of a rolling biologics license application under an accelerated approval pathway. We are excited to have initiated enrollment in the confirmatory clinical trial and will continue to accelerate our commercial readiness campaign for a potential launch in 2025 under the leadership of our newly hired Chief Commercial Officer. Additionally, we plan to maximize portfolio value by focusing on strategic partnerships to further advance our highly promising UltraCAR-T programs."

"Our recent reprioritization and public offering is expected to fund our operations into early 2025 allowing us to focus on advancement of PRGN-2012 while continuing to explore potential non-dilutive financing opportunities for future liquidity," said Harry Thomasian Jr., CFO of Precigen.

Key Program Highlights

- **PRGN-2012 AdenoVerse® Gene Therapy 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 received [Breakthrough Therapy Designation](#) from the US Food and Drug Administration (FDA). PRGN-2012 also received [Orphan Drug Designation](#) from the FDA and [Orphan Drug Designation](#) from the European Commission.
- [Results from the pivotal clinical study of PRGN-2012 for the treatment of RRP](#) were 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.](#)"
 - Pivotal study met primary safety and efficacy endpoints.

- 51% (18 out of 35) of patients achieved Complete Response, requiring no surgeries after treatment with PRGN-2012; Complete Responses have been durable beyond 12 months with median duration of follow up of 20 months as of the May 20, 2024 data cutoff.
 - 86% of patients (30 out of 35) had a decrease in surgical interventions in the year after PRGN-2012 treatment compared to the year prior to treatment; RRP surgeries reduced from a median of 4 (range: 3-10) pre-treatment to 0 (range: 0-7) post-treatment.
 - PRGN-2012 was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
 - PRGN-2012 treatment induced HPV 6/11-specific T cell responses in RRP patients with a significantly greater expansion of peripheral HPV-specific T cells in responders compared with non-responders.
 - PRGN-2012 significantly ($p < 0.0001$) improved Derkey and quality of life scores in complete responders.
 - A rolling Biologics License Application (BLA) submission under an accelerated approval pathway is anticipated in the second half of 2024.
 - The Company has initiated enrollment in the confirmatory clinical trial, in accordance with the guidance from the FDA, prior to submission of the BLA.
 - The Company and the Recurrent Respiratory Papillomatosis Foundation held the inaugural [RRP Awareness Day on June 11, 2024](#). The multi-stakeholder event raised awareness by bringing together individuals living with RRP, caregivers, clinicians, and government officials.
- **Strategic Prioritization:** [In August 2024, the Company announced a strategic prioritization](#) of its clinical portfolio and associated streamlining of resources, including a reduction of over 20% of its workforce, to focus on potential commercialization of PRGN-2012.
 - **PRGN-2009 AdenoVerse[®] Gene Therapy Clinical Trials**
 - The Company plans to continue PRGN-2009 Phase 2 clinical trials under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI) in recurrent/metastatic cervical cancer and in newly diagnosed HPV-associated oropharyngeal cancer.
 - PRGN-2009 cervical cancer clinical trial enrollment at non-NCI clinical sites will be paused.
 - **UltraCAR-T[®] Clinical Programs**
 - The Company has completed enrollment of the [Phase 1b trial for PRGN-3006 in acute myeloid leukemia \(AML\), which received Fast Track designation from the FDA](#), and is preparing for an end of Phase 1b meeting with the FDA to discuss next steps.
 - The Company will pause the PRGN-3005 and PRGN-3007 clinical trials.
 - The Company will minimize UltraCAR-T spend and focus on strategic partnerships to further advance UltraCAR-T programs.
 - **Preclinical Programs**
 - The Company will pause all preclinical programs.
 - **ActoBio**
 - The Company has initiated shutdown of its Belgium-based ActoBio subsidiary operations, including planned elimination of all ActoBio personnel.
 - In conjunction with this shutdown, ActoBio's portfolio of intellectual property will be made available for prospective transactions.

Financial Highlights

- Strategic prioritization resulted in non-cash impairment charges of \$32.9 million, net of tax, in the second quarter and severance charges of \$3.0 million, of which \$2.1 million was recorded in the second quarter and \$0.9 million is expected to be recorded in the third quarter.
- The Company closed a public offering of its common stock in August 2024, resulting in net proceeds of approximately \$31.4 million.

Second Quarter 2024 Financial Results Compared to Prior Year Period

Research and development expenses increased \$3.8 million, or 32%, compared to the three months ended June 30, 2023. Salaries, benefits, and other personnel costs increased \$2.1 million primarily due to severance charges related to the shutdown of the Company's ActoBio subsidiary. Additionally, fees paid to contract research organizations related to the start of the PRGN-2012 confirmatory clinical trial and close out of the PRGN-2012 pivotal clinical trial activities and professional fees incurred related to our manufacturing facility readiness for anticipated BLA submission increased compared to the same period in 2023.

SG&A expenses increased by \$1.0 million, or 11%, compared to the three months ended June 30, 2023. This increase was primarily driven by severance costs incurred related to the suspension of ActoBio operations of \$0.4 million, increased costs associated with PRGN-2012 commercial readiness as well as increased professional fees incurred related to general corporate matters compared to the same period in 2023.

In conjunction with the suspension of ActoBio's operations, the Company recorded \$34.5 million of impairment charges related to goodwill and other

(Amounts in thousands)	June 30, 2024		December 31, 2023	
Assets				
Current assets				
Cash and cash equivalents	\$	9,345	\$	7,578
Short-term investments		10,191		55,277
Receivables				
Trade, net		511		902
Other		505		673
Prepaid expenses and other		3,163		4,325
Total current assets		23,715		68,755
Property, plant and equipment, net		13,451		7,111
Intangible assets, net		5,091		40,701
Goodwill		24,918		26,612
Right-of-use assets		5,550		7,097
Other assets		435		767
Total assets	\$	73,160	\$	151,043
Liabilities and Shareholders' Equity				
Current liabilities				
Accounts payable	\$	4,846	\$	1,726
Accrued compensation and benefits		6,675		8,250
Other accrued liabilities		6,642		6,223
Settlement and Indemnification Accrual		3,213		5,075
Deferred revenue		378		509
Current portion of lease liabilities		1,269		1,202
Total current liabilities		23,023		22,985
Deferred revenue, net of current portion		1,818		1,818
Lease liabilities, net of current portion		5,072		5,895
Deferred tax liabilities		77		1,847
Total liabilities		29,990		32,545
Shareholders' equity				
Common stock		-		-
Additional paid-in capital		2,093,080		2,084,916
Accumulated deficit		(2,047,001)		(1,964,471)
Accumulated other comprehensive loss		(2,909)		(1,947)
Total shareholders' equity		43,170		118,498
Total liabilities and shareholders' equity	\$	73,160	\$	151,043

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

(Amounts in thousands, except share and per share data)	Three Months Ended		Six Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Revenues				
Product revenues	\$ 31	\$ 324	\$ 169	\$ 648
Service revenues	673	1,438	1,592	2,965
Other revenues	13	5	21	5
Total revenues	717	1,767	1,782	3,618
Operating Expenses				
Cost of products and services	1,014	1,697	2,089	3,224
Research and development	15,693	11,874	29,942	24,037
Selling, general and administrative	10,306	9,316	20,457	20,954
Impairment of goodwill	1,630	-	1,630	-
Impairment of other noncurrent assets	32,915	-	32,915	-
Total operating expenses	61,558	22,887	87,033	48,215
Operating loss	(60,841)	(21,120)	(85,251)	(44,597)
Other Income (Expense), Net				
Interest expense	(2)	(136)	(4)	(460)
Interest income	319	828	927	1,460
Other income, net	43	44	80	424

Total other income, net	360	736	1,003	1,424
Loss before income taxes	(60,481)	(20,384)	(84,248)	(43,173)
Income tax benefit	1,689	65	1,718	120
Net loss	\$ (58,792)	\$ (20,319)	\$ (82,530)	\$ (43,053)
Net Loss per share				
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.08)	\$ (0.33)	\$ (0.18)
Weighted average shares outstanding, basic and diluted	252,366,533	248,003,322	250,803,790	240,307,403

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