Graybug Vision Reports Financial Results for the Three and Six Months Ended June 30, 2022, and Recent Corporate Developments

August 11, 2022

BALTIMORE, Aug. 11, 2022 (GLOBE NEWSWIRE) -- Graybug Vision, Inc. (Nasdaq: GRAY), a clinical-stage biopharmaceutical company focused on developing transformative medicines for ocular diseases, today provided an update on recent corporate developments and anticipated milestones, and reported financial results for the three and six months ended June 30, 2022.

Recent Corporate Developments

- **Announced review of strategic alternatives** — On June 28, 2022, Graybug announced that its Board of Directors would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. Alternatives being explored include the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions.
- **Further clinical development is on hold pending outcome of strategic review** — As part of Graybug's previously announced cost-containment measures, all clinical development of GB-102, GB-401, and GB-501 has been put on hold to conserve capital pending outcome of its strategic review.

Financial Results for the Three Months Ended June 30, 2022

Net loss for the quarter ended June 30, 2022 was $8.2 million compared to $7.7 million for the same period in 2021.

Research and development expense for the quarter ended June 30, 2022 was $4.1 million compared to $4.2 million for the same period in 2021. There was little overall change in research and development expense. While clinical trial expense decreased due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021, this decrease was largely offset by an increase in non-clinical outside expense related to the GB-401 program and an increase in consulting fees related to the GB-501 program.

General and administrative expense for the quarter ended June 30, 2022 was $4.2 million compared to $3.6 million for the same period in 2021. The increase was primarily due to an increase in stock-based compensation and an increase in professional services, including legal and accounting.

Financial Results for the Six Months Ended June 30, 2022

Net loss for the six months ended June 30, 2022 was $18.4 million compared to $19.2 million for the same period in 2021.

Research and development expense for the six months ended June 30, 2022 was $10.1 million compared to $10.6 million for the same period in 2021. While clinical trial expenses decreased due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021 and staffing expense also decreased due to severance costs incurred in the first half of 2021, these decreases were mostly offset by the write-off of the in-process research and development intangible asset related to the acquisition of RainBio, Inc in March 2022.

General and administrative expense for the six months ended June 30, 2022 was $8.4 million compared to $8.6 million for the same period in 2021. While general and administrative expense decreased due to the write-off of deposits on fixed asset purchase commitments in March 2021 relating to the GB-102 program, this decrease was largely offset by an increase in stock compensation and an increase in professional services, including legal and accounting.

As of June 30, 2022, the company's cash, cash equivalents, and short-term investments totaled $50.7 million. Management believes Graybug's current cash and investments are sufficient to support its currently planned operations into the fourth quarter of 2023.

About Graybug

Graybug is a clinical-stage biopharmaceutical company focused on developing transformative medicines for ocular diseases. The company's diversified portfolio is designed to treat vision-threatening diseases of the retina, optic nerve, and cornea, by either maintaining effective drug levels in ocular tissues for long periods of time, using innovative technologies, such as injectable sustained-release formulations, or by curing diseases with gene therapies. Graybug's most advanced drug candidate, **GB-102** is a microparticle formulation of a pan-VEGF inhibitor, sunitinib, for the treatment of wet age-related macular degeneration designed for a twice-per-year intravitreal injection. GB-102 has the potential to also benefit patients with diabetic retinopathy. **GB-401** is a first-in-class implant formulation containing a novel prodrug of timolol for the treatment of primary open angle glaucoma (POAG) designed for a twice-per-year intravitreal injection with a proprietary applicator. **GB-501** is an adeno-associated virus (AAV) gene therapy with Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to treat corneal clouding caused by mucopolysaccharidosis type 1 (MPS1), a lysosomal storage disorder. **GB-601** is being developed as a long-acting formulation of a novel cGMP analog to address inherited retinal diseases like retinitis pigmentosa, a group of genetic disorders that involve a loss of cells in the retina. **GB-701** is being developed as a long-acting formulation of a potent factor B inhibitor targeting the complement cascade that plays a role in age-related macular degeneration. Founded in 2011 based on technology licensed from the Johns Hopkins University School of Medicine, Graybug has offices in Redwood City, California and in Baltimore, Maryland. For more information, please visit www.graybug.vision.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform

Act of 1995 including, but not limited to, statements regarding the company's strategic review process, the timing, cost or expense required to pursue any strategic alternative, the ability to successfully consummate one or more strategic transactions on terms that maximize shareholder value, the company's clinical pipeline, its ability to advance GB-102, GB-401, GB-501, GB-601, GB-701 or any future product candidate through preclinical or clinical development, its ability to initiate clinical trials, achieve its anticipated milestones within the timing outlined above or at all, its ability to conduct planned operations within the evolving constraints arising from the COVID-19 pandemic, accurately predict the timing or magnitude of its future cash requirements, the resulting depletion of its cash resources, and the timing, cost, and results of its clinical trials. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties described under the heading "Risk Factors" in the company's annual report on Form 10-K filed for the year ended December 31, 2021, in its subsequent quarterly reports on Form 10-Q, and in the other reports the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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GRAYBUG VISION, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts; unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 4,058	$ 4,166	$ 10,115	$ 10,614
General and administrative	4,243	3,575	8,370	8,615
Total operating expenses	8,301	7,741	18,485	19,229
Loss from operations	(8,301)	(7,741)	(18,485)	(19,229)
Interest income	60	33	95	72
Net loss	(8,241)	(7,708)	(18,390)	(19,157)
Net loss per common share—basic and diluted	$ (0.38)	$ (0.36)	$ (0.86)	$ (0.91)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	21,433,396	21,148,743	21,395,793	21,084,915

GRAYBUG VISION, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2022	December 31, 2021
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 13,872	$ 13,364
Short-term investments	36,817	50,306
Prepaid expenses and other current assets	1,038	3,408
Total current assets	51,727	67,078
Property and equipment, net	1,911	1,981
Operating lease right-of-use asset	384	—
Prepaid expenses and other non-current assets	—	29
Total assets	$ 54,022	$ 69,088
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,014	$ 527
Accrued research and development	463	304
Operating lease liability	398	—
Other current liabilities	2,455	3,226
Total current liabilities	4,330	4,057
Deferred rent, long term portion	—	8
Total liabilities	4,330	4,065
Stockholders' Equity:		
Common stock	2	2

Additional paid-in capital	237,447	234,225
Accumulated deficit	(187,578)	(169,188)
Accumulated other comprehensive loss	(179)	(16)
Total stockholders' equity	49,692	65,023
Total liabilities and stockholders' equity	$ 54,022	$ 69,088