Graybug Vision Reports First Quarter 2022 Financial Results and Recent Corporate Developments

May 10, 2022

BALTIMORE, May 10, 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 quarter ended March 31, 2022.

Recent Corporate Developments

- **Committed to advancing GB-102 into additional wet-AMD clinical trial** — enhanced formulation of GB-102, designed to reduce or eliminate microparticle dispersion, has been developed for an additional Phase 2 trial to further evaluate safety, efficacy and durability demonstrated in the ALTISSIMO trial.
- **Expanded pipeline with novel gene therapy to address rare vision-threatening corneal disease** — platform capabilities diversified with the acquisition of GB-501, a first-in-class gene therapy for corneal clouding associated with mucopolysaccharidosis type 1 (MPS1), an inherited lysosomal storage disorder with very high prevalence of corneal clouding despite existing systemic therapies.
- **Added two early-stage programs to leverage existing ocular sustained-release technologies for treatment of additional retinal disorders** — GB-601, a potential first-in-class, mutation-agnostic long-acting formulation of a cGMP analog to treat patients with inherited retinal diseases, and GB-701, a sustained-release, locally administered ocular formulation of a potent factor B inhibitor as a potential treatment for geographic atrophy.

Anticipated Milestones

- Initiate Phase 2 trial of an enhanced formulation of GB-102 in wet AMD patients in the fourth quarter of 2022.
- Initiate Phase 1/2a trial of GB-401, a proprietary implant formulation containing a novel prodrug of timolol designed for intravitreal injection once every six months in primary open-angle glaucoma patients, in the first quarter of 2023.
- Initiate Phase 1/2a trial of GB-501, an AAV gene therapy for the treatment of MPS1-associated corneal clouding, in the second quarter of 2023.

First Quarter 2022 Financial Results

Net loss for the quarter ended March 31, 2022 was $10.1 million compared to $11.4 million for the same period in 2021.

Research and development expense for the quarter ended March 31, 2022 was $6.1 million compared to $6.4 million for the same period in 2021. There was little overall change in research and development expenses. 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 a reduction in headcount, these decreases were largely offset by the write-off of the in-process research and development intangible asset related to the acquisition of RainBio, Inc.

General and administrative expense for the quarter ended March 31, 2022 was $4.1 million compared to $5.0 million for the same period in 2021. The decrease was primarily due to the write-off of deposits on fixed assets purchase commitments for the quarter ended March 31, 2021, offset in part by an increase in stock-based compensation for the quarter ended March 31, 2022.

As of March 31, 2022, the company's cash, cash equivalents, and short-term investments totaled $55.3 million, compared to $63.7 million as of December 31, 2021. The decrease was primarily due to the loss from operations of $10.2 million. The company'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 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 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 6,057	$ 6,448
General and administrative	4,127	5,040
Total operating expenses	10,184	11,448
Loss from operations	(10,184)	(11,488)
Interest income	35	39
Net loss	(10,149)	(11,449)
Net loss per common share—basic and diluted	$ (0.48)	$ (0.54)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	21,357,773	21,020,378

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

	March 31, 2022	**December 31, 2021**
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 8,360	$ 13,364
Short-term investments	46,920	50,306
Prepaid expenses and other current assets	2,942	3,408
Total current assets	58,222	67,078
Property and equipment, net	1,859	1,981
Operating lease right-of-use asset	476	—
Prepaid expenses and other non-current assets	29	29
Total assets	$ 60,586	$ 69,088
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 541	$ 527
Accrued research and development	1,014	304
Operating lease liability, current	389	—
Other current liabilities	2,284	3,226
Total current liabilities	4,228	4,057
Deferred rent, long term portion	—	8
Operating lease liability, net of current portion	102	—
Total liabilities	4,330	4,065
Stockholders’ Equity:		
Common stock	2	2
Additional paid-in capital	235,767	234,225

Accumulated deficit	(179,337)	(169,188)
Accumulated other comprehensive loss	(176)	(16)
Total stockholders' equity	56,256	65,023
Total liabilities and stockholders' equity	$ 60,586	$ 69,088