Graybug Vision Announces First Quarter 2021 Financial Results and Recent Corporate Developments

May 12, 2021

REDWOOD CITY, Calif., May 12, 2021 (GLOBE NEWSWIRE) -- Graybug Vision, Inc. (Nasdaq: GRAY), a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve, today provided an update on recent corporate developments and reported financial results for the quarter ended March 31, 2021.

Recent Corporate Developments

- **Full-data analysis from 12-month treatment phase of ALTISSIMO Phase 2b trial in wet AMD** — GB-102 1mg has shown competitive durability and anatomical control versus aflibercept; trend in mean BCVA of GB-102 1mg compared to aflibercept driven primarily by a subgroup of patients.
- **Six-month observational trial extension of ALTISSIMO still underway** — 14 of 28 patients enrolled have completed at least five months of the extension period without requiring additional supportive therapy, with six of those having completed all six months.
- **Seeking partner for funding of additional wet AMD clinical trials** — Enhanced formulations of GB-102 being developed and preclinical work progressing in parallel.
- **Clinical focus shifting to advancement of GB-401 implant for glaucoma** — Disclosed development of implant technology for GB-401 with potential application to GB-102.

Anticipated Milestones

- Complete six-month observational trial extension of ALTISSIMO by June 2021, with topline data expected in 3Q 2021.
- Expected to present full results of ALTISSIMO trial at a medical conference in 4Q 2021.
- Submit Investigational New Drug (IND) application for GB-401, an injectable formulation of a beta-adrenergic blocker prodrug, for primary open-angle glaucoma, with a dosing regimen of once every six months or longer, in the first half of 2022.
- Commence a Phase 1 trial for GB-401 implant in glaucoma in the first half of 2022.

First Quarter 2021 Financial Results

Net loss for the quarter ended March 31, 2021 was $11.4 million compared to $7.8 million for the same period in 2020.

Research and development expense for the quarter ended March 31, 2021 was $6.4 million compared to $6.1 million for the same period in 2020. The increase was primarily due to fees incurred upon the cancellation of clinical supply orders for the GB-102 Phase 3 trial and increased compensation costs, offset in part by a reduction in clinical trial expenses due to the completion of the treatment phase of the ALTISSIMO trial in December 2020.

General and administrative expense for the quarter ended March 31, 2021 was $5.0 million compared to $1.7 million for the same period in 2020. The increase in 2021 was primarily due to the write-off of deposits on fixed assets purchase commitments, an increase in stock-based compensation and an increase in headcount, and the increased cost of additional directors and officers insurance as a result of becoming a public company.

As of March 31, 2021, the company's cash, cash equivalents, and short-term investments totaled $85.7 million, compared to $95.0 million as of December 31, 2020. The decrease was primarily due to the loss from operations of $11.5 million. The company's current cash and investments are sufficient to support its currently planned operations into the first half of 2023.

About Graybug

Graybug is a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve. The company's proprietary ocular delivery technologies are designed to maintain effective drug levels in ocular tissue for six months and potentially longer, improving disease management, reducing healthcare burdens and ultimately delivering better clinical outcomes. Graybug's lead product candidate, GB-102, a formulation of the pan-vascular endothelial growth factor (VEGF) inhibitor, sunitinib malate targeting a six-month or longer dosing regimen, inhibits multiple neovascular pathways for the intravitreal treatment of retinal diseases, including wet age-related macular degeneration. Graybug's other product candidates developed using its proprietary technologies also include GB-401, an injectable sustained-release formulation of a beta-adrenergic blocker prodrug, for primary open-angle glaucoma, with a dosing regimen of once every six months or longer, and GB-103, a longer-acting version of GB-102, designed to maintain therapeutic drug levels in the retinal tissue for 12 months with a single injection. Founded in 2011 on the basis of technology licensed from the Johns Hopkins University School of Medicine, Graybug is headquartered in Redwood City, California. 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 identify a partner to advance the development of GB-102 for wet AMD, the timing or outcomes of its interactions with regulatory authorities, its ability to advance GB-102, GB-103, GB-401, or any future product candidate through preclinical or clinical development, its ability to timely secure a partner to fund further development of GB-102 on reasonable terms if at all, its ability to 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, the company’s operating results and use of cash, the company’s operations as a public company, the company’s management and board of directors, 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, 2020, and 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 Statements of Operations
(In thousands, except share and per share amounts; unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 6,448	$ 6,085
General and administrative	5,040	1,711
Total operating expenses	11,488	7,796
Loss from operations	(11,488)	(7,796)
Interest income	39	108
Change in fair value of preferred stock tranche obligation	—	(106)
Net loss	(11,449)	(7,794)
Cumulative dividends on convertible preferred stock	—	(1,299)
Net loss attributable to common stockholders	$ (11,449)	$ (9,093)
Net loss per common share—basic and diluted	$ (0.54)	$ (6.61)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	21,020,378	1,375,177

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

	March 31, 2021	**December 31, 2020**
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,589	$ 33,418
Short-term investments	75,099	61,615
Prepaid expenses and other current assets	3,133	4,207
Total current assets	88,821	99,240
Property and equipment, net	2,002	1,946
Prepaid expenses and other non-current assets	29	608
Total assets	$ 90,852	$ 101,794
Liabilities, Convertible Preferred Stock and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 1,956	$ 2,513
Accrued research and development	2,097	1,356
Other current liabilities	2,225	3,128
Total current liabilities	6,278	6,997
Deferred rent, long term portion	12	11
Total liabilities	6,290	7,008
Commitments and contingencies		
Convertible preferred stock		

Stockholders' Equity:		
Preferred stock	—	—
Common stock	2	2
Additional paid-in capital	229,376	228,155
Accumulated deficit	(144,816)	(133,367)
Accumulated other comprehensive loss	—	(4)
Total stockholders' equity	84,562	94,786
Total liabilities, convertible preferred stock and stockholders' equity	$ 90,852	$ 101,794