Graybug Vision Announces Full Year 2020 Financial Results and Recent Corporate Developments

March 4, 2021

REDWOOD CITY, Calif., March 04, 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 full year ended December 31, 2020.

"We are very pleased with Graybug's achievements in 2020. Amidst a challenging pandemic, we completed our initial public offering and advanced our lead product candidate GB-102 in retinal disease through the treatment phase of its Phase 2b ALTISSIMO trial in wet age-related macular degeneration (wet AMD). I am excited to share that we are now on track to report topline data from our ALTISSIMO trial by the end of this month," said Frederic Guerard, PharmD, Chief Executive Officer of Graybug.

Recent Corporate Developments

- **Completion of 12-month treatment phase of ALTISSIMO trial in wet AMD** — 50 patients out of the 56 initially enrolled completed the 12-month treatment phase of the three-arm, randomized, and masked trial of GB-102 in December 2020. Six patients did not complete the study for reasons unrelated to their treatments. Topline data for this 12-month treatment phase are expected to be announced in March 2021.
- **Initiation of 6-month observational trial extension of ALTISSIMO** — 28 of the 50 patients who completed their Month 12 visit were eligible and agreed to continue masked clinical monitoring until the point at which they require additional supportive therapy, up to a maximum of six months. As of today, 22 patients have successfully completed two months or more of this six-month extension period without the need for further treatment.
- **Named Bettina Maunz as Chief People Officer** — Ms. Maunz is building and leading the human resources function as a member of Graybug's executive team and serves as Head of Communications.

Anticipated Milestones in 2021

- Communicate topline data for the 12-month treatment phase of ALTISSIMO in March 2021, with full results to be presented at a medical conference expected in 3Q 2021.
- Complete 6-month observational trial extension of ALTISSIMO by June 2021, with topline data expected in 3Q 2021.
- Initiate two pivotal Phase 3 trials for GB-102 in patients with wet AMD in the second half of 2021.
- Initiate Phase 2b trial for GB-102 in patients with diabetic macular edema (DME) in the second half of 2021.
- Submit Investigational New Drug (IND) application for GB-401, an injectable depot 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 second half of 2021.
- Commence a Phase 1 trial for GB-401 in the second half of 2021.

Full Year 2020 Financial Results

Net loss for 2020 was $27.5 million compared to $37.0 million for 2019. Net loss for 2020 included a non-cash gain of $2.2 million resulting from the modification and expiration of the liability related to the preferred stock tranche obligation that was permanently eliminated in connection with the company's initial public offering, or IPO, in September 2020. Excluding this gain, the 2020 net loss would have been $29.7 million.

Research and development expense for 2020 was $21.0 million compared to $30.6 million for 2019. The decrease in 2020 was primarily due to the fact that the company did not engage in any primary manufacturing activities in 2020 compared with 2019, during which the company manufactured the clinical supplies for the ALTISSIMO clinical trial that commenced later in the third quarter of 2019.

General and administrative expense for 2020 was $8.9 million compared to $6.9 million for 2019. The increase in 2020 was primarily due to additional professional services, related in part to preparing for and becoming a public company, and the related increased cost of additional D&O insurance.

As of December 31, 2020, the company's cash, cash equivalents, and short-term investments totaled $95.0 million, compared to $36.0 million as of December 31, 2019. The increase was due to the receipt of $92.1 million in net proceeds from the company's IPO. The company's current cash and investments are sufficient to support its planned operations into the first quarter of 2022.

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 microparticle depot 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 is also using its proprietary technologies to develop GB-401, an injectable depot 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 advance GB-102, GB-103, GB-401, or any future product candidate through clinical development, 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 cash positions, the company's operations as a public company, the company's management and board of directors, and the timing 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 quarterly report on Form 10-Q for the three months ended September 30, 2020, its annual report on Form 10-K to be 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)
(2020 unaudited)

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 20,962	$ 30,580
General and administrative	8,870	6,922
Total operating expenses	29,832	37,502
Loss from operations	(29,832)	(37,502)
Interest income	143	393
Change in fair value of preferred stock tranche obligation	2,158	72
Net loss	(27,531)	(37,037)
Cumulative dividends on convertible preferred stock	(7,189)	(7,055)
Net loss attributable to common stockholders	$ (34,720)	$ (44,092)
Net loss per common share—basic and diluted	$ (5.25)	$ (33.41)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	6,618,445	1,319,912

GRAYBUG VISION, INC.
Condensed Balance Sheets
(In thousands)
(2020 unaudited)

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 33,418	$ 15,870
Short-term investments	61,615	20,086
Prepaid expenses and other current assets	4,207	315
Total current assets	99,240	36,271
Property and equipment, net	1,946	1,975
Prepaid expenses and other non-current assets	608	2,414
Total assets	$ 101,794	$ 40,660
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		

Accounts payable	$ 2,513	$ 4,636
Accrued research and development	1,356	2,333
Other current liabilities	3,128	3,124
Preferred stock tranche obligation	—	2,158
Total current liabilities	6,997	12,251
Deferred rent, long term portion	11	—
Total liabilities	7,008	12,251
Commitments and contingencies		
Convertible preferred stock	—	131,363
Stockholders' Equity (Deficit):		
Preferred stock	—	—
Common stock	2	—
Additional paid-in capital	228,155	2,879
Accumulated deficit	(133,367)	(105,836)
Accumulated other comprehensive (loss) income	(4)	3
Total stockholders' equity (deficit)	94,786	(102,954)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 101,794	$ 40,660