UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 10, 2022

Graybug Vision, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39538**	**45-2120079**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
203 Redwood Shores Parkway, Suite 620 Redwood City, California		**94065**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (650) 487-2800

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	GRAY	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2022, Graybug Vision, Inc. issued a press release announcing its financial results for the full year ended December 31, 2021. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Graybug Vision, Inc. regarding its full year 2021 financial results, dated March 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GRAYBUG VISION, INC.

Date: March 10, 2022

By: /s/ Frederic Guerard

Frederic Guerard, Pharm.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Graybug Vision Reports Full Year 2021 Financial Results and Recent Corporate Developments

Management to host R&D Day for investors on March 30, 2022 at 11 a.m. ET

BALTIMORE, March 10, 2022 - Graybug Vision, Inc. (Nasdaq: GRAY), a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of ocular diseases, today provided an update on recent corporate developments and reported financial results for the full year ended December 31, 2021.

“Graybug made important progress in advancing its retina (GB-102) and glaucoma (GB-401) programs in 2021. We developed a new enhanced formulation of GB-102 that capitalizes on the duration demonstrated by our Phase 2b ALTISSIMO trial, where half of patients were controlled for six months after a single intravitreal (IVT) injection,” said Frederic Guerard, PharmD, Chief Executive Officer of Graybug Vision. “We are in ongoing discussions to partner GB-102 for its next clinical trial, while finalizing the preparation of an IND application for our GB-401 implant formulation, and pursuing other novel ocular therapeutics.”

Recent Corporate Developments

- **Completed ALTISSIMO Phase 2b trial in wet age-related macular degeneration (wet AMD)** — Final results confirm unprecedented duration in an aflibercept-controlled clinical trial. GB-102 1mg demonstrated six-month duration in 48% of patients and 12 months in 30% of patients, with well-controlled central subretinal thickness (CST), as compared to aflibercept. Best corrected visual acuity (BCVA) of patients in the GB-102 1mg arm trended lower than aflibercept’s, mainly driven by 4 subjects. These subjects had a combination of high anti-VEGF need prior to enrollment, particle dispersion during the study, or adverse events unrelated to the drug, which we expect to address in the next trial with optimized inclusion and rescue criteria, and our new enhanced formulation.

- **Ongoing partnering discussions to support funding of additional GB-102 wet-AMD clinical trials** — New enhanced formulation of GB-102 to further reduce or eliminate microparticle dispersion has been developed, and design of future Phase 2 trial to evaluate safety, efficacy, and durability has been finalized.

- **Developed lead GB-401 formulation and custom pre-loaded applicator —** Expanded biodegradable polymer platform technology with implant formulation of GB-401, which has the potential to be administered IVT once every six months with a pre-loaded applicator to reduce elevated intraocular pressure in glaucoma patients, is currently in a repeat-dose GLP-tox study.

- **Pursuing expansion of pipeline with focus on early-stage novel therapeutics addressing unmet ophthalmic needs** — In-licensing efforts targeted at capital-efficient

development opportunities are expected to both leverage and expand current platform technologies.

Anticipated Milestones

- Enhanced GB-102 formulation ready for Phase 2 trial in patients with wet AMD as soon as second half of 2022.
- Initiate GB-401, a proprietary implant formulation of a beta-adrenergic receptor inhibitor designed for IVT injection once every six months, Phase 1 trial in first half 2023.

Full Year 2021 Financial Results

Net loss for 2021 was $35.8 million compared to $27.5 million for 2020. 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 2021 was $18.9 million compared to $21.0 million for 2020. The decrease in 2021 was primarily due to a reduction in clinical trial expenses due to the completion of the treatment phase of the GB-102 Phase 2b ALTISSIMO clinical trial in December 2020, offset in part by an increase in compensation costs.

General and administrative expense for 2021 was $17.0 million compared to $8.9 million for 2020. The increase in 2021 was primarily due to a $2.8 million increase in stock-based compensation, a $1.8 million increase in the cost of directors and officers insurance as a result of becoming a public company and a $1.3 million write-off of deposits on fixed assets purchase commitments.

As of December 31, 2021, the company's cash, cash equivalents, and short-term investments totaled $63.7 million, compared to $95.0 million as of December 31, 2020. The decrease was primarily due to our net loss in 2021 of $35.8 million. The company's current cash and investments are sufficient to support its planned operations into the second half of 2023.

R&D Day for Investors

Management plans to host an Investor R&D Day on March 30, 2022 from 11 a.m. to 12:45 p.m. ET. The meeting will feature updates on the company's advancing pipeline of transformative medicines for the treatment of ocular diseases. Speakers will include Graybug management and key opinion leaders in ophthalmology. A link to attendee registration and additional details about the meeting will be coming soon and will be made available in the Investors and Media section of the company's website at https://investors.graybug.vision/news-events/events-presentations.

About Graybug

Graybug is a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of ocular diseases. 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, a proprietary implant formulation of a beta-adrenergic blocker prodrug, for primary open-angle glaucoma, with a dosing regimen of once every six months. Founded in 2011 on the basis of technology licensed from the Johns Hopkins University School of Medicine, with offices in Baltimore, Maryland, and 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 timely identify a partner to fund further development of GB-102 for wet AMD on reasonable terms if at all, its ability to successfully execute one or more other licensing arrangements, the timing or outcomes of its interactions with regulatory authorities, its ability to advance GB-102, GB-401, or any future product candidate through preclinical or 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 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 quarterly report on Form 10-Q for the three months ended September 30, its annual report on Form 10-K to be filed for the year ended December 31, 2021, and 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)
(2021 unaudited)

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 18,903	$ 20,962
General and administrative	17,044	8,870
Total operating expenses	35,947	29,832
Loss from operations	(35,947)	(29,832)
Interest income	126	143
Change in fair value of preferred stock tranche obligation	—	2,158
Net loss	(35,821)	(27,531)
Cumulative dividends on convertible preferred stock	—	(7,189)
Net loss attributable to common stockholders	$ (35,821)	$ (34,720)
Net loss per common share—basic and diluted	$ (1.69)	$ (5.25)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	21,199,291	6,618,445

GRAYBUG VISION, INC.
Condensed Balance Sheets
(In thousands)
(2021 unaudited)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 13,364	$ 33,418
Short-term investments	50,306	61,615
Prepaid expenses and other current assets	3,408	4,207
Total current assets	67,078	99,240
Property and equipment, net	1,981	1,946
Prepaid expenses and other non-current assets	29	608
Total assets	$ 69,088	$ 101,794
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 527	$ 2,513
Accrued research and development	304	1,356
Other current liabilities	3,226	3,128
Total current liabilities	4,057	6,997
Deferred rent, long term portion	8	11
Total liabilities	4,065	7,008
Commitments and contingencies		
Stockholders' Equity:		
Common stock	2	2
Additional paid-in capital	234,225	228,155
Accumulated deficit	(169,188)	(133,367)
Accumulated other comprehensive loss	(16)	(4)
Total stockholders' equity	65,023	94,786
Total liabilities and stockholders' equity	$ 69,088	$ 101,794