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): August 11, 2021

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.)**

275 Shoreline Drive, Suite 450 **Redwood City, California** **(Address of principal executive offices)**	**94065** **(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 August 11, 2021, Graybug Vision, Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 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, dated August 11, 2021

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: August 11, 2021

By: /s/ Frederic Guerard
Frederic Guerard, Pharm.D.
Chief Executive Officer
(Principal Executive Officer)

Graybug Vision, Inc.
275 Shoreline Drive, Suite 450
Redwood City, CA 94065
www.graybug.vision

Graybug Vision Announces Financial Results for the Three and Six Months Ended June 30, 2021, and Recent Corporate Developments

REDWOOD CITY, Calif., August 11, 2021 - 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 three and six months ended June 30, 2021.

Recent Corporate Developments

- **Completed six-month extended observation period of ALTISSIMO Phase 2b trial in wet AMD**— 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 required additional supportive therapy, up to a maximum of six months. 25 of those patients completed their first visit at Month 13. In June 2021, the last patient exited the extension period, with 60% of GB-102 1 mg patients requiring no supportive therapy during the six-month extension period.
- **Seeking partner for funding of additional wet AMD clinical trials**— Enhanced formulations of GB-102 are being developed to further reduce or eliminate microparticle dispersion, and pre-clinical development is progressing in parallel.
- **Pursuing expansion of pipeline with focus on early-stage novel therapeutics addressing unmet needs**— In-licensing efforts targeted at capital-efficient development opportunities are expected to both leverage and expand current platform technologies.

Anticipated Milestones

- Provide topline data analysis of ALTISSIMO six-month extended observation period in September 2021.
- Present 12-month ALTISSIMO Phase 2b clinical trial data at the American Academy of Ophthalmology (AAO) meeting, November 12-15, 2021.

Financial Results for the Three Months Ended June 30, 2021

Net loss for the quarter ended June 30, 2021 was $7.7 million, compared to $5.9 million for the same period in 2020.

Research and development expense for the quarter ended June 30, 2021 was $4.2 million, compared to $4.6 million for the same period in 2020. The decrease was primarily due to a

reduction in clinical trial expenses due to the completion of the treatment phase of the GB-102 Phase 2b clinical trial in December 2020, offset in part by an increase in compensation costs.

General and administrative expense for the quarter ended June 30, 2021 was $3.6 million, compared to $1.4 million for the same period in 2020. The increase in 2021 was primarily due to a $0.8 million increase in stock-based compensation, a $0.6 million increase in the cost of directors and officers insurance as a result of becoming a public company, and an increase in headcount.

Financial Results for the Six Months Ended June 30, 2021

Net loss for the six months June 30, 2021 was $19.2 million, compared to $13.7 million for the same period in 2020.

Research and development expense for the six months ended June 30, 2021 was $10.6 million, compared to $10.7 million for the same period in 2020. While there was little overall change in research and development expenses, clinical trial expenses decreased in 2021 due to the completion of the treatment phase of the GB-102 Phase 2b clinical trial in December 2020, which was largely offset by fees incurred upon the cancellation of clinical supply orders for the GB-102 Phase 3 clinical trial and an increase in compensation costs.

General and administrative expense for the six months ended June 30, 2021 was $8.6 million, compared to $3.1 million for the same period in 2020. The increase in 2021 was primarily due to a $1.5 million increase in stock-based compensation, a $1.3 million increase in the cost of directors and officers insurance as a result of becoming a public company, a $1.3 million write-off of deposits on fixed assets purchase commitments, and an increase in headcount.

As of June 30, 2021, the company’s cash and cash equivalents, and short-term and long-term investments totaled $78.2 million. Management believes the company’s current cash and investments are sufficient to support its currently planned operations into 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 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-103, 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 annual report on Form 10-K filed for the year ended December 31, 2020, 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 Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 4,166	$ 4,632	$ 10,614	$ 10,717
General and administrative	3,575	1,408	8,615	3,119
Total operating expenses	7,741	6,040	19,229	13,836
Loss from operations	(7,741)	(6,040)	(19,229)	(13,836)
Interest income	33	9	72	117
Change in fair value of preferred stock tranche obligation	—	162	—	56
Net loss	(7,708)	(5,869)	(19,157)	(13,663)
Cumulative dividends on convertible preferred stock	—	(3,494)	—	(4,793)
Net loss attributable to common stockholders	$ (7,708)	$ (9,363)	$ (19,157)	$ (18,456)
Net loss per common share—basic and diluted	$ (0.36)	$ (6.79)	$ (0.91)	$ (13.40)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	21,148,743	1,379,644	21,084,915	1,377,431

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

	June 30, 2021	December 31, 2020 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 7,864	$ 33,418
Short-term investments	65,722	61,615
Prepaid expenses and other current assets	2,465	4,207
Total current assets	76,051	99,240
Property and equipment, net	2,006	1,946
Prepaid expenses and other non-current assets	136	608
Long-term investments	4,628	—
Total assets	$ 82,821	$ 101,794
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,101	$ 2,513
Accrued research and development	396	1,356
Other current liabilities	1,644	3,128
Total current liabilities	4,141	6,997
Deferred rent, long term portion	13	11
Total liabilities	4,154	7,008
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock	—	—
Common stock	2	2
Additional paid-in capital	231,183	228,155
Accumulated deficit	(152,524)	(133,367)
Accumulated other comprehensive loss	6	(4)
Total stockholders' equity	78,667	94,786
Total liabilities and stockholders' equity	$ 82,821	$ 101,794