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): November 12, 2020

GRAYBUG VISION, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39538**	**452120079**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
275 Shoreline Drive, Suite 450 Redwood City, CA		**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, par value $0.0001 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.

(a) If a registrant, or any person acting on its behalf, makes any public announcement or release (including any update of an earlier announcement or release) disclosing material non-public information regarding the registrant's results of operations or financial condition for a completed quarterly or annual fiscal period, the registrant shall disclose the date of the announcement or release, briefly identify the announcement or release and include the text of that announcement or release as an exhibit.

(b) A Form 8-K is not required to be furnished to the Commission under this Item 2.02 in the case of disclosure of material non-public information that is disclosed orally, telephonically, by webcast, by broadcast, or by similar means if:

(1) the information is provided as part of a presentation that is complementary to, and initially occurs within 48 hours after, a related, written announcement or release that has been furnished on Form 8-K pursuant to this Item 2.02 prior to the presentation;

(2) the presentation is broadly accessible to the public by dial-in conference call, by webcast, by broadcast or by similar means;

(3) the financial and other statistical information contained in the presentation is provided on the registrant's website, together with any information that would be required under 17 CFR 244.100; and

(4) the presentation was announced by a widely disseminated press release, that included instructions as to when and how to access the presentation and the location on the registrant's website where the information would be available.

Item 9.01 Financial Statements and Exhibits.

List below the financial statements, pro forma financial information and exhibits, if any, filed as a part of this report.

(a) Financial statements of businesses acquired.

(1) For any business acquisition required to be described in answer to Item 2.01 of this form, financial statements of the business acquired shall be filed for the periods specified in Rule 3-05(b) of Regulation S-X (17 CFR 210.3-05(b)) or Rule 8-04(b) of Regulation S-X (17 CFR 210.8-04(b)) for smaller reporting companies.

(2) The financial statements shall be prepared pursuant to Regulation S-X except that supporting schedules need not be filed. A manually signed accountant's report should be provided pursuant to Rule 2-02 of Regulation S-X (17 CFR 210.2-02).

(3) With regard to the acquisition of one or more real estate properties, the financial statements and any additional information specified by Rule 3-14 of Regulation S-X (17 CFR 210.3-14) or Rule 8-06 of Regulation S-X (17 CFR 210.8-06) for smaller reporting companies.

(4) Financial statements required by this item may be filed with the initial report, or by amendment not later than 71 calendar days after the date that the initial report on Form 8-K must be filed. If the financial statements are not included in the initial report, the registrant should so indicate in the Form 8-K report and state when the required financial statements will be filed. The registrant may, at its option, include unaudited financial statements in the initial report on Form 8-K.

(b) Pro forma financial information.

(1) For any transaction required to be described in answer to Item 2.01 of this form, furnish any pro forma financial information that would be required pursuant to Article 11 of Regulation S-X (17 CFR 210) or Rule 8-05 of Regulation S-X (17 CFR 210.8-05) for smaller reporting companies.

(2) The provisions of paragraph (a)(4) of this Item 9.01 shall also apply to pro forma financial information relative to the acquired business.

(c) Shell company transactions. The provisions of paragraph (a)(4) and (b)(2) of this Item shall not apply to the financial statements or pro forma financial information required to be filed under this Item with regard to any transaction required to be described in answer to Item 2.01 of this Form by a registrant that was a shell company, other than a business combination related shell company, as those terms are defined in Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2), immediately before that transaction. Accordingly, with regard to any transaction required to be described in answer to Item 2.01 of this Form by a registrant that was a shell company, other than a business combination related shell company, immediately before that transaction, the financial statements and pro forma

financial information required by this Item must be filed in the initial report. Notwithstanding General Instruction B.3. to Form 8-K, if any financial statement or any financial information required to be filed in the initial report by this Item 9.01(c) is previously reported, as that term is defined in Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2), the registrant may identify the filing in which that disclosure is included instead of including that disclosure in the initial report.

(d) Exhibits. The exhibits shall be deemed to be filed or furnished, depending on the relevant item requiring such exhibit, in accordance with the provisions of Item 601 of Regulation S-K (17 CFR 229.601)and Instruction B.2 to this form.

Exhibit Number	Description
99.1*	Press Release dated November 12, 2020

* Filed herewith.

SIGNATURES

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 thereunto duly authorized.

Company Name

Date: November 12, 2020

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

Exhibit 99.1

Graybug Vision Announces Financial Results for the Three and Nine Months Ended September 30, 2020 and Recent Corporate Developments

REDWOOD CITY, Calif., November 12, 2020 - 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 nine months ended September 30, 2020.

“Graybug continues to make important progress in advancing its programs in retinal diseases and glaucoma. We have now completed our initial public offering, raising over $92 million in net proceeds, which provides us with significant financial strength to execute our business strategy,” said Frederic Guerard, PharmD, Chief Executive Officer of Graybug Vision. “We are particularly excited about our lead product candidate, GB-102, currently in Phase 2b clinical development, which seeks to reduce the current need for up to 12 intravitreal injections per year to two or, potentially, fewer treatments per year,” Fred concluded.

Recent Corporate Developments

- **Successfully completed initial public offering** — On September 24, 2020, Graybug priced its upsized IPO of 5,625,000 shares of common stock at a public offering price of $16.00 per share, following which the underwriters exercised their option to purchase an additional 843,750 shares, resulting in total gross proceeds of $103.5 million.
- **Completed GB-102 Phase 2a safety trial in macular edema** — Final safety and tolerability results confirm the satisfactory safety profile of GB-102 1mg with no ocular serious adverse events or dose-limiting toxicity reported.
- **Named three new members to the Board of Directors** — Graybug appointed Christina Ackermann, Eric Bjerkholt, and Julie Eastland to its Board of Directors in September 2020. Each new member brings deep expertise as leaders in health care and biotechnology, as well as significant strategic and operational experience, to the board.
- **Named Robert Breuil as Chief Financial Officer** — In September 2020, Robert Breuil, joined Graybug. He brings over 20 years of experience in the biopharmaceutical and drug delivery sectors, as well as experience serving as the CFO of three public companies since 2003.
- **Leading ophthalmologists and retina experts joined Scientific Advisory Board** — In August 2020, Graybug appointed a distinguished group of ophthalmic thought leaders to provide external scientific counsel on the company’s research and development programs aiming to address critical unmet medical needs in retinal diseases and glaucoma. Graybug’s Scientific Advisory Board members are David S. Boyer, M.D., Frederick L. Ferris III, M.D.,

Jeffrey S. Heier, M.D., Arshad M. Khanani, M.D., M.A., Carl D. Regillo, M.D., F.A.C.S., and Rishi P. Singh, M.D.

Anticipated Milestones in 2021

- Complete GB-102 Phase 2b ALTISSIMO trial in patients with wet age-related macular degeneration (wet AMD), with topline data expected in the first half of 2021.
- Initiate two pivotal GB-102 Phase 3 trials in patients with wet AMD in the second half of 2021.
- Initiate GB-102 Phase 2b trial 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.

Financial Results for the Three Months Ended September 30, 2020

As of September 30, 2020, Graybug's cash and investments totaled $95.0 million, compared to $36.0 million as of December 31, 2019. The increase was due to the receipt of $79.5 million in net proceeds from Graybug's IPO, completed in September 2020. In October 2020, the underwriters exercised their over-allotment option resulting in additional net proceeds of $12.6 million, resulting in total net proceeds from the offering of $92.1 million.

Net loss for the quarter ended September 30, 2020 was $4.7 million compared to $10.2 million for the third quarter ended September 30, 2019. Net loss for the quarter ended September 30, 2020 included a non-cash gain of $2.1 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 IPO. Excluding this amount, our net loss would have been $6.8 million.

Research and development expense for the third quarter of 2020 was $4.8 million compared to $8.4 million for the third quarter of 2019. The higher level of expense in the third quarter of 2019 was primarily due to the manufacturing of clinical supplies for the ALTISSIMO clinical trial that commenced later in the third quarter of 2019.

General and administrative expense for the third quarter of 2020 was $2.1 million compared to $2.0 million for the third quarter of 2019.

Financial Results for the Nine Months Ended September 30, 2020

Net loss for the nine months ended September 30, 2020 was $18.4 million, compared to $26.8 million for the same period in 2019. The decrease was primarily due to a $7.1 million decrease in research and development expense and the non-cash gain of $2.2 million resulting primarily from the modification and expiration of the liability related to the preferred stock tranche obligation, partially offset by a $0.8 million increase in general and administrative expense.

Research and development expense for the nine months ended September 30, 2020 was $15.5 million, compared to $22.6 million for the same period in 2019. The was primarily due to the completion of manufacturing of all clinical supplies required for the commencement of our Phase 2b, or ALTISSIMO, trial for GB-102 during 2019. We did not engage in any primary manufacturing activities in the nine-month period ended September 30, 2020.

General and administrative expenses for the nine months ended September 30, 2020 was $5.2 million, compared to $4.4 million for the same period in 2019. The increase was primarily due to additional professional services related in part to the preparation for our IPO.

The change in fair value of preferred stock tranche obligation for the nine months ended September 30, 2020 relates to the fair value adjustments of $2.2 million primarily due to the $2.1 million gain recognized in connection with our IPO. In September 2020, the preferred stock tranche obligation expired upon the effectiveness of the registration statement for our IPO, resulting in a corresponding elimination of the associated liability.

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, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,757	$ 8,403	$ 15,474	$ 22,570
General and administrative	2,064	1,962	5,183	4,404
Total operating expenses	6,821	10,365	20,657	26,974
Loss from operations	(6,821)	(10,365)	(20,657)	(26,974)
Interest income	3	160	120	211
Change in fair value of preferred stock tranche obligation	2,102	—	2,158	—
Net loss	(4,716)	(10,205)	(18,379)	(26,763)
Cumulative dividends on convertible preferred stock	(2,396)	(2,048)	(7,189)	(4,633)
Net loss attributable to common stockholders	$ (7,112)	$ (12,253)	$ (25,568)	$ (31,396)
Net loss per common share—basic and diluted	$ (2.52)	$ (9.30)	$ (13.74)	$ (24.10)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	2,818,349	1,317,497	1,861,229	1,302,687

GRAYBUG VISION, INC.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 94,968	$ 15,870
Short-term investments	—	20,086
Prepaid expenses and other current assets	138	315
Total current assets	95,106	36,271
Property and equipment, net	1,788	1,975
Prepaid expenses and other non-current assets	1,491	2,414
Total assets	$ 98,385	$ 40,660
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,562	$ 4,636
Accrued research and development	1,023	2,333
Other current liabilities	2,156	3,124
Preferred stock tranche obligation	—	2,158
Total current liabilities	7,741	12,251
Deferred rent, long term portion	10	—
Total liabilities	7,751	12,251
Commitments and contingencies		
Convertible preferred stock	—	131,363
Stockholders' Equity (Deficit):		
Common stock	2	—
Additional paid-in capital	214,847	2,879
Accumulated deficit	(124,215)	(105,836)
Accumulated other comprehensive income	—	3
Total stockholders' equity (deficit)	90,634	(102,954)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 98,385	$ 40,660