# 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 5, 2021**

# 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 March 4, 2021 |

* 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: March 5, 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

**Exhibit 99.1**

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

**REDWOOD CITY, Calif.,** March 4, 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 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.

**Investor Contact**
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(650) 487-2409

**Media Contact**
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(404) 384-0067

**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 |