# 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, 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**<br>**Redwood City, California**<br>**(Address of principal executive offices)** | **94065**<br>**(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, 2022, Graybug Vision, Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 2022. 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, 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: August 11, 2022

By: /s/ Frederic Guerard

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

Graybug Vision, Inc.
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Suite North 200 (N200)
Baltimore, MD 21224
www.graybug.vision

**Exhibit 99.1**

# Graybug Vision Reports Financial Results for the Three and Six Months Ended June 30, 2022, and Recent Corporate Developments

**BALTIMORE, August 11, 2022** - Graybug Vision, Inc. (Nasdaq: GRAY), a clinical-stage biopharmaceutical company focused on developing transformative medicines for ocular diseases, today provided an update on recent corporate developments and anticipated milestones, and reported financial results for the three and six months ended June 30, 2022.

## Recent Corporate Developments

- **Announced review of strategic alternatives** — On June 28, 2022, Graybug announced that its Board of Directors would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. Alternatives being explored include the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions.
- **Further clinical development is on hold pending outcome of strategic review** — As part of Graybug's previously announced cost-containment measures, all clinical development of GB-102, GB-401, and GB-501 has been put on hold to conserve capital pending outcome of its strategic review.

## Financial Results for the Three Months Ended June 30, 2022

Net loss for the quarter ended June 30, 2022 was $8.2 million compared to $7.7 million for the same period in 2021.

Research and development expense for the quarter ended June 30, 2022 was $4.1 million compared to $4.2 million for the same period in 2021. There was little overall change in research and development expense. While clinical trial expense decreased due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021, this decrease was largely offset by an increase in non-clinical outside expense related to the GB-401 program and an increase in consulting fees related to the GB-501 program.

General and administrative expense for the quarter ended June 30, 2022 was $4.2 million compared to $3.6 million for the same period in 2021. The increase was primarily due to an increase in stock-based compensation and an increase in professional services, including legal and accounting.

**Financial Results for the Six Months Ended June 30, 2022**

Net loss for the six months ended June 30, 2022 was $18.4 million compared to $19.2 million for the same period in 2021.

Research and development expense for the six months ended June 30, 2022 was $10.1 million compared to $10.6 million for the same period in 2021. While clinical trial expenses decreased due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021 and staffing expense also decreased due to severance costs incurred in the first half of 2021, these decreases were mostly offset by the write-off of the in-process research and development intangible asset related to the acquisition of RainBio, Inc in March 2022.

General and administrative expense for the six months ended June 30, 2022 was $8.4 million compared to $8.6 million for the same period in 2021. While general and administrative expense decreased due to the write-off of deposits on fixed asset purchase commitments in March 2021 relating to the GB-102 program, this decrease was largely offset by an increase in stock compensation and an increase in professional services, including legal and accounting.

As of June 30, 2022, the company's cash, cash equivalents, and short-term investments totaled $50.7 million. Management believes Graybug's current cash and investments are sufficient to support its currently planned operations into the fourth quarter of 2023.

**About Graybug**

Graybug is a clinical-stage biopharmaceutical company focused on developing transformative medicines for ocular diseases. The company's diversified portfolio is designed to treat vision-threatening diseases of the retina, optic nerve, and cornea, by either maintaining effective drug levels in ocular tissues for long periods of time, using innovative technologies, such as injectable sustained-release formulations, or by curing diseases with gene therapies. Graybug's most advanced drug candidate, **GB-102** is a microparticle formulation of a pan-VEGF inhibitor, sunitinib, for the treatment of wet age-related macular degeneration designed for a twice-per-year intravitreal injection. GB-102 has the potential to also benefit patients with diabetic retinopathy. **GB-401** is a first-in-class implant formulation containing a novel prodrug of timolol for the treatment of primary open angle glaucoma (POAG) designed for a twice-per-year intravitreal injection with a proprietary applicator. **GB-501** is an adeno-associated virus (AAV) gene therapy with Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to treat corneal clouding caused by mucopolysaccharidosis type 1 (MPS1), a lysosomal storage disorder. **GB-601** is being developed as a long-acting formulation of a novel cGMP analog to address inherited retinal diseases like retinitis pigmentosa, a group of genetic disorders that involve a loss of cells in the retina. **GB-701** is being developed as a long-acting formulation of a potent factor B inhibitor targeting the complement cascade that plays a role in age-related macular degeneration. Founded in 2011 based on technology licensed from the Johns Hopkins University School of Medicine, Graybug has offices in Redwood City, California and in Baltimore, Maryland. 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 strategic review process, the timing, cost or expense required to pursue any strategic alternative, the ability to successfully consummate one or more strategic transactions on terms that maximize shareholder value, the company's clinical pipeline, its ability to advance GB-102, GB-401, GB-501, GB-601, GB-701 or any future product

candidate through preclinical or clinical development, its ability to initiate clinical trials, 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, accurately predict the timing or magnitude of its future cash requirements, the resulting depletion of its cash resources, 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, 2021, 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 Consolidated Statements of Operations**
**(In thousands, except share and per share amounts; unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 4,058 | $ 4,166 | $ 10,115 | $ 10,614 |
| General and administrative | 4,243 | 3,575 | 8,370 | 8,615 |
| Total operating expenses | 8,301 | 7,741 | 18,485 | 19,229 |
| Loss from operations | (8,301) | (7,741) | (18,485) | (19,229) |
| Interest income | 60 | 33 | 95 | 72 |
| Net loss | (8,241) | (7,708) | (18,390) | (19,157) |
| Net loss per common share—basic and diluted | $ (0.38) | $ (0.36) | $ (0.86) | $ (0.91) |
| Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted | 21,433,396 | 21,148,743 | 21,395,793 | 21,084,915 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| | (unaudited) | (audited) |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,872 | $ 13,364 |
| Short-term investments | 36,817 | 50,306 |
| Prepaid expenses and other current assets | 1,038 | 3,408 |
| Total current assets | 51,727 | 67,078 |
| Property and equipment, net | 1,911 | 1,981 |
| Operating lease right-of-use asset | 384 | — |
| Prepaid expenses and other non-current assets | — | 29 |
| Total assets | $ 54,022 | $ 69,088 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,014 | $ 527 |
| Accrued research and development | 463 | 304 |
| Operating lease liability | 398 | — |
| Other current liabilities | 2,455 | 3,226 |
| Total current liabilities | 4,330 | 4,057 |
| Deferred rent, long term portion | — | 8 |
| Total liabilities | 4,330 | 4,065 |
| Stockholders' Equity: | | |
| Common stock | 2 | 2 |
| Additional paid-in capital | 237,447 | 234,225 |
| Accumulated deficit | (187,578) | (169,188) |
| Accumulated other comprehensive loss | (179) | (16) |
| Total stockholders' equity | 49,692 | 65,023 |
| Total liabilities and stockholders' equity | $ 54,022 | $ 69,088 |