

**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 10, 2022

Graybug Vision, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39538
(Commission
File Number)

45-2120079
(I.R.S. Employer
Identification No.)

203 Redwood Shores, Suite 620
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 November 10, 2022, Graybug Vision, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 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 November 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: November 10, 2022

By: /s/ Frederic Guerard

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



Graybug Vision, Inc.
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www.graybug.vision

**Graybug Vision Reports Financial Results for the Three
and Nine Months Ended September 30, 2022**

REDWOOD CITY, Calif., November 10, 2022 - Graybug Vision, Inc. (Nasdaq: GRAY) (“Graybug” or the “Company”), a clinical-stage biopharmaceutical company focused historically on developing transformative medicines for ocular diseases, today reported financial results for the three and nine months ended September 30, 2022.

Financial Results for the Three Months Ended September 30, 2022

Net loss for the quarter ended September 30, 2022 was \$9.8 million compared to \$8.0 million for the same period in 2021.

Research and development expense for the quarter ended September 30, 2022 was \$3.2 million compared to \$4.0 million for the same period in 2021. The decrease was primarily due to the August 2022 decision to terminate 20 of its 28 employees and wind-down the GB-102 and GB-401 research and development programs.

Restructuring, impairment and other costs of terminated programs for the quarter ended September 30, 2022 were \$2.4 million. This charge results from the termination of all development activities relating to the GB-102 and GB-401 programs and comprises impairment of capital equipment, severance and termination benefits, and other restructuring costs.

General and administrative expense for the quarter ended September 30, 2022 was \$4.3 million compared to \$4.0 million for the same period in 2021. The increase was primarily due to an increase in stock-based compensation.

Financial Results for the Nine Months Ended September 30, 2022

Net loss for the nine months ended September 30, 2022 was \$28.2 million compared to \$27.1 million for the same period in 2021.

Research and development expense for the nine months ended September 30, 2022 was \$13.4 million compared to \$14.6 million for the same period in 2021. The decrease was primarily due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021 and a decrease in personnel costs due to severance expense incurred in the first half of 2021, offset in part by a \$2.2 million increase due to in-process research and development related to the March 2022 acquisition of RainBio, Inc., and an increase in nonclinical expense related to the since-terminated GB-401 program.

General and administrative expense for the nine months ended September 30, 2022 was \$12.7 million compared to \$12.6 million for the same period in 2021. While general and administrative expenses remained essentially unchanged, the March 2021 decrease in the write-off of deposits on fixed assets purchase commitments was largely offset by an increase in stock-based compensation and an increase in professional services expenses, primarily related to legal and accounting.

As of September 30, 2022, the Company's cash, cash equivalents, and short-term investments totaled \$43.6 million. Subject to the outcome of the previously announced strategic review, which is still ongoing, management believes Graybug's current cash and investments are sufficient to support its currently planned operations beyond 2023.

About Graybug

Graybug has historically been a clinical-stage biopharmaceutical company focused on developing transformative medicines for ocular diseases. In August 2022, the Company announced that it had terminated all activities related to its two lead development programs: **GB-102**, a microparticle formulation of a pan-VEGF inhibitor, sunitinib, for the treatment of wet age-related macular degeneration, and **GB-401**, an implant formulation containing a novel prodrug of timolol for the treatment of primary open angle glaucoma (POAG). The Company's two remaining product candidates are both at the preclinical or earlier stage: **GB-501** is an adeno-associated virus (AAV) gene therapy with Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) being developed to treat corneal clouding caused by mucopolysaccharidosis type 1 (MPS1), a lysosomal storage disorder, and **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 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, its ability to advance GB-501, GB-701, or any future product candidate through preclinical or clinical development, achieve its anticipated milestones, license or sell any of its remaining product candidates, or accurately predict the timing or magnitude of its future cash requirements and the resulting depletion of its cash resources. 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.

Investor Contact

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GRAYBUG VISION, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts; unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 3,249	\$ 4,021	\$ 13,364	\$ 14,635
General and administrative	4,299	3,996	12,669	12,611
Restructuring, impairment, and other costs of terminated programs	2,435	—	2,435	—
Total operating expenses	<u>9,983</u>	<u>8,017</u>	<u>28,468</u>	<u>27,246</u>
Loss from operations	(9,983)	(8,017)	(28,468)	(27,246)
Interest income	171	28	266	100
Net loss	<u>(9,812)</u>	<u>(7,989)</u>	<u>(28,202)</u>	<u>(27,146)</u>
Net loss per share—basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.38)</u>	<u>\$ (1.32)</u>	<u>\$ (1.28)</u>
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	<u>21,536,622</u>	<u>21,287,498</u>	<u>21,443,252</u>	<u>21,153,185</u>

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

	September 30, 2022 <u>(unaudited)</u>	December 31, 2021 <u>(audited)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,170	\$ 13,364
Short-term investments	33,457	50,306
Assets held for sale	350	—
Prepaid expenses and other current assets	1,094	3,408
Total current assets	45,071	67,078
Property and equipment, net	—	1,981
Operating lease right-of-use asset	290	—
Prepaid expenses and other non-current assets	—	29
Total assets	<u>\$ 45,361</u>	<u>\$ 69,088</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 498	\$ 527
Accrued research and development	200	304
Operating lease liability	302	—
Other current liabilities	2,762	3,226
Total current liabilities	3,762	4,057
Deferred rent, long term portion	—	8
Total liabilities	3,762	4,065
Stockholders' Equity:		
Common stock	2	2
Additional paid-in capital	239,110	234,225
Accumulated deficit	(197,390)	(169,188)
Accumulated other comprehensive loss	(123)	(16)
Total stockholders' equity	41,599	65,023
Total liabilities and stockholders' equity	<u>\$ 45,361</u>	<u>\$ 69,088</u>