# 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 9, 2026**

# Aura Biosciences, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-40971** | **32-0271970** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **80 Guest Street**<br>**Boston, Massachusetts** | **02135** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: 617 500-8864**

**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, $0.00001 par value per share | AURA | 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 9, 2026, Aura Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2026. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On November 9, 2026, the Company updated its corporate presentation for use in meetings with investors, analysts, and others. A copy of the corporate presentation is filed as Exhibit 99.2 for purposes of Section 18 of the Exchange Act.

*Cautionary Note Regarding Forward-Looking Statements*

Statements contained under this Item 8.01 and in certain of the materials filed herewith regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements about the initiation, timing, progress, results, and cost of the Company's research and development programs and the Company's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and the Company's research and development programs; statements regarding the Company's expectations for an improved quality of life of patients after treatment with belzupacap sarotalocan ("bel-sar") and changes to the treatment paradigm for patients; the Company's ability to efficiently develop existing product candidates and discover new product candidates; the Company's ability to successfully manufacture its drug substances and product candidates for preclinical studies, for clinical trials and on a larger scale for commercial use, if approved; the pricing and reimbursement of the Company's product candidates, if approved; the ability and willingness of the Company's third-party strategic collaborators to continue research and development activities relating to the Company's development candidates and product candidates; the Company's ability to commercialize its products, if approved; the Company's ability to obtain additional funding for its operations necessary to complete further development and commercialization of its product candidates; the Company's ability to obtain and maintain regulatory approval of its product candidates; statements regarding the Company's beliefs and expectations for the high unmet medical need for an effective local treatment in ocular oncology to preserve organ function; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to serve those markets; the Company's financial performance; the Company's expected cash runway into the first half of 2029; and the implementation of the Company's business model, including strategic plans for its business and product candidates.

Any forward-looking statements are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of the Company's preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; the risk that early or interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; the risk that governmental authorities may disagree with the Company's clinical trial designs, even where the Company has obtained agreement with governmental authorities on the design of such trials, such as the Special Protocol Assessment agreement with the U.S. Food and Drug Administration for the Company's Phase 3 trial; whether the Company will receive regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; the Company's ongoing and planned preclinical activities; and the Company's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in subsequent filings made by the Company with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained under this Item 8.01 or in the materials filed herewith in the event of new information, future developments or otherwise. These forward-looking statements are based on the Company's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated November 9, 2026. |
| 99.2 | Corporate Presentation of the Company. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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 hereunto duly authorized.

**Aura Biosciences, Inc.**

Date: November 9, 2026

By: /s/ Natalie Holles

**Natalie Holles**
**Chief Executive Officer and President**
**(Principal Executive Officer)**

**Aura Biosciences Reports Third Quarter 2026 Financial Results and Recent Business Highlights**

*Phase 3 CoMpass trial on track for topline data in 2H 2027; all participants have completed treatment visits*

*Established relationship with industry-leading CDMO providing designated manufacturing capacity for bel-sar*

*Early choroidal melanoma investor and analyst virtual event planned for December 8, 2026*

*Expected cash runway into 1H 2029*

**BOSTON, MA – November 9, 2026** – Aura Biosciences, Inc. (NASDAQ: AURA) ("Aura" or the "Company") a clinical-stage biotechnology company developing a potentially transformative first-in-class therapy for patients with ocular cancers, today reported financial results for the third quarter ended September 30, 2026, and provided a business update.

"During the third quarter, we continued to execute against our focused ocular oncology strategy and build the operational capabilities needed for our next stage of development," said Natalie Holles, Chief Executive Officer of Aura Biosciences. "With all treatment visits completed in the CoMpass trial, our team is focused on ensuring excellence in all elements of the bel-sar program as we advance toward topline pivotal data in the second half of next year and position bel-sar as the first potential vision-preserving front-line therapy for early choroidal melanoma."

## Recent Business Highlights

### Phase 3 CoMpass Trial in Early Choroidal Melanoma

Enrollment is complete with 108 participants in the Phase 3 CoMpass trial of belzupacap sarotalocan (bel-sar) for the treatment of early choroidal melanoma, the most common primary tumor of the eye which carries an approximately 50% risk of advancing to metastatic disease. As of the third quarter of 2026, all participants have completed their treatment regimen and are in the 24-month follow-up observation period. The trial is on track to deliver topline data from the 15-month primary endpoint in the second half of 2027.

The trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). The SPA represents alignment with the FDA on the trial design and planned analyses to support a potential Biologics License Application (BLA) of bel-sar. If successful, bel-sar would be the first approved front-line vision-preserving therapy for patients with early choroidal melanoma, providing a meaningful new treatment option where no FDA-approved drug therapies currently exist.

### *Additional Ocular Oncology Programs*

Aura continues to advance the development of bel-sar in metastases to the choroid and cancers of the ocular surface in ongoing early clinical trials. In the first quarter of 2027, Aura expects to provide an update on both programs, including details on disease burden, trial design, and timelines to future data read-outs from these studies.

**Operational Updates**

During the quarter, Aura established a new supply relationship with an industry-leading contract development and manufacturing organization (CDMO) with extensive commercial experience in the manufacture of viral vector-based medicinal products. In a key element of the relationship, Aura and its CDMO partner are establishing manufacturing capacity which will be designated for bel-sar development and commercial supply production.

“We are very pleased to enter this new CDMO relationship, which we believe positions bel-sar for regulatory and commercial success as we advance toward topline data and completion of the CoMpass study,” said Susan Abu-Absi, Ph.D., Chief Operating Officer of Aura Biosciences. “Designated capacity is intended to provide us with long-term control over our production scheduling, and we look forward to working with our new partner to advance this important element of the bel-sar program.”

**Upcoming Events**

Aura will host an early choroidal melanoma investor and analyst virtual event on Tuesday, December 8, 2026, from 7:30-9:00 a.m. ET. Members of Aura’s management team will be joined by key opinion leader, Dr. Arun Singh, Director of the Department of Ophthalmic Oncology in the Cole Eye Institute of the Cleveland Clinic. The event will address the current treatment paradigm and unmet need, and an updated analysis of the epidemiology of early choroidal melanoma. To register for the virtual event, click here.

Aura also announced that Natalie Holles, Chief Executive Officer and President, will participate in the following upcoming investor conferences in the fourth quarter of 2026:

- Stifel 2026 Healthcare Conference on Tuesday, November 10, 2026.
  - Fireside chat at 2:40 p.m. ET
- 9th Annual Evercore Healthcare Conference on Tuesday, December 1, 2026.
  - Fireside chat at 2:10 p.m. ET

The live webcast of the events will be available on the “Investors & Media” page under the “Events & Presentations” section of the Company’s website at https://ir.aurabiosciences.com/events-and-presentations, where a replay of the webcasts will be archived for 90 days following the presentation date.

**Third Quarter 2026 Financial Results**

- As of September 30, 2026, Aura had cash and cash equivalents and marketable securities totaling $297.2 million. The Company believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the first half of 2029.

- Research and development expenses increased to $24.7 million for the three months ended September 30, 2026 from $22.2 million for the three months ended September 30, 2025, primarily due to ongoing clinical and contract research organization (CRO) costs associated with the progression of the global Phase 3 CoMpass trial of bel-sar in early choroidal melanoma.

- General and administrative expenses increased to $10.3 million for the three months ended September 30, 2026 from $5.7 million for the three months ended September 30, 2025. General and administrative expenses include $2.8 million and $1.7 million of stock-based compensation for the three months ended September 30, 2026 and 2025, respectively. The increase was primarily driven by restructuring charges recognized in accordance with the Company's organizational restructuring during the third quarter of 2026.

- Net loss for the three months ended September 30, 2026 was $32.1 million compared to $26.1 million for the three months ended September 30, 2025.

- In connection with the Company's organizational restructuring to align resources behind its ocular oncology portfolio, the Company incurred restructuring charges of approximately $4.5 million, comprised of employee termination benefits which include severance, continuation of health care benefits, and outplacement services as well as incremental stock-based compensation expense resulting from the acceleration of vesting of certain stock-based awards. The restructuring plan was completed in the third quarter of 2026.

**About Aura Biosciences**

Aura Biosciences is a clinical-stage biotechnology company developing bel-sar, a potentially transformative, first-in-class front-line vision-preserving therapy for patients living with ocular cancers. Bel-sar represents an entirely novel approach to treating ocular cancers via its dual mechanisms of action of acute tumor necrosis and secondary anti-tumor immune activation. The Phase 3 registration study of bel-sar in early choroidal melanoma, the largest patient segment of uveal melanoma, is fully enrolled, and earlier stage studies in metastases to the choroid and cancers of the ocular surface are ongoing. Aura's mission is to improve outcomes for patients living with ocular cancers by delivering a therapy that not only arrests tumor growth but also preserves vision and quality of life.

For more information, visit aurabiosciences.com. Follow us on X, @AuraBiosciences, and visit us on LinkedIn.

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements that are not statements of historical fact may be deemed to be forward-looking statements. Words such as “may,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “seeks,” “endeavor,” “potential,” “continue” or the negative of such words or other similar expressions can be used to identify forward-looking statements. These forward-looking statements include express or implied statements regarding Aura’s future expectations, plans and prospects, including, without limitation, statements regarding the therapeutic potential of bel-sar; statements regarding Aura’s plans and expectations for its ongoing and future clinical trials of bel-sar in multiple oncology indications, including with respect to clinical trial initiations; statements regarding the timing and plans for the Company’s Phase 3 CoMpass trial in early choroidal melanoma, including the timing of topline data; statements regarding Aura’s expectations for an improved quality of life of patients after treatment with bel-sar and changes to the treatment paradigm for patients; statements regarding Aura’s expectations for the estimated patient populations and related market opportunities for bel-sar; statements regarding Aura’s manufacturing plans and relationships, including the establishment of designated manufacturing capacity; statements regarding the Company’s expected cash runway; and statements regarding potential strategic discussions.

The forward-looking statements in this press release are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond Aura's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of Aura's preclinical and clinical trials may not be predictive of future results in connection with future clinical trials; the risk that early or interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; the risk that governmental authorities may disagree with Aura's clinical trial designs, even where Aura has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 SPA agreement with the FDA; whether Aura will receive regulatory approvals to conduct trials or to market products; whether Aura's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; Aura's reliance on third-party manufacturers; Aura's ongoing and planned preclinical activities; and Aura's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties and other factors include those risks and uncertainties described under the heading "Risk Factors" in Aura's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission (SEC) and in subsequent filings made by Aura with the SEC, which are available on the SEC's website at www.sec.gov/. Except as required by law, Aura disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Aura's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

**Investor and Media Relations Contact:**

Alex Dasalla

Head of Corporate Affairs

IR@aurabiosciences.com

**Aura Biosciences, Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(Unaudited)**
**(in thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| **Operating Expenses:** | | | | |
| Research and development | $ 24,742 | $ 22,178 | $ 83,451 | $ 68,403 |
| General and administrative | 10,320 | 5,728 | 34,546 | 17,151 |
| Total operating expenses | 35,062 | 27,906 | 117,997 | 85,554 |
| Total operating loss | (35,062) | (27,906) | (117,997) | (85,554) |
| Other income (expense): | | | | |
| Interest income, including amortization and accretion income | 3,017 | 1,815 | 6,514 | 5,087 |
| Other income (expense) | 17 | (13) | 172 | (72) |
| Total other income | 3,034 | 1,802 | 6,686 | 5,015 |
| Loss before income taxes | (32,028) | (26,104) | (111,311) | (80,539) |
| Income tax provision, net | (38) | (26) | (77) | (93) |
| Net loss | $ (32,066) | $ (26,130) | $ (111,388) | $ (80,632) |
| Net loss per common share—basic and diluted | $ (0.29) | $ (0.40) | $ (1.22) | $ (1.39) |
| Weighted average common stock outstanding—basic and diluted | 111,072,722 | 65,936,672 | 91,287,699 | 58,084,093 |
| Comprehensive loss: | | | | |
| Net loss | $ (32,066) | $ (26,130) | $ (111,388) | $ (80,632) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain (loss) on marketable securities | (855) | 57 | (1,223) | (168) |
| Currency translation adjustment | (47) | (13) | (247) | (26) |
| Total other comprehensive income (loss) | (902) | 44 | (1,470) | (194) |
| Total comprehensive loss | $ (32,968) | $ (26,086) | $ (112,858) | $ (80,826) |

**Aura Biosciences, Inc.**
**Condensed Consolidated Balance Sheets**
**(Unaudited)**
**(in thousands, except share and per share amounts)**

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 41,669 | $ 59,515 |
| Marketable securities | 255,564 | 84,726 |
| Prepaid expenses and other current assets | 5,865 | 5,498 |
| Total current assets | 303,098 | 149,739 |
| Restricted cash and deposits | 768 | 768 |
| Right-of-use assets—operating lease | 14,560 | 15,828 |
| Other long-term assets | 1,167 | 471 |
| Property and equipment, net | 2,024 | 2,624 |
| **Total Assets** | $ 321,617 | $ 169,430 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | 1,722 | 1,549 |
| Short-term operating lease liability | 3,316 | 3,243 |
| Accrued expenses and other current liabilities | 16,299 | 13,591 |
| Total current liabilities | 21,337 | 18,383 |
| Long-term operating lease liability | 12,853 | 14,134 |
| **Total Liabilities** | 34,190 | 32,517 |
| **Commitments and Contingencies** | | |
| **Stockholders' Equity:** | | |
| Common stock, $0.00001 par value, 500,000,000 and 150,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively, and 103,950,771 and 63,587,777 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively | 1 | — |
| Additional paid-in capital | 919,897 | 617,433 |
| Treasury stock, at cost, 6,922,870 shares held at September 30, 2026 and no shares held at December 31, 2025 | (39,093) | — |
| Accumulated deficit | (591,806) | (480,418) |
| Accumulated other comprehensive loss | (1,572) | (102) |
| **Total Stockholders' Equity** | 287,427 | 136,913 |
| **Total Liabilities and Stockholders' Equity** | $ 321,617 | $ 169,430 |

Exhibit 99.2

November 2026



# A Focused Vision: Targeted Therapy to Transform Ocular Cancer Care

aura

# Legal Disclosure

This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could", "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words. These forward-looking statements include statements about the initiation, timing, progress, results and cost of our research and development programs and our current and future nonclinical, preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; our ability to efficiently develop our existing product candidates and discover new product candidates; our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved; our ability to commercialize our products, if approved; our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the risk that the FDA may disagree with our clinical trial designs, even with the Phase 3 SPA agreement; statements regarding our beliefs and expectations for the high unmet medical need for an effective local treatment in ocular oncology to preserve organ function; the size and growth potential of the markets for our product candidates and our ability to serve those markets; our financial performance; our expected cash runway into the first half of 2029; and the implementation of our business model, including strategic plans for our business and product candidates.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and we undertake no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the SEC, which are available on the SEC's website at www.sec.gov. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We caution you not to place undue reliance on the forward-looking statements contained in this presentation.

This presentation discusses product candidates that are under preclinical or clinical evaluation and that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority. Until finalized in a clinical study report, clinical trial data presented herein remain subject to adjustment as a result of clinical site audits and other review processes. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

# **Aura is Positioned** to Become the Global Leader in Ocular Oncology

| Transform the Treatment Paradigm in Early Choroidal Melanoma | Execute from a Position of Strength | Unlock a Compelling Commercial Opportunity | Build the World's Leading Ocular Oncology Franchise |
|---|---|---|---|
| Patients face risks of vision loss, morbidity and metastatic disease with current SoC | Positive Phase 2 data support high statistical powering of Phase 3 design | Potential blockbuster opportunity with no FDA approved therapies | Opportunity to expand into other forms of ocular cancer |
| Potential to deliver the first curative, vision-preserving therapy in early choroidal melanoma | CoMpass, Phase 3 trial fully enrolled – supported by FDA SPA agreement | Focused call point with potential for favorable reimbursement model | Synergies across indications with large patient populations with significant unmet need |

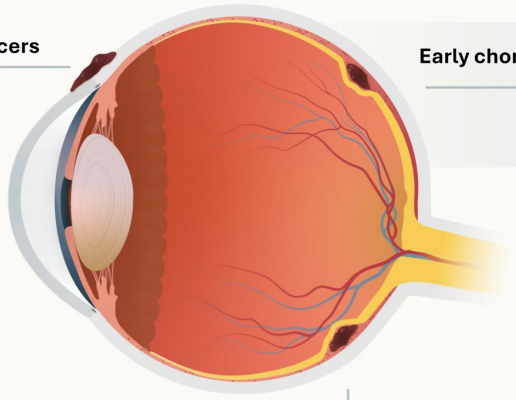
**SOC**, standard of care
**FDA**, Food and Drug Administration
**SPA**, Special Protocol Assessment

# **Ocular Oncology:** High Unmet Need with No Vision-Sparing Therapies

*Highly Synergistic Opportunities in a Potential Multi-Billion-Dollar Addressable Market*

**Ocular surface cancers**

**~35,000/yr**[a,1–5]



**Early choroidal melanoma**

**~11,000/yr**[6]

**Metastases to the choroid**

**~20,000/yr**[6]

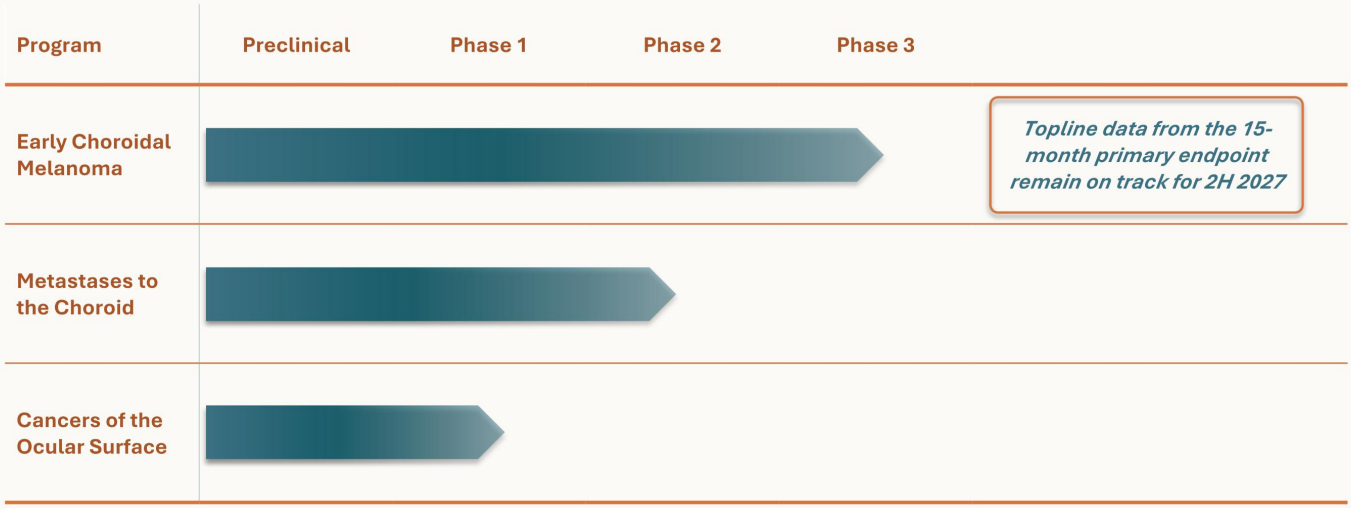
**Choroidal melanoma (CM) is the most common primary intraocular cancer in adults**[7]

**~80%** of patients are diagnosed with **early-stage disease**[6]

[a] Includes conjunctival melanoma, primary acquired melanosis, squamous cell carcinoma and ocular surface squamous neoplasia.[1-5]

**1.** Yu G-P, et al. *Am J Ophthalmol.* 2003;135(6):800–6. **2.** Triay E, et al. *Br J Ophthalmol*. 2009;93(11):1524–8. **3.** Newton R, et al. *Lancet*. 1996;347(9013):1450–1. **4.** Dalvin LA. *Br J Ophthalmol*. 2018;102(12):1728–34. **5.** Sun EC, et al. *Cancer Epidemiol Biomarkers Prev*. 1997;6(2):73–7. **6.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **7.** Kaliki S and Shields CL. *Eye (Lond).* 2017;31(2):241–57. **CM**, choroidal melanoma; **SoC**, standard-of-care.

# **Clinical Pipeline** Across Ocular Oncology




**PoC**, proof-of-concept.
ClinicalTrial.gov identifiers: phase 3 choroidal melanoma (CoMpass) NCT06007690; phase 2 metastases to the choroid NCT06643884.

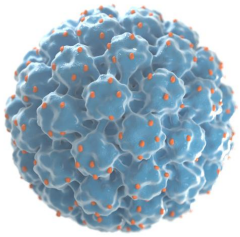
# **A Novel, Targeted** Therapeutic Modality

### Unique tumor selectivity

VLP-drug conjugate targets a key receptor molecule expressed in the early stages of malignant tumor transformation

### Dual MoA

Targeted cytotoxicity and immune activation; potential to generate lasting anti-tumor T-cell memory



### Tumor and mutation-agnostic

>100 cell lines
>15 animal tumor models

### High potency

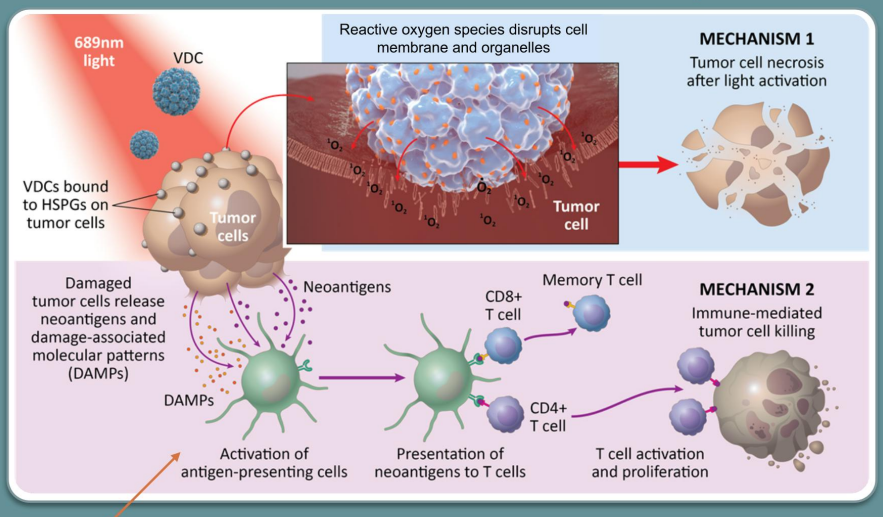
~200 cytotoxic molecules per VLP; demonstrated picomolar efficacy in multiple animal tumor models

**MoA**, mechanism of action; **VLP**, virus-like particle.

# Bel-sar's Dual Mechanism of Anti-Tumor Activity

Pro-immunogenic necrosis leads to T cell activation and immune-mediated tumor cell killing

## Targeted Cytotoxicity and Long-Term Anti-Tumor Immune Memory



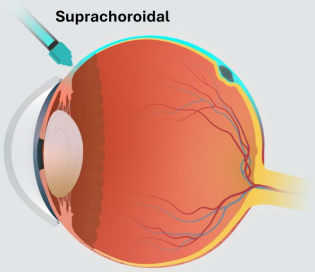

Release of **DAMPs** induces **anti-tumor immunity**

Bel-sar treatment is designed to be cytopathic to resident suppressor cells, reducing the immune-suppressive microenvironment and contributing to **anti-tumor immunity**

Kines RC, et al. *Int J Cancer.* 2016;138(4):901–11. Kines RC, et al. *Mol Cancer Ther.* 2018;17(2):565–74. Kines RC, et al. *Cancer Immunol Res.* 2021;9:693–706.
**Bel-sar**, belzupacap sarotalocan; **DAMPs**, damage-associated molecular patterns; **HSPG**, heparan sulfate proteoglycan; **VDC**, virus-like drug conjugate. Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.

# **Bel-sar is Administered** as a Targeted In-Office Procedure with the Potential for Durable Benefit

**Delivery via suprachoroidal injection**




Two injections (2 min. each) 30 min. apart

**Light activation with standard ophthalmic laser**

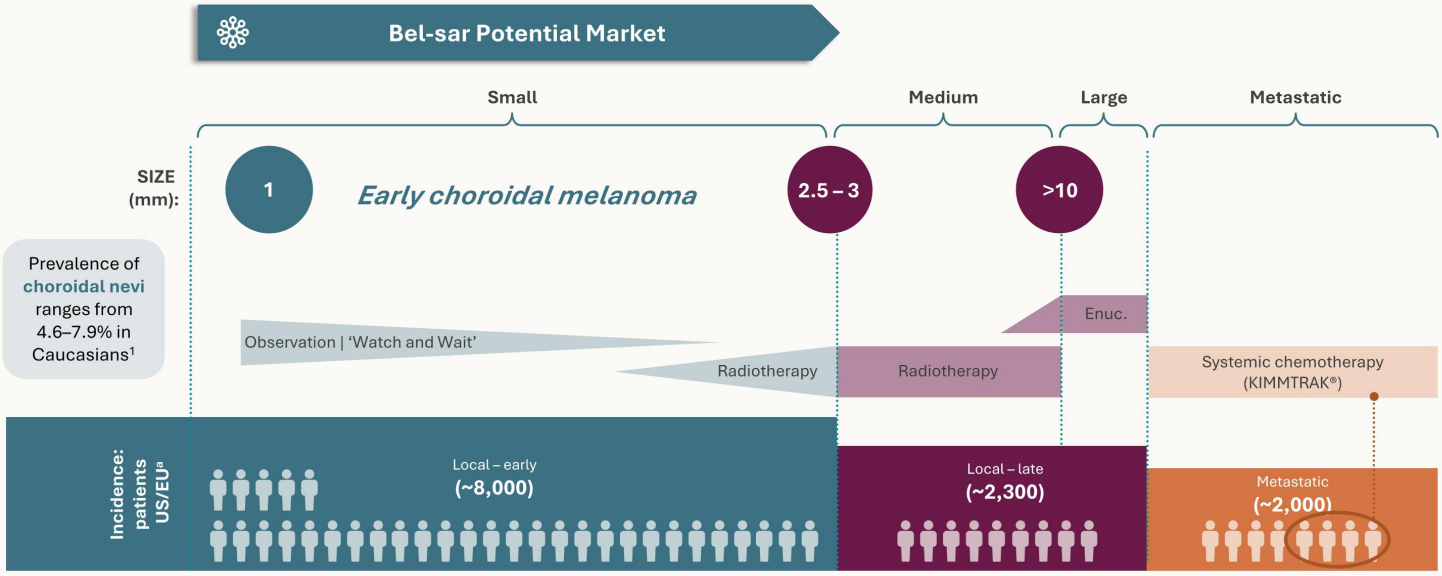


10–30 min. procedure

- Local tumor control
- Vision preservation
- No radiation-related morbidity
- Reduce metastasis risk with early treatment
- Improve safety and quality of life

**Bel-sar**, belzupacap sarotalocan.

# **Bel-sar:** Potentially Frontline Vision-Sparing Anti-Tumor Treatment for Largest CM Patient Segment



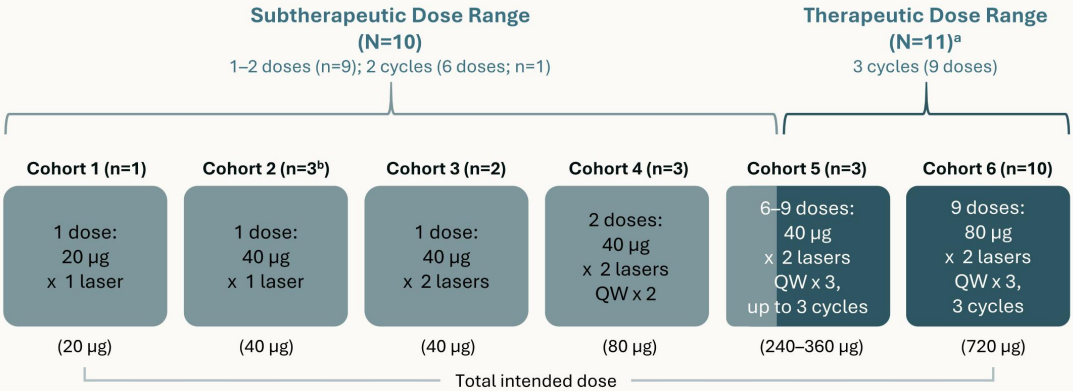

[a] Each figure represents ~250 persons.

**1.** Singh AD, et al. *Ophthalmology.* 2005;112(10):1784–89 (U.S. population). **2.** Shields CL, et al. Choroidal and ciliary body melanoma. Available at: https://eyewiki.aao.org/Choroidal_and_Ciliary_Body_Melanoma Accessed September 9, 2024. **3.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **Bel-sar**, belzupacap sarotalocan; **CM**, choroidal melanoma; **Enuc.**, enucleation.

# **Phase 2 Trial** In Early Choroidal Melanoma

*Open-label, dose-escalation study of bel-sar delivered via suprachoroidal administration*

## Trial Design (n=22)




### Endpoints

**Tumor progression**
Growth in tumor height ≥0.5 mm or ≥1.5 mm in LBD relative to baseline

**Visual acuity loss**
≥15 letters decrease from baseline

**Tumor thickness growth rate**
Change in rate of growth of tumor thickness

Subtherapeutic and therapeutic dose ranges determined via post-hoc analysis
One cycle = Doses on days 1, 8, and 15.
[a] 12 patients enrolled, 1 patient who discontinued after 1 cycle due to unrelated SAEs is not included in data analysis (n=11). [b] Cohort 2:2 participants were planned; third participant was additionally enrolled due to dose error in 1 participant.
**Bel-sar**, belzupacap sarotalocan; **LBD,** largest basal diameter; **QW,** every week. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

# Bel-sar has Demonstrated a Favorable Safety Profile

- No posterior inflammation
- No treatment-related SAEs
- No grade 3–5 treatment-related AEs

## Phase 2 Safety Outcomes (Bel-sar/Laser-Related)

| | All treated participants (n=22)* | | | |
|---|---|---|---|---|
| **Drug/laser-related adverse events** | **Grade I** | **Grade II** | **Grade III-V** | **Total** |
| Anterior chamber inflammation** | 4 (18.2%) | 0 | 0 | 4 (18.2%) |
| Anterior chamber cell** | 2 (9.1%) | 0 | 0 | 2 (9.1%) |
| Eye pain | 2 (9.1%) | 0 | 0 | 2 (9.1%) |
| Anisocoria | 1 (4.5%) | 0 | 0 | 1 (4.5%) |
| Conjunctival edema | 1 (4.5%) | 0 | 0 | 1 (4.5%) |
| Cystoid macular edema | 1 (4.5%) | 0 | 0 | 1 (4.5%) |
| Pupillary reflex impaired | 1 (4.5%) | 0 | 0 | 1 (4.5%) |
| Salivary gland enlargement | 0 | 1 (4.5%) | 0 | 1 (4.5%) |

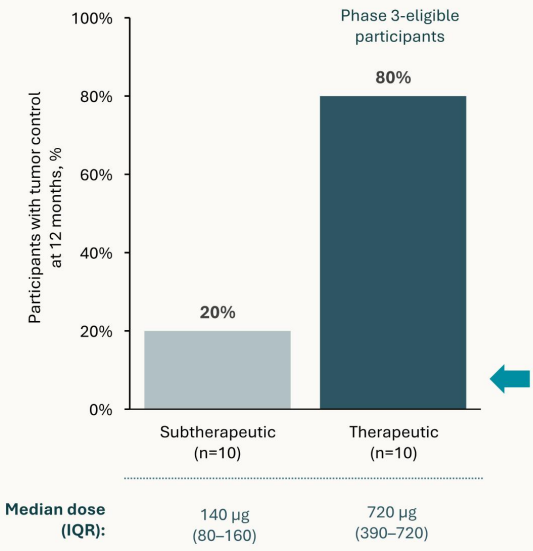
***Median duration 6 days (IQR: 3–10 days); All resolved with no or minimal treatment; If topical steroids given, median treatment duration 6 days*

* Table presents participants with AEs related to bel-sar or laser by severity and overall; participants with >1 AE are counted in the highest severity group.
**AEs**, adverse events; **bel-sar**, belzupacap sarotalocan; **IQR,** interquartile range; **SAE**, serious adverse events.
ClinicalTrials.gov Identifier, NCT04417530; AU-011-202. **Data on file, Aura Biosciences.**

# High Local Complete Response Rate at 12 Months Follow-Up

80% tumor control rate[a] at 12 months among the 10 Phase 3-eligible patients in the 3-cycle cohorts

## High Tumor Control Rates with Therapeutic Regimen in Phase 3-Eligible Patients

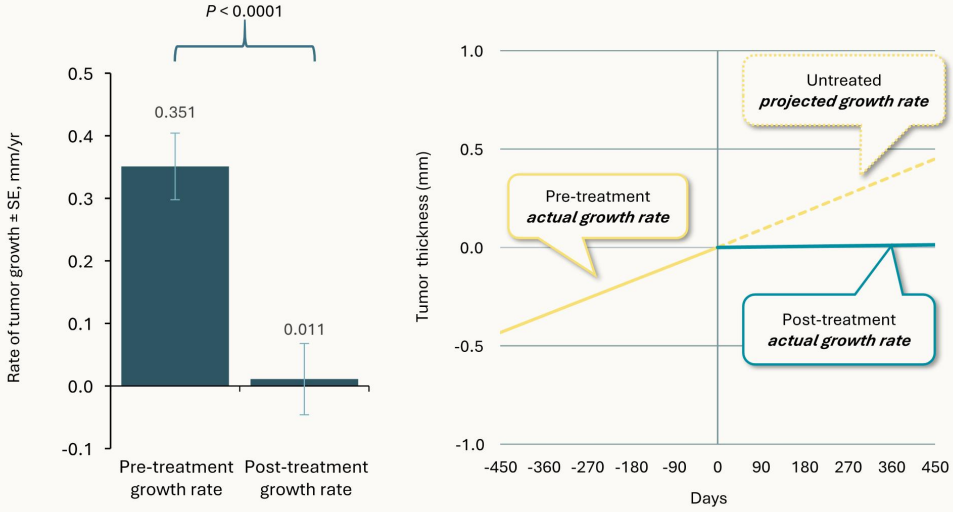



| Dose/ Regimen | n | Tumor control rate, % |
|---|---|---|
| **Subtherapeutic regimen** | | |
| ≤2 cycles | 10 | 20% (2/10) |
| **Therapeutic regimen** | | |
| 3 cycles, phase 3-eligible[b] | 10 | 80% (8/10) |

[a] Local complete response, or CR, in early-stage choroidal melanoma is described as tumor control and complete arrest of tumor growth by ocular oncologists.
[b] One participant with circumpapillary tumor that did not meet phase 3 criteria is not included.
**IQR,** interquartile range. ClinicalTrials.gov Identifier, NCT04417530; AU-011-202. **Data on file, Aura Biosciences.**

## In Phase 3-Eligible Patients, the 3-Cycle Regimen Resulted in Cessation of Growth Among Responders (N=8)

### Rate of Tumor Growth with Bel-sar Treatment

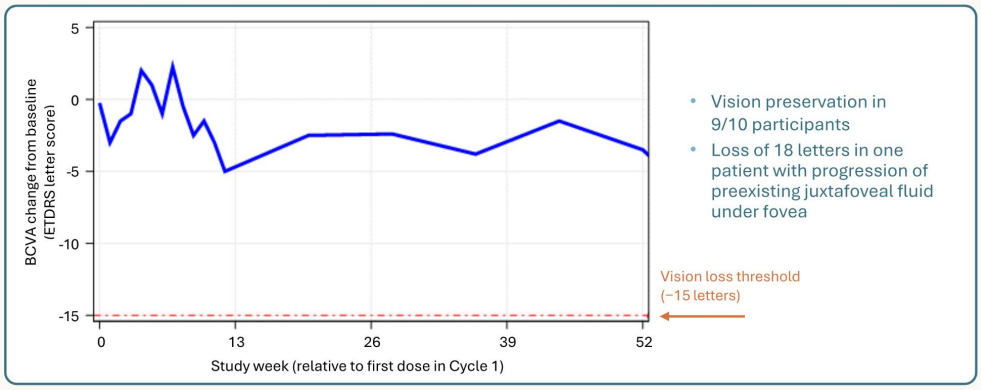



Tumor thickness growth rates/slopes estimated using Mixed Models for Repeat Measures (MMRM); random intercept and slope model for Historical and Study periods. **bel-sar**, belzupacap sarotalocan;.ClinicalTrials.gov Identifier, NCT04417530; AU-011-202. **Data on file, Aura Biosciences.**

# Visual Acuity Was Preserved in 90% of Phase 3-Eligible Patients Receiving a Bel-sar Therapeutic Regimen

- 80% were at high risk of vision loss with tumors < 3 mm to the fovea or optic nerve
- 90% visual acuity preservation supports the potential for bel-sar to be a front-line therapy for early-stage disease

## Median Change in BCVA in Phase 3-Eligible Participants with Therapeutic Regimen (N=10)[a]




[a] One participant with circumpapillary tumor that did not meet phase 3 criteria is not included. **BCVA,** best-corrected visual acuity; **bel-sar**, belzupacap sarotalocan; **ETDRS,** early treatment diabetic retinopathy study . ClinicalTrials.gov Identifier, NCT04417530; AU-011-202. **Data on file, Aura Biosciences.**

# Phase 3 Registration Study is Fully Enrolled

*Special Protocol Assessment, Fast Track and Orphan Drug Designations*

**Participants with Early Choroidal Melanoma[a] (N=108)**

Randomization 2:1:2

- 80 µg bel-sar
- 40 µg bel-sar[b]
- Sham control

*Sites in North America, Europe, Middle East and Asia-Pacific Regions*

15-month primary efficacy analysis
24-month follow-up period

**Primary Endpoint**

**Time to tumor progression**

Increase in tumor thickness ≥0.5 mm or ≥1.5 mm in LBD

**First Key Secondary Endpoint**

**Time to composite endpoint**

| **Tumor progression** | | **Visual acuity failure** |
|---|---|---|
| Increase in tumor thickness ≥0.5 mm or ≥1.5 mm in LBD | OR | ≥15 decrease in ETDRS-BCVA letter score from baseline |

**Objective**

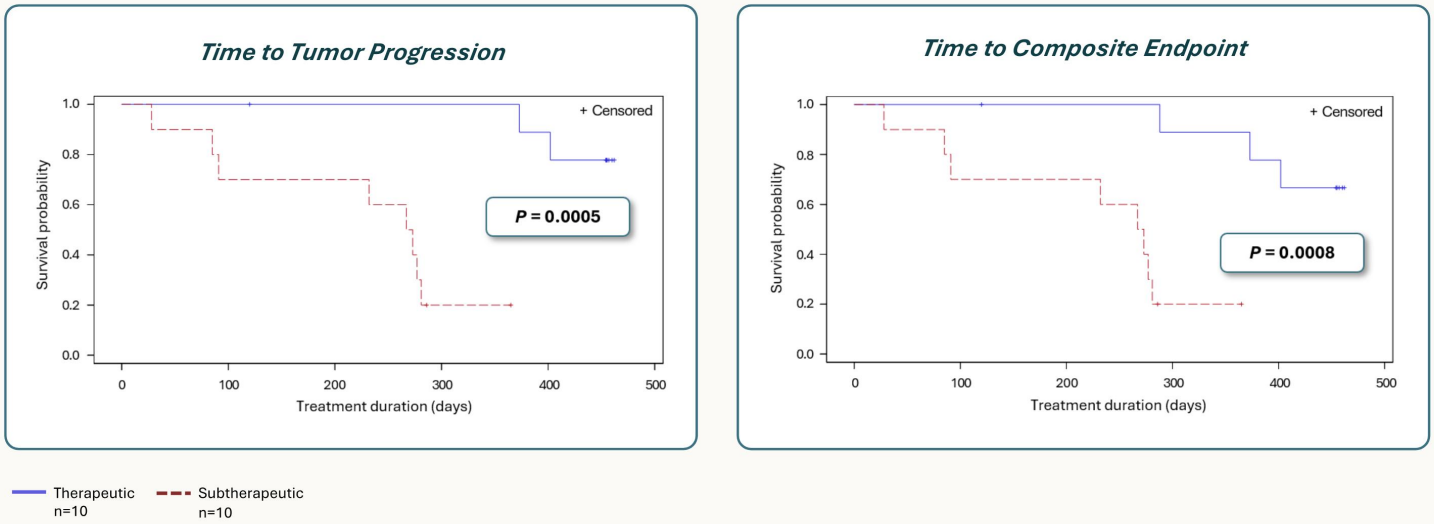
**Determine efficacy and safety of bel-sar vs sham control for treatment of early choroidal melanoma**

On track for **topline data 2H 2027**

[a] Early choroidal melanoma, small choroidal melanoma or indeterminate lesions. [b] 40 µg bel-sar arm included for masking; excluded from statistical analysis.
**bel-sar**, belzupacap sarotalocan; **BCVA,** best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **FDA**, United States Food and Drug Administration; **LBD**, largest basal diameter; **SPA**, special protocol assessment.
ClinicalTrials.gov Identifier, NCT06007690; AU-011-301.

# **Phase 3 CoMpass Trial is Highly Powered for Success** Based on Phase 2 Results

*Kaplan-Meier Simulation of Time-to-Event Endpoints Using Phase 2 Data*

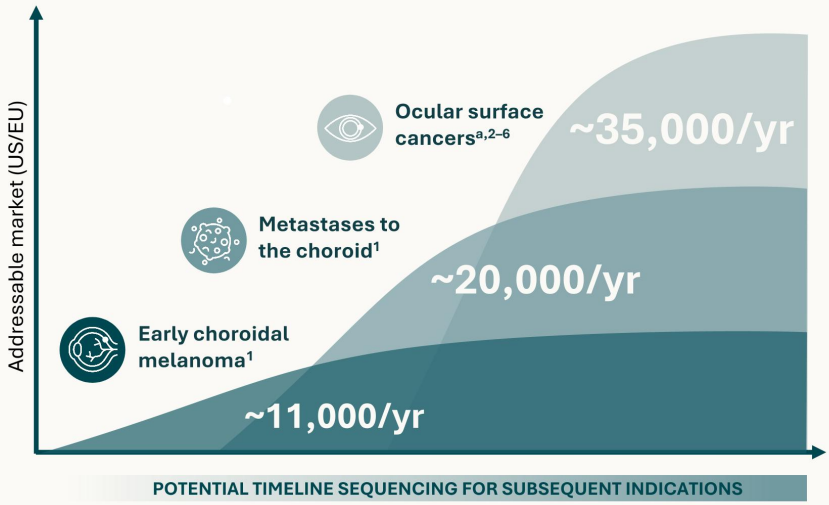



Study duration 12 months. Participants either had an event or were censored at the last visit; some had their Week 52 visit after 365 days. Any events at the final visit are assigned to the actual time of that visit. Log-rank test *p*-value based on unsimulated original Kaplan-Meier curves.

**BCVA,** best-corrected visual acuity; **ETDRS,** early treatment diabetic retinopathy study; **FDA**, United States Food and Drug Administration; **LBD,** largest basal diameter; **SPA**, special protocol assessment. ClinicalTrials.gov Identifiers: NCT04417530; AU-011-202 (phase 2); NCT06007690; AU-011-301 (phase 3).

**Data on file, Aura Biosciences.**

# **Bel-sar Has a Significant Commercial Opportunity** to Expand into Additional Ocular Oncology Indications




## Bel-sar's Potential Value Drivers

- Potential to be first approved therapy in all three disease states
- Development and regulatory synergies
- Focused call point (~100 ocular oncologists in US/EU) with potential expansion to retina specialists
- Buy-and-bill reimbursement

Opportunity to transform the field of ocular oncology with the **first potentially curative, vision-preserving therapy**

[a] Includes conjunctival melanoma, primary acquired melanosis, squamous cell carcinoma and ocular surface squamous neoplasia[2-6]

**1.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **2.** Yu G-P, et al. *Am J Ophthalmol.* 2003;135(6):800-6. **3.** Triay E, et al. *Br J Ophthalmol.* 2009;93(11):1524-8. **4.** Newton R, et al. *Lancet.* 1996;347(9013):1450-1. **5.** Dalvin LA. *Br J Ophthalmol.* 2018;102(12):1728-1734. **6.** Sun EC, et al. *Cancer Epidemiol Biomarkers Prev.* 1997;6(2):73-7. **Bel-sar**, belzupacap sarotalocan.

# **Aura is Positioned** to Become the Global Leader in Ocular Oncology

| | |
|---|---|
| ***Refined Strategic Focus*** | Advancing the development of bel-sar in ocular oncology |
| ***Disciplined Capital Allocation*** | Under current operating plan, expected cash runway is into 1H 2029 |
| ***Key Upcoming Value Driver*** | Highly powered Phase 3 CoMpass trial on track for topline data in 2H 2027 |
| ***Long-term Value Potential*** | Opportunity to build a durable leadership position in ocular oncology |

# Appendix

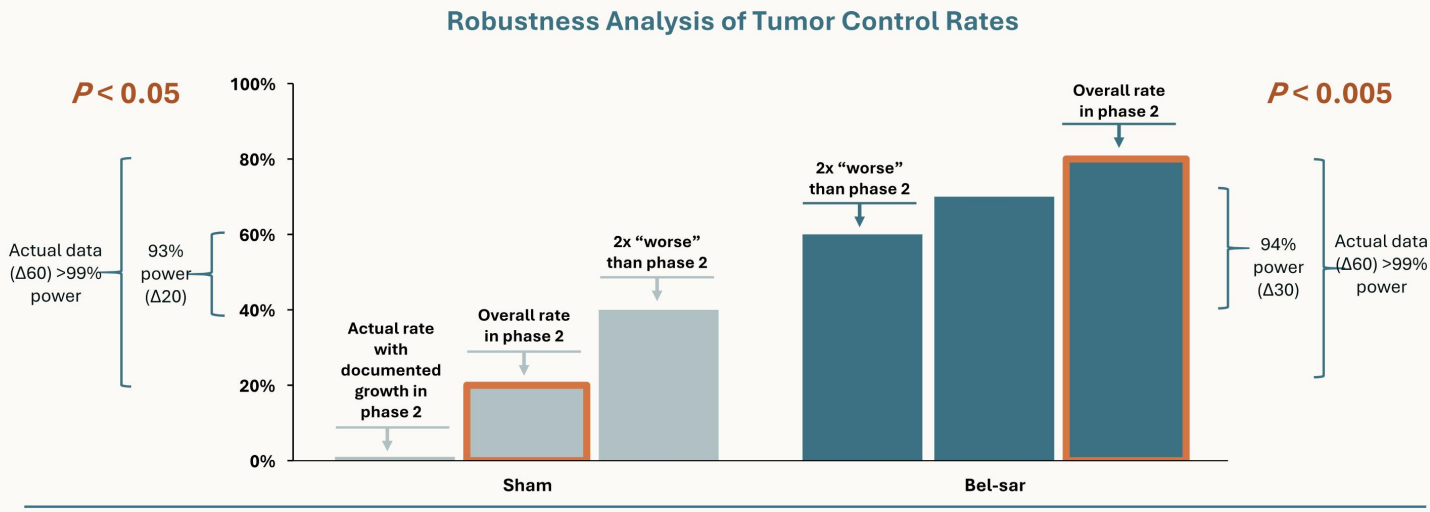
# Phase 2 Baseline Characteristics

*All Study Participants*

| | All patients (n=22) |
|---|---|
| Female (%) | 54.5 |
| White, not Hispanic or Latino (%) | 100 |
| Subretinal fluid at screening (%) | 100 |
| Orange pigment at screening (%) | 86.4 |
| Documented growth prior to screening (%) | 86.4<br>*(100% of therapeutic group)* |
| Mean age at screening (years, ± SD) | 59.2 (±16.5) |
| Mean baseline BCVA in study eye (ETDRS letters, ± SD) | 83.2 (±7.2) |
| Mean baseline LBD (mm, ± SD) | 8.5 (±1.4) |
| Mean baseline tumor thickness (mm, ± SD) | 2.0 (±0.5) |
| Mean tumor distance to closest vision-critical structure at screening (mm, ± SD) | 2.0 (±2.3) |
| Tumors at high risk for vision loss (%)[a] | 73%<br>*(80% [8/10] of therapeutic group)* |

[a] High risk for vision loss defined as tumor edge within either 3 mm of foveal center or 3 mm of optic disc edge.
**BCVA,** best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **LBD**, largest basal diameter. **Data on file, Aura Biosciences.**

# Phase 2 Data Support Phase 3 Assumptions




**Phase 3 trial design**

Same dose, regimen, route of administration, range of tumor sizes, and reading center as phase 2 trial

- Similar population to phase 2 participants receiving the therapeutic regimen
- Enriching for early documented growth; phase 3 randomization stratified by growth rate

**Bel-sar**, belzupacap sarotalocan. ClinicalTrials.gov Identifier, NCT06007690; AU-011-301.