#### 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): January 8, 2024

#### Aura Biosciences, Inc.

(Exact name of registrant as specified in its charter)

001-40971 32-0271970 Delaware (State or other jurisdiction of incorporation) (I.R.S. Employer Identification No.) (Commission File Number) 80 Guest Street 02135 Boston, MA (Address of principal executive offices 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 ☐ 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)) 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.  $\ \Box$ Securities registered pursuant to Section 12(b) of the Act: Name of each exchange on which registered

AURA

The Nasdaq Global Market

Common Stock, \$0.00001 par value per share

#### Item 8.01. Other Events.

Aura Biosciences, Inc. (the "Company") will be conducting meetings with investors attending the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco beginning on January 8, 2024. The Company updated its corporate presentation for use in these meetings. A copy of the corporate presentation is filed as Exhibit 99.1 for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

#### Forward Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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 our research and development programs and our 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 our research and development programs; 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; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; 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 size and growth potential of the markets for our product candidates, and our ability to serve those markets; our financial performance; our ability to commercialize our products, if approved; and the implementation of our business model, and strategic plans for our 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 clinical trials may not be predictive of future results in connection with future clinical trials; the risk that 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 Phase 3 Special Protocol agreement with the United States Food and Drug Administration; 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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 <u>Corporate presentation of the Company</u>

104 Cover Page Interactive Data (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.

Date: January 8, 2024

AURA BIOSCIENCES, INC.

By: /s/ Julie Feder
Julie Feder
Chief Financial Officer





#### 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 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 successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our financial performance; and the implementation of our business model, and 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, as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the Securities and Exchange Commission. 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 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 Biosciences - Developing a Novel Class of Drugs in Oncology

# Ocular Oncology Franchise

• Choroidal Melanoma – Global Ph 3 CoMpass Trial:

- FPI was Q4 2023
- · Most US sites activated; Trial actively enrolling
- · Special Protocol Assessment (SPA) Agreement with FDA
- Ph 3 assumptions supported by Ph 2 data
- Choroidal Metastasis Ph 2 trial planned to initiate in mid-2024
- Second ocular indication potentially doubles market opportunity

#### **Urologic Oncology Franchise**

- · Clinical complete response in first patient with single dose
- Data supports dual mechanism
- Updated protocol includes both NMIBC and MIBC

**Strong Cash Position** 

Current cash runway expected to fund operations into 2H 2026

# Pipeline Targeting Life-Threatening Cancers with High Unmet Needs

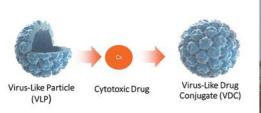


\*VDCs bind to a subset of modified tumor associated glycosaminoglycans (GAGs) that are part of the heparan sulphate chain of HSPGs. Schiller et al. Viruses 2022, 14(8), 1656

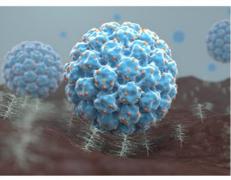


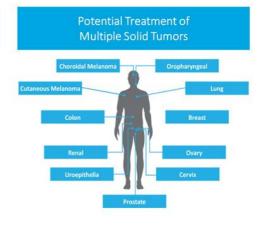
# Targeted Oncology Platform: Virus-Like Drug Conjugates (VDCs)

Virus-Like Particle Conjugated to a Cytotoxic Payload



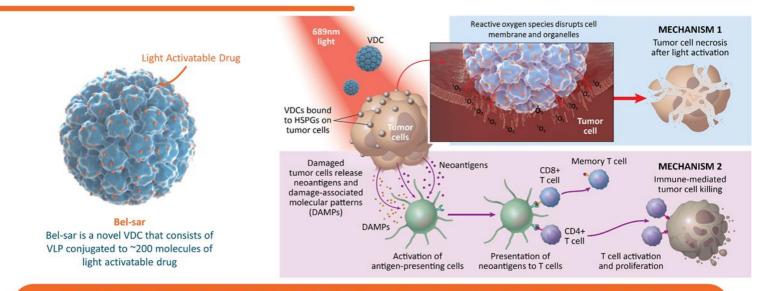
Selective Binding to Tumor Associated HSPGs\*





Potential Key Differentiation: Potency, Multivalent Binding and Selectivity

#### Bel-sar is a VDC with a Novel Dual Mechanism of Action



Potential Key Differentiation: Agnostic to Genetic Mutations, Less Susceptible to Resistance Mechanisms, Long Term Anti-tumor Immunity

Kines et al.; Cancer Immunology Research, May 2021
VDCs bind to a subset of modified tumor associated glycosaminoglycans (GAG) that are part of the heparan sulphate chain of HSPGs. Schiller et al. Viruses 2022, 14(8), 165/



## Ocular Oncology Franchise





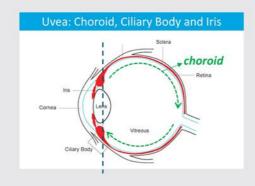
#### **Target Indications:**

- Early-Stage Choroidal Melanoma
- Choroidal Metastasis
- Other Ocular Cancers

## Primary Choroidal Melanoma—High Unmet Medical Need

#### Choroid is 90% of the uvea1

50% of patients develop metastasis within 15 years (metastatic uveal melanoma)2









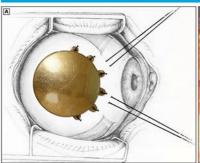


- 1. Heiting, G. Iris/uvea of the eye. Accessed Oct. 3, 2023. https://www.allaboutvision.com/en-gb/resources/uvea-iris-choroid/2. Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.2753. Clearview & Putnam & Assoc. Market Research



## Radiotherapy is the Standard of Care for Early-Stage Disease

#### Plaque Brachytherapy for Choroidal Melanoma Requires Invasive Surgery with Irreversible Complications and Does Not Prevent Metastasis







(A) Schematic drawing showing a Collaborative Ocular Melanoma Study (COMS) style plaque sutured to the sclera overlying the location of the uveal melanoma<sup>1</sup>

Surgical treatment of large choroidal melanoma with ruthenium 106 plaque brachytherapy

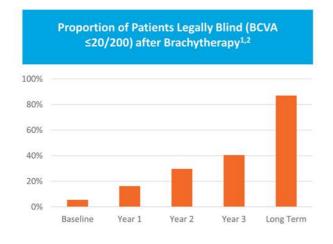
(B) Intraoperative photograph showing COMS plaque in place. The plaque stays in place for 3

Maculopathy, Cataract, Glaucoma, Vitreous Detachment and Vitreous Hemorrhage are Common Vision Threatening Complications of Brachytherapy<sup>3</sup>

- 1. Up To Date. Plaque brachytherapy for uveal melanoma. Accessed September 20, 2023. https://ykhoa.org/d/image.htm?imageKey=ONC/116591
  2. Kim M, Lee SM, Lee. Surgical treatment of a large choroidal melanoma. American Academy of Optometry 2022 Video Program. March 1, 2023. Accessed September 20, 2023. https://www.aao.org/education/annual-meeting-video/surgical-treatment-of-large-choroidal-melanoma
  3. Peddada KV, Sangani R, Menon H, Verma V. Complications and adverse events of plaque brachytherapy for ocular melanoma. *J Contemp Brachytherapy*. 2019;11(4):392-397. doi:10.5114/jcb.2019.87407



# Up to 87% of Patients Will be Blinded when Treated with Radiotherapy



**Contrast Sensitivity Diminishes Significantly within** the First Year after Brachytherapy and Continues to Deteriorate Over Time<sup>2</sup>





Normal Vision

Vision with Reduced Contrast Sensitivity

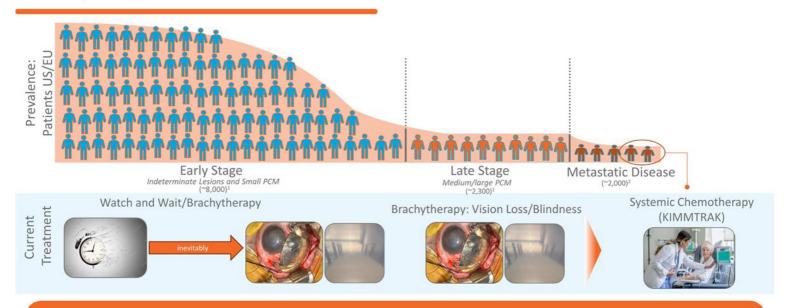
Visual Acuity, Color Vision and Contrast Sensitivity Decrease Significantly within the First Year after Treatment and Continue to Decrease Over Time

- 1. Jarczak J, Karska-Basta I, Romanowska-Dixon B. Deterioration of visual acuity after brachytherapy and proton therapy of uveal melanoma, and methods of counteracting this complication based on recent publications. Medicina (Kaunas). 2023;59(6):1131.

  2. Tsui I, Beardsley RM, McCannel TA, Oliver SC, et al. Visual acuity, contrast sensitivity and color vision three years after iodine-125 brachytherapy for choroidal and ciliary body melanoma. Open Ophthalmol J. 2015;9:131-5.



## Benefit/Risk of Radiotherapy Drives "Watch and Wait" in Patients with Early-Stage Disease



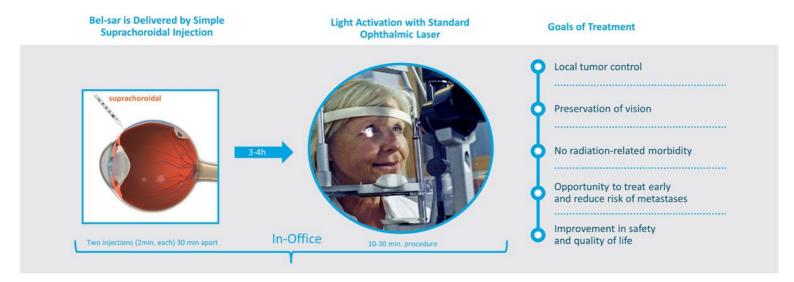
Most of the Addressable Population is Untreated Due to Risk of Treatment Related Vision Loss and Severe Comorbidities

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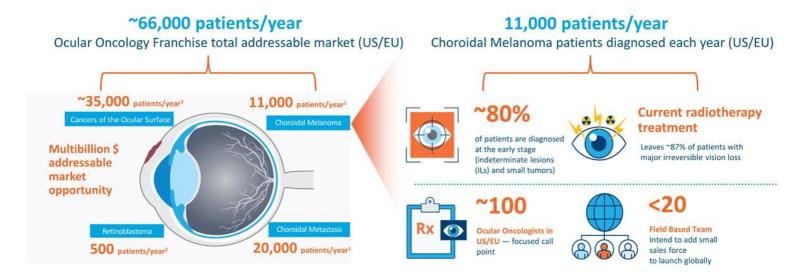
Clearview & Putnam & Assoc. Market Research
Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.275



#### Bel-sar has the Potential to be the First Approved Therapy in Primary Choroidal Melanoma



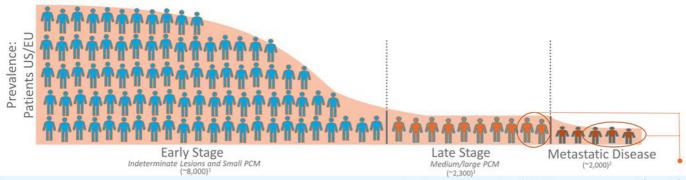
#### Ocular Oncology Franchise Represents a Multi-Billion Dollar Addressable Market Opportunity





 Includes Conjunctival Melanoma, Primary Acquired Melanosis, Squamous Cell Carcinoma and Ocular Surface Squamous Neoplasia https://pubmed.ncbi.nlm.nih.gov/12788119/: https://pubmed.ncbi.nlm.nih.gov/19628487/: https://pubmed.ncbi.nlm.nih.gov/8676629/

#### Potential Future Patient Treatment Journey



Treatment



First Line Treatment with Bel-sar





Chemotherapy (KIMMTRAK)

Bel-Sar has the Potential to be an Effective, Vision Preserving Therapy for the Treatment of Indeterminate Lesions and Small Choroidal Melanoma

Clearview & Putnam & Assoc. Market Research
Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.275



# Bel-sar has Demonstrated a Favorable Profile for the Treatment of Early-Stage Disease

Adverse Event or Adverse Reactions	KIMMTRAK <sup>1</sup>	Darovasertib + Crizotinib Combination <sup>2</sup>	Bel-Sar	
	Any Grade	Any Grade	Any Grade*	
Cytokine release syndrome	89%	Not Disclosed	0%	
Rash	83%	Not Disclosed	0%	
Pyrexia	76%	Not Disclosed	0%	
Pruritus	69%	Not Disclosed	0%	
Fatigue	64%	40%	0%	
Nausea	49%	79%	0%	
Vomiting	Not Disclosed	52%	0%	
Chills	48%	Not Disclosed	0%	
Hypo-/hyperpigmentation	47%	Not Disclosed	0%	
Abdominal pain	45%	Not Disclosed	0%	
Edema	45%	57%	0%	
dermatitis acneiform	Not Disclosed	44% 0%		
Hypotension	Not Disclosed	34%	0%	
Hypoalbuminemia	Not Disclosed	32%	0%	
Dizziness	Not Disclosed	28%	0%	

<sup>1.</sup> Immunocore Corporate Presentation, 2023 August, Slide 12, https://ir.immunocore.com/static-files/415c5cbb-caae-4ffa-9beb-cb40cfcfc132

Note: Certain data in this presentation are based on a cross-trial compansons and are not based on any head-to-head clinical trials. Cross-trial compansons are inherently limited and ma suggest misleading similarities or differences. Results of head-to-head-compansons may differ significantly from those set forth herein.

\*Safety outcomes for company PPS study with ball-styrage and the day of the companion of t

\*Safety outcomes for ongoing Ph2 study with bel-sar presented on slide 22



<sup>2.</sup> IDEAYA Clinical Update Presentation. 2023 April 24. Slide 10

# Choroidal Melanoma Ph 2 Data



# Ph 2 Trial – Dose Escalation and Expansion with Suprachoroidal Administration

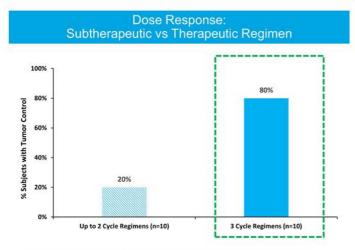
#### Patient Population Representative of Early-Stage Disease: Indeterminate Lesions and Small Choroidal Melanoma Trial Design – Enrollment Complete (n=22) Growth in Tumor Height **Tumor Progression** ≥0.5mm or ≥1.5 mm in Largest Basal Diameter (LBD) Cohort 2 (n=3\*) Decrease from Baseline: **Visual Acuity Loss** ≥15 letters Change in Rate of Growth of **Tumor Thickness Growth Rate Tumor Thickness** N=11\*\* 3 Cycles (9 doses) N=10 1- 2 Doses (n=9); 2 cycles-6 doses (n=1) One Cycle = Doses on days 1, 8, and 15

Goal: To Determine Safety, Optimal Dose and Therapeutic Regimen with Suprachoroidal Administration

\*Cohort 2: 2 subjects were planned; third subject was additionally enrolled due to dose error in 1 subject
\*\*12 patients enrolled, 1 subject who discontinued after 1 cycle due to unrelated SAEs is not included in data analysis (n=11). Data that follows will be based on a cohort of 11
ClinicalTrials gov Identifier: NCT04417530; AU-011-202



# High Tumor Control Rates Observed – Durable at 12 Months Follow Up



Dose/Regimen	Total Patients (n)	Tumor Control Rate
Subtherapeutic Regimens		
Single dose up to 2 cycles	10	20% (2/10)
Therapeutic Regimen		
3 Cycles (n=11)	11	73% (8/11)
3 Cycles and Ph 3 eligible (n=10)*	10	80% (8/10)

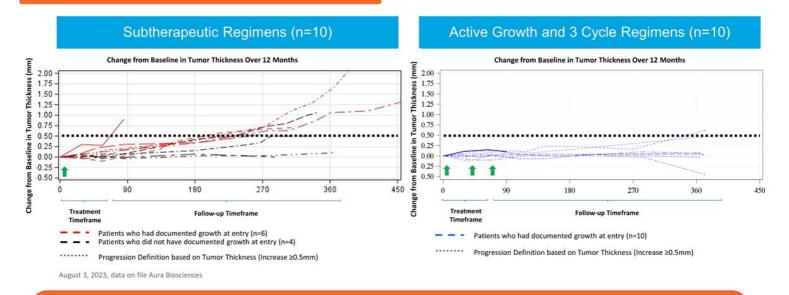
<sup>\*</sup> One subject with circumpapillary tumor that did not meet Ph 3 criteria is not included

Tumor Progression: change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment August 3, 2023, data on file Aura Biosciences

High Tumor Control Rates with Therapeutic Regimen in Ph 3 Eligible Patients with Active Growth



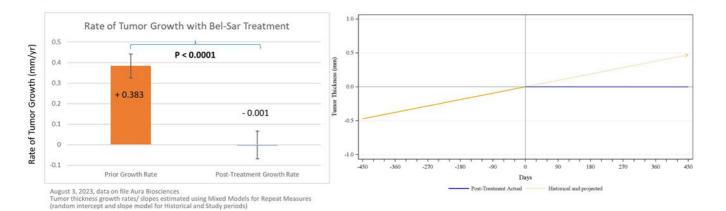
# High Tumor Control Rates Observed in Ph 3 Population Treated with Therapeutic Regimen



Ph 2 Interim Data Demonstrated Tumor Control Rate of 80%, with 90% of Patients at 12 Months of Follow Up

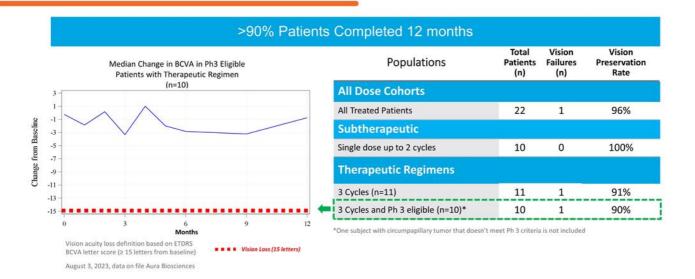
#### Ph 2 Interim Data Demonstrated a Negative Growth Rate Post-Treatment

Successful Treatment with 3 Cycle Regimen in Ph 3 Eligible Tumors with Active Growth Change in Tumor Growth (mm/yr) (n=8)



Interim Data Showed Negative Growth Rate Among Responders in Planned Ph 3 Population (P < 0.0001)

## 90% Visual Acuity Preservation Despite 80% of These Patients Being at High Risk for Vision Loss



90% Visual Acuity Preservation Data Supports Potential to be Front Line Therapy for Early-Stage Disease



## Ph 2 Safety Data Supports Potential to be First Line Treatment in Early-Stage Disease

Ongoing Ph 2 Safety Outcomes with SC Administration					
All Treated Subjects (n=22) Drug/Laser Related Adverse Events >5% Subjects*	Grade I	Grade II	Grade III	Total	
Anterior Chamber Inflammation	18%	0	0	18%	
Anterior Chamber Cell	9%	0	0	9%	
Eye Pain	9%	0	0	9%	

Table presents percentage of subjects with AEs related to bel-sar or laser by severity and overall; subjects with more than 1 AE are counted in the highest severity group
\*Treatment-emergent AEs related to bel-sar or laser in 1 patient each or <5% (anisocoria, conjunctival edema, cystoid macular edema, pupillary reflex impaired, retinal pigment epitheliopathy, salivary gland enlargement)

August 3, 2023, data on file Aura Biosciences

Adverse Event	Radiotherapy*	Bel-Sar	
Surgeries secondary to AEs+ (e.g., Cataracts)	40%+	0%	
Radiation Retinopathy	40%+	0%	
Neovascular Glaucoma	10%		
Dry Eye Syndrome	20%	0%	
Strabismus	2%+	0%	
Retinal Detachment	1-2%	0%	
Vision Loss (≥15 letters)	~70%	~5%	
Serious Adverse Event	Radiotherapy*	Bel-Sar	
Scleral Necrosis	0-5%	0%	
Enucleation/Eye Loss	10-15%	0%	
Severe Vision Loss (≥30 letters) in HRVL**	~90%	0%++	

clinical trials. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences.

Results of head-to-head comparisons may differ significantly from those set forth herein.

\*Related to bel-sar or laser

\*\*73% (16/22) of patients in Ph2 SC trial were at high risk for vision loss.

#### No Posterior Inflammation, No SAEs and No Grade 3 Related Adverse Events

\*J. Contemp Brachytherapy, J. 2019 Aug; 11(4): 392–397.; Arch Ophthalmol. 2009;118(9): 1219-1228; Curr. Opin. Ophthalmol. 2019 May;30(3): 206-214; Eye 2017 Feb;31(2): 241-257

\*\*High-Risk Vision Loss (HRVL) are those subjects with tumors <3mm to fovea or optic nerve
Bel-Sar — Belzupacap Sarotalocan; AEs — Adverse Events; SAEs — Serious Adverse Events

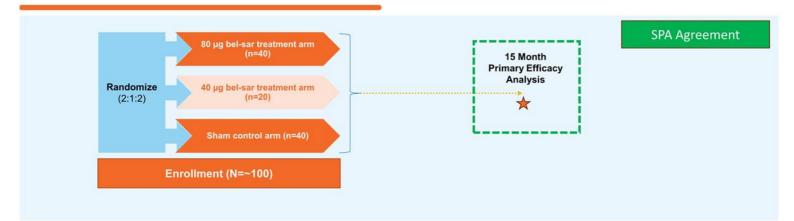


# Randomized Controlled Global Ph 3 Trial



#### SPA Agreement with FDA Supports Global Ph 3 Trial Design

Fast Track and Orphan Designations



#### **Primary Endpoint**

First Key Secondary Endpoint

Time to Tumor Progression

• Time to Composite Endpoint: Tumor Progression or Visual Acuity Failure

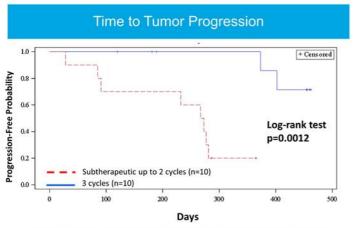
An SPA Indicates Concurrence by the FDA that the Design of the Trial can Adequately Support a Regulatory Submission

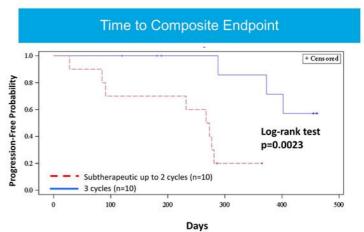
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SPA - Special Protocol Assessment; Bel-sar - Belzupacap Sarotalocar



# Kaplan-Meier Analysis Simulation of Key Primary & Secondary Endpoint with Ph 2 Data

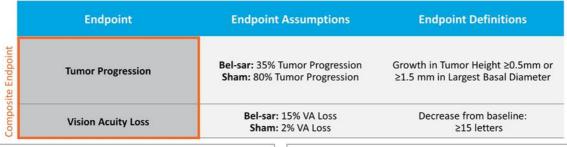


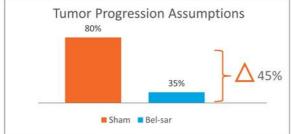


Note: Subjects either had an event or were consored at the last visit. Some subjects had Week 52 visit after 365 days. Time to Composite Endpoint is defined as time to tumor progression or vision acuity failure, whichever occurs earlier. Tumor progression is defined as a change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment. Log-rank test, p-value based on unsimulated original KM curves August 3, 2023 data on file Junz Blosciences

Ph 2 Interim Data Supports Assumptions for the Potential Success of Ph 3 with High Statistical Significance

# Clinical Endpoints to Support Potential Approval in Alignment with Regulatory Agencies







Conservative Assumptions Provide Support for Potential for Regulatory Submission (Phase 3 Trial Powered at 95%)

2

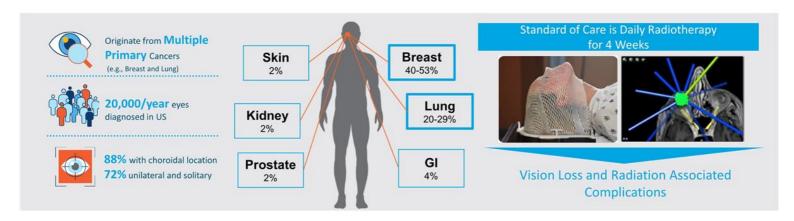
Note: Tumor Height is synonymous with Tumor Thickness; VA – Visual Acuity; Bel-sar – Belzupacap Sarotalocan



# Choroidal Metastasis



## Choroidal Metastasis is a High Unmet Medical Need



Choroidal Metastasis Cause Decreased Vision and Decreased Quality of Life in Patients Fighting Metastatic Cancer

## Choroidal Metastasis – Ph 2 Trial Design

# Cohort 1a N=3 patients 80µg x 2L 1 cycle Cohort 2a N=3 patients 140µg x 2L 1 cycle Cohort 3a N=3 patients 200µg x 2L 1 cycle Cohort 3b N=3 patients 200µg x 2L 1 cycle 2 cycles

#### **Study Objectives**

- Safety/DLT
- Efficacy
  - Choroidal Tumor Progression
  - · Choroidal Tumor Growth rate
  - Vision improvement

#### **Study Population**

- Patients with unilateral, unifocal choroidal metastasis
- Breast or Lung Primary
- No changes in concurrent systemic medications planned

Highlights: Primary Endpoint at one-month post-treatment; possibility to see tumor shrinkage; FDA oncology division



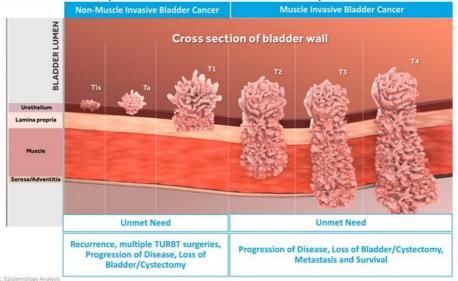
# Target Indications: Bladder Cancer

# Bladder Cancer is a High Unmet Medical Need







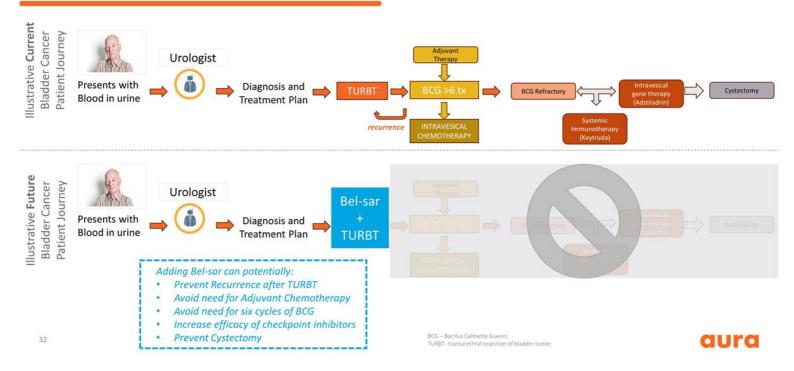




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Putnam & Assoc. Epidemiology Analysis
 Campbell-Walsh-wein Urology, 2021, 12th edition; Chapter 137, page 3112

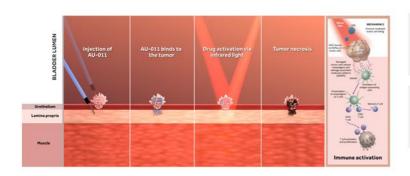
## Bel-Sar has the Potential to be Front Line in Conjunction with TURBT



## Bel-Sar has a Unique MoA Designed for the Local Treatment

#### Local Administration and Light Activation with Standard Cystoscope

#### **Treatment Aligned with Current Urologic Oncology Practice**



Lasers are commonly used by urologists

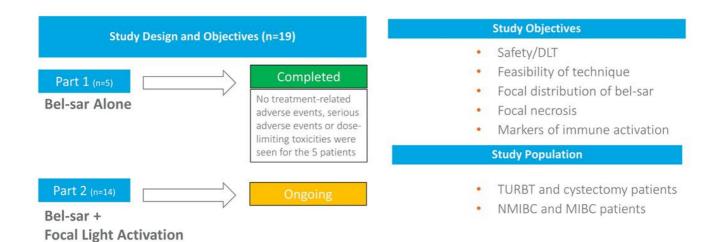
Local delivery in the bladder increases tumor drug exposure

Bladder injections are common and simple to perform (e.g., Botox)

Precedent for immune-mediated tumor clearance (BCG & checkpoint inhibitors)

Bel-sar's Local Administration is Aligned with Clinical Practice and has a Unique MoA that may be Complementary to Other Drugs

## Ph 1 Trial Designed to Evaluate Safety, Feasibility and MoA



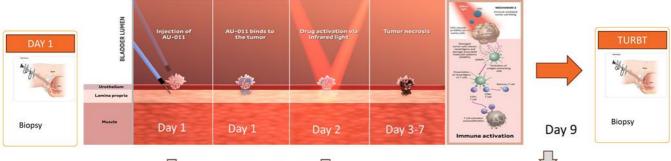
Ph 1 Data is Anticipated to Support the Future Development of Bel-sar for the Treatment of Both NMIBC and MIBC

Bel-sar – Belzupacap Sarotalocán MoA – Mechanism of Action



#### Clinical Complete Response with Immune Activation after Single Dose Confirmed by Histopathology

Ph 1- Preliminary Data Light Activated Cohort (n=1)



#### Day 1



carcinoma Injection of Bel-sar (100ug) performed within tumor and below

(Aura present w/ Urologist)

Bel-sar, AU-011 – Belzupacap Sarotalocan TURBT- transurethral resection of bladder tumor

#### Day 2

Urologist performs Light activation with 689nm infrared light (50J/cm<sup>2</sup>) (~5 min duration) (Aura present w/ Urologist)

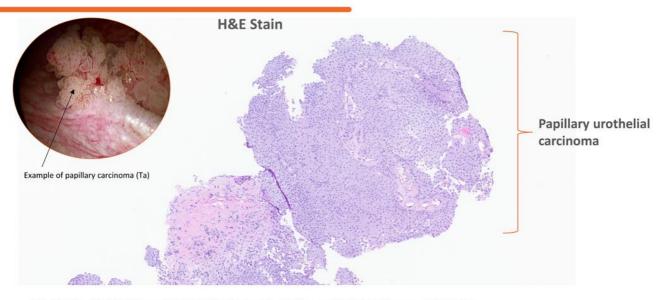
#### Day 9

Urologist performs TURBT in area where tumor used to be present. Biopsy shows denuded urothelial mucosa, no cancer cells;

focal ulcer and chronic inflammation (eosinophils/lymphocytes)

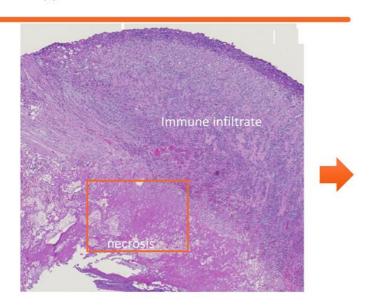


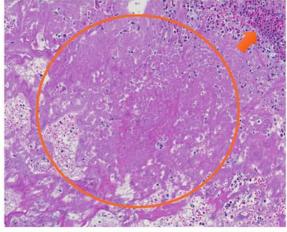
# Pre-Treatment Biopsy (Day 1) shows Papillary Urothelial Carcinoma



Pre-injection bladder biopsy demonstrating low-grade papillary urothelial carcinoma; non-invasive.

# Clinical Complete Response Confirmed by Histopathology after Single Dose of Bel-sar Disappearance of all cancer cells after treatment and immune activation



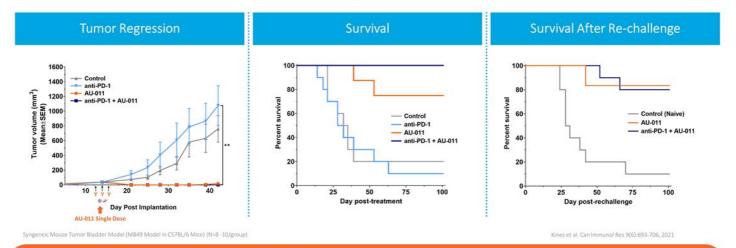


Post-treatment TURBT demonstrating necrosis, inflammatory infiltrate, and no residual carcinoma. Circled region shows area of necrosis; arrow indicates edge of inflammatory infiltrate.

**Evidence of Complete Response by Absence of Tumor Cells after Single Dose Treatment in First Patient** 

#### Durable CRs with Single Administration of Bel-sar in Bladder Cancer Model

Treatment of Tumor Caused Anti-Tumor Immune Response and Prevented Tumor Growth After Re-Challenge



Data Demonstrated Robust Nonclinical Activity Supporting Development of Bel-sar as Single Agent and in Combination with Checkpoint Inhibitors



## Aura Biosciences - Developing a Novel Class of Drugs in Oncology

# Ocular Oncology Franchise

Choroidal Melanoma – Global Ph 3 CoMpass Trial:

- FPI was Q4 2023
- · Most US sites activated; Trial actively enrolling
- · Special Protocol Assessment (SPA) Agreement with FDA
- Ph 3 assumptions supported by Ph 2 data
- Choroidal Metastasis Ph 2 trial planned to initiate in mid-2024
- Second ocular indication potentially doubles market opportunity

#### **Urologic Oncology Franchise**

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Clinical complete response in first patient with single dose

- Data supports dual mechanism
- Updated protocol includes both NMIBC and MIBC

**Strong Cash Position** 

Current cash runway expected to fund operations into 2H 2026