

**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 6, 2023

Aura Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40971
(Commission
File Number)

32-0271970
(I.R.S. Employer
Identification No.)

80 Guest Street
Boston, MA
(Address of principal executive offices)

02135
(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))

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	AURA	The Nasdaq Global Market

Item 8.01. Other Events

Aura Biosciences, Inc. (the "Company") will be conducting meetings with investors attending the 41st Annual J.P. Morgan Healthcare Conference in San Francisco beginning on January 9, 2023. 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; the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; 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, an improved quality of life of patients after treatment with belzupacap sarotalocan; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; 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; 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; risks, assumptions and uncertainties regarding the impact of the continuing COVID-19 pandemic on the Company's business, operations, strategy, goals and anticipated timelines; the Company's ongoing and planned pre-clinical 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 in this press release 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate presentation of the Company
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.

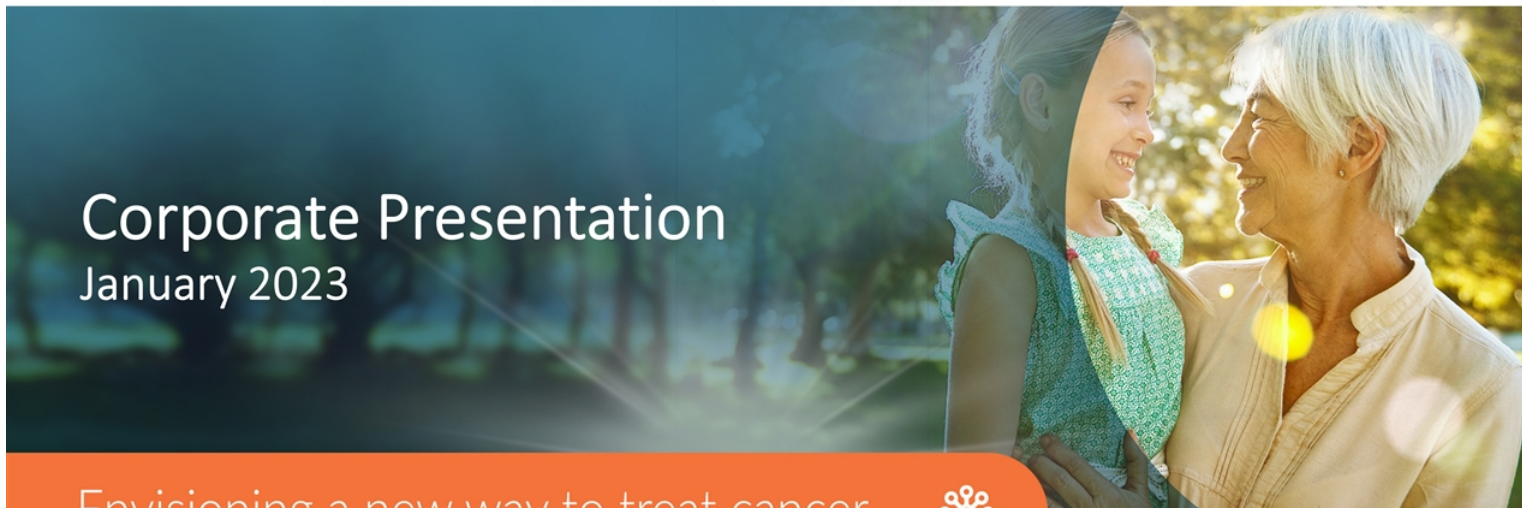
Date: January 6, 2023

AURA BIOSCIENCES, INC.

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

Corporate Presentation January 2023

Envisioning a new way to treat cancer



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 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; the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; our ability to commercialize our products, if approved; 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 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 Highlights

Novel Platform to Treat Cancer

- Developing virus-like drug conjugates (VDCs) that bind to tumor associated HSPGs* and deliver a therapeutic payload
- Targeting multiple solid tumor indications including ocular and bladder cancers

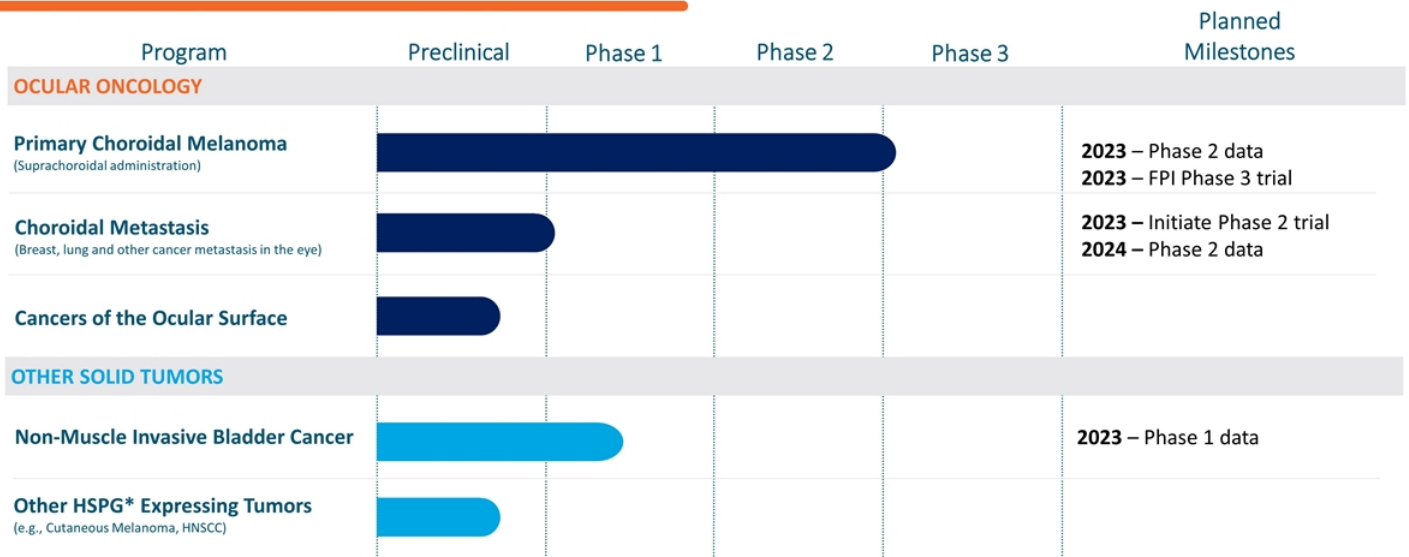
Ocular Oncology Franchise

- Multi-billion-dollar addressable market opportunity to treat early-stage choroidal melanoma (CM) and other ocular tumors
- Standard of care is invasive and may lead to blindness and loss of eye
- Clinical proof of concept with two routes of administration
- Advancing to global Phase 3 trial

Strong Cash Position

- Expected to fund operations into 2025

Pipeline Targeting Life-Threatening Cancers with High Unmet Needs



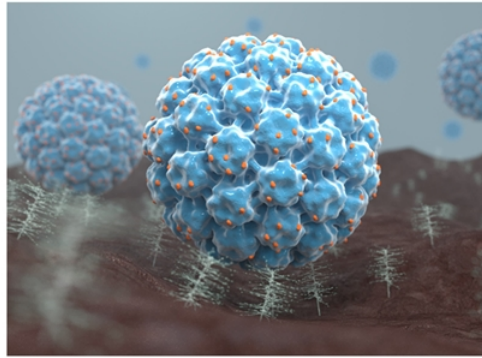
Global Commercial Rights for All Product Candidate Indications

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

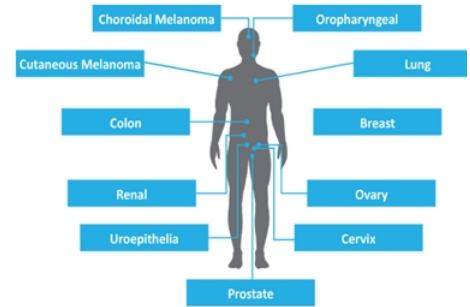
Virus-Like Particle Conjugated to a Cytotoxic Payload



Selective Binding to Tumor Associated HSPGs*

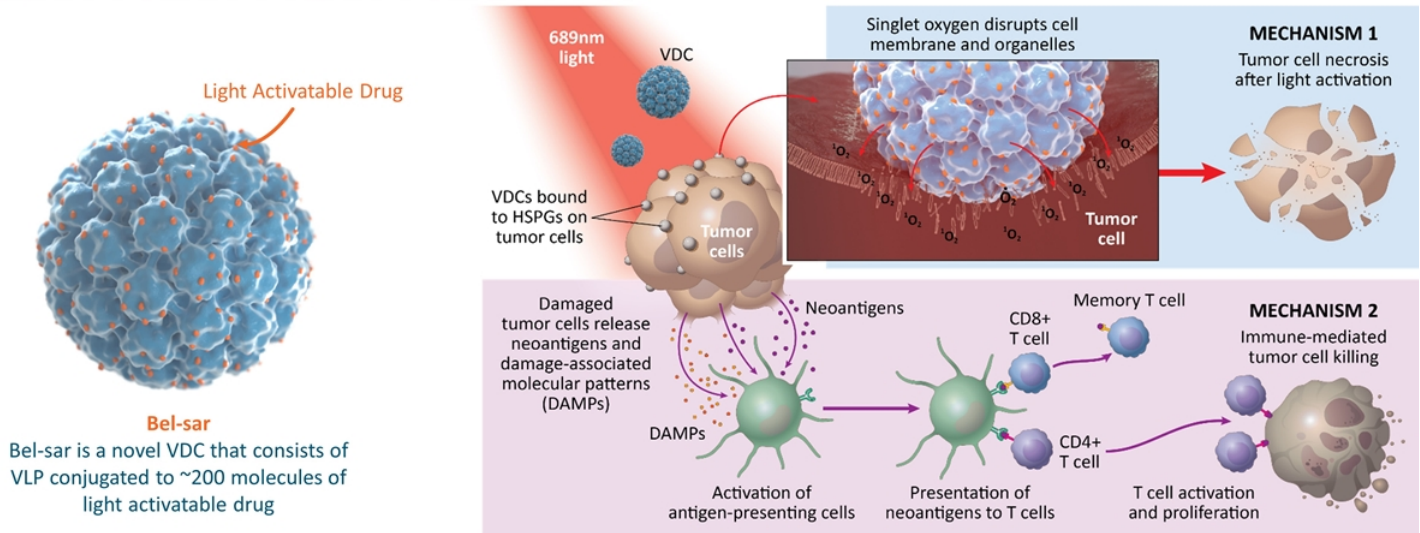


Potential Treatment of Multiple Solid Tumors



Potential Key Differentiation: Potency, 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), 1656
Bel-sar – Belzupacap Sarotalocan

Ocular Oncology Franchise



Bel-sar
INN: *belzupacap sarotalocan*



Target Indications:

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

Choroidal Melanoma – High Unmet Medical Need with No Drugs Approved



Most common primary intraocular cancer in adults

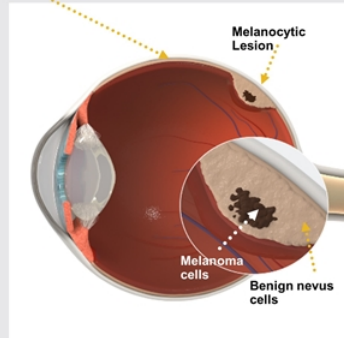


Impacts **11,000** patients in US/Europe per year

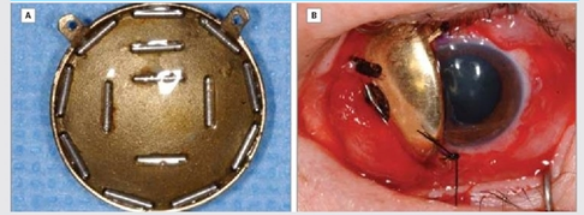


~80% patients diagnosed with early-stage disease

The choroid is the part of the uvea that is behind the retina



Standard of Care is Radiotherapy or Enucleation



Blindness, Eye Loss, and Disfiguration

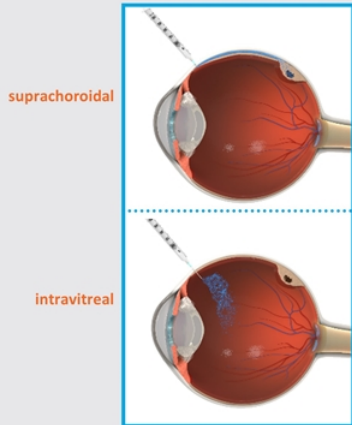
Choroidal Melanoma is a Rare and Life-Threatening Ocular Cancer

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

Bel-sar is Delivered by Simple Intravitreal or Suprachoroidal Injection

Light Activation with Standard Ophthalmic Laser

Goals of Treatment

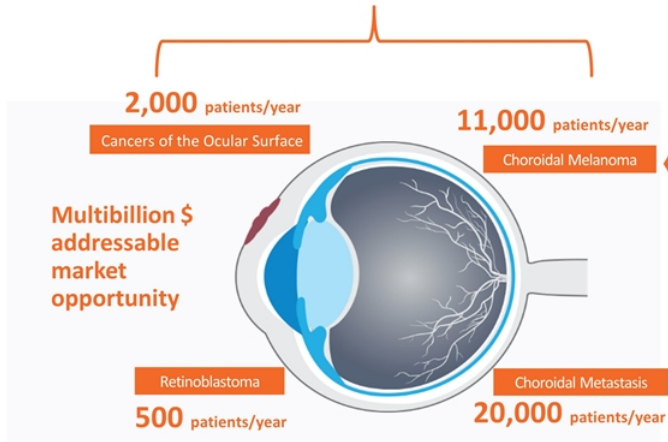


- Local tumor control
- Preservation of vision
- No radioactive co-morbidities
- Opportunity to treat early and reduce risk of metastases
- Improvement in safety and quality of life

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

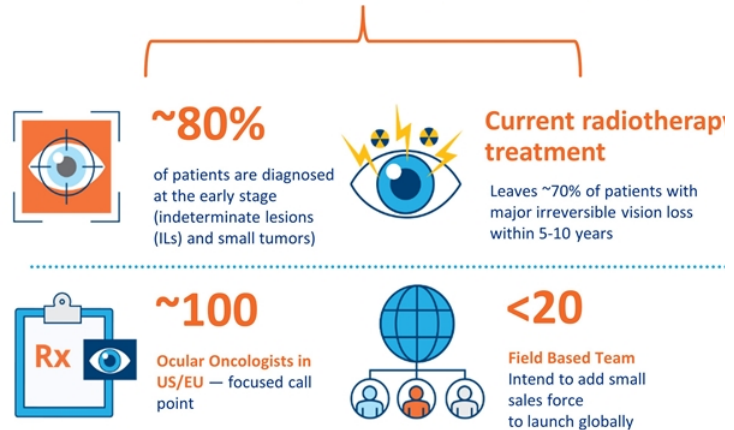
33,500

Ocular Oncology Franchise total addressable market



11,000

Choroidal Melanoma patients diagnosed each year (US/EU)

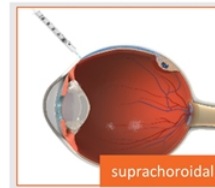
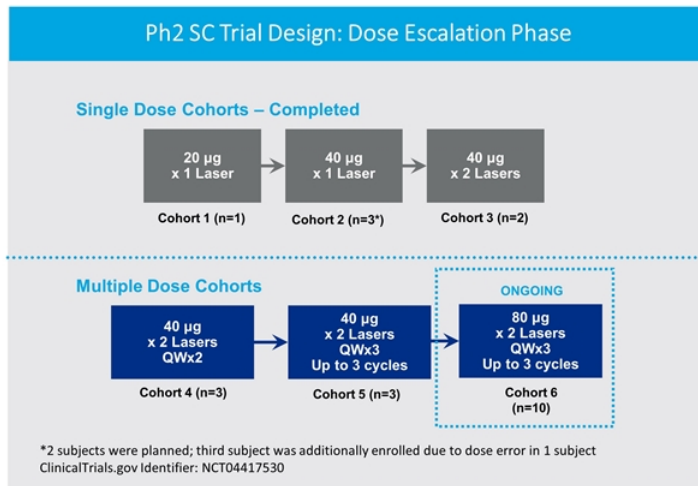


Choroidal Melanoma – Initial Indication

aura

ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis
American Cancer Society- Retinoblastoma statistics
Batsi et al Cornea 2003 Ocular Surface squamous neoplasia: a review

Ph 2 Trial - Evaluating Suprachoroidal Administration to Determine Optimal Administration Route



Patient Population Representative of Early-Stage Disease (IL/CM)

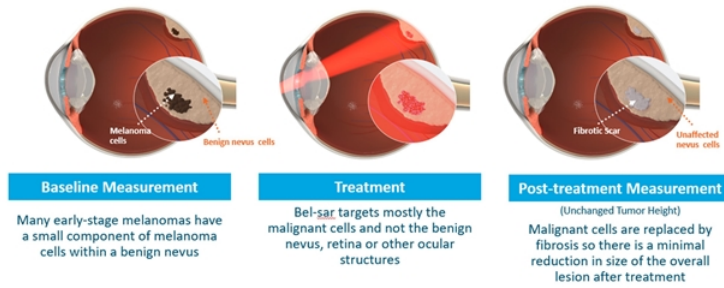


Small Tumors with Active Growth

- Tumor thickness ≥ 0.5 mm and ≤ 2.5 mm
- LBD ≤ 10 mm
- Active tumor growth (>0.3 mm) within 2 years of screening
- Same criteria as the planned Phase 3

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

Goal for Bel-sar: Eliminate Malignant Cells in the Choroid and Preserve Vision

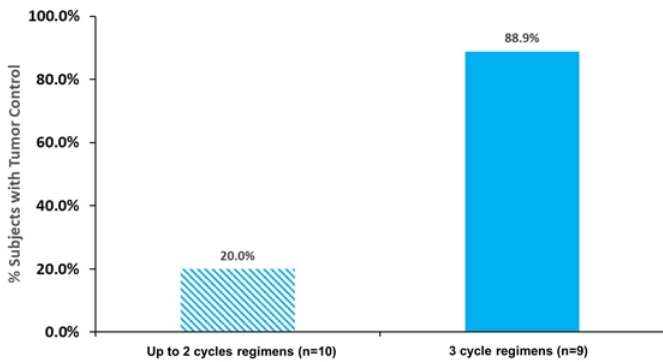


Endpoint Definition	Threshold	Methodology
Tumor Progression	Growth in Tumor Height $\geq 0.5\text{mm}$ or $\geq 1.5\text{ mm}$ in Largest Basal Diameter (LBD)	Ultrasound and Digital Photography
Visual Acuity Loss	Long Term Loss ≥ 15 letters	ETDRS-BCVA
Tumor Thickness Growth Rate	Tumor Thickness Growth over 12 Months	Ultrasound

Key Endpoints Aligned with Ocular Oncology Clinical Practice and FDA

Ph 2 Interim Tumor Control Rates Demonstrate a Dose Response

3 Cycle Regimens vs. Lower Regimens



Tumor Progression: change from baseline in thickness $\geq 0.5\text{mm}$; or in LBD $\geq 1.5\text{mm}$ confirmed by at least one repeat assessment
19-Aug-2022 cutoff, interim data

Average 6 Months of Follow Up

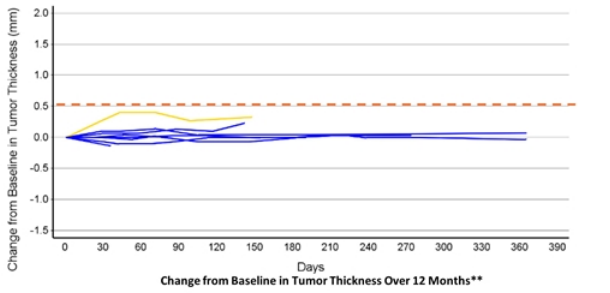
Populations	Total Patients (n)	Tumor Control Rate	Average Follow-up (months)
All Doses/Regimens			
All Treated Patients	20	55.0% (11/20)	8
Lower Doses/Regimens⁺			
Less than 1 cycle (20 μg -40 μg)	9	22.2% (2/9)	11
2 Cycles (40 μg)	1	0% (0/1)	6
Highest Doses/Regimens^{***}			
3 Cycles (n=9)	9	88.9% (8/9)	6
40 μg (n=2)/80 μg (n=7)			

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
⁺Assigned regimens- up to two cycles: with doses of 20 μg x 1 Laser or 40 μg x 1 or 2 Lasers
^{**} Assigned regimens- 3 cycles, each cycle comprised of 3 once/week treatments of 40 μg x 2 Laser or 80 μg x 2 Laser
^{***} 2 Laser

Dose Response and Interim Tumor Control Rates Demonstrate Meaningful Clinical Benefit

Ph 2 Interim Analysis Demonstrates Tumor Control Rate 89%-100%

89%-100% Tumor Control Rate: Active Growth and Therapeutic Regimen (3 cycles)

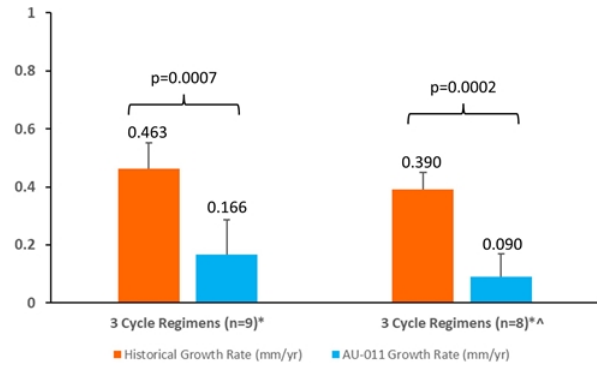


----- Progression Definition based on Tumor Thickness (Increase ≥ 0.5 mm)
 Subject 015-2029 had circumpapillary tumor – similar subjects will be excluded from Phase 3 trial

Tumor Progression: change from baseline in thickness ≥ 0.5 mm; or in LBD ≥ 1.5 mm confirmed by at least one repeat assessment; Interim data cutoff August 19, 2022

**1 subject without post-baseline tumor thickness data not included in plot

Statistically Significant Change in Tumor Growth (mm/yr): Therapeutic Regimen (3 cycles)



*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
 ^One subject in C6 with circumpapillary tumor not included (similar subjects not planned in Phase 3 trial)

Tumor thickness growth rates/ slopes estimated using MMRM (random intercept and slope model for Hx and Study periods)

Established Therapeutic Regimen of 3 Cycles using SC Administration

Ph 2 Interim Analysis Shows Visual Acuity Preservation 89%-100%

Vision Preservation Rates					
Populations	Total Patients (n)	Vision Failures** (n)	Vision Preservation Rate	Mean Change from Baseline at Last Visit (letters)	Average Follow-up (months)
All Dose Cohorts					
All Treated Patients	20	2	90.0%	-3.3	8
High Risk for Vision Loss	15	2	86.7%	-4.5	7
Highest Doses/Regimens*					
2 Cycles (40µg)	1	0	100%	-3.0	6
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=7)	9	1	88.9%	-3.9	6

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included

**Confirmed loss ≥ 15 letters at \geq Week 39; post-SOC data not included

Interim data cutoff August 19, 2022

Interim Data Showed High Vision Preservation Rates Across All Groups Including Subjects at High Risk for Vision Loss

Ph 2 Ongoing Tolerability Evaluation Continues to Be Favorable

All Treated Subjects (n=20) Drug/Laser Related Adverse Events ≥10% Subjects	Grade I	Grade II	Grade III	Total
Anterior Chamber Cell/ Inflammation	25%	0	0	25%
Conjunctival hyperemia	15%	0	0	15%
Eye Pain	5%	5%	0	10%
Punctate Keratitis	10%	0	0	10%

- Majority of AEs were transient and resolved without clinical sequelae
- No DLTs or treatment related SAEs
- No significant vitritis to date through 3 cycles with 80 µg of AU-011
- No pigmentary changes observed at edge of tumor treatment

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
Interim Data cutoff Aug 19, 2022

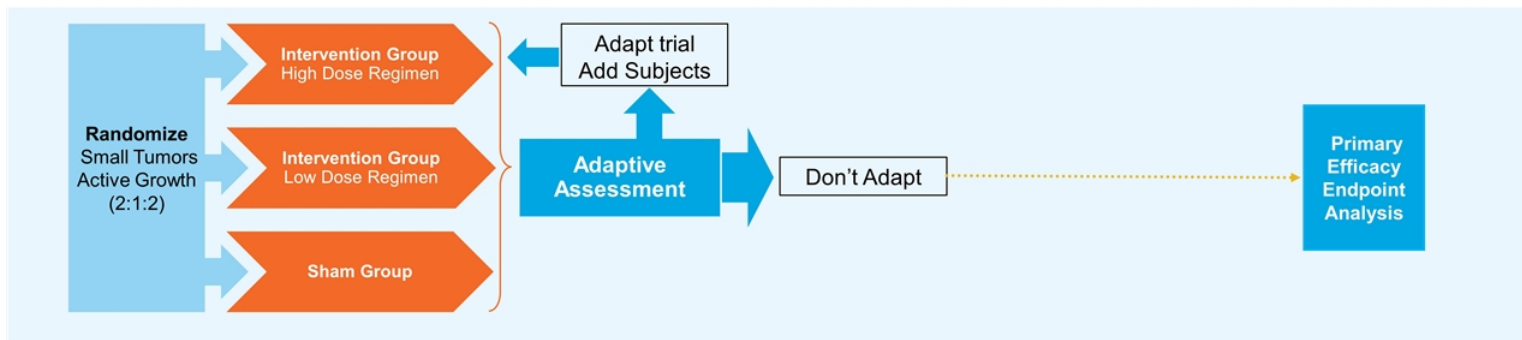
Interim SC Data Showed No Posterior Inflammation and No TR-SAEs Supportive of Superior Tolerability Profile vs IVT

Phase 3 Trial



Global Phase 3 Trial Design Using Suprachoroidal Administration

Fast Track and Orphan Designations



Primary Endpoint

- Composite time to event analysis:
 - Tumor progression or visual acuity failure between Intervention Group (High Dose) and Sham Group

Key Secondary Endpoints

- Time to Tumor Progression
- Tumor Growth Rate over 52 weeks

Adaptive Design Optimizes Probability of Success

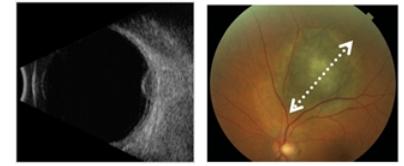
Clinical Endpoints to Support Approval in Alignment with Regulatory Agencies

Composite Endpoint

<p>Tumor Progression Assumptions</p>	<p>Tumor Height (TH): Ultrasound Largest Basal Diameter (LBD): fundus photography <i>Bel-sar: 35% Tumor Progression</i> <i>Sham: 85% Tumor Progression</i></p>
<p>Vision Failure Assumptions</p>	<p>Visual Acuity - ETDRS BCVA <i>Bel-sar: 15% VA Failure</i> <i>Sham: 2% VA Failure</i></p>
<p>Growth Rate Assumptions</p>	<p>Change in Tumor Height (TH) over time: Ultrasound <i>Bel-sar vs Sham : -0.28mm/year reduction</i></p>

Disease Progression

Increase from baseline:
TH $\geq 0.5\text{mm}$
LBD $\geq 1.5\text{mm}$



Ultrasound

Fundus photography

Visual Acuity Failure

Decrease from baseline:
 ≥ 15 letters



Growth Rate

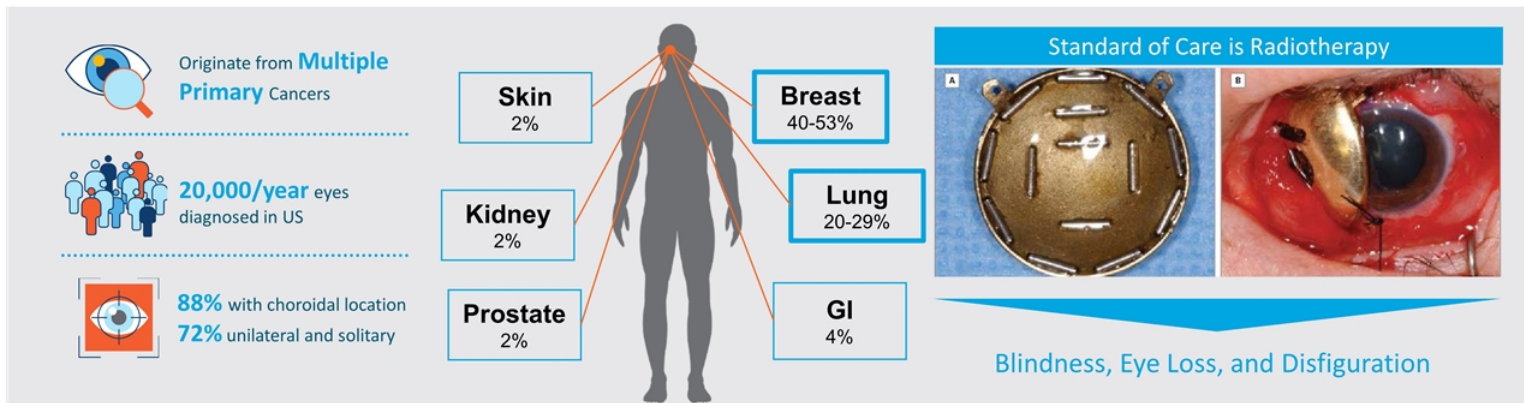
Change in tumor height over time

Conservative Assumptions Provide >90% Power to Maximize Probability of Success with Single Phase 3 Trial

Choroidal Metastasis



Choroidal Metastasis is a High Unmet Medical Need

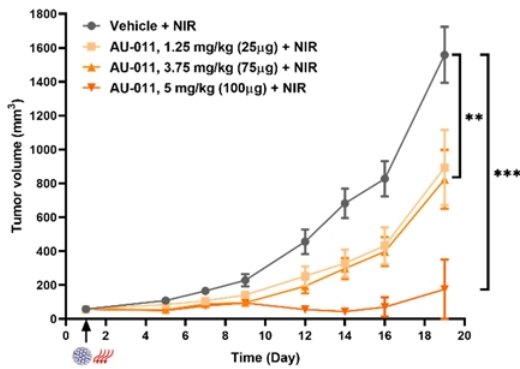


Choroidal Metastasis Cause Decreased Vision and Decreased Quality of Life in Patients Fighting Metastatic Cancer

Bel-sar has Demonstrated Dose-Dependent Activity for Cancer Types Known to Metastasize to the Choroid

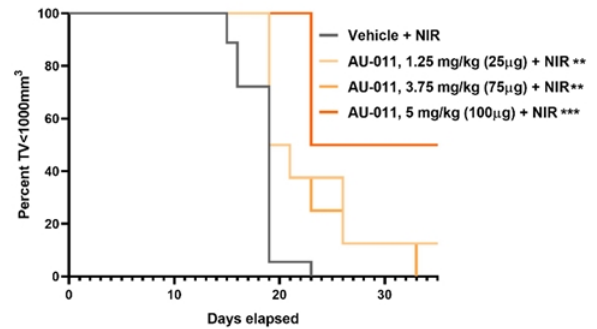
Breast Cancer In-Vivo (Syngeneic Mouse Model, EMT-6)

Reduced Tumor Growth



Tumor cells were implanted subcutaneously. AU-011 treatment was initiated when tumors reached approximately 50 mm³. Treatment consisted of a single intravenous administration of AU-011 followed 12 hours later by light activation (400 mW/cm², 58 J/cm²). Tumor volumes were measured over time (N=8-12)

Prolonged Survival



Single Administration of Bel-sar Showed Tumor Regression and Prolonged Survival in a Dose-Dependent Fashion
Data Supportive of Moving into Clinical Trials

Urologic Oncology



Bel-sar
INN: belzupacap sarotalocan



Target Indications:
Non-Muscle Invasive Bladder Cancer

Bel-Sar is a Clinical Asset with a Multibillion Dollar Market Opportunity in Non-Muscle Invasive Bladder Cancer

NMIBC is High Unmet Need

- High Incidence across all geographies >200,000 patients/year
- Rate of recurrence is high

Bel-Sar's MoA Well Suited to NMIBC

- Strong precedent for immune-activators in NMIBC (BCG)
- Bladder tumors physically accessible via cystoscope (injection, laser)

Robust Nonclinical Data Package

- Durable CRs and improved survival in *in vivo* bladder cancer models
- Synergy with checkpoint inhibitors (durable immunologic memory)

Clinical Proof of Concept

- Two clinical trials demonstrate robust efficacy in Ocular Oncology
- Initiating global Ph 3 study in choroidal melanoma

Phase 1 Study Ongoing

- Initial data available in 2023

NMIBC is a High Unmet Need with High Recurrence Rate



573,000

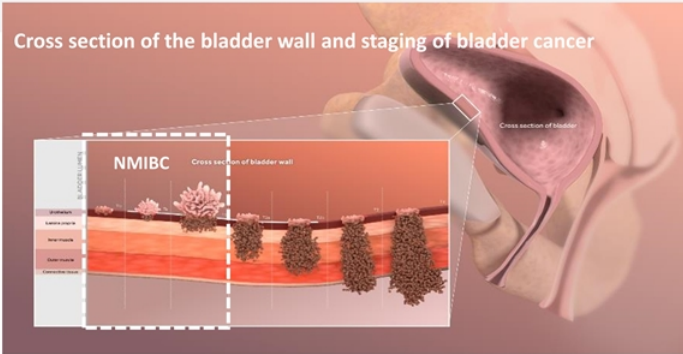
New cases NMIBC/year globally



81,000

New cases/year in the US

Cross section of the bladder wall and staging of bladder cancer

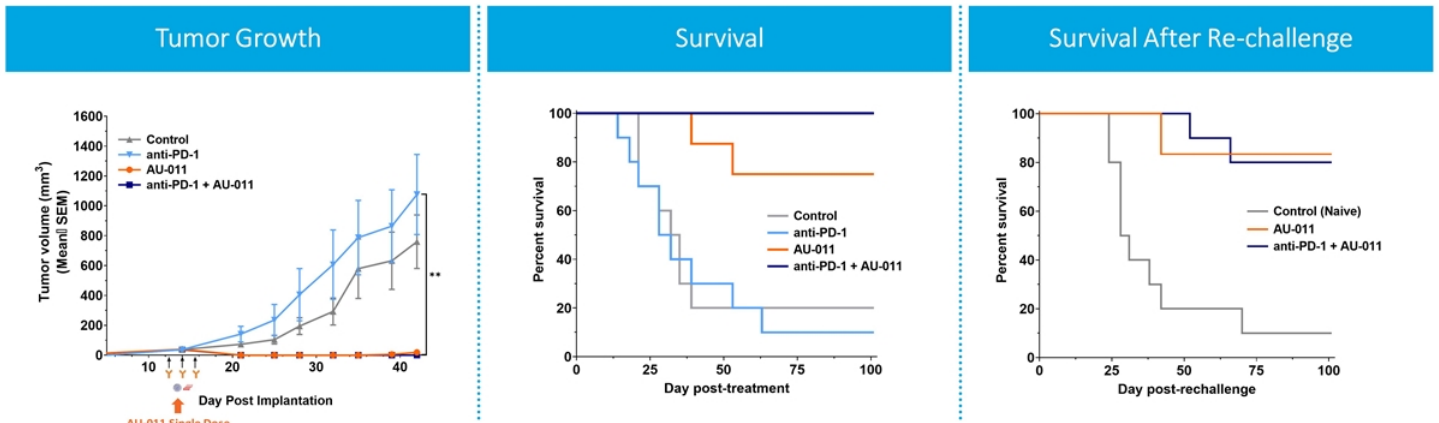


Risk Stratification	Treatment Guidelines	Problem
Low Risk (40%)	Surveillance or TURBT + Chemo	Recurrence after TURBT
Intermediate Risk (30%)	Mix of TURBT + Chemo / BCG	Failure of BCG/Chemo ~40%
High Risk (30%)	Mix of Chemo / BCG	Progression with no alternative option but Cystectomy

Mechanism of Action Supports Bel-sar Opportunity as Potential Front-Line Treatment Following Initial Diagnosis and/or BCG Refractory Disease

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



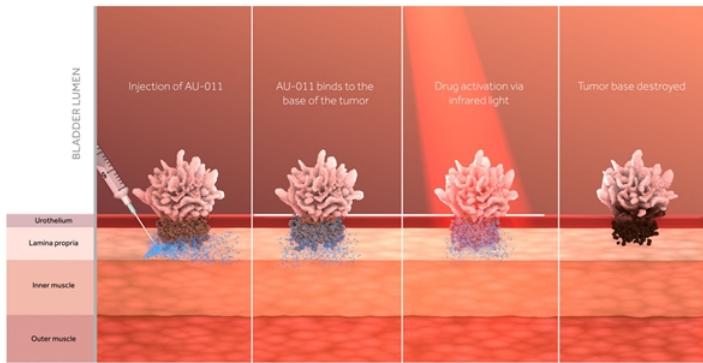
Syngeneic Mouse Tumor Bladder Model (MB49 Model in C57BL/6 Mice) (N=8-10/group)

Kines et al. Can Immunol Res 9(6):693-706, 2021

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

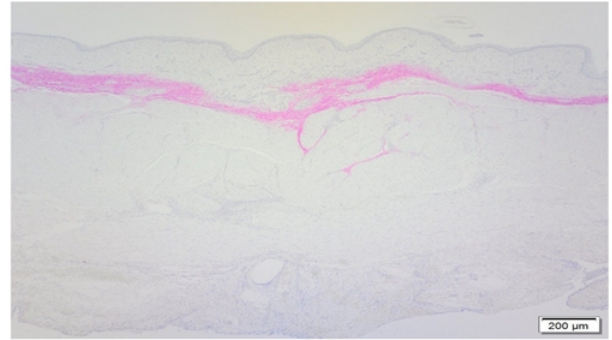
Novel Approach using Intra-mural Administration

Intra-mural Administration



Bel-sar will be administered in the lamina propria close to the base of the tumor

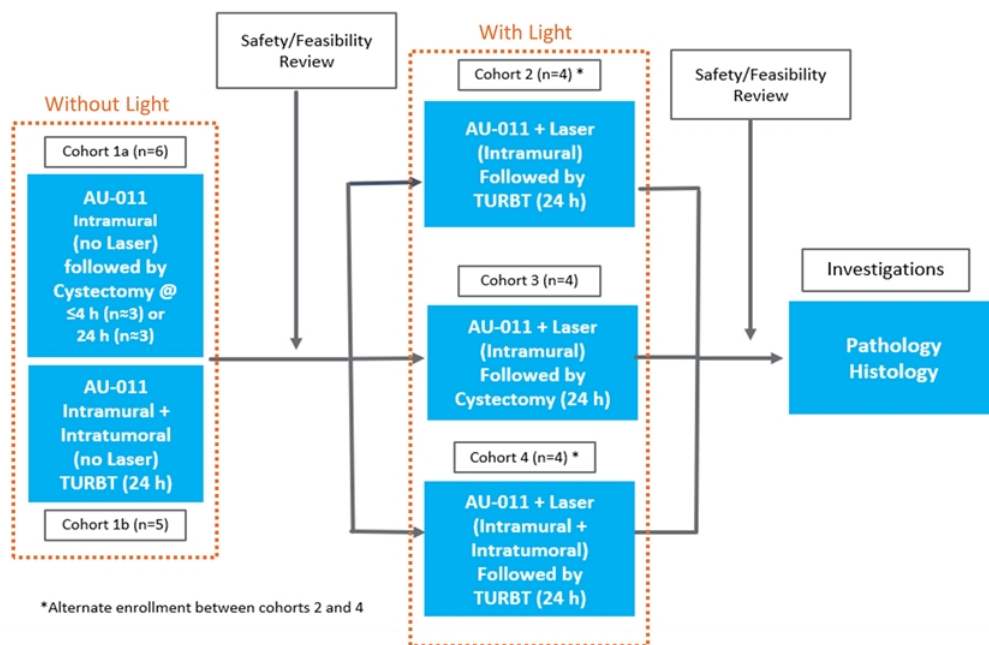
Distribution Into the Mucosal Layer Into the Bladder Wall



3 Hour Post AU-011 Injection (Dog tox study):
Bel-Sar positive staining (pink) extends laterally at the junction between the submucosa and superficial muscularis of the bladder

Ongoing Phase 1 Designed to Establish Safety, and Optimize Administration in Intermediate and High Risk NMIBC Patients

Ongoing Ph 1 Trial Evaluating Bel-sar Distribution, Local Necrosis and Evidence of Immune Activation



Strategy & Key
Milestones



Aura Biosciences Investment Highlights

Technology Platform

Virus-like Drug Conjugates

- Novel class of oncology targeted therapies
- Targeting multiple solid tumor indications including ocular and bladder cancers

Clinical Data Highlights

Ocular Oncology Franchise

- Positive data in completed Phase 1b/2 study (IVT)
- Positive interim data in ongoing Phase 2 study (SC)

2023 Milestones

Primary Choroidal Melanoma:

- 1H 2023: Dose First Patient in Phase 3 Trial
- 2H 2023: Phase 2 SC Data

Choroidal Metastasis:

- 2H 2023: Initiate Phase 2 Trial

Non-Muscle Invasive Bladder Cancer:

- 2023: Phase 1 Data

Strong Cash Position

Expected to fund operations into 2025

aura

Appendix: Phase 1b/2 IVT Trial



Phase 1b/2 IVT – Key Patient Populations and Objectives

All Patients Enrolled with Clinical Diagnosis of Choroidal Melanoma or Indeterminate Lesions

Safety Evaluation
(All Treated)

All Treated
Patients



Efficacy Evaluation
Therapeutic Regimen (2 Cycles)

Patients Treated
with 2 Cycles



Patients with Active
Growth
Treated with 2 Cycles



Primary Objective: Safety

- Drug or treatment related adverse events (AEs) / serious adverse events (SAEs)

Secondary Objective: Efficacy

- Tumor thickness growth rate before and after treatment
- Local tumor control
- Visual acuity preservation

Enrichment Strategy to Enroll Subjects with Actively Growing Tumors
Provides Important Insight into How Bel-sar May Perform in Phase 3 Trial

Phase 1b/2 – Demonstrated Favorable Tolerability Profile

Majority of AEs Were Transient and Resolved Without Clinical Sequelae

AU-011 Treatment Related AEs ≥15% Subjects (n=56) Final	Grade I/II	Grade III
Vitreous Inflammation	83.9%	7.1%
Anterior Chamber Inflammation	67.9%	3.6%
Increase in Intraocular Pressure	46.4%	0
Pigmentary Changes/Peritumoral	37.5%	0
Keratic Precipitates	23.2%	0
Floater/Vitreous Opacity	19.7%	1.8%
Decreased visual acuity	19.6%	1.8%

Treatment Related SAEs (n=56)		
Vision Loss (juxtafoveal tumor, n=2)		3.6%

SAE of vision loss in two subjects with tumors close to fovea due to pigmentary changes at the edge of the tumor
SAEs are listed separately in the SAE table Completed Ph 1b/2 IVT trial (AU-011-101)

Adverse Event	Radiotherapy*	Bel-Sar
Surgeries secondary to AEs (e.g., Cataracts)	40%+	~13%
Radiation Retinopathy	40%+	0%
Neovascular Glaucoma	10%	0%
Dry Eye Syndrome	20%	~2%
Strabismus	2%+	0%
Retinal Detachment	1-2%	~2%
Vision Loss (≥15 letters)	~70%	~21%

Serious Adverse Event	Radiotherapy*	Bel-Sar
Scleral Necrosis	0-5%	0%
Enucleation/Eye Loss	10-15%	0%
Vision Loss in High-Risk Subjects** (≥30 letters)	~90%	4.6%*

Cross-trial comparison of AU-011-101 and Radiotherapy *77% (43/56) of patients in Ph1b/2 IVT trial were at high risk for vision loss ; 2/43= 4.6%

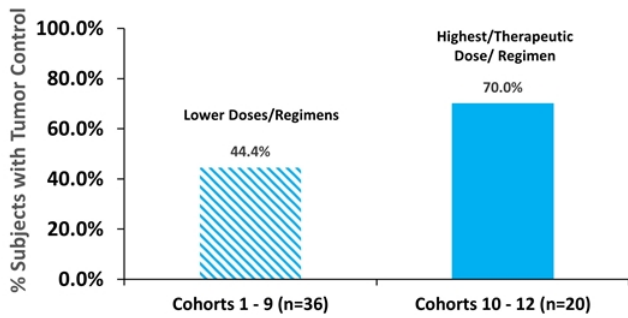
Tolerability Profile Supports Indication as a First Line Treatment in Early-Stage Disease

*J. Contemp Brachytherapy. J. 2019 Aug; 11(4): 392–397.; Arch Ophthalmol. 2000;118(9):1219-1228; Curr. Opin. Ophthalmol. 2019 May;30(3):206-214; Eye 2017 Feb;31(2):241-257

**High-Risk Subjects are those with tumors <3mm to fovea or optic nerve
Bel-Sar – Belzupacap Sarotalocan

Phase 1b/2 IVT- 70% Tumor Control Rate and Statistically Significant Growth Rate Reduction

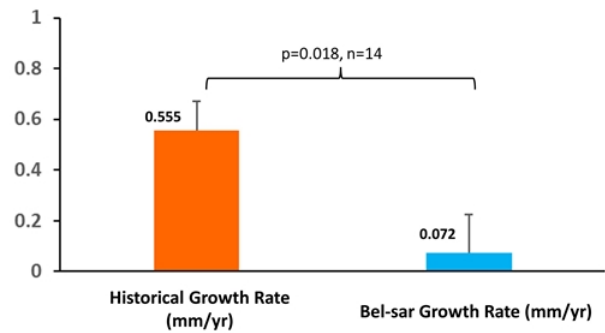
Tumor Control Rates at 12 months



Cohorts 1-9 include single dose escalation cohorts and multiple dose escalation cohorts up to 1 cycle of treatment; Cohorts 10-12 include 2 cycles of treatment at the highest dose

Completed Ph1b/2 IVT trial (AU-011-101)

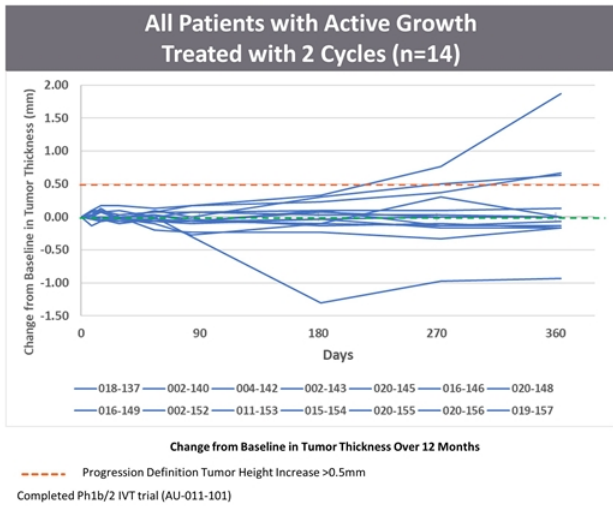
Change in Tumor Growth Rate



- Disease-modifying effect supports tumor is inactive and malignant cells have been targeted by bel-sar

Positive Data in Two Efficacy Endpoints in Patients with Early-Stage Choroidal Melanoma

Phase 1b/2 – 64% Patients with Active Growth Achieved Tumor Control when Treated with Therapeutic Regimen

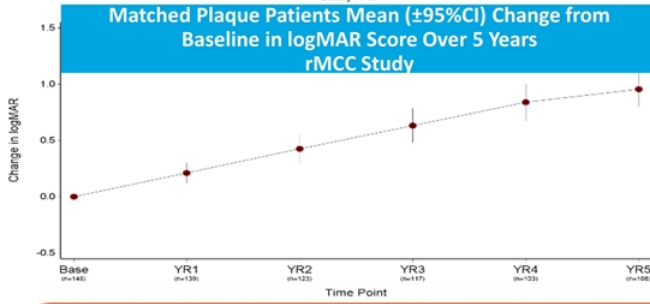
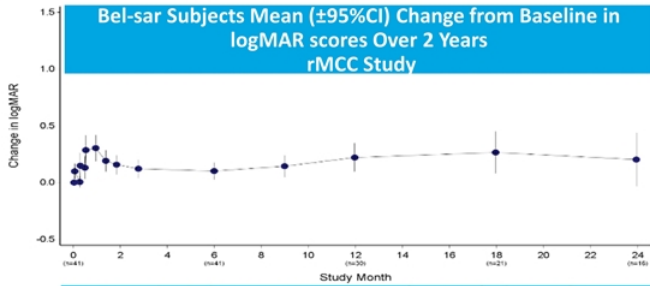


Tumor Control Rate at 12 months		
Populations	Total Patients (n)	Tumor Control Rate (at 12 months)
Therapeutic Dose/Regimen (2 Cycles)		
All Patients Treated with 2 Cycles	20	70% (14/20)
All Patients with Active Growth Treated with 2 Cycles	14	64% (9/14)

Tumor control failure (progression): Growth from baseline in Tumor Height >0.5mm or LBD >1.0mm due to definitive Tumor Growth (ie, not judged by the Investigator to be due to inflammation/swelling, hemorrhage or pigmentary changes) and not treated with standard of care

We Believe Results Support Bel-sar as First Line Treatment to help Many Patients Avoid the Need for Radiotherapy

Visual Acuity was Preserved in Majority of Patients with IVT Administration of Bel-sar



Vision Preservation Rates Phase 1b/2 IVT Study Follow up 12 months

Populations	Total Patients (n)	Vision Preservation Rate Failure: Long-term loss ≥ 15 letters
All Dose Cohorts		
All Treated Patients	56	86% (48/56)
Patients with Active Growth - High Risk for Vision Loss	17	76% (13/17)
Therapeutic Regimen (2 cycles)		
All Treated Patients	20	75% (15/20)
Patients with Active Growth	14	71% (10/14)

1 patient had loss ≥ 15 letters at Week 52 visit which recovered within 15 letters at the next visit which was ~3 weeks after standard of care (SOC); all other post-SOC data excluded for all subjects Completed Ph1b/2 IVT trial (AU-011-101)

Vision was Preserved in Majority of Patients Whereas Radiotherapy Often Leads to Irreversible and Long-Term Severe Vision Loss