UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 13, 2025

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 **Boston, Massachusetts** **(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))

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 August 13, 2025, Aura Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2025. 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 August 13, 2025, 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 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 use, for clinical trials and on a larger scale for commercial use, 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 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 and urologic 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 2027; 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 and 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 United States 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 August 13, 2025.
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: August 13, 2025

By: /s/ Elisabet de los Pinos

Elisabet de los Pinos
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Aura Biosciences Reports Second Quarter 2025 Financial Results and Business Highlights

Continued Clinical Program Execution in the Phase 3 CoMpass Trial in Early Choroidal Melanoma and the Phase 1b/2 Trial in Non-Muscle Invasive Bladder Cancer (NMIBC)

Strengthened Balance Sheet with $75 Million Equity Financing; Cash Position Expected to Fund Operations into the First Half of 2027

BOSTON, MA – August 13, 2025 – Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision therapies for solid tumors designed to preserve organ function, today reported financial results for the second quarter ended June 30, 2025, and provided recent business highlights.

“We continued to focus on execution in our clinical programs in the second quarter, including our ongoing global Phase 3 CoMpass trial in early choroidal melanoma and our Phase 1b/2 trial in NMIBC,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. “With the successful completion of our recent equity financing, we believe we are well positioned to advance the clinical development of bel-sar in our ocular and urologic oncology programs, where we believe our unique mechanism of action has the potential to meaningfully impact the lives of patients.”

Recent Pipeline Developments

Early Choroidal Melanoma

Ongoing Phase 3 CoMpass Trial: CoMpass is the first registration-enabling study in early choroidal melanoma. The study is a global, Phase 3, randomized trial evaluating bel-sar treatment against a sham control arm utilizing an enrichment strategy to enroll approximately 100 patients with documented tumor growth.

The CoMpass trial is actively enrolling globally. To identify patients meeting the enrichment criteria of documented growth, the Company implemented a pre-screening ‘run in’ period. Investigators have registered over 240 patients in this pre-screening tool as having met initial enrollment criteria for the study, highlighting the global need for a frontline vision-preserving therapy. With this progress globally, the Company believes study enrollment may be completed as early as the end of 2025.

The Company previously received Orphan Drug Designation from the FDA and the European Medicines Agency and Fast Track designation from the FDA for the treatment of early choroidal melanoma. The CoMpass trial is under a Special Protocol Assessment agreement with the FDA.

Additional Ocular Oncology Indications

In addition to early choroidal melanoma, bel-sar is in development for metastases to the choroid and cancers of the ocular surface. These three ocular oncology indications have a collective annual incidence of greater than 60,000 patients in the United States and Europe.

Metastases to the Choroid

Metastases to the choroid is an indication with high unmet medical need and no approved therapies. Bel-sar has the potential to treat a wide variety of tumor types that metastasize from several primary tumors. The Company has initiated a Phase 2 clinical trial in metastases to the choroid from breast and lung cancer and have activated sites with patients in prescreening in the United States. The Company is currently implementing a protocol amendment for the Phase 2 trial to broaden the inclusion criteria beyond breast and lung cancer to include all metastases from different solid tumors, an approach supported by pre-clinical models that demonstrate robust efficacy across a range of solid tumors. The Company believes that this approach, in addition to advancing bel-sar in metastases to the choroid, can provide clinical insights into multiple tumor types that could be impacted by bel-sar. The Company expects initial data from this trial in 2025.

Metastases to the choroid represents the second potential ocular oncology indication for bel-sar, affecting approximately 20,000 patients annually in the United States and Europe. The Company previously received FDA Fast Track designation for bel-sar in this indication.

Cancers of the Ocular Surface

The Company's third potential ocular oncology indication is cancers of the ocular surface, which affects approximately 35,000 patients in the United States and Europe annually and has no approved therapies. The Company's pre-clinical activities in cancers of the ocular surface remain on track, and we plan to have initial data from an early proof of concept Phase 1 clinical trial in 2026.

Bladder Cancer

Ongoing Phase 1b/2 Trial: Based on the positive data from the Phase 1 window of opportunity trial, the Company is advancing the development of bel-sar in NMIBC. The ongoing Phase 1b/2 trial will evaluate additional doses and cycles of bel-sar in approximately 26 intermediate and high-risk NMIBC patients. The trial will evaluate two approaches: an immune ablative design and a multimodal neoadjuvant design. In the immune ablative approach, bel-sar will be administered in two cycles without the need for a transurethral resection of the bladder tumor (TURBT). In the multimodal neoadjuvant cohorts, bel-sar will be administered in two cycles ahead of TURBT. For both approaches, patients will be monitored for response assessments and recurrence at 3, 6, 9, and 12 months. This trial is actively enrolling and remains on track.

Patent Application Filed for New Formulation of Bel-sar for Use in Bladder Cancer: The Company has filed a patent application with the U.S. Patent and Trademark Office for a new formulation of bel-sar for use in urologic oncology, which if issued, would provide patent coverage for this formulation into 2046. This new formulation is designed to enable convenient in-office urologist procedures with enhanced storage and handling at refrigerated conditions (2-8 Celsius).

Second Quarter 2025 Financial Results

- As of June 30, 2025, Aura had cash and cash equivalents and marketable securities totaling $177.3 million. The Company believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the first half of 2027.
- Research and development expenses increased to $22.9 million for the three months ended June 30, 2025 from $16.9 million for the three months ended June 30, 2024, primarily due to ongoing clinical and CRO costs associated with the progression of our global Phase 3 trial of bel-sar in early choroidal melanoma and manufacturing and development costs for bel-sar.
- General and administrative expenses decreased to $5.7 million for the three months ended June 30, 2025 from $5.9 million for the three months ended June 30, 2024. General and administrative expenses include $1.8 million and $1.6 million of stock-based compensation for the three months ended June 30, 2025 and 2024, respectively. The decrease was primarily driven by reduced professional fees.
- Net loss for the three months ended June 30, 2025 was $27.0 million compared to $20.3 million for the three months ended June 30, 2024.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company focused on developing precision therapies for solid tumors that aim to preserve organ function. Our lead candidate, bel-sar (AU-011), is currently in late-stage development for early choroidal melanoma and in early-stage development in other ocular oncology indications and bladder cancer. Aura Biosciences is headquartered in Boston, MA. Our mission is to grow as an innovative global oncology company that positively transforms the lives of patients.

For more information, visit aurabiosciences.com. Follow us on X (formerly Twitter) @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 for the treatment of multiple cancers; 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 to present initial data with respect to its Phase 2 clinical trial of bel-sar for the treatment of metastases to the choroid and Phase 1b/2 clinical trial of bel-sar for the treatment of NMIBC; 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; and statements regarding the Company’s expected cash runway.

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 special protocol assessment agreement with the U.S. Food and Drug Administration; 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 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 Investor Relations and Corporate Communications

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating Expenses:				
Research and development	$ 22,882	$ 16,879	$ 46,225	$ 33,932
General and administrative	5,731	5,883	11,423	11,145
Total operating expenses	28,613	22,762	57,648	45,077
Total operating loss	(28,613)	(22,762)	(57,648)	(45,077)
Other income (expense):				
Interest income, including amortization and accretion income	1,678	2,451	3,271	5,137
Other expense	(36)	(26)	(59)	(57)
Total other income	1,642	2,425	3,212	5,080
Loss before income taxes	(26,971)	(20,337)	(54,436)	(39,997)
Income tax provision, net	(48)	—	(66)	(46)
Net loss	$ (27,019)	$ (20,337)	$ (54,502)	$ (40,043)
Net loss per common share—basic and diluted	$ (0.47)	$ (0.41)	$ (1.01)	$ (0.81)
Weighted average common stock outstanding—basic and diluted	58,015,718	49,548,120	54,092,728	49,500,032
Comprehensive loss:				
Net loss	$ (27,019)	$ (20,337)	$ (54,502)	$ (40,043)
Other comprehensive items:				
Unrealized loss on marketable securities	(88)	(201)	(226)	(722)
Currency translation adjustment	8	—	(12)	—
Total other comprehensive loss	(80)	(201)	(238)	(722)
Total comprehensive loss	$ (27,099)	$ (20,538)	$ (54,740)	$ (40,765)

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 107,367	$ 31,693
Marketable securities	69,944	119,401
Prepaid expenses and other current assets	6,647	9,529
Total current assets	183,958	160,623
Restricted cash and deposits	768	768
Right-of-use assets - operating lease	16,622	17,379
Other long-term assets	185	518
Property and equipment, net	2,864	3,215
Total Assets	$ 204,397	$ 182,503
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,286	2,304
Short-term operating lease liability	3,196	3,149
Accrued expenses and other current liabilities	10,370	9,460
Total current liabilities	14,852	14,913
Long-term operating lease liability	14,916	15,620
Total Liabilities	29,768	30,533
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at June 30, 2025 and December 31, 2024, and 62,071,050 and 49,998,279 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	603,333	525,934
Accumulated deficit	(428,729)	(374,227)
Accumulated other comprehensive income	25	263
Total Stockholders' Equity	174,629	151,970
Total Liabilities and Stockholders' Equity	$ 204,397	$ 182,503

Exhibit 99.2

August 2025

Innovating the future of cancer care to cure patients and preserve organ function

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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; 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 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; statements regarding our beliefs and expectations for the high unmet medical need for an effective local treatment in ocular and urologic 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 2027; 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.

Well positioned for continued clinical program execution

Novel class of drugs: virus-like drug conjugates

VDCs have the potential to transform early cancer treatment

Novel MoA: direct tumor cell killing and immune cell activation

Positive clinical data in multiple indications

Positive phase 2 data in early choroidal melanoma with phase 3 ongoing under FDA SPA agreement

Multiple clinical complete responses with single low dose in phase 1 trial in NMIBC

Large market opportunity in areas of unmet need

Ocular oncology
~66,000 patients/yr (US/EU)[1–7]

Urologic oncology
~500,000 patients/yr (globally)[8]

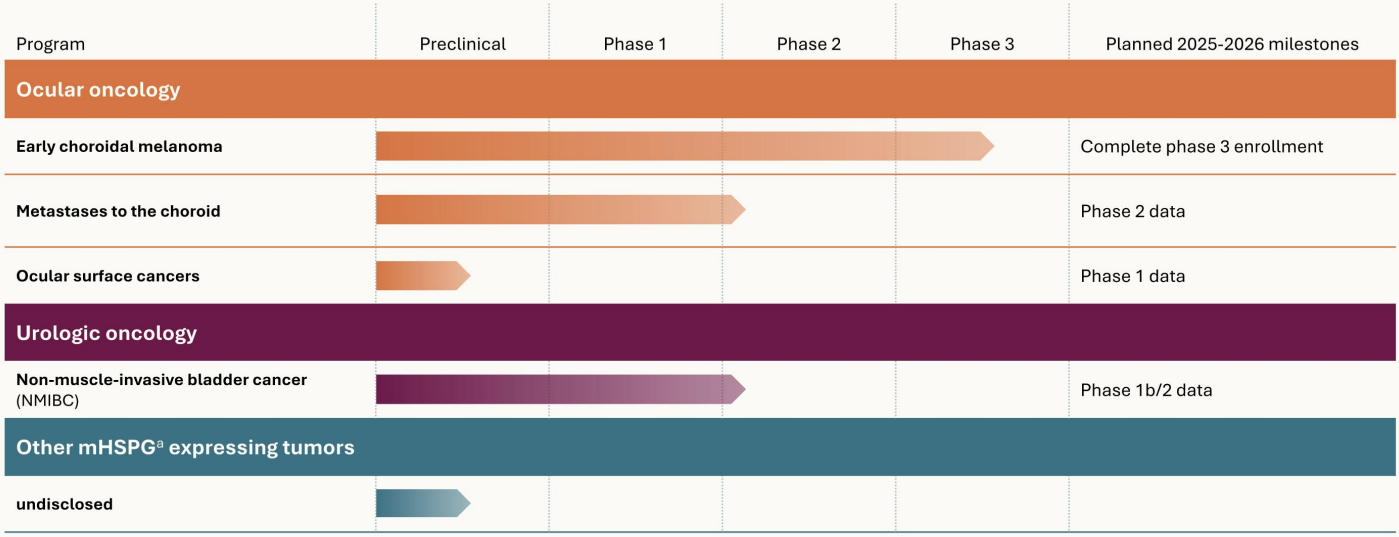
Key upcoming milestones

Complete enrollment in the phase 3 trial in early choroidal melanoma and phase 1b/2 trial in NMIBC

Current cash expected to fund operations into 1H 2027

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):1728-1734. **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.** American Cancer Society. Key statistics for retinoblastoma. Available at: https://www.cancer.org/cancer/types/retinoblastoma/about/key-statistics.html. Accessed Sept 5, 2024. **8.** Bladder cancer. Putnam & Assoc. Epidemiology Analysis.
Early choroidal melanoma, small choroidal melanoma or indeterminate lesions; **FDA**, United States Food and Drug Administration; **SPA**, Special Protocol Assessment; **VDC,** Virus-like drug conjugate, **MoA,** Mechanism of action; **NMIBC,** Non-muscle-invasive bladder cancer

Clinical pipeline across multiple solid tumor indications



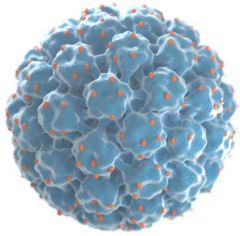
a.Virus-like drug conjugates (VDCs) bind to a subset of modified tumor associated glycosaminoglycans (GAGs) that are part of the heparan sulphate chain of heparan sulfate proteoglycans (HSPGs).[1]

1. Kines RC, and Schiller JT. *Viruses.* 2022;14(8):1656. **mHSPG**, modified heparan sulphate proteoglycan.

Virus-like drug conjugates have the potential to transform early cancer treatment

Unique tumor selectivity
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

Positive clinical data in multiple early-stage local cancers
- **Choroidal melanoma:** Positive phase 2 end of study data; phase 3 ongoing
- **NMIBC:** Positive phase 1 data; phase 1b/2 ongoing

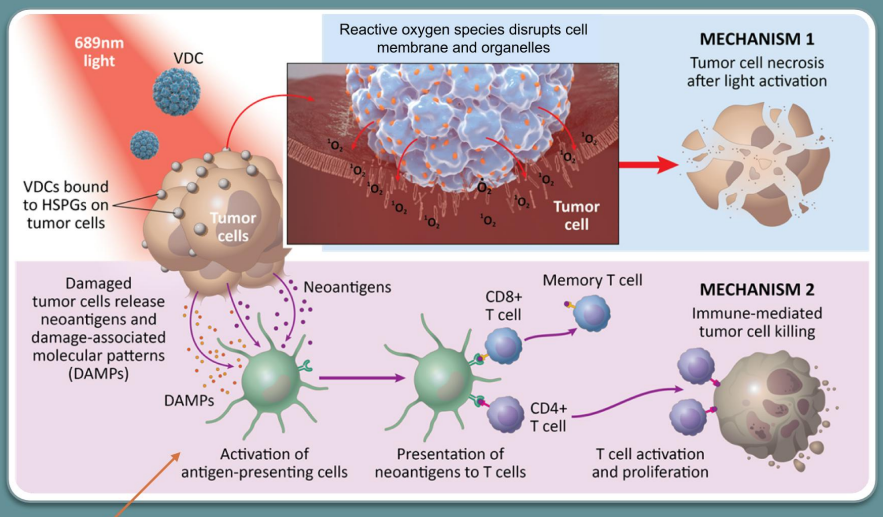
Favorable safety profile
No treatment-related SAEs and no DLTs reported in phase 2 choroidal melanoma trial or phase 1 data readout in NMIBC trial

DLT, dose-limiting toxicity; **SAE**, serious adverse event; **VLP**, virus-like particle.

AU-011 has a novel dual mechanism of action

Disruption of the tumor cell membrane and pro-immunogenic cell death by necrosis leads to T cell activation and immune-mediated tumor cell killing

VLPs bind to macrophages, B cells, dendritic cells and neutrophils and are capable of **stimulating antigen-presenting cells** through TLR-4 engagement and NFk-β production

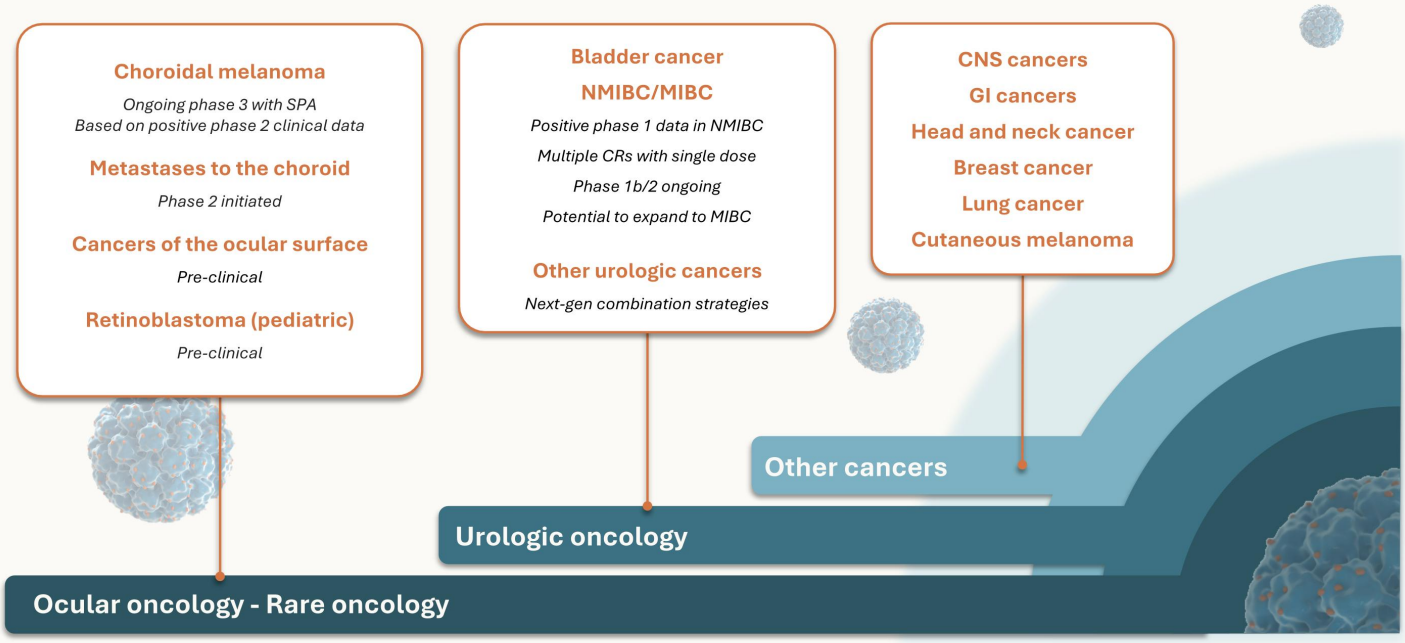


Release of **DAMPs** induces **anti-tumor immunity**

AU-011 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.
DAMPs, damage-associated molecular patterns; **HSPG**, heparan sulfate proteoglycan.

Bel-sar's **unique platform technology** is potentially applicable across **multiple cancers**



Bel-sar, belzupacap sarotalocan; **CR**, clinical complete response; **CNS**, central nervous system; **GI**, gastrointestinal; **MIBC**, muscle-invasive bladder cancer. The effectiveness and safety of bel-sar have not been established or clinically evaluated in tumors outside the ocular or bladder setting, and bel-sar is not approved for use in any jurisdiction.

Ocular Oncology

Bel-sar target indications:

Early choroidal melanoma | Metastases to the choroid | Ocular surface cancers

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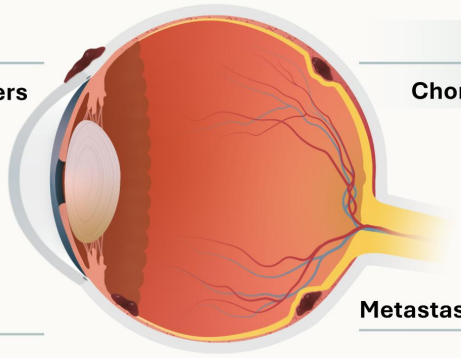
Bel-sar opportunities in ocular oncology represent a multi-billion-dollar addressable market

- With only ~100 ocular oncologists in the US/EU, a global launch may be accomplished with a small (<20) field-based team

~66,000 patients/year

Ocular oncology franchise total addressable market (US/EU)



~35,000/yr[a,1–5]
Ocular surface cancers

~11,000/yr[6]
Choroidal melanoma

Retinoblastoma
~500/yr[7]

Metastases to the choroid
~20,000/yr[6]

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

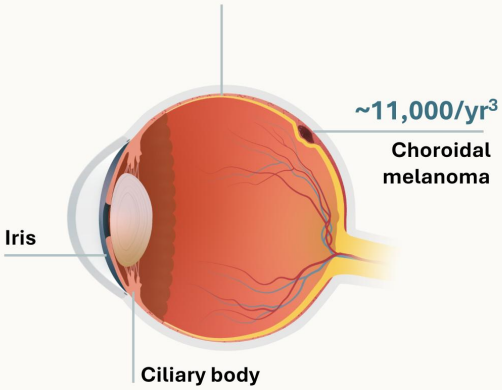
1. Yu G-P et al. *Am J Ophthalmol.* 2003;135(6):800-6. **2.** Triay E et al. *Br J Ophthalmol*. 2009;93(11):1524-8. **3.** Newton R et al. *Lancet*. 1996;347(9013):1450-1. **4.** Dalvin LA. *Br J Ophthalmol*. 2018;102(12):1728-1734. **5.** Sun EC et al. *Cancer Epidemiol Biomarkers Prev*. 1997;6(2):73-7. **6.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **7.** American Cancer Society. Key statistics for retinoblastoma. Available at: https://www.cancer.org/cancer/types/retinoblastoma/about/key-statistics.html. Accessed Sept 5, 2024. 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 in phase 3 for early choroidal melanoma, the most common primary intraocular cancer in adults

- Early choroidal melanoma is a high unmet medical need
- With no currently approved vision-preserving therapies, the current standard-of-care is radiotherapy – treatment that leads to legal blindness[4,5]

Choroid is 90%
of the uvea[1]



Uvea: Choroid, ciliary body and iris

Most common primary intraocular cancer in adults[2,3]

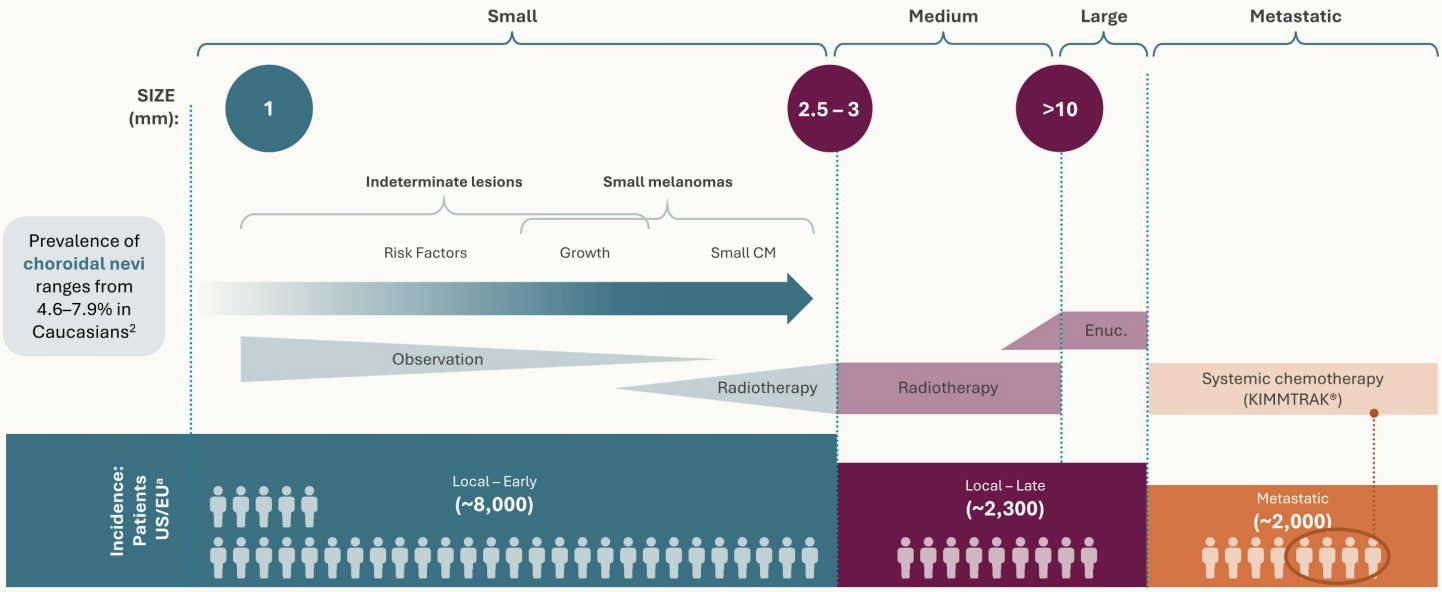
~80% of patients diagnosed with **early-stage disease**[3]

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

Bel-sar has the potential to provide a treatment option that preserves vision

1. Heiting, G. Iris/uvea of the eye. Available at: https://www.allaboutvision.com/en-gb/resources/uvea-iris-choroid/. Accessed Oct. 3, 2023. **2.** Kaliki S and Shields CL. *Eye (Lond).* 2017;31(2):241-257. **3.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **4.** 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. **5.**. 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.

Current treatment paradigm for choroidal melanoma[1–3]



[a]Each figure represents ~250 persons.

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

Current SoC: Associated with high morbidity and blindness

Treat early and risk vision loss | Delay treatment and risk metastasis[1]

Diagnosis of early CM[a]

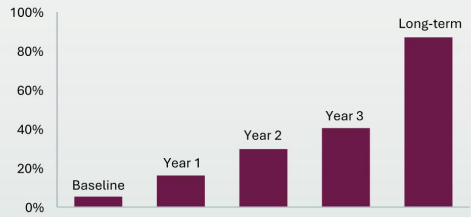
Observation 'Watch-and-wait'

Regular monitoring for risk factors/growth[6]

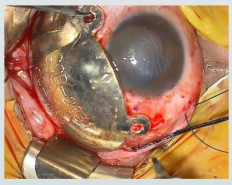
SoC radiotherapy

Bel-sar has the potential to be used early with the opportunity to preserve vision and improve patient outcomes

Patients with BCVA ≤20/200 after brachytherapy[2, 3]



Frequent AEs; Up to 87% become legally blind in the treated eye[1, 4–6]



Radiation retinopathy	>40%
Surgeries secondary to AEs	>40%
Dry eye syndrome	~20%
Enucleation/eye loss	~10–15%
Neovascular glaucoma	~10%

[a]75-80% of patients diagnosed with early-stage disease[7]. 2/3 of patients present with symptoms, 1/3 of patients diagnosed during routine exam.[8]

1. Kaliki S, Shields CL. *Eye.* 2017;31(2):241–257. **2.** Jarczak J et al. *Medicina (Kaunas).* 2023;59(6):1131. **3.** Tsui I, et al. *Open Ophthalmol J.* 2015;9:131–5. **4.** Shields CL, et al. *Arch Ophthalmol.* 2000;118(9):1219–1228. **5.** Peddada KV, et al. *J Contemp Brachytherapy.* 2019;11(4):392–397. **6.** Shields CL et al. *Curr Opin Ophthalmol.* 2019;30(3):206–214. **7.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **8.** Milam RW, Daniels AB. Uveal melanoma. In Riker AI, ed. Melanoma: A Modern Multidisciplinary Approach. Cham, Switzerland: Springer International Publishing, 2018, p. 273–312. **AE**, adverse event; **BCVA,** best-corrected visual acuity; **SoC**, standard-of-care.

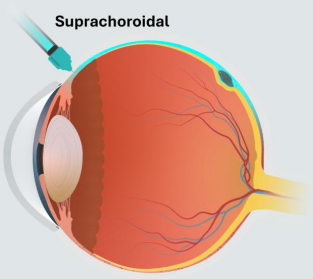
Bel-sar has the potential to be the first approved vision-preserving therapy in early choroidal melanoma

Treatment Goals

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

In-office procedure

Delivery via suprachoroidal injection



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

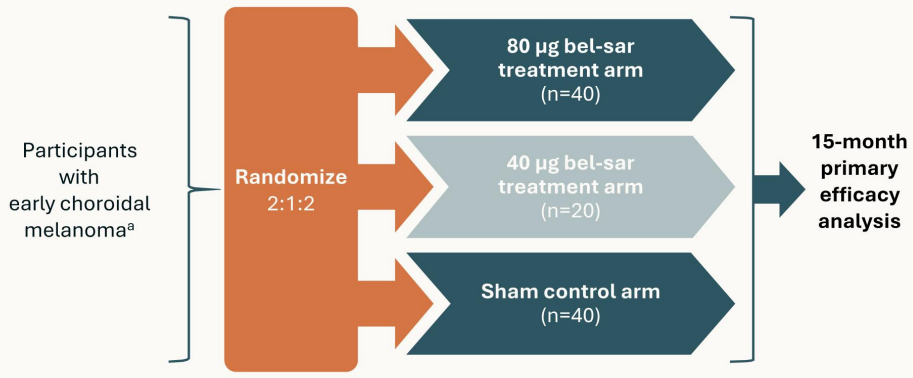
Light activation with standard ophthalmic laser

10-30 min. procedure

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 for early choroidal melanoma[a]: Global phase 3 CoMpass trial now enrolling

Target enrollment ~100 participants globally
Sites in North America, Europe, Middle East and Asia-Pacific Regions



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 or 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

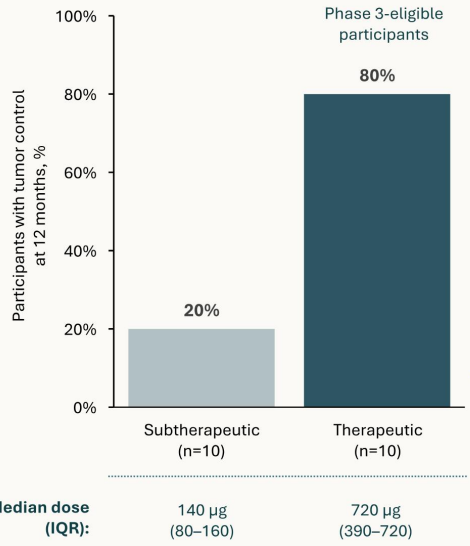
Received **fast track** and **orphan drug designations**
An **SPA agreement** indicates concurrence by the FDA that the design of the trial can adequately support a regulatory submission

[a]**Early choroidal melanoma,** small choroidal melanoma or indeterminite lesions.
ETDRS, Early Treatment Diabetic Retinopathy Study; **LBD**, largest basal diameter.
ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

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

Phase 2 end of study data in early choroidal melanoma:
High tumor control rates with therapeutic regimen in phase 3-eligible patients with active growth



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)

	Subtherapeutic (n=10)	Therapeutic (n=10)
Median dose (IQR):	140 µg (80–160)	720 µg (390–720)

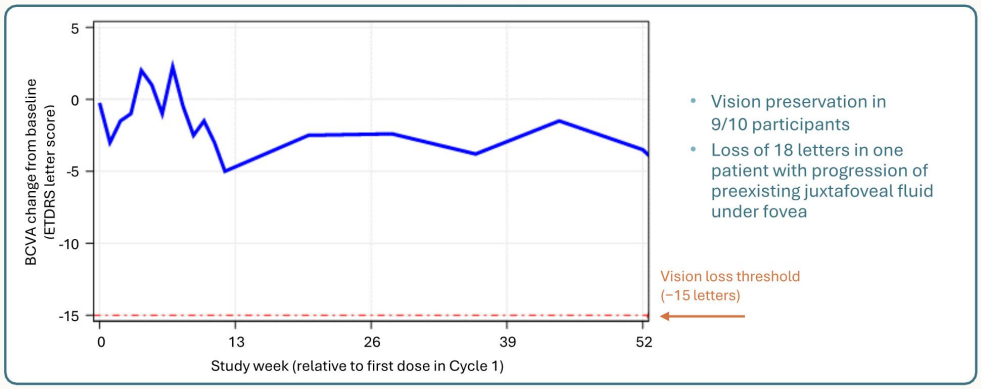
[a]Local complete response, or CR, in early-stage choroidal melanoma is described as tumor control and complete arrest of tumor growth by ocular oncologists.
[b]One participant with circumpapillary tumor that did not meet phase 3 criteria is not included.
IQR, interquartile range. ClinicalTrials.gov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

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

Phase 2 end of study data in early choroidal melanoma:

Median change in BCVA in phase 3-eligible participants with therapeutic regimen (N=10)[a]



- Vision preservation in 9/10 participants
- Loss of 18 letters in one patient with progression of preexisting juxtafoveal fluid under fovea

Populations	Patients (n)	Vision failures[b] (n)	Vision preservation rate (%)
All dose cohorts			
All treated patients	22	1	95%
Subtherapeutic			
≤2 cycles	10	0	100%
Therapeutic			
3 cycles and phase 3-eligible[a]	10	1	90%

[a]One participant with circumpapillary tumor that did not meet phase 3 criteria is not included. [b]Vision acuity loss defined as ≥15 letters decrease from baseline in ETDRS BCVA letter score.
ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Phase 2 end of study data represented using phase 3 endpoints

Kaplan-Meier analysis simulation of time-to-event

Time to tumor progression

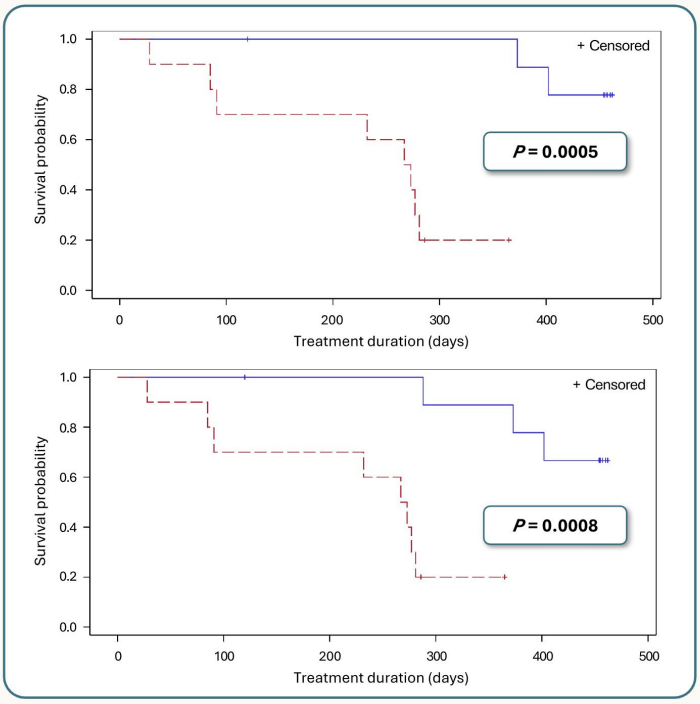
Change from baseline in thickness ≥0.5 mm; or in LBD ≥1.5 mm confirmed by at least one repeat assessment

Therapeutic n=10

Subtherapeutic n=10

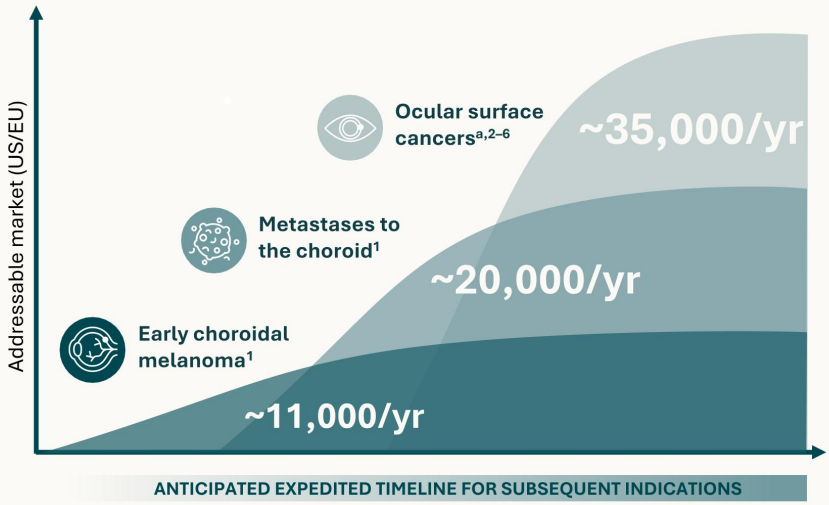
Time to composite endpoint

Time to tumor progression or vision acuity failure (≥15 letter loss in ETDRS-BCVA), whichever occurs earlier



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.
ETDRS, Early Treatment Diabetic Retinopathy Study. 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** in ocular oncology



Bel-sar's potential value drivers

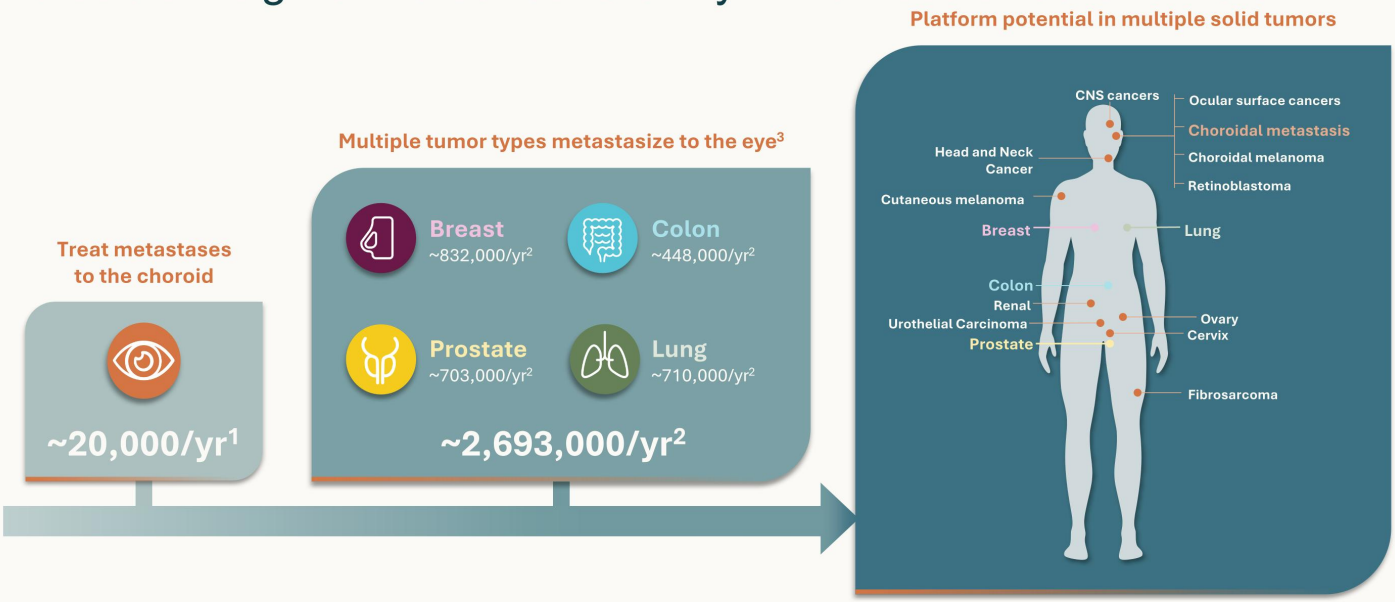
- Highly favorable competitive landscape
- Regulatory and manufacturing synergies
- Focused call point (~100 ocular oncologists in US/EU) with potential expansion to retina specialists
- Same centers
- Small (<20) field-based team
- Buy-and-bill reimbursement

Bel-sar has the potential to transform the ocular oncology field as a **vision-preserving therapy** that **alleviates patient burden** and potentially **reduces local recurrence and risk of metastasis with early treatment**

[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.

Metastases to the choroid:
Evaluating metastases from multiple tumor types may provide valuable insights into bel-sar's utility in non-ocular solid tumors



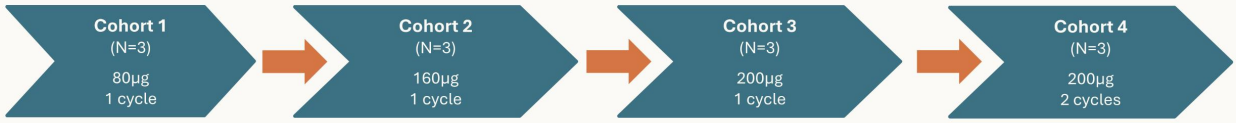
US/EU incidence.

1. Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putnam. **2.** IARC Cancer Today. GLOBOCAN 2022 (version 1.1). Available at: Cancer Today. Accessed May 6, 2025.

3. Mathis T et al. *Prog Ret Eye Res.* 2019;68:144-176. Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established or clinically evaluated in tumors outside the ocular or bladder setting, and bel-sar is not approved for use in any jurisdiction.

Metastases to the choroid:
Study expanded to include patients with *any systemic carcinoma*

Study Design (n=12)[a,b]



Study Objectives

- Safety/dose-limiting toxicity
- Efficacy
  - Change in tumor size
  - Change in vision letter score

Study Population

- Patients with unilateral, unifocal metastases to the choroid
- **Any systemic carcinoma** *(previously breast or lung only)*
- No changes in concurrent systemic medications planned

- **Multiple sites activated**
- Primary endpoint at one-month post-treatment; possibility to see tumor shrinkage and vision preservation/improvement

[a]3+3 Design. Each cohort to have a minimum of 3 and a maximum of 6 patients.
[b]Simplified schema of study design.

Cancers of the Ocular Surface:

One of the largest ocular oncology indications, with high unmet need

Cancer Types[1-5]

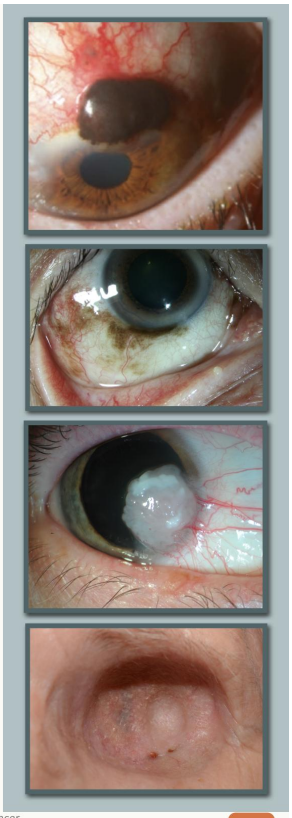
- Conjunctival Melanoma & other Melanocytic Tumors (PAM): **~30,000**
- Conjunctival Squamous Cell Carcinoma / OSSN: **~5,000**

Treatment[6,7]

- Surgery/Excision
- Neoadjuvant and/or adjuvant local chemotherapy
  - No drugs specifically approved for conjunctival tumors
- Exenteration (removal of eye and entire orbital contents)
- High recurrence rate

Mortality & Morbidity

- Mortality: ~25% (for conjunctival melanoma) with maximal treatment [6]
- Morbidity: ocular irritation/pain, dry eye, vision loss, loss of eye [6,7]

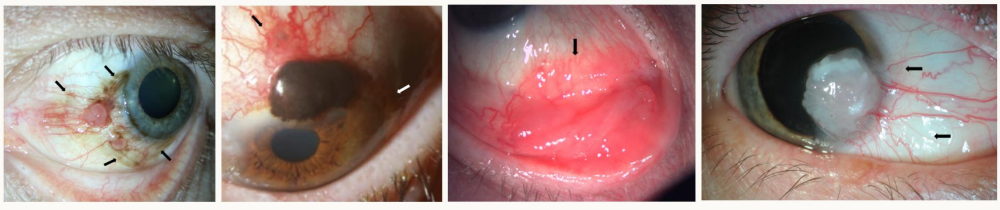


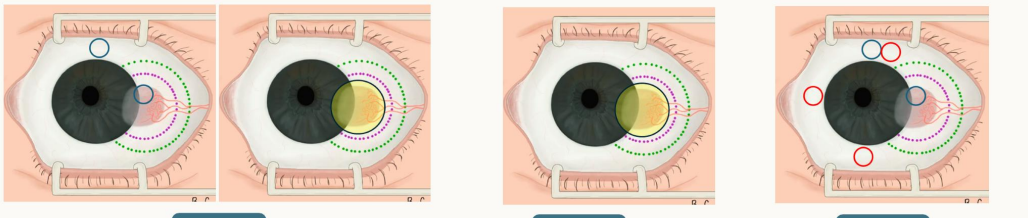
1. Yu G-P et al. *Am J Ophthalmol.* 2003;135(6):800-6. **2.** Triay E et al. *Br J Ophthalmol.* 2009;93(11):1524-8. **3.** Newton R et al. *Lancet.* 1996;347(9013):1450-1. **4.** Dalvin LA. *Br J Ophthalmol.* 2018;102(12):1728-1734. **5.** Sun EC et al. *Cancer Epidemiol Biomarkers Prev.* 1997;6(2):73-7. **6.** Vora et al. *Surv Ophthalmol.* 2017;62(1):26-42. **7.** Alvarez et al. *BMJ Open Ophthalmol.* 2021;6(1):e000842

PAM, Primary Acquired Melanosis; **OSSN**, Ocular Surface Squamous Neoplasia

Planned proof-of-concept phase 1 study of bel-sar for ocular surface tumors

- Assess safety, feasibility, histopathologic and immune response





Day 1

- IMAGE:
  - Measure tumor
- BIOPSY:
  - Main tumor
  - Adjacent flat tumor

- TREATMENT #1:
  - Inject bel-sar intratumorally
  - Light activate only over main tumor

Day 8

- TREATMENT #2:
  - Inject bel-sar intratumorally
  - Light activate only over main tumor

Day 15

- IMAGE:
  - Measure tumor
- SOC EXCISION:
  - Main tumor
  - Map Biopsies near previous biopsy sites

Urologic Oncology

Bel-sar target indications:

Intermediate-risk NMIBC | High-risk NMIBC

aura

Bladder cancer: High unmet medical need for function-preserving organ-sparing therapies

9th most common cancer worldwide[1]

>600,000 cases/year globally[1]

614,298 diagnosed in 2022[1]
(>7% increase from 2020)[1,2]

Ranked 13th for mortality[1]

Significant patient burden; one of the highest lifetime treatment costs of all cancers

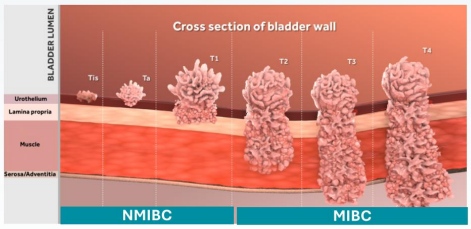
>$6 billion
Annual cost of treatment in US[5]

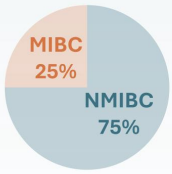
Conventional bladder cancer treatments are suboptimal[4]

- *Short- and long-term side effects*
- *Considerable impact on QoL*
- *Inadequate efficacy*
- *Multiple TURBT surgeries*
- *Disease progression/metastasis*
- *Loss of bladder/cystectomy*

84% of patients do not complete a full course of BCG treatment[6]

Patients are receiving fewer courses of BCG due to global shortage[7]



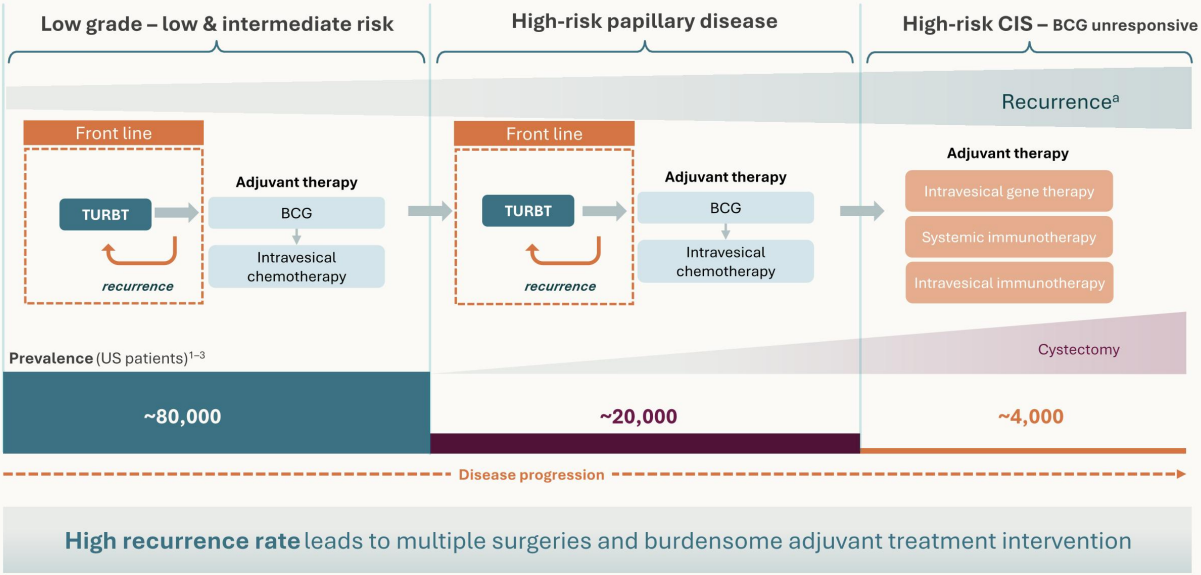


The majority of bladder cancer patients present with NMIBC[3]

~70-80% of patients with NMIBC develop recurrence after treatment[8]

1. GLOBOCAN 2022. Bladder. Available at: https://gco.iarc.who.int/media/globocan/factsheets/cancers/30-bladder-fact-sheet.pdf. [Accessed October 1, 2024]. **2.** Sung H, et al. *CA Cancer J Clin.* 2021;71(3):209–49. **3.** Burger M, et al. *Eur Urol.* 2013;63(2):234–41. **4.** Flaig TW, et al. *J Natl Compr Canc Netw.* 2018;16(9):1041–53. **5.** Clark O, et al. *Pharmacoecon Open.* 2024 Aug 18. doi: 10.1007/s41669-024-00512-8. [Online ahead of print]. **6**. Lamm DL, et al. *J Urol.* 2000;163(4):1124-9. **7.** Shore ND, et al. *Urol Oncol.* 39(10):642–63. **8.** Shalata AT, et al. *Cancers (Basel).* 2022;14(20):5019. **BCG**, Bacillus Calmette-Guerin; **QoL**, quality of life; **TURBT,** transurethral resection of bladder tumor.

Current treatment paradigm based on upfront resection leads to recurrence



High recurrence rate leads to multiple surgeries and burdensome adjuvant treatment intervention

[a]42–84% of low-grade IR patients develop recurrence.[4,5] **1.** Holzbeierlein JM et al. *J Urol.* 2024;212(1):3–10. **2.** Holzbeierlein JM et al. *J Urol.* 2024 Apr;211(4):533–58. **3.** Internal Aura epidemiology of market size; data on file. **4.** Shalata AT, et al. *Cancers (Basel).* 2022;14(20):5019. **5.** van Rhijn BWG, et al. *Eur Urol.* 2009;56(3):430–42. **BCG**, Bacillus Calmette-Guérin; **CIS**, carcinoma in situ.

Bel-sar has an innovative dual MoA

Bel-sar is designed to increase bladder preservation while reducing risk of recurrence and treatment burden

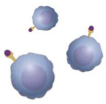
1

Robust targeted cytotoxicity

designed to rapidly destroy cancer cells

+

2



Long-term anti-tumor immune memory

has the potential to provide immune surveillance, urothelial field effect, and prevent recurrence

Immune ablation offers an effective front-line therapy, leveraging the immune system to fight cancer at an early stage

- **Focal administration** treats the tumor, not the entire urothelium
- **No need for general anesthesia** – administration is aligned with current urology office practice
- **Procedure is brief (<15 min for both injection and activation) and familiar to urologists,** using standard cystoscopy needles and common technique for laser application

Virus-like drug conjugates (VDCs) have potential advantages over oncolytic viruses

- **Broader and more specific tropism** for binding over normal tissue
- **No viral genes expressed** to compete with tumor antigens for induction of CMI
- **Killing mechanism** promotes induction of CMI to tumor antigens
- **Evolution of escape mutants less likely;** unlike virus cell surface and uptake receptors, HSPG modifications appear to be drivers of oncogenesis

CMI, cell-mediated immunity.

New formulation of **bel-sar** for use in bladder cancer

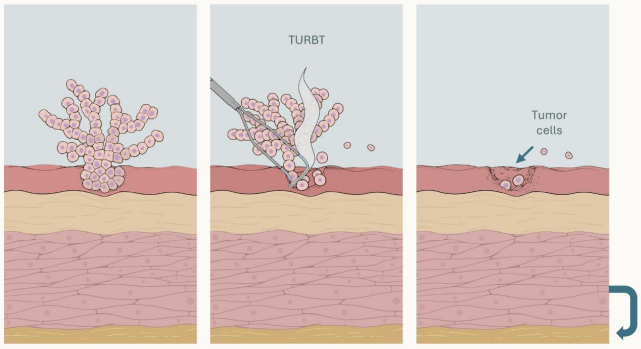
New formulation for urologic therapeutic area

- **Stable at 2–8°C** with simple refrigeration
- Convenient administration in **urologist office** anticipated
  - No need for cold chain (–70°C)
  - No need for biosafety (BSL-2)
  - No need for general anesthesia
  - <20-minute procedure
- **No special delivery or handling expected**
- Adjusted volume and concentration

BSL, biosafety level.

Bel-sar may shift the treatment paradigm from resection-based to immune-ablative front-line treatment

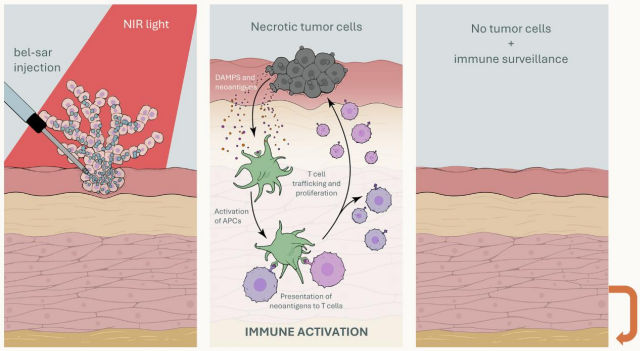
Current SoC: TURBT + adjuvant treatment



TURBT followed by multiple adjuvant treatments (maintenance for up to 12 months or longer)

High treatment burden (potential multiple surgeries)
High risk of recurrence

Bel-sar has an immune-mediated MoA



Opportunity for direct tumor cell killing + long-term anti-tumor immunity

Anti-tumor immunity has the potential to provide immune surveillance and long-term protection with minimal treatment burden

A, adjuvant treatment; **APC**, antigen-presenting cell; **B**, bel-sar; **M**, month; **NIR**, near-infrared.

Phase 1: Bel-sar administered before scheduled biopsy and standard of care (SoC) TURBT

Clinical response data up to 21 days; safety data up to 56 days

Treatment Phase: Feasibility and mechanism of action

Day 1

Cystoscopy + biopsy

bel-sar injection

Pathology specimen

Day 2

Cystoscopy

Laser light activation

Day 9 ± 1 (Cohort A)
Day 14+7 (Cohort B+C)

Final Cystoscopy

SoC TURBT

Pathology specimen

Final efficacy evaluation

Follow-up Phase: Safety

Day 56 ± 7

End of follow-up

Final safety evaluation

Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Cohort A-C: Single-dose drug with light activation

Safety data

- No serious adverse events
- No dose limiting toxicities

Cohort A-C: Single-dose drug with light activation (n=12)[a]

Event	Grade	Number of patients
Adverse events (related to study drug)		
Nocturia	1	1/12
Urinary urgency	1	1/12
Adverse events (related to injection or laser procedure)		
Hematuria	1	1/12
Urinary blood clots	1	1/12
Nocturia	1	1/12
Urinary urgency	1	1/12
Dysuria	1	1/12

Favorable safety profile observed

- <10% of patients experienced Grade 1 TEAEs related to study drug
- No grade 2/3 adverse events related to study drug (n=17)

[A]Compiled safety data includes all completed light-activated cohorts (A, B, and C), including two patients treated but not efficacy evaluable.
TEAE, treatment-emergent adverse event.
Clinicaltrials.gov identifier: NCT05483868; bel-sar-102. Data cutoff date of July 28, 2025.

Efficacy data: Ta intermediate-risk NMIBC

Cohorts A–C (single-dose drug with light activation)

4/5 patients demonstrated CR; 5/5 patients with immune response in target tumor

	Patient A1	Patient A3	Patient A4[c]	Patient B2	Patient C1[d]
Screening diagnosis	Multiple (TURBT) Ta low-grade	Multiple Ta low-grade	Multiple Ta low-grade Prior Ta high-grade	Multiple Ta low-grade	Multiple Ta low-grade
Screening AUA risk classification	Intermediate (TURBT)[f]	Intermediate	Intermediate	Intermediate	Intermediate
AU-011 dose/delivery	100 µg IT/IM	100 µg IT/IM	100 µg IT/IM	100 µg IT	200 µg IT
Clinical complete response: Target tumor[a]	✓	✓	✓	-	✓
Clinical complete response: Non-target tumor[a] (bladder urothelial field effect[b])	2/2	1/2	1/1	0/1	0/1
Immune response[e]: Target tumor	✓	✓	✓	✓	✓
Immune response[e]: Non-target tumor	✓	✓	✓	✓	✓
Necrosis	✓	✓	✓	-	-
Visual changes on cystoscopy	✓	✓	-	Tumor visually smaller	✓

[a]For purposes of this analysis, Clinical complete response defined as absence of tumor cells on histopathologic evaluation. [b]Bladder urothelial field effect: absence of tumor cells in non-target lesions. [c]Previously treated tumor demonstrated high-grade disease but pathology at time of treatment revealed low-grade disease in non-target tumor. [d]Local pathology with no evidence of carcinoma in 3/3 target specimens. Central pathology demonstrated single fibrovascular core in 1/3 target specimens consistent with small area of papillary disease of unclear distance from target injection. [e]Immune response is defined by immunocyte infiltration on post-treatment histopathology. [f]Single lesion visualized at screening on office cystoscopy. Multiple lesions subsequently seen with improved visualization at time of TURBT qualifying for intermediate risk classification. **AUA**, American Urological Association; **IM**, intramural; **IT**, intratumoral. Clinicaltrials.gov identifier: NCT05483868; AU-011-102. Data cutoff date of March 3, 2025.

Efficacy data: Ta high-risk NMIBC

Cohorts A–C (single-dose drug with light activation)

1/5 patients demonstrated CR; 5/5 patients with immune response in target tumor

	Patient A2	Patient B1	Patient B3	Patient C2	Patient C3[d]
Screening diagnosis	Single Ta high-grade	Multiple Ta high-grade	Single Ta high-grade	Multiple Ta high-grade	Multiple Ta low-grade Prior Ta high-grade
Screening AUA risk classification	High	High	High	High	High (BCG Failure)
AU-011 dose/ delivery	100 µg IT/IM	100 µg IT	100 µg IT	200 µg IT	200 µg IT
Clinical complete response: Target tumor[a]	-	-	-	-	✓
Clinical complete response: Non-target tumor[a] (bladder urothelial field effect[b])	NA	0/1	NA	NA	1/3
Immune response[c]: Target tumor	✓	✓	✓	✓	✓
Immune response[c]: Non-target tumor	NA	✓	NA	NA	✓
Necrosis	-	-	-	-	✓
Visual changes on cystoscopy	Tumor visually smaller	Tumor visually smaller	-	Tumor visually smaller	✓

[a]Clinical complete response defined as absence of tumor cells on histopathologic evaluation.[b]Bladder urothelial field effect: absence of tumor cells in non-target lesions. [c]Immune response is defined by immunocyte infiltration on post-treatment histopathology. [d]Two tumors in target tumor field with 1/2 tumors with clinical complete response. BCG failure qualifying as high risk by AUA criteria Clinicaltrials.gov identifier: NCT05483868; AU-011-102. Data cutoff date of March 3, 2025.

Patient A3

72-year-old Hispanic male

Screening diagnosis: (2024)
- Multiple
- **Ta low-grade (<3 cm)**
- No CIS

Screening AUA risk classification:
Intermediate

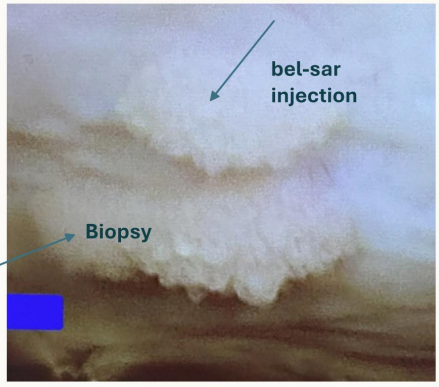
Initial diagnosis: (2019)
- Ta high-grade <3 cm
- No CIS
- Intermediate risk

Prior TURBT:
- 2019, 2020 (x2), 2021 (x2), 2023

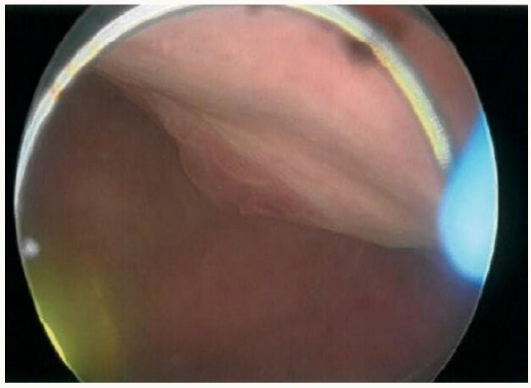
Prior adjuvant therapies:
- BCG induction and maintenance (2020-2021)

Cohort A:
Single-dose drug with light activation

Clinical complete response visualized at time of TURBT confirmed with histopathologic evaluation



Pre-injection/pre-biopsy appearance of tumor on office cystoscopy



Post-injection edema and ecchymosis at injection site

Clinicaltrials.gov identifier: NCT05483868; AU-011-102. Data cutoff date of March 3, 2025.

Mature Tertiary Lymphoid Structures (TLS) in Target (Treated) Lesion:

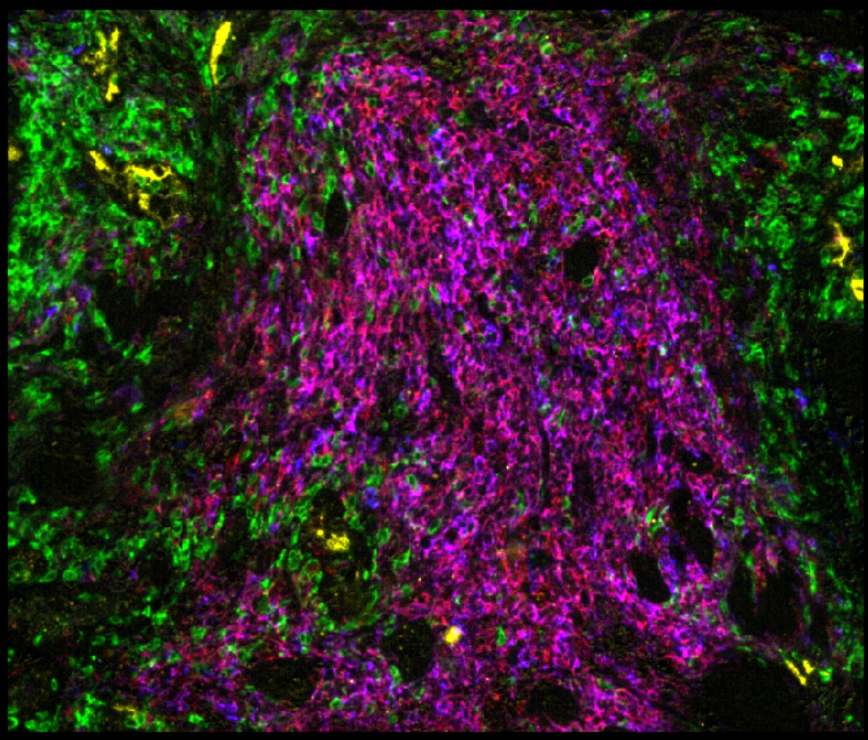
Active Immunosurveillance After Bel-sar Treatment

CD3: T cells

CD20: B cells

CD23: Follicular Dendritic Cells (FDC)
(Found in B cell follicles, only present in mature TLS)

PNAd: Peripheral Node Addressin
(Stains for high endothelial venules, evidence of lymphocyte trafficking from periphery)



Multiplex Immunofluorescence: Patient A3 (Intermediate-Risk NMIBC)

TLS Not Present in Lesion Prior to Treatment

Early Tertiary Lymphoid Structures (TLS) in Distant Non-Target (Non-Treated) Lesion:

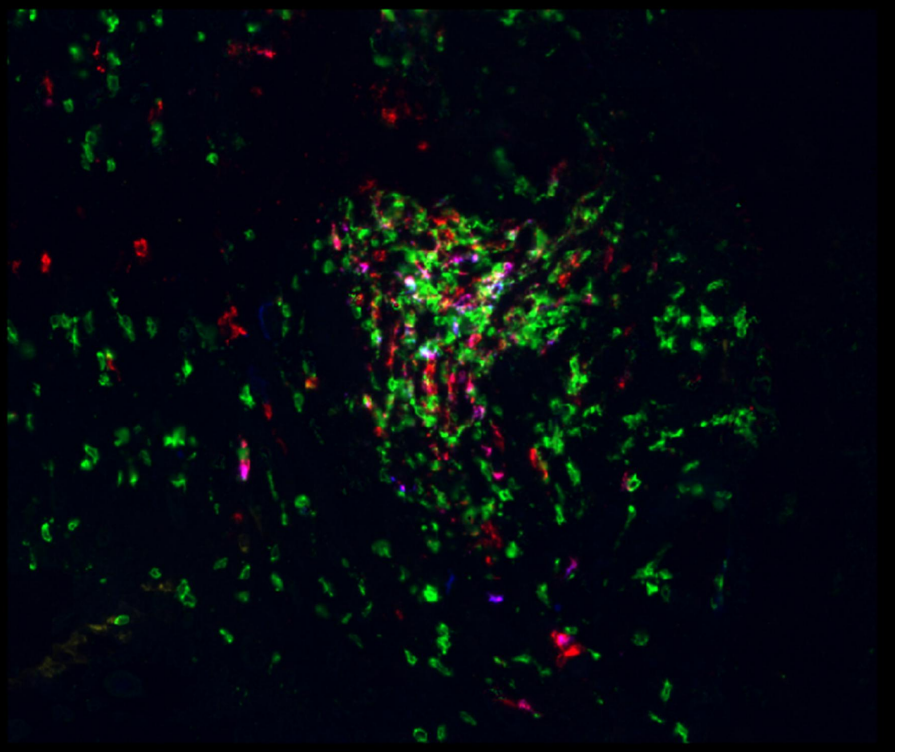
Urothelial Immune Field Effect After Bel-sar Treatment

CD3: T cells

CD20: B cells

CD23: Follicular Dendritic Cells (FDC)
(Found in B cell follicles, only present in mature TLS)

PNAd: Peripheral Node Addressin
(Stains for high endothelial venules, evidence of lymphocyte trafficking from periphery)



Multiplex Immunofluorescence: Patient A3
(Intermediate-Risk NMIBC)

Advancing bel-sar in NMIBC: **Phase 1b/2 trial overview**

Goal: Evaluate potential across disease spectrum and determine dose levels to advance clinical development of bel-sar in bladder cancer

Potential use across disease spectrum

~26 patients with NMIBC

Intermediate-risk

High-risk

Two front-line treatment approaches

Immune-ablative

Multimodal neoadjuvant (bel-sar followed by TURBT)

Dose escalation and multiple doses

Higher dose bel-sar

Up to 3 tumors per treatment

Two treatment cycles

Patients assessed for **response/recurrence** at 3, 6, 9 and 12 months | **Duration of response** monitored up to 12 months

Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Company highlights

Corporate

- **Current Cash** expected to fund operations into **1H 2027**
- **Experienced leadership** team across functions

Urologic Oncology Therapeutic Area

- **Multiple clinical complete responses** with single low dose in phase 1 NMIBC trial
- **Phase 1b/2 trial** evaluating additional doses, treatment regimens, and durability of response in NMIBC advancing on track

Ocular Oncology Therapeutic Area

Early choroidal melanoma

- **Global phase 3 CoMpass** trial actively enrolling; study enrollment may be completed as early as the end of 2025
- **Special Protocol Assessment (SPA)** agreement with FDA

Metastases to the choroid

- **Initial phase 2 data** expected in 2025
- This ocular oncology indication **potentially doubles market opportunity**[1]

Cancers of the ocular surface

- **Initial phase 1 data** expected in 2026
- One of the largest ocular oncology indications

1. ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis.
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.

Appendix VDC Platform

Virus-like drug conjugates (VDCs) have potential advantages over antibody-drug conjugates (ADCs)

High tumor cell killing with preservation of organs and function

	Antibody-drug conjugate	Bel-sar
DAR (drug-antibody/VLP ratio)	2–8	200–500
Binding	Bivalent	Multivalent
Tumor Tropism	Narrow	Broad
Delivery	Systemic	Local
Cytotoxicity	Active systemically when unbound	Active only when lasered; laser applied only to tumor
Mechanism of action	Varied; payload-dependent and often cancer pathway-dependent	Direct tumor cell killing and immune activation; unrelated to tumor genetics
Safety	Potential binding/activation in healthy tissues	Tumor-localized binding and focused light activation

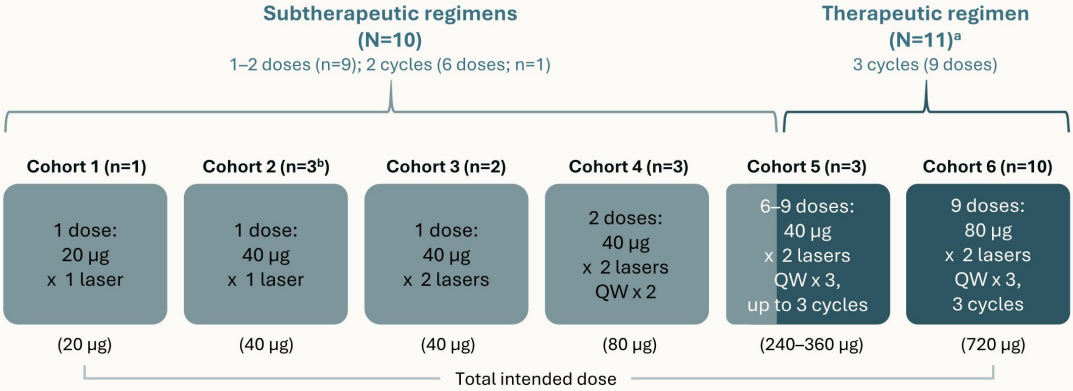
Appendix Ocular Oncology

aura

Phase 2 trial of bel-sar for choroidal melanoma: Open-label, dose-escalation with suprachoroidal administration

Trial design – 22 participants enrolled

Patient population representative of early-stage disease: Small choroidal melanoma and indeterminate lesions



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

Goal: To determine safety, optimal dose and therapeutic regimen with suprachoroidal administration

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.
QW, every week. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Baseline characteristics

All study participants

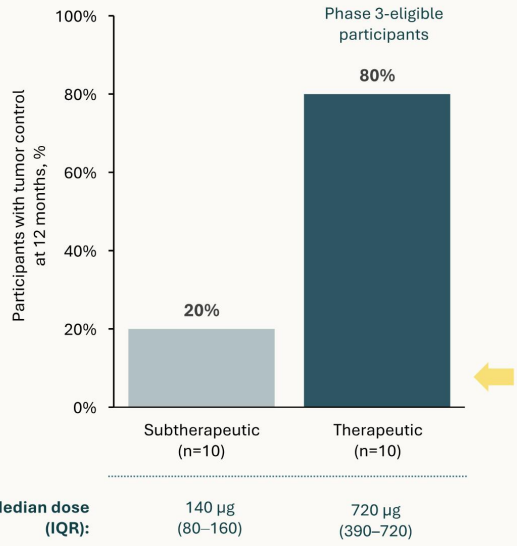
	All patients (n=22)
Female (%)	54.5
White, not Hispanic or Latino (%)	100
Subretinal fluid at screening (%)	100
Orange pigment at screening (%)	86.4
Documented growth prior to screening (%)	86.4 *(100% of therapeutic group)*
Mean age at screening (years, ± SD)	59.2 (±16.5)
Mean baseline BCVA in study 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% *(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.
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 with active growth



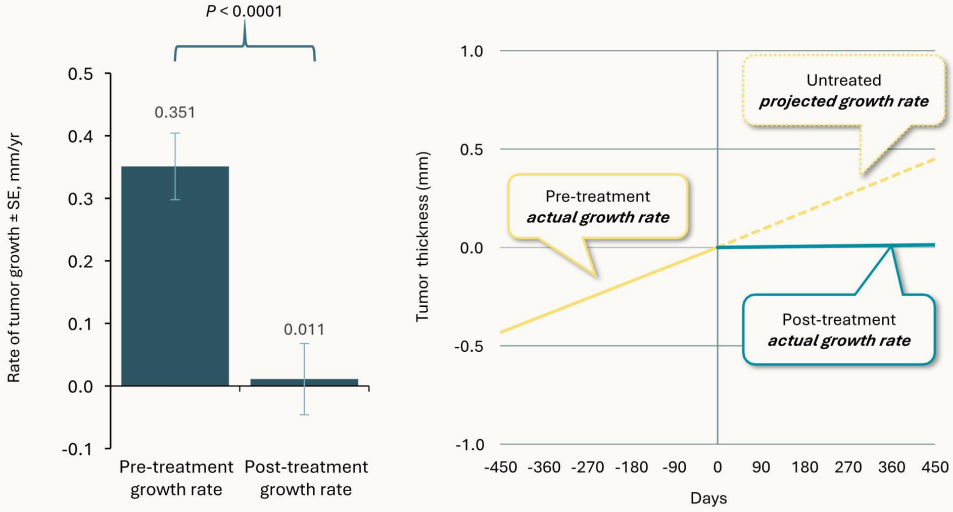
Median dose (IQR):	140 µg (80–160)	720 µg (390–720)

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

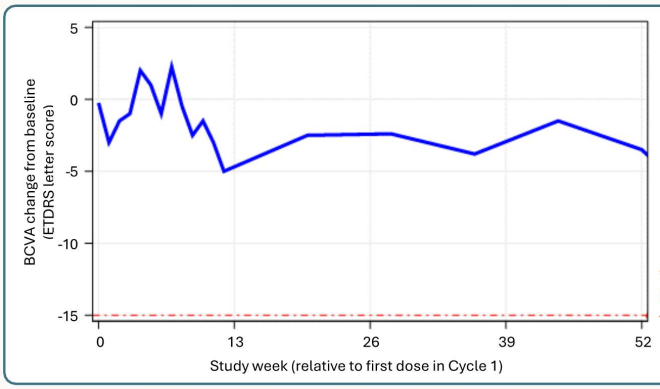


Tumor thickness growth rates/slopes estimated using Mixed Models for Repeat Measures (MMRM); random intercept and slope model for Historical and Study periods. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

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]



- Vision preservation in 9/10 participants
- Loss of 18 letters in one patient with progression of preexisting juxtafoveal fluid under fovea

Populations	Patients (n)	Vision failures[b] (n)	Vision preservation rate (%)
All dose cohorts			
All treated patients	22	1	95%
Subtherapeutic			
≤2 cycles	10	0	100%
Therapeutic			
3 cycles and phase 3-eligible[a]	10	1	90%

[a]One participant with circumpapillary tumor that did not meet phase 3 criteria is not included. [b]Vision acuity loss defined as ≥15 letters decrease from baseline in ETDRS BCVA letter score.
ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Bel-sar treatment had a favorable safety profile

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

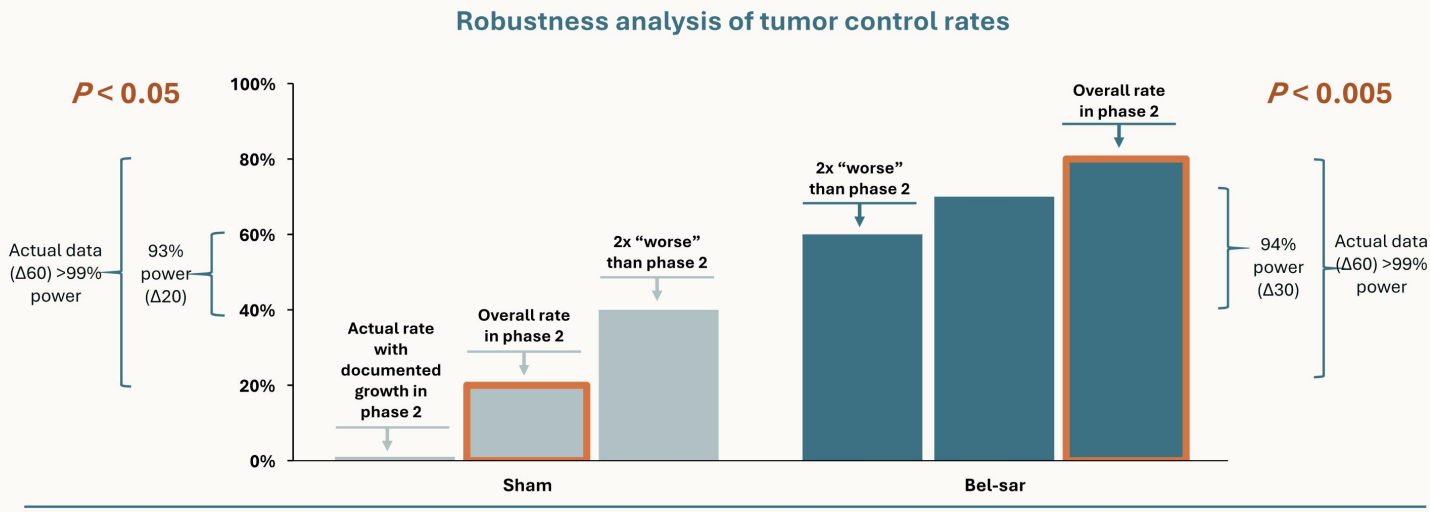
Phase 2 safety outcomes (bel-sar/laser-related)

	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.
ClinicalTrials.gov Identifier: NCT04417530; AU-011-202. **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

ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

Appendix Urologic Oncology

aura

Paradigm-shifting treatment approach

Treat the tumor first to generate cell-mediated immunity (CMI)

Immune-ablative (-TURBT)

Treat tumor with bel-sar first and avoid the need for TURBT

Value proposition:

- Prevent recurrence and progression by treating the tumor and generating CMI
- Avoid surgery (TURBT) and general anesthesia
- Office-based procedure

Patient population:

- Intermediate-risk NMIBC patients

Neoadjuvant/multimodal (+ TURBT)

Treat tumor with bel-sar first ahead of TURBT

Value proposition:

- Prevent recurrence and progression by treating the tumor first and generating CMI
- Avoid multiple cycles of adjuvant treatments (e.g., BCG, chemotherapy)
- Office-based procedure

Patient population:

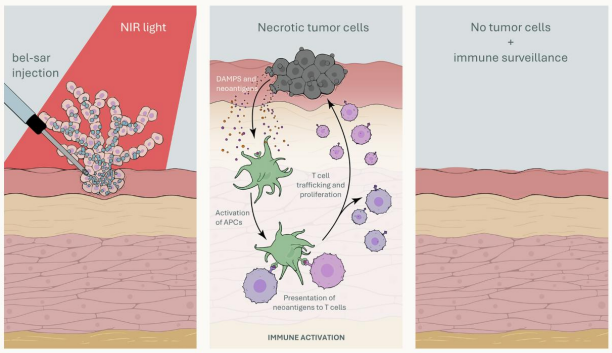
- Intermediate-risk and high-risk NMIBC patients; potential to expand to MIBC

Bel-sar has potential as a standalone immune-ablative treatment or as a neoadjuvant to TURBT

Immune-ablative approach could eliminate the need for TURBT, or be used prior to resection to improve treatment outcomes

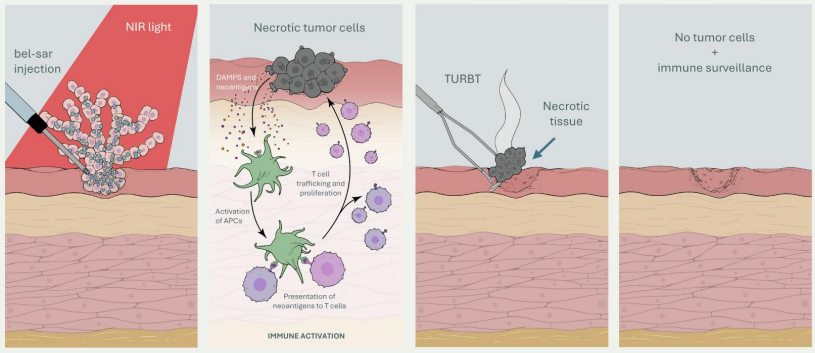
1 **Immune-ablative treatment without TURBT**

(LR/IR NMIBC)



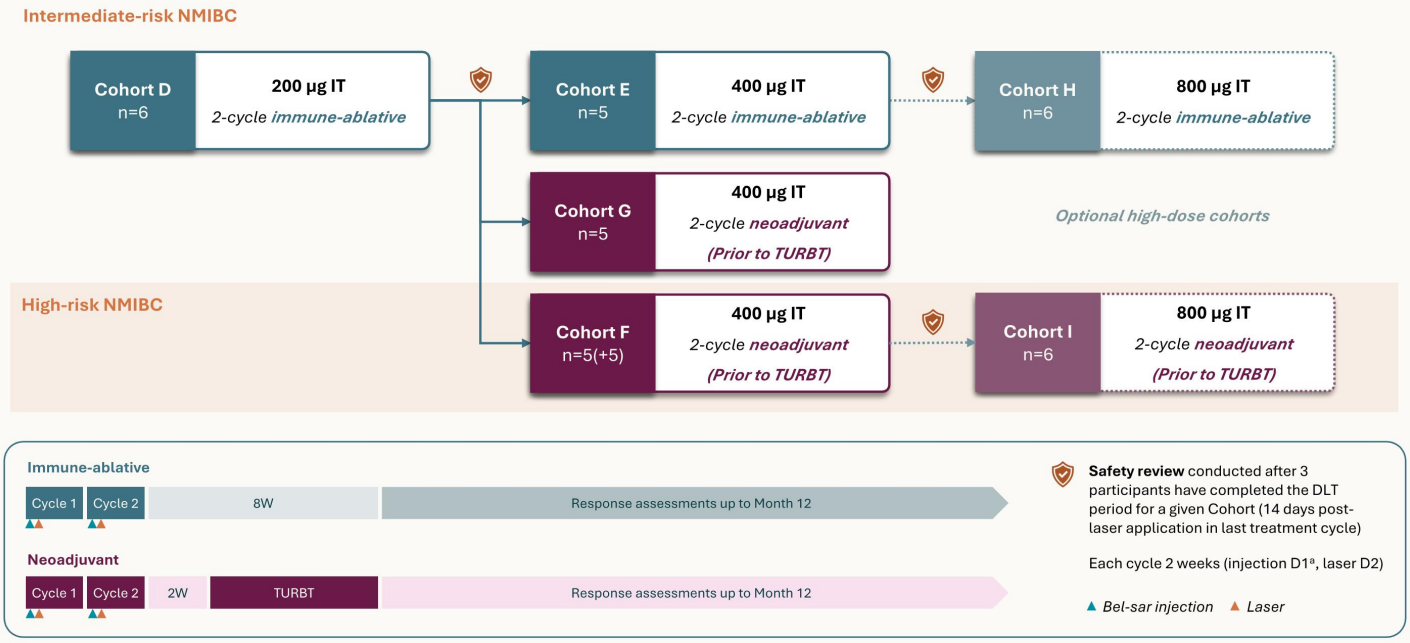
2 **Neoadjuvant/ multimodal therapy followed by TURBT**

(IR/HR NMIBC)



HR, high-risk; **IR**, intermediate risk; **LR**, low-risk.

Advancing bel-sar in NMIBC: **Phase 1b/2 study design**

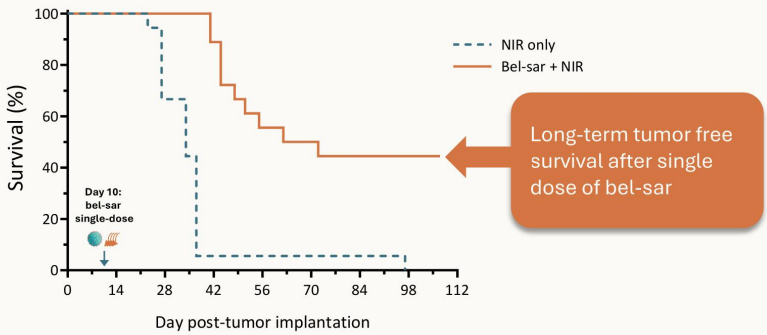


Dose per tumor, per treatment. Up to three tumors treated per visit. [a]+2-day window for injection in 2nd treatment cycle.
D, day; **W**, week.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

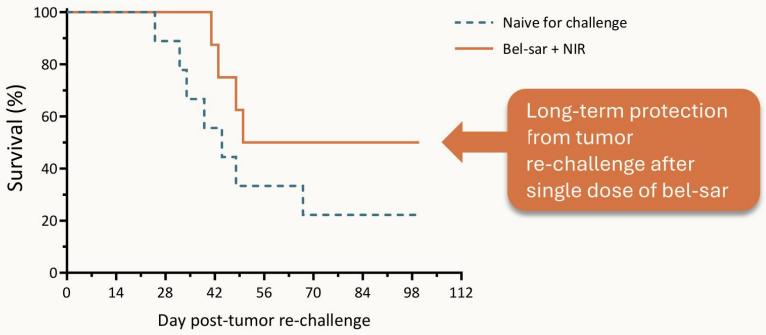
A single systemic treatment of bel-sar resulted in long-term tumor-free survival and induction of anti-tumor responses in TC-1 murine tumor model

- Long-term tumor-free survival and protection from tumor re-challenge
- CD4+ and CD8+ T-cells are required both at the time of treatment and at the time of re-challenge

Tumor-free survival after single dose of bel-sar



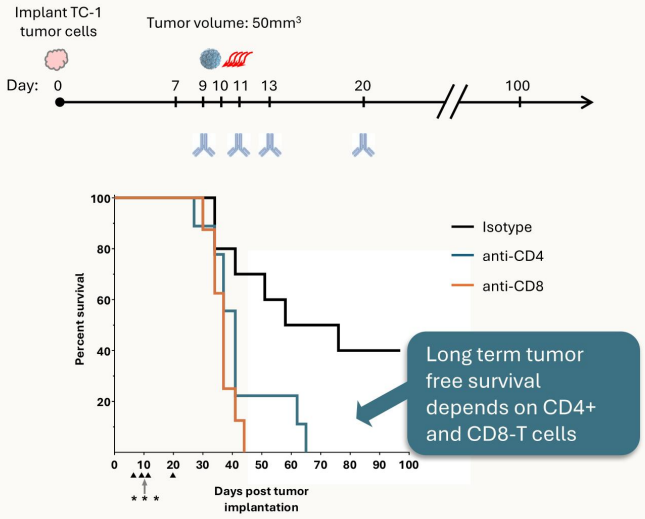
Tumor-free survival after tumor re-challenge



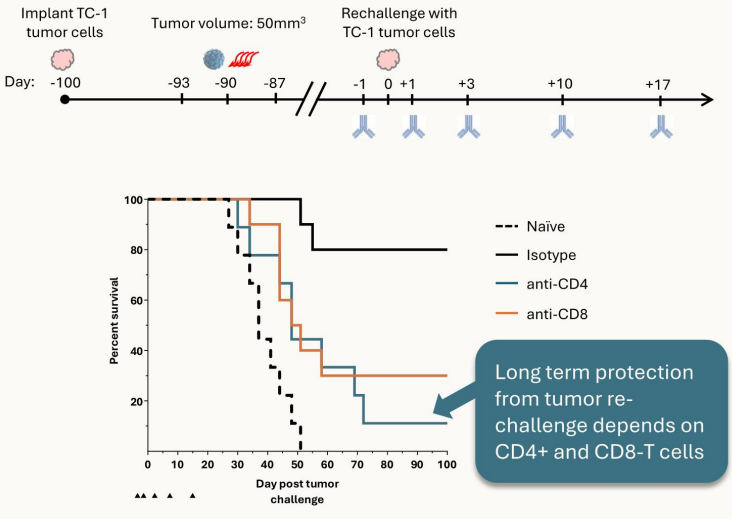
Kines RC, et al. *Cancer Immunol Res.* 2021;9(6):693–706.

CD4+ and CD8+ T-cells are key to the **long-term durability of response** and protection of rechallenge with bel-sar

Depletion of CD4+ and CD8+T cells at the time of treatment



Depletion of CD4+ and CD8+T cells at the time of rechallenge



Intravenous bel-sar NIR treatment Depleting or matched isotype

Kines RC, et al. *Cancer Immunol Res.* 2021;9(6):693–706.