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 09, 2023

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	**02135**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2023, Aura Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K, 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 9, 2023, 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.

Forward Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements about the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our financial performance; our ability to commercialize our products, if approved; and the implementation of our business model, and strategic plans for our business and product candidates.

Any forward-looking statements are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of the Company's clinical trials may not be predictive of future results in connection with future clinical trials; the risk that interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; the risk that governmental authorities may disagree with the Company's clinical trial designs; 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 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.

Exhibit No.	Description
99.1	Press Release Dated August 9, 2023
99.2	Corporate presentation of the Company
104	Cover Page Interactive Data File (embedded within 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 thereunto duly authorized.

Aura Biosciences, Inc.

Date: August 9, 2023

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

Aura Biosciences Reports Second Quarter 2023 Financial Results and Provides Clinical Development and Operational Highlights

Strengthened Clinical and Regulatory Leadership Team with Key Appointments

Start-up Activities for the Global Phase 3 Trial Ongoing with Release of Drug Product Manufactured with Commercial Process and First Patient Expected to be Dosed in 2H 2023

BOSTON, MA – August 9, 2023 – Aura Biosciences Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today reported financial results for the second quarter ended June 30, 2023, and provided clinical development and operational highlights.

"As we build momentum across our portfolio, we are happy to welcome Drs. Bruce Brown and Anthony Daniels as our Therapeutic Area Heads in Urologic Oncology and Ocular Oncology, respectively, as well as Dr. Richard Mountfield as our new Senior Vice President of Regulatory Affairs and Quality. These key appointments are critical in supporting our corporate growth and expansion of our clinical programs in two important oncology therapeutic areas with high unmet medical needs for patients," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura.

Dr. de los Pinos added, "We are excited to announce that we have released our drug product manufactured using the commercial process to be used in the global Phase 3 trial and remain encouraged by the progress we have made with the start-up activities, with multiple sites ready to enroll patients in the United States. We remain focused on the execution of our clinical studies and plan to share 12-month data from the Phase 2 trial in choroidal melanoma in the second half of 2023."

Recent Pipeline Developments

- **Global Start up Activities for the Phase 3 trial ongoing.**
  - The Phase 3 trial is designed as a superiority trial comparing belzupacap sarotalocan (bel-sar) versus sham. The trial is a global Phase 3, randomized, multi-center, masked study, and it is intended to enroll approximately 100 patients randomized 2:1:2 to receive high dose regimen of bel-sar, low dose regimen of bel-sar with suprachoroidal (SC) administration, or a sham control.
  - The primary endpoint is time to tumor progression and the first key secondary endpoint is a composite time to event analysis that will compare the tumor control and visual acuity of the bel-sar high dose regimen to sham when the last patient completes their 12 months of follow up.

- Aura released the commercial process material for the global Phase 3 trial. The majority of sites are qualified globally, and multiple sites are ready to enroll patients in the United States.
- The first patient is expected to be dosed in the second half of 2023.

- **Enrollment is complete in the Phase 2 trial evaluating SC administration of bel-sar for the first-line treatment of adult patients with early-stage choroidal melanoma (CM).** Updated efficacy data with 12 months median follow up of patients treated with the therapeutic regimen intended to be used in the global Phase 3 trial is on track to be presented in the second half of 2023.

- **The Phase 1 trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC) is currently ongoing, and Aura expects to report data in 2024.** This represents an area of high unmet need with approximately 60,000 patients diagnosed in the United States every year. Aura received Fast Track Designation from the Oncology Division of the FDA for this indication in June 2022.

  - The Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 19 adult patients. The trial is designed to assess the safety and tolerability of bel-sar as a single agent. The primary endpoint of the Phase 1 trial is the incidence and severity of treatment-related adverse events, serious adverse events and/or the incidence of dose-limiting toxicities. The trial will provide histopathological evaluation after the local treatment to support bel-sar's biological activity.

- **Beyond early-stage CM, Aura continues to build its ocular oncology franchise.** Aura's goal is to initiate clinical development in choroidal metastasis, an indication with a high unmet medical need and no approved therapies, as the second ocular oncology indication. Aura is on track to initiate the Phase 2 trial in 2024.

Recent Corporate Events

Strengthened the clinical leadership team with the following key appointments:

- Dr. Bruce Brown joined Aura as Therapeutic Area Head Urologic Oncology. Dr. Brown is responsible for leading the bladder cancer program, including the current ongoing trial, as well as driving future strategy and development plans. Dr. Brown was previously VP, Clinical Development at Myovant Sciences. Dr. Brown is a board-certified urologist and joined the pharmaceutical industry after practicing urology for 17 years.

- Dr. Anthony Daniels is joining Aura as the Therapeutic Area Head Ocular Oncology. Dr. Daniels will be responsible for leading the ocular oncology program and driving future strategy. Dr. Daniels is a board-certified ophthalmologist who has treated ocular oncology patients for 15 years, and most recently was Chief of the Division of Ocular Oncology at Vanderbilt University Medical Center.

- Dr. Richard Mountfield joined Aura as SVP, Regulatory Affairs & Quality. Dr. Mountfield is responsible for overseeing regulatory affairs and quality activities for all programs. Dr. Mountfield was previously the SVP of Regulatory Affairs & Quality at Zenas BioPharma.

Second Quarter 2023 Financial Results

- As of June 30, 2023, Aura had cash and cash equivalents and marketable securities totaling $162.0 million. Aura believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the second half of 2025.

- Research and development expenses increased to $15.1 million for the three months ended June 30, 2023 from $9.5 million for the three months ended June 30, 2022, primarily due to ongoing clinical costs associated with the progression of our Phase 2 study and CRO costs associated with the start of our Phase 3 global trial, manufacturing and development costs for bel-sar, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $5.2 million for the three months ended June 30, 2023 from $4.3 million for the three months ended June 30, 2022. General and administrative expenses include $1.2 million and $0.8 million of stock-based compensation for the three months ended June 30, 2023 and 2022, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to growth of the Company.

- Net loss for the three months ended June 30, 2023 was $18.3 million compared to $13.5 million for the three months ended June 30, 2022.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing virus-like drug conjugates (VDCs), a novel class of therapies, for the treatment of multiple oncology indications. Aura's lead VDC candidate, belzupacap sarotalocan (bel-sar; AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Bel-sar is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting, anti-tumor immunity. Bel-sar is currently in development for ocular cancers, and Aura has initiated activities for the global Phase 3 trial evaluating first-line treatment of early-stage choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care with radiotherapy leaves patients with severe comorbidities, including major vision loss. Aura plans to pursue development of bel-sar across its ocular oncology franchise including for the treatment of patients with choroidal metastasis. In addition, leveraging Aura's technology platform, Aura is developing bel-sar more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer. Aura is headquartered in Boston, MA.

For more information, visit aurabiosciences.com, or follow us on Twitter and 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 that 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 cancers including choroidal melanoma, non-muscle invasive bladder cancer and choroidal metastasis; any express or implied statements regarding the Company’s expectations for the Phase 2 and Phase 3 clinical trials of bel-sar for early-stage choroidal melanoma and the Phase 1 trial of bel-sar for non-muscle invasive bladder cancer; the potential approvability of bel-sar; the Phase 2 trial of bel-sar for choroidal metastasis; Aura’s expectations regarding the estimated patient populations and related market opportunities for bel-sar; and Aura’s expectations regarding 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 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 Aura’s clinical trial designs; 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 pre-clinical 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 filed with the U.S. 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 Contact:

Alex Dasalla
Head of Investor Relations and Corporate Communications
adasalla@aurabiosciences.com

Aura Biosciences, Inc.
Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development	$ 15,120	$ 9,510	$ 29,524	$ 17,786
General and administrative	5,156	$ 4,306	10,196	8,841
Total operating expenses	20,276	13,816	39,720	26,627
Total operating loss	(20,276)	(13,816)	(39,720)	(26,627)
Other income (expense):				
Interest income, including amortization and accretion income	2,009	292	4,000	319
Other income (expense)	(32)	56	(45)	5
Total other income	1,977	348	3,955	324
Net loss	(18,299)	(13,468)	(35,765)	(26,303)
Net loss per common share—basic and diluted	(0.48)	(0.46)	(0.95)	(0.90)
Weighted average common stock outstanding—basic and diluted	37,855,533	29,251,480	37,820,104	29,232,661
Comprehensive loss:				
Net loss	$ (18,299)	$ (13,468)	$ (35,765)	$ (26,303)
Other comprehensive items:				
Unrealized loss on marketable securities	$ (178)	(123)	(151)	(128)
Total other comprehensive loss	(178)	(123)	(151)	(128)
Total comprehensive loss	$ (18,477)	$ (13,591)	$ (35,916)	$ (26,431)

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 47,732	$ 121,582
Marketable securities	114,281	67,229
Restricted cash and deposits	20	20
Prepaid expenses and other current assets	4,178	7,871
Total current assets	166,211	196,702
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	20,003	20,671
Other long-term assets	700	423
Property and equipment, net	5,057	5,371
Total Assets	$ 192,739	$ 223,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	553	2,921
Short-term operating lease liability	3,008	2,963
Accrued expenses and other current liabilities	5,334	4,573
Total current liabilities	8,895	10,457
Long-term operating lease liability	17,407	17,895
Total Liabilities	26,302	28,352
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at June 30, 2023 and December 31, 2022, and 38,086,606 and 37,771,918 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	413,325	406,555
Accumulated deficit	(246,665)	(210,900)
Accumulated other comprehensive loss	(223)	(72)
Total Stockholders' Equity	166,437	195,583
Total Liabilities and Stockholders' Equity	$ 192,739	$ 223,935

Exhibit 99.2

Corporate Presentation

August 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; and the implementation of our business model, and strategic plans for our business and product candidates.

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

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

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

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Aura Biosciences Highlights

Novel Platform to Treat Multiple Solid Tumors

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

Ocular Oncology Franchise

- Multi-billion-dollar addressable market opportunity
- Invasive standard of care that may lead to blindness and loss of eye
- Clinical proof of concept with two routes of administration
- **Choroidal Melanoma:** Startup activities ongoing for the global Phase 3 trial
- **Choroidal Metastasis:** Open IND and plan to initiate Phase 2 trial in 2024

Urologic Oncology Franchise

- Durable complete responses and improved survival in *in vivo* bladder cancer models
- Synergy with checkpoint inhibitors (durable immunologic memory)
- Ongoing enrollment of Phase 1 trial

Strong Cash Position

- Cash runway to fund operations into 2H 2025

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

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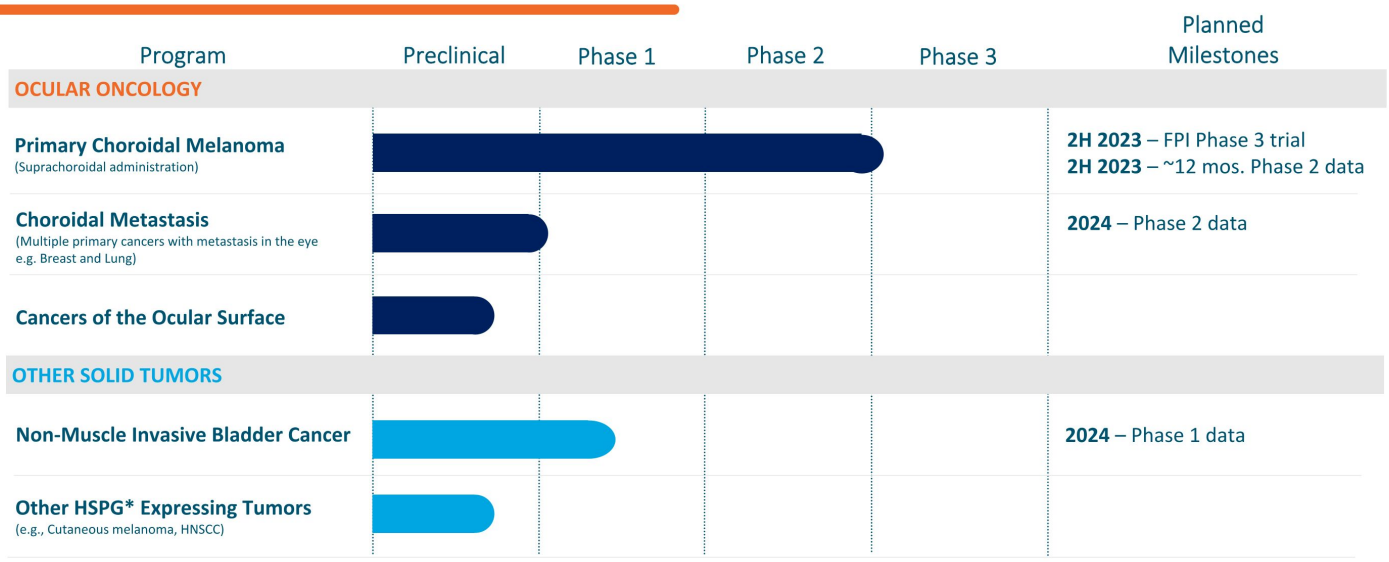
Pipeline Targeting Life-Threatening Cancers with High Unmet Needs



Global Commercial Rights for All Product Candidate Indications

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

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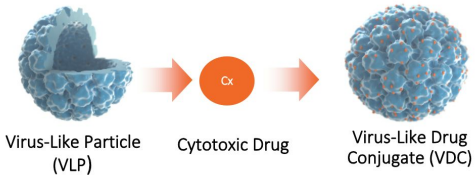
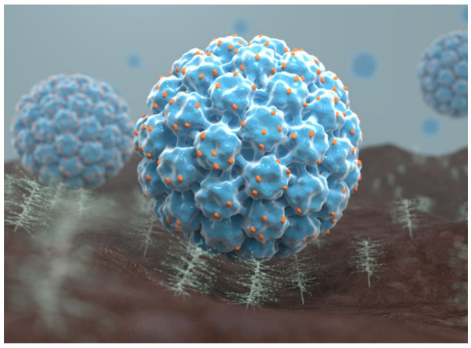
Targeted Oncology Platform: Virus-Like Drug Conjugates (VDCs)

Virus-Like Particle Conjugated to a Cytotoxic Payload

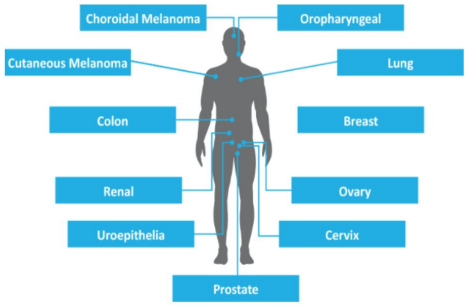


Virus-Like Particle (VLP) | Cytotoxic Drug | Virus-Like Drug Conjugate (VDC)

Selective Binding to Tumor Associated HSPGs*



Potential Treatment of Multiple Solid Tumors



Potential Key Differentiation: Potency, Multivalent Binding and Selectivity

Kines et al; *International Journal of Cancer*, 138;901–911, February 2016; Kines et al; *Molecular Cancer Therapeutics*, 17(2) February 2018; Kines et al; *Cancer Immunology Research*, May 2021

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

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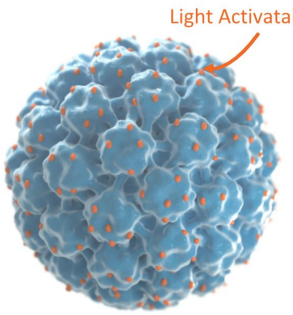
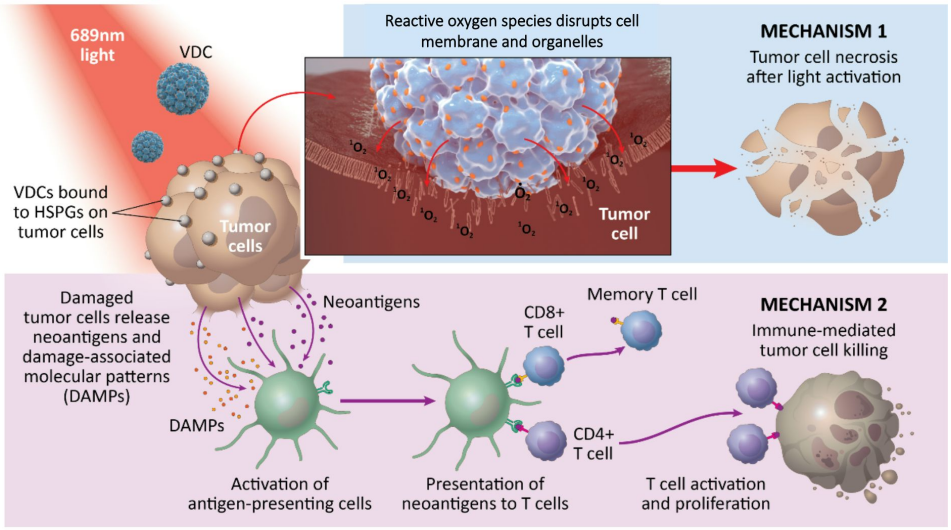
Bel-sar is a VDC with a Novel Dual Mechanism of Action



Bel-sar

Bel-sar is a novel VDC that consists of VLP conjugated to ~200 molecules of light activatable drug



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

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Ocular Oncology Franchise

Bel-sar
INN: belzupacap sarotalocan

Target Indications:

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

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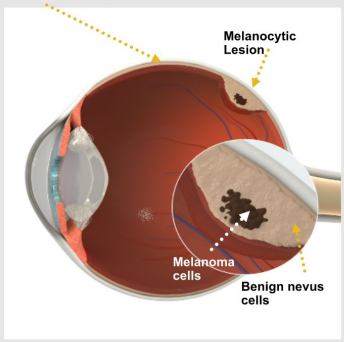
Primary Choroidal Melanoma – High Unmet Medical Need with No Drugs Approved

Most common primary intraocular cancer in adults

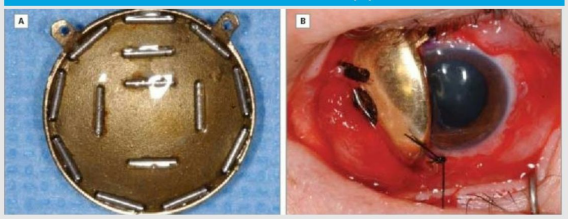
Impacts **11,000** patients in US/Europe per year

~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

Kaliki et al; Eye (Lond) 2017 Feb; 31(2): 241–257; Clearview & Putnam & Assoc. Market Research; Source: Peddada. J Contemp Brachytherapy. August 2019

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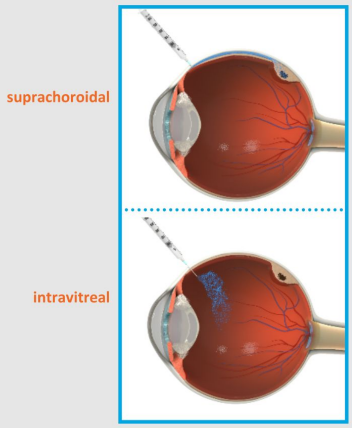
Bel-sar has the Potential to be the First Approved Therapy in Primary Choroidal Melanoma

Bel-sar is Delivered by Simple Intravitreal or Suprachoroidal Injection



Light Activation with Standard Ophthalmic Laser

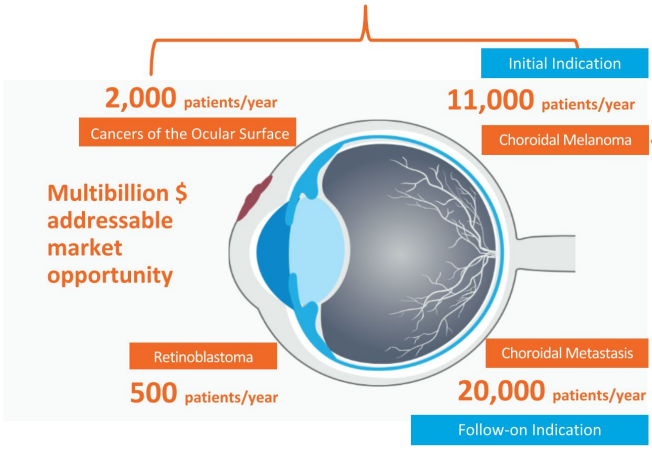
Goals of Treatment

- 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)

~80%

of patients are diagnosed at the early stage (indeterminate lesions (ILs) and small tumors)

Current radiotherapy treatment

Leaves ~70% of patients with major irreversible vision loss within 5-10 years

~100

Ocular Oncologists in US/EU — focused call point

<20

Field Based Team
Intend to add small sales force to launch globally

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

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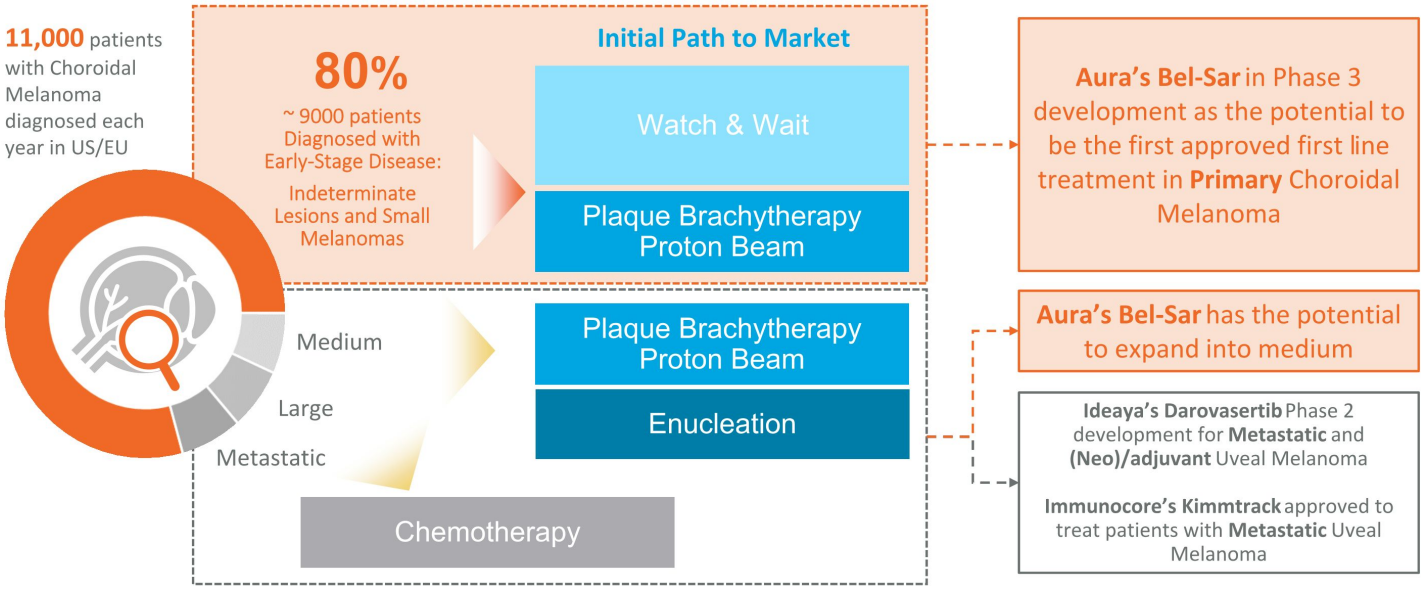
No Drugs Approved and No Known Competition in Early-Stage Disease



CM – Choroidal Melanoma

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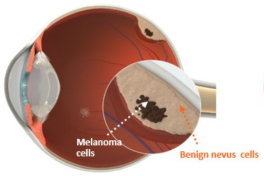
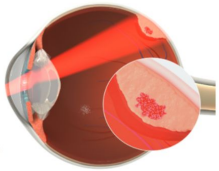
Goal for Bel-sar: Eliminate Malignant Cells in the Choroid and Preserve Vision

Similar to Current Clinical Practice with Radiotherapy - Local Tumor Control is Equivalent to a Local Cure



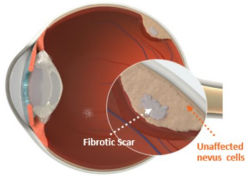
Baseline Measurement

Many early-stage melanomas have a small component of melanoma cells within a benign nevus



Treatment

Bel-sar targets mostly the malignant cells and not the benign nevus, retina or other ocular structures



Post-treatment Measurement

(Unchanged Tumor Height)

Malignant cells are replaced by fibrosis so there is a minimal reduction in size of the overall lesion after treatment

Key Endpoints Aligned with Clinical Practice and FDA

Endpoint	Endpoint Definitions
Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter (LBD)
Visual Acuity Failure	Decrease from baseline: ≥15 letters
Tumor Thickness Growth Rate	Change in tumor height over time

Objective of Treatment is to Obtain a Local Cure with Visual Acuity Preservation

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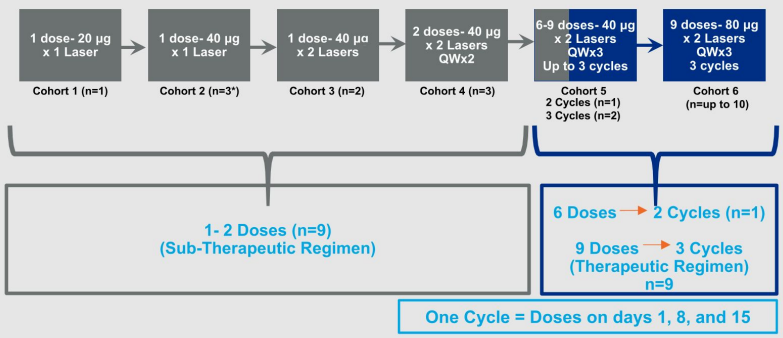
Ph 2 Trial - Evaluating Suprachoroidal Administration to Determine Optimal Administration Route

Enrollment Criteria

- Representative of Early-Stage Disease:
  - Indeterminate lesions and small choroidal melanomas
- Enrichment Strategy with active growth:
  - Tumor thickness ≥0.5 mm and ≤2.5 mm
  - LBD ≤10 mm
  - Active tumor growth (≥0.3mm) within 2 years of screening
  - Same criteria as the planned Phase 3

Ph2 SC Trial Design – Enrollment Complete



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

*2 subjects were planned; third subject was additionally enrolled due to dose error in 1 subject
ClinicalTrials.gov Identifier: NCT04417530 ; AU-011-202
Interim Data- January 10, 2023; Last two subjects enrolled after data cut not included in dataset
SC – Suprachoroidal; LBD – Largest Basal Diameter

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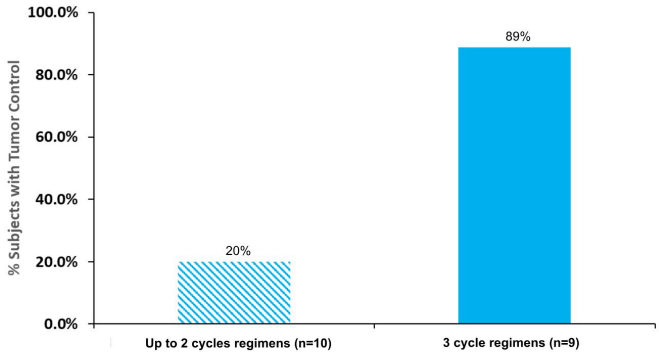
Ph 2 Interim Tumor Control Rates Demonstrated a Dose Response

Dose Response: Lower Regimens vs. 3 Cycle Regimens



Tumor Progression: change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment

Interim Data- January 10, 2023; Last two subjects enrolled after data cut not included in dataset

Average 8-10 Months of Follow Up

Populations	Total Patients (n)	Tumor Control Rate	Average Follow-up (months)
All Doses/Regimens			
All Treated Patients	20	55% (11/20)	9
Lower Doses/Regimens			
Up to 2 Cycles (20µg-40µg)	10	20% (2/10)	10
Highest Doses/Regimens*+			
3 Cycles (n=9) 40µg (n=2)/80µg (n=7)	9	89% (8/9)	8

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
+Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
Lower dose regimens (n=10) include cohorts 1-4 and 1 patient in Cohort 5 that received 2 cycles

Dose Response Observed with Interim Tumor Control Rates Demonstrated Meaningful Clinical Benefit

LBD – Largest Basal Diameter

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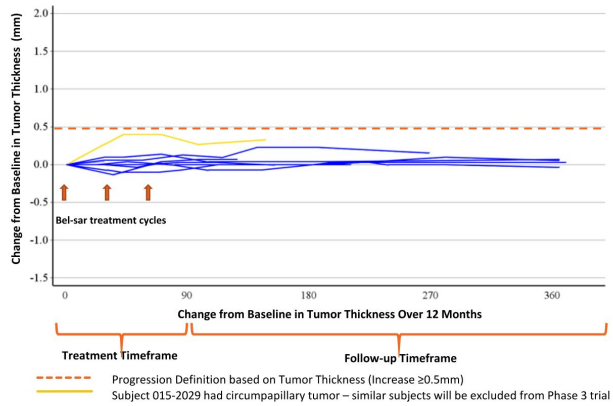
Ph 2 Interim Analysis Demonstrated Tumor Control Rate 89%-100%

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



Tumor Progression: change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment; Interim Data- January 10, 2023; Last two subjects enrolled after data cut not included in dataset ; post-SOC data not included

Average 8-9 Months of Follow Up

Populations	Total Patients (n)	Tumor Control Rate	Average Follow-up (months)
Highest Doses/Regimens			
3 Cycles (n=9) 40µg (n=2)/80µg (n=7)	9	89% (8/9)	8
Highest Doses/Regimens - Planned Phase 3^			
3 Cycles (n=8) 40µg (n=2)/80µg (n=6)	8	100% (8/8)	9

One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
^ One subject in C6 with circumpapillary tumor not included (similar subjects not planned in Phase 3 trial)

Ph 2 Interim Analysis Demonstrated Tumor Control Rate of 100% in Planned Ph 3 Population^

Ph 2 Interim Analysis Demonstrated Visual Acuity Preservation ~90%

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%	-3.7	9
Lower Doses/Regimens					
Up to 2 cycles (20µg-40µg)	10	1	90%	-3.2	10
Highest Doses/Regimens*+					
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=7)	9	1	89%	-4.8	8
Highest Doses/Regimens - Planned Phase 3*+					
3 Cycles (40µg-80µg)^ 40µg (n=2)/80µg (n=6)	8	1	88%	-5.3	9

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
+Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
Vision Failure confirmed loss ≥15 letters at ≥Week 39; post-SOC data not included
^7 out of 8 subjects in this subgroup were high-risk for vision loss (tumor edge ≤ 3 mm from the foveola or optic disc)
Interim Data- January 10, 2023 ; Last two subjects enrolled after data cut not included in dataset

Interim Data Demonstrated High Vision Preservation Rates Across All Groups Including Patients at High Risk for Vision Loss

SC – Suprachoroidal

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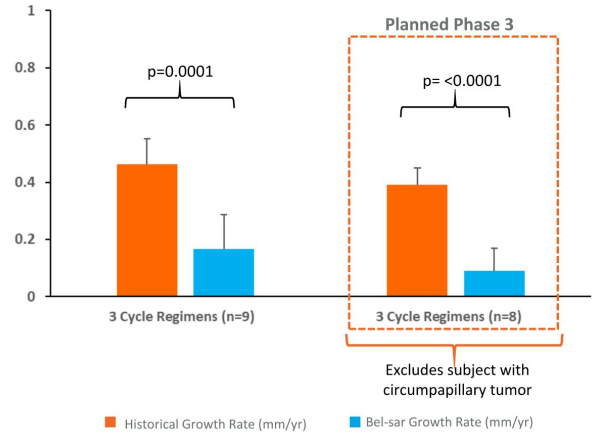
Ph 2 Interim Data Demonstrated Statistically Significant Tumor Growth Rate Reduction

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



Change in Tumor Growth After Treatment with Bel-sar

	n	Historical Growth Rate (mm/yr)	AU-011 Growth Rate (mm/yr)	Growth Rate Reduction (mm/yr)	p-value	Average Follow up (months)
Highest Doses/Regimens						
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=7)	9	0.454	0.169	-0.285	0.0001	8
Highest Doses/Regimens - Planned Phase 3^						
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=6)	8	0.382	0.093	-0.289	<0.0001	9

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

One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
^One subject in C6 with circumpapillary tumor not included (similar subjects not planned in Phase 3 trial)

Interim Data Showed Growth Arrest in Planned Phase 3 Population with a p-value of <0.0001

Bel-sar – Belzupacap Sarotalocan
Interim Data- January 10, 2023; ; Last two subjects enrolled after data cut not included in dataset

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Ph 2 Ongoing Tolerability Evaluation Continues to Be Favorable

No Grade 3 AEs and Majority of AEs Were Transient and Resolved Without Clinical Sequelae

Ongoing Phase 2 Safety Outcomes with SC Administration

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	10%	5%	0	**15%**
Punctate Keratitis	10%	0	0	**10%**

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- January 10, 2023; Last two subjects enrolled after data cut not included in dataset

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

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%**	**0%⁺⁺**

*Cross-trial comparison of Radiotherapy and AU-011-202 with suprachoroidal administration
⁺Related to bel-sar or laser
⁺⁺75% (15/20) of patients in Ph2 SC trial were at high risk for vision loss

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

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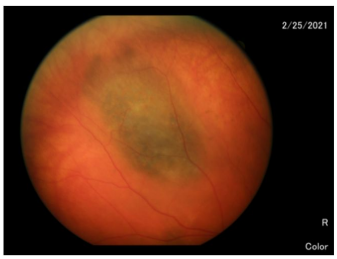
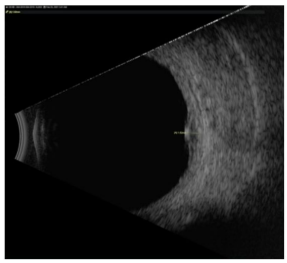
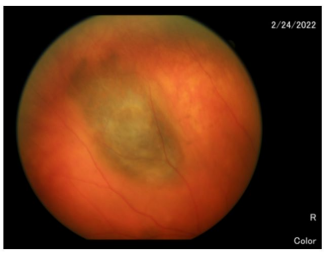
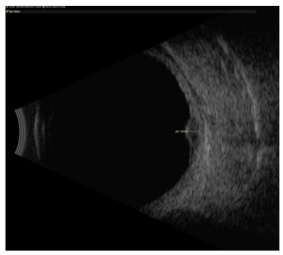
Durable Response to Treatment with Tumor Control & Vision Preservation at 1 Year, with 3 Cycles





Photograph and ultrasound at baseline
TT: 1.50 mm, LBD: 8.92 mm (IRC reads)

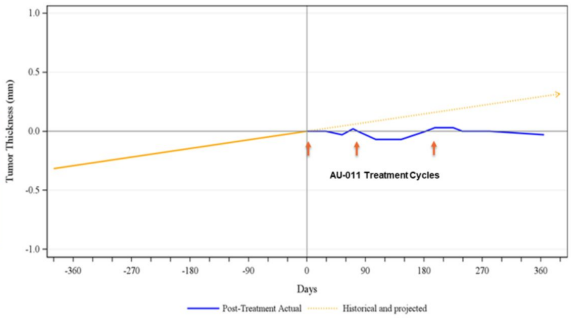




Photograph and ultrasound at 12 months
TT: 1.47 mm, LBD: 8.55 mm (IRC reads)

Cohort 5 Subject with Documented Tumor Growth
Tumor location: Superotemporal

	Baseline	Week 4	Week 8	Week 12	Week 26	Week 39	Week 52
BCVA (letter score)	91	92	92	89	89	90	89



Historical and projected growth based on MMRM

BCVA: best corrected visual acuity; IRC: independent reading center; LBD: largest basal diameter; TT: tumor thickness; AU-011= Bel-sar

Randomized Controlled Global Phase 3 Trial

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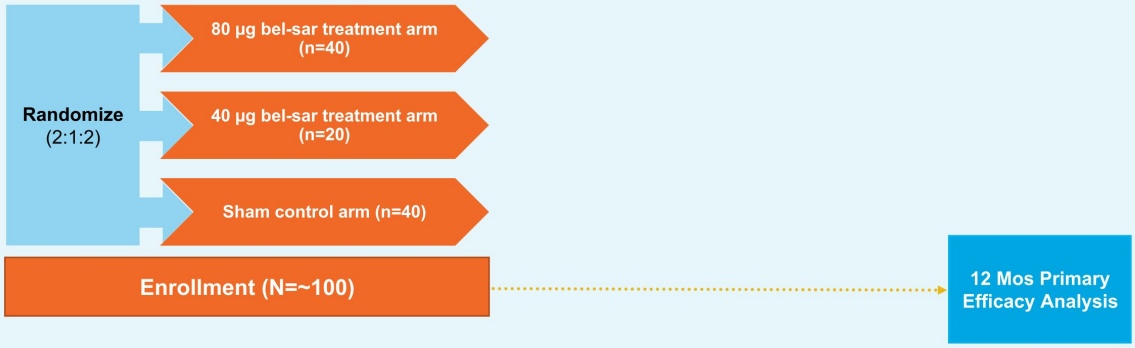
Global Phase 3 Trial Design Using Suprachoroidal Administration

Fast Track and Orphan Designations



Endpoint analysis is based on the comparison between high dose arm and sham arm

Primary Endpoint

- Time to Tumor Progression

Key Secondary Endpoints

- Composite Time to Event Analysis - Tumor progression or visual acuity failure
- Tumor Growth Rate

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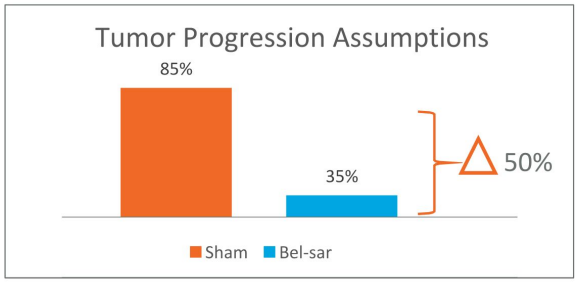
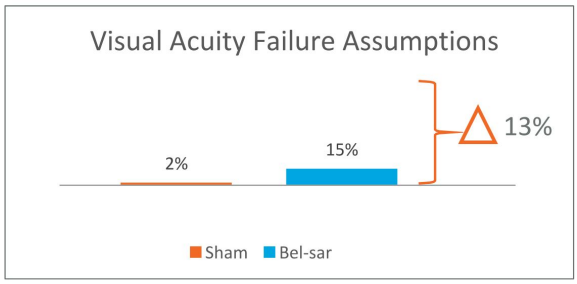
Clinical Endpoints to Support Potential Approval in Alignment with Regulatory Agencies

Composite Endpoint

Endpoint @ 12 mos.	Endpoint Assumptions	Endpoint Definitions
Tumor Progression	**Bel-sar:** 35% Tumor Progression **Sham:** 85% Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter
Vision Acuity Failure	**Bel-sar:** 15% VA Failure **Sham:** 2% VA Failure	Decrease from baseline: ≥15 letters
Tumor Thickness Growth Rate	Bel-sar vs Sham : -0.28mm/year reduction	Change in tumor height over time





Conservative Assumptions Provide >90% Power to Support Potential for a Single Global Phase 3 Trial

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

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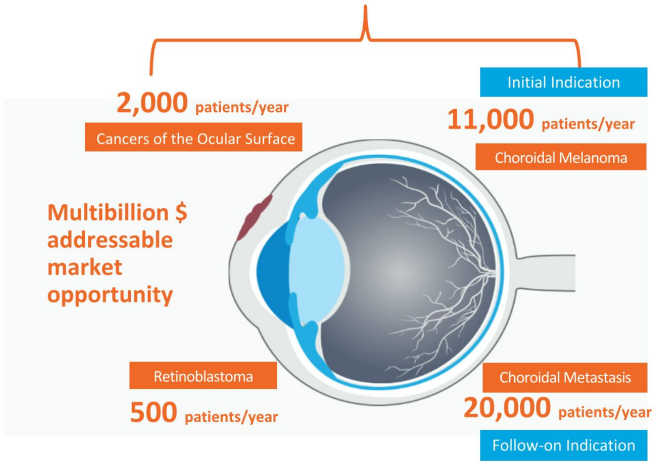
Choroidal Metastasis

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

33,500

Ocular Oncology Franchise total addressable market



20,000

Choroidal Metastasis patients diagnosed each year (US/EU)

2x

Doubles the market opportunity

Same Call Point as CM

~100 Ocular Oncologists in US/EU — focused call point

Same Field Force as CM

<20 Field Based Team

Intend to add small sales force to launch globally

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
CM – Choroidal Melanoma

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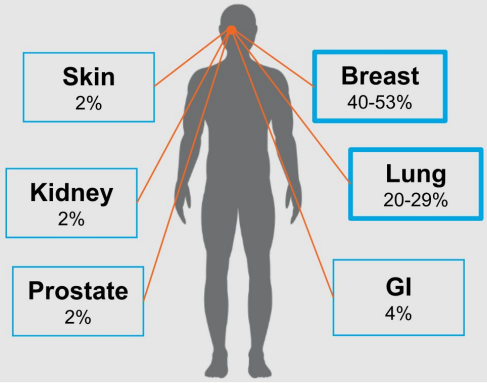
Choroidal Metastasis is a High Unmet Medical Need

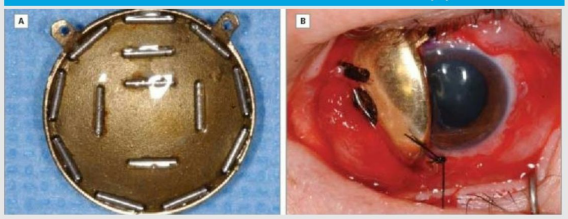
Originate from **Multiple Primary** Cancers
(e.g. Breast and Lung)

20,000/year eyes diagnosed in US

88% with choroidal location
72% unilateral and solitary



Standard of Care is Radiotherapy



Blindness, Eye Loss, and Disfiguration

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

Mathis et al. New concepts in choroidal metastasis, *Progress in retinal and eye research* (2019), Cohen, Ocular metastasis, Eye (2014), Shields et al. Survey of 520 eyes with uveal metastases. *Ophthalmology* (1997), Namad et al. Bilateral choroidal metastasis from non-small lung cancer, Case reports in oncological medicine (2014).

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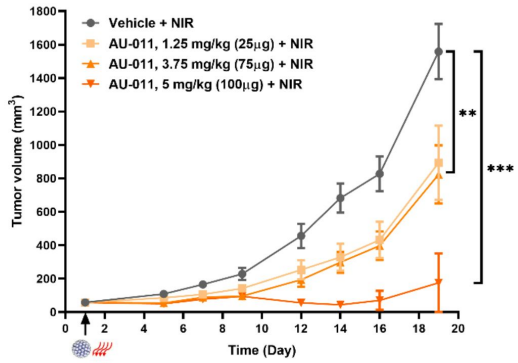
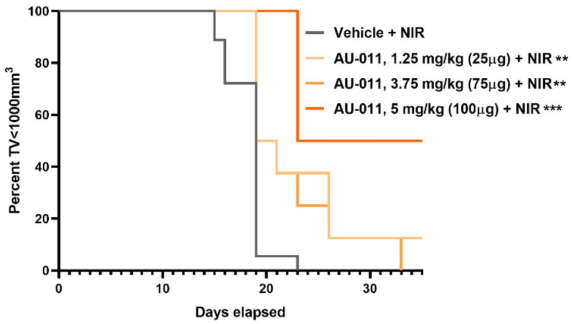
Bel-sar has Demonstrated Dose-Dependent Activity for Cancer Types Known to Metastasize to the Choroid

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

Tumor Regression



Prolonged Survival



Tumor cells were implanted subcutaneously. AU-011 treatment was initiated when tumors reached approximately 50 mm^3. Treatment consisted of a single intravenous administration of AU-011 followed 12 hours later by light activation (400 mW/cm^2, 58 J/cm^2). Tumor volumes were measured over time (N=8-12)

Single Administration of Bel-sar Showed Tumor Regression and Prolonged Survival in a Dose-Dependent Fashion Data Supportive of Moving into Phase 2 Trial in 2024

Savinainen et al., ARVO 2022 Abstract # 3709397; AU-011 – Bel-sar – Belzupacap Sarotalocan

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Urologic Oncology

Bel-sar

INN: belzupacap sarotalocan

Target Indications:

Non-Muscle Invasive Bladder Cancer

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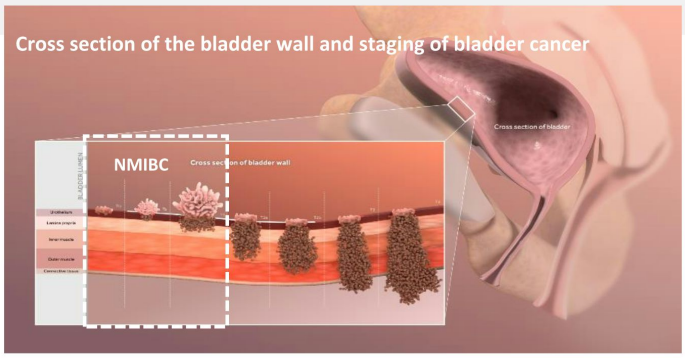
NMIBC is a High Unmet Need with High Recurrence Rate

422,000
New cases NMIBC/year globally

61,000
New cases/year in the US



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

Source: Putnam Associates Primary Research & Literature Review, July 2021; NMIBC – Non-Muscle Invasive Bladder Cancer; TURBT - trans urethral resection of bladder tumor; BCG - Bacillus Calmette–Guérin; Bel-sar – Belzupacap Sarotalocan

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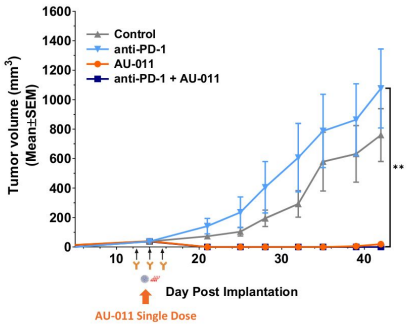
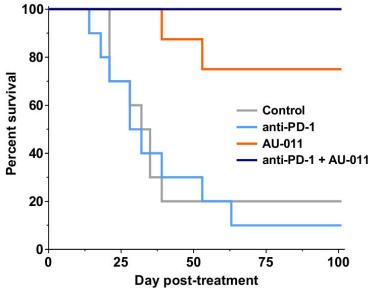
Durable CRs with Single Administration of Bel-sar in Bladder Cancer Model

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

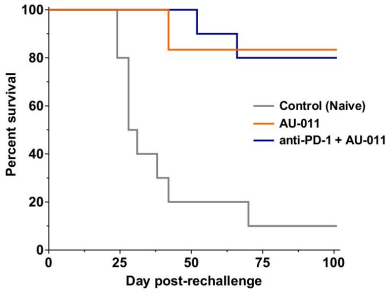
Tumor Regression



Survival



Survival After Re-challenge



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

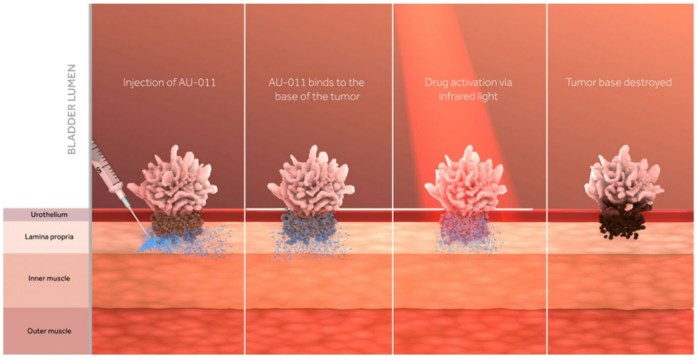
Kines et al. Can Immunol Res 9(6):693-706, 2021

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

Bel-sar: Belzupacap Sarotalocan; CR: Complete Responses

Novel Approach using Local Administration

Local Administration and Light Activation into the Bladder with Standard Cystoscope



Bel-sar will be administered locally and activated with light using standard cystoscope

Study Design and Objectives

Part 1

Bel-sar alone

- Safety
- Feasibility
- Distribution

Part 2

Bel-sar + Focal Light activation

- Safety
- Feasibility
- Distribution
- Biological Activity

Ongoing Phase 1 Trial Designed to Establish Safety and Optimize Administration

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 globally >400,000 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)
Read Through from Ocular Clinical Proof of Concept	- Two clinical trials demonstrate robust efficacy in Ocular Oncology - Initiating global Ph 3 trial in choroidal melanoma
Phase 1 Study Ongoing	- Initial data available in 2024

CR – complete responses; BCG - Bacillus Calmette–Guérin

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Strategy & Key Milestones

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Aura Biosciences Investment Highlights

Technology Platform

Virus-like Drug Conjugates

- Novel class of cancer therapies - tumor specific cytotoxicity combined with immune activation
- Targeting multiple solid tumor indications initially focusing on ocular and urologic cancers

Clinical Data Highlights

Ocular Oncology Franchise:

- Positive data in completed Phase 2 trial (IVT)
- Positive interim data in ongoing Phase 2 trial (SC)
- Startup activities ongoing for the global Phase 3 trial

Urologic Oncology Franchise:

- Enrolling patients in Phase 1 trial in NMIBC

2023 Milestones

Primary Choroidal Melanoma:

- 2H 2023: Dose first patient in global Phase 3 trial
- 2H 2023: Phase 2 SC Data

Choroidal Metastasis:

- 2024: Phase 2 data

Non-Muscle Invasive Bladder Cancer:

- 2024: Phase 1 data

Key Highlights

Strong Phase 2 Clinical Proof of Concept in CM

Startup Activities Ongoing - Phase 3 Trial to Support Registration in CM

Multi-Billion Dollar Market Opportunity

Strong Cash Position

CM – Choroidal Melanoma

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