ALTITUD 100K SPA

# SPHERA

## 3D spatial mapping for surgical margin relocation

Evaluation dossier for investors, strategic partners, and clinical pilot sites.

**PRODUCT**

**Functional MVP**
Team-reported TRL 5

**EVIDENCE**

**76 scans · 31 cases**
Case series with FALP; prospective pilot approved

**FUNDING**

**Ignite grant awarded**
Start-Up Chile - Corfo; starts September 8, 2026

**REPORTED CLINICAL COLLABORATION**

FALP
Juntos contra el cáncer

Non-confidential information for preliminary evaluation
Santiago, Chile · August 26, 2026

# 01 Executive overview

Essential information for deciding whether to pursue an investment, partnership, or pilot discussion.

SPHERA addresses a specific gap: when the pathology team identifies a positive or close margin in the resected surgical specimen, the surgical team must relocate that site in a surgical bed that has already changed. SPHERA is designed to provide a shared 3D reference across the two spaces to support visualization, communication, and case documentation.

**TRL 5**
FUNCTIONAL MVP; DECLARED TARGET OF TRL 7 AT THE END OF THE IGNITE PROGRAM

**76 / 31**
3D SCANS AND CLINICAL CASES IN THE FALP SERIES, ACROSS 33 OPERATING DAYS

**USD 49K**
ANNUAL CLINICAL LICENSE PER INSTITUTION; STATED PRICE, NO SALES TO DATE

**USD 40.5K**
IGNITE IN INITIAL IMPLEMENTATION; CONDITIONAL CUMULATIVE POTENTIAL UP TO USD 67.6K

### WHAT EXISTS TODAY

- ✓ MVP with model loading, four co-registration modes, annotation, dual view, and reporting.
- ✓ Local operation and a shared session over the institution's internal network.
- ✓ A series of 76 3D scans across 31 clinical cases and 33 operating days, with an acquisition protocol and an auditable technical inventory.
- ✓ Prospective pilot approved by a research ethics committee and reportedly underway with FALP.
- ✓ Start-Up Chile Ignite grant awarded to strengthen the product, evidence base, and regulatory pathway.

### WHAT REMAINS TO BE DEMONSTRATED

- Prospectively measured and published clinical accuracy.
- Impact on repeat resections, recurrence, or other oncologic outcomes.
- Clinical safety and production-grade cybersecurity controls, including authentication, encryption, and audit logging.
- Formal regulatory classification and pathway for each target market.
- Pricing, sales cycle, retention, and unit economics validated with customers.

### OPPORTUNITY THESIS

Low-cost 3D acquisition now makes it possible to create a structured spatial reference where teams previously relied mainly on memory, verbal descriptions, and 2D images.

### CORE RISK

The product exists, but its clinical and commercial value still requires validation through prospective evidence, safe and cybersecure clinical deployment, and institutional adoption.

### WHY ENGAGE NOW

The funded stage supports evidence generation and initial product stability. A partnership could accelerate multicenter validation, regulatory work, technical capabilities, and market entry.

# 02 The clinical problem

Evidence shows that surgical margin relocation in head and neck surgery is imprecise, even among specialists.

The pathologic finding is identified on the surgical specimen, while any additional margin resection is performed in the patient. Between these stages, orientation is lost, tissue deforms, and the operative field changes. The challenge is not only to detect the finding, but to relocate it within anatomy that is no longer the same.

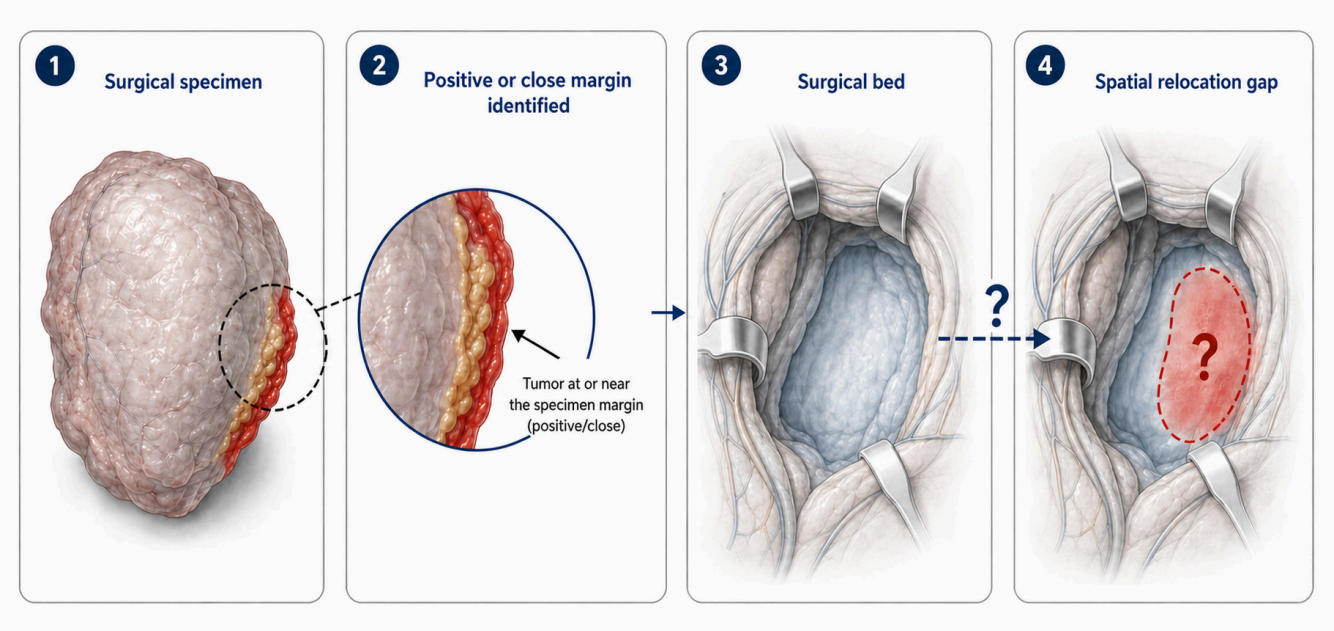



**Figure 1.** Conceptual representation of the relocation gap between the surgical specimen and the surgical bed. This is not a patient image and does not demonstrate SPHERA's performance.

**49.7%**
OF PERPENDICULAR-MARGIN RELOCATIONS WERE MORE THAN 1 CM FROM THE TRUE SITE

**10.2 mm**
MEAN OBSERVED RELOCATION ERROR

**13.8%**
OF SHAVE-MARGIN RELOCATIONS DID NOT OVERLAP THE TRUE MARGIN

**Source:** Miller et al., Head & Neck, 2024. Prospective multi-institutional study involving 32 specialists, 10 specimen models, and 640 margins. These figures describe the clinical problem; they are not SPHERA results.

> **Clinical relevance.** In head and neck surgery, removing additional tissue at the wrong site may compromise structures involved in speech, swallowing, breathing, and appearance; leaving residual disease may also affect oncologic control. SPHERA is intended to improve spatial referencing, not replace the judgment of the surgeon or pathologist.

# 03 The solution

A shared 3D reference between the operating room and pathology, deployed on premises.

SPHERA loads 3D models of the specimen and surgical bed, co-registers them within a shared reference frame, supports margin annotation using real-world dimensions, and enables review from two synchronized workstations. The goal is to help surgical and pathology teams communicate an anatomic location with less ambiguity.


**Figure 2.** End-to-end overview of the proposed workflow, from preparation and scanning through co-registration and communication. This is a product representation; adoption at each center requires local evaluation.

ACQUISITION

### 3D specimen and surgical bed

Scanning under a standardized procedure, followed by operational checks for coverage, texture, and anatomic landmarks.

CO-REGISTRATION

### Shared spatial reference

Four implemented modes combine automation and user guidance. Internal quality metrics still require prospective clinical performance evaluation.

COLLABORATION

### Review and reporting

Dual view, annotations, a shared session over the local network, and structured PDF reporting inspired by synoptic pathology workflows.

INTENDED-USE BOUNDARY

SPHERA is designed to support visualization, communication, and documentation. It does not diagnose or autonomously classify margins, make resection decisions, or replace clinical judgment. The final intended-use statement and applicable regulatory classification remain to be formally established.

VIEW THE PRODUCT

MVP demo - 2 min

Project pitch - 90 sec

SPHERA product page

# 04 3D acquisition

Co-registration quality begins with controlled acquisition; the detailed SOP is reserved for each pilot.

Preparation, lighting, and scan coverage must remain consistent for the models to be comparable. This public document presents the general approach; acquisition parameters, internal criteria, and complete operating procedures are agreed confidentially with each institution.


**Figure 3.** Conceptual representation of the preparation, scanning, and quality-control procedure. Approval labels shown in the illustration refer to operational input checks, not validation of clinical accuracy.

**1. PREPARE**

Washing, drying, and landmark placement under the institution-approved protocol.

**2. CAPTURE**

Scanning of the specimen and surgical bed with checks for lighting, coverage, and anatomic orientation.

**3. VERIFY**

Review of mesh, texture, visible landmarks, and metadata before loading the models.

**CONTENT OBSERVED IN THE INVENTORY**

The repository contains meshes and textures, JPG images, native scanner files, derived data, and process logs. OBJ, PLY, STL, 3MF, GLB, and ASC representations are present; the existence of a format in the inventory does not mean that SPHERA imports it directly.

**DATA AND SECURITY**

SPHERA is designed for **on-premises operation by default**. Any export of appropriately de-identified technical or clinical data for research or development would be optional, separate from software use, and subject to applicable ethics approval, contractual terms, and data-protection requirements. Each pilot must account for Chilean Law No. 20,584, Law No. 19,628, and Law No. 21,719, which takes effect on December 1, 2026.

# 05 Evidence and scientific activity

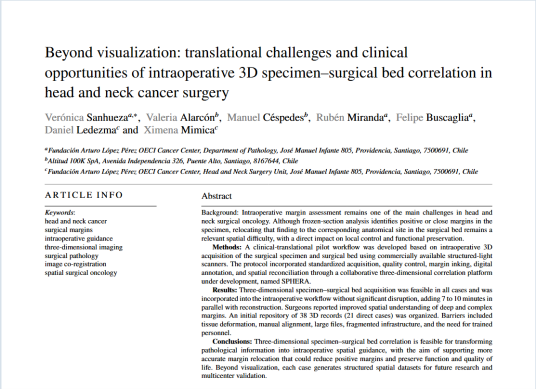
The project has already produced clinical and technical work; prospective clinical evaluation and publication remain pending.

SPHERA is being developed with clinical professionals. Its 3D acquisition work has contributed to a manuscript in preparation and to participation in an international conference. This activity supports the relevance of the problem but should not be interpreted as clinical validation of the product.

MANUSCRIPT

## Intraoperative 3D correlation

The manuscript *Beyond visualization: translational challenges and clinical opportunities of intraoperative 3D specimen–surgical bed correlation in head and neck cancer surgery* is **being prepared for submission to *Oral Oncology*** and reports a retrospective series of **31 cases and 76 3D scans** obtained with FALP. The journal is the intended venue; this does not imply acceptance or publication.



Beyond visualization: translational challenges and clinical opportunities of intraoperative 3D specimen–surgical bed correlation in head and neck cancer surgery

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ARTICLE INFO

*Keywords:*
head and neck cancer
surgical margins
intraoperative guidance
three-dimensional imaging
surgical pathology
image co-registration
spatial surgical oncology

Abstract

Background: Intraoperative margin assessment remains one of the main challenges in head and neck surgical oncology. Although frozen-section analysis identifies positive or close margins in the specimen, relocating that finding to the corresponding anatomical site in the surgical bed remains a relevant spatial difficulty, with a direct impact on local control and functional preservation.

**Methods:** A clinical-translational pilot workflow was developed based on intraoperative 3D acquisition of the surgical specimen and surgical bed using commercially available structured-light scanners. The protocol incorporated standardized acquisition, quality control, margin inking, digital annotation, and spatial reconciliation through a collaborative three-dimensional correlation platform under development, named SPHERA.

**Results:** Three-dimensional specimen–surgical bed acquisition was feasible in all cases and was incorporated into the intraoperative workflow without significant disruption, adding 7 to 10 minutes in parallel with reconstruction. Surgeons reported improved spatial understanding of deep and complex margins. An initial repository of 38 3D records (21 direct cases) was organized. Barriers included tissue deformation, manual alignment, large files, fragmented infrastructure, and the need for trained personnel.

**Conclusions:** Three-dimensional specimen–surgical bed correlation is feasible for transforming pathological information into intraoperative spatial guidance, with the aim of supporting more accurate margin relocation that could reduce positive margins and preserve function and quality of life. Beyond visualization, each case generates structured spatial datasets for future research and multicenter validation.

**Figure 4.** Manuscript thumbnail. Wider distribution requires authorization from the coauthors and the relevant institutions.

INTERNATIONAL DISSEMINATION

## Two international conferences

Altitud 100K reports participating in the **SLAP 2025 Latin American Congress of Pathology** and in the **AHNS 12th International Conference on Head and Neck Cancer**, held in Boston, July 18–22, 2026, with the work *Implementation of a 3D scanning workflow for accurate specimen–bed localization in head and neck cancer resections*.

Implementation of a 3D Scanning Workflow for Accurate Specimen–Bed Localization in Head and Neck Cancer Resections Ximena Mimica, MD[1]; Valeria F Alarcon Leiva, BSc[2]; Manuel A Cespedes Araya, MBA[2]; Ruben Miranda, MD[1]; Daniel Ledezma, MD[1]; Felipe Buscaglia, MD[1]; Veronica Sanhueza, MD[1]. [1]Instituto Oncológico Fundación Arturo López Pérez; [2]ALTITUD100K SpA

**Background:** Head and neck squamous cell carcinoma presents high rates of positive margins and local recurrence, frequently occurring 2–3 years after treatment. Current intraoperative orientation of surgical specimens relies on verbal descriptions, sketches, markers, and photographs, which limits accurate margin re-identification and reduces the ability to perform selective and effective re-resections. Emerging evidence indicates that optical 3D scanning, digital mapping, and deformable-registration frameworks can enhance surgeon–pathologist communication; however, no standardized, feasible, real-time workflow has yet been integrated into routine surgical practice.

**Methods:** We developed a clinical–technical workflow for real-time intraoperative acquisition, processing, and registration of 3D models of the resected specimen and surgical bed in head and neck oncologic surgery. The protocol integrates practical requirements identified during pilot testing, including a brief preoperative calibration to verify scanner accuracy and illumination. The workflow comprises: (1) optical 3D scanning of the specimen immediately after resection; (2) scanning of the surgical bed after hemostasis; (3) mesh and point-cloud reconstruction, cleaning, smoothing, and global scaling to account for tissue shrinkage; (4) anatomical landmark selection; and (5) specimen–bed registration using landmark-based initialization and iterative closest point, followed by manual refinement of scale, orientation, and transparency of the specimen. This standardized workflow establishes consistent acquisition conditions that facilitate accurate alignment of 3D models and provides a foundation for future integration of AI-driven deformable registration and augmented-reality visualization.

**Results:** In this pilot series (20 cases scanned; 8 complete specimen–bed pairs suitable for registration), we observed a clear learning curve that progressively reduced scanning and processing times. Median added time remained below the predetermined operational threshold (7–10 minutes). Standardizing the 3D acquisition process for head and neck surgery improves the perception of deep or complex margins, providing the surgeon with a three-dimensional model before reconstruction began. Compared with conventional documentation, surgeons reported improved spatial understanding of deep and hard-to-access margins, and pathologists noted clearer communication when marking positive or close margins directly on the 3D model. The protocol defines the full technical pathway from operator training and technological requirements to minimum scanning times and enables consistent documentation.

**Conclusions:** Implementation of this protocol confirms that real-time intraoperative 3D scanning and specimen–bed registration are feasible, reproducible, and compatible with clinical timelines. Standardization enhances quality, safety, and efficiency while enabling the creation of a structured 3D repository for future cancer-engineering applications. Potential expansions include training machine-learning models for automated deformable registration particularly relevant for tongue surgery and integrating near-real-time augmented reality into the operating room. The methodology also supports external collaboration through anonymized datasets and shared imaging banks.

Overall, this work represents a fundamental step toward next-generation intraoperative guidance systems aimed at reducing local recurrence and improving long-term oncologic outcomes.

**Figure 5.** Scientific abstract thumbnail. Presentation format, abstract number, and program listing are available for verification when applicable.

PROGRESS INDICATORS

- ✓ 76 3D scans across 31 clinical cases and 33 operating days; 1,142 files and 171.9 GB.
- ✓ Coverage from December 2024 through June 2026; 63 of 76 folders retain the six primary 3D exports.
- ✓ Prospective pilot approved and reportedly underway with FALP.
- ✓ Seven coauthors and an institutional letter signed in May 2026.

CORRECT INTERPRETATION

- A retrospective, non-consecutive convenience series: it measures acquisition feasibility, not accuracy.
- 29 of the 31 cases have a clinical record: 21 head and neck and 8 from other anatomic regions.
- Only 14 of 31 cases include both specimen and surgical bed, which is what co-registration requires.
- No published accuracy metrics or demonstrated oncologic outcomes are available.

| 76 | 31 | 33 | 171.9 GB |
|---|---|---|---|
| 3D SCANS | CLINICAL CASES | OPERATING DAYS | ACROSS 1,142 FILES |

EXSTAR INVENTORY - CONSOLIDATED, AUGUST 2026

Thirty-six are specimen scans and 40 are surgical-bed scans. The full set of six primary 3D export formats is present in 63 of 76 folders; 59 retain the EXStar project file. Coverage: December 2024 through June 2026.

**Source:** Internal EXStar technical inventory, consolidated in August 2026. These are aggregate operational counts; they do not identify patients and do not measure clinical performance. Verify the pilot, manuscript, abstract, and institutional support against primary sources.

# 06 Status, roadmap, and risks

A clear distinction between what is in place, what remains under development, and what depends on third parties.

CURRENT

## MVP - TRL 5

Status and maturity as reported by the team. The inventory confirms 3D technical assets and EXStar project files, but does not independently validate the TRL, MVP functionality, or co-registration accuracy.

IGNITE TARGET

## Pilot-ready version - TRL 7

Version-controlled build, manuals, improved stability, prospective evidence, and a preliminary regulatory pathway, at the end of the program that starts on September 8, 2026. This is a target, not an achieved result.

LATER STAGE

## Production readiness and expansion

Enhanced clinical safety and cybersecurity controls, formal regulatory assessment, initial licenses, and multicenter pilots, subject to evidence, procurement processes, and approvals.

### REPORTED MVP CAPABILITIES

- ✓ Reported support for GLB/glTF, 3MF, and OBJ imports; the inventory does not verify this functionality.
- ✓ Four co-registration modes with internal quality indicators.
- ✓ Point and area annotations using real-world dimensions.
- ✓ Dual view, model transparency, and overlay.
- ✓ Shared session between two workstations over a local network.
- ✓ Structured PDF report and a de-identification mode.
- ✓ Local software assistant, reportedly without access to case data.

### DEVELOPMENT AND DEPENDENCIES

- AI-based automatic detection of anatomic landmarks.
- Non-rigid registration to compensate for tissue deformation.
- Performance optimization for high-density meshes.
- Authentication, encryption, and audit trails for production use.
- Quality documentation, risk matrix, and regulatory strategy.
- Standardization gap: 13 of 76 components do not contain the full set of six export formats, and 17 do not include an EXStar project file.

### RISKS A POTENTIAL PARTNER SHOULD ASSESS

**Clinical**
Prospective evidence remains pending; no oncologic outcomes have been demonstrated.

**Technical**
Tissue deformation, acquisition quality, and variable file completeness.

**Regulatory**
No applicable regulatory authorization. ISP regulation in transition through 2029; classification undetermined.

**Execution**
Product knowledge and the clinical relationship are concentrated in one founder.

INITIAL FUNDED STAGE

## USD 40.5K

**Conditional potential up to USD 67.6K**

**Start-Up Chile Ignite:** initial funding of CLP 30M from Corfo and CLP 7.5M from Altitud 100K, totaling CLP 37.5M (approximately USD 40.5K). The program starts on September 8, 2026, with four months of acceleration and an initial grant implementation period of up to six months. Conditional cumulative funding with the extension, subject to program milestones and eligibility, would comprise CLP 50M from Corfo plus estimated company co-funding of CLP 12.5M (20%), totaling CLP 62.5M (approximately USD 67.6K).

# 07 How to evaluate a pilot

An initial framework for a center to define scope, responsibilities, data, metrics, and close-out criteria.

The proposed pilot is a controlled evaluation of feasibility, workflow, and technical performance. It does not, in itself, authorize diagnostic use or autonomous clinical decision-making. The final protocol must be approved by the institution and adapted to its infrastructure, clinical team, and applicable ethics and governance requirements.

**01**
### Preparation
Review of the clinical service, scanner, local network, accountable parties, and pilot use case.

**02**
### Agreements
Ethics, data governance, support, rights in results, and stopping criteria.

**03**
### Training
Installation, workflow simulation, and operational verification before the first case.

**04**
### Pilot conduct
Four months or 25 co-registered cases, whichever comes first, under the approved protocol.

**05**
### Decision
Joint report: continue, adjust, expand to multiple centers, or conclude the pilot.

#### SITE RESPONSIBILITIES

- Clinical lead and site coordinator.
- Access to head and neck surgery and pathology workflows.
- Compatible 3D scanner or a specific hardware arrangement.
- Approved IT infrastructure and local network.
- Applicable ethics, institutional, and data-governance approvals.
- De-identified manifest covering files, timing, technical issues, and user feedback.

#### ALTITUD 100K RESPONSIBILITIES

- Site readiness assessment and MVP installation.
- Training, an agreed SOP, and support throughout the pilot.
- Co-registration, annotation, and reporting tools.
- File inventory, completeness checks, and version control.
- Aggregate analysis of feasibility and user experience.
- Final report and recommendation for the next stage.

#### SUGGESTED METRICS

Preparation and scanning time; percentage of usable acquisitions; loading and co-registration time; technical issues; session completion rate; ease of use; perceived usefulness; fit with the clinical workflow; and completeness of the file package and report. Any clinical-accuracy metric requires a dedicated protocol and analysis plan.

#### DATA, COST, AND CLOSE-OUT

Data remain on-premises by default, and each acquisition is accompanied by a de-identified manifest. Any secondary use is optional and subject to a separate agreement. The **pilot plan has a stated price of USD 6,000 for four months** —a USD 2,000 setup fee plus USD 1,000 per month— of which **USD 4,000 is credited** against the first annual license. Hardware requirements are defined after assessing the site. Deliverables, rights in results, data-retention rules, and continuation or close-out terms are agreed before the pilot begins.

# 08 Market opportunity and business model

An institutional B2B thesis under validation; commercial figures are not audited forecasts.

**947,000**
GLOBAL ANNUAL INCIDENCE ACROSS INCLUDED CANCER SITES

**21 · 200**
ELIGIBLE INSTITUTIONS IN CHILE AND ACROSS LATIN AMERICA; INTERNAL UNAUDITED ESTIMATE

**USD 0**
CURRENT SPHERA ARR; PRE-REVENUE PRODUCT

PROPOSED MODEL

## Paid pilot, then an annual license

- Buyer: hospital, clinic, or cancer center. Users: head and neck surgery and pathology teams.
- **Pilot plan: USD 6,000 for four months**, of which USD 4,000 is credited against the first license.
- **Clinical license: USD 49,000 per year.** A USD 45,000 base including 100 cases, plus USD 200 per additional case, capped at USD 65,000. At 120 cases a year this is **USD 408 per surgery**.
- Implementation and training: USD 7,500. Add-on modules: USD 5,000 per year.
- Pilot-to-license conversion assumed in the model: 70%.

**Caution:** these are stated list prices, not transacted prices. Procurement cycle, conversion, customer acquisition cost (CAC), and retention remain to be validated with real customers.

MARKET-ENTRY STRATEGY

## The regulator sets the order

1. **Chile:** evidence base, safety and cybersecurity controls, the pilot proposition, and the ISP submission.
2. **Colombia:** INVIMA grants automatic approval for Class I and IIa devices. It is the fastest and least costly entry point in the region, ahead of Peru.
3. **Peru:** DIGEMID, 90 business days for Class II.
4. **Mexico and Brazil, through partners:** COFEPRIS in 3 to 6 months —Chile is not among the jurisdictions eligible for the abbreviated pathway— and ANVISA in 6 to 12 months with MDSAP.
5. **United States and Europe:** 510(k) Class II, with the United Kingdom as the entry point to the European Union.

All five regional markets require a local legal representative: this is a per-country entry cost. Timing and extension to other solid tumors remain hypotheses subject to results and regulatory requirements.

UNIT ECONOMICS FROM THE FINANCIAL MODEL - MODELED VALUES, NOT OBSERVED RESULTS

| 84% to 96% | 17.8× | 2.0 months | USD 408 |
|---|---|---|---|
| GROSS MARGIN, YEAR 1 TO YEAR 3 | LTV TO CAC IN YEAR 3 | CAC PAYBACK | PER SURGERY AT 120 CASES A YEAR |

> **Investor takeaway.** The opportunity depends on converting a documented clinical problem and a functional MVP into prospective evidence, a safe and cybersecure implementation, and a repeatable procurement process. Due diligence should test those three assumptions before committing to expansion.

**Source:** IARC, 2022 incidence data and GLOBOCAN 2022. The 947,000 figure combines approximately 758,000 cases of cancers of the lip, oral cavity, and pharynx with 189,211 cases of laryngeal cancer; not all are surgical cases or potential SPHERA candidates. The eligible-institution universe (21 in Chile and on the order of 200 across Latin America) is an internal estimate under a filter of in-house intraoperative frozen section, surgical volume, and 3D scanner availability; it has not been audited name by name, and a stricter filter reduces it. Pricing and unit economics: internal financial model *Modelamiento SPHERA* v4.4, August 2026.

# 09 Team and execution capability

Three founders, clinical collaboration, and a recognized concentration risk.

MC

### Manuel Céspedes Araya

**CFO and COO**

Founder · Full-time

Project Engineer with a BSc in Engineering Sciences (USM). He also holds a degree in Automotive Mechanics and Autotronics, a Diploma in Astronomy (University of Chile), and an MBA. He completed international training in entrepreneurship, innovation, and creativity at Babson College. He leads product, operations, technology projects, the business model, applied AI, and clinical relationships.

VA

### Valeria Alarcón Leiva

**Chief Technology Officer (CTO)**

Co-founder · Significant part-time commitment

Electronics Engineer (USM), with experience in mission-critical engineering and involvement with Chile's National Space Center. Contributes systems architecture, data analysis, 3D repository curation, and methodological validation. Coauthor of the clinical and technical manuscript.

SG

### Sofía Galaz Meléndez

**CEO**

Co-founder · Part-time

Engineering Physics student (USM) and captain of the USM CubeSat Team. Responsible for general management and the institutional adoption model. Further executive development and clearer allocation of responsibilities are part of the next governance stage.

**REPORTED SUPPORT**

- ✓ Clinical collaboration with FALP/OECI teams.
- ✓ Prospective pilot approved by a research ethics committee.
- ✓ Institutional letter of recommendation signed in May 2026.
- ✓ Clinical coauthorship of the manuscript and dissemination at SLAP 2025 and AHNS 2026.
- ✓ Support from the 3IE Institute at Universidad Técnica Federico Santa María.

**RISK AND MITIGATION**

A substantial portion of product knowledge and the primary clinical relationship are currently concentrated in Manuel. Proposed mitigations include documentation, version control, additional computer-vision capabilities, clear assignment of installation and support responsibilities, and distribution of critical knowledge across multiple team members.

**GOVERNANCE AND DUE DILIGENCE**

**Information disclosed in this dossier**

Company incorporated in March 2025; founder-owned; no prior institutional funding reported; SPHERA is pre-revenue; roles and time commitments as reported.

**Available under NDA**

Cap table and corporate records; grant award and budget; contracts and approvals; architecture, source code ownership, IP, and cybersecurity; protocols, component-level inventory, and traceability; de-identified clinical results, if available and authorized; sales pipeline and detailed regulatory plan.

> **Discussion point.** Manuel is listed as CFO and COO and also serves as Team Leader of the Ignite project on a full-time basis before Corfo. Before a pilot or investment, the parties should formalize accountability for technology, support, security, clinical operations, and executive decisions.

# 10 Ways to engage

Collaboration can begin through capital, a pilot, specialized capabilities, or a targeted introduction.

SPHERA's next stage is to turn an MVP and an initial clinical collaboration into multicenter clinical evidence, production readiness, clinical safety evidence, cybersecurity controls, regulatory clarity, and a repeatable commercial model. Stakeholders can contribute in different ways.

## 01 Invest

Capital to expand validation to additional centers, strengthen the product, accelerate computer-vision capabilities, and fund regulatory and quality-management work.

### CAPITAL REQUIREMENT BY STAGE

**USD 100 thousand** at this stage, through the regulatory milestone: 40% team, 30% regulatory and validation, 20% commercial, 10% working capital. **USD 320 thousand** in a second stage, against that milestone, to enter the United States. Valuation, instrument, and deal structure are discussed case by case.

### BEFORE DECIDING

- Review the corporate and financial data room.
- Verify source-code ownership and clinical agreements.
- Review the evidence, regulatory plan, safety, and cybersecurity.
- Agree on milestones, governance, investment amount, and deal structure.

## 02 Become a strategic partner or pilot site

Clinical centers, healthcare teams, manufacturers, and distributors can contribute a real-world environment, hardware, support, institutional access, or complementary capabilities.

### BEFORE STARTING

- Define the objective, scope, and accountable parties.
- Review infrastructure requirements.
- Agree on ethics requirements, data governance, costs, and rights in results.
- Define metrics, support, and pilot close-out criteria.

## 03 Share expertise

Specialists in medical software, cybersecurity, computer vision, regulation, quality, and technology transfer can make a valuable contribution. Introductions to clinical networks are equally valuable.

### CONCRETE CONTRIBUTIONS

- A targeted introduction to a relevant clinical leader.
- Expert review of a specific gap.
- Access to manufacturers or distributors.
- Mentoring on regulation, healthcare procurement, or scaling.

### INITIAL MEETING

30–45 minutes to assess fit, interest, constraints, and the appropriate next step. No sensitive information needs to be shared at this stage.

### SECOND STAGE

Guided demo, technical session, or site-readiness assessment, depending on the type of collaboration.

### DUE DILIGENCE

An NDA followed by staged access to the documents required for an informed decision.

### BASIS FOR TRUST

Trust does not require accepting every project hypothesis. It depends on clearly distinguishing what has been built, what has been observed, what remains pending, and what each party is prepared to verify before committing resources, reputation, or clinical access.

# Let's agree on a concrete next step

An investment, a pilot, and a strategic partnership each begin differently. What they share is the need to review the available evidence, identify the gaps, and agree on what must be verified before moving forward.

**SPHERA - PRIMARY LINK**

**www.altitud100k.cl/sphera.html**

Product information, value proposition, and contact channels.

**ALTITUD 100K**

**www.altitud100k.cl**

MVP demo
Project pitch


**CONTACT**

## Manuel Céspedes Araya

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**DOCUMENTS FOR A FOLLOW-UP EVALUATION**

- ✓ Guided demo and technical Q&A session.
- ✓ Pilot proposal adapted to the site.
- ✓ Corporate, financial, and technical data room under NDA.
- ✓ Aggregate, de-identified summary of the inventory, evidence, ethics documentation, IP, and regulatory plan.

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**MAIN SOURCES**


1. Miller A. et al. *How far are we off? Analyzing the accuracy of surgical margin relocation in the head and neck*. Head & Neck. 2024;46(11):2709–2716. PMID 38702976. DOI 10.1002/hed.27793.
2. IARC. Global incidence of lip, oral cavity and pharyngeal cancers by subsite in 2022; GLOBOCAN 2022 data for laryngeal cancer.
3. American Head and Neck Society. AHNS 12th International Conference on Head and Neck Cancer, Boston, July 18–22, 2026. Sociedad Latinoamericana de Patología, SLAP 2025 Congress.
4. Library of the National Congress of Chile. Law No. 21,719, effective December 1, 2026.
5. Instituto de Salud Pública de Chile: medical-device regulation in force since March 2026, with a 36-month transition period for clinical software.
6. FALP institutional letter, Start-Up Chile Ignite award, pilot documents, and EXStar inventory consolidated in August 2026: internal supporting materials available for verification subject to authorization.
7. Pricing, unit economics, and commercial assumptions: internal financial model *Modelamiento SPHERA* v4.4, August 2026. These are modeled values based on stated assumptions, not observed results or audited forecasts.
8. Reference exchange rate used for converted amounts: USD 1 = CLP 925, the same rate used in the financial model. USD amounts are approximate.


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FALP
Juntos contra el cáncer

ALTITUD 100K