

Why We Choose to Implement a Pay-Per-Use Business Model for Our High-End Medical Device

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Oraya Therapeutics

Case Study: Medical Procedure Entitlement Management

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About Oraya Therapeutics

Privately held medical device company

Founded in 2007
Newark, California

**External Beam Stereotactic
Radiotherapy**

for treating

**Neovascular Age-related
Macular Degeneration (wet
AMD)**



**CAUTION: INVESTIGATIONAL DEVICE.
LIMITED BY UNITED STATES LAW TO
INVESTIGATIONAL USE. NOT
AVAILABLE FOR SALE IN USA.**

Agenda

Wet AMD – the clinical problem

Oraya's solution

Business case & needs

How Flexera Software's FlexNet Embedded and FlexNet Operations fits into our solution

Wet Age-Related Macular Degeneration (AMD) Leading Cause of Irreversible Legal Blindness



Normal Vision



Age-related Macular Degeneration

AMD Prevalence and Worldwide Growth (in Thousands)

United States

2010	2035	
1,395	2,754	+97%
<i>320 eyes/yr</i>		

EU5

2010	2035	
2,059	3,139	+52%
<i>260 eyes/yr</i>		

China

2010	2035	
3,390	8,151	+140%
<i>810 eyes/yr</i>		

India

2010	2035	
1,692	4,177	+146%
<i>390 eyes/yr</i>		

Searching For The Solution

2005



**Anti-VEGF Therapy
(Lucentis, Avastin, Macugen)**

Gold Standard Care -- monthly injections of Lucentis into the eye

Care as practiced -- 5-8 injections per year

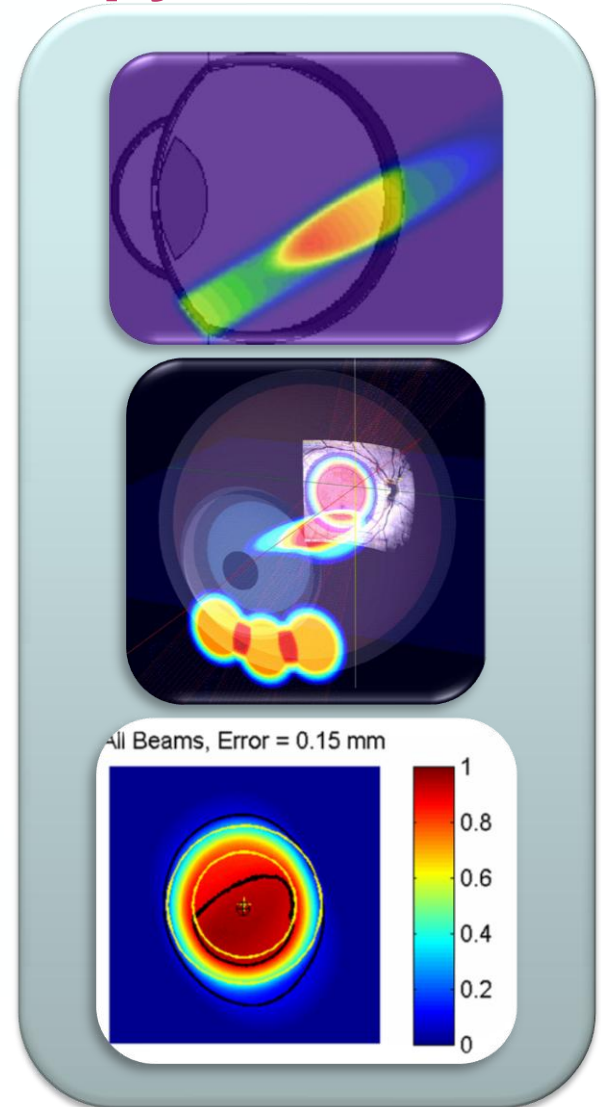
Annual cost per eye

US - \$17,000 per year

UK - £8,850 per year

Significant value can be created with a more durable treatment

Oraya Stereotactic Radiotherapy



The Business Case

The value is in the Oraya Therapy

The Oraya Therapy should create a value *surplus*

Oraya must sustainably capture part of the surplus to be successful



Business Needs

Protect the procedure revenue



Business Needs

Negate the reesterilization risk



Business Needs

Segment the market &
Defeat cross-market
purchasing



Business Needs

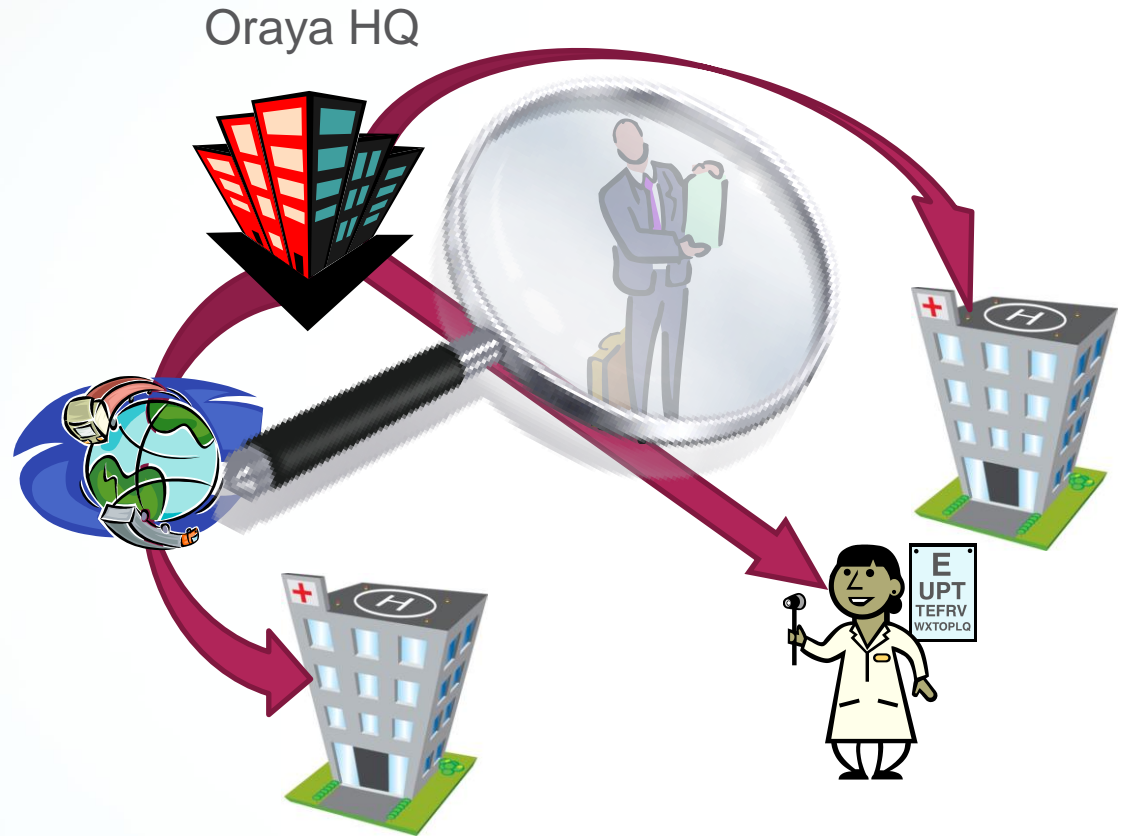
Establish a flexible product and revenue recognition structure



Business Needs

Support multi-tier entitlement distribution

Enable perfect visibility into sales and consumption through all channels



Product Needs

Manage device modes

Tie specific procedure products to device modes



Training



Clinical Trials



Normal Treatment

Flexera Software FlexNet Embedded – FlexNet Operations Solution



FlexNet Operations

- Device Mgt
- Account Mgt
- Entitlement Mgt
- Distribution
- Reporting



FlexNet Embedded

- Mode Mgt
- Entitlement request
- Procedure entitlement enforcement

Meeting the Business Needs

Need	Addressed
Protect the procedure revenue	Oraya sells a procedure protected by a single use (counted) entitlement
Negate the resterilization risk	Procedure is metered, consumable is only a procedure enabler
Segment the market & Defeat cross-market purchasing	<ul style="list-style-type: none">•Accounts are market based•Devices are assigned to accounts•Accounts are entitled•Accounts assign entitlements to devices•Entitlements are locked to device

Meeting the Business Needs

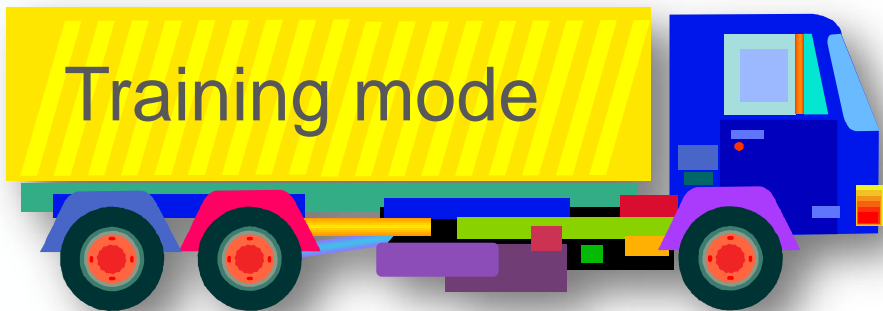
Need	Addressed
Establish a flexible product and revenue recognition structure	<ul style="list-style-type: none">•Flexible feature-to-capability mapping•Entitlements enable revenue recognition at either time-of-sale, or after service (procedure) delivery
Support multi-tier distribution	<ul style="list-style-type: none">•Oraya entitles distributor•Distributor can transfer entitlements to their accounts using Authorization Codes

Meeting the Business Needs

Need	Addressed
Enable perfect visibility into sales and consumption through all channels	<ul style="list-style-type: none">•Oraya HQ has full visibility of every transaction down to the device level•Distributors can have visibility to their accounts via HQ generated reports•Consumption requires a separate implementation for upstream reporting (FlexNet Connect or other)

Meeting the Product Needs

- Manage device modes
- Tie specific procedure products to device modes



Business Logic



Query Entitlements

Trusted Storage



Activate Modes

Other Needs

Manage the customer experience

We can make the entitling and feature activation process invisible to the end-user customer.

- Initially: Account reps update entitlements at the device during regular site visits
- Internet-enabled FlexNet Operations - FlexNet Embedded handshake to deliver entitlements.

“Don’t let procurement delays prevent a treatment””

FlexNet Embedded has the ability to allow “overdrafts” that can be configured individually for each device – creates a negative balance that is reconciled during the next entitlement “deposit.”

Device-Account association at time of entitlement

Conclusion

The FlexNet Operations – FlexNet Embedded system offers a convenient solution to Oraya’s business and product needs

Securing procedure revenue

Enforcing our value proposition

Facilitating distribution

Enabling perfect visibility and reporting

Managing device functionality automatically

Q&A

Thank you!