益安生醫 (TPEX: 6499)

Delivering the Next Gold Standard of Care

Investor Presentation 法人說明會

May 2025

免責聲明

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Urocross經營團隊: 累計超過125年醫療器材領域經驗

Paul Edwards

President
and CEO

Medtronic
Boston Scientific
SURMODICS
ENDOTEX
integenX
Latterell Venture Partners
LAUNCHPAD DIGITAL HEALTH
Hercules CAPITAL

Paul Edwards 於醫材投資領域擁有豐富的高階管理經驗。他曾任 Amicomed, Inc. 的資深副總裁、Launchpad Digital Health 的總營運合夥人，以及 Hercules Capital（NYSE: HTGC）的董事總經理。此外，他亦於多家知名醫療科技公司擔任要職，包括波士頓科學（Boston Scientific）行銷副總裁、Endotex Interventional Systems 行銷與業務開發副總裁，以及美敦力（Medtronic）策略定價資深經理。

Trial Status

- **Enrollment Status**
  - Dec 2024: 240 (2:1) subjects randomized, enrollment closed
  - March 2025: All subjects completed 3-month follow-up

- **Retrieval and Crossover Status**
  - 84% (135/160) Treatment Arm subjects retrieved
  - 85% (68/80) Sham Arm subjects crossed over to treatment

Safety Summary

Comparable to other commercially available treatment options

- Device/procedural serious adverse events – **None (0)**
- Majority of urological adverse events were **mild** and resolved within 30 days
- Procedure was well tolerated based on Pain Score
- Majority of subjects recovered within 24 hours post procedure
- Catheterization was below expected rate compared to other BPH Therapies

Safety Data – Adverse Events

	Expander 2 Tx Arm 0-30 days Implant and Retrieval		iTind Tx Arm 0-30 days (n=118)[2]	LIFT Tx Arm 0-3 mos (n=140)[1]
	Implant (n=160 subjects)	**Retrieval** (n=128 subjects)		
Device/Procedure Related Serious AE's	0% (0)	0% (0)	**2.3% (3)**	**0.7% (1)**
Subjects with Device/Procedure Related AE's	**25.6% (41)**	**13.2% (17)**	**33.1% (39)**	**80.7% (133)**
Dysuria	3.1% (5)	0.8% (1)	22.9% (27)	34.3% (48)
Hematuria / Blood clot	8.7% (14)	3.1% (4)	13.6% (16)	25.7% (36)
Abdominal / Urinary System / Pelvic Pain	3.1% (5)	0.8% (1)	0.8% (1)	17.9% (25)
Urgency	4.4% (7)	0%	5.1% (6)	7.1% (10)
Nocturia	2.5% (4)	0%	Not Reported	7.1% (10)
Leakage / Incontinence	0.6% (1)	0%	3.4% (4)	3.6% (5)
Catheter placed > 7 days	0.6% (1)	0.6% (1)	2 (SAE)	2
UTI	2.5% (4)	0.8% (1)	1.7% (2)	2.9% (4)
Pollakiuria (Frequency)	3.8% (6)	0%	6.8% (8)	Not Reported

Data Safety Monitoring Board (DSMB) confirms Expander-2 Study results meet the safety endpoint

1. https://clinicaltrials.gov/study/NCT01294150?cond=BPH&intr=LIFT&rank=4&tab=results
2. Elterman D, Alshak MN, et.al. An Evaluation of Sexual Function in the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men Treated with the Temporary Implanted Nitinol Device. J Endourol. 2023 Jan;37(1):74-79.

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Safety Data – Procedural Tolerability

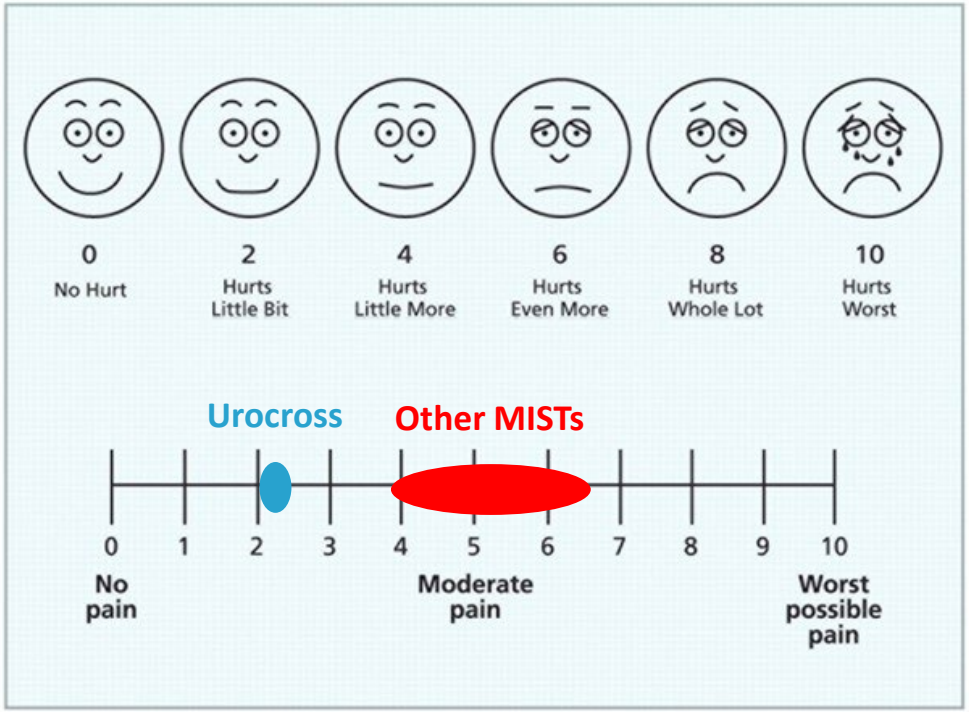
VAS 2.5 (n=160) at deployment discharge

VAS 2.0 (n=127) at retrieval discharge

- **Other MIST VAS comparison:**

Urolift VAS	5.0[1]
ITind VAS	4.2 (implant) and 3.3 (retrieval)[2]
Optilume VAS	4.1[3]
Rezum VAS	6.4[4]
Aquablation VAS	3.8 (1 week post treatment)[5]
Standard cystoscopy	~2 (flexible), ~4 (rigid)

VAS = Visual Analogue Score (Pain)



Urocross VAS supports favorable tolerability of Implant and Retrieval procedures

1. *Can J Urol. 2014 Feb;21(1):7094-101*
2. *Prostatic Diseases and Male Voiding Dysfunction, Volume 153, p270-276, July 2021*
3. Optilume FDA P220029B SSED
4. J Urol. 2016 May;195(5):1529-1538.
5. Urology. 2025 Jan:195:132-138

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Preliminary Efficacy Summary

Data exhibited sustained treatment effect

Equivalent to Rezum, Optilume, UroLift and iTind

- IPSS end point was achieved and sustained at 6, 9, 12 months
  - **Urocross -52.1%** iTind -42.7% Proverum -38.3%
- Further substantial IPSS improvement post implant retrieval
  - Additional 12% reduction
- Met FDA Guidance expectation

1. *Prostatic Diseases and Male Voiding Dysfunction, Volume 153, p270-276, July 2021*
2. Journal of Urology, Volume 213, Issue 5S2, Page: e4, May 2025

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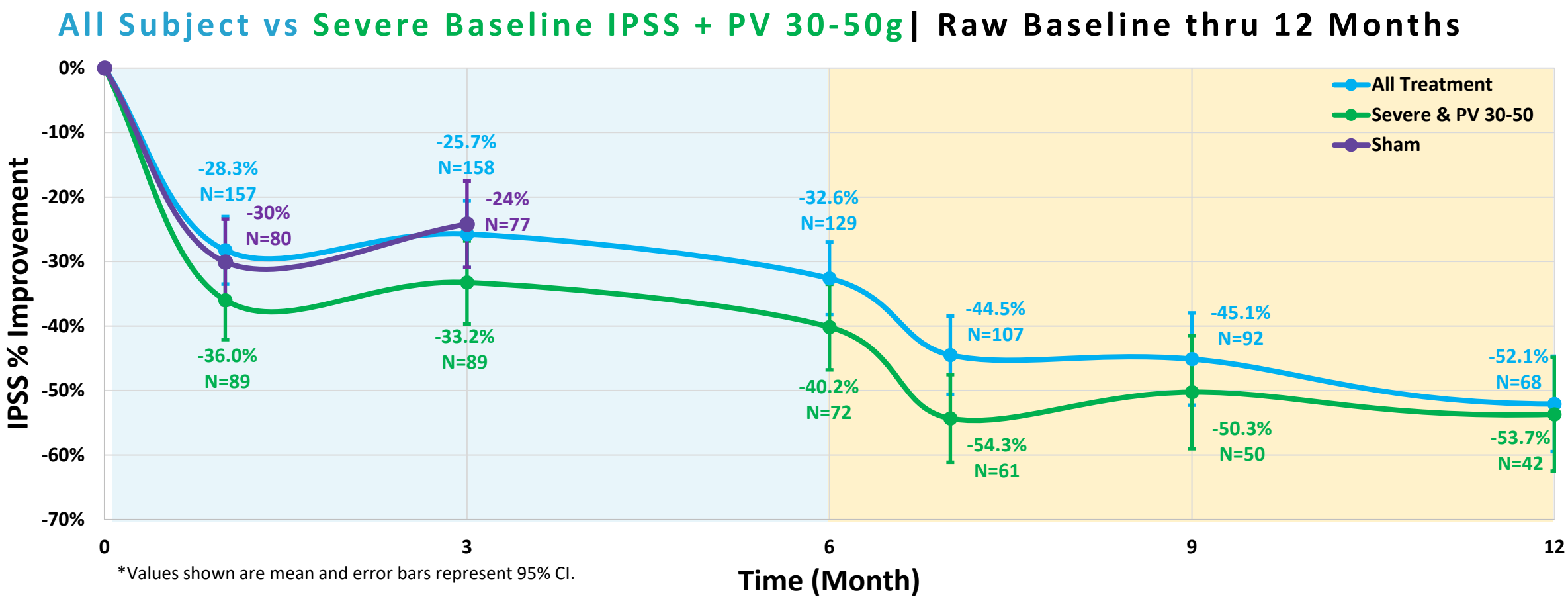
Efficacy Data – IPSS % Change

IPSS = International Prostate Symptom Score



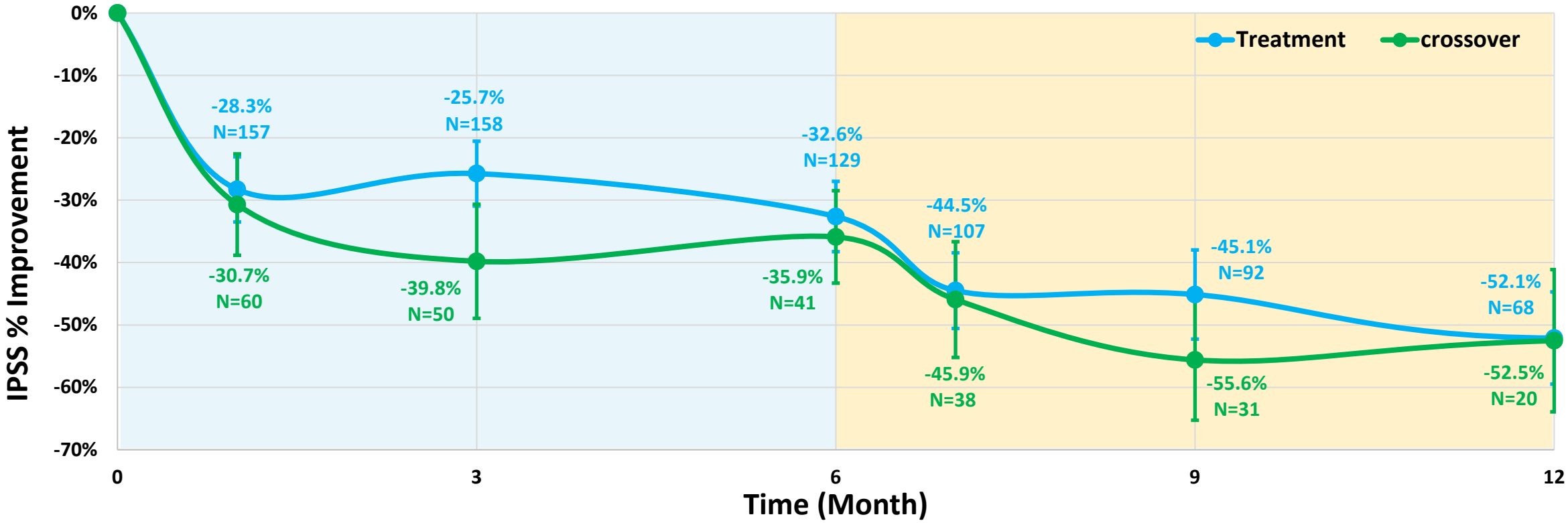
*Values shown are mean and error bars represent 95% CI.

Efficacy Data – IPSS % Change

Treatment-Arm vs Crossover-Arm | Baseline thru 12 Months

IPSS = International Prostate Symptom Score

*Values shown are mean and error bars represent 95% CI.



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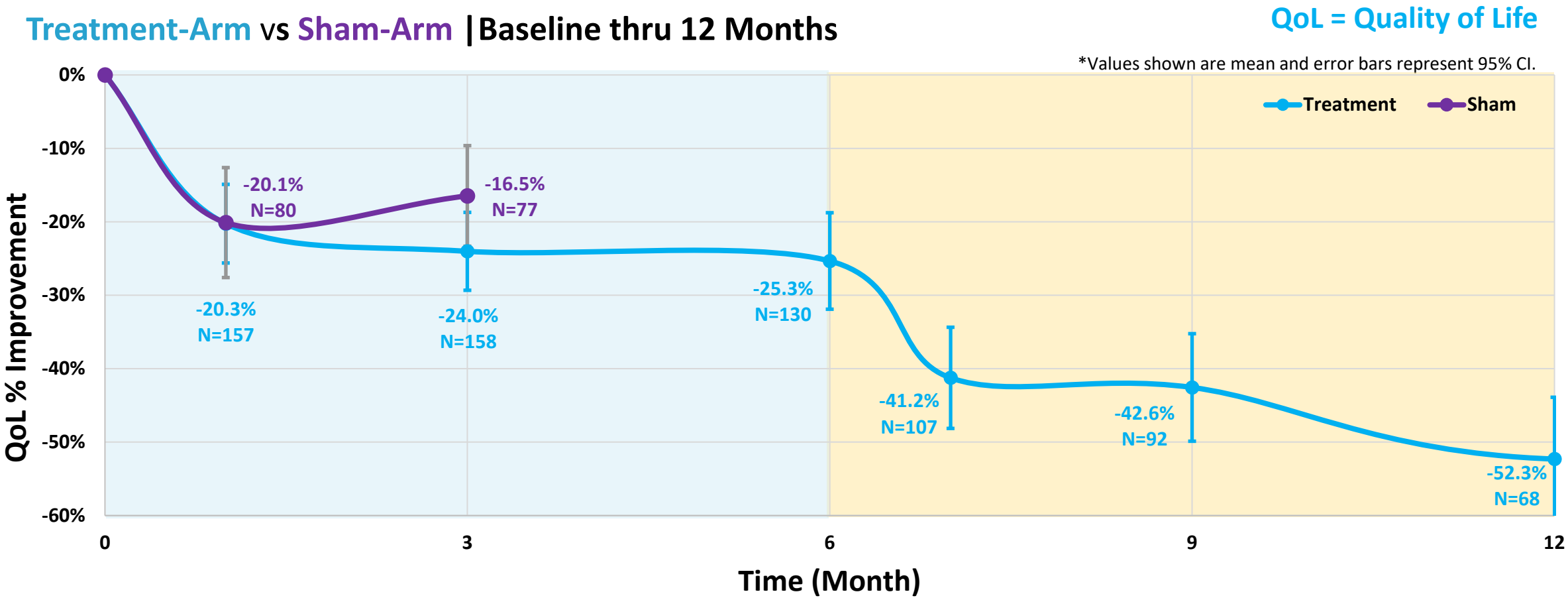
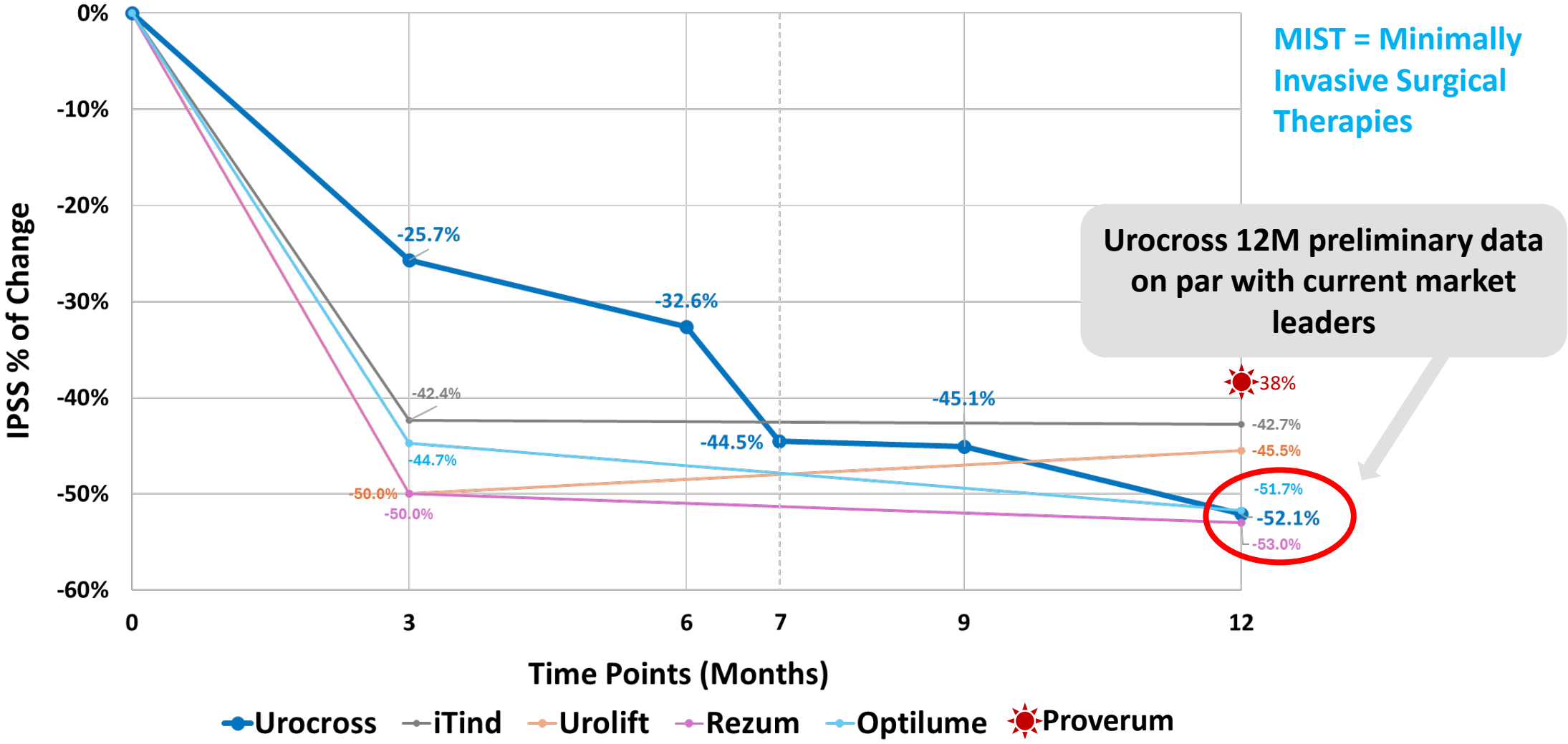
QoL % Change



Urocross vs other MIST Procedures



MIST = Minimally Invasive Surgical Therapies

Urocross 12M preliminary data on par with current market leaders

1. Prostatic Diseases and Male Voiding Dysfunction, Volume 153, p270-276, July 2021
2. Urolift K130651 Decision Summary
3. J Urol. 2016 May;195(5):1529-1538.
4. The Journal of Urology 210(3):p 500-509, September 2023.

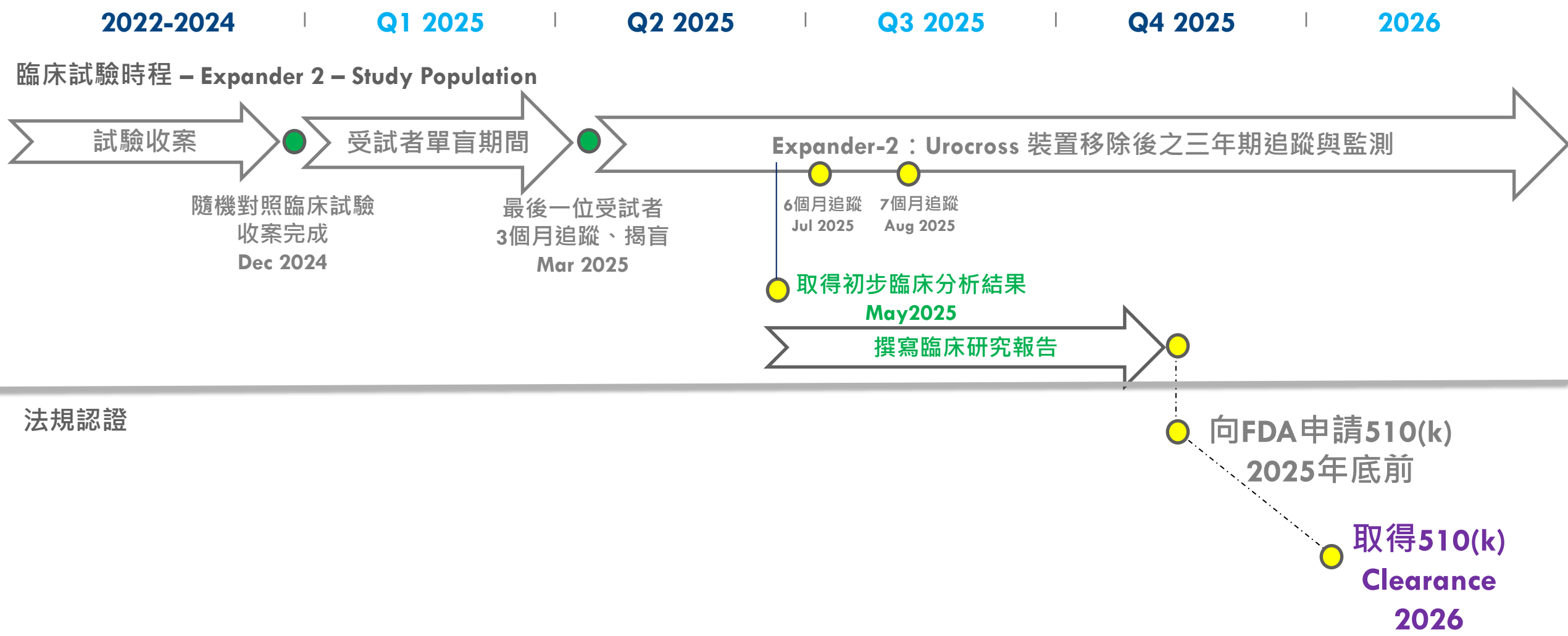
Urocross Competitive Advantages

- **Strong safety profile**
  - None (0) device/procedural-relate SAE's
- **Clinical benefit**
  - > 50% IPSS reduction at 12 months,
  - > 25% improvement over sham with statistical significance at 6 months
- **Flexible cystoscopy yields extremely tolerable pain score**
  - 2.5 for implantation
  - 2.0 for retrieval
- **Short user learning curve**
  - ~ 5 procedures vs UroLift (~25)

Urocross could be a 1st line therapy

- Subjects with **severe** baseline IPSS (>20) are "**early responders**" at 3M
  - **Subjects not have taken BPH Meds**
  - **≥ 1 void (BPH) to storage (bladder) on IPSS**
  - **Prostate volume ≤ 50 g**
- Sexual function (IIEF) and Ejaculatory function (MSHQ) maintained 12 months
- Incontinence score (M-ISI) maintained/improved through 12 months

Expander-2 樞紐性臨床試驗/法規申請時程



BPH領域：高出場估值機會

收購方	治療種類	被收購 公司名/產品名	收購時間	交易/估值 (USD)	產品取證途徑	保險給付
Boston Scientific	水蒸氣消融 **Vapor Ablation**	NxTHERA rezūm	2018/3	收購/ **$406M**	*de Novo* 510(k) (2015/8)	Reimbursement
Teleflex®	永久植入物 **Permanent implant**	**NeoTract** UROLIFT	2017/10	收購/ **$1.2B** ($725M up front, $475M earnout-achieved)	*de Novo* 510(k) (2013/9)	Reimbursement
OLYMPUS	非永久植入物 **Non-permanent implant**	**Medi-Tate Ltd** iTind RESHAPING BPH TREATMENT	2021/2	收購/ **$300M**	*de Novo* 510(k) (2020/2)	Reimbursement
Nasdaq (PRCT:NASDAQ)	微創水刀刮除 **Robotic assisted fluid jet removal system**	PROCEPT® BioRobotics AQUABEAM® ROBOTIC SYSTEM	2021/9	IPO/ 估值**$1.1B** 募得 $164M (目前市值$3.9B, 2025/2)	510(k) (2021/3)	Temporary Code (預計2026年取得正式code)
LABORIE	塗藥球囊 **Tissue Drug coated balloon**	Urotronic OPTILUME	2023/10	收購/ **$600M** ($255M Upfront, $345M Earnout)	PMA (2023/6)	Temporary Code (預計2027年取得正式code)

逐步實現益安2.0願景

CDMO持續創造穩定現金流
Steady Cash flow

+

醫材創新研發專案取得優秀臨床結果
Innovation

+

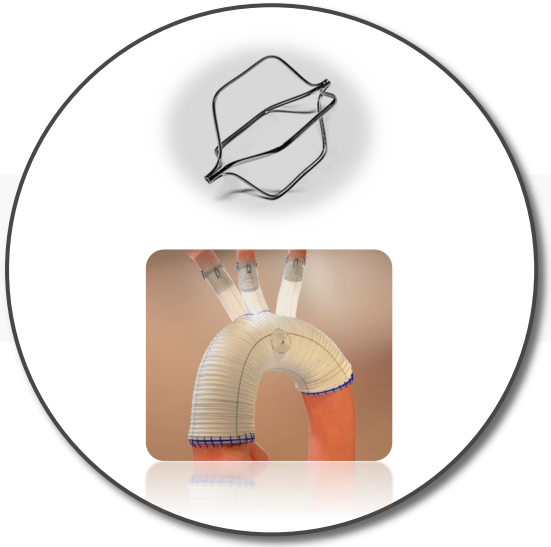
策略投資
M&A

=

逐步實現營收成長及營運綜效
Growth with scale benefits

medeologix

+



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新研發機會

可發揮綜效之製造技術

益安 2.0

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CDMO營收持續成長

2025 Q1營收較去年同期成長116%

Duett™產品開發專案時程規劃

2023/8
取得美國FDA核准
進行
第一階段樞紐試驗

2024/2
完成**首例臨床收案**

同步優化
產品設計

Now
第一階段樞紐試驗
已完成20例收案

Clinical Study Expansion Approved By US FDA

2025年
第二階段樞紐試驗/
申請Breakthrough Designation

- **地區: 美國5家醫學中心**
- **療效指標:**
  - ✓ **安全性:** 永久性術後中風、術後30天中風及再次手術
  - ✓ **有效性**: 吻合止血時間、血管通暢、無滲血

FDA已同意增加
收案15例

第二階段
預計2025年中核准

現正與授權夥伴、策略投資人洽談中

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THANK YOU