

**ASX RELEASE**

**Ellex Medical Lasers Limited (ASX:ELX)**

**Adelaide, Australia**

**Date: 6 January 2014**

**Release: Immediate**

**Topic: Ellex Completes Acquisition of the Canaloplasty Business of  
iScience Interventional Inc**



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**Adelaide, Australia, 6 January 2014** – Ellex Medical Lasers Limited (ASX:ELX), a pioneer in medical technologies for the diagnosis and treatment of eye disease, today announced that, pursuant to the binding agreement it entered into on 18 December 2013, it has acquired the canaloplasty business of US-based iScience Interventional, Inc., which comprises the world-leading iTRACK™ 250 catheter and suture device. .

According to Ellex CEO, Tom Spurling: “This acquisition is very exciting. The new canaloplasty business will augment our capital equipment sales business with a recurring consumable revenue stream. It will also allow us to provide our customers with a minimally invasive product offering for the treatment of mild-moderate glaucoma. We intend to support and grow this new product line.”

“Combined with our SLT laser product portfolio, which targets the early stage of glaucoma, iTrack™ will enable Ellex to cement its position as the global leader in early to moderate glaucoma treatment intervention,” added Mr. Spurling.

On 31 December 2013 (California time) Ellex paid US\$1.5 million in exchange for iScience Interventional’s canaloplasty business, including accounts receivable (approximately US\$0.5m) and inventory (approximately US\$0.5m). It also covers manufacturing machinery and equipment and intellectual property. Consideration for the purchase also includes an earn-out over several years based on a percentage of business revenues. Ellex has retained 6 permanent staff plus a small transition team, who will all commence with for Ellex on 6 January 2014. The business will continue to operate from Menlo Park, California.

Further details are provided in the accompanying presentation.

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**ABOUT ELLEX**

Ellex Medical Lasers Limited (ASX:ELX) is a pioneer in the development of medical technologies for the diagnosis and treatment of eye disease. With more than 20,000 systems delivered to the market, Ellex has evolved since 1985 from a manufacturing company of primarily OEM products, to direct marketing of its own branded products through subsidiaries in the United States, Japan, Germany and Australia, and a network of distribution partners in more than 100 countries. In recent years, Ellex has diversified its product range beyond lasers and ultrasound equipment to include distribution of a number of complementary third-party ophthalmic products.

For additional information about Ellex and its products, please visit [www.ellex.com](http://www.ellex.com).

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# Ellex Medical Lasers

## iScience Glaucoma Treatment Business Acquisition



6 January 2014



One Powerful Vision

Slide 1

# Ellex in a Snapshot

Australian ophthalmic device company with a robust existing business model selling ophthalmic products coupled with blue-sky potential

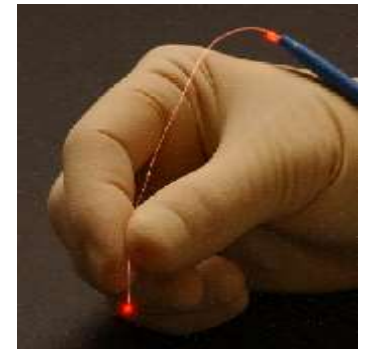
- Globally competitive, innovative player
- Leading supplier in a large, growing global market
- Ophthalmic laser market expected to grow at a **CAGR of 3.3%** from 2012-2017, drivers being
  - Ageing population
  - Advanced medical treatment in the developing world
  - New technology innovation
  - Lack of cost-effective drug treatments
- Potential for growth beyond FY14 from new products offering new and improved treatments for eye disease, geographic expansion and exploitation of device service and manufacturing capabilities and FX tailwinds YTD



# Deal Structure

- Ellex to acquire the glaucoma business of iScience Interventional, which specifically relates to an advanced, minimally invasive procedure called canaloplasty
- Asset purchase comprises a disposable microcatheter (iTRACK™ 250), associated instrumentation (iLumin, iUltrasound) used in the treatment of mild to moderate glaucoma and associated IP
- Consideration of US\$1.5m cash, funded by Equity
- Earn out over several years based on a percentage of revenues
- Ellex acquires approximately US\$1m in current receivables + inventory and P&E with a replacement value estimated at US\$0.5m
- Expected to deliver CY13 sales of approximately US\$4.0m
- EBITDA accretive from 12 months post acquisition onwards

**i**TRACK™ 250



# Strategic Rationale for the Acquisition

1. Ellex is a global leader in the supply of lasers for treatment of cataracts, retinal diseases and in particular glaucoma. Ellex has been looking for complementary products that have a recurring, non-capital equipment revenue stream.
2. Ellex Selective Laser Trabeculoplasty (SLT) laser for the treatment of glaucoma has a ~42% ex-US market share. SLT laser launch in the US since July 2013 has been very successful.
3. Glaucoma is a degenerative disease. Early-stage glaucoma is treated with an SLT laser. iTRACK™ 250 is for treatment of later stage glaucoma.
4. Ellex believes that the iScience canaloplasty product and procedure will broaden Ellex's offering to glaucoma practitioners.
5. The iScience canaloplasty business is a recurring revenue business – comprised of a disposable microcatheter (~US\$800 per unit) and associated instrumentation (light source, ultrasound).



# Features of Acquisition for Ellex

1. The iTRACK™ 250 is a single use , composite microcatheter designed to access and dilate key outflow structures in the eye. This is a recurring revenue business model which Ellex can deliver globally through our distribution channel to market.
2. The product is FDA approved – 2008, CE Mark (Europe)
3. The product has a top tier, unique category 1 reimbursement code in the US – CPT I
4. The product has Medicare Reimbursement and 3 out of 6 Major Private Payors Covering
5. The product is patent protected for approximately 10 years across all major jurisdictions
6. In addition to regulatory approval in all major territories (excluding Japan), the product has unexploited approvals in China and Brazil.
7. The business is a manageable size for integration into Ellex's US business.



# Canaloplasty Business & iScience

1. iScience Interventional is owned by a group of high quality US based venture capitalists including Affinity Ventures, CHV Capital, Clarion, Three Arch and Sightline Partners
2. iScience has also attracted several strategic investors, including Medtronic and J&J
3. The canaloplasty business has been operating for about 3 to 4 years and has revenues currently of ~US\$4.0m per annum
4. In the US there is a core user group of ~170 glaucoma specialists out of a potential population of ~1,700 ophthalmologists that specialise in glaucoma treatment in the US
5. The device confers significant advantages to traditional trabeculectomy surgery, and can be used in conjunction with existing laser and drug based regimens
6. Excellent website resource; <http://www.canaloplasty.com>

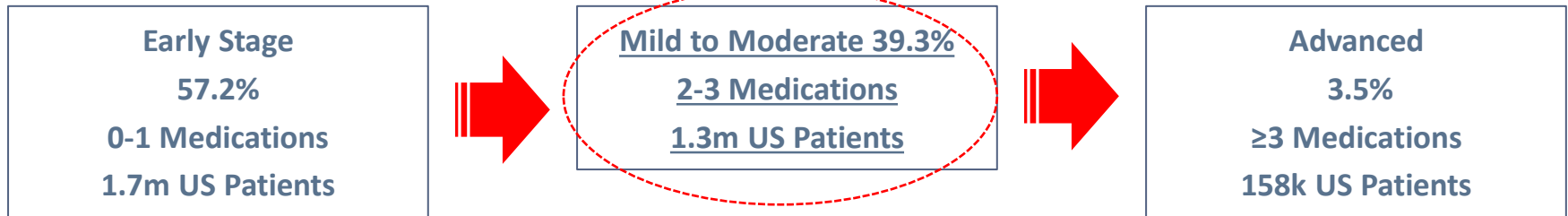




# Glaucoma Treatment Spectrum

- With the iScience Asset Acquisition, Ellex will cement its position as the global leader in early to moderate glaucoma interventions, representing **3.0m** US glaucoma patients
- Glaucoma market expected to show CAGR of **2.8%** to 2017, driven by ageing patient demographics

## Percentage of Glaucoma Patients by Number of Medications\*



## Treatment Options



\* Source: Market Scope 2011



# Category I Reimbursement - USA

- Medicare CPT Category I Reimbursement Code approved effective January 2011
- Category I Codes are approved by Centers for Medicare & Medicaid Services (CMS) and the American Medical Association (AMA) for procedures that are consistent with contemporary medical practice and are widely performed. Broad private insurer coverage established nationwide
- Favorable provider economic profile 2013:

Procedure	Medicare Facility Fee Hospital	Medicare Facility Fee ASC	Medicare Surgeon Fee
Cataract Surgery	\$ 1,672	\$ 964	\$ 761
Canaloplasty	\$ 2,978	\$1,671	\$ 1,128
PhacoCanaloplasty (Combined cataract and canaloplasty procedure)	\$ 3,814	\$ 2,153	\$ 1,508

## US national averages

- In Germany, the average payment is **Euro 3,000** and coded DRG C06Z – placing it in the highest reimbursement category



# Development of Canaloplasty

2013

As of Oct. 15 2012

Journal Publications: - 51  
 Textbook Citations: - 17  
 Scientific Presentations & Posters: - 161  
 Trade Press Articles - 153  
 Online Surgical Videos - 37

TODAY: 28,000  
 Procedures and  
 Continuing

iScience Surgical  
 Incorporated

Cadaver Research Started  
 for Enhanced  
 Viscocanalostomy

Canaloplasty with  
 Suture Tension

iTRACK™  
 Microcatheter  
 Development

First Patient 360  
 Visco-Dilation  
 (Canaloplasty)

15,000<sup>th</sup> CP  
 Procedure

10,000<sup>th</sup> CP  
 Procedure

24,000<sup>th</sup> CP  
 Procedure

3-Year  
 Canaloplasty  
 Clinical Data  
 Published

iUltraSound  
 Development

International Multi-  
 Center Clinical Trial  
 of Canaloplasty  
 Initiated

iTRACK™ International  
 Commercialization

Canaloplasty is Considered  
 Standard of Care in USA –  
 Awarded Category 1  
 Reimbursement code

iTRACK™ USA  
 Commercialization

Canaloplasty Defined

360 Degree Viscodilation of  
 TM, SC, CC



One Powerful Vision

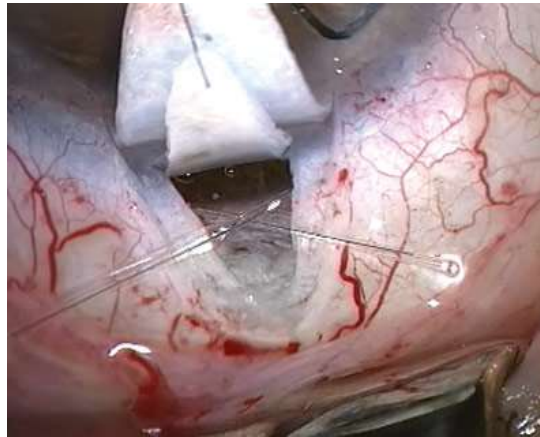
Slide 9

# Canaloplasty Procedure

**Step 1** – scleral flaps cut to expose Schlemm’s canal



**Step 2** – catheter routed through canal



**Step 3** – suture attached & catheter removed.



**Short overall procedure time of 10 to 25 minutes**

**Step 4** – suture tied and flaps closed.

Confidential



One Powerful Vision  
Slide 10

# Study Review: Canaloplasty. Trabeculectomy

## Retrospective Comparisons of Canaloplasty to Trabeculectomy

Study	Canaloplasty					Trabeculectomy				
	N	Baseline IOP mm Hg ± SD	12M IOP mm Hg ± SD	Baseline Meds #	12M Meds #	N	Baseline IOP mm Hg ± SD	12M IOP mm Hg ± SD	Baseline Meds #	12M Meds #
Ayyala, et al <sup>1</sup>	33	21.2 ± 6.6	13.8 ± 4.9	2.5 ± 0.8	0.6 ± 0.9	46	23.4 ± 10.4	11.6 ± 4.0	2.6 ± 0.6	0.3 ± 0.7
Ahmed, et al <sup>2</sup>	50	26.4 ± 6.5	13.4 ± 2.7	3.6 ± 0.9	0.6 ± 1.1	48	26.8 ± 8.1	12.3 ± 3.5	3.6 ± 1.1	0.7 ± 1.3
Reynolds, et al <sup>3</sup> Multicenter	116	25.5 ± 6.2	15.5 ± 5.1	3.1 ± 1.1	1.0 ± 1.2	102	26.2 ± 7.5	13.5 ± 5.5	3.2 ± 1.1	0.9 ± 1.3

IOP = intraocular pressure  
SD = standard deviation

**Data highlights canaloplasty is effective in lowering intraocular pressure (IOP) vs. major surgery & reduces requirement for ongoing medications**

1. Ayyala RS, Chaudhry AL, Okogbaa CB, Zurakowski D. Comparison of surgical outcomes between canaloplasty and trabeculectomy at 12 months' follow-up. *Ophthalmology*. 2011 Dec;118(12):2427-33.
2. Ahmed I, Tam D. Poster, American Society of Cataract and Refractive Surgery, Annual Meeting April 2010
3. Reynolds A, et al. A Multicenter Retrospective Case Series Comparing Outcomes of Canaloplasty and Trabeculectomy, Manuscript in preparation for submission.

# Study Review: Canaloplasty. Trabeculectomy. Tube Shunts: Serious Complication Rates

	Canaloplasty N = 157 (Multi-Centre Trial) <sup>1</sup>	Trabeculectomy N = 107 (TvT) <sup>2</sup>	Tube Shunts N = 105 (TvT) <sup>2</sup>
Reoperation for Complications	5 (3.2%)	9 (9%)	15 (14%)
Vision Loss of ≥ 2 Snellen lines	0 (0%)	23 (22%)	17 (16%)
Total number of patients with serious complications	1 (0.6%)	28 (27%)	24 (22%)

## Confers Major Safety Benefits Over and Above Similar IOP Lowering Effects

1. Canaloplasty: Three Year Results of Circumferential Viscodilation and Tensioning of Schlemm's Canal Using a Microcatheter for the Treatment of Open Angle Glaucoma. Lewis RA, von Wolff K, Tetz M, Koerber N, Kearney JR, Shingleton BJ, Samuelson TW. *J Cataract Refract Surg*. 2011 Apr;37(4):682-90
2. Gedde, SJ et al Review of the results from the Tube vs. Trabeculectomy Study *Current Opinion in Ophthalmology* 2010, 21:123-128



# Competitive Products

Company	Product	Comments
<b>DORC</b>	<b>Glaucolight</b>	<ul style="list-style-type: none"> <li>• Competitive product to iTRACK™ 250 (but unable to dilate outflow structures of the eye ).</li> <li>• Not available in US (due to issued iScience patent).</li> <li>• Europe – making sales (iScience patent pending)</li> <li>• No long term data on effectiveness</li> </ul>
<b>Glaukos</b>	<b>iStent</b>	<ul style="list-style-type: none"> <li>• Used to treat glaucoma in conjunction with cataract surgery</li> <li>• Key competition in US market</li> <li>• Inferior reimbursement code – CPT 3 (canaloplasty – CPT 1)</li> <li>• Cannot leverage off iScience code</li> <li>• Very limited reimbursement available</li> </ul>
<b>Various</b>	<b>Tube/shunt</b>	<ul style="list-style-type: none"> <li>• An alternative for when trabeculectomy has failed (or will most likely fail).</li> </ul>



# Significant Operating Synergies

- **Channel Benefits** – Ellex has an existing US Sales/Marketing force of 12 persons.
- **Major Cross Selling Opportunities** – High % of iScience glaucoma specialists and those of Ellex are not necessarily users of both products.
- **Multiple Product Offering in Glaucoma** – Ellex now able to offer products that treat two fully accepted, standard of care approaches in glaucoma.
- **Highly motivated US Sales Force** – Post SLT Glaucoma launch in July, sales demand has been very strong.
- **Majority of EU sales in Germany** – Sales are via a distributor. Ellex has ability to drive sales in other EMEA jurisdictions.
- **New Market Approvals in Japan** – Ellex maintains a direct sales force in Japan and may seek regulatory approval for iTRACK™ 250 in due course.





# Integration Plan

- As of the date of acquisition business will trade as “Ellex iScience Inc”
- FDA-approved production facility at Menlo Park in the Bay Area of San Francisco will remain the site for iTRACK™ 250 production
- Existing production and sales and marketing staff have become employees of Ellex
- Expansion of canaloplasty clinical training team to commence immediately
- Existing management team of iScience to assist with transition and to ensure existing customers are kept informed and not negatively impacted by the change of ownership
- Experienced Ellex Group Manager appointed to take responsibility for transition and integration



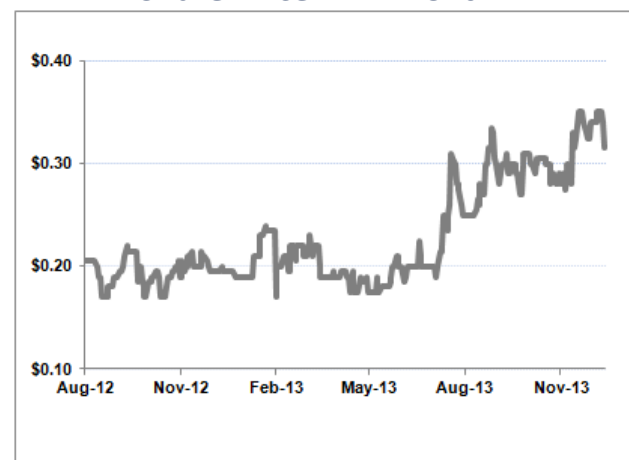
# Market and Financial Summary

Summary Financials			
Period	FY12A	FY13A	Change (%)
Revenue (\$m)	47.5	42.8	-9.9%
EBITDA (\$m)	3.1	1.7	-45.2%
EBIT (\$m)	1.5	0.4	-73.3%
<b>Reported NPAT (\$m)</b>	<b>0.9</b>	<b>(0.8)</b>	n/a
EPS (c)	1.1	(1.0)	n/a
<b>PER (x)</b>	<b>28.1</b>	<b>n/a</b>	
<b>EV/Sales (x)</b>	<b>0.7</b>	<b>0.8</b>	
<b>EV/EBITDA (x)</b>	<b>9.5</b>	<b>17.6</b>	
OCF (\$m)	1.8	1.9	5.6%
NTA Per Share (c)	19.8	17.3	-12.6%
<b>ROE (%)</b>	<b>2.9</b>	<b>(2.6)</b>	

Share Register	
Australian Ethical	10.1%
Top 20	45.3%
Directors	21.4%
Ave. Mthly Volume (m)	1.6

Market Summary	
Shares on Issue	97.6m
Share Price @ Dec 13	\$0.32
12 month Range	\$0.17-\$0.36
<b>Market Cap</b>	<b>\$30.7m</b>
Net Debt @ 30/6/13	\$6.6m
<b>Gearing (D/D+E)</b>	<b>19%</b>
<b>EV</b>	<b>\$37.3m</b>

Share Price – 12 month



END

