CustomVis plc

AIM – Health **Recent Price 11.5p** **Market Cap. £4.0m**

LVC an evolving discipline

CustomVis was established in March 2001 in Australia to address a number of problems being experienced in the field of laser vision correction (LVC). Refractive surgery has been evolving for some time and advances in LASIK surgery have established its reputation for treating both standard and irregular vision disorders with excellent results and few complications.

…in which CustomVis is a technology leader

CustomVis claims that its laser system, the Pulzar Z1, has several advantages over other systems still using excimer (gas) laser technology which may be at the end of its product development and life cycle. The Pulzar Z1 is a solid state laser which provides greater reliability, lower maintenance costs, no usage of toxic gases, and combines state of the art eye scanning ('wavefront') and tracking technologies. The latter are indispensable for customised treatments. The CustomVis system thus enables ophthalmic surgeons to take on cases not susceptible to standard LASIK and potentially to charge higher fees.

…able to cater to large and growing LVC markets

The Company has access to large and growing markets for LVC through having Australia's TGA approval, which is mutually recognised in the European Community. This enables its product to be distributed in Australasia, the EC, Asia Pacific regions and Latin America. The worldwide market for LVC, based on numbers treated and typical procedure costs, is estimated to be c.US$4bn.

…with a number of systems already in place

Pulzar Z1 systems are currently installed (though not sold) in Columbia, Germany, Norway, the Middle East, Spain and its home city of Perth, Australia. CustomVis has recently sold one system in Korea, and has reasonable prospects of two further sales before the end of June, including converting at least one of the installed trial lasers into sales. The Company has three more saleable units in stock and three more being completed.

The Company' present focus is on cash conservation through accelerating sales, and actions to cut costs and thus its cash burn. With good results from clinical trials and one sale already achieved, the momentum is building.

Y/e June (Figs in £)	Turnover	Operating Loss	Loss before tax	Loss per share (p)	Div (p)
2003	2,848	(665,377)	(657,609)	(7.6)	-
2004	8,851	(4,352,324)	(4,010,932)	(11.6)	-
2005E	n.a.	n.a.	n.a.	n.a.	
2006E*	n.a.	n.a.	n.a.	n.a.	
** No forecasts available*					
Net Assets (31/12/04)		£5.5m	Net cash (31/12/04)		£3.5m
No. of shares in issue		34.7m	NAV (31/12/04)		16.0p

This research may be viewed on **www.cityinsights.co.uk** Tony Cooper Apr 2005

Introduction

Origins only in 2001

CustomVis plc has its origins in a small Australian company, CLVR Pty. Ltd., which was founded by Dr. Paul van Saarloos in Perth in March 2001. Management of CLVR (whose initial letters stand for Customised Laser Vision Research) was expanded significantly and CustomVis, the name under which CLVR traded, was incorporated as the holding company, in December 2002 in England. This was with a view to a subsequent listing on AIM.

CLVR, the CustomVis forerunner, pioneered ocular laser surgery in Australia

In September 2002, the CustomVis system gained considerable benefit from the positive results of clinical trials at Laser Sight Centres in Australia, the largest laser vision correction (LVC) clinic in the sub-continent. While limited in terms of numbers, these trials involved patients suffering from what had previously been considered untreatable visual disorders or irregular astigmatisms. Following the conclusion of these trials, the system developed by CLVR was approved for use by Therapeutic Goods Administration (TGA), Australia's regulatory authority for drugs and medical devices. This enjoys mutual recognition with the regulatory authorities in European Community, and thus the CustomVis system also gained the latter's CE (Conformité Européene, or 'European Conformity') mark. This certifies that the manufacturer of the product is in compliance with the general safety regulations in the CE marking directives. (CE marking is mandatory in the EC).

CustomVis system able to be widely marketed

These certifications allowed for the immediate distribution of the CustomVis system not only into the whole of Australasia but also into the UK, the EC, the Asia Pacific region and Latin America. Interest in the system thus spread and enabled ophthalmic surgeons in various countries to place orders. Approvals are being sought in other areas, notably China (a twelve to eighteen months process). USA approval will not be sought until sufficient market penetration has been achieved and the Company is cash flow positive, allowing the whole procedure to be funded internally or through a specific fund raising.

Admission to AIM in July 2003 with an institutional placing

While the clinical trials were still ongoing during 2002, CLVR completed its first round of fund raising, totalling AUS$760,000 (£305,220), mainly supported by Custom Lasers, Inc, a US based biotechnology investment group of ophthalmologists and ophthalmic distributors. A further fund raising in 2003 generated AUS$1.55m (£662,489) from private investors for the Company. In April of that year, the whole issued share capital of CLVR was acquired by CustomVis for shares, which then achieved an AIM listing in July 2003 accompanied by an institutional share placing raising £11.5m before costs (12.64m shares were issued at a placing price of 91p) and £10.6m after. These funds were earmarked primarily to scale up the Company's production, sales and service networks; to pay for clinical trials; and to raise working capital for everyday needs, including R&D on upgrades of the laser system. In addition, £1.34m was received by a single investor in consideration for the issue of loan notes. Further funds totalling AUD$527,000 (£212,000) have been provided by the Australian Federal Government in the form of grants under various heads.

Substantial investment to date

From the above, over £13m has been invested in the CustomVis system, although that is a significant understatement. The figure ignores the substantial private investments made previously totalling over A$10m.

The opportunity

Six CustomVis laser systems are installed for use

CustomVis is a technology leader in refractive laser surgery for non-standard or irregular eye disorders, and the Directors believe that its high specification technology, notably in the use of topography and wavefront 3-D eye-mapping, confers a significant comparative advantage compared with many of its competitors' products. CustomVis' production, sales and service capabilities are now established and the first five lasers, which are badged Pulzar Z1 with accompanying system components, were delivered before the last year end at 30th June. These are installed in Columbia, Germany, Korea, Saudi Arabia and Spain; (a new site for trials is being sought in the latter). There is also one in CustomVis' home city of Perth. The lasers installed in Columbia, Germany, Norway and Perth, which are available for sale, are being used for the collection of clinical data and feedback on the surgical process which, by providing assurance on efficacy and quality, should encourage sales.

…of which one has now been sold

The first CustomVis laser sale, to a Korean buyer, was concluded at the end of February 2005, and the Company has signed distributor agreements for Korea, the Middle East and Turkey. Other distribution agreements, embodied in various 'Memorandum of Understanding' (i.e. legal documents setting out general descriptions of the responsibilities assumed by the parties to the agreement) are in place for China, Germany, India and Indonesia. These agreements should lead to sales in the next few years. These developments and the latest Interim financial results are discussed later.

The market

LVC gaining acceptance and popularity

Vision disorders are generally classified as myopia (shortsightedness), hypermetropia - or hyperopia, the US designation - (longsightness), and astigmatism (image distortion due to abnormal curvature of the cornea). The incidence of these disorders is increasing (environmental and work based factors), and with it the potential for laser vision

corrective (LVC) surgery as an alternative to wearing glasses or contact lens. LVC has also gained acceptance and popularity as complications affecting vision after surgery are reported at a rate of less than one per cent, while there is a lesser risk of infection than wearing contact lenses.

Variable means of payment for laser systems

CustomVis aims to supply its system to users around the world where it has gained, or is seeking, approvals. Each machine it supplies can be bought, or leased, by specialist regional or national eye centres and clinics for corrective laser surgery. CustomVis will consider payment for lasers in any one of three ways, or a mix or all three - full cash up front; deposit plus per procedure fee, i.e. pay per treatment (with minimum payment per month), or full per procedure fee (with minimum payment per month). From the point of view of the purchaser of a laser system, he would expect to recoup his costs by charging a fee, of varying size, depending on the type of surgery performed and the amount of any after-treatment provided. The surgery procedure fees charged by the clinic to the patient will in turn take account of any royalty payable to the laser manufacturer for its use if the equipment has not been bought outright.

Patients pay more for custom LASIK

Some US data revealed that the overall average price to the patient for LASIK laser eye surgery (which we describe in detail later) had risen to over $1,710 in October 2003 for a complete treatment. More recent information from a January 2004 issue of the Wall Street Journal indicated that the price per eye for LASIK custom surgery, for more complex disorders requiring customised treatment and wavefront mapping, added $100 - $400 to the cost of conventional LASIK, which was stated to run from $500 to $2,500 per eye. More recently, TLC Laser Eye Centers in the US claimed an increase of over $400 per eye for non-standard procedures.

A predicted 1.35m LASIK procedures in the US in 2004

Based on published information on typical prices for surgical procedures and estimates of the number carried out in a year, it is possible to arrive at the size of the global market or, more accurately, that part of it for which this information is available. Thus in the US, the 15th October 2004 issue of the Review of Optometry predicted about 1.35m total LASIK procedures would be performed in the US by the year end, up from 1.15m in 2003. Information is generally not so readily available in other less well developed parts of the world.

US market opportunity with 5% LVC penetration

Some estimates have nevertheless been attempted of the total size of the LVC market and the extent of its penetration. The worldwide LVC market in 2004 in terms of annual procedure revenues has been estimated at some US$4bn (£2.4bn) of which the US accounts for about a half (e.g. 1.35m x $1,500 per each LASIK treatment totalling US$2bn approximately). The US has a relatively high penetration of five per cent for LVC eye treatments and this is one of the attractions to CustomVis which will seek FDA approval for its laser system.

Some Asian markets offer high potential

Outside the US, LVC penetration is much lower and, for the world as a whole, probably less than two per cent of myopia-afflicted individuals have received such treatment. Nevertheless, there are the more complex disorders requiring custom surgery, a largely untapped market to date which is estimated to account for between ten and twenty per

cent of the US$4bn worldwide LVC market, i.e. in the range US$400m – US$800m. This is the segment of particular interest to CustomVis, because its high grade Pulzar Z1 lasers are especially designed to provide customised treatment for the non-standard cases.

US is a large but competitive market

In terms of size, the largest regional markets for LVC are in North and South America, but access here may be constrained by both regulatory and competitive factors. In the US, FDA approval of the procedure came in 1995 after ten years of clinical trials, although not for all cases and no companies have yet been granted approval for custom surgery in irregular astigmatism. At the same time, with LVC very well established in that market, the market has become more competitive with a number of national and regional eye centres offering it. In consequence, several laser manufacturers have designed systems to cater for the market, such as Bausch & Lomb (Zypotix system), Alcon Laboratories (LADAR Vision), Advanced Medical Optics, formerly VISX, (Star S4 Active Trak) and the German WaveLight Technologie AG (Wavelight Allegretto Wave) and it appears that certain brand names are now recognised. In such conditions, it may be harder for CustomVis to break into the market, even with a high quality product.

Faster growth in Asia Pacific region

LVC continues to grow steadily in both Western and Eastern Europe and penetration is high in certain countries of Asia, such as Korea. CustomVis is vitally interested in targeting its lasers at those countries with large potential markets likely to show steady growth, such as Korea, China and India. The Company has stated its intention of advancing the approval process in China and will ship a laser to that country for their final trial.

…much weaker in poor countries

In the poorer countries of South America, Africa and elsewhere, the market for LVC is probably limited to a very small, wealthier segment of the population. At the same time, under-capitalised ophthalmologists are less likely to be able or willing to buy a laser probably costing over US$200,000, although other purchase options are an alternative to outright purchase in such markets including, as mentioned above, an initial deposit plus per procedure fee or simply on the basis of procedure fees.

CustomVis offers low mainten-ance and flexible scheduling

In brief, the opportunity for CustomVis is to sell its high end laser system into a growing but increasingly competitive market; and enabling the prospective purchaser to offer customised surgery at, say, the equivalent of $2,000 a time on average using the equipment at maximum intensity, or days per year. Importantly, the CustomVis system with its lower maintenance requirements and greater flexibility in terms of treatment scheduling, is superior to existing gas based laser treatments. This arises from the fact that surgeries can be carried out on any day at any time with limited pre-operation procedures. Gas based systems due to extended preparation (twenty- thirty minutes gas warm up time) require ‘block’ bookings of surgeries which limit flexibility for the surgeon and the patient alike. CustomVis, by contrast, is much more flexible whether it is dealing with low volume, complicated high value treatments or the high volume, basic treatment cases.

Laser surgery for corrective vision disorders - a brief summary

RK is used for low level disorders

Refractive surgery to correct vision disorders has been evolving since the 1940s. Earlier treatment did not involve laser surgery. The method known as radial keratotomy, RK in brief, corrects vision defects by the surgical process of making a series of radial incisions on the cornea radiating from the centre, but not touching the central optical zone. Therefore only low degrees of myopia and astigmatism (distortion) are achievable using this technique.

PRK used lasers

More advanced than RK is photorefractive keratectomy (PRK), a process that uses a very precise laser to correct more serious vision disorders by removing corneal tissue effectively to sculpt a permanent contact lens into the eye. This is not painless and the cornea takes time to heal, during which vision is blurred.

LASIK is an advanced and fast growing type of ocular surgery

From the above evolved the technique known as LASIK (laser in situ keratomileusis), now widely used for both standard and the more severe vision disorders. LASIK, one of the fastest growing types of ocular surgery today, uses an excimer (gas) laser to remove very tiny but predetermined amounts (1/500th of the thickness of a human hair) of the *underlying tissue* from the cornea, while not touching the sensitive outer surface of the cornea. The surgeon is able to do this by cutting a circular flap from the top corneal layer which is lifted and folded out of the way until the predetermined amount of underlying tissue has been removed by the laser. Once that is done, the flap is lowered back to its original position and stays in place without requiring stitching due to the pressure within the cornea. The tissue removal alters the curvature of the cornea thus correcting the defect. LASIK is much less painful and heals more quickly than PRK.

LASEK for special cases

LASEK (laser epithelial keratomileusis) is a relatively new procedure that is technically a variation of PRK. Also known as epi-LASIK or E-LASIK, LASEK is used mostly for people with corneas that are too thin for LASIK, or to reduce the chance of complications that may occur. The surgeon covers the eye with an alcohol solution to loosen the edges of the epithelium before lifting the epithelium flap and folding it back out of the way. A laser is then used, as in LASIK or PRK, to sculpt the corneal tissue underneath before replacing the flap back on the cornea in the same way as in the LASIK procedure.

Custom LASIK not yet able to treat presbyopia

Like conventional LASIK, custom LASIK will not cure all vision-related problems but research is ongoing into the latter's use in creating multi-focal corrections, enabling older people whose eyes have developed presbyopia, to see objects at near, middle and long distances at the same time. Presbyopia manifests itself in the eye's inability to focus on and read material at the usual distance of one foot from the eye.

…using narrow, rotating beams

In earlier LASIK surgery, a feature of the laser equipment, apart from its lesser reliability, was that it used a wide beam, a disadvantage in that the laser could not sculpt the cornea to any reasonable resolution. Attention was given to designing lasers with more defined beams, which can also be controlled by tracking sensors to stay in contact with just one small area of the cornea. Earlier types of 'flying spot' excimer lasers, developed by different manufacturers, had beams of 1 – 2mm

and were able to move around the treatment area. This enabled the fragments of discarded tissue to be removed from one spot before the beam arrived again. This, in conjunction with the laser's controlled pulse rate, produced a smoother corneal shape and increased the efficacy of the surgery.

The CustomVis system

CustomVis overcomes limitations in existing gas-based laser systems

Custom LASIK is claimed to be the next generation in laser eye surgery and CustomVis believes that its system represents a step change in technology for laser vision correction in that it can overcome limitations in the existing gas-based laser technology. First, some ten to fifteen per cent of the total eye patient population have vision disorders which are untreatable; secondly, ten per cent of patients require retreatment because the first treatment was not accurate enough, and thirdly, a sizeable proportion of those who received treatment could have achieved a better result. CustomVis also claims that its system can repair eyes damaged by previous eye laser surgery. The CustomVis patented Pulzar Z1 laser can be used for LASEK and PRK treatments. The software allows the surgeon to select the preferred treatment type for each eye surgery.

Pulzar Z1 solid state laser embodies key advances in technology

The Pulzar Z1 laser combines the following key features: solid state technology, a fast pulse rate (300-400Hz), small spot size (0.6mm beam) and innovative tracking and scanning systems. We take each in turn to explain the importance of each component. First, solid state technology, which has no moving parts, delivers a more reliable performance and does not use toxic gases for cooling. A fast pulse rate (300-400 Hz compares with an average for the industry of <100Hz) is required to deliver the desired spot size in an acceptable treatment time. A spot size of only 0.6mm (compared with a typical industry figure of 1mm or more) gives greater precision on the surface of the eye. A laser beam profile and longer wavelength of 213nm (industry standard 193nm) is more reliable, and less affected by moisture and humidity.

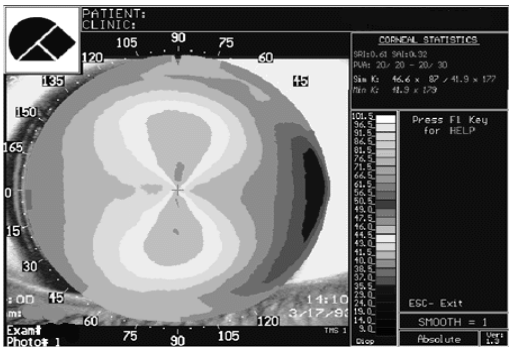
…as do other parts of the system

The laser is only one part of the CustomVis system containing key advances in technology. There are many other advances of which scanning and tracking are of the utmost importance to the success of the procedure. A patented high speed scanner (Crystal Scan) adjusts the position of the laser beam to compensate for the movement of the eye and in this, CustomVis claims to have a system which is ten times faster than the industry norm. ZTRACK^{TM}, a fast tracking closed loop response system (one thousand samples per second), senses the position of the eye and adjusts the position of the laser beam for more accurate ablation. Other companies' eye trackers assume the patient is looking at the fixed target and return false data if he/she is not. CustomVis has developed an extra tracker to ensure the patient is looking in the direction of the fixed target. The system thus ensures that the laser beam is directed to the precise area of the cornea in the event of a movement in the eye during the procedure.

Wavefront technology is the key to customised treatment

Of greatest importance for successful surgery is the initial diagnosis and plan, particularly for the more complex cases, and this is one of the key features that distinguishes CustomVis from its rivals. Custom LASIK surgery (from which the CustomVis name emerged) starts from a 3-D topographical mapping of how the eye processes images to guide the laser in re-shaping the front part of the eye know as the cornea. This system, called wavefront, enables an extremely precise, individualised vision correction outcome to be achieved which would be impossible with traditional LASIK surgery, glasses or contact lenses.

ZCAD™ is software to generate unique treatment plans



CustomVis' ZCAD™ is special treatment planning software that amalgamates wavefront corneal topography to obtain images and measurements of the whole eye, including undulations in the corneal surface, pupil size and dilation, plus any refractive abnormalities. (The image to the right shows a case of corneal astigmatism). ZCAD™ is thus an advanced surgical diagnostic process to generate the information required prior to customised surgery. Once obtained, the data, stored on a CDROM disc, is able to generate a unique treatment plan for the patient.

iTrace Visual Function Analysers now to be incorporated

A more recent development has linked CustomVis with Tracey Technologies, a company in the forefront of developing wavefront devices for measuring the refractive power of the eye. Its patented iTrace system is an advance on other wavefront systems in being able to assess complete visual function using the thin beam principle of optical ray tracing, a first in eye care diagnostics. It measures both lower and higher order aberrations with greater accuracy, speed and range than achieved using conventional refractive techniques. A number of surgeons have thus expressed a preference for integrating iTrace 'visual function analysers' into the CustomVis system, and CustomVis has, this March, finalised a purchase agreement with Tracey (five units initially) for the supply of customised dedicated product. The first Laser machines incorporating Tracey's wavefont devices have already been despatched.

Following on, CustomVis and Tracey will jointly develop a topographical interface and upgraded imaging system, which is expected to be available for roll-out in the second quarter of 2005.

CustomVis' – the surgical procedure

In practice, the CustomVis procedure involves the following stages:

1. The ophthalmologist provides the computer with information on the patient's eye (a standard procedure) or, in the case of customised treatments, the data is obtained from the ZCAD™ software and loaded up from a CDROM disc.

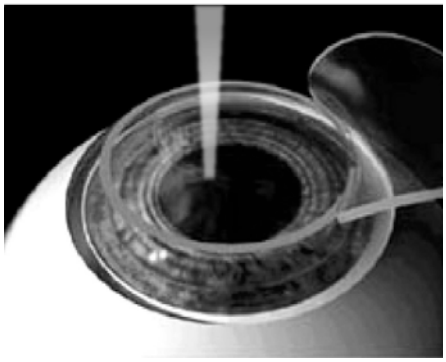
2. The patient is prepared for surgery using one of the three procedures outlined, PRK, LASIK or LASEK.

3. The eye-tracking equipment, ZTRACK™ (the fast eye tracker) locks on to the eye, and the ablation begins, the laser being fully integrated with the tracking and scanning systems.

Surgery continues until the surgeon has completed the surgery plan. The surgeon can pause or stop the procedure if required.

Patient benefits are considerable

In general, LASIK (and LASEK) surgery is fast. The actual laser treatment can be as little as thirty to ninety seconds, while the entire procedure, including the rolling back and repositioning of the flap, typically takes about ten minutes for each eye. The procedures are now considered relatively low risk, the results are almost immediate, and there is relatively little discomfort during recovery for the patient.



…while higher levels of improvement are achievable

The critical question is how much correction can be achieved with LASIK. Vision improvement is measured in diopters, a unit for measuring the refractive power of a lens. Thus one diopter is the power of a lens that brings parallel rays of light to a focal point one metre from a lens after passing through it. LASIK can now typically achieve –12 diopters of myopia, +4 to +6 diopters of hypermetropia, and -3 to -5 diopters of astigmatism. These average results actually depend on the type of laser used and the thickness of the corneal tissue.

Results are from clinical trials

A summary of results from different systems of laser surgery is available from the organisations charged with approving the systems, such as the FDA in the US. The results are from available patient data provided from clinical follow-ups extending over periods varying usually up to three years, and sometimes FDA approval is given on condition that data continues to be collected.

Patients' visual acuity

Illustrative results are usually given as the percentage of those treated achieving different levels of 'visual acuity'. While this is usually measured by how much a person can see (using the standard eye chart), it also refers to how well he/she can see in terms of contrast sensitivity and fine detail. 20/20 is normal eyesight, the top number being the distance a reader stands from the chart, usually 20 feet, and

the bottom number the distance at which a person with normal eyesight can correctly read the line with the smallest letters. 20/40 means that the line you can correctly read at 20 feet can be read by a person with normal vision at 40 feet, and is the value required to obtain a driver's license in the without a corrective lenses restriction.

…is usually much improved with few compli-cations

Some laser systems claim that over ninety per cent of their patients achieve 20/40 vision after LASIK surgery and, for some systems, a percentage nearly as high achieving 20/20. Moreover, only in a very small percentage of cases are there vision complications, e.g. night vision difficulties, glare, halos around lights or simply under- or over-correction compared with the pre-operative condition.

CustomVis claims good results

For CustomVis, the number of patients treated has risen and, at the time of the 2004 Annual Report, ninety surgical operations had been carried out around the world. At the same time, the Report noted, the available clinical data on the CustomVis systems installed in Columbia and Norway were good (though not formally announced), and already able to match those of competitors' products. Clinical data from CustomVis' laser system in Germany, while limited to date in terms of numbers and the time period after surgery, are also claimed to be encouraging.

Recent developments at CustomVis

Ninety surgical operations to date

While the technology is highly developed and acclaimed, CustomVis admitted in its Annual Report for 2004 that, while it had 'delivered' (not sold) five lasers in the year to 30th June, it had been able to scale up production as rapidly as expected. The Company had no proven commercial scale manufacturing capability and has produced mainly prototypes for testing. This has resulted in a fairly slow gathering of clinical data and surgical feedback, thus rendering it more difficult to convert the interest of ophthalmologists and surgeons into firm orders and sales.

The Financials - manufacturing and sales

Attention is now keenly focused on sales

In the past year, attention has moved from production to sales as the major constraint has become the availability of cash. No units were in fact sold in the last financial year and none in the first half of the current year. One cash sale has recently been made to a buyer in Korea and a second laser is expected to be delivered to this country in April or May. The lasers currently out on trial in Columbia, Germany, Norway and Saudi Arabia are also potential sales, and there is some expectation that the latter unit will be purchased at the end of the current trial period. The same situation could apply to the one in Germany, which is being used for a formal ethical trial, and the initial results for which are expected in the second quarter of 2005. Potentially, therefore, a possible total of three units could be sold within the current financial year ending in June. CustomVis is also in an advanced stage of negotiation for the delivery of four more lasers to sites in Europe, South America and Asia during the period to 30th June 2005, following which trials these may also result in actual sales.

…which will assist cash flow

CustomVis has three lasers in stock essentially complete and has another three nearing completion of the build-out process. These would all be available for shipping to interested parties during 2005. This suggests that it is less a problem of availability of machines at present, and more one of getting customers to buy them. As sales are achieved, stock will be replaced. The annual rate of sales given the current production facilities is probably about three per month which, with each unit selling for between £125,000 and £150,000 at current prices, annual revenues would be up to £5m. This is on the basis of the currently produced standard models and ignoring any upgrades on which CustomVis has been working. With a regular sales flow, cash flow should be greatly improved, and the Company expects to become cash positive in operational terms in 2006.

Interim results for the half year to 31st December 2004

Profit and loss account				
Year end 30th June		2003/4		2004/5
Figures in £	H1	H2	Year	H1
Turnover and gross profit	1,589	(7,262)	8,851	11,704
Admin expenses	(1,452,400)	(2,968,128)	(4,420,528)	(2,170,636)
Other operating income	-	59,353	59,353	-
Operating loss	**(1,450,811)**	**(2,901,513)**	**(4,352,324)**	**(2,158,932)**
Interest receivable	289,201	52,191	341,392	105,163
Pre-tax Loss	**(1,161,610)**	**(2,849,322)**	**(4,010,932)**	**(2,053,769)**
Tax	(7,610)	7,610	-	-
Loss after tax tr'sf'r to reserves	(1,169,220)	(2,841,712)	(4,010,932)	(2,053,769)
Loss per share basic	(3.5p)	(8.1p)	(11.6p)	(5.9p)

Cash reduction is the main feature of the balance sheet

First half results for the six months ended 31st December showed an operating loss of £2.2m (£1.5m) and a loss after tax of £2.1m (£1.2m). The loss per share thus increased from 3.5p to 5.9p. The major factors were an increase in activity, such as key project laser upgrading work, in conjunction with a delay in achieving sales. The effect of this has been a progressive deterioration in the balance sheet, particularly on the cash position, net assets having reduced to £5.5m (against £10.4m a year ago) and cash funds to £3.5m (£10.2m).

…but strong measures taken to cut costs

CustomVis has taken action both on the cost front (reduced the number of staff from seventy to fifty (though without impacting on the skills base), closing the UK office and operating from one site only in Perth, Australia. Staffing costs were running at over £2m last year, but should now reduce to c.£1.5m. The impact of the cost reductions is primarily intended to improve cash flow for. As the Chairman, Bill Colvin, stated, 'our absolute focus is on improving the cash position of the Group. We are seeking to achieve this through a combination of accelerated laser sales and upgrades, supported by positive clinical data from the installed base as well as further and cost reductions'. The rate of cash burn has reduced from £550,000 per month in the second half of 2003/04 to £270,000 per month, and will fall further to below £250,000 per month as a result of the cost reduction measures. Cash flow should also benefit if CustomVis succeeds in obtaining additional funding from an Australian Federal Government Commercial Ready grant.

Cash flow				
Year end 30th June	2003/4			2004/5
Figures in £	H1	H2	Year	H1
Operating activities	(1,450,811)	(2,901,513)	(4,352,324)	(2,158,932)
Depreciation and amortisation	211,335	189,369	400,704	204,716
Impairment of intangibles	-	22,247	22,247	-
Increase in stock	(195,700)	(486,327)	(682,027)	(243,519)
(Incr.)/decr. in debtors	120,235	(69,889)	50,346	76,715
Incr./(decr.) in creditors	61,995	81,740	143,735	(158,637)
Exchange rate effects on bal's	101,006	(225,838)	(124,832)	174,216
Net cash from operations	**(1,151,940)**	**(3,390,211)**	**(4,542,151)**	**(2,105,441)**
Interest and tax	156,187	185,205	341,392	105,163
Capital expenditure	(191,922)	(91,827)	(283,749)	(65,683)
Cash flow before financing	**(1,187,675)**	**(3,321, 231)**	**(4,484,508)**	**(2,065,961)**
Financing:				
Issue of share capital	10,592,293	12,662	10,604,955	(1,342,844)
Incr./(decr.) in cash	**9,404,618**	**(3,284,171)**	**6,120,447**	**(3,408,805)**
Net cash/(debt) at start	**(569,386)**	**8,835,332**	**(569,386)**	**5,551,061**
Incr./(decr.) in cash	**9,404,618**	**(3,284,171)**	**6,120,447**	**(3,408,805)**
Cash outflow from repayment of loan notes*	-	-	-	1,342844
Net cash/(debt) at period end	**8,835,232**	**5,551,061**	**5,551,061**	**3,485,100**
**The non-interest bearing convertible loan stock of £1.34m was repaid in July 2004.*				

..and more grant funding is sought

The Commercial Ready programme, which started in October 2004, is the Australian Government's flagship innovation grants program providing around $200 million a year to mainly small companies. It replaces R&D Start, the Biotechnology Innovation Fund (BIF) and elements of the Innovation Access Programme, and grants range from $50,000 up to a limit of $5 million for projects including early stage commercialisation activities for which CustomVis meets the criteria.

Balance sheet

Balance sheet weakened

The changes in the balance sheet encapsulate the increase in the units available for sale but the absence, up to the period end, of sales. The £1.1m of intangibles is represented entirely by goodwill, there being a zero valuation assigned to patents after amortisation and impairment charges in the last financial year ended 30th June 2004. CustomVis' policy was to write off the cost of patents over two years only. The acquired goodwill was created on consolidation of the acquisition by CustomVis of the net assets of CLVR, and is amortised over five years. Stock is represented by the seven saleable lasers, three nearly built and three in semi-finished condition at the balance sheet date, plus any component parts.

…but could be trans-formed

The Company is cash positive with no debt. The £1.34m of convertible loan notes, included within creditors due within one year, have been fully repaid. At the half year end 31st December 2004, therefore, there was no loan stock, bank or other debt. The relatively low cash position is acknowledged, but the balance sheet should be transformed as sales take off and the Company is re-rated. Moreover, CustomVis acknowledges the requirement to complete a number of sales and provide independent clinical trial data to support acceleration of the marketing and production push in late 2005/early2006.

Consolidated balance sheet				
Year end 30th June Figures in £	At 31st Dec 2003 (Unaudited)	At 30th June 2004 (Audited)	At 31st Dec 2004 (Unaudited)	Change year on year
Fixed assets				
Intangible assets	1,448,786	1,216,988	1,053,966	(394,820)
Tangible assets	197,112	298,303	338,475	141,363
Total	1,645,898	1,515,291	1,391,441	(254,457)
Current assets				
Stock	195,700	682,027	925,546	729,846
Debtors	166,310	236,199	159,484	(6,826)
Cash at hand and in bank	10,178,076	6,893,905	3,485,100	(6,692,976)
Total	**10,540,086**	**7,812,131**	**4,570,130**	**(5,969,956)**
Creditors falling due < one year	(1,834,075)	(1,915,815)	(414,334)	(1,419,741)
Net current assets	**8,706,011**	**5,896,316**	**4,155,796**	**(4,550,215)**
Net assets less curr. Liabilities	10,351,909	7,411,607	5,548,238	(4,803,671)
Creditors due > one year	-	-	-	-
Net assets	**10,351,909**	**7,411,607**	**5,548,238**	**(4,803,671)**

The Management Team

Lean management team

Recently, as part of the restructuring of the business, the executive management team has also been reshaped and downsized, two directors having resigned in November 2004 - Simon Gordon, a former Managing Director and Chief Operating Officer of the Company, and Hugh Grant, a chartered accountant with experience on regulatory and corporate finance matters. The tightly knit executive team now comprises three individuals:

…with extensive business and scientific expertise

Dr. Paul van Saarloos - Chief Executive Officer - has significant experience managing medical technology companies and creating patented, commercially successful products in the refractive surgery field. Holding over one hundred patents, he has also developed and commercialised technologies in the field of refractive laser surgery. Dr. van Saarloos previously served as managing director of Q-Vis, as a researcher at the Lions Eye Institute, and as a laser physicist for numerous medical technology companies involved in ophthalmology. In addition to being the C.E.O., he also performs the role of Chief Scientist and R&D manager on the CLVR Operations Board.

Mr John McEvoy - Executive Finance Director and Company Secretary - is a recent promotion. Mr McEvoy joined CustomVis in August 2004 as Financial Controller and Company Secretary, and only took over the FD role in March 2005. He is a member of the Institute of Chartered Accountants in England and Wales having qualified in 1987 and has over fifteen years experience in a variety of finance related positions in various industries.

Dr. Mukesh Jain - Chief Operating Officer/Marketing Director - has extensive international business exposure with qualifications in science and engineering. Dr Jain has worked in the industry for organisations such as like NIDEK, Q-Vis and the Lions Eye Institute. He has a proven track record as successful international sales and marketing executive.

The non-executives include:

Bill Colvin – Chairman - was, until its recent acquisition by Blackstone, the Chief Executive of NHP plc, a quoted nursing home owner and operator, from November 2000. Mr. Colvin, a Chartered Accountant, is also currently a non-executive director of Sondex plc, a technology Company in the oil and gas sector to the upstream oil and gas industry. Mr. Colvin was appointed in July 2003 at the time of the AIM admission.

Emanuel Rosen was the medical director of Boots Opticians Eye Laser Service until this business was discontinued. He is also a past president of the International Implant Club, The European Society of Cataract and Refractive Surgeons and the UK and Ireland Society of Cataract and Refractive Surgeons. Mr. Rosen has extensive experience in the medical field, and the author and editor of a number of publications, including being co-editor of The Journal of Cataract and Refractive Surgery.

Dr. William Ardrey, who resigned as an executive director and appointed as a non-executive director of CustomVis in July 2004, has served as president, CEO, CFO, and marketing director of a number of companies in the medical and technology fields. He has led five technology companies from start up to trade sales, is a widely published author on marketing and strategy, and is a frequent visiting professor at universities in the US and Australia.

While the business appears to have become undercapitalised through the slow process of building sales, there is sufficient business experience and acumen among the executive team to commercialise the product and build revenues and profitability.

The Prospects – summary and conclusions

Laser surgery now well established

Laser surgery for the correction of vision disorders is on the increase. PRK, LASIK and LASEK are well established procedures. Of the total market estimated at some $4bn in procedure revenue per annum, half is in the US, while the Far East is also significant and fast growing. The market for custom treatments, especially where vision defects are non-standard, represents ten to twenty per cent of the total and this is of particular interest to CustomVis.

CustomVis claims superiority over existing systems

CustomVis has an established product the clinical results which at least equals those of competing systems according to clinical results based on the conventional success criteria. Moreover, the CustomVis system claims to be superior to existing gas-based laser technology where the latter's limitations mean that it is unable to treat all cases. To date, over three hundred eyes have received CustomVis surgery, but the number should grow rapidly as sales increase. One sale has just been made, and two more are possible before the year end.

Approvals in place for market access

CustomVis has approval from the Australian TGA and been granted its CE mark, allowing the Company to access not only Australasia but also the UK, EC, Asia Pacific region and Latin America. Approvals are also sought in other areas, notably China and the USA.

Action has been taken to cut costs and cash burn

The Company has taken steps to accelerate sales, and reduced costs to cut the cash outflow. The monthly cash burn has fallen from over £550,000 in H2 of 2003/04 to below £250,000 through downsizing the workforce and one site operation. Apart from via sales, additional funds are being sought from the Australian Federal Government Commercial Ready programme.

…then production will become key

CustomVis has a stock of eleven laser systems for sale, and cash from these will enable it to accelerate its production to three units a month with existing capacity. After cash flow has stabilised, and this is the current priority, attention will shift to increasing marketing, sales and manufacturing capability.

Tony Cooper April 2005