**THIS DOCUMENT IS IMPORTANT AND REQUIRES YOUR IMMEDIATE ATTENTION. If you are in any doubt about the contents of this document or as to the action you should take, you are recommended to seek immediately your own personal financial advice from your stockbroker, bank manager, solicitor, accountant or other independent financial adviser authorised pursuant to the Financial Services and Markets Act 2000, who specialises in advising on the acquisition of shares and other securities.**

A copy of this document, which comprises a prospectus and has been drawn up in accordance with the Public Offers of Securities Regulations 1995 (as amended) (the "POS Regulations"), has been delivered to the Registrar of Companies in England and Wales for registration in accordance with regulation 4(2) of the POS Regulations. Copies of this document will be available free of charge to the public during normal business hours on any day (Saturdays, Sundays and public holidays excepted) at the offices of Collins Stewart, 9th Floor, 88 Wood Street, London EC2V 7QR from the date of this document until the date on which Admission takes place, which is expected to be 8 July 2003.

The Directors of the Company, whose names appear on page 8 of this document, accept responsibility for the information contained in this document including individual and collective responsibility for compliance with the AIM Rules. To the best of the knowledge and belief of the Directors (who have taken all reasonable care to ensure that such is the case) the information contained in this document is in accordance with the facts and there is no other material information the omission of which is likely to affect the import of such information.

Application has been made for the Ordinary Shares issued and to be issued pursuant to the Placing to be admitted to trading on AIM, a market operated by the London Stock Exchange. AIM is a market designed primarily for emerging or smaller companies to which a higher investment risk tends to be attached than to larger or more established companies. AIM securities are not admitted to the official list of the United Kingdom Listing Authority. A prospective investor should be aware of the risks of investing in such companies and should make the decision to invest only after careful consideration and, if appropriate, consultation with an independent financial adviser. The London Stock Exchange plc has not itself examined or approved the contents of this document. It is expected that dealings in the Ordinary Shares will commence on AIM on 8 July 2003.

Your attention is drawn to the section entitled "Risk Factors" on pages 28 to 31 of this document.

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# CustomVis plc

*(Incorporated and registered in England and Wales under the Companies Act 1985 with registered number 4609602)*

## Placing of 12,637,363 ordinary shares of 5p each at 91p per share

## Admission to trading on the Alternative Investment Market of the whole of the issued ordinary share capital

## Nominated Adviser and Broker
## Collins Stewart Limited

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Collins Stewart, which is regulated and authorised by the Financial Services Authority, is acting exclusively for the Company and no-one else in connection with the Placing and the proposed Admission. Collins Stewart will not regard any other person as its customer or be responsible to any other person for providing the protections afforded to customers of Collins Stewart nor for providing advice in relation to the transactions and arrangements detailed in this document. Collins Stewart is not making any representation or warranty, express or implied, as to the contents of this document.

This document does not constitute an offer or buy or to subscribe for, or the solicitation of an offer to buy or subscribe for, Ordinary Shares in any jurisdiction in which such offer or solicitation is unlawful. In particular the Ordinary Shares offered by this document have not been, and will not be, registered under the United States Securities Act of 1933 as amended (the "Securities Act") or qualified for sale under the laws of any state of the United States or under the applicable laws of any of Canada, Australia or Japan and, subject to certain exceptions, may not be offered or sold in the United States or to, or for the account or benefit of, US persons (as such term is defined in Regulation S under the Securities Act) or to any national, resident or citizen of Canada, Australia or Japan. The distribution of this document in other jurisdictions may be restricted by law and therefore persons into whose possession this document comes should inform themselves about and observe such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. In particular, this document must not be distributed, directly or indirectly, in or into the United States, Canada, Australia or Japan.

## CONTENTS

## DEFINITIONS

The following definitions apply throughout this document unless the context requires otherwise:

| | |
|---|---|
| "Act" | the Companies Act 1985 (as amended) |
| "Admission" | the admission of the Ordinary Shares, issued and to be issued pursuant to the Placing, to trading on AIM becoming effective in accordance with the AIM Rules |
| "AIM" | a market operated by the London Stock Exchange |
| "ASX" | Australian Stock Exchange Limited |
| "AIM Rules" | AIM Rules for Companies |
| "Board" | the Board of Directors of the Company |
| "Certificated Share" | a share in the capital of the Company which is not an uncertificated share |
| "CLVR" | CLVR Pty Ltd, a wholly owned subsidiary of the Company registered in Australia |
| "CLVR Operations Board" | each of Dr Paul van Saarloos, Simon Gordon, Dr William Ardrey, Richard Gilroy, Frank Zanin and Antonia Valentine |
| "Collins Stewart" | Collins Stewart Limited, the Company's nominated adviser and broker (as defined in the AIM Rules) |
| "Combined Code" | the principles of good governance and code of best practice prepared by the Committee on Corporate Governance and published in June 1998 |
| "Company" or "CustomVis" | CustomVis plc, the ultimate holding company of the Group |
| "CREST" | the Relevant System (as defined in the CREST Regulations) in respect of which CRESTCo Limited is the Operator (as defined in the CREST Regulations) in accordance with which securities may be held and transferred in uncertificated form |
| "CRESTCo" | CRESTCo Limited |
| "CREST Regulations" | The Uncertificated Securities Regulations 2001 (SI 2001 No. 3755) |
| "CustomVis™ System" | CustomVis™ Custom Corneal Reshaping System |
| "Directors" | the directors of the Company, whose names are set out on page 8 of this document |
| "Executive Directors" | each of Dr Paul van Saarloos, Simon Gordon, Hugh Grant and Dr William Ardrey |
| "Group" | the Company and, where applicable, its subsidiaries |
| "Loan Notes" | the unsecured convertible loan notes in the aggregate amount of £1,342,844 constituted by deed by the Company on 22 April 2003, as varied, particular details of which are set out in paragraph 11.3 of Part IX of this document |

| | |
|---|---|
| "London Stock Exchange" | London Stock Exchange plc |
| "Mutual Recognition Agreement" | an agreement between the Australian Therapeutic Goods Administration (TGA) and European regulators, permitting the TGA to grant the CE mark device approval in Australia concurrent with TGA regulatory approval |
| "Official List" | the Official List of the UK Listing Authority |
| "Ordinary Shares" | ordinary shares of 5p each in the capital of the Company |
| "Participant ID" | the identification code or membership number used in CREST to identify a particular CREST member or other CREST participant |
| "Placing" | the placing by Collins Stewart of the Placing Shares at the Placing Price pursuant to the Placing Agreement and as described in this document |
| "Placing Agreement" | the conditional agreement dated 2 July 2003 between the Company, the Directors and Collins Stewart relating to the Placing, as described in paragraph 11.6 of Part IX of this document |
| "Placing Price" | 91p per Ordinary Share |
| "Placing Shares" | the 12,637,363 new Ordinary Shares to be issued pursuant to the Placing |
| "POS Regulations" | the Public Offers of Securities Regulations 1995 (as amended) |
| "Q-Vis" | Q-Vis Limited, a company registered in Australia and listed on the ASX |
| "Statutes" | means the Act and every statute (including any orders, regulations or other subordinate legislation made under them) for the time being in force affecting the Company |
| "Shareholders" | holders of the Ordinary Shares |
| "Uncertificated Share" | a share in the capital of the Company which is recorded in the register of members of the Company as being held in uncertificated form and title to which may be transferred by means of a Relevant System (as defined in the CREST Regulations) |
| "UK" or "United Kingdom" | United Kingdom of Great Britain and Northern Ireland |
| "US" or "United States" | United States of America, its territories and possessions, any state of the United States and the District of Columbia |

## GLOSSARY OF TERMS

The following terms apply throughout this document unless the context requires otherwise:

| | |
|---|---|
| ablation | surgical removal of a body part or tissue; eg: removal of micron thickness layers of the cornea during LVC surgery |
| astigmatism | a refractive abnormality where light is not focused to a point on the retina. This is often caused by the cornea or front window of the eye being elliptical (shaped more like an egg) rather than spherical (shaped like an orange), resulting in blurred vision. It can accompany either myopia or hyperopia or be a standalone disorder |
| carcinogenesis | the process of a normal cell becoming cancerous |
| CE mark | regulatory approval system for all medical devices to be sold in the European Union (EU) – implemented in July 1998 |
| cornea | the transparent front window of the eye. The cornea is the first part of the eye that bends (or focuses) the light and provides most of the focusing power of the eye. The cornea can be considered to have 5 layers:<br>1. the corneal epithelium,<br>2. Bowman's layer,<br>3. corneal stroma,<br>4. Descemet's layer, and<br>5. the corneal endothelium |
| dioptre | a unit employed by oculists when numbering the refractive strength of glasses according to the metric system; a refractive power equal to that of a lens with a principle focal distance of one metre |
| dongles | a hardware device that serves as copy protection for certain software by rendering the software inoperable when the device is not present |
| excimer laser | laser energy produced by several rare gas-halide mixtures. The term excimer comes from the concept of an energized molecule with two identical components or excited dimer (contracted to one word excimer). In LASIK the term has for practical purposes become synonymous with the argon-fluoride (ArF) gas version. The wave length of an ArF excimer laser is in the far ultraviolet range at 193 nm |
| FDA | Food and Drug Administration. The FDA is the United States government agency responsible for the evaluation and approval of pharmaceuticals and medical devices |
| gaussian | the bell-shaped curve that represents the normal distribution of a large number of possible events |
| hyperopia | a refractive abnormality of the eye requiring a plus (positive or convex) lens for correction (also known as long-sightedness). People who are long sighted can see objects far away or in the distance without glasses |
| iris | the coloured ring of tissue suspended behind the cornea and immediately in front of the lens (the coloured part of the eye). The iris is partly responsible for regulating the amount of light permitted to enter the eye |
| keratectomy | surgical excision (removal) of any portion of the cornea. In a penetrating keratectomy (or PK) a button-like full thickness segment of the cornea is removed and replaced with a donor cornea from another person |
| LASEK | Laser Epithelial Keratomileusis: is a refrective surgery procedure that permanently changes the shape of the cornea. The epithelium (the outermost layer of the cornea) is detached by using an alcohol solution that weakens the epithelium and allows it to fold back into a flap and enables the laser to ablate the cornea. After the tissue is reshaped, the flap is returned back to its original position and a contact lens is placed on the cornea to aid in the healing and the reduction of pain of the cornea |

| | |
|---|---|
| laser | Light amplification by stimulated emission of radiation: any of several devices that emit highly amplified and coherent radiation of one or more discreet frequencies |
| LASIK | Laser Assisted In-Situ Keratomileusis: in this LVC procedure, the surgeon creates a flap by cutting across the front edge of the cornea with a microkeratome, folding it back to reveal the corneal "bed" or stroma. The stroma is ablated with a laser, reshaping the underlying cornea. The flap is then replaced. The amount and shape of the removed tissue is determined by the preoperative refractive error i.e. myopia, hyperopia or astigmatism |
| lens | a part of the eye that provides some focusing power. The lens is able to change shape allowing the eye to focus at different distances |
| limbus | the visible borderline between the clear window (cornea) and the white globe (sclera) of the eye. The conjungtival layer which covers the globe also joins at the limbus |
| LVC | laser vision correction |
| mechtronic | a combination of mechanical and electronic design skills |
| mutagenicity | the capability of a substance to cause damage to genetic material |
| microkeratomes | a surgical device which is used to create a "flap" of tissue under which the laser is applied. This device is used in the LASIK procedure |
| myopia | a refractive abnormality of the eye requiring a minus (negative or concave) lens for correction (also known as short- or near-sightedness). People who are near sighted can see objects up close or at near distance without glasses |
| ophthalmologist | a medical doctor specializing in medical and surgical care of the eyes, and in the prevention of eye disease and injury. An ophthalmologist uses their medical education, training and experience to diagnose, treat and manage the visual systems |
| PRK | Photo Refractive Keratectomy: sculpting of an astigmatic, myopic or hyperopic lens for refractive reasons on the front surface of the eye with the use of a "cold" laser light |
| pupil | appears as a small black circle in the centre of the iris and changes its diameter in response to ambient lighting |
| refraction | the bending of light at an interface change. In ophthalmology it is the test performed to determine the refractive error of the eye |
| retina | light sensitive nerve layer which converts light images into electrical signals for transmission to the brain |
| stroma | thick, middle layer of cells in the cornea |
| TGA | Therapeutic Goods Administration: Australia's regulatory authority for evaluation and approval of pharmaceuticals and medical devices |
| topography | accurate and detailed description or drawing of places or items and their surface details. Used to determine the corneal profile in order to programme the LASIK computer for refractive correction as well as for postoperative corneal analysis |
| wave length | the distance between the top of one wave and the top of the next wave. The argon fluoride excimer wavelength is 193 nm. This wavelength is in the far ultraviolet end of the electromagnetic spectrum |

## PLACING STATISTICS

| | |
|---|---|
| Placing Price | 91p |
| Number of Ordinary Shares in issue prior to the Placing | 22,081,785 |
| Number of Placing Shares being issued | 12,637,363 |
| Number of Ordinary Shares in issue following the Placing | 34,719,148 |
| Number of Ordinary Shares under option | 1,567,321 |
| Number of Ordinary Shares into which the Loan Notes may convert | 2,165,877 |
| Fully diluted share capital following the Placing† | 38,452,346 |
| Estimated expenses of the Placing for the Company | £1.5 million |
| Estimated net proceeds of the Placing receivable by the Company | £10 million |
| Market capitalisation at the Placing Price | £31.6 million |

## EXPECTED PLACING AND ADMISSION TIMETABLE

| | |
|---|---|
| Trading to commence in the enlarged issued ordinary share capital on AIM | 8 July 2003 |
| CREST stock accounts credited (as applicable) | 8 July 2003 |
| Definitive share certificates despatched (as applicable) | 15 July 2003 |

† Fully diluted assumes the conversion of the Loan Notes in full and the exercise of all outstanding share options as more particularly described in paragraphs 3.7 and 3.8 of Part IX

# DIRECTORS AND ADVISERS

| | |
|---|---|
| Directors | William Colvin *(Non-executive Chairman)*<br>Dr Paul van Saarloos *(Chief Executive Officer)*<br>Simon Doig Gordon *(Managing Director)*<br>Hugh Alexander Grant *(Finance Director)*<br>Dr William Ardrey *(Executive Director)*<br>Emanuel Saul Rosen *(Non-executive Director)*<br><br>all of:<br>7 Devonshire Square, Cutlers Gardens, London EC2M 4YH |
| Company Secretary and Registered Office | Hugh Alexander Grant<br>7 Devonshire Square<br>Cutlers Gardens<br>London EC2M 4YH |
| Nominated Adviser and Broker | Collins Stewart Limited<br>9th Floor<br>88 Wood Street<br>London EC2V 7QR |
| Auditors and Reporting Accountants (United Kingdom) | PKF<br>New Garden House<br>78 Hatton Garden<br>London EC1N 8JA |
| Auditors (Australia) | PKF<br>Level 7<br>BGC Centre<br>28 The Esplanade<br>Perth, Western Australia 6000 |
| Solicitors to the Company (United Kingdom) | Hammonds<br>7 Devonshire Square<br>Cutlers Gardens<br>London EC2M 4YH |
| Solicitors to the Company (Australia) | Bennett & Co<br>Level 6<br>89 St. Georges Terrace<br>Perth, Western Australia 6000 |
| Solicitors to the Nominated Adviser | Mayer, Brown, Rowe & Maw LLP<br>11 Pilgrim Street<br>London EC4V 6RW |
| Principal Bankers | Clydesdale Bank<br>West End Branch<br>158 Nethergate<br>Dundee DD1 4DY |
| Reporting Experts | Bridgehead Technologies Limited<br>Pera Innovation Park<br>Nottingham Road<br>Melton Mowbray<br>Leicestershire LE13 0PB |
| Public Relations Advisers | Weber Shandwick Square Mile<br>Fox Court<br>14 Gray's Inn Road<br>London WC1X 8WS |
| Registrars | Capita IRG plc<br>Bourne House<br>34 Beckenham Road<br>Beckenham<br>Kent BR3 4TU |
| Patent Agent | Wray & Associates<br>Level 4<br>The Quadrant<br>1 William Street<br>Perth, Western Australia 6000 |

# KEY INFORMATION

**Introduction**

The CustomVis business was set up in March 2001 to address a number of problems being experienced in the field of laser vision correction ("LVC"). LVC surgery involves the use of a laser to re-shape the cornea to try to correct visual abnormalities. Currently, the most common form of LVC surgery utilises excimer laser technology. The Directors believe that this technology is approaching the end of its product development cycle as its ability to perform high quality custom laser treatment is proving difficult. This is mainly due to technological limitations including eye tracking technologies, pulse rates and/or beam spot sizes of the laser. The CustomVis™ System has been designed to address these issues and meet the requirements of effective custom LVC surgery.

The Directors believe that successful LVC surgery requires precision, accuracy and reliability. To perform these requirements successfully the Directors believe that a laser requires a fine, fast cutting spot to effectively ablate the cornea without damaging the remaining corneal tissue, a comprehensive tracking system to track any movement or rotation of the eye during surgery and leading edge diagnostic tools to collate the data and produce a surgical plan. The Directors believe that CustomVis produces the only system that can offer all of these features in a fully integrated package.

**Key Strengths**

The Directors believe that the CustomVis™ System has the following key technical strengths:

- a fast pulse rate, desired spot size and innovative tracking and scanning systems which allow for:
  - (i) treatment of higher order vision disorders which were previously considered untreatable;
  - (ii) improved visual acuity and contrast sensitivity for standard treatments; and
  - (iii) the ability to repair eyes damaged by previous eye laser surgery;
- the laser's longer wavelength of 213nm is less affected by moisture and humidity. This appears to reduce the potential for thermal damage to the remaining corneal tissue, which leads to safer and more consistent treatments;
- the solid state system increases reliability and avoids the need to use toxic gases and their environmental controls thereby reducing running costs; and
- the CustomVis™ System is a composite system and is easy to use. The touch screen system incorporates the pre-operative registration of the eye tracker with the wavefront and topography data, and provides the surgeon with the flexibility to optimise treatment.

The Directors believe that CustomVis has the following key strengths:

- this proven, patent pending technology with a number of innovative features should enable entry to new markets by allowing a more customised approach to standard and non-standard vision disorders;
- significant market opportunity initially in UK, Europe, Asia Pacific, Latin America and Australasia having received confirmation from TGA of its intention to issue both TGA approval and the CE mark;
- orders received from globally recognised leading ophthalmic surgeons operating in a variety of countries;
- an experienced management team and a board of Directors who have achieved international recognition amongst leading surgeons and clinics;
- technological expertise and low cost production in Perth, Western Australia; and
- as indicated in Part VII of this document, near term profitability in prospect.

**Market strategy and opportunities**

Technology is the key driver of new laser system sales. With the smallest spot size, fastest pulse rate, and fastest eye-tracker response, the Directors believe that the CustomVis™ System is currently the only system on the market capable of delivering the full requirements of customised surgery. Surgeons and opinion leaders in the LVC industry are continually looking for new technology to enhance their offering and many of these are already expressing an interest in the CustomVis™ System.

The Company's initial strategy is to target the world's leading ophthalmic surgeons and eye care clinics. Whilst CustomVis will continue to regard these activities as its primary focus, it also intends to establish its market share through a combination of direct and agent distribution and service models depending on specific markets.

The Directors believe that using the current gas-based LVC technology:

- approximately 10 per cent. of patients require re-treatment;
- a significant proportion of patients who have been treated could have achieved a better outcome; and
- approximately 10 – 15 per cent. of patients are not currently suitable for treatment.

The Directors believe that the above represents a significant market opportunity. With the incidence of common disorders such as myopia and hyperopia increasing, a large proportion of the world's population are now potential candidates for LVC surgery.

Having received confirmation from TGA of its intention to issue both TGA approval and the CE mark, the Company initially has access to LVC markets outside the US and Japan, estimated at £1.2 billion in annual procedures revenue. In due course the Company intends to secure access to the US LVC market which is currently estimated to represent a further £1.2 billion. Custom surgery is a largely untapped market, currently representing some 15 – 20 per cent. or approximately £400 million of the total LVC market.

**Current trading and prospects**

CustomVis unveiled the prototype of the CustomVis™ System in November 2002 at the American Academy of Ophthalmology conference in Orlando, Florida. Following the first ever successful treatments of highly irregular astigmatisms using the CustomVis™ System, the Company has recently treated the second set of patients.

Having received confirmation from TGA of its intention to issue both TGA approval and the CE mark, the Company aims to manufacture and distribute the CustomVis™ System throughout the UK, Europe, Asia Pacific, Latin America and Australasia.

Discussions have been held with several leading opinion forming refractive surgeons across various countries. These have resulted in orders being placed for these new systems (equivalent to the first six months' production) and further interest has been received in relation to additional sales of new systems.

**Reasons for the Placing and use of proceeds**

The Placing will raise approximately £10 million, net of expenses, for the Company. These proceeds will be used to increase the scale and production capacity for the CustomVis™ System and further expand the Company's existing sales, service and marketing infrastructure. If required, part of these proceeds will also be used to redeem the Loan Notes. To maintain competitive advantage, the Directors will also use a portion of the funds for further research and development.

The Directors believe that the increased financial resources and enhanced profile of the Company within the market place will further enable CustomVis to develop and commercialise its CustomVis™ System. Plans are underway to seek FDA approval thereby enabling access to the United States market.

Admission to AIM will also provide opportunities for the Company's employees to participate in the future success of the Company, through the benefit of the proposed employee share option scheme.

# PART I

## Information on the Company

### Introduction

The CustomVis business was set up in March 2001 to address a number of problems being experienced in the field of laser vision correction ("LVC"). LVC surgery involves the use of a laser to re-shape the cornea to try to correct visual abnormalities. Currently, the most common form of LVC surgery uses excimer (gas) laser technology. The Directors believe that this technology has a number of limitations resulting in a failure to optimise current treatments and address the needs of a significant number of people with standard and non-standard visual disorders.

The Directors believe that using the current gas-based LVC technology:

- approximately 10 per cent. of patients require re-treatment;
- a significant proportion of patients who have been treated could have achieved a better outcome; and
- approximately 10-15 per cent. of patients are not currently suitable for treatment.

The Directors believe that the CustomVis™ System represents a step change in technology for LVC in that it can overcome certain limitations in existing LVC technology. The Directors believe that this represents a significant market opportunity.

The CustomVis™ System incorporates a solid state laser, solid state scanning integrated with rapid eye tracking devices to track the movement of the patient's eye and the ability to incorporate data from a variety of diagnostic systems into surgical planning software and the treatment process. These features enable the CustomVis™ System to map out a surgical plan for any individual eye accurately, allowing a customised approach to correction of both standard and non-standard vision disorders. The Company is also involved in developing a number of tools for diagnosing the visual pathways of the eye, as well as additional related laser products.

In September 2002 limited clinical trials on what are currently considered untreatable visual disorders or irregular astigmatisms were successfully concluded using the CustomVis™ System at the Laser Sight centres in Australia. Following these trials and an audit of the Company's systems and procedures, the Company received confirmation from TGA of its intention to issue both TGA approval and the CE mark. These certifications allow for the immediate distribution of the CustomVis™ System into the UK, Europe, Asia Pacific, Latin America and Australasia. Discussions have been held with several leading opinion forming refractive surgeons across various countries. These have resulted in orders being placed for these new systems (equivalent to the first six months' production) and further interest has been received in relation to additional sales of new systems.

### Key strengths

The CustomVis™ System has been developed by Dr Paul van Saarloos and is a composite system to meet the surgical requirements of customised surgery. The Directors believe that the CustomVis™ System offers an innovative opportunity to customise both standard and non-standard vision disorders.

The Directors believe that the CustomVis™ System has the following key strengths:

*Technical advantages*

- a fast pulse rate (300 – 400Hz) which is required to deliver the desired spot size in an acceptable treatment time (current industry average <100Hz);
- a small laser spot size (0.6mm) required to address detailed ablation profiles (current industry average greater than 1mm);

- a solid state laser scanner required to adjust the laser beam position rapidly to compensate for movement of the eye (CustomVis™ System is approximately ten times faster than the current industry average);
- the fastest eye tracking closed loop response currently available in the industry (>1000 frames per second) which is required to sense the position of the eye, process the information and position the laser beam for accurate ablation (existing systems currently track at approximately 155 frames per second);
- a reliable beam profile and wavelength of 213nm which is less affected by hydration and humidity (current industry wavelength of 193nm);
- an intra-operative gaze tracker to ensure that the laser beam energy is directed to the correct position of the cornea in the event of a tilt in the eye during surgery;
- an automated surgical plan set-up which allows computerised ablation design and simulation;
- a registration match of 1:1 with corneal position which ensures accurate positioning of treatment on the eye; and
- no pupil dilation required which ensures patients are more comfortable and increases clinic through-put.

*Other advantages*

- this proven, patent pending technology with a number of innovative features should enable entry to new markets by allowing a more customised approach to standard and non-standard vision disorders;
- significant market opportunity initially in UK, Europe, Asia Pacific, Latin America and Australasia having received confirmation from TGA of its intention to issue both TGA approval and CE mark;
- orders received from globally recognised leading ophthalmic surgeons operating in a variety of countries;
- experienced management team and a board of Directors who have achieved international recognition amongst their peer group;
- recognition of the CustomVis technology and expertise by industry experts and opinion formers;
- technological expertise and low cost production in Perth, Western Australia; and
- as indicated in Part VII of this document, near term profitability in prospect.

In the view of the Directors, this step change in technology provides the Company with a number of competitive advantages which will enable CustomVis to capitalise upon the substantial market opportunity for its products.

**History and development**

On 8 March 2001 Dr Paul van Saarloos founded CLVR, a company registered in Australia, with the intention of becoming a leader in the field of laser vision correction by supplying innovative technology with a particular focus on the need for customised refractive eye laser surgery. During 2002, CLVR broadened its management capabilities with the addition of Dr William Ardrey and Mr Simon Gordon, followed in 2003 by Mr Hugh Grant and Mr Richard Gilroy. CustomVis was formed and incorporated in England and Wales on 5 December 2002 in anticipation of seeking a listing on AIM. On 17 April 2003, CustomVis acquired the whole of the issued share capital of CLVR by way of a share exchange as a consequence of which CLVR became a wholly owned subsidiary of CustomVis.

*Funding*

In mid 2002, CLVR completed its first round of fund raising predominantly supported by Custom Lasers Inc, a US-based biotechnology investment firm together with other private investors. AUD$760,000 (approximately £305,220) was invested in CLVR through this initial round of funding. In 2003 a further round of fund raising was completed with private investors committing an amount of AUD$1,550,000 (approximately £662,489) and following the share exchange referred to above an additional £1.34 million was invested by a single private investor in the Company in consideration for the issue of the Loan Notes.

Since the incorporation of CLVR the Group has been awarded Australian Federal Government grants from the Biotechnology Innovation Fund, Commercialising Emerging Technologies, Research and Development Tax Concession and an Export Market Development Grant totalling AUD$527,000 (approximately £212,000).

Through Australian Federal Government grants and private financial backing the Company has achieved several important development milestones since launch. These include:

- the successful stabilisation of laser generation, a patent pending method of achieving safe and stable solid state wavefront technology for refractive surgery;
- the development of a new patent pending solid state scanning machine able to achieve a closed-loop response time of greater than 1kHz;
- the development of a computer aided design custom treatment software capable of integrating diagnostic information including topography, wavefront, pupilometry and refraction information creating an ablation profile of the patients eye allowing the surgeon to customise the eye treatment;
- the establishment of offices in Dundee, Scotland and Perth, Australia to facilitate management and production of the CustomVis™ System;
- so far as the Directors are aware, the first ever successful laser treatment of highly irregular astigmatisms; and
- the commencement of the second set of patient treatments by CustomVis in April 2003.

The Company unveiled its first generation solid state laser at the American Academy of Opthalmology conference, Orlando Florida in November 2002. The CustomVis™ System has subsequently received confirmation from TGA of its intention to issue both TGA approval and CE mark, authorising the commercial sale of the CustomVis™ System in the UK, Europe, Asia Pacific, Latin America and Australiasia.

**Business review**

*Technology*

The new CustomVis™ System comprises a diagnostic device which generates a surgical plan for each individual eye, systems to ensure correct registration of the surgical plan with the patient's eye and a solid state laser integrated with a scanning system which allows for accurate and fast movement of the laser beam over the surface of the cornea.

The diagnostic element, the ZCAD™ advanced surgical planning system, incorporates pre-operative topography (undulations in the height of the corneal surface), wavefront data (detection of refractive abnormalities in the whole eye), pupil size and refraction data. This system integrates the data to produce a precise map of the cornea, permitting further refinement by the surgeon and allowing for customised ablation needed to achieve optimal visual acuity.

This surgical map is introduced into the CustomVis™ System which incorporates:

- the Pulzar™ solid state laser, a small spot laser (0.6 mm), with fast pulse repetition rate (300Khz) and improved laser beam profile;
- ZTRACK™ fast eye tracking of the eye, which ensures that the surgical plan generated by ZCAD™ is accurately positioned relative to the patient's eye. This system matches the

limbus in the surgical plan to those in the patient's eye. This maintains an accurate central reference point for direction of the laser in ablation of the corneal surface. Current systems using the centre of the pupil as a reference point can be inaccurate as the position of the pupil centre may vary during surgery by as much as 0.7mm, according to the dilation of the pupil; and

- the ZSCAN™ solid state scanning device which is responsible for the scanning (movement) of the laser beam. This device is required in order to accurately carry out the surgical plan that is produced by the ZCAD™ diagnostic.

The laser is integrated with the tracking (ZTRACK™) and scanning system (ZSCAN™), thus any movement of the eye is detected and the laser position is adjusted to compensate for the movement. The closed loop response of the system allows the laser to respond extremely rapidly to any shift in gaze. This ultra rapid and accurate system has the fastest tracking time currently available and overcomes the thermal drift associated with other systems currently on the market. The gaze tracking functionality provides an additional level of safety by immediately stopping the laser should the direction of gaze change during the ablation procedure.

*Surgical procedure*

The steps below describe briefly the surgical procedure when using the CustomVis™ System:

- the ophthalmologist provides the computer with information on the patient's eye. The information includes pupilometry, refraction, pachymetry, topography and wavefront data;
- in turn, the software (ZCAD™) custom designs and refines a surgical plan to correct the optical system's aberrations. The surgical plan and patient information is saved on a CDROM and inserted into the CustomVis™ System;
- the ophthalmologist prepares the patient for refractive surgery by using one of three surgical procedures: LASIK, LASEK or PRK;
- the eye tracking system (ZTRACK™) locks onto the limbus of the eye and tracks the movement of the eye;
- to undergo the refractive surgery on the patient's eye, the ophthalmologist activates the 213nm solid state laser beam to follow the surgical plan designed by ZCAD™. The laser is integrated with the tracking (ZTRACK™) and scanning (ZSCAN™) system, thus any movement of the eye is detected and laser position is adjusted to compensate for the movement. The closed loop response of the system allows the laser to respond faster than horizontal and rotational eye movement; and
- the laser ablation takes between twenty seconds and a few minutes to perform depending upon the complexity of the surgical plan.

**The CustomVis technology has a number of technical advantages as outlined above. These key advantages are more particularly described in the expert's report in Part IV of this document.**

**CE mark, TGA approval and FDA trials**

On 20 May 2003 the Australian Therapeutic Goods Administration agreed as part of the Mutual Recognition Agreement in relation to conformity assessment, certificates and marking between the European Community and Australia, that application for both the CE mark and TGA approval could be run concurrently.

As part of the audit process undertaken by the TGA, the Company has had to update its quality management system to ensure full compliance with ISO 13485 (medical equivalent of ISO9001) and in particular with the general requirements for safety of medical devices, electromagnetic compliance, laser safety regulations for medical devices, software compliance for medical devices and risk management procedures for medical devices.

The Company has received confirmation from TGA of its intention to issue both TGA approval and the CE mark following full compliance in each of the above categories.

To coordinate the FDA approval programme, the Company has retained a leading FDA investigating body "The Center for Clinical Research" in Chicago. The Center has engaged leading FDA investigators and doctors to conduct trials globally, finalise FDA protocols and advise the Company throughout the regulatory process in the United States. The Company has commenced discussions with the FDA on the necessary protocols required for patient trials and anticipates completion of FDA approval during 2006. This is in line with previous FDA laser technology approvals.

**Intellectual property**

The Company seeks to protect its intellectual property by a combination of patents and trade mark applications, copyright, know-how, trade secrets and confidentiality.

The Company seeks confidentiality agreements protecting its technology whenever the Company's technology is disclosed to third parties. Agreements are in place with all employees and consultants to ensure that any intellectual property developed whilst such individuals are employed or retained by the Company is owned by or if necessary assigned to the Company without additional consideration and that all information concerning the Company's technology remains confidential both during and after the individual's employment or retention by the Company. To date, no employee has or is making any claim for compensation for any inventions and the Company does not anticipate any such claims.

The CustomVis™ System possesses a number of innovative features currently not found in any refractive laser system on the market. The Company is seeking protection for the technology behind the CustomVis™ System through the Group's patent and trade mark applications. Further details on the status of these applications is set out below and in Part V. Non-patentable know-how relating to the CustomVis™ System technology is protected as trade secret by confidentiality agreements.

*Patent applications*

CustomVis has filed two provisional patent applications in Australia and two international patent ("PCT") applications:

| *Description* | *Provisional Australian patent application date:* | *PCT application date:* |
|---|---|---|
| Solid State UV Laser Scanning Device and Method of Scanning of Optical Beam Over a surface | 30 May 2002 | 28 May 2003 |
| | 28 June 2002 | 27 June 2003 |

Work is currently underway on patent applications in respect of another two inventions in the fields of eye tracking and laser structure. The two applications will be the subject of another two provisional patent applications to be filed with the Australian Patent office during July 2003.

The filing dates of the two Australian provisional patent applications have established priority dates that can be claimed when filing corresponding patent applications in most other countries, provided that the applications in those other countries are filed within specified times from the priority dates.

Filing a PCT application enables a large number of countries to be designated in the single PCT application. However, a PCT application does not itself mature into a granted patent. Instead, the PCT application is a vehicle that is used to file national patent applications (referred to as "national phase applications") in any of the countries that were designated in the PCT application. The national phase applications that are filed are then processed according to the national law and procedures of the relevant countries.

No third parties have informed the Company that they oppose or dispute or intend to oppose or dispute the patentability of the inventions that are the subject of the applications that have been

filed, nor the validity of the applications. However, the contents of the applications have not yet been officially published (i.e. made available to third parties) by the Australian Patent Office nor by WIPO (the authority that administers the PCT system) and as such are not yet open to opposition by third parties.

*Trade Mark Applications*

The Group has prepared and filed six trade mark applications in Australia. The applications are currently awaiting examination in the Australian Trade Marks Office.

The filing dates of these six trade mark applications establish priority dates that can be claimed when filing corresponding trade mark applications in most other countries, provided that the applications in those countries are filed within 6 months from the priority dates.

The Group's intellectual property is more particularly described in the Patent Agent's Report on pages 62 to 76 of this document.

**Q-Vis**

Q-Vis is an Australian company whose business was the manufacture and sale of laser vision correction systems. It was admitted to trading on ASX in July 2000. In December 2002 Q-Vis appointed administrators and was placed into voluntary administration.

Dr Paul van Saarloos and Simon Gordon were previously employed with Q-Vis. Dr Paul van Saarloos was the company's chief technical officer and developed eye laser technology for Q-Vis. At the time of its flotation on the ASX he was a director and its chief scientific officer. Simon Gordon was previously employed as the sales and marketing director of Q-Vis but he left the company prior to its flotation. As a result of disagreements between Dr Paul van Saarloos and other members of the Q-Vis board over the future of the company, Dr Paul van Saarloos left Q-Vis in October 2000. Both Dr Paul van Saarloos and Simon Gordon subsequently brought unfair dismissal claims against Q-Vis and were both party to actions in the Supreme Court of Western Australia against Q-Vis for their outstanding contractual entitlements as former employees of Q-Vis. These employment claims have been successfully resolved, and the administrator of Q-Vis settled the claims on the basis that significant payments will be made to each of Dr Paul van Saarloos and Simon Gordon as well as both of them being entitled to receive certain rights in relation to the acquisition of intellectual property, plant, equipment and stock of Q-Vis.

Further details relating to the litigation conducted by Dr Paul van Saarloos and Simon Gordon against Q-Vis are set out in paragraph 12 of Part IX of this document.

**Q-Vis patents**

Pursuant to the settlement terms agreed between the administrator of Q-Vis and Dr Paul van Saarloos and Simon Gordon referred to above, Dr Paul van Saarloos and Simon Gordon have the right to acquire, either outright or via an interest in a proposed joint venture, the benefit of patents from the existing Q-Vis patent portfolio. Dr Paul van Saarloos and Simon Gordon have entered into an option agreement with the Company, on an arm's length basis, giving an option to the Company to purchase from Dr Paul van Saarloos and Simon Gordon, their interests in such joint venture and/or patents. Notwithstanding this option agreement, the Directors do not believe that securing any of the rights from the Q-Vis patent portfolio is business critical to the Group on the basis that none of the Q-Vis patents support the CustomVis™ System.

Further details relating to the proposed joint venture arrangements and the option agreement are set out in paragraphs 11.9 and 12.3 respectively of Part IX of this document.

**Product development and plans**

In addition to the laser system, the Company is developing further technologies to improve LVC surgery. These technologies are designed to enhance the diagnostic information available to surgeons, or to improve the surgical outcome.

***Diagnostic enhancements***

*Topographer*

Topographers create a map of the corneal surface of the eye, much like an ordnance survey map, measuring the peaks and troughs of the cornea. Provided that the laser is similarly accurate, topography allows surgeons to remove tissue from the cornea selectively. CustomVis's management believe that one of today's best topography system is the Orbscan from Bausch & Lomb. Orbscan currently provides highly accurate data for patients in need of custom surgery. Partly to avoid relying on components from a competitor, and partly to create a genuinely better solution, CustomVis is in late-stage development of its own topography system that it believes is at least as accurate as the Orbscan, but is faster by avoiding using moving parts.

As well as this top-end topography system, CustomVis has plans to produce a lower-end, mass market topographer which would be useful for opticians dispensing other corneal treatments, eg. contact lenses.

*Pupilometer*

One of the most common side effects experienced by patients after LVC operations is glare and haloes when night driving. For many, this is caused because the pupil dilates in the dark at night. Night driving problems usually occur when the pupil opens wider than the area that the surgeon has corrected. Pupilometers measure the pupil and its responses to light to avoid operating on potential problem patients. CustomVis plans to develop an integrated pupilometer-topographer.

*Wavefront*

Originally, ophthalmologists made visual corrections by relying on the visual acuity (eye chart) information only. Topography measurements were included later and found to achieve better results. Over the last two years, doctors have realised that eye chart plus topography is not sufficient for many patients. Higher order aberrations can only be assessed by measuring the entire optical system. Wavefront uses imaging to measure this. There are various technologies to make these measurements. CustomVis's management believe that currently available systems could be optimised. There are several options open to CustomVis for integration of wavefront technology into their system. These are:

(i) license an available technology – the Company has the offer of entering into an agreement with Tracey Technologies under which the first wave of the CustomVis™ Systems will be shipped using the Tracey VFA Wavefront technology;

(ii) acquire an existing system – the Company believes that existing wavefront systems could be acquired and optimised;

(iii) collaborate on the development of a new system representing a step change in the technology; and

(iv) develop the technology in-house.

***Surgical Enhancements***

*Post-operative healing accelerant*

CustomVis is currently negotiating for exclusive licenses for a wound healing accelerator which heals the eye more quickly, more smoothly and without inflammatory side effects. Proven efficacy in humans would allow surgeons to perform the potentially safer LASEK/PRK procedures whilst dramatically reducing the pain and healing time.

*Multi-wavelength lasers*

Today's ophthalmologists use three different lasers for different surgical procedures, ie. UV laser to correct vision, Nd YAG for capsule operations and green laser to coagulate blood vessels in the retina. CustomVis will assess the viability of producing a combined laser offering all three types of beam, reducing costs and space requirements for doctors and clinics.

The Company believes that by improving the diagnostic devices required for laser vision surgery, it will improve the precision, accuracy and reliability of the treatment and further support the business model being pursued by the Company.

**Manufacturing**

Due to the high level of technical expertise and the relatively low cost of production, the manufacturing and production of the CustomVis™ System is currently undertaken in Balcatta, Western Australia, an industrial area just outside the city of Perth. The manufacturing process is being overseen by Richard Gilroy, the recently appointed production manager, who has over 25 years of experience setting up and managing quality and manufacturing systems in medical technology.

Although the CustomVis™ System has only been produced as a functioning prototype, the CustomVis laser has an established protocol for assembly, testing and evaluation. For IP protection and quality control reasons, CustomVis intends to retain in-house the key production processes such as the final assembly of parts, installation and testing of software, installation of optics and the alignment of the system. Further, it is intended that the final tests and commissioning of the system, which are critical to system performance and quality control, will also be conducted in-house by highly trained personnel, including Dr Paul van Saarloos. The Company will further protect its software and key components through encryption and software dongles.

The key components of the CustomVis™ System are the crystals, the laser parts, the optics and the diode pump module. To mitigate any reliance on any one supplier, the Company has existing relationships with a minimum of two suppliers for each of these key components (other than the diode pump module). In addition, the Company intends to maintain an appropriate number of key components in stock to mitigate any supplier risk.

A critical issue in refractive laser production involves quality control and the Company's strategy is to manufacture and deploy products as they have the capacity to support and service them in the field. To ensure continued production quality, the CustomVis Operations Board is carefully increasing production to meet expectations of patient trials, doctor-perceived service quality, as well as commercial requirements. The Company's manufacturing and quality assurance teams have extensive experience in increasing production in technology in general and medical lasers in particular.

As commercial production of the CustomVis™ System increases, the scope for outsourcing for additional mechanical components increases. The Company's location facilitates outsourcing of non-critical mechanical and electronic components, the recruitment of technical product assembly, testing staff and delivery and shipment of lasers and components. The physical plant has been recently refurbished for the purposes of laser assembly. It consists of 800 sq metres of space, separately segregated for compliance with CE mark and TGA quality and regulatory regimes. The site currently accommodates 25 employees but could be increased to accommodate up to 45 employees.

**Market strategy and opportunities**

Technology is a key driver of new laser system sales and with the smallest spot size, fastest pulse rate, fastest eye-tracker and other solid state advantages, the Directors believe that the CustomVis™ System is currently the only system on the market capable of delivering the full requirements of customised surgery. Surgeons and opinion leaders in the LVC industry are continually looking for new technology to enhance their offering and many of these are ready to embrace the CustomVis™ System.

The most common form of LVC surgery is the use of excimer laser technology, however the Directors believe that this technology is approaching the end of its product development cycle and as such the ability to perform high quality custom laser treatment is proving difficult. This is due to inadequacies in some eye tracking technologies, current average pulse rates and/or beam spot sizes. The CustomVis™ System has been designed to address these issues and answer the requirements of effective custom surgery.

With the incidence of common disorders such as myopia and hyperopia increasing, a large proportion of the world's population are now potential candidates for LVC surgery. To date, approximately 2 per cent. of the £2.4 billion per annum worldwide target market has been treated.

Custom surgery is a largely untapped market, currently representing some 15 – 20 per cent. of the total market, or approximately £400 million out of the £2.4 billion annual global procedures revenue.

*Europe and Middle East*

The market continues to show steady growth in both Western and Eastern Europe. Leading ophthalmologists are often associated with university clinics and are important opinion leaders in the industry. These leading clinics represent a significant market opportunity through higher prices and the desire of the leading clinics to offer custom treatment in order to differentiate themselves.

*Asia Pacific and India*

Outside of the United States, the Asia Pacific region is the second largest global market for LVC, with myopia being more prevalent in a number of Asian countries than the United States. The fastest growing markets in the Asia Pacific region include Korea and China. The Indian economy has shown steady growth in recent years and, in line with the improving economic environment, the number of LVC treatments has continued to increase.

*North America, South America and Canada*

This is the largest of the current LVC regions and continues to show steady growth. A critical success component to sales in South America and Canada is financing arrangements. The Company is investigating options for equipment financing to ensure under-capitalised ophthalmologists, especially prevalent in South America, have access to its products.

**Marketing and sales**

CustomVis will use a combination of direct and agent distribution and service models depending on the general practice of the market involved. Over time, CustomVis and its senior management team have established excellent worldwide relationships with leading ophthalmologists and respected agencies which it is anticipated will provide the base for the distribution network. All commercial activity worldwide will be managed by Simon Gordon, the Managing Director, who is based in the Company's European office.

*Europe, Middle East and Africa*

CustomVis will use a combination of direct and agent distribution in Europe, Middle East and Africa. Simon Gordon will drive the direct sales and distribution processes. Agents will also be appointed in some markets. These operations will be serviced from the UK.

*Asian Pacific and India*

Asia Pacific and Indian markets will be addressed through licensed agents. Several potential agents have already been identified by CustomVis and discussions are currently underway to finalise distribution agreements. A draft agreement with a Korean distributor is currently under discussion.

*North America, South America and Canada*

The US market will be approached using a direct sales method based on geographic areas. The Company will retain several experienced sales people over the next 2 years so that the distribution network is operational before FDA approval is achieved. Custom Lasers Inc currently holds the distribution rights to the US, Canada, Mexico, Latin America and Caribbean regions and is scaling up distribution capability.

**Competition**

The Company faces direct competition from companies with other laser-based refractive surgery systems. Due to the relatively rapid growth in uptake of refractive surgery, there are an increasing number of these laser-based systems available to the market. Most of these systems have been available for at least a year and incorporate the use of an excimer laser. However, the Directors believe that to date, no potentially competitive system based around the use of solid state lasers has been developed which has progressed to clinical trials in humans. A summary of potential competitors' systems is outlined in Figure 1 below:

**Figure 1: Comparative table**

| Company<br>Laser system | Laser | | | | Eye tracker | | |
|---|---|---|---|---|---|---|---|
| | Solid State | Pulse rate (Hz) | Spot size (mm) | Shape | Detection rate (Hz) | Response rate (Hz) | Delay time (ms) |
| **CustomVis**<br>CustomVis™ | Yes | 300 | 0.6 | Gaussian | 5,000 | 1,000 | 0.5 |
| **Alcon**<br>LADARvision 4000 | No | 60 | 0.8 – 0.9 | Gaussian | 4,000 | 100 | 6-8 |
| **VISX**<br>Star S3 | No | 10 | Varies 0.65 to 6.5 | 7-beam array | 60 | 60 | — |
| **Bausch & Lomb**<br>Technolas 217z Zyoptix | No | 50 | 1.0 – 2.0 | Truncated Gaussian | 120 | 120 | 11 |
| **Nidek**<br>EC-5000 | No | 5-50 | 7.5 × 2 + 1 | Quasi-gaussian | 200 | 200 | 6 |
| **LaserSight**<br>LaserScan LSX | No | 200 | 0.8 – 1.0 | Gaussian | 200 | 200 | 8 |
| **Asclepion Meditech**<br>MEL 70, G-Scan | No | 35-50 | 1.8 | Gaussian | 50 | 50 | 10 |

Information derived from various sources including company websites and Spectrum Consulting 2002, and believed by the Directors to be correct at time of printing.

Further information on potential competitors for the Company is as follows:

*Alcon Inc*

The core technology behind the success of Alcon is the LADARVision® technology which was originally developed by Autonomous Inc.. In 1998 Autonomous Inc., for whom Simon Gordon was then working, was purchased by Summit Autonomous Inc. for approximately US$200 million. In September 2000 Alcon subsequently purchased Summit Autonomous Inc. for a consideration of approximately US$900 million. Simon Gordon, the Managing Director of CustomVis, was involved with Autonomous from a very early stage in its development. Mr Gordon invested in and joined Autonomous in 1995, when only a few of its prototype systems were in place. Mr Gordon was the director of sales and marketing for Europe and was also a member of the Autonomous strategy team. During this time he helped place systems at high profile universities around Europe and helped drive the commercial sales of the product.

Alcon produces one of the most advanced systems currently on the market, the LADARVision 4000 Excimer Laser System incorporating the LADARWave Wavefront device. This product provides a combination of a small spot gaussian beam and a fast eye tracker. The tracker samples at 4,000 times per second (4kHz) and has a closed-loop bandwidth of 100Hz-120Hz, allowing adjustments to be made 100 times per second.

On 1 August 2002, the FDA Ophthalmic Devices Panel recommended approval of the Alcon customised wavefront-guided excimer laser eye surgery application for low level myopia only (between 0 and −7 dioptres). This demonstrates that the FDA is prepared to approve custom surgery technology, however the Directors believe that the Alcon system does not specifically address the irregular eyes or cases of astigmatism which the CustomVis™ System is designed to treat.

*VISX Inc*

VISX has developed its Star S3 ActiveTrak™ Excimer Laser System. The Star S3 incorporates variable spot scanning, allowing the beam to change size and shape to compensate for this laser's slow pulse repetition rate during standard treatments and a 3D tracker.

The system incorporates the Star S3 ActiveTrak™ System together with a Carl Zeiss Ophthalmic Systems Humphrey® ATLAS™ corneal topographer and associated VisionPro™ Ablation Planning Software.

*Bausch & Lomb Inc*

Bausch & Lomb has recently obtained FDA approval for its Zyoptix System for Customized Vision Correction. The system combines the upgraded Technolas 217z excimer laser with the diagnostic capabilities of the new Zyoptix Diagnostic Workstation, Zylink Customised Treatment Calculation software and the Hansatome Microkeratome. The scanner and laser are linked through specialist software developed for the system. The Bausch & Lomb laser has a minimum spot size of 1mm diameter and a pulse rate of 50 Hz.

*Nidek Co Ltd*

The Nidek laser, the EC-5000 CXII Excimer Laser System, is based on a scanning slit laser beam with shaping performed by the type of masks used in large beam laser systems. In the Directors' opinion this type of technology is difficult to adapt for custom treatments.

*LaserSight Inc*

LaserSight's products include excimer laser systems, software for custom ablation planning and programming, diagnostic products and microkeratomes.

*Carl Zeiss Meditec AG*

The Meditec MEL 70 G-Scan Excimer Laser system combines topography and wavefront technology.

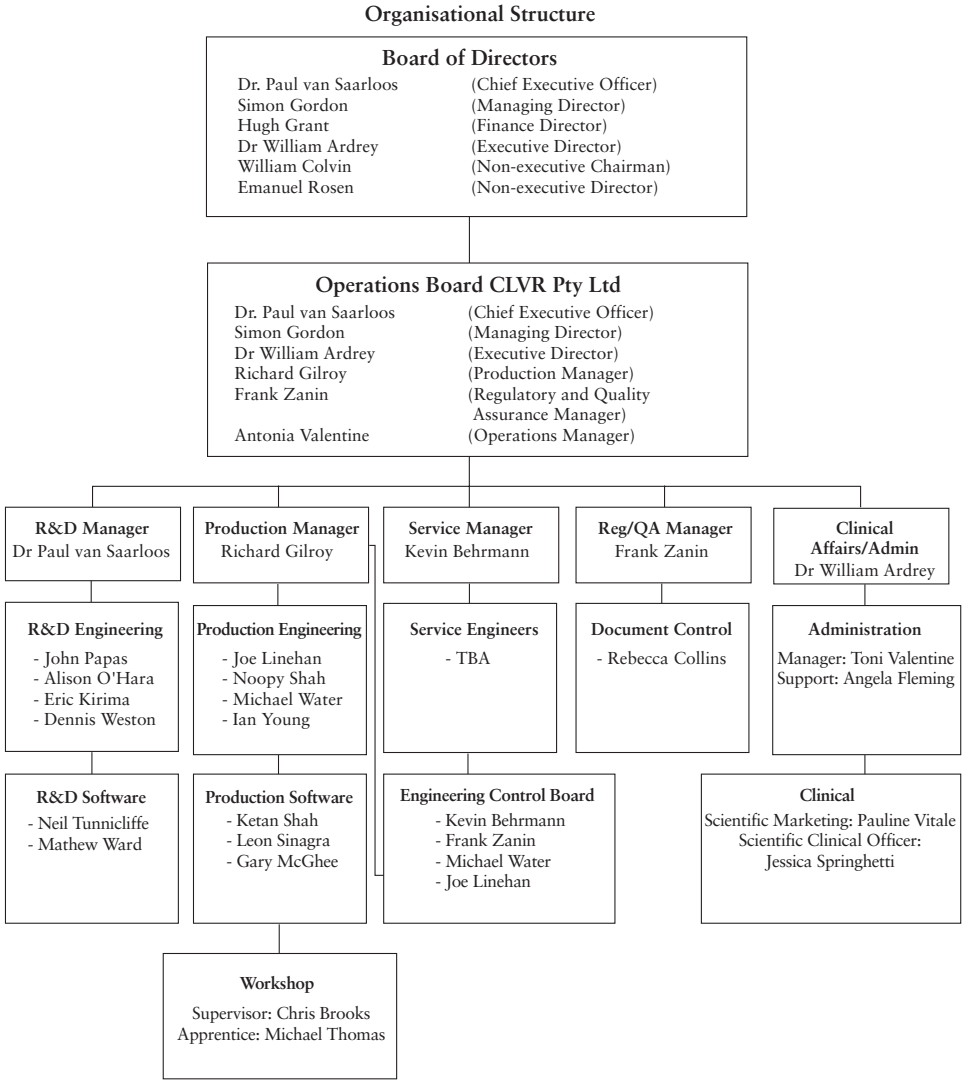
There are a number of other smaller companies who may be potential competitors for the Company but who currently have a minimal global market share within the LVC market and as such the Company does not envisage that these companies are currently a significant threat to the custom surgery market.

Further information on the above competitors is more particularly described in the expert's report in Part IV of this document.

**Organisational structure**

CustomVis currently employs 26 people in Dundee, Scotland and Perth, Western Australia. The Company intends to run its management activities through the European office in Dundee with both the Managing Director and the Finance Director based there. Production and manufacturing aspects of the business will continue to be run through Perth, Australia where the Chief Executive Officer and local production manager are based. The Company has introduced an Operations Board to ensure the continued high quality and safe production of the CustomVis™ System.

The organisational structure of the Group is as follows:




**Directors, senior management and employees**

***CustomVis Directors***

***Executive Directors***

**Dr. Paul van Saarloos** *(Chief Executive Officer)*, aged 41, has significant experience managing medical technology companies and creating patented, commercially successful products in the field of refractive surgery. He holds over 100 patents, has co-authored over 30 published scientific papers in the area of ophthalmic technology, and has developed, patented and commercialised numerous technologies (e.g. Zeiss Humphrey Atlas topographer; Dishler laser; Q-Vis laser). Dr. Paul van Saarloos previously served as managing director of Q-Vis, as a researcher at the Lion's Eye Institute, and as a laser physicist for numerous medical technology companies involved in ophthalmology. In addition to his CEO position, he also performs the roles of Chief Scientist and Research & Development manager on the CLVR Operations Board.

**Simon Gordon** *(Managing Director)*, aged 49, has extensive skills in commercialising and marketing refractive lasers, with experience in sales, marketing and product development at such firms as Lasersight, Q-Vis and Autonomous Inc. He has extensive experience managing medical companies. Mr Gordon also acts in the capacity of chief operating officer for CustomVis™, as well as managing the European business for the Group.

**Hugh Grant** *(Finance Director)*, aged 45, is currently a partner of the accounting firm Findlay & Company with whom he has been employed since 1991. He has experience on regulatory and corporate finance matters, including advising in the medical healthcare sector. He is an accredited expert witness with the Law Society of Scotland and sits on the Committee for Authorisation of Student Training Offices of the Institute of Chartered Accountants of Scotland, having previously sat on the Committee for Student Education. Mr Grant will devote eighty per cent. of his working time with CustomVis. He will however, retain his partnership with Findlay & Company.

**Dr William Ardrey** *(Executive Director),* aged 37, has served as president, CEO, CFO and marketing director of a number of companies in the medical and technology fields. He has led 5 technology companies from start-up to trade sales, and served as a president at Thomson Financial Services, a US$2 billion publicly listed financial information provider. Dr William Ardrey is also a widely published author on marketing and strategy, and a frequent visiting professor at such universities as Columbia University, George Washington University, University of Adelaide and University of Western Australia. He also serves on the CLVR Operating Board.

***Non-Executive Directors***

**William Colvin** *(Non-executive Chairman)*, aged 45, is currently Chief Executive of NHP plc, a quoted nursing home owner and operator, whose market capitalisation has significantly increased since he was appointed Chief Executive in November 2000. He 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 is a Scottish Chartered Accountant.

**Emanuel Rosen** *(Non-executive Director),* aged 67, is currently the medical director of the Boots Opticians Eye Laser Service. He is also president of the International Implant Club and a past president of both The European Society of Cataract and Refractive Surgeons and the UK and Ireland Society of Cataract and Refractive Surgeons. Mr Rosen has over 35 years of experience in the medical field and is also the author and editor of a number of publications.

Further details of the Directors are set out in paragraph 6 of Part IX.

***CLVR Operations Board***

In addition to Dr. Paul van Saarloos, Simon Gordon and Dr. William Ardrey:

**Richard Gilroy** *(Production Manager),* aged 50, is responsible for mechtronic engineering and initial production of laser systems. He has over 25 years of experience setting up and managing quality systems and manufacturing systems in medical technology, medical products and pharmaceuticals. Mr Gilroy's principal experience as an engineering manager involved establishing and running quality systems of Uniliver, under medical and sterility regimes as well as under the company's best practice quality management system. At CustomVis, he has been instrumental in leading the upgrades to the quality management system necessary to both meet regulatory approvals, and to move the production side of the business into manufacturing mode able to meet the milestones demanded by the business plans.

**Frank Zanin** *(Regulatory and Quality Assurance Manager)*, aged 48, has three years experience in the refractive surgery industry. He previously worked in Switzerland for eight years with Ascon-Ericsson as technical quality manager. At CustomVis he is responsible for quality assurance and general regulatory affairs.

**Antonia Valentine** *(Operations Manager)*, aged 32, has seven years experience in accounts and financial management. Since working at CustomVis, she has set up the Company's computer accounting system. She also manages the administration of the Perth office and provides secretarial support to Dr Paul van Saarloos.

Interviews for the role of financial controller have recently been held and a suitable candidate has been offered the position.

*Senior Technical Employees*

**Mr John Papas** *(Senior Design Engineer),* aged 46, is responsible for mechanical and mechtronics design, mechnical and optical systems design. He has over 20 years of experience as a mechanical design engineer for the design of systems ranging from safety systems to laser fluorescence test measurement equipment. Previous experience includes such companies as Safe Effect Technologies, Orbital Engines, MEMTEC and Western Mining.

**Kevin Behrmann** *(R&D Electronic Engineering Manager)*, aged 34, has since the inception of the Company been managing the electrical and electronics department, which is involved in design and manufacture. His roles have recently been expanded to include establishing a service and training function for CustomVis. His experience and background are in engineering and laser service and he serves as CustomVis laser safety officer. Mr Behrmann was involved with Q-Vis for eight years in the research and production of medical laser systems dealing with eye surgery including four years servicing lasers and managing the service department.

**Ketan Shah** *(Senior Software Engineer),* aged 33, has maintained computer networks for German non-government organisations in Africa and private and public entities in Australia. Mr Shah is currently the product manager for the "ZCAD" surgical planning software. He also assists in general marketing support for new products and enhancements and managed the software documentation programmes in preparation of the various regulatory approval audits.

**Leon Sinagra** *(Senior Software Engineer)*, aged 38, is a senior programmer/software manager and is involved in writing the software that controls the CustomVis laser. He is also responsible for testing and evaluating any software upgrades and has provided on-site support for early clinical trials.

*Other Key Employees*

**Alison O'Hara** *(Electronics Engineer),* aged 28, is responsible at CustomVis for research, development, establishment of design specifications and the quality management system requirements. Alison has worked within ISO 9001 QMS regimes at such companies as QMAC Electronics, IHG Technologies and MITS.

**Jessica Springbett** *(Scientific Officer),* aged 24, is responsible for clinical affairs and regulatory issues. At CustomVis she is responsible for analysis of laser treatment profiles on PMMA and on animal eyes, concurrent to general support for clinical trials and ethics committee protocols submissions.

**Gary McGhee** *(Software Engineer)*, aged 32, is the main developer of the ZCAD product and provides expertise on the development of the software process in general with particular focus on the QA and user interface software.

**Matthew Ward** *(Junior Software Engineer),* aged 22, brings experience gained in the Intelligent Information Processing department at University of Western Australia, as well as at Alias Internet, to CustomVis. In 2002, Matthew graduated from University of Western Australia with an Honour's degree in software engineering in 2002.

**Neil Tunnicliffe** *(Junior Software Engineer),* aged 22, brings experience as a software tutor at University of Western Australia to CustomVis including programming skills ranging from C/C++ to Java and SQL. Neil graduated with Honours from University of Western Australia in 2002, and brings experience gained as a software designer at Isopar Pty Ltd and IHG Limited.

**Pauline Vitale** *(Scientific Researcher)*, aged 22, joined CustomVis in December 2002. Ms Vitale designs and conducts laboratory experiments, preparing scientific presentations for conferences, managing the scheduling of scientific deadlines, writing up scientific documents/literature reviews for the purpose of regulatory approvals and collaborating with UWA for the application of research grants. She has managed the preparation and publication of 13 peer reviewed scientific publications, ranging from the European Academy of Cataract & Refractive Surgery Proceedings to the American Academy of Ophthalmology Proceedings.

**Current trading and prospects**

CustomVis unveiled the prototype of the CustomVis™ System in November 2002 at the American Academy of Ophthalmology conference in Orlando, Florida. Following what the Directors believe to have been the first ever successful laser treatments of highly irregular astigmatisms, the Company has recently commenced the second set of patient treatments.

Having received confirmation from TGA of its intention to issue both the CE mark and TGA approval, the Company aims to manufacture and distribute the CustomVis™ System throughout the UK, Europe, Asia Pacific, Latin America and Australasia. Discussions have been held with several leading opinion forming refractive surgeons across various countries. These have resulted in orders being placed for these new systems (equivalent to the first six months' production) and further interest has been received in relation to additional sales of new systems.

The Company has retained a leading FDA investigating body "The Center for Clinical Research" in Chicago to engage top FDA investigators and global trial doctors, finalise FDA protocols and advise the Company through the regulatory process in the United States. The Company has commenced discussions with the FDA surrounding the necessary protocols required for patient trials and anticipates completion of the FDA approval process during 2006.

**Reasons for the Placing and use of proceeds**

The Placing will raise approximately £10 million, net of expenses, for the Company. These proceeds will be used to increase the scale and production capacity for the CustomVis™ System and further expand the existing sales, service and marketing infrastructure. If required, part of these proceeds will also be used to redeem the Loan Notes. To maintain competitive advantage, the Directors will also use a portion of the funds for further research and development.

The Directors believe that the increased financial resources and enhanced profile of the Company within the market place will further enable CustomVis to develop and commercialise it's CustomVis™ System.

Admission to AIM will also provide opportunities for the Company's employees to participate in the future success of the Company, through the benefit of the proposed employee share option scheme.

## PART II

## Placing, Admission and related matters

**The Placing**

The Company is issuing 12,637,363 new Ordinary Shares pursuant to the Placing at the Placing Price, which will raise approximately £10 million (net of expenses) for the Company and will represent approximately 36.4 per cent. of the enlarged issued share capital following the Placing. The Placing Shares have been placed by Collins Stewart with institutional and other investors.

The Placing is conditional upon Admission becoming effective and the Placing Agreement becoming unconditional in all respects. Details of the Placing Agreement are contained in paragraph 11.6 of Part IX of this document.

There are no existing shareholders who are selling shares pursuant to the Placing. Following the Placing, it is expected that the interests of the Directors will, in aggregate, amount to 43.1 per cent. of the issued share capital.

**Lock-in arrangements**

The Directors and Novamed Limited (a company controlled by Simon Gordon, one of the directors) have undertaken to the Company and Collins Stewart not to dispose of any interest which they have in the share capital of the Company for a period of two years after Admission or, if earlier, until such date as the Company announces an interim profit for the six month period to 31 December 2004. The Directors and Novamed Limited have also given orderly marketing undertakings to the Company and Collins Stewart for the 12 months following the end of the lock-in arrangements.

Jennifer van Saarloos, Custom Lasers Inc, Asian Lasers Inc and Moksh Pty Ltd, who together hold approximately 27.1 per cent. of the issued share capital of the Company following the Placing, have each entered into a lock-in agreement with the Company and Collins Stewart pursuant to which they have agreed not to dispose of any of the Ordinary Shares held by them for a period of 12 months after Admission. These Shareholders have also agreed to orderly marketing undertakings to the Company and Collins Stewart for the 12 months following the end of the lock-in arrangements.

All remaining existing Shareholders (other than the trustees of the Thorstone (S.E.) Retirement and Death Benefit Scheme) have entered into orderly marketing undertakings with the Company and Collins Stewart pursuant to which, *inter alia*, they have agreed not to sell any Ordinary Shares for a period of 12 months following Admission without first seeking to sell them through the Company's broker.

**Corporate governance**

The Company intends to comply, as soon as practicable and so far as possible given the Group's size and the constitution of the Board, with the Combined Code.

The audit committee has been appointed and consists of William Colvin and Emanuel Rosen although the Finance Director will normally attend as an invitee. It will meet twice a year and be responsible for ensuring that the financial performance of the Group is properly reported on and monitored. It will also meet the auditors and review their reports relating to accounts and internal control systems.

Similarly, the remuneration committee has been appointed and consists of William Colvin and Emanuel Rosen although the Chief Executive Officer will normally attend as an invitee (except when his own remuneration is being considered). It will make recommendations to the Directors of the Company on matters relating to the remuneration and terms of employment of the existing and proposed Executive Directors of the Company and on proposals for the granting of share options pursuant to any share option scheme in operation from time to time.

**CREST**

CREST is a paperless settlement procedure enabling securities to be evidenced otherwise than by a certificate and transferred otherwise than by a written instrument. The Articles of Association of the Company permit the holding of Ordinary Shares under the CREST system. All the Ordinary Shares will be in registered form and no temporary documents of title will be issued. The Company has applied for the Ordinary Shares to be admitted to CREST and it is expected that the Ordinary Shares will be so admitted and accordingly enabled for settlement in CREST on the date of Admission. It is expected that Admission will become effective and dealings in Ordinary Shares will commence on 8 July 2003. Accordingly, settlement of transactions in the Ordinary Shares following Admission may take place within the CREST system if any shareholder so wishes.

**US securities legislation and no offer to Australia**

The Ordinary Shares have not been and will not be registered under the US Securities Act of 1933, as amended and may not be offered or sold within the United States.

Notwithstanding the Group's connections with Australia, the Ordinary Shares have not been and will not be offered for sale under the applicable laws of Australia or any of its states and may not be offered or sold within Australia.

**Share option scheme**

The Directors believe that the success of the Group will depend to a high degree on the future performance of the management team. The Directors also recognise the importance of ensuring that all employees are well motivated and identify closely with the success of the Group.

Accordingly, it is intended that the Company will establish new share option incentive arrangements for the Directors and staff following Admission. To the extent that it will be applicable to employees of the Group, the Company has received an advance confirmation from the Inland Revenue that the Company meets the qualifying company requirements of the Enterprise Management Incentive legislation. Further details of the proposed share option scheme are set out in paragraph 9 of Part IX of this document.

**Further information**

Your attention is drawn to the additional information set out in Parts III to IX of this document.

## PART III

## Risk factors

Investors should consider carefully whether investment in the Ordinary Shares is suitable for them in the light of the information in this document and their personal circumstances. Before making any final decision, prospective investors in any doubt should consult with an investment adviser authorised under the Financial Services and Markets Act 2000. If any of the following risks were to materialise, the Group's business, financial condition, results or future operations could be materially adversely affected. In such case, the market price of the Ordinary Shares could decline and an investor may lose all or part of his investment. Additional risks and uncertainties not presently known to the Directors, or which the Directors currently deem immaterial, may also have an adverse effect upon the Company.

**The following list of risks is not intended to be exhaustive. In particular investors should consider the following:**

### Intellectual property

The Company is in the early stages of its development. It will be essential for the success of the Company to obtain and secure patents for its products and processes. Currently the Company has pending patent applications and no assurance can be given whether such applications will result in the issue of patents or whether issued patents will provide necessary protection or will be circumvented or invalidated. Further, some of the technology (including its manufacturing process) is know-how protected as trade secrets and/or under confidentiality agreements. The Company does not believe that such know-how infringes the proprietary rights of any third party.

The LVC industry has historically been highly litigious and it is possible that competitors may try to claim that CustomVis infringes their patents and may seek injunctions and/or damages against the Company. No assurance can be given that CustomVis will not be subject to claims for infringement of patents or other intellectual property rights of others. If such proceedings were initiated, the Company's defence of its proprietary rights could involve substantial costs and management time.

VISX is expecting to unveil its iris registration method for cyclotorsional rotation later in 2003. As noted in Part IV, this technology may appear to have similarities to that employed by CustomVis.

The Company will need to establish and enforce in relevant jurisdictions intellectual property rights relating to the development, manufacture, use and sale of products. Further, the Company may sell its products in countries where intellectual property rights are not afforded the same protection as in the United States and Europe.

### Technical risks

While clinical findings from the six patients treated to date are encouraging, and the expectations of clinicians regarding this technology are high, insufficient clinical data is currently available to make any meaningful assessment of the overall performance of the system relative to CustomVis's expectations. It is not guaranteed that results in larger scale clinical trials will generate such results equivalent to those for the initial clinical trials. Although initial limited trials have produced good pre-clinical and preliminary clinical testing results, the CustomVis™ System is a new product with potential unknown risks.

### Clinical and regulatory approval

FDA approval allowing for sales of the CustomVis™ System in the United States is not guaranteed, for either the myopia category or the irregular astigmatism category. Several factors could contribute to the potential delay or inability to gain this approval, particularly for use in the irregular astigmatism category. This category has additional risks in that the FDA has not developed a guidance document in relation to such treatment and therefore their requirements could change. Also no other companies have yet been granted FDA approval for custom surgery in irregular astigmatism, so uncertainty about time to approval is greater.

For both groups of patients, being either from the myopia or irregular astigmatism category, study centres both within and outside of the United States will need to be established and then monitored to the same high standards to ensure similarly high quality of data and compliance with protocol requirements. Failure to ensure this may jeopardise the acceptability of the studies for FDA approval purposes. While six months follow up of patients in the clinical studies is anticipated, and in fact may be shorter, this cannot be assured until further experience has been gained. It is possible that longer follow-up studies will be necessary for refractive stability, with a knock-on effect to the study completion. Additionally patients may be lost from the study causing a delay.

In preclinical studies of the mutagenicity of the CustomVis 213nm laser greater mutagenicity has been found compared with the current 193nm lasers in two separate studies. These findings are thought to be due to study design issues. Whilst this may be true, regulators may require further data from studies designed specifically to overcome the difficulties arising from the differences in absorption of the 193 nm and 213 nm beams caused by differences in hydration levels. However no such concerns have been raised to date and there is data to support the general safety of lasers in the 190nm-220nm range.

**Manufacturing**

The Company currently has no proven commercial manufacturing capability. It has only produced prototype machines to date. There is a requirement to establish quickly a production facility capable of commercial manufacturing. The Directors anticipate that expenditure, management resources and time will be required to develop these capabilities. The Company's ability to put this structure in place will, amongst other features, depend on management know-how, allocation of resources, inventiveness of the Group and maintaning and developing relationships with key suppliers and other collaborating organisations.

Loss of the Company's manufacturing facility through fire or other causes could have an adverse effect on the Company's product development and business.

**Distribution**

The Group has only limited distribution arrangements in place at the time of Admission.

To achieve an efficient distribution structure throughout the world will require strategic alliances which have yet to be formed in certain jurisdictions. Negotiations of appropriate terms have yet to be undertaken.

This process will require the need to establish quality testing, safety standards testing, exporting to multiple countries, installation and training of distributors.

**Commercial**

The growth and profitability of the Group will be influenced by the acceptance of laser vision correction surgery and its ability to penetrate this market in the US, Europe and Asia. There can be no assurance that the LVC surgery will be a widely accepted method of treating refractive disorders. Such acceptance may also be adversely affected by cost, safety and effectiveness concerns, a general resistance to laser surgery, the lack of data surrounding such procedures and the possibility of unknown side effects. There can be no assurance that data produced will not reveal defects or complications that may have a material adverse effect on the continuation of LVC surgery.

The Directors believe that commercial success will largely depend on bringing functional, proven and differentiated technology to market. Similarly, no assurance can be given that technologies that are introduced by competitors, which may be perceived to be superior in clinical terms or technologically more advanced or economically more appealing, will not render the Group's product offering obsolete and have a material adverse effect of the business of the Group.

The downturn in the number of LVC procedures completed in 2000-2002 may continue in to 2003-2004 since the market for LVC correction is very much driven by the economy and may be affected by the general downturn in the global economic environment.

CustomVis currently uses what the Directors consider to be one of the best topography systems, the Bausch and Lomb Orbscan. It is possible that Bausch and Lomb might deny them the use of the Orbscan topographer in future as they view CustomVis as a serious competitor.

CustomVis regards the Tracey wavefront system as the best on the market currently and would like to use it in the CustomVis™ System. Tracey and VISX have recently signed a collaborative agreement for use of the Tracey system for the 193 wavelength excimer laser, but this agreement does not extend to the 213mm wavelength used by the CustomVis™ System.

**Competitors**

CustomVis faces direct competition from companies with other laser-based refractive surgery systems. Due to the relatively rapid growth in uptake of refractive surgery there are an increasing number of these laser-based systems available to the market. Most of these systems have been available for at least a year.

Although the Directors believe that no solid state laser system, other than the CustomVis™ System, has reached clinical trials in humans, there are certain companies with interests in the LVC field that may be positioned to develop similar systems in the future. Although these companies may not have shown any intent so far to develop such a system they have the in-house technologies that could assist a transition into this market. However, solid state lasers have proven to be technically difficult to develop.

**Retention of key employees**

The Group is heavily reliant upon its Chief Executive Officer and Managing Director and the skills of its management and scientific team and the loss of any of these key members of staff could reduce the Group's ability to achieve its planned development objectives. The Group has endeavoured to ensure that the principal members of its management and scientific team are incentivised, but the retention of such staff cannot be guaranteed.

**Product liability and insurance**

CustomVis's business exposes it to potential product liability risks which are inherent in research and preclinical study, clinical trials, manufacturing, marketing and the use of ophthalmic products. In addition, it is necessary for CustomVis to secure certain levels of insurance as a condition to the conduct of clinical trials. There can be no assurance that adequate or necessary insurance coverage will be available at an acceptable cost or in sufficient amounts or that, in the event of a claim, the level of insurance carried by the Group now or in the future will be adequate or that a liability or other claim would not materially and adversely affect the business.

**Share price volatility and liquidity**

The share price of publicly traded, emerging companies can be highly volatile. The price at which the Ordinary Shares are quoted and the price which investors may realise for their Ordinary Shares will be influenced by a large number of factors, some specific to the Group and its operations and some which may affect the quoted medical technology sector or quoted companies generally. These factors could include the performance of CustomVis's research and development programmes, its sales and manufacturing performance, large purchases or sales of the Ordinary Shares, currency fluctuations, legislative changes in the healthcare environment and general economic conditions.

Prior to Admission, there has been no public market for the Ordinary Shares and there is no guarantee that an active trading market will develop or be sustained after Admission.

**Fluctuation of operating results**

The operating results of the Group may fluctuate significantly as a result of a variety of factors, many of which are outside CustomVis's control. Period-to-period comparisons of the Group's operating results may not be meaningful and investors should not rely on them as indications of the Group's future performance. CustomVis's operating results may fall below the expectations of securities analysts and investors. In that event, the trading price of the Ordinary Shares would almost certainly fall.

## PART IV

## Expert's report


The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London
EC2M 4YH

and

The Directors
Collins Stewart Limited
9th Floor
88 Wood Street
London
EC2V 7QR

2 July 2003

Dear Sirs

Bridgehead Technologies Ltd ("Bridgehead"), now part of the Bridgehead Pharmalicensing Group Limited, is a privately owned company established in 1995. It is a leading consultancy specialising in the assessment of healthcare companies, projects, products and markets and assisting in their development. Over the past 5 years Bridgehead has prepared public and private placing documents for development stage biotechnology, pharmaceutical and life sciences companies. In addition many due diligence assignments have been successfully completed on behalf of international investors. Bridgehead employs specialists with knowledge of science, technology, product development, markets and business issues in medicine and life sciences. Bridgehead has been instructed by CustomVis plc ("The Company" or "CustomVis") to assess and review certain aspects of its business namely:

*For the CustomVis™ Corneal Reshaping System ("The CustomVis™ System")*, which integrates a number of technology advantages such as use of a solid state laser, solid state scanning, rapid eye movement tracking and integration of diagnostic data into a surgical planning and execution system:

- Key technical merits/risks and competitive position, considering:
    - comparison with other systems for laser vision correction (LVC)
    - the potential advantages of the CustomVis solid state laser as compared with the generally used excimer-based lasers
    - competition from alternatives to currently used LVC techniques
    - clinical risks.

- Development programme, timing, cost, adequacy for marketing authorisation in Europe and the US
- Market potential, drivers and constraints
- Commercial issues around the IP position
- Commercial strategy for the CustomVis™ System in Europe and the US
- Achievability of business plans

*For other projects in the R&D and commercial plan:*

- Brief consideration of the achievability of any projections in the business plan

*For the Company*

- The risk factors which might affect CustomVis's business plan and any mitigating activities/plans which have been carried out or planned.

In preparing this report Bridgehead's consultants have conducted interviews with some of the key Company staff and officers, with the Company's clinical investigators, with the Company's regulatory consultants, reviewed the documentation provided by the Company such as the information memorandum, project plans, flow charts, process engineering cost estimates; and assessed its activities with reference to the proprietary knowledge base possessed by Bridgehead. In addition, the documentation supplied by the Company has been supplemented by Bridgehead's own interviews with external independent experts.

This report has been prepared with care and due diligence, based upon information provided to Bridgehead at the time of preparation. Bridgehead has no reason to doubt the veracity of such information but Bridgehead has only verified it to the extent indicated above. Changes in circumstances may render such information invalid at any point hereafter. The scope of this report does not address the legal aspects of the Company's operations or its intellectual property. No audit or assessment of facilities was undertaken.

## 1. Background

The Group is currently commercialising its flagship product, "the CustomVis™ System". This addresses the LVC market, also termed the refractive surgery market. LVC surgery is carried out by ophthalmologists using a computer controlled laser beam to alter the shape of the cornea, the front surface of the eye, by ablation (removal of micron thickness layers of corneal tissue). The pattern of the ablation carried out by the laser is determined via a number of diagnostic methods.

Lasers used currently in LVC are generally excimers, which suffer from a number of disadvantages, such as high cost, being based on the use of potentially problematic gases, and difficulty in delivering anything other than a standard vision correction for myopia (short sight) and/or low levels of astigmatism.

The CustomVis™ System represents a step change in technology for LVC. Its design is based on the CEO's composite view of the surgical requirements for effective custom surgery. It incorporates a solid state laser, solid state scanning integrated with rapid eye tracking devices, and the ability to incorporate data from a variety of diagnostic systems into the surgical planning software and process. All these advances enable accurate implementation of the surgical plan developed for any individual eye, allowing a more customised approach to correction of both standard and non-standard vision disorders. The Company is also involved in developing a number of tools for diagnosing the visual pathways of the eye, as well as additional laser products.

### 1.1 *Organisation, management, key staff*

CustomVis currently employs over 25 people at its facility near Perth, Western Australia and two in the UK, with the intention of expanding to three, adding administrative capability. In quarter 4, 2002 the Company leased new facilities in Perth, which provide more space than is currently required and ample room for the production of the initial 15 systems, required by the Company's commercial plan, with the capability of manufacturing up to four systems concurrently.

Bridgehead considers that the Company has assembled senior management, scientific and production teams with recognised experience and excellence in solid state lasers and refractive surgical techniques. The management team's involvement in the industry over the past two decades provides the Company with an extensive network of industry contacts that will be used to drive the commercialisation of the technology. Further details of the Company's organisational structure can be found in Part I of the Prospectus. The board of Directors includes:

*Executive Directors*

- Dr Paul van Saarloos (Chief Executive Officer), who is recognised as a world leader in developing refractive laser technology. He has been responsible for the invention of many of the tools used in the LVC field, e.g. the Carl Zeiss Ophthalmic Systems Humphrey® ATLAS™ corneal topographer, excimer lasers and solid state lasers.

- Simon Gordon (Managing Director), who is regarded as one of the world's pre-eminent sales and marketing people in the LVC industry. He has 26 years experience of sales and marketing within the health care industry with an involvement in the refractive laser business during the last 12 – 13 years.

- Hugh Grant (Finance Director), is currently a partner with the accounting firm Findlay & Co. He is an accredited expert witness of the Law Society of Scotland and has extensive experience of accountancy.

- Dr William Ardrey (Executive Director), is a professional business accelerator with a long history of successful commercialisation of ophthalmic and other technology. Dr William Ardrey will be developing the Company's business in the US.

*The Non Executive Directors*

- William Colvin (Non-executive Chairman) with extensive experience of operating and developing companies such as CustomVis; and

- Emanuel Rosen (Non-executive Director), who has significant experience in the LVC field in the UK and Europe.

In addition to the management and scientific team the Company has several senior technical employees, see details in Part I of the Prospectus, who have extensive relevant expertise in engineering, laser manufacture, production, quality assurance, software applications, servicing and the LVC industry. Bridgehead understands that the Company has recently employed an experienced production manager whose expertise is seen as critical to the commercial success of the company.

### 1.2 *Significant achievements to date*

Since its first round funding in June 2002, the Company has achieved several important development milestones at relatively low cost, managing the business on approximately AUD$60,000 per month. The Company has received Australian Federal Government grants (BIF Grant, COMET Grant, Research and Development Tax Concession and Export Market Development Grant) totalling almost AUD$527,000.

### 1.3 *Commercialisation strategy*

The Company's first round investors were mainly ophthalmologists running successful LVC practices, with a keen interest in accessing leading edge technology. CustomVis is now developing and evolving the CustomVis™ System by working with a core group of industry experts and key opinion leaders in LVC, including some of the Company's investors. This core group includes leading members of the American Society of Cataract and Refractive Surgeons (ASCRS), the International Society for Refractive Surgery (ISRS) and the European Society of Refractive Surgeons (ESRS). Many of these have been interviewed by Bridgehead and confirmed their belief and interest in the CustomVis approach. Bridgehead considers the advantages of the approach are that it can:

- Enhance the reputation of the Company
- Ensure that the best surgeons are using the CustomVis technology, which validates it to an increasingly educated surgeon and patient base
- Offer the potential to develop and evolve the system based on feedback from a highly skilled user group.

1.4 *Intellectual property*

Bridgehead understands that the technology underpinning the CustomVis™ System is the subject of two provisional patent applications lodged with the Australian Patents Office as follows:

- Solid State UV Laser – filed 30 May 2002; and
- Laser Scanning Method and Apparatus Therefore – filed 28 June 2002.

Protection will be sought in foreign jurisdictions and all necessary steps taken to maintain the applications in force.

CustomVis has two further inventions in the field of "Eye Tracking" and "Laser Structure" that will be the subject of two further provisional patent applications to be filed some time in July 2003. The Company will be filing further patent applications with the intention of supporting its IP position as new technological developments are created from the Company's research and development programme.

The Company believes that if its two currrent and two anticipated patent applications proceed to grant they will provide significant protection of underlying technology and that the Company will be free to use them commercially. In particular, the Company believes that its solid state laser scanning patent will become an industry cornerstone patent in the future, since achieving a comparable total closed loop response time appears impossible without infringing the claims of the patent application.

The Company considers that there is reasonable evidence to suggest that it does not infringe the key scanning patent, United States Patent No. RE37,504 (the '504 Patent') owned by LaserSight and licensed non-exclusively to Alcon and Bausch & Lomb. This covers use of a galvanometer scanner and galvanometric forces to scan a pulsed output laser beam, whilst CustomVis's technology uses a solid state device. The '504 Patent' is currently the key scanning patent in the industry, and LaserSight strictly enforces its rights and charges 'per-use' royalties to licencees. Bridgehead considers that there may be potential for the Company to derive significant revenues from licensing the alternative scanning technology. It could also make the Company an attractive acquisition target for large industry players wishing to avoid paying royalties to LaserSight.

Bridgehead believes that Dr Paul van Saarloos and Simon Gordon have recently reached an agreement pursuant to which they will acquire rights in relation to intellectual property owned by Q-Vis, a public company which was placed in administration late in 2002. The Company's agents confirm that Dr Paul van Saarloos and Mr Gordon intend to make their rights to the Q-Vis intellectual property available to CustomVis via a licence or transfer on arms length commercial terms. More detail on the interactions with Q-Vis is given in Part I and Part IX of the Prospectus.

Additionally, Bridgehead understands that CustomVis™ Systems will be protected by the use of dongles (a physical key which prevents unauthorised use or copying of software code and ensures "per use" revenues are accurately recorded and collected). Registration and protection of product names and trademarks is also underway.

**2. Technology overview**

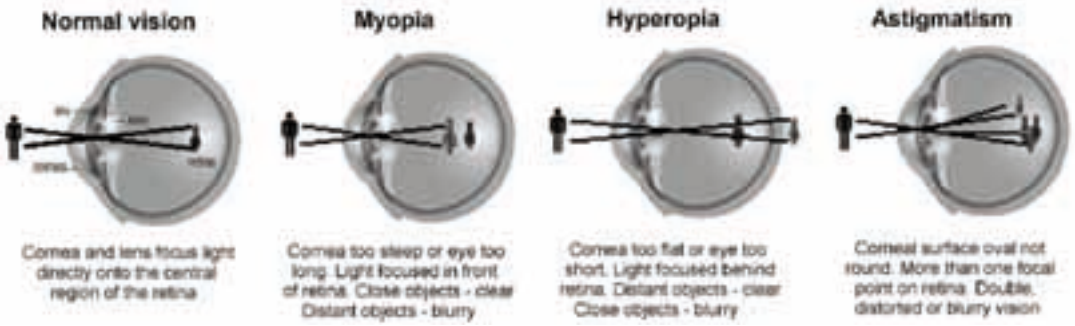
2.1 ***Laser Vision Correction(LVC)***

Historically vision correction has been achieved through prescribing spectacles, contact lenses, intraocular lenses and the use of LVC, where a laser beam is used to reshape the cornea. This corneal reshaping can be carried out using an excimer laser (current LVC systems) or a solid state laser (the CustomVis™ System).

### 2.1.1 Conditions treated by LVC

A number of conditions can be treated by LVC (using excimer or solid state lasers). These include myopia (short sight), hyperopia (long sight) and astigmatism as shown in Figure 1.

**Figure 1: Opthalmologic conditions treatable by LVC**




### 2.1.2 LVC techniques

Three main LVC techniques are in use and are described below. These currently depend on the use of excimer lasers, but the CustomVis solid state system represents an alternative for use with all the techniques and for correction of all the visual abnormalities currently treated with excimer lasers.

*Photorefractive keratectomy (PRK)*

PRK involves scraping away the epithelium from the surface of the cornea and then laser ablation of small amounts of corneal tissue. The procedure takes 1 to 2 minutes following anaesthesia with topical eye drops. Post PRK, a soft contact lens is placed on the eye and left for 3-4 days whilst the ablated epithelium restores itself. There may be mild to moderate discomfort for 1 to 2 days following PRK, because of the healing taking place on the outer layer of the cornea; this is usually controlled with topical or oral medications. Other reported problems include glare, halos and poor night vision. Vision generally improves following PRK over a period of weeks to months. Use of PRK has been in decline, particularly in the US, with the widespread adoption of LASIK.

*Laser in-situ keratomileusis (LASIK)*

In LASIK a microthin flap (stromal flap) is cut in the surface of the cornea which is then ablated by laser. A number of preoperative tests are required to determine whether LASIK is safe and appropriate, particularly to ensure that the cornea is sufficiently thick to allow the flap to be created. A suction ring is placed over the sclera to hold the eye firmly and a microkeratome (device for cutting ultrathin slices) then cuts a thin flap which is hinged back away from the cornea. The laser, which has been previously programmed for the appropriate corneal correction, removes very precise amounts of corneal tissue and the stromal flap is laid back to its original position, where it adheres without the need for sutures. LASIK is rapid, with laser treatment typically taking less than one minute and is generally painless with the use of anaesthetic eye drops. Most patients experience improved vision on the same day as surgery and are able to return to work the next day. Antibiotic eye drops are administered for a week following the procedure to reduce the chance of infection.

*Laser epithelial keratomileusis (LASEK)*

In LASEK, the newest of the refractive surgeries, epithelial cells forming the outer layer of the cornea are gently lifted and folded over, using a mild alcohol solution to loosen the cells. Corneal reshaping with the laser then occurs, the cell layer is repositioned and a soft contact lens placed over the eye for 3-4 days to help keep the cells in place during healing.

There is considerable discussion as to the advantages and disadvantages of the three techniques with proponents of LASEK considering that compared with PRK there is significantly less post-operative discomfort, less risk of infection and a faster recovery. LASEK and PRK also eliminate the stromal flap repositioning problems seen in LASIK and remove risks associated with the use of the microkeratome. LASEK and PRK have the disadvantage of the need to use a soft

contact lens for the first 3 to 4 days after surgery, and the longer corneal healing response and initial visual stability restoration period (3 to 4 days versus 1 to 2 days with LASIK). LASEK and PRK are best suited for people involved in activities or occupations where the possibility of contact with the eye is probable and who cannot risk cutting the stromal flap, e.g. pilots, athletes, or patients with higher myopic values, larger pupils or thinner corneas.

### 2.1.3 Excimer laser LVC systems

Currently reshaping the cornea is achieved with excimer lasers, which use a combination of two gases – a noble gas (e.g. argon) and halogen (e.g. fluorine), both generally stable in their normal low energy state. When a high voltage electrical discharge is delivered into the laser cavity the gases combine to form a higher energy gas state compound. On dissociation of this compound, a photon of energy is released corresponding to the bond energy of the noble gas:halogen molecule. This wavelength of light energy is amplified in the laser system resulting in the production of a discrete high energy pulse of laser energy.

Excimer lasers based on argon and fluorine emit a wavelength of 193 nanometres (nm), which is very well absorbed by the proteins, glycosaminoglycans, and nucleic acids which make up the cornea. Absorption of the laser energy results in breaking of bonds in these molecules and resulting molecular fragments are ejected from the surface of the cornea at supersonic speeds. Thus the excimer laser does not cut tissue like a scalpel; it ablates or removes tissue from the corneal surface, resulting in an effluent plume of high molecular weight hydrocarbons.

The excimer laser is appropriate for corneal sculpting as its energy is very well absorbed near the corneal surface; the ablation process is rapid and excess energy is ejected with the effluent plume, delivering minimal thermal damage to the tissue. With any laser radiation, there is always concern of the potential for mutagenesis or carcinogenesis, but a number of studies have shown this not to be true for the 193nm excimer laser.

The clinical excimer laser system used for LVC comprises gases; power source; laser cavity; beam forming optics; delivery system; aiming system and surgical microscope. For clinical use, the initial broad rectangular beam of irregular energy level delivered from the laser cavity needs to be homogenised to yield a consistent energy over the entire delivery area, to ensure smooth controlled tissue removal. The beam also needs to be masked in two dimensions to the appropriate size and shape. Beam homogenisation and shaping are achieved through a number of beam shaping optics in the optical train of the laser and the use of a diaphragm to deliver a circular spot of chosen diameter.

### 2.1.4 Solid state laser LVC systems

Bridgehead understands that CustomVis is the only company which is close to commercial sale of a system using solid state laser technology to improve on the capabilities of the gas excimer-based LVC systems. The Company's diode pumped solid state technology produces a beam of 213nm wavelength, which exhibits similar behaviour to the 193nm excimer laser beam. The technology generates an accurate and reliable beam, and permits good control of beam characteristics (eg. fluence, energy), delivering significant advantages compared with excimer lasers. These advantages are discussed in more detail in Section 2.2.3.

## 2.2 *Custom corneal surgery*

Custom surgery aims to optimise a patient's vision by using effective diagnostic systems to accurately measure the optical abnormalities of each individual eye and designing a unique surgical plan to treat that eye, rather than basing treatment on removal of microthin layers of cornea to achieve a standard lens shape.

The excimer lasers currently in use in LVC have not been designed specifically for custom surgery, but for ablating standard microthin layers from the cornea, and thus are not ideal for treating patients with atypical optical aberrations and for delivering effective customised vision correction. However companies in the LVC field are moving towards customised solutions in order to deliver better quality vision to their patients. They are continuously improving their diagnostic systems, employing topography and increasingly using wavefront measurement systems, such as Hartmann Shack or Tracey VFA.

### 2.2.1 Custom surgery requirements

Key to custom surgery are accurate diagnosis of the true nature of the variations in the cornea and the eye; translation of these into a surgical plan and accurate execution of this plan with laser ablation, using LASIK, PRK or LASEK techniques. The requirements for effective custom surgery are therefore:

*(i) Effective diagnostic tools to monitor*

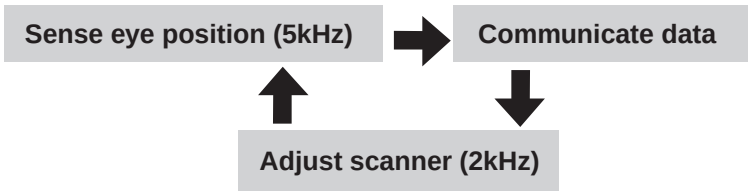
- Corneal topography – the surface undulations and aberrations of the cornea
- Wavefront characteristics – which consider the refractive effects on visual acuity of the whole optical system – cornea, lens, vitreous humour (the jelly like material which fills the cavity between the lens and the retina) and the retina.

*(ii) Small laser spot size* allowing for more customised ablation tailored to each individual eye.

*(iii) Effective registration of the laser on the eye coupled with fast closed loop tracking and scanning* as illustrated in Figure 2, ensuring that:

- The designed ablation pattern is actually positioned and executed on the correct portion of the cornea
- The laser is moved rapidly over the surface of the eye ensuring that the small spot focused beam only ablates the required amount of the corneal surface (does not burn a deeper hole by being focused on one spot for too long a time).

**Figure 2: Closed loop eye tracking and laser scanning**




Excimer systems may be pushed to their limits to deliver the small spot beams, accurate tracking and fast scanning capable of dealing with the level of complexity generated by improved diagnostics. Shortfalls in many systems mean that surgeons need to pre-screen their patients to ensure that only relatively simple cases, requiring less detailed ablation, are treated.

### 2.2.2 The CustomVis™ System solution

The CustomVis™ System, illustrated in Figure 3, has been designed to provide an effective custom surgery solution for disorders, currently not treatable via LVC whilst also providing a cost effective system for performing high quality standard treatments. Patients currently not treatable by LVC, who would benefit from custom surgery, include patients suffering from irregular abnormalities as a result of laser refractive laser surgery, corneal incisional surgery, or corneal transplants (post penetrating keratoplasty).

Industry experts agree that there is a trend towards custom surgery and that the CustomVis approach is well positioned to benefit from this trend, as exemplified in the following quotes.

*"There is now a real race for custom and a new platform is needed. CustomVis is the only company which is truly capable of delivering this in the short term. I have followed Dr Paul van Saarloos and his genius for many years. Many companies have tried to recruit him but he is his own person and has not succumbed."*

Competitor in LVC

*"The CustomVis™ System potentially represents the next generation of technology in Laser Vision Correction"*

Marguerite McDonald, retiring president of ASCRS

*"CustomVis represents the next generation in refractive surgery technology particularly in the light of the move towards custom surgery which is generally seen to give a better result and also allows the surgeon to charge more for the procedure."*

Emanuel Rosen, co-editor of the Journal of Refractive and Cataract Surgery*

The Company's core competency lies in the integration of a number of different technology aspects, such as solid state lasers, closed loop eye tracking and solid state scanning, and diagnostic tools, required for the optimal performance of customised LVC. The CustomVis Custom Corneal Reshaping System (Figure 3) comprises a diagnostic element which generates a surgical plan for each individual eye, systems to ensure correct registration of the surgical plan with the patient's eye and a solid state laser integrated with a scanning system which allows for accurate and fast movement of the laser beam over the surface of the cornea.

***The diagnostic element,*** the **ZCAD™ advanced surgical planning system** can incorporate information on the pre-operative condition of each individual eye. This can include information from various sources on topography, wavefront data, pupil size, pachymetry (corneal thickness) and other refractory data. The ZCAD™ diagnostic software combines and integrates the data, gathered prior to the operation to produce a precise map of the cornea and where ablation is needed to achieve optimal visual acuity – the treatment plan. The software allows for planning, simulation and refinement of the treatment plan, delivering the surgical map, which controls the execution of the laser ablotion pattern.

This surgical map produced via the ZCAD™ system is introduced (via a CD) into the ***CustomVis™ surgical system*** which incorporates:

- **ZTRACK™ "Superspeed Eye Tracking"** of the eye, which ensures that the surgical plan generated by ZCad™ is accurately positioned relative to the patient's eye. This system matches the iris pattern and the patterns of the blood vessels on the limbus in the surgical plan to those in the patient's eye to maintain an accurate central reference point for direction of the laser in ablation of the corneal surface.

- **ZSCAN™** scanning device which is responsible for the scanning (movement) of the laser beam; the device is required in order to carry out the surgical plan that is produced by the ZCAD™ diagnostic.

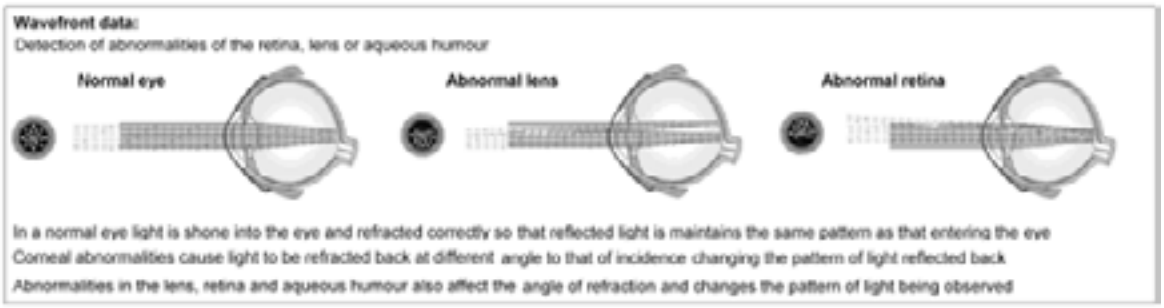
- **The Pulzar™ solid state laser**, a 213nm small spot laser (0.6 mm), with fast pulse repetition rate (300Khz) and improved beam profile. The laser is integrated with the tracking (ZTRACK™) and scanning system (ZSCAN™), thus any movement of the eye is detected and laser position is adjusted ensuring that the laser ablates the correct position on the cornea at all times during the procedure. The closed loop response of the system allows the laser to respond very fast to horizontal and rotational eye movement and any shift in gaze from the fixation light.

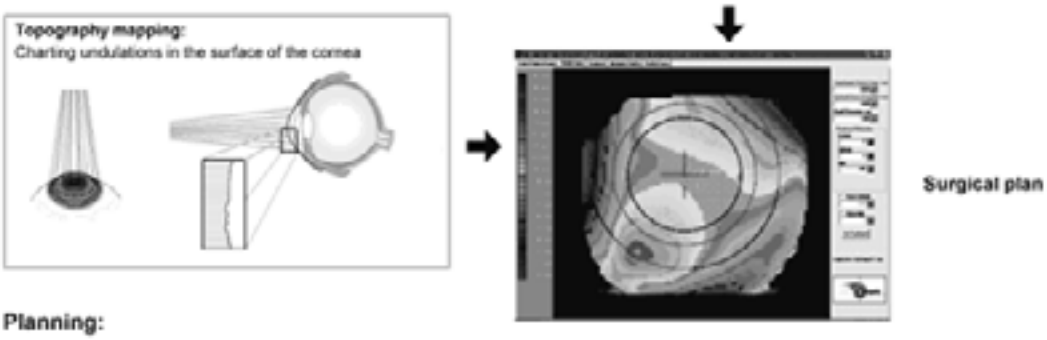
* Emanuel Rosen's quotation was taken in advance of any approach to him regarding his appointment as a non-executive director of the Company.

**Figure 3: The CustomVis Corneal Reshaping System**

**Diagnostic:**

1. **The ophthalmologist provides the computer with information on the patient's eye, such as pupilometry (pupil size), refraction, pachymetry (the thickness of the cornea), topography and wavefront data**



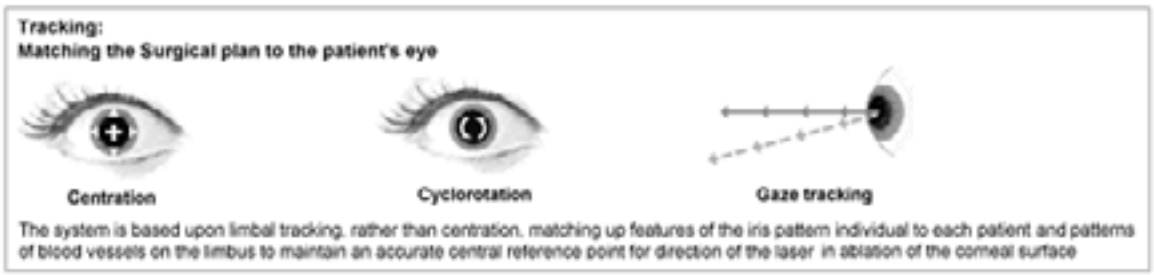




**Planning:**

2. **The software (ZCAD™) designs a surgical plan, which is saved onto a CD-ROM for transfer into the CustomVis system**
3. **The patient lies on the bed underneath the CustomVis laser delivery system and is prepared for one of three surgical procedures; LASIK, LASEK or PRK**

**Closed-loop tracking & scanning:**

4. **The superspeed eye tracking system (ZTRACK™) locks onto the limbus of the eye and tracks the movement of the eye**




5. **The ophthalmologist activates the 213nm laser beam to follow the surgical plan generated by ZCAD™**
   **The laser is integrated with the tracking (ZTRACK™) and scanning system (ZSCAN™), thus any movement by the eye is detected and the position of the laser adjusted to compensate for the movement**
   **The closed loop response of the system allows the laser to respond very fast to both horizontal and rotational eye movement**

**Treatment:**

6. **The laser ablation treatment takes from 20 seconds to a few minutes to perform, depending on the complexity of the ablation pattern**

### 2.2.3 Advantages of the CustomVis™ System for custom surgery

The elements of the CustomVis™ System individually and together deliver significant advantages for custom surgery, which are considered below.

**The Pulzar™ solid state laser**

The diode pumped solid state technology uses a frequency-quintupled q-switched neodymium: yttrium aluminium garnet (Nd:YAG) laser. An infra red light beam at 1064 nm is directed through 3 non linear crystals, where its frequency is doubled twice and then mixed with the original wavelength to produce the 213 nm wavelength. The beam is fine tuned by control of the angle of propagation of the beam through the crystal and the temperature of the crystals. This overcomes the problem of light of different frequencies travelling at different speeds through the crystals, making the frequency doubled light out of phase with the input light. The technology generates an accurate and reliable beam, and permits good control of beam characteristics (eg. fluence, energy), delivering significant advantages compared with excimer lasers. These advantages include:

(i) ***Spot size*** – the Pulzar™ laser has the smallest spot size currently on the market at 0.6 mm, offering the potential for very accurate custom surgery. Studies have confirmed that small laser beam spot size is essential for the creation of customised ablation profiles, with one study showing that a beam size of 1mm or less is required for treatment of higher order aberrations. Small spot size can prevent:

- Formation of steep central islands (mountains on the cornea) potentially attributable to the non-homogenity of the broad beam or fluid accumulation during ablation.
- Stress waves which are propagated through the eye when excimer lasers are used as well as an ablation plume, which is projected away from the eye. With spot size of less than or equal to 1.5 mm this energy quickly dissipates beyond the corneal endothelium. Stress waves within the eye may lead to vitreoretinal or lens abnormalities.

(ii) ***Wavelength*** – the ablation rate of the 213 nm laser has been shown to be much less dependent on water content than the 193 nm excimer laser. Stringent monitoring of corneal hydration may not be required, allowing greater control of ablation rate, reducing incidents of over/under correction during LVC.

(iii) ***Practicality*** – the solid state laser also avoids the practical drawbacks of the current generation of argon fluoride excimer lasers, which include:

- Use of fluorine gas which must be carefully contained to avoid harm to patients and operating room personnel. It also has a short half life, and is corrosive to the laser cavity and resonator optics
- Large size
- High maintenance requirement due to their complexity. Maintenance costs are estimated at £37,000 – £56,000 annually per machine, plus the costs of downtime
- Relatively slow pulse frequency; although some excimers can go up to 200Hz there are potential stability problems as the lasers are pushed to these upper limits
- The laser beam must be manipulated through a complex delivery system, due to the high spatial mode of operation, in order to obtain a sufficiently homogenous beam of the desired shape before exposing it to the cornea.

To quote a competitor in LVC *"Excimer technology will always be challenging simply because it is not robust."* It is of interest to note that 25-30 years ago argon excimer lasers were the mainstay for diabetes/glaucoma treatment. Solid state lasers came onto the market in 1993 offering essentially the same procedure at lower cost and potentially offering benefits from the different wavelength. They have now taken over the market, with 99 per cent. of the lasers being green solid state lasers. Bridgehead considers that this may be a useful indicator of the potential for the solid state laser to increase its share of the LVC market in a similar way.

**ZTRACK™ "Superspeed eye tracking"**

ZTRACK™ incorporates: analogue eye tracking; video/digital eye tracking; and gaze tracking. It uses limbal eye tracking and is incorporated with ZSCAN™ to produce what CustomVis believes to be the fastest closed-loop response (>1kHz) in the market. The advantages of this approach are:

(i) ***Limbal tracking*** – the CustomVis™ System uses the centre of the limbus (a point which remains constant) to track the eye, rather than the pupil centre (used by many other LVC systems), which can move by up to 0.7mm as the pupil diameter changes. Pre-operative dilation of the pupil is not required and the system delivers greater accuracy, potentially reducing the incidence of de-centered ablations.

(ii) ***Fast analogue eye tracker and video tracker*** – the speed of the analogue CustomVis™ System's eye tracker, or sampling rate, is 5 kHz. The LADARVision system, which currently incorporates the fastest closed loop eye tracking on the market, operates at 4kHz. The LADARVision system was authorized for clinical trials, which yielded outstanding clinical outcomes, on the basis that the fast eye tracking system was used. Fast, closed loop eye tracking, as illustrated in Figure 2, is needed because when the patient's gaze is fixed on a fixation light frequent, random, rapid saccadic eye movements occur (around 5 times per second). Typical saccadic movements travel 0.1 to 2.0 mm at a rate of 22 to 170 mm/second. To adequately follow and track these movements during fixation, a 100 Hz closed-loop bandwidth tracker is needed because the closed-loop tracking frequency (sampling rate) must be approximately 10 times the desired tracker bandwidth (10 x 100 = 1 kHz). At 4 kHZ and 5 kHz respectively the LADARVision and CustomVis™ Systems offer sampling rates well above those needed. In addition to analogue eye tracking ZTRACK™ has video eye tracking which uses a different tracking technique from the analogue system.

(iii) ***Gaze tracking during the custom surgery*** – the analogue and video eye trackers are based on two-dimensional detected features (i.e. the limbal edge) and do not account for tilting of the eye, e.g. when the patient's gaze shifts from the fixation light. ZTRACK™ determines when (or if) the patient's gaze drifts away from the fixation point. If the patients gaze drifts significantly, the laser beam emission stops preventing extreme decentred ablations – an unique safety measure.

(iv) ***Fast closed loop response time of more than 1 kHz*** – during laser surgery, the eye/gaze trackers detect eye movement, but there will be processing delays before the laser can compensate for this movement. During these delays, the eye can continue to move significantly from the original detected eye position, resulting in an inaccurately positioned ablation. ZTRACK™ detects eye and gaze movement, processes this information rapidly and passes the information to the ZSCAN™ device allowing for change in the position of the laser beam to compensate for the eye movement more quickly than other systems currently on the market. The current fastest reaction time in the LVC industry is 115 frames per second; by comparison the CustomVis™ System reaction time is greater than 1,000 frames per second (>1kHz).

**ZSCAN™ scanner**

The ZSCAN™ device is responsible for the movement of the small spot laser beam and is incorporated with ZTRACK™ in order to compensate for eye movement in any plane. Most current systems are based on mirrrors which focus the laser beam onto the required position on the cornea, using galvanometers or springs. This type of system inevitably encounters problems when used for rapid movement of the beam over the corneal surface as speed is limited by the mechanical ability to move the mirror rapidly. ZSCAN™ overcomes this problem by scanning the laser beam through the solid state system, allowing seven times faster closed loop tracking/scanning than other systems, allowing advantages such as:

(i) ***Smoother surfaces*** – which are predictive of greater precision in custom surgery and believed, but not yet proven, to result in better healing and outcome.

(ii) ***Capability for correcting higher order aberrations*** – with a fast scan mechanism, each pulse etches away a very thin layer of the tissue (submicrometer) within a small area, delivering custom contouring of a surface to any desired shape, allowing correction of all optical aberrations, not just myopia or hyperopia and astigmatism.

(iii) ***Non sequential pulse placement*** – where no one laser spot is placed directly next to the previous spot. This semi-randomized placement of the pulses is essential to avoid thermal build up and improper plume evacuation during treatment.

**ZCAD™**

The ZCAD™ device integrates all possible diagnostic information about an eye to produce a unique surgical plan which incorporates topography, wavefront data, pupilometry, pachymetry and refraction data from various sources. The ZCAD™ software allows for the design of the ablation profile plus simulation of and further refinement of the treatment programme.

### 2.2.4 Competition

***Excimer-based custom LVC systems***

CustomVis faces direct competition from companies with an increasing number of excimer-based LVC systems (Table 1), with their well documented disadvantages. No other system, based around the use of a solid state laser, has been found which has reached clinical trials in man.

**Table 1: Major competitors in custom LVC**

| Company | Comment |
|---|---|
| VISX Inc. | VISX focuses purely on the refractive surgery market and dominates in the US (mainly because of its patent position) and Japanese markets. More than 1,400 of its systems have been installed worldwide, significantly more than any other LVC manufacturer, with over 2.5 million procedures carried out. The STAR S3 ActiveTrak broad beam excimer laser was given FDA approval in 2000 as was the WaveScan™ diagnostic system, the first wavefront technology to gain FDA clearance. The FDA has also approved the use of VISX's topographically driven Custom-Contoured Ablation Pattern (Custom-CAP) method under an Humanitarian Use Device Exemption ("HDE"). On 23 May 2003 VISX received FDA approval for the use of its CustomVue™ laser vision correction procedure. This approval is specifically for the wavefront guided LASIK correction of myopic astigmatism. Bridgehead understands that the CustomVue™ system requires some patient preselection ensuring that only patients capable of correction to 20/16 enter the programme. There are several steps in the process, including the production of a "prevue" lens to demonstrate the likely result to the patient. |
| Alcon Laboratories Inc. | Alcon manufactures the LADARVision® system, which was originally developed by Summit Autonomous Inc, which was acquired by Alcon in September 2000 for £600 million. The company claims that the LADARVision® system is the most advanced system currently on the market, incorporating the LADARWave® Wavefront device providing a combination of a flying small spot Gaussian beam and an eye tracking system. The tracker samples at 4,000 times per second (4 kHz) and has a 100 Hz closed-loop bandwidth, allowing adjustments to be made 100 times per second (slower than the pulse repetition rate). The LADARWave® and LADARVision systems were recommended for approval by the FDA on 1 August 2002 for the treatment of low level myopia. Application for use of the system to treat astigmatism was turned down as a result of the inability of the system to accommodate patients with eye irregularities associated with this condition. Bridgehead understands that the LadarVision system is very good but the custom results may have been disappointing, given the capabilities of the system. A drawback for Alcon is that FDA approval is currently strictly for myopia and therefore the system cannot be used to correct the astigmatism in the 50 per cent. of myopics who have it. |
| Bausch & Lomb Inc. | The Bausch and Lomb system comprises The Technolas 217 laser; Zyoptix Wavefront analysis; and Orbscan topographer (which Bridgehead understands is one of the best systems currently available). The tracking system in the Technolas system is based on the use of galvanometers and mirrors, which may struggle to reach the high tracking speeds ideally required for custom surgery. Results are reported to be very good and the company is expecting FDA approval later in 2003. Bridgehead understands that Bausch and Lomb preselect patients for their clinical trials, effectively limiting candidates to those who match the technical capability of the Technolas laser. |
| Laser Sight Inc. | LaserSight Inc.'s technology segment develops, manufactures and markets ophthalmic lasers for use in PRK. In 2002 the company's revenues decreased 30 per cent. to £4 million reflecting lower sales of their LaserScan LSX excimer laser system. The company's CustomEyes Custom Ablation platform consists of the AstraMax Stereo Topographer, a three-camera stereo topographer, the CIPTACE Custom Vision Planning Software, custom corneal ablation planning and programming software, and the AstraScan Custom Laser System. |
| Nidek Inc. | Nidek is a privately owned company which has developed the NAVEX system for customised corneal ablation. This consists of the OPD-Scan, Final Fit Software, and the EC-5000 Excimer Laser with Multipoint Ablation. Nidek's OPD scan is a system which integrates data from wavefront analysis and elevation/topography analysis, with data gathered during one test on the patient. The Nidek laser is a slit beam which moves over the surface of the eye and it is possible that it is unable to deal with the level of data generated by the OPD diagnostic. The company has chosen not to pay royalties to VISX and the companies have fought over this in the courts for 5 years, with a recent settlement of the patent infringement case in April 2003. Nidek is reported to have had a solid state laser project in R&D in Japan 8 years ago, but this was not brought to market. |
| Wavelight Laser Technologic AG | Wavelight is a German company producing the Allegretto system for the correction of myopia via LASIK. Reports from the company suggest that the system has surpassed expectations in clinical trials to date. The Allegretto system has a small spot, scan tracker laser, similar to LADARVision. When the company enters the US (probably late 2003) they will have to pay per procedure royalties to VISX. Bridgehead understands that the Wavelight System has a good specification although industry sources suggest that experience to date is limited. |
| Carl Zeiss Meditec AG | The Carl Zeiss Meditec Mel 80, introduced at the end of 2002, is a small spot fast pulsing scanning laser system with a matching fast response automated pupil capture active eye tracker. The laser is wheel mounted allowing movement from room to room. It is used with the WASCA wavefront aberrometer (based on Wavefront Sciences COAS system) and can also be linked to the TOSCA topographer. |
| Schwind Eye-Tech Solutions | Schwind is a privately held German company which has approximately 400 of its systems installed globally. The Schwind Esiris system claims to offer the following benefits: High pulse frequency – 200 Hz Scanning Spot laser with 0.8 mm spot diameter and Gaussian beam profile; optimal centering and 300 Hz High Speed Eye Tracker. The 300 Hz active eye tracking system is uniquely designed not only to follow the laser beam but every single saccade of the eye. It allows for easy centering onto the desired ablation area, not only onto the centre of the pupil itself. |

*(Bridgehead bases this assessment on review of relevant literature and on interviews with key players in the LVC industry, particularly at the ASCRS conference in San Francisco, April 2003)*

2.2.4.1 *Abilities in custom surgery*

The custom surgery capabilities of the various excimer laser companies involved in LVC are reviewed in Table 2 below.

**Table 2: Specifications of competing "Custom" systems**

| Company<br>Laser system | Laser | | | | Eye tracker | | |
|---|---|---|---|---|---|---|---|
| | Solid State | Pulse rate (Hz) | Spot size (mm) | Shape | Detection rate (Hz)/ | Response rate (Hz) | Delay time (ms) |
| **CustomVis**<br>CustomVis™ | Yes | 300 | 0.6 | Gaussian | 5,000 | 1,000 | 0.5 |
| **VISX**<br>Star S3 | No | 10 | Varies<br>0.65 to 6.5 | 7-beam array | 60 | 60 | — |
| **Alcon**<br>LADARvision 4000 | No | 60 | 0.8 – 0.9 | Gaussian | 4,000 | 100 | 6-8 |
| **Bausch & Lomb**<br>Technolas 217Z<br>Zyoptix | No | 50 | 1.0 – 2.0 | Truncated Gaussian | 120 | 120 | 11 |
| **LaserSight**<br>LaserScan LSX | No | 200 | 0.8 – 1.0 | Gaussian | 200 | 200 | 8 |
| **Nidek**<br>EC-5000 | No | 5 – 50 | 7.5 × 2 + 1 | Quasi-Gaussian | 200 | 200 | 6 |
| **Wavelight**<br>Allegretto | No | 200 | 0.95 | Gaussian | 250 | NA | 8 |
| **Asclepion Meditech**<br>MEL 70, G-Scan | No | 35-50 | 1.8 | Gaussian | 50 | 50 | 10 |
| **Schwind**<br>ERISIS | No | 200 | 1.0 | Gaussian | 300 | 300 | 3.3 |

Information derived from various sources including company websites and Spectrum Consulting 2002, and believed to be correct at time of printing

Details of the state of approval for competitor systems are given in Table 3 below:

**Table 3: US FDA approval status for LVC systems**

| Company | System | Beam | % US installed base | FDA Approval | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | M | M+W | H | H+W | ET |
| Alcon | Infinity | Broad beam | 19 | ✔ | ✔ | ✔ | ✔ | — |
| | LADARVision | Small spot scanning | 12 | ✔ | ✔ | ✔ | ✔ | ✔ |
| B & L | Technolas 217 | Small spot scanning | 4 | ✔ | ✔ | E | E | P |
| Lasersight | Laserscan LSX | Small spot scanning | 3 | ✔ | P | P | P | P |
| Nidek | EC-5000 | Slit scanning | 16 | ✔ | ✔ | P | P | — |
| VISX | Star S3 | Variable spot scanning | 46 | ✔ | ✔ | ✔ | ✔ | ✔ |
| Wavelight | Allegretto | Small spot scanning | 0 | E | E | — | — | — |

M = Myopia; **M + W** = Myopia with wavefront; **H** = Hyperopia; **H + W** = Hyperopia with wavefront; **ET** = Eye tracking; **E** = Enrolling; **P** = Pending

### 2.2.5 Competition from other solid state lasers

Information from industry experts confirms that solid state technology for LVC applications has been under consideration for at least 8 years, with Novatech Technologies managing to develop a good solid state machine with small spot, tracker guidance and highly variable controls for custom surgery. According to industry sources, this system is no longer in development.

*Katana Technologies GmbH* has developed a solid state system which CustomVis believes to be more complex than the Pulzar™ laser, involving extra steps in the generation of the 210nm wavelength laser. The laser has 0.2 – 0.3 near Gaussian spot, which pulses at around 1kHz and is delivered under computer controlled scanning. The active eye tracker is continuous with a latency of 1 millisecond. The system potentially allows for the future introduction of a dual system where two lasers could be combined in one unit, giving a UV refractive wavelength and an IR laser keratome. From discussion with industry sources CustomVis believes that Katana's technology is probably two years away from the current CustomVis position.

### 2.2.6 Indirect competition to LVC

There are certain other companies with interests in the LVC field that may be positioned to develop systems similar to that being developed by CustomVis in the future. Although these companies may not have shown any intent so far to develop such a system they may have the in-house technologies and expertise to make a relatively rapid transition into this market.

*Intralase* has developed a femtosecond laser for cutting the stromal flap in LASIK procedures. Interest in the Intralase technology rests on its potential reduction of the risks involved with microkeratome flap cutting and its superior performance to current microkeratomes. There may be potential to use femtosecond technology for intrastromal ablation, effectively focusing the laser and creating the correction curvature within the cornea without the need for cutting a flap. There are still significant technical hurdles to overcome but this technology could potentially be on the market within five years.

*Sunrise Technologies International, Inc.* produces Holmium laser-based systems which utilise a patented process for shrinking collagen, in a procedure known as laser thermal keratoplasty (LTK). The procedure is quick, lasting a just a few minutes with only a few seconds of actual laser time. The system has been designed for correction of hyperopia, presbyopia, and over-correction resulting from PRK and LASIK treatments for myopia. The presbyopia and over-correction indications are currently under clinical investigation in the US. Since the product's launch, nearly 100 systems have been installed in the field.

*Refractec* produces the Viewpoint CK system, which utilises a radio-frequency probe to alter the corneal curvature in a procedure known as Conductive Keratoplasty (CK). The Viewpoint system completed clinical trials in 2001 and gained FDA approval for the treatment of spherical hyperopia in late 2001. Similarly to LTK, correction of long sight is achieved through the shrinkage of collagen. Conceivably, the CK device could be utilised for other ophthalmic procedures, such as post-LASIK and cataract surgery.

*Pro-Laser Ltd* is an Israeli company focusing on the manufacture of equipment for keratoplasty. Its DTK technology combines an adjustable collagen delivery system with a diode laser source in order to change the corneal shape. The device is still in clinical trials within the US, but there are approximately 50 installed systems worldwide.

Rapid market growth and increased consumer demand for refractive surgery has led to the development of many new permanent vision correction technologies, such as intraocular lenses, corneal inlays, scleral expansion bands, and new laser techniques. They are expected to expand treatment ranges and make refractive surgery available to a wider audience. These options are viewed as supplements or improvements in specific niches, such as extremely high myopia, rather than as replacements for LASIK, PRK or LASEK.

*Phakic Intraocular Lenses (IOLs)* are inserted into the eye's anterior chamber (in front of the pupil) or posterior chamber (between the iris and the normal lens) and are used to treat a wide range of hyperopia and myopia. This procedure is related to Clear Lens Extraction (where the eye's natural lens is removed before the implant is inserted), which is used primarily to treat extremely high myopia. Phakic IOL FDA approvals have been delayed by the FDA's requirement that manufacturers seeking pre-market approval of phakic IOLs must submit three years of clinical outcomes, plus two years of post-market surveillance data. Examples of phakic IOLs include:

- The Artisan or iris claw lens (Ophtec) which is attached on the front of the iris. This was expected to gain FDA approval end 2002. However the FDA panel requested 3 years data rather than 2 years, possibly delaying approval.

- The Implantable Contact Lens (Staar Surgical) which is placed between the iris and the crystalline lens. Enrollment in the myopia trial was completed in late 1999 and the company is anticipating a full panel review H2 2003.

- The Kelman Duet lens which is inserted into the anterior chamber has already received the CE mark and US clinical trials are expected to begin in 2004.
- The Phakic Refractive Lens (Ciba Vision) a posterior chamber foldable lens, which has CE mark approval and has been available in the EU since 2001.

The advantages of IOLs include the ability to treat extreme myopia or hyperopia and reversibility (the lens can be removed from the eye if needed). Disadvantages include the potential to cause premature cataract development during or after surgery and increased risk for sight-threatening infection during or after surgery. Due to the relatively higher risks of intraocular surgery, IOLs are increasingly only offered to patients who can not benefit from LVC. They may be combined with LVC, for example some surgeons correct astigmatism with the laser, then make additional correction with the IOL, or vice versa.

*Corneal Inlays* or intrastromal corneal ring segments are clear crescent-shaped pieces of plastic polymer placed into the peripheral cornea, effectively flattening the cornea and correcting myopia without direct surgery to the optical zone. The procedure takes about 15 minutes and is done on an outpatient basis. FDA approval was gained in April 1999 for mild myopia (−1.0 to −3.0 dioptres). Although the corneal implants are designed for long-term vision correction, they can be removed if adverse effects are suffered by the patient and may be replaced with different-size implants if the prescription changes with age. Researchers are also studying corneal rings to treat mild hyperopia and astigmatism, though these uses have not yet been FDA-approved.

*Scleral Expansion Bands* are used in Surgical Reversal of Presbyopia ("SRP") a technology currently under development by PresbyCorp that involves cutting eight "belt-loops" in the sclera (the white of the eye) and inserting four metal or plastic expansion bands, each approximately 5.5mm long into those belt-loops. These bands pull up the anterior portion of the sclera, altering the shape of the eye, and increasing the distance between the ciliary muscle and the equator of the lens. SRP was developed in California in the early 1990s, and to date over 500 SRP procedures have been performed worldwide with mixed results. Clinical trials are underway in the US. There are some concerns about the procedure's safety, including the risk of perforating the globe, erosion of the expansion bands, infection, and decreasing blood circulation in the eye. This procedure is performed in Mexico and other countries outside the US despite a poor characterisation of its safety and efficacy.

## 3. The commercial potential of the CustomVis™ System

### 3.1 *Market size*

Rapid growth of LVC in private ophthalmology practice started in 1997 through to mid-2000, when the industry witnessed a slowing down to the middle of 2001. The market remained stable through 2002 and has seen modest to strong growth again in the current year to date.

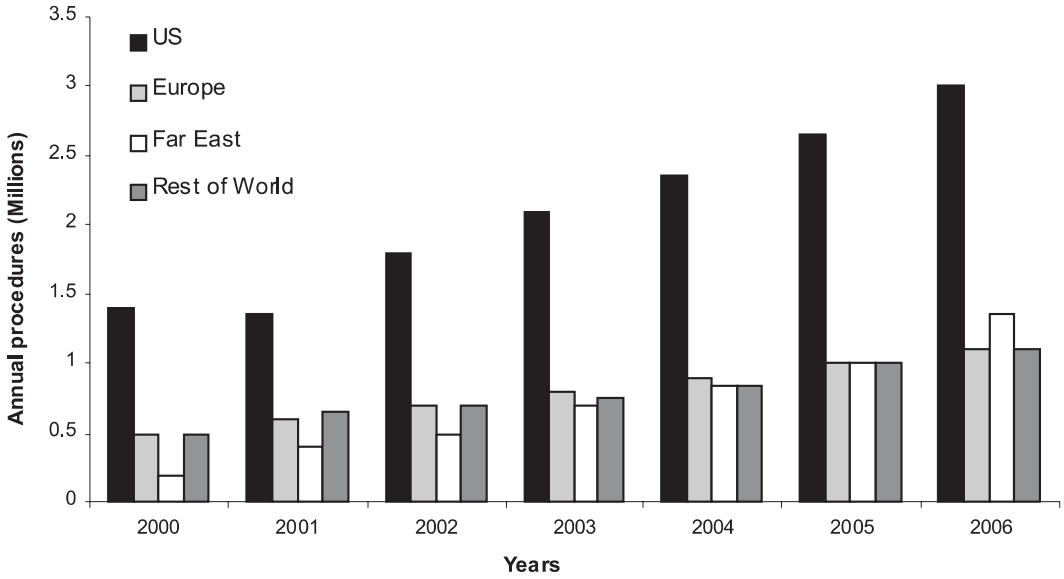
Table 4 shows the estimated worldwide installed laser base. Figure 4 shows the numbers of procedures carried out worldwide with strong growth projected to 2006.

**Table 4: Estimated worldwide installed laser base**

| Region | Installed Base | Fastest Growing Segment |
|---|---|---|
| **US** | 1,840 | Florida |
| **W. Europe** | 1,200 | Spain |
| **E. Europe** | 350 | Russia |
| **M. East/Africa** | 350 | Egypt |
| **E. Asia** | 400 | Korea |
| **China (PRC)** | 500 | Shanghai* |
| **India** | 400 | Delhi |
| **S/L America** | 800 | Mexico |
| **TOTAL** | 5,840 | |

Source: Spectrum Consulting; Various Refractive Market Publications (2002). *Note: LaserSight sales to China 8/2002

**Figure 4: Worldwide LVC Procedure Estimates by Region (2000 – 2006)**




Source: Spectrum Consulting

Extrapolation of data from Figure 4, at an average cost of £620 per procedure, gives an estimated LVC market of £2.4 billion in 2003 projected to rise to £3.7 billion in 2006.

*US market*

**Table 5: US excimer laser procedures (x1000)**

| Year | Quarter | Total procedures | Year to Year growth (%) |
|---|---|---|---|
| 2000 | **1** | **411** | **34** |
| | 2 | 373 | 3 |
| | 3 | 281 | (25) |
| | 4 | 259 | (26) |
| **Total** | | **1,388** | **50** |
| 2001 | 1 | 347 | (16) |
| | 2 | 330 | (12) |
| | 3* | 316 | 13 |
| | 4* | 323 | 25 |
| **Total** | | **1,324** | **(5)** |
| **2002*** | | **1,316** | **(1)** |
| **2003*** | | **1,496** | **14** |

Source: SG Cowen Securities Corporation

The dip in the number of procedures seen between Q2 2000 and Q3 2001 was felt to be the result of a number of factors:

(1) a general slow-down in the global economy;

(2) a number of negative press reports on LASIK following increases in LVC related legal actions in the US; leading to

(3) patient uncertainty regarding LASIK.

*European market*

Research indicates that the LVC markets in France and Spain continue to grow strongly, with the rest of Europe showing more moderate growth. Prices in Europe have tended to soften in recent

times although they are still in the range of £150K to £180K per laser. Excimer laser technology has been used in Europe for over 10 years now and therefore European doctors may understand better the limitations to current excimer technology than US doctors.

In the UK there are a number of corporate clinic chains which tend to focus on price, practice management and business support, making branding very important. Spain operates to a similar model, but elsewhere in Europe there are very few corporate chains with most companies operating on a medical social model.

Market leaders in Europe are Bausch & Lomb with sales estimated at 70-90 units per year and Alcon with 40-50 units per year. Nidek is believed to have been suffering declining brand equity in Europe. A key component to success in the European market will be strong financial backing. In the past doctors who have purchased equipment from small vendors have often been left with unserviceable equipment when the vendors have experienced financial difficulties.

Leading ophthalmologists are often associated with university clinics in Europe and are important opinion leaders in the industry. These leading clinics represent a significant market opportunity since they charge higher prices and may wish to offer custom treatment in order to differentiate themselves.

*Asia/Pacific market*

Asia is the second biggest global market for LVC, outside the US, with myopia in several countries being more prevalent than in the US. In Singapore three in four people are myopic, one of the highest rates in the world. A similar situation exists in Taiwan, which is reported to have the highest rate of myopia in the world. In China and Japan incidence of myopia may exceed 70 per cent., and can be as high as 90 per cent. in selected populations, such as Chinese university students. These figures suggest that the Asian LVC market is set to grow, with the fastest growing markets being Korea and China. China has traditionally been a lower end market characterised by large volume sales of discounted lasers. LaserSight in particular has sold large volumes of systems into China at discounted prices in recent years. The Japanese market has traditionally been very hard to access with regulatory approval from the Japanese Ministry of Health and Welfare for international laser companies proving difficult to achieve. Many of the lower end Asia Pacific markets are facing pricing challenges and will not be initial targets for CustomVis.

*South America/Mexican market*

It is estimated that there are 91 units currently installed in Mexico and 126 in Brazil, where LaserSight has a large installed base after heavily discounting its products. In Mexico, Alcon is currently the strongest player, gaining almost all of the new sales in recent months. Although they have significant installed laser bases, LaserSight, Bausch & Lomb and Nidek are generating minimal new sales. VISX laser sales are recovering and interest is increasing with the introduction of the wavefront device. VISX is currently collecting per use fees on its estimated 30 installed lasers. Financing arrangements are critical to success in South America. Alcon is currently offering a deposit of £15,000 with the remaining cost financed over five years. Interest may or may not be charged depending on bundling options. Bridgehead understands that CustomVis is investigating options for equipment financing in South America to ensure under-capitalised ophthalmologists can have access to its products.

## *3.2 Market trends and drivers*

### Table 6: Relevance of market trends to CustomVis

| Market trend | Relevance to CustomVis approach |
|---|---|
| **Favourable demographics**<br>One of the key drivers behind the growth of the LVC market is the fact that most developed countries have an ageing population. There should be a corresponding rise in visits to ophthalmologists for the treatment of corneal disorders and disease. | It is likely that the requirements of older populations will increasingly be for customised surgery rather than for normal corrections and CustomVis is well equipped to provide to such customised requirements. |
| **Increase in myopia**<br>The many refractive surgery procedures now available to surgeons have the potential to improve the distance vision of many people. LASIK, LASEK, and PRK have now established themselves as being procedures which are reliable for the correction of low to high grade myopia. | Much of the increase in myopia is in Asian countries where the incidence of high levels of myopia and higher order aberrations is significantly greater than the US and Europe. The CustomVis approach is most applicable for these cases which are not amenable to standard surgery. |
| **The growth of customised surgery**<br>Customised procedures offer the promise of tailored corneal laser treatments with the potential to deliver better results and reignite customer interest in LVC during 2003. In November 2002, the FDA approved the Alcon Laboratories LADARVision system with the CustomCornea indication for use in customised laser procedures in treating myopia. A number of other companies expect to gain similar approvals in 2003. The desire within the industry to be able to say that they possess "customised" or "wavefront" technology is common but currently outstrips the ability to deliver results to patients. | The CustomVis™ System has been designed to answer the requirements of custom surgery. It has the smallest spot size, fastest pulse rate, and fastest eye-tracker. These parameters are the most important for custom surgery, and are also considered by many in the refractive industry to be the most important parameters for any type of refractive laser surgery. These attributes make it the only system on the market capable of delivering to the full requirements of custom surgery. |
| **Technology is a key driver of new laser system sales** | Top surgeons and opinion leaders in LVC are continually looking for new technology to enhance their offering. Many of these are already embracing the CustomVis™ System. |
| **Increasing focus on improving quality of vision post LVC**<br>There are trends to:<br>• reduce post operative problems such as glare, halos and poor night vision.<br>• try to reduce the risks involved in use of the keratome.<br>• improve and incorporate diagnostic procedures, to develop the best/most detailed surgical plans possible. | The CustomVis approach offers the potential to treat each eye individually. The small spot size and fast tracking of the solid state laser offer the potential to accurately execute the surgical plan developed using improved diagnostics. The small spot size also offers the potential to reduce errors caused with broad beam technology. |
| **Dependence on economic conditions**<br>Because the technology is expensive and the procedure is discretionary and without government re-imbursements, the market varies hugely with prevailing economic conditions. The US LVC market has been as high as £300 million per annum and as low as £120 million per annum with a slow down in the market in the US between 2000 and 2002, due to the poor economic situation. | Since the CustomVis™ System represents a customised approach it gives surgeons the potential to offer an improved service to customers and also to approach an increased audience of patients, since the system will allow surgery in cases where it is currently impossible. The custom approach will also allow surgeons to charge a premium. |
| **Significant consolidation on the provider side**<br>Autonomous Technologies was acquired by Summit Technology in April 1999; Summit itself was bought by Alcon in 2000. Cardiogenesis was acquired by Eclipse Surgical in 1999 and renamed Cardiogenesis in 2001. Carl Zeiss merged with Asclepion–Meditec in 2002. Premier Laser Systems was declared bankrupt in early 2000 and Sunrise Technologies folded in late 2001. | If the CustomVis™ System is proven clinically, the company will represent an excellent acquisition target for companies such as VISX, Bausch & Lomb and Alcon who are aiming for leadership in the LVC industry. |
| **Importance of reputation of the surgeon** | The reputation of surgeons is likely to be enhanced with their use of the CustomVis™ System which has the potential to offer improved results in standard surgery, corrective surgery and previously difficult or impossible to treat patients. |
| **Trend away from LASIK towards surface treatments**<br>CustomVis considers that PRK is essentially easier to do and less risky; however it can be more painful and healing takes longer. LASIK was introduced to overcome the problems with PRK; however it is a more risky procedure and the majority of the problems encountered with the procedure are as a result of cutting the keratotomy flap. | The CustomVis™ System has the advantage that it is equally appropriate for LASIK, PRK or LASEK and is therefore not dependant on which of the systems is most favoured.<br><br>In addition if the market does move towards PRK, as seems possible, CustomVis has the potential to access rapid wound healing technology which could negate the problems currently encountered with PRK. |

## 4. CustomVis future development

### 4.1 *Clinical and regulatory*

#### 4.1.1 Current status

While LVC in general is growing in popularity, obtaining appropriate regulatory approval for "custom" surgery remains a challenge for all companies in the market. CustomVis intends to demonstrate *safety* (does not harm patients), *quality* (reliable manufacturing standards), and *efficacy* (the device improves the vision of the patient objectively and subjectively) of the CustomVis™ System in two populations of patients.

- *Patient Population #1 "standard myopia,* with or without astigmatism", who are commonly treated by refractive surgeons on an elective, out patient basis. CustomVis is seeking both approval for the laser, and a label permitting treatment for −0.75dioptre to −10dioptre of myopia, and up to −5dioptre of astigmatism. The protocol for this group will seek 350 patients followed to refractive stability.

- *Patient Population #2 "irregular astigmatism"* which includes patients currently untreatable with current LVC systems, such as "retreatments," and more difficult cases with significant visual disorders. The protocol, developed with advice from FDA, will seek a total of 180 patients followed to refractive stability. It will include three "sub-groups" of 60 patients, i.e. "decentered ablations" "induced irregular astigmatism requiring re-treatment," and "enlarging optical zones".

The clinical trials programme in these two populations will be overseen by the Center for Clinical Research (CCR) in Chicago, US a research and regulatory consulting company with specific expertise in ophthalmology and particularly in laser surgery.

The clinical trials programme is currently at an early stage, with the results of treatment of three eyes with irregular astigmatism presented at a scientific meeting. In all three cases good improvement in best spectacle corrected visual acuity (BCVA) were reported. Bridgehead understands that to date a total of six eyes has been treated but results of the second three eyes have not been reported since they are too early. However, Dr Ian Anderson of the Eye Surgery Foundation, who carried out the surgery, is understood to have reported on 2 May 2003 that all six eyes are (a) demonstrating improvements, and (b) their topographies match the surgical plans. These treatments have been conducted under an individual patient protocol approved by the Australian Therapeutic Goods Administration (TGA).

The Company has received confirmation of both the TGA approval and CE mark. A reciprocal agreement exists between Europe and Australia and the CE mark, which will allow commercial sales in Europe, will be granted on the basis of the TGA assessment. Under the conditional approval the TGA required some technical modifications to the device prior to approval.

Bridgehead considers that prior to successful commercialisation it is likely that further clinical data will be required to reassure ophthalmic surgeons of the performance of the device and to provide support for a purchase decision.

In the US, pre IDE (investigational device exemption) submissions have been made and feedback from the FDA indicates that requirements for US approval in both patient groups will be more complex and demanding. Substantial clinical data on "myopia with or without astigmatism" will be required prior to device approval and also prior to the initiation of studies on irregular eyes. A protocol for "myopia with or without astigmatism" is now in final form and appears to conform

to FDA Guidelines for studies for the Refractive Surgery lasers. This study will recruit up to 350 patients in order to provide evaluable data on 300 eyes as required by FDA. Bridgehead understands that FDA has commented on and approved this protocol now that the requested changes have been made. Investigators have been identified in the US and Australia and IRB approvals are being sought. IRB (Institute Review Board) or Ethics Committee approvals are required in the US prior to beginning trials at any particular site. The protocol for "irregular astigmatism" is currently in advanced draft stage and a clinical centre in Singapore has been identified for initiation of this study.

**4.1.2 Clinical and regulatory strategy and plans.**

CustomVis plans to initiate the next stage of clinical studies in Australia (myopia) and Singapore (irregular astigmatism) and to extend these studies to the US when further lasers are available and IDE approval has been granted by FDA, which is expected to take a minimum of 3 months. This strategy avoids delay in the generation of new clinical data, which will support marketing in Australia and Europe and will subsequently be submitted to FDA.

The protocol for the ***standard myopia studies*** in patient population 1 has been prepared by CCR. The management of all clinical centres and the data from these studies will also be monitored by CCR or a CRO (Clinical Research Organisation) under their control to ensure compliance with FDA requirements. The clinical trial will be initiated at the centre in Brisbane, Australia which is expected to contribute 50 patients to the study. Data on 50 patients is required by FDA prior to approval for extension to the full study cohort of 350 patients and therefore this data is expected at around the time that extension to the US centres is expected. To be successful with the application to the FDA it is essential that all overseas patient data is collected and monitored strictly in conformance with FDA requirements. Planned timings for these studies are:

- Australia and Europe in the latter half of 2003 on gaining CE/TGA mark. Approval has already been received from the Perth Eye Surgery Foundation Ethics Committee to conduct trials according to both US FDA protocols.
- Singapore in the second half of 2003 – The primary focus of this study will be patient population #2, however tests of "Asian Myopia" are important validation of the "myopia with or without astigmatism" protocol as high myopia is prevalent in Asian populations
- A number of centres in the US in the second half of 2003, pending US FDA IDE approval, and IRB approval of sites in addition to Dr John Vukich's surgery, which has already gained IRB approval.

The ***visual loss/irregular astigmatism studies*** in patient population #2 are planned for initiation outside of the US, according to the protocol discussed with the FDA, at sites in Australia, Singapore and possibly Europe, where data gathered should prove acceptable to the FDA, then moving to the US following FDA permission to study this group. Timings are:

- Australia and Europe in the latter half of 2003 having received confirmation of the issue of CE/TGA mark
- Singapore in the second half of 2003
- US in the second half of 2003 as in patient population #1

Each patient in both study groups will require follow up for a minimum of 6 months. After completion of the last patient, the results will require collection, analysis, reporting, and the submission will need to be compiled and reviewed by FDA prior to consideration by the Ophthalmic Devices Panel. CustomVis is planning for FDA approval during 2006 and has not projected any revenue based on FDA approved sales in the US based on this timescale, Bridgehead considers that the Company's plan allows adequate time to complete the clinical studies and gain approval during 2006.

The timing of TGA approval and the CE mark was delayed due to a requirement for technical modification, which resulted in a slight delay in the initiation of the clinical programme. It is not anticipated that this delay will affect the timings outlined above.

4.2 *Manufacturing*

The Company is at a very early stage of development and currently has just one prototype CustomVis™ System developed, which was introduced to the market at the American Academy of Opthalomology ("AAO") in Orlando, US in November 2002. Bridgehead understands that manufacturing strategy revolvees around the ability to increase production, with appropriate quality and regulatory conformance, to meet demand for:

- Lasers for commercial sale (as per production and marketing plans)
- Lasers for clinical trials (one laser to be shared among offshore sites)
- Additional 5 subsequent lasers, shared between 6 US clinical trials sites

The US FDA, Australian TGA, European CE mark, and Korean KFDA typically include a manufacturing audit as a potential requirement for regulatory and clinical approvals. These broadly conform to requirements defined for Class 2b Medical Lasers by IS0 9001. Receiving confirmation of the issue of the TGA approval and the CE mark confirms that manufacture is completed to the required quality levels.

The Company is preparing to move into production of the first 3 systems (partially built, with key components in stock). Bridgehead considers that the move from prototype to production models is an area of risk for any company, which is mitigated to the extent that the manufacturing and QA teams have extensive experience in ramping up production in technology in general and medical lasers in particular.

Success in the medical laser industry is critically dependent upon a proper mixture of in-house production, and outsourced and OEM components, managed through appropriately through the supply chain. CustomVis's experience in the area has identified the importance of multiple sourcing of key components, and the company currently has three suppliers for each of the components apart from the crystals for which there are two suppliers. CustomVis will assess suppliers of raw materials and OEM parts according to an approved QA evaluation process, and all key outsourced components carry warranties. Some key suppliers (chiller, power supply) require reasonable lead times, and pre-payments having cash flow implications, and these issues are considered in the financial and production models. All suppliers are monitored for CE mark/TGA compliance, simplifying both quality and reegulatory processes.

Bridgehead considers that CustomVis is well placed to manufacture its solid state laser systems since:

- There are no particularly difficult process technologies involved in the manufacture of the CustomVis™ System.
- All key staff members at CustomVis have had extensive experience in the manufacturing and servicing of refractive surgery laser systems
- The Company has extensive experience with ophthalmic laser manufacture. The CEO, Dr Paul van Saarloos, is named as inventor on over 100 patents in the refractive industry, has co-authored over 50 peer reviewed publications, and managed builds of up to 5 refractive lasers concurrently. The team's experience in refractive lasers, and in moving from prototype to production, is well documented.

In addition the Company has recently recruited a senior experienced production manager with relevant key experience to cover the production scale up.

**4.3** ***Sales, distribution and marketing***

**4.3.1 Sales**

CustomVis has segmented the global market into addressable sectors, and is focusing on building the brand only in these target sectors, initially in the UK, Europe, Asia Pacific, Latin America and Australia. The aim is to position the CustomVis™ System as the top brand within these target sectors, as shown in Table 7.

**Table 7: Target sectors**

| Sector | Target | Positioning | Timing | Rationale |
|---|---|---|---|---|
| Top European Surgeons | ESCRS members, opinion leaders, often connected with top universities in Europe | High value brand with unique features, a must-have for innovators | Year 1 | To support a European capital raising effort through a strong commercial presence in Europe |
| High Volume Refractive Clinics in the Americas | Top Mexican refractive surgeons, with links to US | Allows practitioners to differentiate themselves from the market and reduce overheads with use of solid state | Year 1 | High Average Selling Prices are common, and US doctors often visit to evaluate new technology |
| Top Korean Refractive Surgeons | Opinion leaders in Asia, especially Korea | Innovative technology for high myopia and irregular astigmatism, common in Asia | Year 2 | High incidence of myopia in the population. End stage negotiations in process with Korean distributor with access to top refractive surgeons |

4.3.1.1 *Pricing*

*Prices charged for LVC procedures*

There is a very wide variation in the prices charged by ophthalmologists for LVC surgery both in terms of geography and the specific surgeon carrying out the procedure, as illustrated in Table 8 below.

**Table 8: Examples of prices charged for LASIK treatments**

| Country | Cost of LASIK per eye (UK£) | Cost of customised LASIK (UK£) |
|---|---|---|
| **North America** | | |
| **US:**<br>Atlanta, Georgia<br>Boston, Massachusetts<br>Dallas, Texas<br>Honolulu, Hawaii<br>Los Angeles, California<br>Miami, Florida<br>Manhattan, New York<br>Seattle, Washington<br>Washington, D.C. | <br>1,437<br>1,562<br>1,262<br>937<br>1,375 – 1,875<br>1,250<br>1,407 – 1,720<br>437 – 625<br>937 | |
| **Canada** | 625 – 750 | |
| **Venezuela** | 1,250 | |
| **Europe** | | |
| **France** | 750 – 1,000 | |
| **Germany** | 781 – 937 | 1,250 |
| **United Kingdom** | 687 – 1,250 | 1,812 |
| **East and Pacific** | | |
| **Australia** | **625 – 1,000** | |
| **India** | 112 | 150 |
| **Japan** | 1,344 – 1,625 | |
| **Malaysia** | 275 – 562 | |
| **New Zealand** | 625 – 1,016 | 875 |
| **Thailand** | 312 – 625 | |

*Laser system costs*

Examples of prices quoted for higher end excimer laser systems and associated diagnostics are as follows:

- Laser £150,000 – £200,000
- Wavefront diagnostics £30,000 – £37,000

*Per procedure fees*

There are two parts to the per procedure fees, i.e.

- *Finance fees*, which are deferred payment fees paid by the ophthalmologist to the manufacturer of the laser system. For example the Bausch & Lomb Zyoptics system requires a card per procedure for which the company charges approximately £120. Such per procedure fees are important as they allow for sustained income to the supplier over and above service and maintenance charges.

- *License fees* to cover use of the excimer laser in the US, which have to be passed on to VISX in the form of a royalty. The IP situation in LVC in the US is dominated by the Pillarpoint agreement. Taunton (which merged with VISX) and Summit (which acquired Autonomous in 1999 and was subsequently bought by Alcon in 2000) had certain original patents around the use of excimer lasers in LVC. In the early 1990s the two companies reached the Pillarpoint agreement under which they receive a procedural fee of £90 for every LVC procedure carried out because of the excimer laser used. This per procedure payment has been challenged by Nidek, with VISX and Nidek announcing, on 31 March 2003, that they had signed a "term sheet" outlining a settlement of the patent infringement lawsuit.

For custom ablation per procedure finance fees of around £150 should be possible. Bausch & Lomb has established a precedent in terms of charging a higher per procedure fee for custom surgery in its markets outside the US. This type of activity is helping to build the custom market and the potential for CustomVis to charge a mix of variable up front and per procedure fees, according to purchasers' requirements.

There is a view within the industry that improved diagnostic methods such as wavefront analysis, allowing for custom surgery, will become the standard of care over the next 2-3 years and will be offered at a higher price than standard LASIK. Use of sophisticated diagnostics and custom surgery will give surgeons more control over the way they run their clinics enabling a target price of £1,250 – £1,800 per eye for custom surgery, getting away from the sub-£1,000 for standard surgery now.

CustomVis plans to charge an up front price for the CustomVis™ System, comparable to competing high-end excimer based systems, plus a "per procedure fee". This type of pricing strategy was successfully pioneered by Autonomous, and many of the same stakeholders have been attracted to the CustomVis team. CustomVis's initial sales will be to "premier league surgeons or clinics" with a long history of offering LVC and of being involved in new technology development. A differing sales model will be developed for each customer, varying the up front fees charged for the machine and the payment of per procedure fees. The exact detail of the agreement developed will be based on knowledge of the types of arrangements that these customers have preferred in the past. Thus arrangements could vary from a high up front fee coupled with relatively low per procedure charges, to no up front fees and a continuing high per procedure cost. Bridgehead understands that these initial proposed sales have been confirmed by letters of intent or firm orders from "premier league" customers.

**4.3.2 Distribution**

CustomVis will use a combination of direct and agent distribution in Europe. The Company's Managing Director, Simon Gordon, will drive the direct sales and distribution processes. Agents may also be appointed in some markets. For opinion leaders, especially in Europe, the strong experience and relationships of Simon Gordon in selling refractive lasers will promote direct sales to key accounts, with the office in Scotland supporting sales in Europe.

The US market will be approached using a direct sales method based on geographic areas. The Company intends to retain several experienced sales people over the next 2 years so that the distribution network is operational before FDA approval is achieved. Custom Lasers Inc currently holds the distribution rights to the US, Canada, Mexico, Latin America and Caribbean regions and is scaling up distribution capability. Further South American territories and Asian markets will be addressed through licensed agents. Several potential agents have already been identified by CustomVis and discussions are currently underway to finalise distribution agreements. Bridgehead has been informed that the group is in late-stage negotiations with Lasikwiz over a proposed distribution agreement for Korea, to start in year one of sales.

Independent distributors will be engaged in important markets. As of May 2003 CustomVis has appointed agents as in Table 9 and will identify additional channels as production can meet demand.

**Table 9: CustomVis distributors**

| *Region* | *Distribution* | *Service* | *Timing* |
|---|---|---|---|
| Latin America/Mexico | Visionar/CLI | Visionar | Year 1 |
| Southern Europe/Spain | TBA | CustomVis | Year 1 |
| Latin America/Brazil etc | Visionar/CLI | Visionar | Year 2 |

Different distribution relationships are envisaged:

- Pure sales, where the distributor finds the customers and calls in a CustomVis sales person when the lead has been qualified. These distributors will not service the systems once installed. A typical example would be Belgium, where CustomVis would expect to sell relatively few systems.

- Sales and service distributors, e.g. France, Italy and Spain where enough systems are sold to warrant having the service capability residing within the distributor. Typically such distributors would be selling optical lasers but not other refractive lasers.

### 4.3.3 Marketing

CustomVis's marketing strategy is based on an integrated marketing communications programme which will be delivered through public relations exercises, advertising, publicity and trade shows, direct marketing, and personal selling. Bridgehead understands that CustomVis has already benefited from feature articles in publications such as Eye World, and Ocular Surgery News. In future public relations and personal selling, augmented by trade shows and upgrades to the web site www.customvis.com, will be the key ingredients of CustomVis's strategy. Brand-building communications are also ongoing with medical trade show sponsorship, direct mail, and ultimately advertising to support the brand.

CustomVis's scientific marketing programme delivered 15 peer-reviewed scientific presentations in 2002, and gained invitations for key publications (from the Journal of Cataract and Refractive Surgery), keynote presentations from Dr Paul van Saarloos (at the European Society of Cataract and Refractive Surgery), and from the Company (at the upcoming meeting of the American Academy of Ophthalmology refractive group, the premier global organisation in the LVC market).

## 4.4 Research and development

Bridgehead understands that CustomVis has already been successful in gaining and using Australian government funds rather than investor funds for previous research projects. Planned future diagnostic products will fall within the parameters of the Australian COMET (Commercialising Emerging Technology) programme, and future therapeutic laser products fall under the R&D Start, Biotech Innovation Fund, Australian Research Council and national health

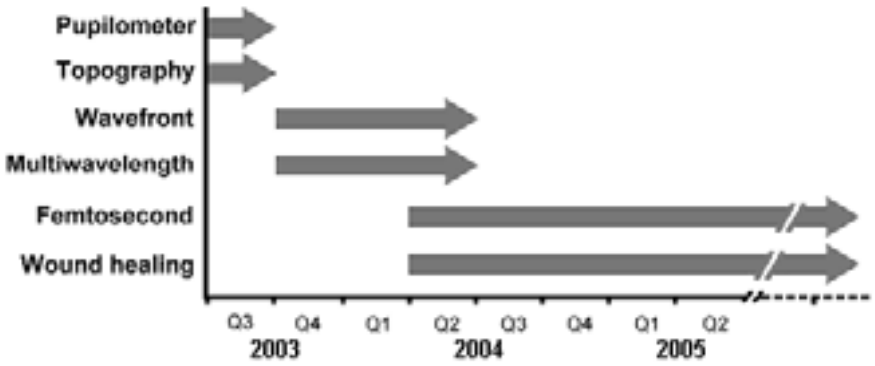
NHMRC grant schemes. CustomVis is also applying for funds in Korea through a biotech Company which is committed to biotech research in Korea and Australia, especially on "Asian Myopia," the high myopia common in Asia. In addition, clinical trials in irregular astigmatism are being carried out in Singapore specifically because there is potential to fund one of the devices via the National Biotechnology Initiative.

The Company R&D plan is primarily focused on the current CustomVis™ System; however CustomVis has a number of further R&D options open to it and has made the decisions on technologies to develop in the short term based on:

- Their ability to deliver shareholder value over the next two years
- The level of synergy with the current laser system
- The level of R&D which has already been carried out on the products
- The ease with which products developed can achieve regulatory compliance
- Their potential to gain public sector funding.

CustomVis has a number of products in their research and development pipeline. Estimates of the proposed developmental timelines are shown in Figure 5.

**Figure 5: CustomVis future development plans**




*Short term diagnostic developments*

CustomVis's next development products, a topographer and a pupilometer will support the development of the laser platform, providing input into the diagnostic portion of the system and are not expected to take up large amounts of Dr Paul van Saarloos' available time.

***Topographer development*** is highly complementary to the CustomVis™ System as a newly developed system could replace the Bausch and Lomb Orbscan topographer currently used. This could remove the risk of Bausch and Lomb withdrawing supply, as they increasingly view CustomVis as a serious competitor. Bridgehead understands that topographer development is already underway, with the first prototype built and launch planned for Q4 2003. This plan seems achievable although challenging given the other demands on the Company's time and resources. Dr Paul van Saarloos' previous experience in developing the Zeiss topographer; his in depth knowledge of time, components and effort required for assembly; and the lower regulatory compliance requirement demonstrating the safety of the device should contribute towards achieving this early launch date.

Development of a ***pupilometer,*** a device for measuring pupil size prior to any surgery would again represent a relatively simple option for CustomVis, and adds to the development of their integrated diagnostic capability. These devices have importance in the LVC area, since most practitioners will

not operate on eyes with a pupil size of more than 7mm and the pupil size represents an important input into the development of the surgical plan. This represents an attractive option as pupilometers are relatively simple and cheap to produce but are currently demanding a high price and have the potential to address a large market. Launch of the pupilometer is estimated as being in Q4 2003. Bridgehead considers this development time could prove challenging due to the same factors considered for the topographer development.

*Longer term developments*

Bridgehead considers that CustomVis's longer term development plans will be challenging given the intensity of the Company's short term development programme and the requirement for significant input from Paul van Saarloos.

Ultimately the addition of ***wavefront technology*** to be incorporated as standard in the CustomVis™ System is an important development for the company, ensuring that they are not locked out of using current wavefront systems, which form the basis of many major company's approaches to custom surgery diagnostics. CustomVis currently has a number of options for the development of a wavefront device, i.e.

- Collaborate with Tracey Technologies in some way, e.g. for CustomVis to use the Tracey VFA Wavefront technology for the 213nm wavelength laser
- Collaborate with other companies which have already developed wavefront technology
- License in developed wavefront technology from other companies
- Collaborate with other parties in the development of a wavefront system which could represent a step change in wavefront technology
- Design a new wavefront device; although this would not be the preferred option since it would risk Dr Paul van Saarloos spending a significant amount of time away from other core activities.

Bridgehead understands that the planned in-house development of wavefront technology is estimated to take approximately nine months. Bridgehead considers this to be optimistic given the other research & development activities taking place concurrently. Collaboration or licensing of an appropriate wavefront technology could be the only way to achieve the estimated launch of the wavefront system for mid 2004.

CustomVis is also developing a ***Multi-wavelength laser*** system for integration into the CustomVis™ platform. Multi-wavelength lasers utilise wavelengths including Green (532nm), Red (680nm) and Yellow (574nm) and are used to treat a range of retinal diseases, associated with diabetes, glaucoma and age related macular degeneration which are increasing globally. Ageing, combined with poor diet and stressful lifestyles, is creating significant eye problems which are currently only curable through laser surgery, increasing the demand for multi-wavelength lasers. Current multi-wavelength lasers use old Argon / Krypton technology and the potential benefits of a solid state multi-wavelength system are similar to the advantages enjoyed over excimer technology in the LVC field.

Within the CustomVis solid state laser system three wavelengths are already available for current ophthalmology applications such as:

- Corneal ablation in refractive surgery
- Green/ yellow lasers for photocoagulation
- Nd YAG lasers for photodisruption, e.g. capsulotomy.

The Company has initiated the development of this technology and estimates that this process will take approximately 9 months. Given Dr Paul van Saarloos' expertise in this field development time could be minimised allowing launch in Q3 2004, although the same concerns regarding intensity of activity and input of Dr van Saarloos time would apply.

CustomVis intends to develop a ***femtosecond laser*** similar to that produced by Intralase for cutting the LASIK stromal flap. Femtosecond technology also has the potential to be used for intrastromal ablation/corneal sculpturing, removing the need for creation of a stromal flap. Intrastromal ablation currently has significant problems in terms of effective focusing of the beams and accuracy of the ablation pattern and significant further development required.

CustomVis is investigating collaboration on a ***wound healing modulator*** to speed up healing post treatment, which will be of particular interest to doctors performing PRK, where post treatment discomfort is currently a major limiting factor. There is increasing interest in the use of PRK since it appears to be more suitable for custom surgery and would eliminate the use of the microkeratome, one of the main risk factors in the LASIK approach. Additionally the use of the microkeratome is an expensive part of the LASIK process as it represents £30K capital expenditure plus around £62.50 per procedure costs for operation and new blades.

The rapid wound healing product which reduces the healing time from 2-3 days to 6 hours therefore may have the potential to solve some of the problems currently seen with the use of PRK, such as:

- Pain — In PRK, pain is generated by exposure of the subepithelial nerves, with pain abating as the epithelium heals over the exposed nerves. In PRK an unablated zone (termed the blend zone) about 1mm wide is left around the ablated zone. This ring of epithelial cells is responsible for the healing process, growing over the ablated zone, covering the exposed epithelial nerves at the rate of 0.1 mm per hour, giving a time of about 10-20 hours for complete healing and subsequent reduction of pain. With use of the accelerated wound healing product this can be reduced to 6 hours, reducing the time that pain is felt.
- Period of delayed rehabilitation, i.e. period of 2-3 days whilst cornea is healing where vision is poor.
- Potential for haze and epithelial scarring.

A project such as this is viewed as long term, due to the longer approval process required of a pharmaceutical drug. It is however potentially an exciting future development as it offers market expansion possibilities and the introduction of a further consumable charge. Bridgehead considers that CustomVis will need to conduct a careful due diligence on this technology before entering into agreements on joint development in the LVC field. This represents a much more demanding development and clinical programme with significant input of cash and long timescales for the development of a medical product. It represents a high risk area where CustomVis does not currently have expertise and is well outside their current knowledge base in medical devices in refractive surgery.

*Other potential pipeline developments*

CustomVis could potentially develop a ***surface profiler***, which allows direct measurement of the energy which the laser delivers to the surface of the cornea. Currently CustomVis believes that no other company is developing such equipment, meaning that this diagnostic device could potentially be sold to all companies involved in the LVC field.

**5. Conclusions**

Bridgehead considers that the Company has developed a significant technology base which has been designed specifically to fulfil the requirements of customised surgery within the LVC field. In contrast, other systems on the market represent modifications of systems designed to carry out standard LVC, and are often pushing the components to the limits of their capability. The CustomVis™ System can also deliver improved quality of vision to cases treatable with current technology and those which fall outside the limits of current technology. The Company has also assembled a very strong management team to harness and further develop the technology, to oversee the clinical and commercial development of the Company, and to market and distribute the CustomVis™ System in their chosen geographic sectors of UK, Europe, Latin America, US and Asia Pacific.

Bridgehead believes that the Company's strategy of engaging the interest of the top players, and opinion leaders in the LVC field, particularly as their investigators for FDA clinical trials, adds to the perceived reputation of the Company and confirms the CustomVis™ System as a step change in technology. In addition the CustomVis™ System is addressing a large, generally buoyant market and the Company is focusing on geographic sectors of the market which are demonstrating the highest interest in and growth of LVC.

Bridgehead considers that CustomVis has brought together an impressive team of people and interviews with top practitioners manufacturers and distributors within the refractive surgery field have highlighted the general good impression of the technology. Dr Paul van Saarloos is widely regarded as an innovator in the refractive surgery field with his technology viewed as 2-3 years ahead of the competition. To quote Dr Emmanuel Rosen, Technical Director of Boots Optical, and co-editor of the Journal of Refractive and Cataract Surgery "Paul is a genius"†. In terms of marketing and sales of the CustomVis™ System, Simon Gordon is extremely well known and highly regarded within the industry and has an extensive network of contacts with ophthalmologists, whom he has dealt with in the past, within refractive surgery companies and with distributors.

CustomVis's initial clinical results, as presented at the ASCRS Conference in San Francisco in April 2003, by Marguerite Macdonald, retiring president of ASCRS, are impressive and represent treatment of very difficult cases which other manufactures would not have attempted to treat. By treating the initial difficult eyes, CustomVis has gained significant scientific exposure for the Company, in the form of over 13 scientific papers, including a keynote presentation at the American Academy of Ophthalmology (November 2002) Refractive Surgery Interest Group and International Society of Refractive Surgeons special joint meeting, the most significant global scientific forum in ophthalmology.

In Australia and Europe, CustomVis has met requirements for safety through receiving confirmation from TGA of its intention to issue TGA approval and the CE mark. In the US, clinical trials protocols have already been agreed with the FDA and investigator sites set up for the "myopia" study. In all clinical studies the Company is monitoring patient improvements both objectively through improvements in visual acuity and subjectively through the National Eye Institute Quality of Life survey administered pre-operatively and post-operatively. Bridgehead understands that, by comparison, several companies 'pre-screen' patients to avoid significant visual disorders within their clinical trials group.

Bridgehead considers that CustomVis's strategy of finalising FDA protocols; engaging top US investigators and overseas trial doctors early; and using a prudent mixture of international and US cases will provide the most efficient regulatory initiative for the Company.

Bridgehead considers that there are some risks to CustomVis in the commercialisation of its technology and execution of its commercial plan. These risks are discussed within the Risk factors section of the Prospectus. Here Bridgehead highlights the activities which the Company has undertaken or is about to undertake in order to mitigate some of these risks.

Much of the risk is due to the early stage of the technology and the limited clinical testing carried out to date. While clinical findings from the six eyes treated to date are very encouraging, and the expectations of appropriate clinicians regarding this technology are high, insufficient clinical data are currently available to make any meaningful assessment of the overall performance of the system relative to CustomVis's expectations. To reduce the risks as far as possible, CustomVis has retained a well known clinical investigating body, CCR, to advise them through the regulatory process. Study centres within and outside of the US need to be monitored to the same high standards to ensure similarly high quality of data and compliance with protocol requirements. Failure to ensure this may jeopardise the acceptability of the studies for FDA approval purposes, so to ensure acceptability, CCR will oversee the monitoring of all sites both within and outside the US.

† Emanuel Rosen's quotation was taken in advance of any approach for him regarding his appointment as a non-executive director of the Company.

In laser refractive surgery studies, it is important to pay the surgeons, both for the extra costs to follow the patients and for them to discount the cost of study treatments to patients to guarantee fast enrolment as it is a trial technology. In the CustomVis studies typical fees paid to surgeons will be around £400 per case, in both US and Australia. CustomVis considers that it is unlikely that they will need to pay patients or doctors for the irregular astigmatism/visual loss patient population as doctors desire to clear their books of problem patients.

In preclinical studies of the mutagenicity (the potential to cause mutations within tissue) of the CustomVis 213nm laser greater mutagenicity has been found compared with the current 193nm lasers in two separate studies. CustomVis considers these findings are due to study design issues. Regulators may require further data from studies designed to remove these deficiencies and to confirm that the mutagenic potential of 213nm lasers is no greater than existing 193nm lasers. However, Bridgehead understands that no such concerns have been raised to date and that there is data to support the general safety of lasers in the 190-220nm range. If there is a requirement for further tests, CustomVis will need to liaise with the FDA on the design of *in vivo* tests on animals to overcome the problems caused by variation in water absorption of the laser beams at 193nm and 213nm. Such tests would be expected to take a maximum of 9-12 months to perform and could be performed concurrently with the clinical trials.

One of the challenges for the Company will be to manufacture 5 further lasers within the timescales required for them to supply them to the clinical trials centres to comply with the needs of their clinical plan. There is an inherent risk for every company in the transfer from prototype to production models. However, the Company has an established protocol for assembly, testing, evaluation and quality assurance of the laser. The manufacture of solid state lasers is simpler than for excimer lasers although extra time has to be spent on calibration and quality assurance. In addition Bridgehead understands that CustomVis has employed an experienced production manager to supervise the ramp up to full production.

The whole LVC area is highly litigious and it is possible that several companies will try to claim that CustomVis infringes their patents. Industry sources suggest that CustomVis should be prepared to fight such opposition. Nidek appears to have been successful in its litigation battles with VISX and Dr Paul van Saarloos has had previous experience of winning an IP dispute with VISX, in which he successfully argued that the original patent in a particular area should not have been granted. VISX is expecting to unveil its iris registration method for cyclotorsional rotation later in 2003. This method appears essentially similar to that employed by CustomVis and there could be IP implications. However, Dr Paul van Saarloos has been using iris registration for monitoring cyclotorsional rotation for some time and considers he should be in a good position regarding prior art.

Bridgehead considers that CustomVis has developed excellent technology which represents a step change in the approach to laser vision correction, particularly in the area of customised refractive surgery. The main risks lie in the commercialisation of this technology; to quote from a competitor:

*"The biggest risk for CustomVis will be survival. This is a highly investment intensive business and experienced people are vital. CustomVis has these and with the right cash and careful selection of the battles it fights the company should have what is needed to succeed and line it up for sale. There is no other serious solid state option at the moment."*

Yours faithfully

**For and on behalf of Bridgehead Technologies Limited**

**Fiona J Paton**
**Director**

## PART V

## Patent agent's report


The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London EC2M 4YM

and

The Directors
Collins Stewart Limited
9th Floor
88 Wood Street
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EC2V 7QR

2 July 2003

Dear Sirs

**Report on CLVR Pty Ltd Intellectual Property Portfolio**

This report has been prepared at the request of CLVR Pty Ltd, which trades under the name of CustomVis, for inclusion in the Prospectus of CustomVis plc. This report confirms details of and comments on aspects of CLVR Pty Ltd's intellectual property (IP) portfolio handled by Wray & Associates.

Wray & Associates is an Australian firm of patent and trade marks attorneys specialising in the law relating to intellectual property, particularly patents, trade marks and designs. The firm was established in 1920 and has a long history in servicing the intellectual property needs of both Australian clients and clients based in other countries.

Each of our partners and registered patent and trade marks attorneys is a Fellow of the Institute of Patent and Trade Mark Attorneys of Australia. Our professional staff are divided into groups based on technology areas. Each group is overseen by a partner of the firm. The firm's structure presently contains groups dedicated to the chemical, pharmaceutical, biotechnology, electronics, computing, physics and mechanical engineering technology areas. Each of our professional staff holds a tertiary qualification in the technology field in which he/she practises.

**Section A – Summary of Patent and Trade Mark Applications**

*Patent Applications*

We have prepared and filed two provisional patent applications in Australia and two international patent ("PCT", i.e. Patent Cooperation Treaty) applications for CLVR Pty Ltd. The details of the first of these applications are set out in Schedule A.

The technology that is the subject of these patent applications relates to solid state lasers, and these patent applications are directed to particular aspects of laser technology. A brief description of these technologies is also set out in Schedule A. The inventions that are the subject of these applications have application in the medical field of laser eye surgery. However, the technology underlying the inventions potentially has wider application to other medical fields and also to industrial applications. In view of this, the description of the inventions contained in the two provisional patent applications and in the PCT applications as well as the claims of the PCT applications do not restrict the inventions merely to application to laser eye surgery, but encompass other medical applications and also use in industrial applications.

We are currently instructed that, as new technical developments are created from CLVR Pty Ltd's research and development programme, it is proposed that further patent applications will be filed to protect those new technical developments, where appropriate. In that regard, work is currently underway, following receipt of instructions from CLVR Pty Ltd, on another two inventions in the fields of "Eye Tracking" and "Laser Structure". These two inventions will be the subject of another two respective provisional patent applications to be filed in Australia in the near future. It is presently anticipated that these two further provisional patent applications will be filed with the Australian Patent Office some time in July 2003.

Under the provisions of an international convention ("Paris Convention") dealing with intellectual property, the filing dates of the two provisional patent applications that have been filed establish respective priority dates that can be claimed when filing a corresponding PCT application, provided that the PCT application is filed within a specified time (12 months) from the priority date of the relevant provisional patent application. The PCT application, PCT/AU03/00688 set out in Schedule A, was filed with such a priority claim from provisional patent application PS2663. Another PCT application was filed on 27 June 2003 and claims priority from the other provisional patent application PS3261.

Schedule B sets out the countries that have been designated in the first PCT application, including both the countries designated for regional patent applications and also for national patent applications. The PCT application to claim priority from the other provisional patent application PS3261 will designate the same countries for regional patent applications and national patent applications that are set out in Schedule B, along with any further countries that joined the PCT by the date that PCT application was filed. Designating countries for regional patent applications and national patent applications in a PCT application does not obligate the applicant to later file regional and national phase patent applications for all the countries designated. The PCT applicant may later select the countries for which the regional and national phase applications will be filed.

Filing a PCT application enables a large number of countries to be designated in the PCT application. However, a PCT application does not itself mature into a granted patent. Instead, the PCT application is a vehicle that is used to file regional and national patent applications (referred to as "regional and national phase applications") in any of the countries that were designated in the PCT application for such regional and national patent applications. The regional and national phase applications that are filed are then processed according to the law and procedures of the relevant regional authorities and countries. In some aspects, these laws and procedures do differ between the regional authorities and countries. Generally, however, they involve an examination of the application by the relevant regional or national Patent Office. Once the examination stage is successfully completed, the application is accepted, or allowed, for grant of a patent. Prior to grant of the patent, the law of some regional authorities and countries provides a period during which third parties may file an opposition against the grant of a patent. Once any opposition that is filed is successfully overcome, the patent is granted.

*Trade Mark Applications*

We have prepared and filed six trade mark applications in Australia for CLVR Pty Ltd. The details of those trade mark applications are set out in Schedule C. The applications are currently awaiting examination in the Australian Trade Marks Office.

Under the provisions of the Paris Convention, the filing dates of these six trade mark applications establish priority dates that can be claimed when filing corresponding trade mark applications ("Convention applications") in most other countries, provided that the applications in those other countries are filed within a specified time ( six months) from the priority date. As all six of these trade mark applications were filed on the same day, viz. 28 May 2003, they all have the same priority date, viz. 28 May 2003. Consequently, the Convention applications do not need to be filed until 28 November 2003. Whilst there is no need to make a decision at this stage as to the countries in which such Convention applications will be filed, the present intention is to file such Convention applications in the United States of America, the United Kingdom and other selected European countries.

The letters "TM" are used as a superscript, e.g. CustomVis™, with the trade marks used by CLVR Pty Ltd to signify that CLVR Pty Ltd is using the words as trade marks. In some jurisdictions, e.g. Australia and the United Kingdom, use of a trade mark, even though not registered, may result in common law rights in relation to that trade mark accruing to the owner and user of that trade mark. Upon the trade marks being formally registered by the relevant Trade Marks Office, the "TM" will be replaced by a reference to the relevant trade mark as being a "registered trade mark", often signified by use of the symbol Û.

The patent and trade mark applications set out in Schedule A and Schedule C will require further funding to process the applications from the current application stages through grant of a patent or registration of a trade mark. This will also apply to any future patent and trade mark applications that are filed. In the case of a large patent and trade mark portfolio these costs can be significant. For example, in the case of a PCT application that proceeds to the regional and national phase in, say 20 – 30 regions and countries, costs from the application stage through to grant would likely be several hundred thousand dollars (Australian currency), incurred over a period of several years. Costs may be higher than initially expected if it is necessary to overcome significant examiner's objections or third party oppositions.

**Section B – Commercial Analysis**

**1. Technology Protected**

The existing patent applications that we have filed, and patent applications proposed to be filed, for CLVR Pty Ltd's technology are referred to above in Section A.

The procedure of obtaining patent protection for an invention normally takes several years in most countries. The applications of CLVR Pty Ltd are at a relatively early stage in this procedure and therefore no patents have been granted. The procedure in most countries requires that specific steps are taken within specified periods to maintain the applications in force. Failure to do so may, in some circumstances, result in an application lapsing, i.e. ceasing to be in force. In the case of CLVR Pty Ltd's applications, all necessary steps to maintain the applications in force have, to date, been taken.

We have not received any notifications from third parties regarding opposition or disputing the patentability of the inventions, that are the subject of the three patent applications, including the PCT application that have been filed, nor regarding validity of those applications. However, the contents of the three patent applications have not been officially published by the Australian Patent Office nor by WIPO (the authority that administers the PCT system). In addition, the three patent applications are not open to opposition by third parties.

**2. Patents in the Field of Laser Technology**

Patents in the field of laser technology are common in the industry, and there is a large number of patents covering different aspects of laser technology. Additionally, there is a large number of organisations that hold patents in the field of laser technology.

## 3. Third Parties' Patents

Three of the organisations that hold a number of patents in the field of laser technology are LaserSight Technologies, Inc., Visx, Inc., and Alcon Laboratories, Inc./Alcon, Inc, although there are others. Some of the patents of LaserSight Technologies, Inc. have been reviewed in detail as CLVR Pty Ltd considered that there may have been aspects of their laser systems that are similar to those of CLVR Pty Ltd. These patents are discussed further in the next section.

Some of the patents of Visx, Inc. have been considered by CLVR Pty Ltd consequent to searches being conducted on behalf of CLVR Pty Ltd by a search organisation. Some of the patents of Alcon Laboratories, Inc./Alcon, Inc. have come to the attention of CLVR Pty Ltd via media releases and commentary in publications in the field of ophthalmology. CLVR Pty Ltd is aware of other competitors in the field (as set out in the Bridgehead Technologies expert report herein). However, none of the patents of these other competitors were cited in the international-type search reports that were issued by the Australian Patent Office in respect of the international-type searches (see later herein) it conducted on the inventions that are the subject of CLVR Pty Ltd's provisional patent applications PS 2663 and PS 3261.

*LaserSight Technologies, Inc.*

One of these organisations is LaserSight Technologies, Inc. ("LaserSight"). Several US patents of LaserSight have come to the attention of CLVR Pty Ltd and have been reviewed for comparison with CLVR Pty Ltd's inventions that are the subject of the two Australian provisional patent applications identified in Section A.

One of the LaserSight patents is directed to a method of performing corneal refractive surgery by reshaping a portion of a corneal surface. However, this method employs a galvanometer scanning mechanism to scan the selected laser output beam which controls the laser beam into an overlapping pattern of adjacent pulses. In contrast, the scanning device and method of CLVR Pty Ltd's provisional patent application PS3261 uses a solid state device to effect the scanning movement.

The LaserSight patent that is closest to the inventions of CLVR Pty Ltd, that are the subject of the two provisional patent applications identified in Section A, relates to an apparatus and method used in performing ophthalmic surgery. However, it uses a galvanometer scanner and galvanometric forces to effect the scanning of a pulsed output laser beam. This patent is also referred to on page 34 of the Bridgehead Technologies expert report herein, i.e. the 504 Patent. In contrast, the scanning device and method of CLVR Pty Ltd's provisional patent application PS3261 uses a solid state device to effect the scanning movement. Comments on the other patents of LaserSight, of which we have been informed, that have come to the attention of CLVR Pty Ltd, is set out below.

A further LaserSight patent is directed to a method for correcting astigmatism that forms a (partial) cylindrical-shaped ablation in the cornea and over-ablates a transition region at each end thereof.

Three further LaserSight patents deal with a system and method for illuminating the eye whilst performing corrective surgery, rather than to a laser or scanning system/method as is the case with CLVR Pty Ltd's two provisional patent applications. These three LaserSight patents cover various combinations and permutations of features of the invention. One feature that seems to be common to these is that the light is directed into the patient's eye at an angle greater than 20 degrees with respect to a plane tangential to the iris of the eye.

Neither of CLVR Pty Ltd's two provisional patent applications are directed to a method or system of the type that are the subject of the further LaserSight patents referenced above.

It is noted that neither of the International-Type Search Reports (see later herein) issued by the Australian Patent Office on CLVR Pty Ltd's provisional patent applications PS2663 and PS3261 included any LaserSight patents.

*Visx, Inc.*

Visx, Inc. ("Visx") holds a large portfolio of patents in the fields of lasers and laser surgery. However, we have not reviewed the patents in the Visx portfolio in detail, though information received from CLVR Pty Ltd is that the control system and laser design used in the CLVR Pty Ltd laser systems are different from those of Visx.

It is noted that neither of the International-Type Search Reports (see later herein) issued by the Australian Patent Office on CLVR Pty Ltd's provisional patent applications PS2663 and PS3261 included any Visx patents.

*Alcon Laboratories, Inc./Alcon, Inc.*

Alcon Laboratories, Inc./Alcon, Inc. ("Alcon") is another organisation that is understood to hold patents in the fields of lasers and laser surgery. However, to date, none of their patents have been encountered in the searches that have been carried out. Two patents of Summit Technology, Inc ("Summit" – from the website of Alcon, Inc, Summit is a corporation understood to have been acquired by Alcon) have been encountered. However, one of these relates to laser apparatus and method for modifying the curvature of the cornea in which a light beam is directed to the eye and the light spot so formed is varied to remove cornea material, as required. The other relates to laser apparatus for eroding a surface that selects and controls the shape and size of the area irradiated by each laser pulse whilst maintaining a substantially constant energy per unit area during each pulse. Neither of CLVR Pty Ltd's three patent applications is directed to an apparatus or method of the types that are the subject of the Summit patents referenced above.

In addition, information received from CLVR Pty Ltd is that the CLVR Pty Ltd laser systems do not vary the light spot in shape or size, but scan a fixed light spot, which is not similar to Alcon's technology.

It is noted that neither of the International-Type Search Reports (see later herein) issued by the Australian Patent Office on CLVR Pty Ltd's provisional patent applications PS2663 and PS3261 included any Alcon patents.

**4. Other Prior Art**

The two provisional patent applications PS2663 and PS3261 of CLVR Pty Ltd refer to prior art patent documents that were known to CLVR Pty Ltd at the time that the two applications were filed. Comments on these prior art documents are set out in the next two sections hereunder.

*Prior Art Referred to in Application PS2663*

The prior art documents disclose various arrangements and aspects of non-linear optical elements for frequency conversion of a laser beam. These arrangements and methods are used for dissipating a laser beam, locating a laser beam and for enhancing frequency conversion. Some of these arrangements use specific frequency converting compounds as the non-linear optical elements. However, they do not disclose the arrangements for reducing instabilities arising from the use of non-linear optical crystals that are the subject of application PS2663.

*Prior Art Referred to in Application PS3261*

One of the prior art documents discloses an inclination adjusting device for a light controlling element that is used in the optical scanner of, for example, a laser printer. Piezoelectric (solid state) elements are used to rotate a shaft upon which a reflecting mirror is mounted. The amount of rotation of the shaft or inclination of the mirror is adjusted by controlling the voltage applied to the piezoelectric elements. However, the invention that is the subject of CLVR Pty Ltd's application PS3261 does not employ an arrangement of a rotatable shaft to adjust the inclination of the mirror.

Another prior patent discloses an apparatus to determine the actual position of an optical fibre array by detecting light transmitted through the short fibres of the array as a laser beam is scanned across the fibre ends. This apparatus uses a mirror to deflect the laser beam. The angle of the mirror

may be adjusted by having an adjustment screw impinge upon a piezoelectric stack (a solid state device). Voltage applied to the piezoelectric stack causes it to expand thereby biasing the adjustment screw which results in changing the angle of the mirror that reflects the laser beam. However, the invention that is the subject of CLVR Pty Ltd's application PS3261 does not employ an adjustment screw impinging upon a piezoelectric stack to change the angle of the reflecting mirror.

A further prior art patent document is directed to a piezoelectric/electrostrictive device and the production method thereof. However, this patent is directed solely to the piezoelectric/electrostrictive device and its operation and does not relate to laser technology.

Patent application PS3261 also refers to the LaserSight US patent first mentioned in relation to the LaserSight patents under the "Third Parties' Patents" heading herein.

*International-Type Searches*

The Australian Patent Office conducts an international-type search in respect of an invention, that is the subject of an Australian patent application, if a request for such a search is filed by the applicant of that patent application. However, having such a search conducted is an entirely optional step available to the applicant. CLVR Pty Ltd has exercised this option in respect of each of the two provisional patent applications identified in Schedule A.

Accordingly, the Australian Patent Office has conducted an international-type search in connection with each of the two provisional patent applications identified in Schedule A. An International-Type Search Report ("ITSR") has been established by the Australian Patent Office in connection with each of those international-type searches.

The ITSRs list the documents located in the international-type searches that the Australian Patent Office considered most relevant to the inventions of the two provisional patent applications based on search statements filed with the requests for the international-type searches. The search statements define the inventions to be searched by the Australian Patent Office; a search statement is similar in format to a claim of a patent specification.

The ITSRs issued by the Patent Office did not list any patents owned by LaserSight, Visx, or Alcon. The conclusions that can be drawn from this are that:

(a) the Australian Patent Office did not consider any of the patents of LaserSight, Visx or Alcon were relevant with respect to the searches they conducted, or not as relevant as the documents that were listed in the ITSRs,

(b) they were considered to be relevant, but no more relevant than those patent documents that were listed in the ITSRs, i.e. they were merely cumulative of the disclosures set out in the documents that were listed in the ITSRs, or

(c) the Australian Patent Office did not locate any of their patents in the searches conducted.

The above possible conclusions do not, however, preclude the patent documents of LaserSight, Visx or Alcon from being cited in the future in relation to CLVR Pty Ltd's PCT applications, or any regional or national phase applications filed in respect of these PCT applications, if the examining Patent Office locates them in a search and considers them relevant. Should that occur, however, CLVR Pty Ltd will have opportunity to make submissions in rebuttal of the citations made by the Patent Office conducting the examination.

*ITSR Issued on Application PS2663*

The patent documents listed in the ITSR issued on this application are owned by The United States of America as represented by the Secretary of the Air force (Assignee), Hughes Aircraft Company (Assignee), Toshiba Corp, Ushio Sogo Gijutsu Kenkyusho:KK, International Business Machines (Assignee), Ushio Research Institute of Technology, Inc and Mitsubishi Heavy Industries, Ltd. The patent documents listed in the ITSR include granted patents and patent applications. The preceding information about the owners of the patent documents listed in the ITSR (and included in the

following paragraphs) has been taken from the copies of the patent documents provided by the Australian Patent Office with the ITSR. However, it is possible that, since the printing of the copies of the patent documents provided with the ITSR (which may, in some instances, have been significantly before the ITSR issued), some of the patents and patent applications have changed ownership, e.g. by way of a subsequent transfer of rights or assignment.

The ITSR issued on CLVR Pty Ltd's provisional patent application PS2663 included a prior patent, owned by The United States of America as represented by the Secretary of the Air Force, directed to an optical beam scanner in which an optical beam is scanned through a non-linear optical crystal by passing the beam through thick optical plates. These optical plates are rotatably mounted on an axle. In contrast, the invention that is the subject of CLVR Pty Ltd's application PS2663 does not mount the optical plates on a rotating axle.

A second granted patent, owned by Hughes Aircraft Company (Assignee), included in the ITSR issued on application PS2663 is directed to various arrangements of prisms and mirrors to reciprocatingly scan a laser beam over the surface of a non linear optical crystal. However, the invention that is the subject of CLVR Pty Ltd's application PS2663 does not employ prisms and mirrors. In addition, our enquiry of the relevant Patent Office computer records indicates that the term of this latter patent has expired.

The ITSR also included an English language abstract of a non-English patent document, owned by Toshiba Corp, along with a computer generated English translation of the document. Since the translation provided by the Australian Patent Office with the ITSR is only a computer generated English translation, the accuracy of the translation may be questionable. Nevertheless, this computer generated English translation discloses vibrating, or oscillating, transmission plates to shift the optical axis of a laser beam travelling through the transmission plates. In contrast, the invention that is the subject of CLVR Pty Ltd's application PS2663 does not employ the technique of vibrating, or oscillating, transmission plates to effect a shift in the optical axis of the laser beam.

Five other patent documents, owned by Hughes Aircraft Company, Ushio Sogo Gijutsu Kenkyusho:KK, International Business Machines (Assignee), Ushio Research Institute of Technology, Inc and Mitsubishi Heavy Industries, Ltd., respectively, included in the ITSR are directed to particular arrangements for heat removal from optical elements (such as non linear optical crystals used in lasers), and temperature control and crystal adjustment of such optical elements. However, the invention that is the subject of CLVR Pty Ltd's application PS2663 does not employ such arrangements.

*ITSR Issued on Application PS3261*

The patent documents listed in the ITSR issued on this application are owned by University of Washington (Assignee), William Henry Stevens and Edwin Deric Gaskell, Victor Co of Japan Ltd, Inst Tekh Kibernet An Brus, Shui T Lai and Kabushiki Kaisha Toshiba.The preceding information about the owners of the patent documents listed in the ITSR (and included in the following paragraphs) has been taken from the copies of the patent documents provided by the Australian Patent Office with the ITSR. However, it is possible that, since the printing of the copies of the patent documents provided with the ITSR (which may, in some instances, have been significantly before the ITSR issued), some of the patents and patent applications have changed ownership, e.g. by way of a subsequent transfer of rights or assignment.

One of the prior patents included in the ITSR issued on CLVR Pty Ltd's provisional patent application PS3261 discloses an optical scanner that uses a mirror which moves to deflect light along a scanning path. The optical scanner employs a counterbalance to counter the forces that are imposed onto the rest of the optical scanner by the motion of the mirror. The patent discloses two specific systems for driving the mirror and counterbalance, one being by an electromagnetic drive and the other being by a solid state piezoelectric device. This prior art patent is owned by University of Washington (Assignee). Whilst the scanning device and method of CLVR Pty Ltd's provisional patent application PS3261 does use a solid state device to effect the scanning movement, the specific

arrangement of the CLVR Pty Ltd device is different from that disclosed in this patent. Furthermore, the CLVR Pty Ltd scanning device does not employ a counterbalance to offset forces induced by the motion of the mirror.

Another prior art patent discloses a laser marking arrangement in which the path of a laser beam is deflected by a mirror between two extreme positions that define a predetermined angle. This arrangement is characterised by the mirror being displaced through the predetermined angle at two different rates in two different directions and the laser being controlled to fire only whilst the mirror is being traversed in the direction affording the slower rate of displacement. The laser marking arrangement enables a desired dot-matrix marking to be obtained over an area of a target. The device employed to displace the mirror may include electrical devices that undergo a change of shape in response to electrical signals, such piezoelectric devices (solid state devices), electro-strictive devices and magneto-strictive devices. This patent is owned by William Henry Stevens and Edwin Deric Gaskell. Whilst the CLVR Pty Ltd scanning device employs a solid state device to effect the scanning movement, the specific arrangement of the CLVR Pty Ltd scanning device is different from that disclosed in this prior art patent. In addition, the CLVR Pty Ltd scanning device that is the subject of provisional patent application PS3261 does not employ displacement of the mirror in one direction at a rate different from the rate of displacement in the other direction and the laser being controlled to fire only whilst the mirror is being traversed at the slower rate of displacement.

The ITSR also included an English language abstract of a non-English patent document, owned by Victor Co of Japan Ltd, along with a computer generated English translation of the document. Since the translation provided by the Australian Patent Office with the ITSR is only a computer generated English translation, the accuracy of the translation may be questionable. However, this computer generated English translation discloses an optical deflector to deflect an optical beam that uses piezoelectric devices (solid state devices) to generate vibrations in deflector elements to not only to deflect the beam but also provide cooling to the piezoelectric devices. This arrangement avoids the need for a separate fan to effect the cooling. In contrast, the invention that is the subject of CLVR Pty Ltd's application PS3261 is not directed to such an arrangement.

The ITSR also included a non-English patent document, owned by Inst Tekh Kibernet An Brus, without any English translation. An English translation of the abstract of this patent document was uncovered in an international patent database. This English language abstract discloses an optical deflector for opto-electronic and laser instruments which uses a mirror to deflect an optical beam. Two piezoelectric drives (solid state devices) are deformed in response to electrical input signals. The deformation is transferred to elastic plates which then act on a moveable platform to which the mirror is attached. The invention that is the subject of CLVR Pty Ltd's application PS3261, however, does not employ elastic plates to transfer deformation from the piezoelectric devices to the moveable platform that supports the mirror.

Another patent, owned by Shui T Lai, included in the ITSR issued on application PS3261 discloses a pair of scanning mirrors used in an apparatus for surgery of the cornea in which the mirrors are mounted on gimbal mounts and movements of the scanning mirrors in the horizontal and vertical directions are achieved by piezoelectric actuators (solid state devices). However, no specific information is included in the patent document about the arrangement and therefore there does not appear to be any disclosure in this patent document of an arrangement similar to the invention that is the subject of CLVR Pty Ltd's application PS3261.

The last patent, owned by Kabushiki Kaisha Toshiba, included in the ITSR was also included as a prior art document referred to in CLVR Pty Ltd's application PS3261, and has already been commented upon in the first paragraph under the heading "Prior Art Referred to in Application PS3261".

*International Search on PCT Application*

As part of the PCT application process, the Australian Patent Office will conduct an international search on the invention that is the subject of the PCT application PCT/AU03/00688 set out in

Schedule A. Since the invention of that application is the same as the invention that is the subject of the provisional application PS2663 and since an international-type search has already been conducted by the Australian Patent Office in respect of the invention that is the subject of provisional patent application PS2663, it can be expected that the Australian Patent Office will base the international search on that PCT application on the international-type search that has already been conducted on provisional patent application PS2663. Thus, little, if any, further prior art is expected in the International Search Report ("ISR") that will issue in the PCT application PCT/AU03/00688. By analogy, similar comments apply to the other PCT application to claim priority from provisional patent application PS3261. The Australian Patent Office usually takes about 4 – 6 weeks to issue an ISR on a PCT application from the filing date of that PCT application. However, for the reasons set out in the preceding paragraph, it can also be expected that in the present circumstances, that period will be shortened.

**Section C – General Comments**

Generally, each country administers its own patent laws and patent system. Whilst the following remarks, in relation to aspects of the rights granted by patents and the validity of patents, apply in a general sense to most countries that have patent systems, there are some variations between countries.

A patent provides the owner with a statutory monopoly for a fixed term in the territory covered by the patent. This monopoly grants the patent owner the right to exercise control over the subject matter of technology covered by the claims of the patent, including taking action against parties that infringe the patent and authorising use of the patented invention through the grant of licences. The granting of a patent does not, however, guarantee that the patent owner is entitled to practise the patented invention without a licence from the owner of an earlier patent. For example, it is possible that practising a patented invention may infringe an earlier granted patent, or will infringe an earlier patent application still to mature into a patent, unless a licence is obtained from the owner of that earlier patent or application (if granted).In addition, if improvements are made in the future by a third party for which that third party then obtains a patent, a licence may be required from that third party if another party requires to use those improvements.

Under the patent laws of most countries, to be patentable, an invention must be novel and possess an inventive step, in addition to meeting other requirements. We have included, in this report, a summary of our opinion of some prior art documents and the differences between those prior art documents and the inventions that are the subject of CLVR Pty Ltd's two provisional patent applications identified in Schedule A. Notwithstanding this, the assessment of whether an invention possesses an inventive step must be made in light of all the relevant prior art. This assessment must be made with reference not only to the cited prior art documents but also to any other relevant documents which exist together with the knowledge possessed by experts skilled in the relevant art, i.e. technical field. Similarly, when assessing whether an invention is an infringement of a granted patent, in addition to reference to experts technically skilled in the art, it may also be necessary, under the patent law and practice of some countries, to consider the relevant Patent Office file history of the patent alleged to be infringed. Accordingly, definitive conclusions about the relevance of the prior art documents from the standpoint of inventive step and infringement cannot be made solely from the comments made in this report about those prior art documents.

In addition, the granting of a patent does not guarantee validity of that patent because granted patents are subject to revocation during their term on grounds of invalidity. For example, relevant prior art disclosures may be discovered after the grant of a patent that may have the effect of rendering the patent invalid due to the patented invention not being new or inventive. However, in some circumstances, amendments may be made to a granted patent to avoid such prior art disclosures and thereby maintain the validity of the patent.

**Schedule A — Details of Patent Applications**

| | | |
|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Provisional Patent Application No.:** | PS2663 |
| **3.** | **Filing Date:** | 30 May 2002 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Invention:** | "Solid State UV Laser" |
| **6.** | **Inventor:** | Dr Paul van Saarloos (employee of CLVR Pty Ltd) |
| **7.** | **Brief Description of the Invention:** | The invention is directed to reducing instabilities that arise from use of non-linear optical crystals in solid state lasers that generate an ultraviolet wavelength laser beam. |

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| | | |
|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Provisional Patent Application No.:** | PS3261 |
| **3.** | **Filing Date:** | 28 June 2002 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Invention:** | "Scanning Device and Method of Scanning an Optical Beam Over a Surface" |
| **6.** | **Inventor:** | Dr Paul van Saarloos (employee of CLVR Pty Ltd) |
| **7.** | **Brief Description of the Invention:** | A scanning device to scan a laser beam over a surface. The scanning mechanism employs a solid state device to effect the scanning movement of the laser beam. |

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| | | |
|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **PCT Patent Application No.:** | PCT/AU03/00688 |
| **3.** | **Priority Date:** | 30 May 2002 — from provisional patent application PS2663 |
| **4.** | **Filing Date:** | 30 May 2003 |
| **5.** | **Countries Designated:** | See Schedule B for list of countries designated for regional and national patent applications |
| **6.** | **Title of Invention:** | "Solid State UV Laser" |
| **7.** | **Inventor:** | Dr Paul van Saarloos (employee of CLVR Pty Ltd) |
| **8.** | **Brief Description of the Invention:** | The invention is directed to reducing instabilities that arise from use of non-linear optical crystals in solid state lasers that generate an ultraviolet wavelength laser beam. |

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**Schedule B — List of Designated countries in PCT Application**

**Regional Patent Applications**

| | | |
|---|---|---|
| AP | ARIPO | GH Ghana, GM The Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, TZ Tanzania, ZM Zambia, ZW Zimbabwe, and any other state which is a contracting state of the Harare Protocol and of the PCT |
| EA | Eurasian Patent | AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other state which is a contracting state of the Eurasian Patent Convention and of the PCT |
| EP | European Patent | AT Austria, BE Belgium, BG Bulgaria, CH and LI Switzerland and Liechtenstein, CY Cyprus, CZ Czech Republic, DE Germany, DK Denmark, EE Estonia, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, HU Hungary, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, *RO Romania, SE Sweden, SI Slovenia, SK Slovakia, TR Turkey, and any other state which is a contracting state of the European Patent Convention and of the PCT. |
| OA | OAPI Patent | BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Cote d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GQ Equatorial Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo and any other state which is a member state of OAPI and a contracting state of the PCT |

## National Patent Applications

| | |
|---|---|
| AE | United Arab Emirates |
| AG | Antigua and Barbuda |
| AM | Armenia |
| AT | Austria |
| AU | Australia |
| AZ | Azerbaijan |
| BA | Bosnia & Herzegovina |
| BB | Barbados |
| BG | Bulgaria |
| BR | Brazil |
| BY | Belarus |
| BZ | Belize |
| CA | Canada |
| CH | Switzerland |
| CN | China |
| CO | Colombia |
| CR | Costa Rica |
| CU | Cuba |
| CZ | Czech Republic |
| DE | Germany |
| DK | Denmark |
| DM | Dominica |
| DZ | Algeria |
| EC | Ecuador |
| EE | Estonia |
| ES | Spain |
| FI | Finland |
| GB | UK |
| GD | Grenada |
| GE | Georgia |
| GH | Ghana |
| GM | The Gambia |
| HR | Croatia |
| HU | Hungary |
| ID | Indonesia |
| IL | Israel |
| IN | India |
| IS | Iceland |
| JP | Japan |
| KE | Kenya |
| KG | Kyrgyzstan |
| KP | Democratic People's Republic of Korea(North Korea) |
| KR | Republic of Korea(South Korea) |
| KZ | Kazakhstan |
| LC | St Lucia |
| LI | Liechtenstein |
| LK | Sri Lanka |
| LR | Liberia |
| LS | Lesotho |
| LT | Lithuania |
| LU | Luxembourg |
| LV | Latvia |
| MA | Morocco |
| MD | Moldova (Republic of) |
| MG | Madagascar |
| MK | Former Yugoslav Republic of Macedonia |
| MN | Mongolia |
| MW | Malawi |
| MX | Mexico |
| MZ | Mozambique |
| NI | Nicaragua |
| NO | Norway |
| NZ | New Zealand |
| OM | Oman |
| PH | Philippines |
| PL | Poland |
| PT | Portugal |
| RO | Romania |
| RU | Russian Federation |
| SC | Seychelles |
| SD | Sudan |
| SE | Sweden |
| SG | Singapore |
| SK | Slovakia |
| SL | Sierra Leone |
| TJ | Tajikistan |
| TM | Turkmenistan |
| TN | Tunisia |
| TR | Turkey |
| TT | Trinidad & Tobago |
| TZ | Tanzania (United Republic of) |
| UA | Ukraine |
| UG | Uganda |
| US | US |
| UZ | Uzbekistan |
| VC | Saint Vincent and the Grenadines |
| VN | Viet Nam |
| YU | Serbia & Montenegro (previously: Yugoslavia) |
| ZA | South Africa |
| ZM | Zambia |
| ZW | Zimbabwe |

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## Schedule C – Trade Mark Applications

| | | |
|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Trade Mark Application No.:** | 955764 |
| **3.** | **Filing Date:** | 28 May 2003 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Mark:** | "CustomVis" |
| **6.** | **Classes and Goods/Services Specified in Application:** | 5, 9, 10, 37 and 42 |

**Class 5:** Drugs for medical purposes and pharmaceutical preparations, including ophthalmic drugs and pharmaceutical preparations.

**Class 9:** Lasers for non-medical purposes; laser beam scanning systems for lasers for non-medical purposes; laser beam scanning apparatus and equipment for lasers for non-medical purposes; tracking systems for lasers for non-medical purposes; tracking apparatus and equipment for lasers for non-medical purposes; parts, fittings and accessories in this class for any of the aforesaid goods; software and computer programs, including software and computer programs for lasers, laser beam scanning systems, laser beam scanning apparatus, tracking systems for lasers, tracking apparatus for lasers, ophthalmic purposes, ophthalmic procedures, ophthalmic surgery, eye tracking and ancillary procedures, ophthalmic apparatus, ophthalmic equipment and diagnostics for measuring the visual pathways of the eye.

**Class 10:** Lasers for medical purposes, including lasers for ophthalmic surgery and ophthalmic procedures; laser beam scanning systems for lasers for medical purposes; laser beam scanning apparatus and equipment for lasers for medical purposes; tracking systems for lasers for medical purposes; tracking apparatus and equipment for lasers for medical purposes; medical apparatus, equipment and instruments, including eye scanning apparatus and equipment, and eye tracking apparatus and equipment; diagnostic apparatus, equipment and tools for measuring the visual pathways of the eye; parts fittings and accessories in this class for any of the aforesaid goods.

**Class 37:** Maintenance and repair of: medical apparatus, equipment, instruments and tools, including lasers for medical purposes (including ophthalmic surgery and ophthalmic procedures), eye scanning systems, apparatus and equipment, eye tracking systems, apparatus and equipment, and diagnostic apparatus, equipment and tools for measuring the visual pathways of the eye; lasers for non-medical purposes, laser beam scanning systems, apparatus and equipment; tracking systems, apparatus and equipment for lasers; and parts, fittings and accessories in this class for any of the aforesaid goods.

**Class 42:** Research & development services and consulting services in the fields of: lasers (including laser beam scanning and tracking for lasers), laser surgery, laser procedures (including medical and non-medical purposes); eye tracking and ancillary procedures; medical procedures, including ophthalmic procedures; diagnostics for measuring the visual pathways of the eye; drugs for medical purposes and pharmaceutical preparations, including ophthalmic drugs and pharmaceutical preparations; and, apparatus, equipment, instruments and tools for the aforesaid fields.

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|---|---|---|
| 1. | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| 2. | **Trade Mark Application No.:** | *955765* |
| 3. | **Filing Date:** | 28 May 2003 |
| 4. | **Country:** | Australia |
| 5. | **Title of Mark:** | "CustomVis PULZAR" |
| 7. | **Classes and Goods/Services Specified in Application:** | 9 and 10 |

**Class 9:** Lasers for non-medical purposes; laser beam scanning systems for lasers for non-medical purposes; laser beam scanning apparatus and equipment for lasers for non-medical purposes; tracking systems for lasers for non-medical purposes; tracking apparatus and equipment for lasers for non-medical purposes; parts, fittings and accessories in this class for any of the aforesaid goods; software and computer programs, including software and computer programs for lasers, laser beam scanning systems, laser beam scanning apparatus, tracking systems for lasers, tracking apparatus for lasers, ophthalmic purposes, ophthalmic procedures, ophthalmic surgery, eye tracking and ancillary procedures, ophthalmic apparatus, ophthalmic equipment and diagnostics for measuring the visual pathways of the eye.

**Class 10:** Lasers for medical purposes, including lasers for ophthalmic surgery and ophthalmic procedures; laser beam scanning systems for lasers for medical purposes; laser beam scanning apparatus and equipment for lasers for medical purposes; tracking systems for lasers for medical purposes; tracking apparatus and equipment for lasers for medical purposes; medical apparatus, equipment and instruments, including eye scanning apparatus and equipment, and eye tracking apparatus and equipment; diagnostic apparatus, equipment and tools for measuring the visual pathways of the eye; parts fittings and accessories in this class for any of the aforesaid goods.

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| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Trade Mark Application No.:** | 955768 |
| **3.** | **Filing Date:** | 28 May 2003 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Mark:** | ZTRAK |
| **9.** | **Classes and Goods/Services Specified in Application:** | 9 and 10 |

**Class 9:** Lasers for non-medical purposes; tracking systems for lasers for non-medical purposes; tracking apparatus and equipment for lasers for non-medical purposes; parts, fittings and accessories in this class for any of the aforesaid goods; software and computer programs, including software and computer programs for lasers, tracking systems for lasers, tracking apparatus for lasers, ophthalmic purposes, ophthalmic procedures, ophthalmic surgery, eye tracking and ancillary procedures, ophthalmic apparatus, ophthalmic equipment and diagnostics for measuring the visual pathways of the eye.

**Class 10:** Lasers for medical purposes, including lasers for ophthalmic surgery and ophthalmic procedures; tracking systems for lasers for medical purposes; tracking apparatus and equipment for lasers for medical purposes; medical apparatus, equipment and instruments, including eye tracking apparatus and equipment; diagnostic apparatus, equipment and tools for measuring the visual pathways of the eye; parts fittings and accessories in this class for any of the aforesaid goods.

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|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Trade Mark Application No.:** | 955770 |
| **3.** | **Filing Date:** | 28 May 2003 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Mark:** | ZCAD |
| **6.** | **Classes and Goods/Services Specified in Application:** | 9 |

**Class 9:** Software and computer programs, including software and computer programs for lasers, laser beam scanning systems, laser beam scanning apparatus, tracking systems for lasers, tracking apparatus for lasers, ophthalmic purposes, ophthalmic procedures, ophthalmic surgery, eye tracking and ancillary procedures, ophthalmic apparatus, ophthalmic equipment and diagnostics for measuring the visual pathways of the eye.

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|---|---|---|
| **1.** | **Applicant/Owner:** | CLVR Pty Ltd<br>(ACN 096 153 954) |
| **2.** | **Trade Mark Application No.:** | 955772 |
| **3.** | **Filing Date:** | 28 May 2003 |
| **4.** | **Country:** | Australia |
| **5.** | **Title of Mark:** | ZSCAN |
| **6.** | **Classes and Goods/Services Specified in Application:** | 9 and 10 |

**Class 9:** Lasers for non-medical purposes; laser beam scanning systems for lasers for non-medical purposes; laser beam scanning apparatus and equipment for lasers for non-medical purposes; parts, fittings and accessories in this class for any of the aforesaid goods; software and computer programs, including software and computer programs for lasers, laser beam scanning systems, laser beam scanning apparatus, ophthalmic purposes, ophthalmic procedures, ophthalmic surgery, ophthalmic apparatus, ophthalmic equipment and diagnostics for measuring the visual pathways of the eye.

**Class 10:** Lasers for medical purposes, including lasers for ophthalmic surgery and ophthalmic procedures; laser beam scanning systems for lasers for medical purposes; laser beam scanning apparatus and equipment for lasers for medical purposes; medical apparatus, equipment and instruments, including eye scanning apparatus and equipment; diagnostic apparatus, equipment and tools for measuring the visual pathways of the eye; parts fittings and accessories in this class for any of the aforesaid goods.

Yours faithfully
WRAY & ASSOCIATES

## PART VI

## Accountants' Report


The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London
EC2M 4YM

and

The Directors
Collins Stewart Limited
9th Floor
88 Wood Street
London
EC2V 7QR

2 July 2003

Dear Sirs

We report on the financial information of CustomVis plc ("the Company") and CLVR Pty Limited ("CLVR") set out below. This financial information has been prepared for inclusion in the Admission Document of the Company dated 2 July 2003.

**Group formation**

The Company was incorporated in England and Wales as a public limited liability company on 5 December 2002 with an authorised share capital of £50,000 divided into 50,000 ordinary shares of £1 each of which 2 shares were issued at par. On 17 April 2003 the Company increased its authorised share capital to £5 million by the creation of 99 million additional ordinary shares of 5 pence each, re-designated and subdivided the two issued ordinary shares into 20 ordinary shares of 5 pence each and re-designated and subdivided the 49,998 authorised but unissued ordinary shares of £1 each into 999,960 ordinary shares of 5 pence each.

Also on 17 April 2003 the Company acquired the whole of the issued share capital of CLVR by way of a share for share issue and since that date CLVR has been a wholly owned subsidiary of the Company.

On 22 April 2003 an investment agreement was entered into between the Company, the directors of the Company and Warrawee Investments Limited relating to, inter alia, the subscription by Warrawee Investments Limited of £1,342,844 in convertible unsecured loan notes. Concurrently, a loan note instrument was executed by the Company constituting £1,342,844 variable rate unsecured convertible loan notes.

On 5 May 2003, 924,693 new Ordinary Shares were allotted to certain subscribers for ordinary shares in consideration for the settlement of loans by them to CLVR and 30,730 new ordinary shares were allotted to The Trustees of Thorstone (SE) Retirement and Death Benefit Scheme in consideration for cash.

On 5 May 2003 an option was granted to Poynton & Partners Pty Ltd (through a nominee company) over 1,120,000 ordinary shares in the Company at an exercise price of £0.62 per share. On 1 July 2003 this option was exercised.

On 20 June 2003 an option was granted to Hugh Grant, a director of the Company, over 70,000 ordinary shares at an exercise price of £0.62 per share. On 20 June 2003 an option was granted to Dr William Ardrey, a director of the Company, over 350,000 ordinary shares at an exercise price of £0.62 per share.

On 20 June 2003 an option was granted to Simon Gordon, a director of the Company, over 1,007,321 ordinary shares at an exercise price of £0.05 per share.

On 20 June 2003 the Company entered into an option agreement wth Dr Donald R Sanders and Center for Clinical Research pursuant to which options were granted to each of Donald R Sanders and Center for Clinical Research over 70,000 ordinary shares at an exercise price of £0.62 per share.

Save for these transactions the Company has not traded, has made up no financial statements and no dividends have been declared or paid.

**Opinion**

In our opinion, the information on the transactions undertaken by the Company since incorporation set out above gives, for the purposes of the Admission Document dated 2 July 2003, a true and fair view of the state of affairs of the Company as at 2 July 2003.

**Basis of preparation**

The financial information set out in this report is based on the audited financial statements of CLVR for the period from incorporation to 30 June 2001, the year ended 30 June 2002 and the nine months ended 31 March 2003 and has been prepared on the basis set out in this report, to which no adjustments were considered necessary.

**Responsibility**

Such financial statements are the responsibility of the directors of CLVR who approved their issue.

The Directors of the Company are responsible for the contents of the Admission Document dated 2 July 2003 in which this report is included.

It is our responsibility to compile the financial information set out in our report from the financial statements, to form an opinion on the financial information and to report our opinion to you.

CLVR has not been required, under Australian law, to prepare audited financial statements. PKF of Level 7, BGC Centre, 28 The Esplanade, Perth, Western Australia 6000 were appointed auditors of CLVR on 5 June 2003 and have, for the purpose of this report, audited the financial statements of CLVR for each of the periods from incorporation to 30 June 2001, the year ended 30 June 2002 and the nine months ended 31 March 2003.

**Basis of opinion**

We conducted our work in accordance with the Statements of Investment Circular Reporting Standards issued by the Auditing Practices Board. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. The evidence included that recorded by the auditors who audited the financial statements underlying the financial information. It also included an assessment of significant estimates and judgements made by those responsible for the preparation of the financial statements underlying the financial information and whether the accounting policies are appropriate to CLVR's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial information is free from material misstatement whether caused by fraud or other irregularity or error.

**Opinion**

In our opinion, the financial information gives, for the purposes of the Admission Document dated 2 July 2003, a true and fair view of the state of affairs of CLVR as at the dates stated and of its results for the periods then ended.

**Consent**

We consent to the inclusion in the Admission Document dated 2 July 2003 of this report and accept responsibility for this report for the purposes of paragraph 45 (1) (b) (iii) of Schedule 1 to the Public Offers of Securities Regulations 1995 (as amended).

## 1. ACCOUNTING POLICIES

**Overall policy**

The financial information has been prepared on the basis of International Accounting Standards and International Financial Reporting Standards (IFRSs) and interpretations of those standards. IFRSs include IASs and interpretations issued by the IASB.

**Financial information presentation**

For the purpose of this report, the financial information of CLVR is presented in pounds sterling, for the ease of understanding of users.

The initial measurement currency of the transactions is Australian Dollars. The following procedures have been used in translating the financial information:

(a) assets and liabilities for all balance sheets presented were translated at the closing rate existing at the date of each balance sheet presented.

(b) income and expense items for all periods presented were translated at the exchange rates existing at the date of the transaction or a rate that approximates to the actual exchange rates.

(c) equity items other than net profit or loss for the period that is included in the balance of retained profits or accumulated losses were translated at the closing rate existing at the balance sheet date.

(d) all exchange differences resulting from the above translations were recognised directly in equity.

**Basis of preparation**

The financial information has been prepared on the going concern basis which takes account of loans provided to the Company after the balance sheet date and the placing agreement entered into with the Company's brokers, Collins Stewart Limited, to place shares on AIM.

**Accounting convention**

The financial information has been prepared on the historical cost basis and, except where stated, does not take into account current valuations of non-current assets.

**Revenue recognition**

(a) Rendering of services

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction is recognised by reference to the percentage of services performed.

(b) Government grants

Government grants are recognised in the income statement when received.

(c) Interest revenue

Interest revenue is recognised on a time proportion basis that takes into account the effective yield of the asset.

**Receivables**

Trade accounts receivable, amounts due from related parties and other receivables represent the principal amounts due at the balance sheet date plus accrued interest and less where applicable, any unearned income.

**Inventories**

All purchases of consumable items used in the research and development process are expensed directly to the income statement.

**Leases**

A distinction is made between finance leases, which transfer from the lessor to the lessee substantially all the risks and rewards incident to ownership of the leased asset and operating leases, under which the lessor retains substantially all the risks and rewards.

Operating lease rental expense is recognised as an expense on a straight-line basis over the term of the lease or on a systematic basis representative of the time pattern of the user's benefit.

**Income taxes**

Income taxes are accounted for using the comprehensive balance sheet liability method whereby:

- The tax consequences of recovering all assets (liabilities) are reflected in the financial statements.
- Current and deferred tax is recognised as income or expense except to the extent that the tax relates to equity items or to a business combination.
- A deferred tax asset is recognised to the extent that it is probable that future taxable profit will be available to realise the asset.

**Translation of foreign currency transactions**

Transactions in foreign currencies are initially measured at the rate of exchange in effect at the date of each transaction.

At each balance sheet date:

Foreign currency monetary items are reported using the rate of exchange at the transaction date.

Non-monetary items, which are carried in terms of historical cost denominated in a foreign currency, are reported using the exchange rate at the date of the transaction.

**Property, plant and equipment**

Depreciation is provided at the following annual rates in order to write off each asset over its estimated useful life

| | | |
|---|---|---|
| Leasehold improvements | — | 15 per cent. on reducing balance |
| Plant and equipment: | | |
| • Electronic | — | 40 – 100 per cent. on reducing balance |
| • Software | — | 40 – 75 per cent. on reducing balance |
| • Machine | — | 30 – 50 per cent. on reducing balance |
| • Other | — | 18.75 – 40 per cent. on reducing balance |
| Office equipment | — | 15 – 50 per cent. on reducing balance |

On disposal of an item of property, plant and equipment, the difference between the net sales proceeds and the carrying amount of the asset at the time of the disposal is recognised as income or expense in the income statement.

**Intangible assets**

Certain costs in respect of patent research and patent registration costs have been capitalised as intangible assets.

These assets are amortised at the following rates:

| | | |
|---|---|---|
| Patent costs | — | 50 per cent. straight line |

**Bank overdrafts and accounts payable**

Bank overdrafts, trade accounts payable, amounts owing to related parties and other payables and accrued liabilities represent the principle amounts outstanding at the balance sheet date together with, where applicable, any accrued interest.

**Research and development expenditure**

Research expenditure is recognised as an expense in the period in which it was incurred.

**Contingent liabilities**

A contingent loss is recognised as an expense and a liability if it is probable that future events will confirm that, after taking into account any related probable recovery, an asset has been impaired or a liability incurred and a reasonable estimate of the amount of the resulting loss can be made.

**Segment information**

CLVR operates in one business segment being the development and sale of laser optical equipment and one geographical segment being Australia.

**Short-term employee benefits**

Short-term employee benefits are employee benefits (other than termination benefits) which fall due wholly within 12 months after the end of the period in which the employee services are rendered. They comprise wages, salaries, social security obligations, short term compensated absences, profit sharing and bonuses payable within 12 months.

**Other long-term employee benefits**

Other long-term employee benefits including long service leave are not recognised.

**Events occurring after the balance sheet date**

Assets and liabilities are adjusted for events occurring after the balance sheet date that provide evidence of conditions existing at the balance sheet date. Important after date balance sheet events, which do not meet this criteria, are disclosed in the notes to the accounts.

## 2. INCOME STATEMENTS

| | Notes | *Period from 8 March 2001 to 30 June 2001* £ | *Year ended 30 June 2002* £ | *Nine months ended 31 March 2003* £ |
|---|---|---|---|---|
| Revenue | (i) | 133,796 | 83,672 | 11,665 |
| Other operating income | (i) | — | 75,992 | 111,167 |
| Research and development expenditure | | (27,829) | (25,015) | (129,894) |
| Staff costs | | (41,591) | (156,328) | (255,225) |
| Depreciation and amortisation | | (4,462) | (59,954) | (18,048) |
| Other operating expenses | | (18,247) | (137,798) | (510,168) |
| Gain/(loss) on disposal of asset | | — | (4,363) | — |
| Profit/(loss) from ordinary activities before income taxes | (ii) | 41,667 | (223,794) | (790,503) |
| Income taxes | (iii) | (14,167) | 5,455 | — |
| Profit/(loss) after income taxes | | 27,500 | (218,339) | (790,503) |
| Net profit/(loss) | | 27,500 | (218,339) | (790,503) |

## 3. BALANCE SHEETS

| | Notes | At 30 June 2001 £ | At 30 June 2002 £ | At 31 March 2003 £ |
|---|---|---|---|---|
| **CURRENT ASSETS** | | | | |
| Cash and cash equivalents | | 101,029 | 173,503 | 122,243 |
| Trade and other receivables | (vi) | 5,805 | 87,585 | 34,509 |
| | | 106,834 | 261,088 | 156,752 |
| **NON-CURRENT ASSETS** | | | | |
| Property, plant and equipment | (iv) | 80,839 | 36,937 | 66,358 |
| Intangible assets | (v) | — | 335 | 3,533 |
| | | 80,839 | 37,272 | 69,891 |
| **TOTAL ASSETS** | | 187,673 | 298,360 | 226,643 |
| **CURRENT LIABILITIES** | | | | |
| Trade and other payables | (vii) | 145,569 | 138,385 | 874,130 |
| Income tax | (iii) | 14,278 | 5,319 | — |
| Provisions | (viii) | — | — | 31,193 |
| **TOTAL LIABILITIES** | | 159,847 | 143,704 | 905,323 |
| **NET ASSETS/(LIABILITIES)** | | 27,826 | 154,656 | (678,680) |
| **SHAREHOLDERS' EQUITY** | | | | |
| Share capital | (ix) | 108 | 348,694 | 362,116 |
| Retained profits/(accumulated losses) | (x) | 27,500 | (190,093) | (992,014) |
| Foreign currency translation reserve | (xi) | 218 | (3,945) | (48,782) |
| **TOTAL SHAREHOLDERS' EQUITY** | | 27,826 | 154,656 | (678,680) |

## 4. CASH FLOW STATEMENTS

| | *Period from 8 March 2001 to 30 June 2001* £ | *Year ended 30 June 2002* £ | *Nine months ended 31 March 2003* £ |
|---|---|---|---|
| *Cash flows from operating activities:* | | | |
| Receipts from customers | 205,196 | 7,132 | 11,487 |
| Interest received | — | — | 4,031 |
| Income tax refund | — | — | 69,732 |
| Receipt of government grants | — | — | 107,136 |
| Payments to suppliers and employees | (61,869) | (288,754) | (720,113) |
| Deposit paid for clinical trials | — | — | (11,785) |
| Net cash provided by/used in operating activities | 143,327 | (281,622) | (539,512) |
| *Cash flows from investing activities:* | | | |
| Payment for property, plant and equipment | (43,168) | (42,435) | (46,239) |
| Payment for intangible assets | — | (669) | (4,110) |
| Net cash used in investing activities | (43,168) | (43,104) | (50,349) |
| *Cash flows from financing activities:* | | | |
| Proceeds from issue of shares | 108 | 348,586 | — |
| Proceeds from borrowing | 544 | 51,777 | 565,247 |
| Net cash provided by financing activities | 652 | 400,363 | 565,247 |
| Net increase/(decrease) in cash and cash equivalents | 100,811 | 75,637 | (24,614) |
| Cash and cash equivalents at the beginning of the period | — | 101,029 | 173,503 |
| Effects of exchange rate changes | 218 | (3,163) | (26,646) |
| Cash and cash equivalents at the end of the period | 101,029 | 173,503 | 122,243 |

**Cash and cash equivalents**

Cash and cash equivalents consist of cash on hand and balances with banks and investments in money market instruments, net of outstanding bank overdrafts. Cash and cash equivalents included in the cash flow statement comprise the following balance sheet amounts:

| | *Period from 8 March 2001 to 30 June 2001* £ | *Year ended 30 June 2002* £ | *Nine months ended 31 March 2003* £ |
|---|---|---|---|
| Cash on hand and with banks | 101,029 | 173,503 | 122,243 |

## 5. NOTES TO THE FINANCIAL STATEMENTS

### (i) Revenue

| | *Period from 8 March 2001 to 30 June 2001* | *Year ended 30 June 2002* | *Nine months ended 31 March 2003* |
|---|---|---|---|
| ***Revenue*** | *£* | *£* | *£* |
| Rendering of Services | 133,796 | 83,672 | 11,665 |
| ***Other operating income*** | | | |
| Research and development tax refund | — | 75,250 | — |
| Government grants | — | — | 107,136 |
| Other income | — | 742 | — |
| Interest received | — | — | 4,031 |
| | — | 75,992 | 111,167 |

### (ii) Operating profit/(loss)

The operating profit/(loss) is stated after charging/(crediting):

| | *Period from 8 March 2001 to 30 June 2001* | *Year ended 30 June 2002* | *Nine months ended 31 March 2003* |
|---|---|---|---|
| | *£* | *£* | *£* |
| Depreciation and amortisation – owned assets | 4,462 | 59,954 | 18,048 |
| Loss on disposal of fixed assets | — | 4,363 | — |
| Operating lease costs | 1,313 | 5,836 | 10,945 |

**(iii) Taxation**

The tax charge on the profit/(loss) on ordinary activities for the year was as follows:

| | *Period from 8 March 2001 to 30 June 2001* £ | *Year ended 30 June 2002* £ | *Nine months ended 31 March 2003* £ |
|---|---|---|---|
| ***Major components of income tax expense*** | | | |
| Corporation tax and other taxes | 14,167 | — | — |
| Under/(over) provided tax | — | (5,455) | — |
| | 14,167 | (5,455) | — |
| ***Reconciliation between income tax expense and prima facie tax on accounting profit/(loss)*** | | | |
| Accounting profit/(loss) | 41,667 | (223,794) | (790,503) |
| Tax at 34% (2001), 30% (2002/03) | 14,167 | (67,138) | (237,151) |
| Non-taxable income – research and development tax refund | — | (22,575) | — |
| Research and development tax concession | — | 60,200 | — |
| Current year losses not recognised as deferred tax asset | — | 29,513 | 237,151 |
| Over provision of tax in prior year | — | (5,455) | — |
| Income tax expense | 14,167 | (5,455) | — |
| ***Current income tax liability*** | | | |
| Corporation tax liability | 14,278 | 5,319 | — |

**(iv) Property, plant and equipment**

| | *Leasehold Improvements* £ | *Office Equipment* £ | *Plant and Equipment* £ | *Total* £ |
|---|---|---|---|---|
| ***Cost*** | | | | |
| At 30 June 2001 | 987 | 7,447 | 76,902 | 85,336 |
| Additions | — | 1,939 | 17,760 | 19,699 |
| Disposals | — | — | (6,219) | (6,219) |
| Foreign Exchange Differences | 19 | 142 | 1,468 | 1,629 |
| At 30 June 2002 | 1,006 | 9,528 | 89,911 | 100,445 |
| Additions | 714 | 9,571 | 35,954 | 46,239 |
| Foreign Exchange Differences | 39 | 366 | 3,460 | 3,865 |
| At 31 March 2003 | 1,759 | 19,465 | 129,325 | 150,549 |
| ***Depreciation*** | | | | |
| At 30 June 2001 | 5 | 390 | 4,102 | 4,497 |
| Charge for the year | 150 | 2,921 | 57,631 | 60,702 |
| Eliminated on disposals | — | — | (1,777) | (1,777) |
| Foreign Exchange Differences | | 8 | 78 | 86 |
| At 30 June 2002 | 155 | 3,319 | 60,034 | 63,508 |
| Charge for the period | 122 | 2,868 | 15,249 | 18,239 |
| Foreign Exchange Differences | 6 | 127 | 2,311 | 2,444 |
| At 31 March 2003 | 283 | 6,314 | 77,594 | 84,191 |
| ***Net book value*** | | | | |
| At 30 June 2001 | 982 | 7,057 | 72,800 | 80,839 |
| At 30 June 2002 | 851 | 6,209 | 29,877 | 36,937 |
| At 31 March 2003 | 1,476 | 13,151 | 51,731 | 66,358 |

**(v) Intangible assets**

| | *Patent Costs* £ |
|---|---|
| ***Cost*** | |
| At 30 June 2001 | — |
| Additions | 669 |
| At 30 June 2002 | 669 |
| Additions | 4,110 |
| Foreign Exchange Differences | 25 |
| At 31 March 2003 | 4,804 |
| ***Amortisation*** | |
| At 30 June 2001 | — |
| Amortised for the period | 334 |
| At 30 June 2002 | 334 |
| Amortised for the period | 923 |
| Foreign Exchange Differences | 14 |
| At 31 March 2003 | 1,271 |
| ***Net Book Value*** | |
| At 30 June 2001 | — |
| At 30 June 2002 | 335 |
| At 31 March 2003 | 3,533 |

**(vi) Trade and other receivables**

| | *At 30 June* | | *At 31 March* |
|---|---|---|---|
| | *2001* £ | *2002* £ | *2003* £ |
| ***Current*** | | | |
| Trade accounts receivable | — | — | 192 |
| Other receivables | 5,805 | 10,975 | 34,317 |
| Research and development tax refunds | — | 76,610 | — |
| | 5,805 | 87,585 | 34,509 |

**(vii) Trade and other payables**

| | *At 30 June* | | *At 31 March* |
|---|---|---|---|
| | *2001* £ | *2002* £ | *2003* £ |
| ***Current*** | | | |
| Trade accounts payable | 47,646 | 31,979 | 154,512 |
| Other taxes | 14,140 | 3,856 | 6,678 |
| Other payables | 6,034 | 187 | 590,879 |
| Accruals and deferred income | 77,205 | — | — |
| Amounts owing to directors | 544 | 102,363 | 122,061 |
| | 145,569 | 138,385 | 874,130 |

On 5 May 2003 loans included in "Other payables" as at 31 March 2003 amounting to some £565,247 were settled by way of an allotment of 909,328 ordinary shares by the Company. The balance due from CLVR is accordingly now an intercompany balance due to the Company.

Subsequent to 31 March 2003, CLVR received a further £9,550 by way of a further loan investment. This has also been settled by way of an allotment of 15,365 ordinary shares by the Company.

**(viii) Provisions**

| | At 30 June 2001 £ | At 30 June 2002 £ | At 31 March 2003 £ |
|---|---|---|---|
| *Current* | | | |
| Employee benefits | — | — | 31,193 |
| | — | — | 31,193 |

**(ix) Share capital**

| | At 30 June 2001 £ | At 30 June 2002 £ | At 31 March 2003 £ |
|---|---|---|---|
| *Fully paid* | | | |
| Ordinary Shares: | | | |
| 200 Ordinary shares (Class A) of AUD$1 | 72 | — | — |
| 100 Ordinary shares (Class B) of AUD$1 | 36 | — | — |
| 957,546 Ordinary shares (Class A) of AUD$1 | — | 352,262 | 365,821 |
| *Partly paid* | | | |
| 1,900,500 Ordinary shares (Class A) of AUD$1 | — | 699,156 | 726,067 |
| Less calls in arrears | — | (699,045) | (725,952) |
| *Transaction costs* | | | |
| Transaction costs deducted from equity | — | (3,679) | (3,820) |
| | 108 | 348,694 | 362,116 |

**(x) Retained profits/(accumulated losses)**

| | At 30 June 2001 £ | At 30 June 2002 £ | At 31 March 2003 £ |
|---|---|---|---|
| Opening retained earnings/(accumulated losses) | — | 27,500 | (190,093) |
| Net profit/(loss) | 27,500 | (218,339) | (790,503) |
| Foreign Exchange Differences | — | 746 | (11,418) |
| Closing retained earnings/(accumulated losses) | 27,500 | (190,093) | (992,014) |

**(xi) Foreign currency translation reserve**

| | At 30 June 2001 £ | At 30 June 2002 £ | At 31 March 2003 £ |
|---|---|---|---|
| Opening Balance | — | 218 | (3,945) |
| Transferred (to)/from income | 218 | (4,163) | (44,837) |
| Closing balance | 218 | (3,945) | (48,782) |

**(xii) Commitments for expenditure**

Operating lease commitment

| | *At 31 March 2003* £ |
|---|---|
| Total future minimum lease payments under non-cancellable operating leases payable: | |
| Not later than one year | 21,012 |
| Later than one year and not later than five years | 17,510 |
| Later than 5 years | — |
| | 38,522 |

**(xiii) Related party disclosures**

On 17 April 2003 the whole of CLVR's issued share capital was acquired by the Company which since that date has been CLVR's ultimate parent enterprise.

The following transactions have taken place with related parties:

***Directors***

| | *At 30 June* | | *At 31 March* |
|---|---|---|---|
| | *2001* £ | *2002* £ | *2003* £ |
| Amounts paid and payable to directors during the periods including superannuation. | 28,782 | 65,850 | 151,413 |

***Other***

The directors plan to enter into a contract with Findlays, a director related entity (based in the United Kingdom), for the provision of reporting and regulatory information, and employee tax requirement services on commercial terms. Findlays have provided payroll processing services from September 2002 at commercial rates to the value of £1,645.

**(xiv) Post balance sheet events**

There have not been any matters or circumstances arising since the end of the financial period that have significantly affected, or may significantly affect, the operations of the entity, the results of those operations, or the state of the affairs of the entity in future years, other than those stated elsewhere in this report.

**(xv) Contingent liabilities**

A third party is seeking a refund of monies paid under a contract with CLVR that was terminated in August 2001. CLVR has a potential counter claim against the third party for damages relating to the breach of this contract.

The Directors believe the risk of a liability arising to the third party to be remote. The amount payable by CLVR in the event of the action being successful cannot be quantified.

Yours faithfully

**PKF**

## PART VII

## Illustrative financial projections of the Group

Set out below are the consolidated illustrative financial projections of the Group for the five financial periods ending 30 June 2008, which the Directors have made after due and careful enquiry and on the basis of preparation and assumptions set out below.

**Illustrative Financial Projections**

| | *Years ending 30 June (£ millions)* | | | | |
|---|---|---|---|---|---|
| | *2004* | *2005* | *2006* | *2007* | *2008* |
| Sales | 2.5 | 12.7 | 24.6 | 34.4 | 44.3 |
| Cost of sales | 0.6 | 3.7 | 6.9 | 9.2 | 11.2 |
| Gross profit | 1.9 | 9.0 | 17.7 | 25.2 | 33.1 |
| Expenditure | 5.9 | 6.0 | 9.3 | 11.4 | 12.9 |
| Profit/(loss) before interest and tax | (4.0) | 3.0 | 8.4 | 13.8 | 20.2 |
| Interest received/(paid) | 0.1 | — | — | 0.1 | 0.3 |
| Profit/(loss) before tax | (3.9) | 3.0 | 8.4 | 13.9 | 20.5 |
| Taxation | — | — | 2.3 | 4.2 | 6.2 |
| Profit/(loss) after tax | (3.9) | 3.0 | 6.1 | 9.7 | 14.3 |

**Bases of preparation of consolidated illustrative financial projections**

The consolidated illustrative financial projections have been prepared on the following bases:

- The projections and their components are based on management estimates, taking into account previous experience and management's assessment of likely future developments. These include estimates of sales, manufacturing costs, labour and other overheads which comprise a step change in the Company's activities.
- The projections have been prepared using accounting policies that are consistent with the accounting practice normally adopted by the Group.
- The projections have neither been audited nor subjected to an independent actuarial review.

**Assumptions**

The principal assumptions underlying the consolidated illustrative financial projections, which are not in the control of the Directors, are as follows:

- The Placing will be successful in raising £10 million (net of estimated costs of £1.5 million).
- The LVC market will not significantly decline during the period of the projections.
- There are no sales of the CustomVis™ System into the United States until year 3, when FDA approval is assumed to be obtained.
- The Company's key milestones do not materially change and the Company achieves those milestones on time and budget.
- CustomVis suffers no materially adverse events. These could include failure to overcome any barrier to market, an intellectual property failure or dispute and poor patient treatment results and other matters referred to in the Risk factors set out in Part III.
- No account of inflation is taken in the projections.
- There will be no significant changes in governmental or regulatory regimes which may effect sales of the CustomVis™ System.
- There will be no significant changes to the current UK or Australian corporation tax regimes and no material changes to the current tax rate.

PKF
Accountants and business advisors
New Garden House 78 Hatton Garden London EC1N 8JA Telephone 020 7831 7393 Facsimile 020 7405 6736
Web site http:/www.pkf.co.uk

The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London
EC2M 4YH

and

The Directors
Collins Stewart Limited
9th Floor
88 Wood Street
London
EC2V 7QR

2 July 2003

Dear Sirs

**CustomVis plc ("the Company")**

We refer to the illustrative financial projections of the Company and its subsidiary, CLVR Pty Ltd (together "the Group"), for the five years ending 30 June 2008. The projections have been prepared in connection with the proposed admission of the Company to AIM and are contained on page 91 of the Admission Document dated 2 July ("the Admission Document").

**Responsibility**

The illustrative financial projections are based on assumptions made by the Directors of the Company, for which they are solely responsible, and which cannot be confirmed or verified in the same way as past results. It should be appreciated that the projections have been prepared for the purposes of illustration only and do not constitute a forecast, as they are based on certain assumptions which may not prove to be valid. We express no opinion as to the validity of the assumptions on which the projections are based.

**Basis of opinion**

We have reviewed the accounting policies and calculations adopted in arriving at the illustrative financial projections of the Group for the five years ending 30 June 2008.

**Opinion**

In our opinion, the illustrative financial projections, so far as the accounting policies and calculations are concerned, have been properly compiled on the basis of the assumptions made by the Directors, as set out in the Admission Document, and are presented on a basis consistent with the accounting policies normally adopted by the Group.

Yours faithfully

**PKF**

COLLINS ♦ STEWART LTD
9TH FLOOR · 88 WOOD STREET · LONDON EC2V 7QR

The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London
EC2M 4YH

2 July 2003

Dear Sirs,

We refer to the consolidated illustrative financial projections of CustomVis plc for the five years ending 30 June 2008 ("the Illustrative Financial Projections"), as set out in Part VII of the Admission Document dated 2 July 2003 ("the Admission Document").

We have discussed with you the Illustrative Financial Projections and the bases and assumptions on which these projections have been made and we have also considered the letter addressed to yourselves and us from PKF relating to the Illustrative Financial Projections, a copy of which is also set out in Part VII of the Admission Document.

Based on these discussions and having regard to the letter from PKF, we consider that the Illustrative Financial Projections (for which you, as Directors, are solely responsible) have been made after due and careful enquiry by the Directors of CustomVis plc.

Yours faithfully,

**Stephen Roberts**
**for Collins Stewart Limited**

## PART VIII

### Unaudited pro forma statement of net assets

The pro forma financial information set out below has been prepared to illustrate the effect of the acquisition of CLVR, the subscription by Warrawee Investments Limited for convertible unsecured loan notes and the proceeds of the Placing on the net assets of CustomVis plc as if these transactions had taken place at 31 March 2003.

The pro forma financial information has been prepared for illustrative purposes only and, because of its nature, may not give a true picture of the financial position of the Group.

| | *(note 1)* *CustomVis Plc* *£000* | *(note 2)* *CLVR* *£000* | *(note 3)* *Adjustments* *£000* | *(note 4)* *Proceeds of the Placing* *£000* | *Pro forma net assets* *£000* |
|---|---|---|---|---|---|
| **Current assets** | | | | | |
| Cash and cash equivalents | — | 122 | 2,066 | 10,000 | 12,188 |
| Trade and other receivables | — | 35 | — | — | 35 |
| | | 157 | 2,066 | 10,000 | 12,223 |
| **Non-current assets** | | | | | |
| Property, plant & equipment | — | 66 | — | — | 66 |
| Intangible assets | — | 4 | — | — | 4 |
| | — | 70 | — | — | 70 |
| **Total assets** | — | 227 | 2,066 | 10,000 | 12,293 |
| **Current liabilities** | | | | | |
| Trade and other payables | — | (874) | (778) | — | (1,652) |
| Provisions | — | (31) | — | — | (31) |
| **Total liabilities** | — | (905) | (778) | — | (1,683) |
| **Net assets/(liabilities)** | — | (678) | 1,288 | 10,000 | 10,610 |

**Notes:**

1. The net assets of CustomVis plc have been extracted from the financial information included in the Accountants' Report set out in Part VI of this document.
2. The audited net assets of CLVR have been extracted from the balance sheet of CLVR at 31 March 2003 included in the Accountants' report set out in Part VI of this document.
3. The adjustments reflect:
   (i) the proceeds arising from the subscription by Warrawee Investments Limited of £1,342,844 in convertible unsecured loan notes in the Company pursuant to an investment agreement entered into between the Company, the Directors of the Company and Warrawee Investments Limited on 22 April 2003.
   (ii) The settlement on 5 May 2003 of amounts due from CLVR of some £565,247 by way of the allotment of 909,328 ordinary shares in the Company, the resulting liability from CLVR to the Company being eliminated on consolidation.
   (iii) The settlement on 5 May 2003 of amounts due subsequent to 31 March 2003 from CLVR of £9,550 by way of allotment of 15,365 ordinary shares in the Company. The resulting liability from CLVR to the Company being eliminated on consolidation.
   (iv) The allotment of 30,730 ordinary shares to the Trustees of Thorstone (SE) Retirement and Death Benefit Scheme at £0.62 per share.
   (v) The exercise by Poynton and Partners Pty Ltd (through a nominee company) of its option over 1,120,000 shares at a price of £0.62 per share (£694,400).
4. This adjustment reflects the minimum gross proceeds of the Placing of £11.5 million net of costs of £1.5 million.
5. No account has been taken of the trading performance of the Company or CLVR since 31 March 2003.

PKF
Accountants and business advisors
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Web site http:/www.pkf.co.uk

The Directors
CustomVis plc
7 Devonshire Square
Cutlers Gardens
London
EC2M 4YH

and

The Directors
Collins Stewart Limited
9th Floor
88 Wood Street
London
EC2V 7QR

2 July 2003

Dear Sirs

**CustomVis plc ("the Company")**

We report on the pro forma statement of net assets set out in Part VIII of the Admission Document dated 2 July 2003 relating to the Company ("the Admission Document"). This has been prepared, for illustrative purposes only, to show the effects of the Company acquiring the whole of the issued share capital of CLVR Pty Ltd and the fund raising.

**Responsibilities**

It is the responsibility solely of the Directors of the Company to prepare the pro forma financial information.

It is our responsibility to form an opinion on the pro forma financial information and to report our opinion to you.

**Basis of opinion**

We conducted our work in accordance with the Statements of Investment Circular Reporting Standards and Bulletin 1998/8 "Reporting on pro forma financial information pursuant to the Listing Rules" issued by the Auditing Practices Board. Our work, which involved no independent examination of the underlying financial information, consisted primarily of comparing the unadjusted financial information with the source documents, considering the evidence supporting the adjustments and discussing the pro forma financial information with the Directors of the Company.

**Opinion**

In our opinion:

- The pro forma net assets statement has been properly compiled on the basis stated;
- Such basis is consistent with the accounting policies of the Company; and
- The adjustments are appropriate for the purposes of the pro forma net assets statement as at 31 March 2003 as disclosed.

Yours faithfully

**PKF**

# PART IX

## Additional information

### 1. Responsibility

The Directors, whose names are set out on page 8 of this document, accept responsibility for the information contained in this document. To the best of the knowledge and belief of the Directors (who have taken all reasonable care to ensure such is the case), the information contained in this document for which they accept responsibility is in accordance with the facts and does not omit anything likely to affect the import of such information.

### 2. Incorporation and registration

2.1 The Company was incorporated and registered in England and Wales on 5 December 2002 under the Act as a public company limited by shares with registration number 4609602. The Company's registered office is at 7 Devonshire Square, Cutlers Gardens, London EC2M 4YH which is the London office of the Company's solicitors, Hammonds.

2.2 The liability of the members of the Company is limited and the principal legislation under which the Company operates is the Act and the regulations made under the Act.

2.3 The accounting reference date of the Company is 30 June.

2.4 The Company received a certificate under section 117 of the Act on 17 April 2003 enabling the Company to do business and exercise its borrowing powers.

### 3. Share capital

3.1 On incorporation, the authorised share capital of the Company was £50,000 divided into 50,000 ordinary shares of £1 each of which two were issued as subscriber shares to the two subscribers to the Memorandum of Association.

3.2 On 17 April 2003 the authorised share capital of the Company was increased from £50,000 to £5,000,000 by the creation of 99,000,000 additional ordinary shares of 5p each. Each of the two issued ordinary shares of £1 was re-designated and sub-divided into 20 ordinary shares of 5p each, and the existing 49,998 authorised but unissued ordinary shares of £1 each in the capital of the Company were re-designated and sub-divided into 999,960 ordinary shares of 5p each.

3.3 On 17 April 2003, 20,006,322 Ordinary Shares were issued to the former shareholders of CLVR in consideration of the transfer by them to the Company of the entire issued share capital of CLVR.

3.4 On 5 May 2003, 924,693 new Ordinary Shares were allotted to certain subscribers for Ordinary Shares in consideration for the settlement of loans by them to CLVR and 30,730 new Ordinary Shares were allotted to The Trustees of Thorstone (SE) Retirement and Death Benefit Scheme in consideration for cash.

3.5 On 1 July 2003, 1,120,000 new Ordinary Shares were allotted to Gem Consulting Pty Limited on exercise of share options granted to it in consideration for financial consulting and advisory services provided to the Company by Poynton & Partners Pty Ltd. An exercise price of 62 pence per new Ordinary Share was paid by Gem Consulting Pty Limited on exercise.

3.6 On 2 July 2003:

(a) the entry into the option agreement with Dr Paul van Saarloos and Simon Gordon summarised at paragraph 11.9 below by the Directors on behalf of the Company was approved for the purposes of Section 320 of the Act;

(b) the Directors were unconditionally authorised for the purposes of section 80 (1) of the Act to allot up to £631,869 in nominal value of Ordinary Shares pursuant to the Placing, such authority to expire on 15 July 2003 and the Directors were generally and

unconditionally authorised for the purposes of section 80 (1) of the Act to exercise all the powers of the Company to allot relevant securities (within the meaning of Section 80 (2) of the Act) up to a maximum aggregate nominal amount of £2,500,000 such authority to expire on 1 July 2008 save that the Company may, before such expiry, make an offer or agreement which would or might require relevant securities to be allotted after such expiry and the Directors may allot relevant securities pursuant to any such offer or agreement as if such authority had not expired;

(c) the Directors were empowered under section 95 of the Act to exercise the powers of the Company to allot equity securities (as defined in section 94 (2) of the Act) of the Company for cash pursuant to the authority referred to in paragraph (b) above as if section 89 (1) of the Act did not apply to the allotment, such authority expiring on 1 July 2008 and limited to:

(i) the allotment pursuant to the Placing of 12,637,363 new Ordinary Shares to persons nominated by Collins Stewart;

(ii) the allotment of up to 2,261,703 new Ordinary Shares to satisfy the exercise of all outstanding share options granted by the Company;

(iii) the allotment of up to 2,165,877 new Ordinary Shares upon conversion of the Loan Notes;

(iv) the allotment to existing members by way of rights or open offer; and

(v) in addition to the foregoing, the allotment of equity securities of an aggregate nominal value up to £1,735,960.

3.7 On 2 July 2003, 12,637,363 new Ordinary Shares were provisionally allotted for subscription pursuant to the Placing Agreement, conditional upon Admission.

3.8 The authorised and issued share capital of the Company at the date of this document is as follows:

| | *Authorised* | | *Issued (fully paid)* | |
|---|---|---|---|---|
| | *Number* | *£* | *Number* | *£* |
| Ordinary Shares of 5p each | 100,000,000 | 5,000,000 | 22,081,785[1] | 1,104,089.20 |

1 The Company has granted options to subscribe for an aggregate of 2,261,703 additional new Ordinary Shares (see paragraphs 6.1, 11.5, 11.8 and 11.13 below) and Loan Notes convertible into 2,165,877 additional new Ordinary Shares.

3.9 Following Admission and completion of the Placing, the authorised and issued share capital of the Company will be as follows:

| | *Authorised* | | *Issued (fully paid)* | |
|---|---|---|---|---|
| | *Number* | *£* | *Number* | *£* |
| Ordinary Shares of 5p each | 100,000,000 | 5,000,000 | 34,719,148[1] | 1,735,957.40 |

1 Disregards any conversion of Loan Notes or exercise of share options.

3.10 Save as disclosed in this document:

(a) no share or loan capital of the Company or any subsidiary is under option or has been agreed, conditionally or unconditionally, to be put under option;

(b) no persons have preferential subscription rights in respect of any authorised but unissued share or loan capital of the Company or any of its subsidiaries; and

(c) other than pursuant to the Placing or pursuant to the exercise of outstanding share options there is no present intention to issue any of the authorised but unissued share capital of the Company.

## 4. The Group

Details of the Company's only subsidiary undertaking (which is wholly owned by the Company) is as follows:

| *Company* | *Place of Incorporation* | *Date of Incorporation* | *Activity* | *Issued Share Capital* |
|---|---|---|---|---|
| CLVR Pty Ltd | Australia | 8 March 2001 | Manufacture of ophthalmic laser equipment | 2,858,046 ordinary shares |

## 5. Memorandum and articles of association

*5.1 Memorandum of association*

The objects of the Company set out in its memorandum of association are to carry on business as a general commercial company.

*5.2 Articles of association*

The Articles contain provisions, *inter alia*, to the following effect. The following is a description of significant rights and does not purport to be complete or exhaustive:

(a) Share capital

The share capital of the Company is divided into one class of share, namely Ordinary Shares.

(b) Voting rights

Subject to any special rights or restrictions as to voting attached to any share by or in accordance with the Articles (including circumstances where a statutory notice requiring disclosure of the beneficial ownership of shares has not been complied with) at a general meeting every member holding an Ordinary Share present in person shall upon a show of hands have one vote and on a poll every member present in person or by proxy shall have one vote for every Ordinary Share of which he is the holder. The quorum for a general meeting is two persons entitled to vote at the meeting each being a member or a proxy for a member or a duly authorised representative of a corporation which is a member.

(c) Dividends

Subject to the Act and the Statutes, the Company may by ordinary resolution declare dividends to be paid to the members in accordance with their respective rights, but no dividend shall exceed the amount recommended by the Directors. The Directors may from time to time declare or pay such interim dividends (including any dividend payable at a fixed rate) as appear to them to be justified by the financial position of the Company. If the share capital of the Company is divided into different classes, the Board may pay such interim dividend on shares which rank after shares conferring preferential rights with regard to dividends as well as on shares conferring preferential rights, unless at the time of payment any preferential dividend is in arrears.

Except as otherwise provided by the rights attached to shares, all dividends shall be declared and paid according to the amounts paid up on the shares in respect of which the dividend is paid and (other than amounts paid up in advance of calls) all dividends shall be apportioned and paid pro rata according to the amounts paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. All unclaimed dividends, interest or other moneys payable to any person on or in respect of a share may be invested or otherwise made use of by the Board for the benefit of the Company until claimed and the Company shall not constitute a trustee in respect of such dividends interests or other sums. All dividends unclaimed for a period of 12 years from the date of declaration shall be forfeited and cease to remain owing by the Company.

The Directors may, with the authority of an ordinary resolution of the Company, direct that the payment of any dividend may be satisfied wholly or in part by the distribution of specific assets and, in particular, of paid up shares or debentures of any other company. The Board may, with the authority of an ordinary resolution of the Company, offer any holders of Ordinary Shares the right to elect to receive further new shares credited as fully paid instead of cash in respect of all (or some part) of any dividend specified by the ordinary resolution.

(d) Distribution of assets on a winding up

If the Company is wound up, the liquidator may, with the authority of an extraordinary resolution of the Company and subject to the Act and the Statutes, divide among the members in specie the whole or any part of the assets of the Company and, for such purpose, value any assets and determine how such division shall be carried out as between members or different classes of members or vest the whole or any part of the assets in trustees upon such trusts for the benefit of the members as the liquidator shall think fit but no member shall be compelled to accept any assets upon which there is any liability.

(e) Transfer of shares

(i) Subject to the restrictions set out in the Articles, a member may transfer all or any of his shares in any manner which is permitted by the Statutes and is from time to time approved by the Board.

(ii) The Company shall register the transfer of any Uncertified Shares in accordance with the Regulations and other Statutes and where permitted the Board may, in its absolute discretion, refuse to register any transfer of an Uncertified Share.

(iii) An instrument of transfer of a Certified Share may be in any usual form or in any other form which the Board may approve and shall be signed by or on behalf of the transferor and (except in the case of a fully paid share) by or on behalf of the transferee. An instrument of transfer need not be under seal.

(iv) The Board may, in its absolute discretion and without giving any reason, refuse to register any transfer of a Certified Share unless:

(A) it is in respect of a share which is fully paid up;

(B) the instrument of transfer is left at the Company's registered office or at such place as the Board may decide, for registration;

(C) the instrument of transfer is left at the Company's registered office, or at such other place as the Board may reasonably require to prove the title of the intending transferor or his right to transfer the shares;

(D) the instrument of transfer is duly stamped (if so required);

(E) it is in respect of only one class of shares; and

(F) it is in favour of not more than four transferees.

(f) Power to increase, consolidate, sub-divide and cancel shares

(i) The Company may by ordinary resolution:

(A) increase its share capital by such sum to be divided into shares of such amount as the resolution prescribes;

(B) consolidate and divide all or any of its share capital into shares of a larger amount than its existing shares;

(C) subject to the Statutes, sub-divide its shares, or any of them, into shares of smaller amount and the resolution may determine that, as between the shares resulting from the sub-division, one or more of the shares may, as compared with the others, have such preferred, deferred or other special rights, or be subject to such restrictions as the Company has power to attach to unissued or new shares; and

(D) cancel any shares which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so cancelled.

(g) Fractions

Whenever as a result of a consolidation or sub-division of shares any member would become entitled to a fraction of a share, the Board may on behalf of the members deal with the fractions as it thinks fit. In particular, but without limitation, the Board may sell the shares representing the fractions for the best price reasonably obtainable to any person (including, subject to the Statutes, the Company) and distribute the net proceeds of sale in due proportion among those members (except that any amount otherwise due to a member, being less than £3 or such other sum as the Board may from time to time determine, may be retained for the benefit of the Company).

(h) Power to reduce capital

Subject to the Statutes, and to any rights for the time being conferred on the holders of any class of shares, the Company may by special resolution reduce its share capital, any capital redemption reserve or any share premium account in any way.

(i) Power to purchase own shares

Subject to the Statutes, and to any rights for the time being conferred on the holders of any class of shares, the Company may purchase all or any of its shares of any class, including any redeemable shares.

(j) Variation of rights

If at any time the share capital of the Company is divided into shares of different classes, any of the rights for the time being attached to any class of shares may be varied or abrogated (whether or not the Company is being wound up) in such manner (if any) as may be provided by those rights or, if no such provision is made, either:

(i) with the consent in writing of the holders of three-quarters in nominal value of the issued shares of that class; or

(ii) with the authority of an extraordinary resolution passed at a separate general meeting of the holders of those shares.

(k) Directors

(i) Subject to the Statutes and subject to disclosure of his interests, a Director notwithstanding his office:

(A) may enter into or otherwise be interested in any contract, arrangement, transaction or proposal with the Company or in which the Company is otherwise interested;

(B) may hold any other office or place of profit under the Company (except as its auditor or auditor of a subsidiary of the Company) in conjunction with the office of Director for such period (subject to the Statutes) and upon such terms as the Board may decide and may be paid such extra remuneration for so doing (whether by way of salary, commission, participation in profits or otherwise) as the Board may decide, either in addition to or in lieu of any remuneration under any other provision of the Articles of Association of the Company;

(C) may be or become a member or director of, or hold any other office or place of profit under, or otherwise be interested in, any other company in which the Company may be interested;

(D) may act by himself or his firm in a professional capacity for the Company (except as its auditor) and he or his firm shall be entitled to remuneration for professional services as if he were not a Director;

(E) shall not be liable to account to the Company for any profit, remuneration or other benefit realised by any such office, employment, contract, arrangement, transaction or proposal

and no such contract, arrangement, transaction or proposal shall be avoided on the grounds of any such interest or benefit.

(ii) Save as otherwise provided by the Articles a Director shall not vote or be counted in the quorum at a meeting in relation to any resolution of the Board or a committee of the Board relating to any contract, arrangement, transaction or other proposal in which he has an interest which, together with any interest of a person connected with him (within the meaning of section 346 of the Act), is to his knowledge a material interest and, if he purports to do so, his vote shall not be counted. The prohibition shall not apply and a Director may vote and be counted in the quorum in respect of any resolution concerning any one or more of the following matters:

(A) any contract, arrangement, transaction or proposal in which he is interested by virtue of an interest in shares, debentures or other securities of the Company or otherwise in or through the Company;

(B) the giving of any guarantee, security or indemnity in respect of:

(I) money lent or obligations incurred by him or by any other person at the request of, or for the benefit of, the Company or any of its subsidiary undertakings; or

(II) a debt or obligation of the Company or any of its subsidiary undertakings for which he himself has assumed responsibility in whole or in part (either alone or jointly with others) under a guarantee or indemnity or by the giving of security;

(C) any issue or offer of shares, debentures or other securities of the Company or any of its subsidiary undertakings in respect of which he is or may be entitled to participate in his capacity as a holder of any such securities or as an underwriter or sub-underwriter;

(D) any contract, arrangement, transaction or proposal concerning any other company in which he, and any persons connected with him (within the meaning of section 346 CA 1985), do not to his knowledge hold an interest in shares (within the meaning of sections 198 to 211 CA 1985) representing one per cent. or more of any class of the equity share capital of that company or of the voting rights available to members of that company;

(E) any arrangement for the benefit of employees of the Company or any of its subsidiary undertakings which does not accord to him any privilege or benefit not generally accorded to the employees to whom the arrangement relates; and/or

(F) the purchase or maintenance of insurance for the benefit of Directors or for the benefit of persons including Directors.

(iii) A Director can not vote or be counted in the quorum in respect of any resolution of the Board or committee of the Board concerning his own appointment (including fixing or varying its terms) or the termination of his own appointment, to an office or place of profit with the Company or any other Company in which the Company is interested but, where proposals are under consideration concerning the appointment (including fixing or varying its terms), or the termination of the appointment, of two or more Directors to offices or places of profit with the Company or any other company in which the Company is interested, those proposals may be divided and a separate resolution may be put in relation to each Director and, in that case, each of the Directors concerned (if not otherwise debarred from voting under this Article) shall be entitled to vote (and be counted in quorum) in respect of each resolution unless it concerns his own appointment or the termination of his own appointment.

(iv) The Directors shall be paid out of the funds of the Company all reasonable travelling, hotel and other expenses properly incurred by him in and about the performance of his duties as Director, including his expenses of travelling to and from Board meetings, committee meetings, general meetings or separate meetings of the holders of any class of shares or debentures in the Company.

(v) At each annual general meeting one-third of the Directors, or if not three or a multiple of three, the number nearest to exceeding one-third, shall retire from office. If there are fewer than three Directors, one Director shall retire from office. Subject to the statutes, the Directors to retire by rotation shall be those who have been longest in office since their appointment or reappointment but, as between Directors who were appointed or reappointed on the same day, those to retire shall (unless otherwise agreed amongst themselves) be determined by lot.

(vi) Unless otherwise determined by the Company by ordinary resolution; the number of Directors is subject to a maximum of ten but is not to be less than two.

(l) Borrowing powers

The Board can exercise all the powers of the Company to borrow money and to mortgage or charge all or any part of the undertaking, property and assets (present and future) and uncalled capital of the Company and, subject to the Statutes, to create and issue debenture and other loan stock and other loan stock and debentures and other securities whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party. The Board shall restrict the borrowings of the Company and exercise all voting and other rights and powers of control exercisable by the Company in respect of its subsidiary undertakings so as to procure (but as regards its subsidiary undertakings only so far as it can procure by such exercise) that the aggregate principal amount at any one time outstanding of all monies borrowed by the Company and/or its group, (excluding amounts borrowed by any member of the Company's group from any other member of the Company's group and after deducting cash deposited) shall not at any time, without the previous sanction of an ordinary resolution of the Company, exceed £2,000,000.

(m) Pensions and benefits

The Board may exercise all the powers of the Company to pay, provide or procure the grant of pensions or other retirement or superannuation benefits and death, disability or other benefits, allowances or gratuities to any person who is or has been at any time a director of the Company or in the employment or service of the Company or of any company which is or was a subsidiary of or associated with the Company or of the predecessors in business of the Company or of any such subsidiary or associated company or the relatives or dependants of any such person. For that purpose the Board may procure the establishment and maintenance of, or participate in, or contribute to, any non-contributory or contributory pension or superannuation fund, scheme or arrangement and pay any insurance premiums.

(n) Uncertificated securities

Pursuant to and subject to the Regulations, the Board may permit shares of any class to be held in uncertified form and to be transferred or otherwise dealt with by means of a Relevant System (as defined in the Regulations), and may revoke such permission.

**6. Directors' and other interests**

6.1 As at 1 July 2003 (the latest practicable business day prior to the date of this document) the interests of the Directors (all of which are beneficial except as shown below) in the issued share capital of the Company, such interests being those which are required to be notified by each Director to the Company under the provisions of section 324 or 328 of the Act or which are required to be entered in the register of interests required to be maintained pursuant to section 325 of the Act or which are interests of persons connected with the Director within the meaning of section 346 of the Act, the existence of which is known or which could, with reasonable diligence, be ascertained by a Director will be, following Admission, as follows:

| *Director* | *Number of Ordinary Shares* | *Approximate percentage of existing issued Ordinary Share capital*[4] |
|---|---|---|
| William Colvin | None | Nil |
| Dr Paul van Saarloos | 13,303,500[1] | 60.3 |
| Simon Gordon | 210,020[2] | 1.0 |
| Hugh Grant | 20 | Nominal |
| Dr William Ardrey | 4,288,718[3] | 19.4 |
| Emanuel Rosen | 32,718 | 0.1 |

[1] Dr Paul van Saarloos' holding includes 4,434,500 Ordinary Shares held by his wife and 4,434,500 Ordinary Shares held by him as trustee for the van Saarloos family trust.

[2] Simon Gordon's holding includes 210,000 Ordinary Shares held by Novamed Limited, a company under his control.

[3] Dr William Ardrey has a non-beneficial interest in such shares as the appointed Board nominee of two shareholders, Custom Lasers Inc. and Asian Lasers Inc.

[4] Disregards any conversion of Loan Notes or exercise of share options.

In addition, the Directors hold the following share options:

| *Director* | *Earliest exercise date* | *Exercise price* | *Number of option shares* |
|---|---|---|---|
| Simon Gordon | 14 January 2003 | £0.05 | 1,007,321 |
| Hugh Grant | 20 June 2003 | £0.62 | 70,000 |
| Dr William Ardrey | 20 June 2003 | £0.62 | 350,000 |

Each of the share options referred to are exercisable from the date of grant for a period of ten years.

6.2 Immediately following the Placing, and assuming all of the Placing Shares are subscribed, the interests (all of which are beneficial, except as shown below) of the Directors, their immediate families and connected persons in the share capital of the Company as appearing in the register maintained under the provisions of Section 324 of the Act will be as follows:

| *Director* | *Number of Ordinary Shares* | *Approximate percentage of enlarged issued Ordinary Share capital*[4] | *Options* |
|---|---|---|---|
| William Colvin | None | Nil | None |
| Dr Paul van Saarloos | 13,303,500[1] | 38.3 | None |
| Simon Gordon | 210,020[2] | 0.6 | 1,007,321 |
| Hugh Grant | 20 | Nominal | 70,000 |
| Dr William Ardrey | 4,288,718[3] | 12.4 | 350,000 |
| Emanuel Rosen | 32,718 | 0.1 | None |

[1] Dr Paul van Saarloos' holding includes 4,434,500 Ordinary Shares held by his wife and 4,434,500 Ordinary Shares held by him as trustee for the van Saarloos family trust.

[2] Simon Gordon's holding includes 210,000 Ordinary Shares held by Novamed Limited, a company under his control.

[3] Dr William Ardrey has a non-beneficial interest in such shares as the appointed Board nominee of two shareholders, Custom Lasers Inc. and Asian Lasers Inc.

[4] Disregards any conversion of Loan Notes or exercise of share options.

6.3 Following the Placing, the Directors are aware that the following persons will be directly or indirectly interested in 3 per cent. or more of the enlarged issued share capital of the Company:

| *Name* | *Number of Ordinary Shares* | **Approximate percentage of enlarged issued Ordinary Share capital* |
|---|---|---|
| Asian Lasers Inc. | 2,144,359 | 6.2 |
| Custom Lasers Inc. | 2,144,359 | 6.2 |
| Poynton & Partners Pty Ltd | 1,400,000 | 4.0 |

* Disregards any conversion of Loan Notes or exercise of share options.

Save as disclosed in this paragraph 6, and in so far as the Company has the information, the Directors are not aware of any person or persons who either alone or, if connected, jointly following the completion of the Placing will (directly or indirectly) exercise or could exercise control over the Company.

6.4 Save as disclosed in this document:

(a) no Director has any interest in the issued share capital of the Company and no Director will acquire shares in the Company pursuant to Placing;

(b) the Directors are not aware of any person interested in 3 per cent. or more of the issued share capital of the Company;

(c) no contract or arrangement with the Company or any of its subsidiaries subsists or has subsisted within the period of two years immediately preceding the date of this document in which any Director is or was materially interested and which is significant in relation to the business of the Company and its subsidiaries taken as a whole;

(d) no Director has had any interest, direct or indirect, in any asset within the period of two years immediately preceding the date of this document which has been or which is proposed to be acquired, disposed of by or leased to the Company or any of its subsidiaries; and

(e) no amount or benefit has been paid or given by the Company within the period of two years before the date of this document to any promoter nor is any such payment or gift intended.

6.5 Other than directorships of companies in the Group and of wholly owned subsidiaries of companies listed below, the directorships and partnerships of the Directors currently held and held over the five years preceding the date of this document are as follows:

| *Director* | *Current* | *Past* |
|---|---|---|
| William Colvin | NHP plc<br>Sondex plc | British-Borneo Oil Limited (previously British Borneo Oil & Gas plc)<br>Jarvis plc |
| Dr Paul van Saarloos | None | Q-Vis Limited[1] |
| Simon Gordon | Novamed Limited | None |
| Hugh Grant | Findlay & Company Financial Services Limited<br>Findlay & Company | None |
| Dr William Ardrey | None | None |
| Emanuel Rosen | The Rosen Eye Surgery Centre Limited<br>Rosen Eye Clinics Limited<br>The European Society of Cataract and Refractive Surgeons<br>The United Kingdom and Ireland Society of Cataract and Refractive Surgeons | Northern Eye Institute<br>Guardwood Limited |

[1] Q-Vis Limited is a company incorporated in Australia which was placed into voluntary administration on 12 December 2002. Further details of this company and the litigation between it and each of Dr Paul van Saarloos and Simon Gordon is set out in paragraph 12 below.

6.6 Save as disclosed in paragraph 6.5 above, none of the Directors:

(a) has any unspent convictions in relation to indictable offences;

(b) has been declared bankrupt or been subject to an individual voluntary arrangement;

(c) has been involved in any receivership, compulsory liquidation, creditors voluntary liquidation, administration, company voluntary arrangement or any composition or arrangement with its creditors generally or any class of its creditors of any company where such Director was a director at the time of or within the 12 months preceding such events;

(d) has been involved in any compulsory liquidation, administration or partnership voluntary arrangement of any partnership where he was a partner at the time of or within the 12 months preceding such events;

(e) has been involved in receivership of any of his assets or of a partnership of which he was a partner at the time of or within the 12 months preceding such events;

(f) has been the subject of any public criticism by statutory or regulatory authorities (including recognised professional bodies), and whether such Director has ever been disqualified by a court from acting as a director of a company or from acting in the management or conduct of the affairs of any company; or

(g) has had a name other than his present name.

6.7 There are no outstanding loans or guarantees provided by any member of the Company to or for the benefit of any of the Directors.

6.8 For the year ending 30 June 2003 the aggregate remuneration paid and benefits in kind granted to the directors of the Group are estimated to be approximately £213,000. Under arrangements now in force, conditional on Admission, the Directors' aggregate remuneration and benefits in kind (including employer's national insurance contributions) for the year ending 30 June 2004 are estimated to be approximately £600,000.

**7. Directors' service agreements**

Each of the Executive Directors has a service agreement with the Company, entered into conditional on Admission, dated 2 July 2003. Each of the Executive Directors has agreed to devote the whole of his time and attention to the Group save for Hugh Grant who shall devote 4 days per week to the Group. Simon Gordon is entitled to devote one day a month to Novamed Limited. Dr Paul van Saarloos, Simon Gordon and Dr William Ardrey all enjoy an initial fixed period of 12 months continuing thereafter subject to termination on not less than six months' notice in writing by either party expiring at any time on or after the end of the initial fixed period. Hugh Grant's service agreement is terminable on not less than six months' notice in writing by either party at any time. In relation to Dr William Ardrey only, if his employment is terminated at any time during the initial fixed period of 12 months (other than for gross misconduct) he will be entitled to receive a lump sum payment equal to 12 months' basic salary (US$175,000). In addition, in the event of relocation, the costs of relocating him and his family will also be met by the Company. Dr William Ardrey is also entitled to receive a bonus payment, payable in two tranches, and conditional on:

(a) confirmation of acceptance by the United States Food and Drug Administration ("FDA") of an Individual Device Exemption submission on the Company's behalf for approval of the CustomVis Custom Corneal Reshaping System which will allow FDA trials to commence in the United States – bonus payable = US$125,000;

(b) confirmation of unconditional final approval from the FDA allowing sales of the CustomVis™ Custom Corneal Reshaping System – bonus payable =US£250,000.

Payment of the bonus is subject to certain conditions in relation to the termination of Dr William Ardrey's employment.

Basic annual salaries under the service agreements are £120,000 for Dr Paul van Saarloos, £120,000 for Simon Gordon, £60,000 for Hugh Grant and US$175,000 for Dr William Ardrey. In addition, each of the Executive Directors is entitled to receive a pension contribution equal to nine per cent. of his basic annual salary and private medical insurance for himself and his family. In the case of Dr William Ardrey, the Company will provide private medical cover to a maximum of US$1,500 per month (index linked).

Each of the Executive Directors has entered into, *inter alia*, the following restrictive covenants:

7.1 for three months after termination of the service agreement not to carry on any competing business.

7.2 for six months after termination of the service agreement, not to carry on any competing business in any country where at the date of termination or commencement of garden leave the Company provided services with which they were previously involved during the last 12 months of their employment; and

7.3 for twelve months after termination of the service agreement not to (i) solicit or deal with customers or (ii) solicit or employ key employees of the Group.

The periods of each of the restrictions referred to above runs consecutively with any period during which the Executive Director is placed on gardening leave. The restrictions referred to above will only apply after the termination of the Executive Director's employment for as long as the Company continues to pay them the salary and benefits (excluding bonus) they would otherwise have received. For Dr William Ardrey this only applies for the periods set out in paragraphs 7.1 and 7.2 above. However, any payment made in lieu of notice will be treated as satisfying this payment requirement. The payment of US$175,000 to be made to Dr William Ardrey if his employment is terminated during the initial fixed term of 12 months will also be treated as satisfying this payment requirement.

The appointments of William Colvin and Emanuel Rosen as non-executive Directors of the Company are governed by the terms of letters of appointment each dated 2 July 2003 and are conditional on Admission. Each such appointment is terminable on not less than 3 months' written notice by either party. Pursuant to the terms of the letters of appointment, William Colvin is entitled to an annual fee of £40,000 as non-executive Chairman and Emanuel Rosen is entitled to an annual fee of £20,000. They are also entitled to reimbursement for all reasonable out of pocket expenses properly incurred by them on Company business.

Each of the non-executive directors has agreed to give a restrictive covenant during the term of his letter of appointment and for 6 months after termination of his appointment not to carry on any competing business.

**8. Lock-ins and orderly marketing arrangements**

The Directors and Novamed Limited (a company controlled by Simon Gordon) have undertaken to the Company and Collins Stewart not to dispose of any interest which they have in the share capital of the Company for a period of 2 years after Admission, or, if earlier, until such date as the Company announces an interim profit for the six month period to 31 December 2004. The Directors and Novamed Limited have also given orderly marketing undertakings to the Company and Collins Stewart for the 12 months following the end of their lock-in arrangements.

Jennifer van Saarloos, Custom Lasers Inc, Asian Lasers Inc and Moksh Pty Ltd, who together hold approximately 27.1 per cent. of the issued share capital of the Company following the Placing, have each entered into a lock-in agreement with the Company and Collins Stewart pursuant to which they have agreed not to dispose of any of the Ordinary Shares held by them for a period of 12 months after Admission. They have also given orderly marketing undertakings to the Company and Collins Stewart for the 12 months following the end of their lock-in arrangments.

All remaining existing Shareholders (other than the Trustees of the Thorstone (S.E.) Retirement and Death Benefit Scheme) have entered into orderly marketing undertakings with the Company and Collins Stewart pursuant to which, *inter alia*, they have agreed not to sell any Ordinary Shares for a period of 12 months following Admission without first seeking to sell them through the Company's broker.

Donald R Sanders, Center for Clinical Research and Gem Consulting Pty Limited (the nominee for Poynton & Partners Pty Ltd) who hold options over 1,260,000 new Ordinary Shares in aggregate have entered into orderly marketing undertakings with the Company and Colllins Stewart pursuant to which, *inter alia*, they have agreed not to sell any Ordinary Shares for a period of 12 months following Admission without first seeking to sell them through the Company's broker.

**9. Employee share scheme**

As at the date of this document no employee share option schemes are in existence. Following Admission the Directors intend to establish an employee share option scheme which it is intended will be fully compliant with the guidelines laid down by the Association of British Insurers and for

which the Directors and staff of the Group will be eligible. The Directors anticipate that the remuneration committee of the Board will set performance criteria for the grant of the share options with the intention that rewards are closely linked to both Group and individual performance targets. The Company has agreed to consult with Collins Stewart to consider appropriate performance criteria before any such scheme is introduced.

The Company has received advance assurance from the Inland Revenue that the Company meets the qualifying company requirements of the Enterprise Management Incentives legislation as set out in the Income Tax (Earnings and Pensions) Act 2003. This assurance is based on the information supplied by the Company and will not apply in circumstances that vary from those described in the information provided.

Details regarding the individual share options which have been granted to certain Directors and others prior to Admission are set out in paragraph 6.1 above and paragraphs 11.5, 11.8 and 11.13 below.

## 10. Taxation

**The following paragraphs are based upon the general law and practice currently in force in the United Kingdom and are designed as a general guide for shareholders who hold shares as investments. They do not constitute tax advice. Each Shareholder's specific circumstances will impact on their tax position. You should be aware that taxation levels, bases and reliefs can change and that any tax you may pay (and available reliefs) will depend on each investor's personal circumstances. If you are in any doubt about the tax treatment of the Ordinary Shares you should consult your tax adviser or an independent financial adviser or other person authorised under the Financial Services and Markets Act 2000 ("FSMA") who specialises in advising on the acquisition or disposal of shares and other securities.**

*Taxation of Dividends*

Under the current UK taxation legislation, no tax will be withheld from dividends paid by the Company.

An individual resident in the UK for tax purposes who receives a dividend from the Company will generally receive a credit in respect of that dividend equal to one-ninth of the cash dividend. UK resident individual Shareholders who are liable to income tax at only the lower rate (10 per cent.) or basic rate (22 per cent.), will have no additional tax to pay on the dividend. UK resident individual Shareholders who are liable to income tax at the higher rate (40 per cent.) will pay tax at the rate of 32.5 per cent. of the gross dividend but will be able to set the tax credit off against this liability. This will reduce the effective rate of tax which such Shareholders will pay on the dividend to 25 per cent.. Individual Shareholders who are non-taxpayers will not be able to claim a repayment of the tax credit from the Inland Revenue.

Individual Shareholders who are resident for tax purposes outside of the United Kingdom but who are liable to income tax in the United Kingdom may be entitled to a tax credit as if they were resident for tax purposes in the United Kingdom. They may set off this tax credit against their total United Kingdom income tax liability. Such individuals include Commonwealth citizens, European Economic Area nationals, residents of the Isle of Man or the Channel Islands and residents of territories with which the UK has a double tax treaty which may provide relief in respect of such tax credit. Such shareholders will generally not be able to claim a repayment of the tax credit from the Inland Revenue.

A UK resident corporate Shareholder will generally not be liable to UK corporation tax on any dividend received. Such Shareholders will not be able to claim repayment of the tax credits attaching to dividends.

A UK resident pension fund will not be entitled to reclaim the tax credit on dividends paid by the Company.

*Taxation of Chargeable Gains*

A Shareholder who, at any time in the relevant UK tax year, is resident or ordinarily resident for tax purposes in the UK will be subject to tax on any profit they make from the disposal. A shareholder who is not resident in the UK for tax purposes but who carries on a trade, profession or vocation in the UK through a branch or agency and has used, held or acquired the Ordinary Shares for the purpose of such trade, profession or vocation may also be subject to UK taxation on chargeable gains on a disposal of those shares. Gains may also be taxable in the UK on disposals made by individuals at a time when they are temporarily not resident or ordinarily resident in the UK.

An individual Shareholder will benefit from an annual exemption from capital gains tax (currently £7,900). It is only gains arising in any tax year in excess of this annual exemption which are subject to tax. In addition, taper relief may be available to reduce the taxable gain. The amount of the relief depends on the length of time for which the Ordinary Shares are held. The Ordinary Shares will be treated as unquoted for taper relief purposes and should therefore qualify as business assets.

Consequently they should be subject to the enhanced taper relief which such assets attract. Individuals will be charged tax on the gains they incur after the annual exemption and taper relief at their marginal rate of tax.

Corporate bodies pay corporation tax on any chargeable gains they incur. Consequently they pay tax on gains at the same rate as that paid on their trading profits. Taper relief is not available to corporate Shareholders. Instead, the deductible cost of the shares is increased to reflect the effect of inflation between the date of acquisition and the date of sale of the shares on the price paid. The chargeable gain may also be exempt from tax where more than a 10 per cent. economic interest in the Company has been held for more than 12 months and the other conditions of the substantial shareholding exemption apply.

Genuinely non-UK resident Shareholders holding their shares as an investment will not normally be liable to UK tax in respect of any disposals of their shares.

*Stamp Duty and Stamp Duty Reserve Tax*

No stamp duty or stamp duty reserve tax ("SDRT") is payable in connection with the issue of Ordinary Shares pursuant to the Placing, unless they fall within certain categories of persons to whom a special charge to either SDRT applies under section 93 (Depository Receipts) or 96 (Clearance Services) Finance Act 1986 or stamp duty as referred to in section 67 (Depository Receipts) or 70 (Clearance Services) Finance Act 1986 or Schedule 15 of Finance Act 1999 (Bearer Instruments).

**11. Material Contracts**

The following contracts, not being contracts entered into in the ordinary course of business, have been entered into by the Company and its subsidiary within two years immediately preceding the date of this document and are, or may be, material:

11.1 On 15 February 2003, CLVR entered into a distribution agreement with Custom Lasers Inc ("CLI") pursuant to which CLI was granted the sole and exclusive right to distribute the CustomVis™ System in *inter alia* North and South America (including US, Canada, Mexico, Latin America), Bahamas, Bermuda and the Caribbean. The agreement, unless terminated by mutual agreement, is for a fixed term of four years or three years after FDA approval whichever is earlier and thereafter renewable on an annual basis. The fees payable by CLI for the CustomVis™ System (US$495,000) and the transfer costs (US$346,500) are payable 50 per cent. before CLVR ships the goods and 50% on installation of the goods. Further fees are payable by CLI per procedure (US$23) and in respect of an annual service contract (US$35,000). Under the terms of the agreement CLI has an exclusive revocable licence to use

CLVR's name and trademarks in connection with the sale and promotion of the products. Under the terms of the agreement, CLVR warrants that until 15 months after delivery or 12 months after sale and delivery to a third party the products are *inter alia* of proper materials and fit for the purpose for which they are designed. The agreement contains uncapped indemnities by CLVR in favour of CLI for *inter alia* any liabilities incurred by CLI in connection with (i) any injury or loss to any customers of CLI caused by CLVR's product; (ii) a breach of the agreement or failure to comply with any laws; (iii) any claims brought as a result of breach of CLVR's warranty or in respect of any of the products infringing any intellectual property rights.

11.2 On 17 April 2003, the Company entered into an agreement for the acquisition of the entire issued share capital of CLVR in consideration for the allotment of shares in the Company. Each shareholder was allotted seven Ordinary Shares for every one share held in CLVR.

11.3 On 22 April 2003, the Company and the Executive Directors entered into an investment agreement with Warrawee Investments Limited (the "Investor"), which agreement was subsequently varied by a deed on 1 July 2003. The Investor subscribed for £1,342,844 of Loan Notes. Warranties were given to the Investor by the Company and the Executive Directors (other than Mr Hugh Grant) A disclosure letter, and accompanying disclosure bundle, was prepared in respect of these warranties.

The Investor has the right to appoint one person to the Board as a non-executive director of the Company. This right to appoint a director to the Board continues even after Admission but terminates at the Board's discretion in the event that the Investor no longer holds any Loan Notes and its shareholding in the Company is less than 5 per cent. of the issued share capital of the Company. Pursuant to these arrangements the Investor appointed Jeremy Brooks to the Board but he resigned on 20 June 2003.

The Loan Notes are redeemable in full on the first anniversary of Admission or earlier at the insistance of the Investor. Alternatively, the Investor has the right to convert the Loan Notes into 2,165,877 new Ordinary Shares at any time in which event the Company has agreed to use its reasonable endeavours to procure that its broker finds buyers for such number of shares as shall generate a capital sum equal to the aggregate subscription monies paid by the Investor for the Loan Notes, being £1,342,844. At the date of this document the Investor has not indicated its intention to convert or to require redemption of the Loan Notes.

The Investor has entered into an orderly market arrangement with Collins Stewart with respect to any residual shareholding held by it, further details of which are set out in paragraph 8 above.

On Admission this investment agreement shall terminate save for clauses relating to the Investor's director (see above), and certain operative provisions relating to notices, confidentiality and general procedural matters.

11.4 The deed consitituting the Investor's Loan Notes was executed as a deed by the Company on 22 April 2003. The aggregate principal amount of the notes constituted was limited to £1,342,844. The notes were issued in multipes of £1 and are unsecured. The Loan Notes are convertible in whole or in part into Ordinary Shares in CustomVis. The Loan Notes are convertible at any time, at a conversion price of £0.62 per share. The Investor may exercise this conversion right as mentioned in paragraph 11.3 above.

11.5 On 5 May 2003 the Company granted an option to Gem Consulting Pty Limited, a nominee of Poynton & Partners Pty Ltd, over 1,120,000 new Ordinary Shares with an exercise price of £0.62 per share. The grant of the option was conditional on a number of conditions precedent, relating to pre-flotation fundraisings being successfully completed and the appointment of advisers prior to Admission, which have been satisfied. Poynton & Partners Pty Ltd has provided financial, consulting and advisory services to the Group since March 2001. The option was exercised in full on 1 July 2003 as noted in paragraph 3.5 above.

11.6 On 2 July 2003 the Company entered in to the Placing Agreement with Collins Stewart and the Directors pursuant to which Collins Stewart has agreed to use its reasonable endeavours to procure subscribers on behalf of the Company for up to 12,637,363 new Ordinary Shares at the Placing Price. The Placing Agreement is conditional on the entire issued and to be issued share capital of the Company being admitted to AIM by no later than 11 July 2003 (or such other date as may be agreed between the parties).

In consideration of its services in connection with Admission and the Placing, the Company will pay Collins Stewart a corporate finance fee of £150,000 and a commission of 4 per cent. of the Placing Price for each of the Placing Shares for which Collins Stewart procures placees on behalf of the Company. In addition, Collins Stewart has been granted the option described in paragraph 11.8 below.

The Placing Agreement contains warranties given by the Company and the Directors as to the accuracy of the information contained in this document and other matters relating to the Company and its business. In addition, the Company has given an indemnity to Collins Stewart in respect of certain matters. Collins Stewart is entitled to terminate the Placing Agreement prior to Admission, principally in the event of a material breach of the Placing Agreement or of any of the warranties contained in it or if an event of force majeure arises.

11.7 On 2 July 2003, the Company entered into a nominated adviser and broker agreement with the Directors and Collins Stewart pursuant to which the Company has appointed Collins Stewart to act as nominated adviser and broker to the Company for the purposes of the AIM Rules. The Company has agreed to pay Collins Stewart a fee of £35,000 plus VAT per annum for these services. The agreement contains certain warranties, undertakings and indemnities given by the Company and the Directors in respect of, *inter alia*, compliance with applicable laws and regulations. The agreement is subject to one month's written notice by either party.

11.8 On 2 July 2003, the Company entered into an option agreement with Collins Stewart pursuant to which the Company granted Collins Stewart the option to subscribe for 694,383 new Ordinary Shares at the Placing Price (representing 2 per cent. of the enlarged issued ordinary share capital of the Company immediately following the Placing) exercisable at any time on or before the fifth anniversary of Admission.

11.9 On 2 July 2003, the Company entered into an option agreement with Dr Paul van Saarloos and Simon Gordon relating to their joint venture interests and/or their direct interests in all intellectual property rights vesting in them pursuant to the settlement which they had reached with the administrator of Q-Vis pursuant to the Q-Vis Deed of Company Arrangement, particular details of which are set out in paragraph 12 below. The agreement gives an option to the Company to purchase from Dr Paul van Saaloos and Simon Gordon such joint venture and/or direct intellectual property rights, including all patent rights, during an 18 month period for a sum based on an independent valuation of all such rights prior to exercise of the option. Further, the option includes non-compete undertakings from Dr Paul van Saarloos and Simon Gordon that they will not exploit such joint venture interests and/or direct intellectual property rights, whilst the same are in their possession, in competition with the Group.

11.10 On 20 June 2003, the Company entered into a consultancy agreement with Dr Donald R Sanders Ltd doing business as the Center for Clinical Research and Dr Donald R Sanders pursuant to which Donald R Sanders Ltd agreed to procure that Dr Sanders provided advisory consultative services with respect to the CustomVis™ System to the Company including assisting in regulatory approval preparations and clinical trials prior to the Group seeking FDA approval for the US LVC market. Donald R Sanders Ltd will receive a fee of US$15,000 per month in consideration of the provision of these services. The agreement is terminable by any party giving three months written notice to the other parties.

11.11 Under the terms of a letter dated 23 June 2003, the Company agreed to pay an intermediaries fee to Equilateral Limited ("Equilateral") in the sum of 2 per cent. of the gross placing proceeds on Admission. In consideration for this fee, each of Equilateral and Equilateral Corporate Finance Limited waived all and any claims it might have had against the Company pursuant to earlier mandate letters between the parties relating to fees payable or remuneration due for services provided by Equilateral or Equilateral Corporate Finance Limited to the Company.

11.12 Under the terms of a letter dated 20 June 2003 the Company agreed that in part consideration of the option granted to Gem Consulting Limited, a nominee of Poynton & Partners Pty Ltd ("Poyntons") (see paragraph 11.4 above) Poyntons waived all and any claims it might have had against the Company pursuant to earlier mandate letters between the parties relating to fees payable or remuneration due for services provided by Poyntons to the Company. Further, the Company agreed to engage Poynton's, *inter alia*, as their corporate adviser on an exclusive basis for a two year period save that such appointment should not conflict with the appointment of the Company's nominated adviser or offend any obligations of the Company pursuant to the AIM Rules.

11.13 On 20 June 2003, the Company entered into an option agreement with Dr Donald R Sanders and the Center for Clinical Research pursuant to which the Company granted each of Donald R Sanders and the Center for Clinical Research an option to subscribe for 70,000 new Ordinary Shares each at a price of £0.62 per Ordinary Share. The options are exercisable at any time in whole or in part during the three year period commencing on 20 June 2003.

## 12. Litigation

12.1 *Summary of Supreme Court of Western Australia proceedings between Q-Vis and Dr Paul van Saarloos*

Dr Paul van Saarloos entered into a service agreement with Q-Vis dated 21 May 1999. Pursuant to the service agreement, Dr Paul van Saarloos was appointed managing director of Q-Vis and also chief technical officer. Dr Paul van Saarloos remained in the position of managing director until 15 May 2000 when he was replaced. Dr Paul van Saarloos considered his replacement constituted a breach by Q-Vis of the service agreement. Dr Paul van Saarloos terminated the service agreement with effect from 18 October 2000. On 15 November 2000 Dr Paul van Saarloos commenced proceedings in the Western Australian Industrial Relations Commission for unfair dismissal. Those proceedings were settled on a confidential basis in February 2002. Q-Vis denied that Dr Paul van Saarloos was entitled to terminate the service agreement and separately commenced proceedings against him in early 2002 in the Supreme Court of Western Australia seeking damages for that termination. Dr Paul van Saarloos filed a defence and counterclaim in the proceedings denying Q-Vis' claims and seeking substantial damages for what he alleged was Q-Vis' breach of the service agreement.

On 12 December 2002, Q-Vis was placed into voluntary administration. Dr Paul van Saarloos lodged a proof of debt claim with the administrators for damages arising out of Q-Vis' repudiation of the service agreement. The effect of the administration was that Dr Paul van Saarloos' action against the Company was stayed pursuant to the Australian Corporations Act 2001. On 2 April 2003 Q-Vis, the administrators and others together with Dr Paul van Saarloos entered into a Deed of Company Arrangement approved by the creditors on 14 March 2003 and executed by the Company on 28 March 2003. Pursuant to the Deed of Company Arrangement the claims brought in the Supreme Court proceedings were resolved on terms, *inter alia*, that Dr Paul van Saarloos be paid the sum of $100,000 by Q-Vis, and Dr Paul van Saarloos also received certain rights to intellectual property, plant, equipment and stock owned by Q-Vis.

The Deed contained a release in the following terms:

"[Q-Vis] and the Administrator release and forever discharge [Dr Paul] van Saarloos from all claims they have or either of them has or may have or whatever nature whether known or unknown arising from any circumstances occurring prior to the execution of this Deed against [Dr Paul] van Saarloos including, without limitation, the Supreme Court proceedings or the subject matter of the Supreme Court proceedings."

Pursuant to the Deed, once the payment of the sum of AUD$100,000 is made to Dr Paul van Saarloos, he and Q-Vis agree to an order being made in the Supreme Court proceedings that the action and counterclaim be dismissed and that any costs orders be vacated. The sum of AUD$100,000 is due to be paid to Dr Paul van Saarloos by 8 October 2003.

12.2 *Summary of Supreme Court of Western Australia proceedings between Q-Vis and Simon Gordon*

Q-Vis employed Simon Gordon as sales and marketing director commencing 1 September 1999. Mr Gordon's employment agreement provided that he would be employed for a minimum of 1 year on an annual salary of £93,000 but Q-Vis summarily dismissed him on 19 May 2000. On 31 May 2001 the Industrial Relations Commission of Western Australia held that Q-Vis had unfairly dismissed Mr Gordon and awarded him statutory compensation in the sum of £46,500. Mr Gordon also commenced an action in the Supreme Court of Western Australia seeking damages for breach of the employment agreement and an option agreement which formed part of his employment arrangement. Mr Gordon also sought damages for loss of reputation. The total value of the claim exceeded AUD$1,045,500. Q-Vis defended the action.

As noted previously, Q-Vis was placed into voluntary administration on 12 December 2002. The effect of the administration was that Mr Gordon's action against the Company was stayed pursuant to the Australian Corporations Act 2001. Mr Gordon compromised his claim as part of a Deed of Company Arrangement approved by the creditors on 14 March 2003 and executed by Q-Vis on 28 March 2003. Pursuant to the Deed of Company Arrangement the claims brought in the Supreme Court proceedings were resolved on terms, *inter alia*, that Simon Gordon be paid the sum of AUD$66,500 by Q-Vis, and also received certain rights to intellectual property, plant, equipment and stock owned by Q-Vis.

The Deed contained a release in the following terms:

"[Q-Vis] and the Administrator release and forever discharge [Simon] Gordon from all claims they have or either of them has or may have or whatever nature whether known or unknown arising from any circumstances occurring prior to the execution of this Deed against [Simon] Gordon including, without limitation, the Supreme Court proceedings or the subject matter of the Supreme Court proceedings."

Pursuant to the Deed, once the payment of the sum of AUD$66,500 is made to Simon Gordon, he and Q-Vis agree to an order being made in the Supreme Court proceedings that the action and counterclaim be dismissed and that any costs orders be vacated. The sum of AUD$66,500 is due to be paid to Simon Gordon by 8 October 2003.

12.3 *Details of the proposed joint venture*

In the event of a successful re-capitalisation of Q-Vis by a specialist re-capitalisation firm, and following the settlement reached with the administrator of Q-Vis, it is agreed between certain parties to the Q-Vis Deed of Company Arrangement that the Q-Vis intellectual property rights will be placed in a joint venture between Q-Vis and Dr Paul van Saarloos and Simon Gordon. If the recapitalisation proposal fails, the Q-Vis intellectual property will be transferred to Dr Paul van Saarloos and Simon Gordon in its entirety.

The re-capitalisation proposal, whilst it has been approved by Q-Vis creditors, still remains conditional on a number of factors including shareholder approval, a capital raising and re-listing of Q-Vis on ASX. The Directors anticipate that the specialist re-capitalisation firm will, on behalf of Q-Vis, look to acquire a new business to reverse into Q-Vis, at which time Q-Vis will be free to dispose of any retained interest in the joint venture between itself and Dr Paul van Saarloos and Simon Gordon. Initially, Q-Vis shall have a 50 per cent. interest, and Dr Paul van Saarloos and Simon Gordon shall together have a 50 per cent. interest in the joint venture. Q-Vis will provide initial funding to the joint venture and at the end of the first year the joint venture Q-Vis will have the option to subscribe further funding to retain its 50 per cent. interest. In the event Q-Vis elects not to contribute extra funding its interest in the joint venture will be diluted to 10 per cent. After the second year of the joint venture the parties will assess the commercial viability of the intellectual property technology and make a decision whether to continue the joint venture or sell the joint venture assets. In the event that, *inter alia*, the shareholders of Q-Vis approve a significant change in the activities of Q-Vis pursuant to the rules of ASX, Dr Paul van Saarloos and Simon Gordon will have the right to acquire all but 10 per cent. of the Q-Vis interest in the joint venture for AUD$10.

Since entering into the settlement with the administrator, Dr Paul van Saarloos has met the necessary fees to keep the various Q-Vis patent applications live.

Dr Paul van Saarloos and Simon Gordon have entered into an option agreement with the Company giving the Company an option to acquire their respective interests in the joint venture and/or the Q-Vis intellectual property in which they have any beneficial interest, together with certain non-compete undertakings in respect of the same in favour of the Company. Further details of the option agreement are set out in paragraph 11 above.

12.4 *Ligi Technologie Medicali*

CLVR and Ligi Technologie Medicali ("LIGI") entered into a contract in or around March 2001 which related to the development, and provision to LIGI of know-how relating to the production of a laser system to ablate the cornea for refractive purposes. The contract specifically contemplated a subsequent formal contract being signed within 15 days but this step was not completed. Dr Paul van Saarloos has confirmed that payments were made by LIGI to CLVR up to June 2001 but LIGI failed to pay the July 2001 invoice and the payment due in August 2001. As a consequence, CLVR accepted LIGI's repudiation of the arrangements by the non-payment of monthly fees on 16 August 2001. Further correspondence ensued in which LIGI accepted that the contract had been terminated but wanted the goods shipped to LIGI and CLVR to refrain from competing with LIGI in the world refractive market or, alternatively, for CLVR to pay back the full amount paid by LIGI to CLVR equal to $303,600 plus interest at 8 per cent.. CLVR's former Australian solicitors sent a without prejudice settlement offer to LIGI's lawyers on 14 December 2001 offering for CLVR to ship the goods if LIGI pay all the costs of CLVR incurred up to 17 August 2001 but their file does not disclose that any response was received. Dr Paul van Saarloos has been in sporadic contact with LIGI including at various LVC trade conferences. LIGI have historically claimed that US$303,600 should be returned to them due to CLVR's purported failure to complete the contract terms. The Directors believe that any contractual arrangements with LIGI have terminated and that the Group has no liability to LIGI. Accordingly any claims arising from LIGI would be vigorously defended.

12.5 Save as set out above, neither the Company nor its subsidiary is or has been engaged in any legal or arbitration proceedings which may have, or has had during the twelve months preceding the date of this document, a significant effect on the Group's financial position nor are any such proceedings pending or threatened.

## 13. Working Capital

The Directors are of the opinion having made due and careful enquiry that, taking into account the net proceeds of the Placing, the Company will have sufficient working capital for its present requirements, that is, for at least 12 months from Admission.

## 14. Consents

PKF, Bridgehead Technologies, Wray & Associates and Collins Stewart have each given and have not withdrawn their written consent to the inclusion in this document of their respective reports and/or names as appropriate and references thereto in the form and context in which they are included.

## 15. General

15.1 Other than as described in this document, there has been no significant change in the trading or financial position or prospects of CLVR since 31 March 2003 the date to which the latest audited accounts of CLVR were made up. Other than as described in this document, there has been no significant change in the trading or financial position or prospects of the Company since its incorporation.

15.2 It is estimated that the total expenses payable by the Company in connection with the Placing and Admission will amount to approximately £1.5 million (excluding value added tax).

15.3 As at the date of this document, no statutory accounts have been delivered to the Registrar of Companies by the Company. The financial information set out in Part VI of this document does not constitute full statutory accounts as referred to in section 240 of the Act.

15.4 The amount payable on application and allotment of each Placing Share is 91p of which 86p is payable by way of premium.

15.5 The Company is making an application to CRESTCo Limited for the Ordinary Shares to be settled through CREST and to be admitted as a participating security. It is expected that the admission of the Ordinary Shares in CREST as a participating security will be effective from Admission. Holders of the Company's Ordinary Shares who are direct or sponsored members of CRESTCo Limited will be able to dematerialise their Ordinary Shares in accordance with the rules and practices instituted by CRESTCo Limited.

15.6 Except as detailed in this document, no person (other than professional advisers as referred to in this document and trade suppliers) has received, directly or indirectly, from the Company within the twelve months preceding the Company's application for Admission, and no persons have entered into contractual arrangements to receive, directly or indirectly, from the Company on or after Admission:

(a) fees totalling £10,000 or more;

(b) securities in the Company with a value of £10,000 or more calculated by reference to the Placing Price; or

(c) any other benefit with a value of £10,000 or more at the date of Admission, which includes all the existing shareholders of the Company.

## 16. Documents available for inspection

Copies of this document will be available free of charge at the registered office of the Company and at the offices of Collins Stewart, 9th Floor, 88 Wood Street, London EC2V 7QR during normal business hours (excluding Saturdays, Sundays and public holidays), from the date of this document until a date one month following Admission. Copies of the following documents will be available for inspection at the offices of Hammonds, 7 Devonshire Square, Cutlers Gardens, London EC2M 4YH during normal business hours (excluding Saturdays, Sundays and public holidays) for the same period:

(a) the memorandum and articles of association of the Company;

(b) the report produced by PKF set out in Part VI of this document;

(c) the long form report of Bridgehead Technologies Limited referred to in Part IV of this document;

(d) the report produced by Wray & Associates set out in Part V of this document;

(e) the lock-in and orderly market agreements referred to in paragraph 8 above;

(f) the Directors' service agreements and letters of appointment referred to in paragraph 7 above;

(g) the material contracts referred to in paragraph 11 above; and

(h) the consent letters referred to in paragraph 14 above.

Date: 2 July 2003