Zacks Small-Cap Research

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Bio Light Israeli (BLGTY-OTC)

BLGTY: BioLight gets CE Mark for CellDetect…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/05/2015
Current Price (06/30/15)	$5.23
Target Price	**$14.00**

OUTLOOK

Today, BioLight announced that the European Patent Office has issued a patent for the CellDetect technology that will be in effect until March 2027. The company also announced that the CellDetect non-invasive test for detecting bladder cancer in urine has obtained CE Mark thus enabling commercialization in the European Union. Obtaining the CE Mark for the CellDetect technology to detect the recurrence of bladder cancer represents a significant milestone and achievement for BioLight.

On June 1, 2015 BioLight reported their financials for the first quarter ending Mar 31, 2015. On May 12, 2015 the company announced that Hong Kong based Rock-One International Holdings Ltd. invested $6.6 million in BioLight. BioLight's development plans are on track and there are several catalysts expected in subsequent quarters of 2015. We continue to remain highly positive on BioLight and are maintaining our Buy recommendation and $14.00/share price target.

SUMMARY DATA

52-Week High	**$5.41**
52-Week Low	**$3.79**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**98**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**23.7**
P/E using 2016 Estimate	**-4.4**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Large - Growth**
Industry	**Medical Services**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					$0.2A
2015	$0.04A	$0.1E	$0.2E	$0.3E	$0.7E
2016					$1.5E
2017					$4.6E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					-0.02A
2015	-0.003A	-0.003E	-0.003E	-0.002E	-0.01E
2016					-0.01E
2017					-0.01E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

BLGTY: BioLight gets CE Mark for CellDetect…

A large unmet need exists in the U.S. and Europe for non-invasive screening of bladder cancer. Studies have shown the incidence/mortality rates as well as the costs associated with the disease detection to be high.

The company reported successful results from their blinded, multi-center clinical study using the CellDetect technology for detecting bladder cancer. The primary endpoint of effectively detecting the recurrence of bladder cancer in subjects with a history of the disease was achieved. The need to detect bladder cancer noninvasively is large and the CellDetect technology has shown 84.4% sensitivity and specificity of 82.7% in detection of cancerous cells in clinical studies. The sensitivity performance of three other noninvasive tests to detect the recurrence of bladder cancer currently in the market are urine cytology test (50%), BTA stat (68.8%) and NMP22 BladderCheck (17.4%).

Today, BioLight announced that the European Patent Office has issued a patent for the CellDetect technology that will be in effect until March 2027. The company also announced that the CellDetect non-invasive test for detecting bladder cancer in urine has obtained CE Mark thus enabling commercialization in the European Union. Obtaining the CE Mark for the CellDetect technology to detect the recurrence of bladder cancer represents a significant milestone and achievement for BioLight.

The company is now focused on building awareness of the product to facilitate broader roll-out in Europe using distribution agreements in CE Mark territories. The company may use the CE Mark as a stepping-stone to submit a Pre-IDE application for CellDetect to the U.S. FDA sometime during the first half of 2016.

…TeaRx…

In February 2015, the company reported clinical study findings that identified positive statistical correlations between the TeaRx multi-parameter diagnostic test and widely used benchmark tests for dry eye syndrome (DES). The process of defining the reliable combination of parameters that are required for the DES diagnostic kit is underway. In mid-June 2015, BioLight announced their collaboration with Ora Inc., a world-leading independent, full-service ophthalmic contract research organization (CRO) and product development firm, to aid in the commercial development of TeaRx. The two companies have agreed to fund the clinical study and other activities required to obtain U.S. 510K regulatory approval for TeaRx as well as to incorporate the test kit in other clinical trials sponsored by third parties and performed by Ora.

HIGHLIGHTS

- BioLight Life Sciences Investments Ltd. invests in, manages and commercializes biomedical innovations grouped around defined medical conditions. The two current fields of solutions are in ophthalmology via 100% ownership of XLVision Sciences, and in cancer diagnostics via a 39.6% controlling ownership of Micromedic Technologies. This permits the subsidiaries to collaborate and create synergistic opportunities which in turn will secure greater interest and involvement from the financial community, both domestically as well as internationally.

- Two of the company's products, the IOPtiMate™, an innovative, non-penetrating laser assisted surgical device for glaucoma, and the CellDetect® cervical cancer diagnostic kit, have recently begun commercialization.

- In BioLight's ophthalmology field, it was announced at September 2014, that a first IOPtiMate™ system sale was made in Hong Kong, and an additional IOPtiMate™ system has been installed on a trial basis at a second medical center in Hong Kong. Hong Kong market is an important reference to the strategic distribution agreement in China (which is the world's largest glaucoma market) that was announced earlier in 2014 with a target of at least 100 IOPtiMate™ systems.

- Also in BioLight's ophthalmology field, it was announced in June 2014, that the Eye-D® product commenced an FDA Phase I/IIa clinical trial to test the sub-conjunctival insert with controlled-release latanoprost for the treatment of glaucoma. This clinical trial is expected to be completed in H1 2016.

- In BioLight's cancer diagnostic field, regulatory approval in Europe for the CellDetect technology is expected around mid-year 2015.

- Since February 2014, BioLight's ADR (Level 1) have traded in the U.S. OTCQX under the symbol BLGTY. Each ADR equals 100 ordinary shares. BioLight also trades on the Tel Aviv Stock Exchange (TASE: BOLT) which is BioLight's primary Stock Exchange. BioLight is included in the Tel Aviv Biomed Index (TA – Biomed) and also in the Tel-Aviv BlueTech index (TA – BlueTech), effective June 15, 2014.

BACKGROUND

BioLight Israeli Life Sciences Investments Ltd. (OTCQX: BLGTY, TASE: BOLT) was established in 2005 in Tel Aviv, Israel and manages and commercializes biomedical innovations grouped around defined medical conditions. BioLight has two main medical fields through XLVision Sciences Ltd., a wholly-owned subsidiary in ophthalmology focused on developing treatments for glaucoma and dry-eye syndrome (DES), and the cancer diagnostics field through its 31.24% controlling ownership in Micromedic Technologies Ltd. that offers a range of cancer diagnostic activities for cervical, bladder, multiple myeloma and other cancers. The BioLight group owns 17 patents and has filed others that are pending approval.

XLVision Sciences is comprised of three separate technologies. It owns 87.2% of IOPtima that commercializes the IOPtiMate™. IOPtiMate™ is a laser-assisted surgical device that enables eye surgeons to perform an accurate deep sclerectomy glaucoma surgery to reduce elevated intra-ocular pressure (IOP) without penetrating the eyeball. This safe, non-invasive one-time laser procedure provides significant long-term reduction of IOP, has a low post-operation complication rate, reduces the need for medications, enjoys broad IP protection, and is easy to learn and simple to perform. The product commenced a soft launch in China, the world's largest glaucoma market, in the second quarter of 2014. IOPtima has received a commitment from the distributor in China to purchase at least 100 systems during the initial term of the agreement. The company expects that this will translate into continued strong performance in the coming years. IOPtima has regulatory approvals to market the IOPtiMate™ system in Europe, Mexico and Israel. BioLight is

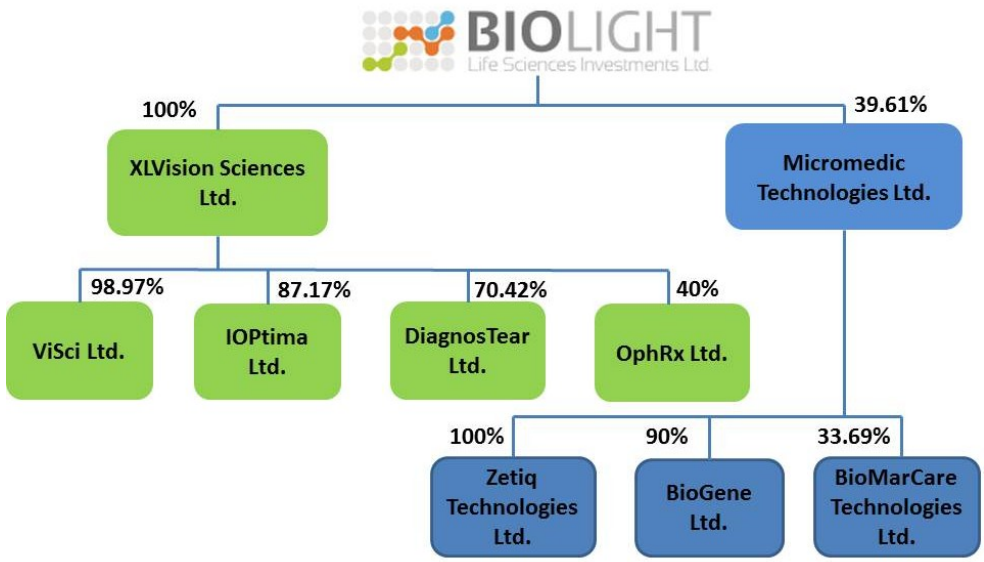
looking to expand its commercial operations in Asia; in early September, 2014, the first IOPtiMate™ system was sold in Hong Kong and the company has installed the IOPtiMate™ system in another medical center in Hong Kong for a trial period. The company is also awaiting regulatory approval to commence marketing and sales in Taiwan.

ViSci, a wholly-owned subsidiary of XLVision, has an exclusive global license for the Eye-D®, a controlled-release drug-delivery insert platform with a first indication using latanoprost for the treatment of glaucoma. In June 2014, ViSci initiated the Phase 1/2a clinical trial to determine the dosage level and to evaluate the safety and ocular hypotensive efficacy of the Eye-D®. Seven sites across the U.S. expect to enroll up to 68 glaucoma patients over a three month period. The patients will be receiving either the three doses of controlled-release latanoprost or the once-daily dosed latanoprost eye drops. The study is expected to be completed in H1 2015.

DiagnosTear, (70% owned) develops the TeaRx, a point-of-care multi-parameter diagnostic test for dry-eye syndrome that easily and inexpensively provides semi-quantitative measures analysis using the tear film for initial diagnosis, screening and monitoring the selected treatment. The company has started a clinical trial at the beginning of 2014 to validate the effectiveness of its test methods in tears of healthy subjects as well as with DES. In February 2015, the company reported clinical study findings that identified positive statistical correlations between the TeaRx test's diagnostic parameters and widely used benchmark tests for dry eye syndrome (DES). BioLight has initiated a second clinical trial in order to assess the effectiveness of the tests in tears of healthy subjects as well as patients with severe DES. The results from this second trial are expected in Q2 2015.

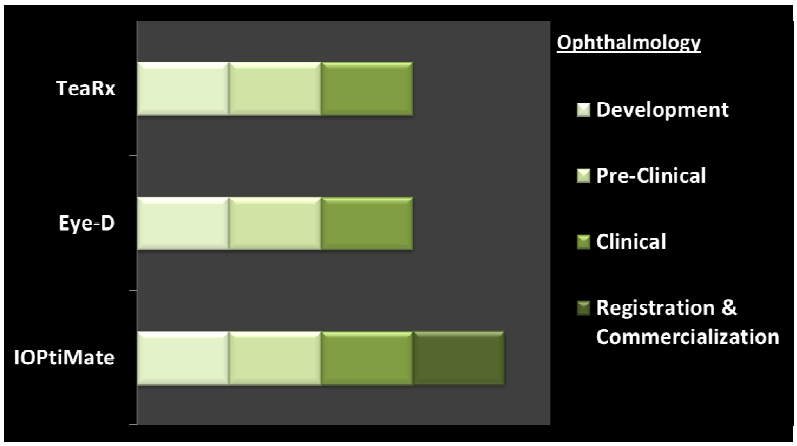
Micromedic Technologies Ltd. specializes in the development and commercialization of innovative diagnostic tools for early detection of cancer cells as well as monitoring of its recurrence. Zetiq (100% owned by Micromedic) has developed an innovative cell staining technology, CellDetect® for early detection of cervical cancer. It is now being commercialized in China and in process of commercialization in India. The second indication for monitoring bladder cancer recurrence in urine samples is in clinical trial. Micromedic owns 90% of Bio-Gene, a subsidiary involved in developing a profiling assay to identify carriers of a gene mutation that is known to increase the risk for developing breast and/or ovarian cancer. Micromedic acquired 33% of BioMarCare which develops solutions for early detection of colorectal cancer. Micromedic has also developed an assay that is intended for the qualitative analysis of genetic changes which may be indicative of increased risk of developing Bisphosphonate-related Osteonecrosis of the Jaw (BRONJ) following intravenous administration of drugs of the bisphosphonate family. Micromedic has strategic alliances with scientific institutions from the local as well as global markets to collaborate and in-license their research/products. Micromedic is a publicly traded company on the Tel Aviv Stock Exchange (TASE: MCTC).

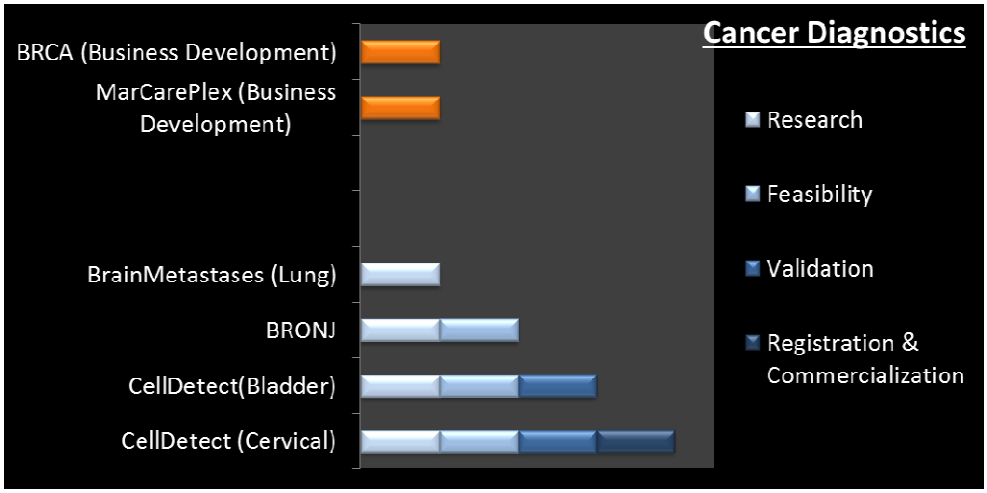
Corporate Structure



BioLight is lead by a strong management team that has substantial expertise in business, pharmaceutical and biomedical sectors. Mr. Dilip Shanghvi, a key investor in BioLight, has wide and extensive industrial experience in the pharmaceutical industry. He founded Sun Pharmaceuticals Ltd. and has been its Managing Director since May 2012. Mr.Shanghvi has been the Chairman of Taro Pharmaceutical Industries Ltd., since July 2013. Mr. Israel Makov, the Chairman of BioLight, and a key investor, has been the Chairman of Sun Pharmaceuticals, former CEO and President of Teva Pharmaceuticals and former Chairman of Given Imaging. About 20% of the company's shares are held by institutional investors[1]. XL Vision's Scientific Advisory Board comprising of Dr. Robert David, Prof. Alon Harris, Dr. Howard Barnebey and Prof. Alan Robin provides professional and scientific advisory services to BioLight's ophthalmology field.

PRODUCTS OFFERING STRATEGIC OPPORTUNITY





The technologies and related products shown in the graph above are described in detail in the following paragraphs.

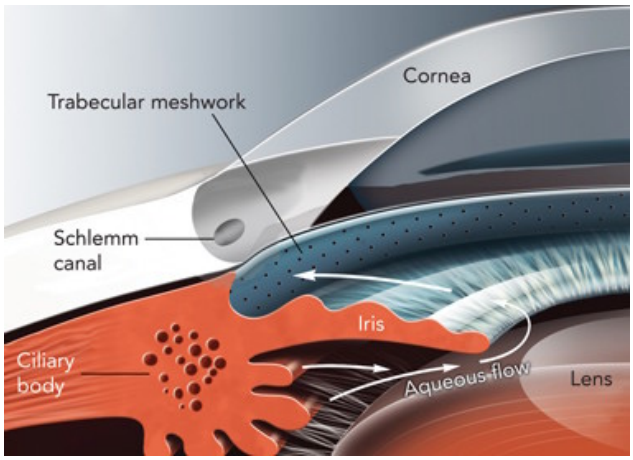
[1] http://www.tase.co.il/Eng/General/Company/Pages/companyDetails.aspx?CompanyId=001293

XLVision Sciences is comprised of three separate technologies involved in addressing the issues in ophthalmology for the monitoring and treatment of glaucoma and DES, and is directed to a growing market of billions of US dollars with unmet needs.

Indication: Glaucoma

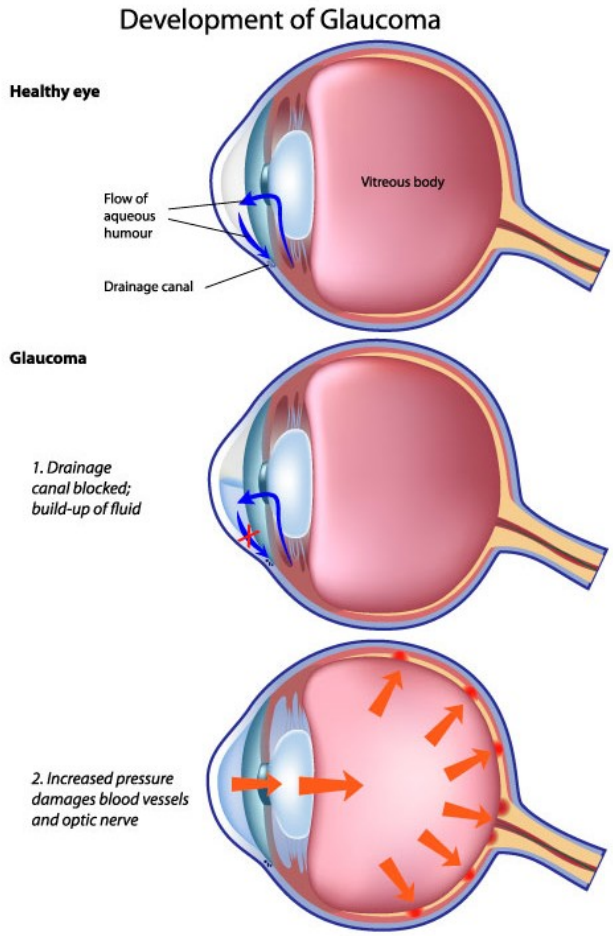
The anterior part of the eye houses a clear fluid called aqueous humor that is produced by the ciliary body. It passes from the posterior chamber through the pupil, trabecular meshwork, and canal of Schlemm into the anterior chamber (AC). In order to maintain a normal pressure inside the eye, this fluid is con being continuously produced and drained in equal amounts.

Glaucoma is a condition of the eye that results in the loss of retinal ganglion cells. The pathophysiology associated with glaucoma is not completely understood. However, elevated intraocular pressure (IOP) has been found to be one of the primary risk factors in glaucoma patients. As IOP increases it leads to optic neuropathy which occurs progressively resulting in irreversible visual field loss. The primary concern in patients with glaucoma is that either the detection of the condition is significantly delayed or remains undetected. Since IOP is probably the only known risk factor for glaucoma, the treatments for glaucoma are centered on the reduction of IOP, which secondarily prevents the



Production and outflow of aqueous humor in a normal eye[2]

[2] Adam K Rudkin, Jwu J Khong and Theresa M Casey. "Recognizing congenital glaucoma." 2009. Medical Journal of Australia, 191(8): 466-467



(Source: holbert.com/eye-diseases/)

progression of visual field loss. The treatment methods are comprised of medications, laser therapies and invasive surgical treatments that aim to arrest the disease progression and prevent blindness. The drugs that are currently available attempt to decrease the IOP by reducing aqueous humor production or by facilitating its outflow. Lasers such as argon, YAG, or diode laser when applied to the trabecular meshwork reduces the resistance to outflow for aqueous humor and can be repeated only a few times. Another method to reduce the production of aqueous humor is to destroy the ciliary processes using laser energy as in cyclophotocoagulation. Trabeculotomy and trabeculectomy are invasive surgical procedures where a surgical passageway is created to facilitate the outflow of aqueous humor. In sclerectomy and calanoplasty layers of scleral tissue are removed surgically to expand the Schlemm's canal and increase aqueous outflow. Aqueous drainage devices use stents that are inserted into the eye and sewn to allow the fluid to bypass the trabecular meshwork and provide an alternate routing for the fluid to drain the system.

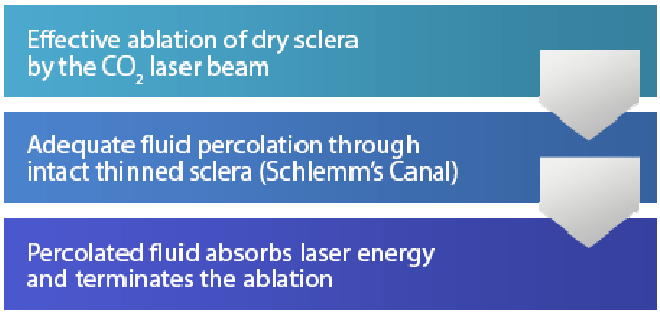
When patients remain unresponsive to topical therapy, surgical treatment is often preferred. A trabeculectomy, known to be a very invasive procedure (the current gold standard), or a drainage device is required for people whose condition is progressing towards optic neuropathy or visual field damage. The mainstays in the surgical treatment of glaucoma have been tube shunts and trabeculectomies, both of which have been associated with severe infections, wound leaks, and the risk of hypotony. Trabeculectomy is still the most commonly performed incisional glaucoma procedure worldwide but due to post-operative complications its use is declining in favor of aqueous shunts and other newer glaucoma surgical procedures.

Minimally invasive surgical options, such as the CLASS procedure, offer the option to intervene earlier in the disease process, which reduces disease progression as well as the need for more aggressive and invasive surgical treatments. The CLASS procedure, rather than creating a thermal burn, enhances fluid outflow without thermal destruction of the

targeted cells. This implies that the procedure is repeatable. The CLASS technique is convenient because the micro dissection is performed under direct microscopic observation and the safety profile is high as the anterior chamber of the eye is not penetrated. The CO2 laser has certain qualities that confer significant advantages when it is used specifically to facilitate deep sclerectomy filtration surgeries. These include photo ablation of dry tissues and almost complete absorption of the laser energy by even minute amounts of water.

IOPtiMate™ Technology: IOPtima has developed and now commercializes the IOPtiMate™ system offers a unique surgical solution called CLASS (CO_2 Laser Assisted Sclerectomy Surgery) for the long-term sustainable treatment of glaucoma.

CLASS using the IOPtiMate™ utilizes CO_2 laser technology to reduce internal eye pressure by allowing better flow of aqueous humor (the fluid inside the anterior chamber of the eye). In utilizing the particular properties of the CO_2 laser, the procedure thins the sclera wall via ablating soft tissues at the normal eye drainage area (Schlemm's Canal region), in a simple and highly controlled and specific process. The technology is highly effective in ablating dry tissue and allows the surgeon to thin the sclera by gradually removing most of the scleral tissue, leaving a thin intact layer which transforms the safety of the procedure to a higher level. The remaining layer is thin enough to allow the internal eye fluid to percolate through, thus relieving the eye of the inner excessive pressure. Because infrared CO_2 laser radiation is absorbed and blocked by nature by aqueous solutions, the laser energy does not penetrate into the eye. Therefore the remaining thin scleral layer remains intact, reducing the likelihood of surgery complications, adverse events and side effects.



The IOPtiMate™ CLASS principle of operation (Source: ioptima.co.il/technology/class-procedure/)

The IOPtiMate™ procedure reduces the elevated IOP by thinning the sclera of the eye, thus improving drainage without penetrating the eyeball. Keeping the eyeball intact significantly reduces the risk of intra-operative and post-operative complications and the follow up interventions and manipulations commonly associated with penetrating surgical alternatives. Furthermore, unlike many surgical options, CLASS does not involve leaving a foreign body in the eye.

The novel IOPtiMate™ procedure is designed to provide the clinicians a relatively simple technique with a short learning curve as incisional surgeries are often followed by complications. A clinical evaluation of the technology twelve months post-operatively showed a 45% average decrease in IOP from baseline[3] and substantial reduction in medication use. The most frequent intraoperative complication that occurs with other surgical methodologies is the perforation of the trabecular membrane that is substantially reduced while using the the IOPtiMate™ procedure. One pilot study of the IOPtiMate™ procedure on 37 patients reported complete success attaining 77% at 6 months and 60% at 12 months with no major ensuing complications[4,5]. A prospective study conducted on 111 patients, yielded a reduction in IOP of 20 percent or greater, maintaining an IOP less than or equal to 18 mmHg, in 87.5% of the patients at three years post-surgical follow-up. Of those 59.4% of patients were able to maintain the IOP goals without use of

[3] Skaat, Alon, Modi Goldenfeld, Daniel Cotlear, and Shlomo Melamed. "CO2 Laser-assisted Deep Sclerectomy in Glaucoma Patients." 2014. Journal of glaucoma 23(3): 179-184.
[4] Ton, Yokrat, Noa Geffen, Dvora Kidron, Joshua Degani, and Ehud I. Assia. "CO2 laser-assisted sclerectomy surgery part I: concept and experimental models." Journal of glaucoma 21, no. 2 (2012): 135-140.
[5] Geffen, Noa, Yokrat Ton, Joshua Degani, and Ehud I. Assia. "CO2 laser-assisted sclerectomy surgery, part II: multicenter clinical preliminary study." Journal of glaucoma 21, no. 3 (2012): 193-198.

any medication. In eight patients the IOP was reduced by about 50% when they were evaluated at the five year post-surgical follow-up[6].



The IOPtiMate™ System (Source: ioptima.co.il/technology/the-ioptimate-system/)

Strategic opportunity: Glaucoma has a high rate of prevalence globally and is the second leading cause of blindness around the world. Although known to be the largest markets for ophthalmology drugs and devices, developed markets such as North America and Europe have shown little growth due to the recent economic slowdown and market saturation. Developing countries in Asia, such as China and India are expected to drive the growth of ophthalmology devices and drugs primarily due to growing awareness of eye diseases in these markets. According to a new market report published by Transparency Market Research "Ophthalmology Diagnostics and Surgical Devices Market", the global ophthalmology devices market was valued at $26 billion in 2012 and estimated to reach a market size of $40 billion in 2019 growing at a CAGR of 6.6% from 2013 to 2019. The ophthalmic surgery devices market is expected to exhibit significant growth potential majorly owing to continuous evolution of minimally invasive surgical techniques. In addition, there has been a consistent rise in patient population being diagnosed for several ocular disorders such as glaucoma. Transparency Market Research also forecasts that Asia-Pacific region is expected to grow at a robust CAGR of 8.9 % from 2013 to 2019. Factors such as increased efforts of respective nation's governments to improve healthcare infrastructure, growing disposable incomes of middle class population, increased investments by key market players in the emerging economies and high growth potential prove favorable for growth in this region.

[6] http://ioptima.co.il/wp-content/uploads/2014/04/CLASS-y-Laser-Treats-Glaucoma-Asia.pdf

Competitors: Trabeculectomy has been a gold standard in glaucoma management, however, the surgery is associated with a high rate of serious complications such as hypotony, flat anterior chamber and endophthalmitis. These complications arise as the surgery is invasive and involves penetration of the anterior chamber. To avoid the postoperative complications of trabeculectomy, non□penetrating deep sclerectomy (NPDS) procedure was used for the surgical treatment of glaucoma. NPDS is a non□perforating filtration procedure. The IOPtiMate™ procedure is a modification of NPDS. Although studies have reported lower risk of complication following the NPDS procedure, it requires trained hands and a long learning curve needed by physicians. As a result, NPDS has not been widely adopted[7].

ExPress™mini glaucoma shunt is implanted under the scleral flap to shunt the aqueous humor from the anterior chamber to a subconjunctival reservoir in a similar fashion as trabeculectomy, without removal of any sclera or iris tissue. The IOPtiMate™ procedure provides a convenient alternative to these issues (as described in prior paragraphs) and therefore offers a competitive advantage.

Other procedures and devices with competing technologies for the surgical treatment of glaucoma that have FDA clearance or are currently in phase III clinical trials in the United States are: the Fugo blade (Medisurg Ltd., PA), Ex-PRESS mini glaucoma shunt (Alcon, Inc., Switzerland), SOLX Gold Shunt (SOLX Ltd., MA), Excimer laser trabeculotomy (AIDA, Glautec AG, Germany), canaloplasty (iScience Interventional Corp., CA), trabeculotomy by internal approach (Trabectome, NeoMedix, Inc., CA), and trabecular micro-bypass stent (iStent, Glaukos Corporation, CA). The Solx Gold Shunt (Solx Inc., Waltham, MA) is currently undergoing FDA clinical trials. This implant, made of 99.95% pure gold, is biocompatible and uses the eye's natural pressure differential between the anterior chamber and the suprachoroidal space to reduce IOP. Glaukos iStent, which was approved by the FDA in June 2012, is a titanium tube which bypasses the trabaecular meshwork and provides a direct connection between the anterior chamber and Schlemm's canal. The device promises to provide a long-term solution for patients with ocular hypertension. As per Ellex's research, Glaukos enjoys a market share of 12%, and Ellex has about 11% market share in the glaucoma surgical devices market[8]

IOPtiMate™ *system Rollout:* The IOPtiMate™ is ISO 13485: 2003 certified[9] and the product is approved for sale by the regulatory bodies in Europe (CE Mark), Israel (AMAR), Mexico (Cofepris) and China (CFDA). IOPtima is in the preliminary stages of marketing its technology and has established distribution partnerships in leading markets to sell the IOPtiMate™ to both governmental and private hospitals that perform eye surgeries. As part of the agreement, the distributor in China has committed to purchase a minimum of 100 systems during the initial four year term. As per the agreement, the distributor is responsible for on-site installation, training and support as well as local marketing, advertising and sales activities of the system in China. The revenue model offered is either using a one-time capital payment for the equipment or pay per-procedure fees wherein the use of the equipment is monitored by BioLight. Currently, the IOPtimMate™ has been installed in many medical centers around the world to promote its utilization among ophthalmologists as well as inclusion in government reimbursement.

A medical center in Hong Kong purchased the IOPtiMate™ system following a successful trial with it. Installation of additional systems at other medical centers in Hong Kong and China are currently underway to determine the efficacy and tolerability of the CLASS procedure post-operatively. The medical centers in Hong Kong are at the forefront of technological adoption and are considered to be held in high regard by the Chinese hospitals. We view the adoption of IOPtiMate™ in Hong Kong as an encouraging sign for BioLight and one which we think will serve as a catalyst to further their foothold in the broader Chinese glaucoma community.

A recent NBER study (NBER Working Paper 14865) by Jonathan Skinner and Douglas Staiger examined the diffusion of technology in healthcare. The study found higher adoption rates at U.S. hospitals with large patient volume located in high income areas. They also found that research focused hospitals were quicker to adopt new technologies. We think that this may also translate to the Chinese market and expect hospitals in the urbanized areas to adopt the technology first. China's healthcare spend is expected to grow at a CAGR 13.8% annually and reach close to $890

[7] Skaat, Alon, Modi Goldenfeld, Daniel Cotlear, and Shlomo Melamed. "CO2 Laser-assisted Deep Sclerectomy in Glaucoma Patients." 2014. Journal of glaucoma 23(3): 179-184.
[8] www.ellex.com/files/2014/03/InvestorPresentationHY14.pdf, Slice 12
[9] ISO is an International Organization for Standardization that specifies requirements for a firm that develops and manufactures medical devices. More information regarding ISO can be found at http://www.iso.org/iso/catalogue_detail?csnumber=36786

billion by 2017 according a recent report by Deloitte[10]. Further, the report states that the Chinese government is likely to adopt a tiered approach to meet the healthcare needs of the different regions. For large, urbanized cities the government's focus will be to close the gap with more developed countries. As such, these factors lead us to believe that the IOPtima system is entering the Chinese market at an opportunistic time when demands for such products are on the rise.

Eye-D®

Technology: ViSci has in-licensed ocular insert technology (Eye-D®) from Novear LLC (an Aerie Pharmaceuticals. Affiliate) The Eye-D® is a sub-conjunctival insert for the controlled release of ophthalmic medications such as latanoprost. Latanoprost is known to be a specific prostaglandin analogue to the receptor (FP) found in the eyes and was developed to reduce IOP. FP receptor and latanoprost increase the outflow of aqueous humor through the ciliary muscle, suprachoroidal space, and the sclera instead of exiting the eye through the trabecular meshwork and the canal of Schlemm.

Competitors: Durasert (pSividia Corp.) is an implant device that is undergoing clinical trials in the U.S. The bio erodible implant is inserted under the scleral conjunctiva and is designed to provide long-term sustained release of the glaucoma medicine latanoprost, reducing or eliminating the need for daily medicated eye drops to treat glaucoma. It has been a rocky road for pSividia as its biodegradable implant device failed to prove safety and treatment benefits in previous FDA approval submissions. Allergan's data from Phase 2 clinical trials with bimatoprost suggests that the sustained-release implant efficacy is comparable to daily topical bimatoprost with duration of 4-6 months.

Strategic Opportunity: Despite a number of pharmacological options available to treat glaucoma, failure of medical treatment is a significant issue owing not only to drug ineffectiveness and intolerance, but also to poor patient compliance and persistence. Furthermore, many patients, particularly the elderly, either miss a topical administration of the dose or are unable to correctly administer drops.

In addition to having successful pre-clinical results thus far from the Eye-D insert, BioLight has adopted a least risky approach to developing a novel drug delivery product that employs an already approved latanoprost. This provides Eye-D® with a potentially significant competitive advantage over existing treatment options.

Commencement of Phase 1/2a clinical study and most recent patent protection: The U.S. Patent and Trademark Office has recently approved the patent application of the technology used in Eye-D®, the company's controlled-release latanoprost insert. The patent expires in May 2031. The patent for the proprietary formulation of latanoprost expires in April 2030. ViSci filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) during Q1 2014, and in June 2014, commenced a Phase I/IIa clinical trial in the U.S. for the treatment of glaucoma. This clinical trial is expected to be completed in H1 2016.

Depending on the results from the clinical study, the device may be replaceable every 3 or 6 months. Existing glaucoma patients who currently use topical drops could benefit tremendously from the Eye-D® technology as the drug need not be administered daily and there is potential long-term cost savings that justify a higher initial cost of the sustained-release drug-delivery device. Due to the ease of use and lower dose medication, this technology can be leveraged to other medications that require sustained/controlled release, as well as a platform for other indications such as back of the eye diseases.

Indication: Dry eye syndrome

Tears lubricate the eyes and wash away foreign particles. A tear film on the eye is necessary for a healthy ocular surface. Oil, water, and mucus form three layers in a tear fluid that protect and nourish the front surface of the eye. The oil layer helps to prevent the ocular surface from dehydration and the mucin layer spreads the tears evenly over the surface of the eye. When the tears evaporate too quickly or do not spread evenly over the corneal surface due to deficiencies with any of the three tear layers, dry eye symptoms can develop. The most common condition of DES is when the eye is unable to maintain a healthy coating of water. Keratoconjunctivitis sicca (KCS) is a disorder that occurs due to multiple physiological factors such as inflammation of the ocular surface and lacrimal gland, neurotrophic deficiency and meibomian gland dysfunction. Patients with dry eyes are prone to potentially blinding infections, such as bacterial keratitis and also at an increased risk of complications following common procedures such as laser refractive

[10] 2014 Global Healthcare Outlook: Shared challenges, Shared Opportunities, Deloitte.

surgery. It is of prime importance to diagnose the condition early so that the therapy can be customized and monitored for the efficacy of the treatment.

TeaRx

Technology: DiagnosTear is developing the TeaRx, which is a multi-parameter semi-quantitative diagnostic kit that tests the composition of tear fluid to help in the diagnosis of DES, as well as to monitor the progression of the condition and the effectiveness of its treatment. The TeaRx offers a novel low-cost solution to the dry eye diagnostics space and has different reagents on the test strip. The reagent on the test strip changes color based on the tear fluid composition. This procedure is simple, inexpensive, and highly sensitive that can reliably aid in the diagnosis of dry eye and lead to more specific treatments for dry eye disease that could target the source of the DES. A clinical trial at four medical centers (including in the US) was commenced to validate the effectiveness of the test methods developed in the tears of healthy subjects as well as patients with DES. In February 2015, the company reported clinical study findings that identified positive statistical correlations between the TeaRx test's diagnostic parameters and widely used benchmark tests for dry eye syndrome (DES). BioLight has initiated a second clinical trial in order to assess the effectiveness of the tests in tears of healthy subjects as well as patients with severe DES. The results from this second trial are expected in Q2 2015. The process of defining the reliable combination of parameters that are required for the DES diagnostic kit is underway.

In February 2015, the company reported clinical study findings that identified positive statistical correlations between the TeaRx multi-parameter diagnostic test and widely used benchmark tests for dry eye syndrome (DES). The process of defining the reliable combination of parameters that are required for the DES diagnostic kit is underway. In mid-June 2015, BioLight announced their collaboration with Ora Inc., a world-leading independent, full-service ophthalmic contract research organization (CRO) and product development firm, to aid in the commercial development of TeaRx. The two companies have agreed to fund the clinical study and other activities required to obtain U.S. 510K regulatory approval for TeaRx as well as to incorporate the test kit in other clinical trials sponsored by third parties and performed by Ora.

Competitors: Thus far the existing tests for DES have been unsatisfactory for the clinicians as well as patients. The Schirmer test is a quantitative indicator for tears but since the reason for dry eye syndrome is both the quantity and quality of the tears, it offers only less than 50 percent sensitivity. The method that measures the time taken for tear-film breakup is highly sensitive but lacks specificity. The corneal staining procedure is primarily helpful in the advanced stage of the disease. Although validated questionnaires demonstrate about 80% sensitivity and 72% specificity, they have not been effective in matching patient symptoms with the underlying cause. Specific diagnosis is essential in directing patients towards targeted treatments and monitoring it.

Today there are two main commercialized devices for diagnosing DES in the physician office. The most popular one is the TearLab device that measures osmolarity of the tear fluid. The second device is the InflammaDry, developed by Rapid Pathogen Screening (RPS), which is a test that detects levels of matrix metalloprotease 9 (MMP-9), a reliable marker for the presence of inflammation, in the tear fluid sample.

Although the Schirmer test is one of the most widely used tools in diagnosing dry eye, the lengthy nature of the test, the fact that most patients find the test irritating and invasive, and its unreliablility and largely irreproducible nature may explain a high risk of under diagnosis. Although osmolarity testing is a diagnostic for dry eye, the TearLab device identifies that the patient has dry eyes with an indication of its severity. TearLab has a dedicated CPT code so the test is reimbursable by Medicare (at $24 per eye) with no patient co-insurance or deductible. On the downside, the instrument costs about $9,500 (including 80 test cards) and requires the lab to be CLIA certified.

Strategic opportunity: DES is prevalent among wide spectrums of the population. About 25 million people in the U.S. and 100 million worldwide suffer from this condition with different levels of severity and many more suffer from the same symptoms. The condition worsens with age, dryness in the environment (wind, air condition), long exposure to the sun, smoking or second-hand smoke exposure, as well as cold or allergy medications. According to analysts at Research and Markets, the global ophthalmic diagnostic devices market is expected to grow at a CAGR of 4.75% over the period 2013 - 2018.

The process of diagnosing this syndrome is complex and based on a number of different parameters. The objective tests for DES either examine the tears' quantity, quality, or functional properties and those that investigate the integrity of the ocular surface. The measurement of tear film composition seems to provide a powerful tool in the diagnosis of DES and has the potential to be accepted as a gold standard for the disease. An essential element in the assessment and treatment of dry eye is the clinical judgment of which parameters contribute to the dry eye syndrome. Other current

methodologies, as described above, are not sufficiently predictive of parameters to facilitate effective disease diagnosis and prognosis. We believe this makes TeaRx a superior technology when compared with other products in the market which should provide it with a competitive advantage when introduced. TeaRx technology is in the form of a disposable test panel which will be significantly cheaper than the table-top devices currently in use, but could potentially benefit from the reimbursement by Medicare as the others (such as TearLab) per test although manufacturing costs will be negligent.

Oph-Rx – In-licensed drug delivery platform

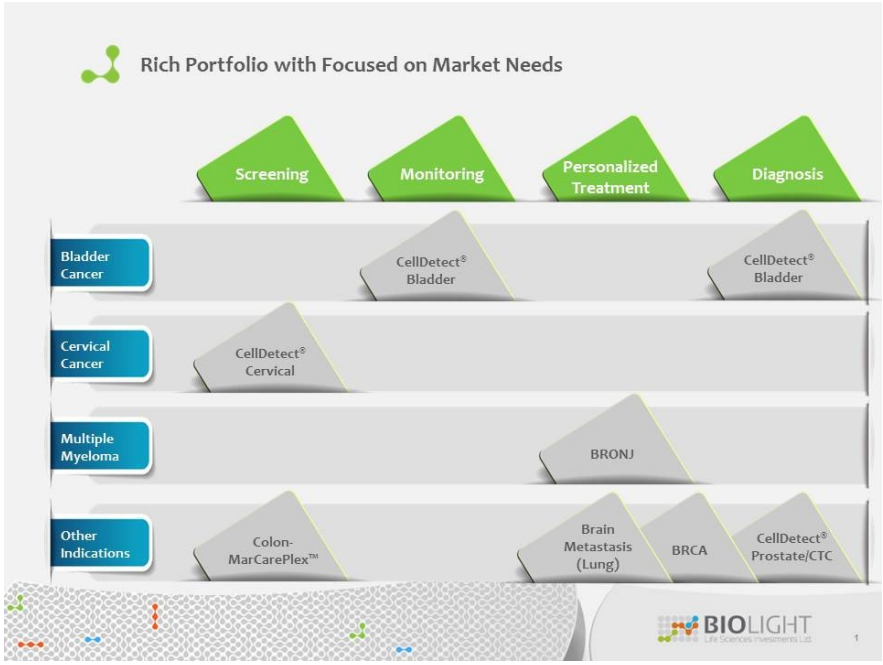
To overcome the challenge of drug delivery by conventional treatments in ocular diseases, BioLight is developing two products that improve the bioavailability within the ocular surface. One of them is the EyeD technology, an ocular insert for sustained drug delivery of latanoprost. The other drug delivery technology is based on the principle of molecular transport across cell membranes using liquid crystals. The technology has been in use in other applications. BioLight conducted preliminary tests to extend the technology's application for ophthalmic purposes. BioLight has expanded their ophthalmological product portfolio by investing in the company that has in-licensed this novel drug delivery platform from Hebrew University, Israel. BioLight will co-manage and hold 40% stake in the new company.

BioLight is currently working on developing a novel formulation for the molecule that is most effective to deliver the correct dose, follows a predictive route, and releases the drug, either in a controlled or sustained pattern, according to the pathophysiology and course of the targeted ophthalmic disease.

CANCER DIAGNOSTICS FIELD

Micromedic
Life Saving Cancer Diagnostics

Micromedic manages a variety of technologies across the cancer diagnostic value chain. From screening and risk identification, through diagnostics, personalized medicine, and monitoring disease recurrence, Micromedic identifies projects that fill unmet needs in various cancer related indications and turns them into viable and marketable products.



Micromedic's Portfolio (Source: http://www.m-medic.com/215646/About-Us)

Zetiq, a wholly-owned subsidiary of Micromedic, develops cancer diagnostic tools. Its proprietary, the CellDetect® technology, employs a platform of novel histochemical staining kit for clearer identification of abnormal cancer cells. Micromedic also owns a 90% stake in Bio-Gene, a subsidiary that is developing a functional gene expression profiling assay to identify carriers of cancer susceptibility gene mutations who are at an increased risk of developing breast and/or ovarian cancer. Micromedic is working on developing new genetic markers to predict necrosis of the jawbone in multiple myeloma patients who are treated with bisphosphonate drugs. BioMarCare, a 33% controlling ownership of Micromedic, is committed to developing Colon MarCare Plex™, a molecular (RNA) biomarker panel for the detection of both cancer and pre-cancerous polyps in blood and is in the process of forming strategic partnerships for continued product development.

Micromedic's pipeline consists of the following candidates in the development/clinical stage and one that has been commercialized:

- Completed development of the cervical cancer diagnostic kit and has commenced the product's soft launch in China and in process to commercialize it in India.
- Expects to complete the development of its bladder cancer monitoring recurrence kit in 2015.
- Developing a test to detect individuals who are at a higher risk of developing Bisphosphonate Related Osteonecrosis of the Jaw (BRONJ), a side effect in patients treated with bisphosphonates.
- Micromedic is also engaged in the development of genetic test to detect lung cancer patients who are at a high risk of developing brain metastases.

CellDetect®

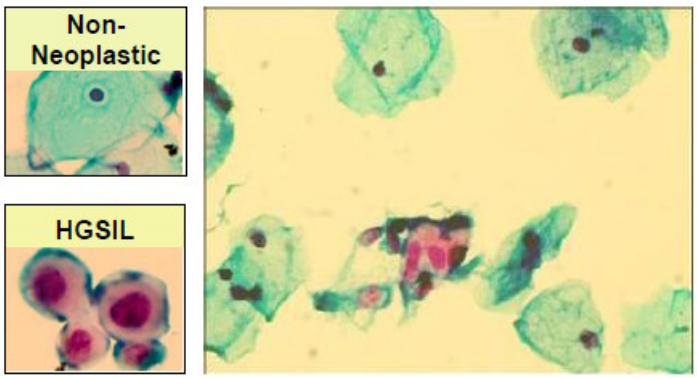
Technology: Cancer and pre-cancer cells are characterized by atypical morphology including enlarged nuclei, increased nuclear-to-cytoplasm ratio, hyperchromasia, and irregularity of nuclear membrane, which can be screened using the standard microscopic diagnostic criteria. Cytological preparations are conventionally visualized by either Papanicolau or hematoxylin and eosin stains for the differentiation of neoplasia from non-neoplastic states. Since such cells are colorless they need to be stained in order to differentiate and identify their various types from normal cells. . The CellDetect® technology is a novel cell staining method based on a proprietary plant extract that enables color discrimination between benign and malignant cells, while preserving critical features of cell morphology. This staining technology has been shown to consistently differentiate cancer from normal and reactive states in histological and cytological preparations. The discriminative capacity of the stain is related to specific metabolic alterations and increased metabolic activity observed in neoplastic cells.

The CellDetect® technology appears to be superior and more effective for early diagnosis and in some cases such as bladder cancer, also in follow up monitoring recurrence. As per the Zetiq's trials, the technology was found to simplify the process of identifying suspected cancer or pre-cancer cells and to enhance detection accuracy by reducing erroneous detection resulting from both false negatives and positives[11]. Moreover, it has a potential to be fully automated. CellDetect® staining technique provides a dual tinctorial discrimination and morphological analysis that affords superior sensitivity compared with Pap staining as well as higher specificity than HPV testing in cervical cell smears[12]. Clinical studies showed that the sensitivity and specificity of the CellDetect® staining technique for cervical cancer are 95% and 87%, respectively[13].

[11] Idelevich, Pavel, Don Kristt, Elimelech Okon, Dov Terkieltaub, Ilia Rivkin, Ami Fishman, Sylvia Lew, Eduardo Schejter, and Adi Elkeles. "Novel histochemical stain for tinctorial detection of cancer and neoplastic cells." Journal of Histotechnology 32, no. 3 (2009): 97-105.

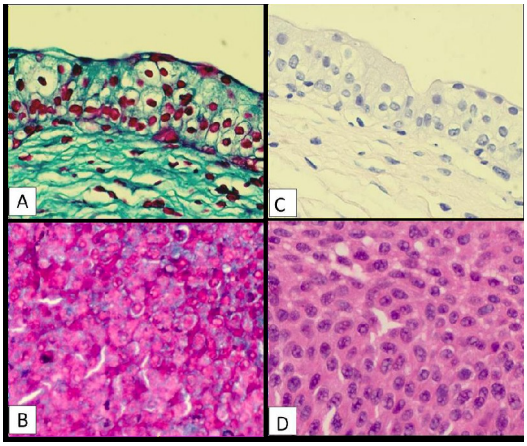
[12] Idelevich, Pavel, Don Kristt, Eduardo Schechter, Sylvia Lew, Adi Elkeles, Dov Terkieltaub, Ilia Rivkin, Ilan Bruchim, and Ami Fishman. "Screening for cervical neoplasia: A community□based trial comparing Pap staining, human papilloma virus testing, and the new bi□functional celldetect® stain." Diagnostic cytopathology 40, no. 12 (2012): 1054-1061.

[13] Song He, Gui-lan Wang, Yuan-yuan Zhu, Mei-hua Wu, Zhi-guo Ji, Juan Seng, Yi Ji, Jia-ming Zhou, Li Chen, "Application of the CellDetect® staining technique in diagnosis of human cervical cancer", Gynecologic Oncology Volume 132, Issue 2 , Pages 383-388, February 2014



CellDetect® technology used to differentiate normal cells from cancer cells[14]

The CellDetect® bladder kit aims to identify bladder cancer cells from urine cytology samples[15].An open label, proof of concept study has demonstrated 94% sensitivity and 89% specificity. Currently, a large scale, multi-center, blinded study is being conducted. The interim results from the bladder cancer clinical trial using CellDetect® technology are very encouraging - using 65 urine samples from advanced-stage as well as early-stage cancer patients, of which 25 samples were from bladder cancer patients and 40 samples from healthy individuals with a history of bladder cancer, the CellDetect® technology yielded 88% sensitivity and 68% specificity.

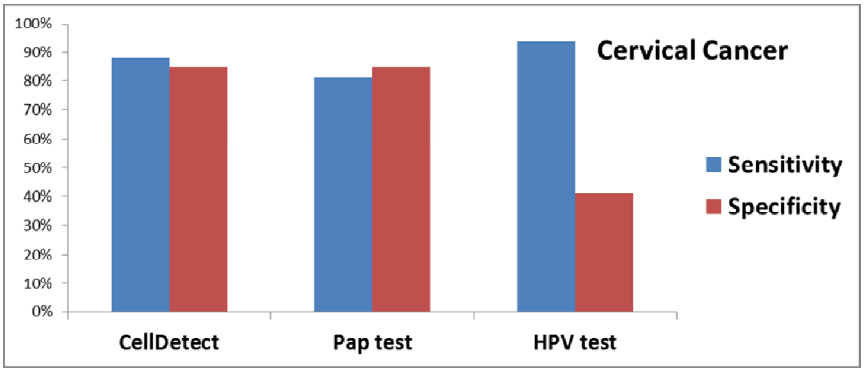


Panels A & B are images of histological sections stained with CellDetect® and panels C & D are images of histological sections stained with H&E. The cells comprising the normal transitional epithelium (Panels A & C) had a greenish-blue cytoplasm, whereas morphologically recognizable neoplastic cells exhibited red/magenta tinged cytoplasm (Panels B & D)[16].

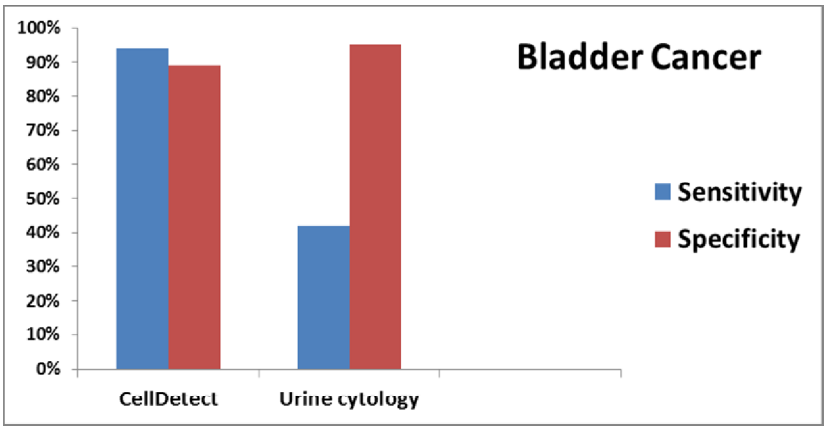
[14] www.zetiq.co.il/image/users/161586/ftp/my_files/Presentations/Zetiq-short-company-presentation-Q4-2010.pdf?id=7129691

[15] Noa Davis, Yoram Mor, Pavel Idelevich, Dov Terkieltaub, Vivi Ziv, Adi Elkeles, Sylvia Lew, Elimelech Okon, Menachem Laufer,Jacob Ramon, Daniel Kedar, Jack Baniel, Ofer Yossepowitch. "A novel urine cytology test for the detection and monitoring of urothelial carcinoma". In press.

[16] Noa Davis, Yoram Mor, Pavel Idelevich, Dov Terkieltaub, Vivi Ziv, Adi Elkeles, Sylvia Lew, Elimelech Okon, Menachem Laufer,Jacob Ramon, Daniel Kedar, Jack Baniel, Ofer Yossepowitch. "A novel urine cytology test for the detection and monitoring of urothelial carcinoma". In press.



(Source: www.zetiq.co.il/)



(Source: www.m-medic.com/image/users/215646/ftp/my_files/Zetiq%20Bladder%20histology%20and%20cytology%20article-%20final%20with%20figures.pdf?id=17286869)

Strategic opportunity

Indication: Cervical Cancer

About 80% to 90% of cervical cancers are squamous cell cervical cancer. The primary goal of cervical cancer screening test is to prevent morbidity and mortality resulting from cervical cancer. The ideal screening methodology would have the ability to identify the cancerous precursor cells that are likely to become invasive cancers and avoid the occurrence of false positives that can effectively reduce unnecessary treatment procedures. Cytology screening (Pap test) has been very successful in screening for cancer and reducing its incidence and mortality in developed countries where good-quality screening is available. In developing countries several factors such as the socio-economic conditions, ineffective screening methodologies, medically underserved regions, and racial disparities contribute to the prevalence of cervical cancer.

Cervical Cancer Market: Cervical cancer is one of the major reasons for mortality in women. A strong association exists between the human papillomavirus (HPV) infection and cervical dysplasia and cancer. Although HPV plays an important etiological role in cervical carcinogenesis, most people eventually clear the virus without further development of carcinogenesis.

In the U.S. alone, the annual direct medical cost of preventing and treating cervical cancer was estimated to be $8.0 billion in 2010. Of this total cost, about $6.6 billion (82.3%) was for routine cervical cancer screening and follow-up[17]. In contrast, in developing countries it is the second most common type of cancer and a leading cause of death among

[17] Harrell W. Chesson, Donatus U. Ekwueme, Mona Saraiya, Meg Watson, Douglas R. Lowy, Lauri E. Markowitz. Estimates of the annual direct medical costs of the prevention and treatment of disease associated with human papillomavirus in the United States, Vaccine. 2012 September 14; 30(42): 6016–6019.

women[18]. As per Transparency Market Research, the U.S. makes up 31% of the global cervical cancer diagnostic tests market. Among the BRIC countries, India and China together belong to a lucrative segment of this market. Rapidly developing economies with large growing populations and high disposable incomes also warrant for high healthcare-related expenditures.

CellDetect® Cervical Kit Rollout: A European CE mark (Adjunct) and CFDA in China for the CellDetect® Cervical Kit were obtained. The company has collaborated with Biomics Biotechnology from Jiangsu Province, China, to introduce the CellDetect® Cervical Kit to China. Micromedic received an order for the purchase of cervical cancer detection kits comprising kit materials for 100,000 tests from Biomics, of which many of these tests have already been supplied. Earlier this year, the company received an endorsement letter from a leading hospital in Beijing, China, after a successful pilot study using the CellDetect® Cervical Kit that will further support the marketing and sales efforts within China.

Indication: Bladder Cancer

Precancerous cells are often present in the inner lining wall of the bladder (urothelial carcinoma). Although this type of cancer can be detected early, the recurrence rate is high (50-80%). Bladder cancer is more prevalent in people aged 55 and older and more so in men than women. Besides age and gender, smoking, hazardous workplace exposures, race and ethnicity (Caucasians are at a higher risk for reasons not clearly understood), as well as genetics may play a significant role in contributing to the likelihood of developing pathogenesis of bladder cancer. Genetic changes related to bladder cancer are known to occur during a person's life rather than being acquired congenitally.

The company reported successful results from their blinded, multi-center clinical study using the CellDetect technology for detecting bladder cancer. The primary endpoint of effectively detecting the recurrence of bladder cancer in subjects with a history of the disease was achieved. The need to detect bladder cancer noninvasively is large and the CellDetect technology has shown 84.4% sensitivity and specificity of 82.7% in detection of cancerous cells in clinical studies. The sensitivity performance of three other noninvasive tests to detect the recurrence of bladder cancer currently in the market are urine cytology test (50%), BTA stat (68.8%) and NMP22 BladderCheck (17.4%).

Today, BioLight announced that the European Patent Office has issued a patent for the CellDetect technology that will be in effect until March 2027. The company also announced that the CellDetect non-invasive test for detecting bladder cancer in urine has obtained CE Mark thus enabling commercialization in the European Union. Obtaining the CE Mark for the CellDetect technology to detect the recurrence of bladder cancer represents a significant milestone and achievement for BioLight.

The company is now focused on building awareness of the product to facilitate broader roll-out in Europe using distribution agreements in CE Mark territories. The company may use the CE Mark as a stepping-stone to submit a Pre-IDE application for CellDetect to the U.S. FDA sometime during the first half of 2016.

Bladder Cancer Market

$4 billion is spent annually for bladder cancer treatment in the U.S.[19]. There are 386,000 new bladder cancer cases worldwide each year of which 20% occur in the U.S. alone. Bladder cancer is the most expensive cancer to treat, costing between $100,000 and $200,000 per patient and, as noted, has a recurrence rate of up to 80%. Standard treatment has remained relatively unchanged with no new drugs approved since 1998.

Indication: Colorectal Cancer (CRC)

Abnormal growth of cells in the inner lining of the colon or rectum can develop into cancer. Adenocarcinomas are the most commonly occurring CRCs that affect the normal functioning of the glands that form mucus to lubricate the inner wall of the colon. Age, genetic predisposition and lifestyle related factors (such as obesity and diet) have been linked to increased risk of developing the disease.

[18] M. Arbyn1,2,3,*, X. Castellsagué3,4,5, S. de Sanjosé3,4,5, L. Bruni3,4,5, M. Saraiya6, F. Bray7 and J. Ferlay7. Worldwide burden of cervical cancer in 2008. Annals of Oncology (2011)

[19] progressreport.cancer.gov/doc_detail.asp?pid=1&did=2009&chid=95&coid=926&mid=

Epidermal growth factor (EGF) plays an important role in the regulation of cell growth, proliferation and differentiation. It binds with high affinity to epidermal growth factor receptor (EGFR) on the cell surface and stimulates the intrinsic protein tyrosine kinase activity of the receptor. EGFRs play an important role in the initiation and progression of CRC. The receptor tyrosine kinase (RTK) is a high-affinity cell surface receptor. KRAS, a small intracellular Guanosine triphosphatase (GTPase), is a central intermediary of the EGFR and other TKR pathways. KRAS is an effector molecule responsible for signal transduction from ligand-bound EGFR to the nucleus. The tyrosine kinase activity in-turn initiates a signal transduction cascade that results in a variety of biochemical changes within the cell such as a rise in intracellular calcium levels, increased glycolysis, and protein synthesis. In addition it increases the expression of certain genes including the gene for EGFR that ultimately leads to DNA synthesis and cell proliferation.

***Colon* MarCarePlex™**

Technology: MarCarePlex is a blood test utilizing a panel of biomarkers for early diagnosis of CRC. The test aims to replace less specific tests such as colonoscopy by offering a simple, non-invasive, test that will increase compliance towards CRC identifying screening tests.

Strategic opportunity: BioMarCare is currently seeking a strategic alliance for clinical studies, development and commercialization of the diagnostic kit. The company has filed a patent application on this technology with the U.S. Patent and Trademark Office as of 10 April, 2014.

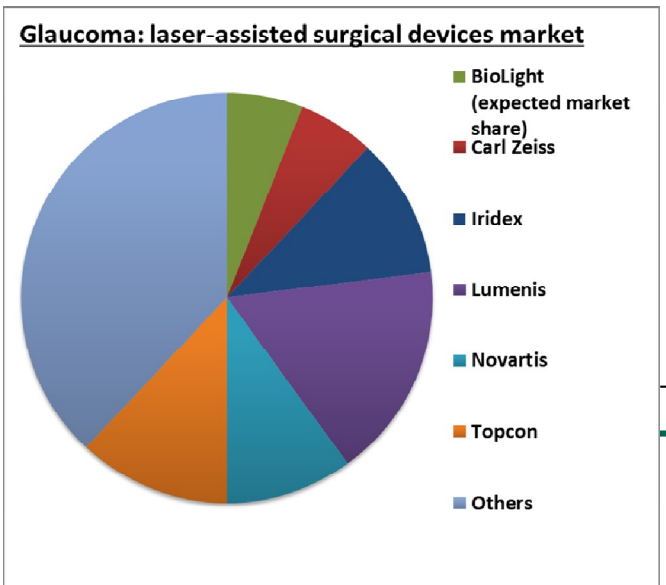
BRONJ:

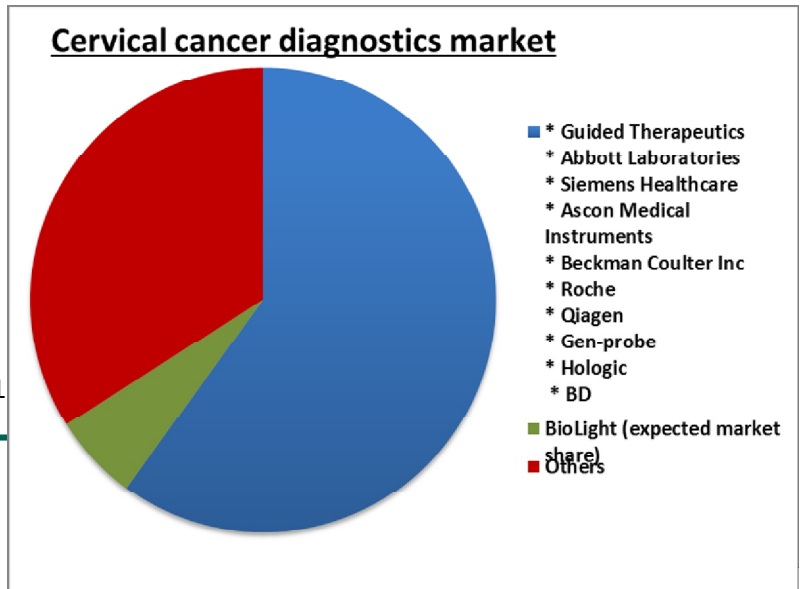
Technology: Biophosphonates Related Osteonecrosis of the Jaw (BRONJ) is a condition that has been primarily related to the treatment with bisphosphonates which belong to the category of bone antiresorptive agents, in patients affected by cancer bone disease[20]. From more recent studies, data supports the theory that BRONJ has a higher rate of incidence in osteoporosis patients as well as in oncological patients who are treated with nitrogen containing biophosphonates. Micromedic had designed a clinical study at the Tel Hashomer Medical Center in Israel to identify the unique genetic profile that enables the assessment of risk among cancer patients. From the study, they identified several new genetic markers with high potential to predict necrosis of the jawbone in multiple myeloma patients treated with bisphosphonate drugs. The company has filed patents for the newly discovered markers. Currently, Micromedic is engaged in the development and commercialization of a novel diagnostic kit for the identification of a genetic profile which may increase the risk of developing BRONJ.

Strategic opportunity: Besides the known risk factors, previously published results from pharmacogenetic studies have indicated that genetic factors might be the central cause in BRONJ disposition. Currently, no biomarkers exist to identify patients at risk of developing BRONJ. As per management's estimates, there are about 100,000 patients with multiple myeloma, 300,000 patients with breast cancer, 60,000 patients with prostate cancer and 200 million patients with osteoporosis. Of these, BRONJ prevalence is 1%-18% among these different diseases.

NOFAR Project:

Technology: Micromedic is involved in researching a gene expression profiling assay to identify lung cancer patients who are at increased risk of developing brain metastasis. An earlier study conducted at Sheba Medical Center identified a unique genetic signature of lung cancer patients who are at enhanced risk of developing brain metastasis. Micromedic, along with researchers from the Tel Homer Medical Center, is currently engaged in substantiating the study results and working towards identifying additional markers to improve predictability. The study's results are expected to be available in the near-term and based on the data, Micromedic may continue in the product development.





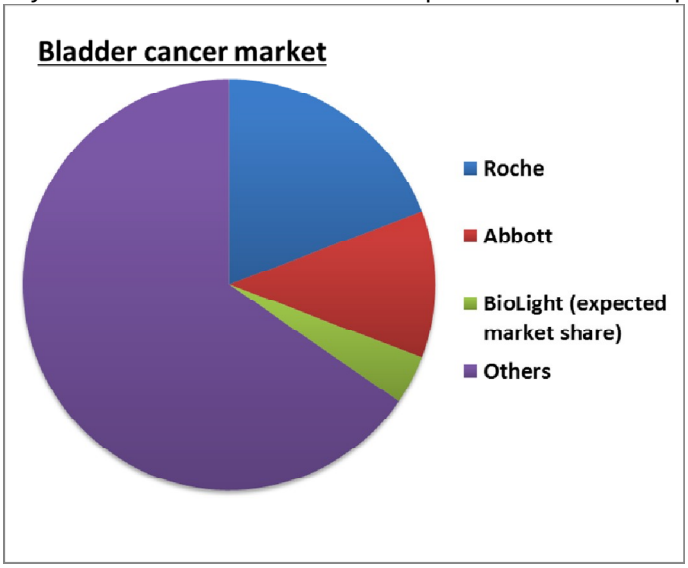
(Source: www.ellex.com/files/2014/03/InvestorPresentationHY14.pdf, www.zacks.com)

FINANCIAL CONDITION

BioLight is an early stage growth company, currently with only nominal revenue. We expect the company will incur significant investment and expense related to research and development (R&D), regulatory approvals and activities associated with collaborations, business development and product commercialization. We expect BioLight to generate net losses and remain cash flow negative until the company is able to commercialize additional products and/or potentially consummate strategic partnerships which could offset or absorb some of these early expenses. Annual cash burn was $7.7M in 2014.

The company commenced a soft launch of their minimally-invasive surgical product for treating glaucoma (IOPtiMate™) as well as cervical cancer detection kit using CellDetect® technology in developing markets (mainly in China) in the beginning of 2014. The company has been successful in raising capital in the past and has primarily relied on equity financing.

For the three months ended March 31, 2015, BioLight's revenues were $39,000, mostly from the sales of IOPtiMate systems. The net loss for the first quarter of 2015 was approximately $1.7 million vs. $2.3 million in Q1 2014. EPS for Q1



2015 came in at ($0.003), close to our estimate. R&D reduced 28% to $820,000 vs. $1.3 million in Q1 2014. R&D expenditure decreased because of the completion of clinical studies and related costs including recruitment of contractors and patient volunteers, manufacturing small batches of test kits, patient health monitoring via lab tests, etc. SG&A spend came in at about $800,000, which was in-line with our estimate.

BioLight exited the first quarter with a strong balance sheet. As of 31 March 2015, the company had approximately $6 million in cash and short-term deposits. Moreover, subsequent to quarter-end, the company raised an additional $6.6 million in a May 2015 private placement as part of a new strategic partnership with Rock-One. An investor from China, focused on introducing high-tech biomedical devices into the Chinese market, invested another $350k in the company.

VALUATION/RECOMMENDATION

Valuation: Despite their small size and relative immaturity, we expect BioLight to gain a foothold in the biotechnology industry due to their cluster strategy. This permits the subsidiaries to collaborate and create synergy opportunities which in turn will secure greater interest and involvement from the financial community, both domestically as well as

internationally. The effective cluster dynamics also helps in generating new and commercially valuable innovations and strengthen the processes around the commercialization of those innovations.

BioLight has a market cap of roughly $34 million. The ADRs commenced trading on the OTCQX earlier in 2014 and currently trade on light volume at approximately $5.23/ADR in the U.S - although the shares trade at much higher volume on TASE which is the primary Stock Exchange of BioLight. The company has a number of products in clinical trials, a few of which are expected to conclude next year. Assuming positive clinical data from these trials, we think the stock price could react favorably. Additionally, we expect the management team to form strategic partnerships to fully leverage their cutting-edge technology. Achieving major business milestones thus far is a sure demonstration of BioLight's successful management team. We expect the firm to keep up their forward strides leading to commercialization of their products.

Other specialized pharma/drug delivery companies have recently struck lucrative partnership deals. In 2011, pSivida signed an investment agreement with Pfizer which included $2.3 immediate cash payment, $20 million for an option to take over the R&D upon completion of Phase 2 clinical trial of their Durasert implantable medical device and a commitment of $146.6 million in combined milestone payments and royalties with Pfizer for its latanoprost biodegradable eye implant. In December 2010, Genentech entered into an agreement with ForSight VISION4 for exclusive worldwide rights to the proprietary implantable ocular device for $10M in milestone payments and royalties. Similarly, contingent on the pace of the development of Eye-D® through clinical trials and regulatory approvals, we anticipate partnerships with big players in this space could materialize in the future.

While this is an important consideration in the valuation of BioLight we also need to consider the large untapped market for glaucoma treatment in China. As discussed above, the company has already formed strategic partnerships in China and demonstrated the efficacy of their technology. We expect to see strong revenue growth for BioLight as the adoption of IOPtiMate ™ increases in the market.

Since the etiology of DES is not completely understood, treatment options lag behind. Underscoring this issue is the fact that several parameters contribute towards this condition. We believe that pharmaceutical companies would welcome a partnership with products like TeaRx that tests for multiple parameters (at least 5) that is known to contribute to this condition. None of the existing technologies provide a comprehensive test package similar to TeaRx. Hence, we believe that there is potential that TeaRx could be rapdily adopted in the testing as well as companion diagnostics space.

We use a Discounted Cash Flow (DCF) model to value BioLight. We use a discount rate of 12% based on the risk profile for this company. Given the emerging stage of the company, we apply a terminal growth rate of 1.5% in our financial model as we expect the company to continue growing at an above average rate beyond 2024. The revenue drivers in our model are the IOPtiMate™ systems, CellDetect® diagnostic and monitoring kit. We also include TeaRx tear-fluid diagnostic kit that is expected to launch in 2016 and the Eye-D® insert that is expected to be introduced in 2018 assuming the devices have cleared regulatory approvals and are in the commercialization stage. Thus far, the regulatory proceedings have not yet been initiated with TeaRx.

Our model assumes BioLight gains significant market share globally in the ophthalmology segment as well as in the cancer diagnostics space and achieves annual revenues of about $25M by year five while stabilizing their costs. Based on the high prevalence of glaucoma, dry eye and cancer cases globally, and particularly in developing economies, we think it is quite possible for BioLight to be able to reach this target. In their initial sales year, we expect BioLight to generate very minimal revenue. For subsequent years, we expect a boost in the top line from increase in sales through strategic partnerships with distributors globally. We expect that the revenues generated from these products could help in the sustainability of BioLight's maturing product pipeline and R&D operations.

Recommendation: As life expectancy has increased and an aging population is prone to degenerative diseases and life-threatening illnesses, healthcare has become a necessity for which people are willing to pay. We expect to see BioLight show significant growth as their products fan out in the market and targeted therapies in medical technology space continue to develop. The results from clinical trials to-date related to bladder cancer monitoring using CellDetect® technology, and sustained drug delivery through subcutaneous insert have been clinically proven and robust. We are very encouraged by BioLight's pioneering efforts and the efficacy of the novel IOPtiMate™ CLASS methodology for glaucoma surgery. Consequently, we see fiscal year 2015 as a transition year for BioLight. As revenue ramps in 2015 and continues to accelerate in subsequent years, we think BioLight will gain significantly greater visibility in the global market.

BioLight ADRs (BLGTY) currently trades at $5.23, well below our calculated and targeted fair value. We utilized a risk-adjusted Net Present Value (NPV) analysis to determine our price target objective. Using a Discounted Cash Flow (DCF) model, we derived a total equity value of approximately $70 million. This projection is based solely on expected sales of the IOPtiMate™, Eye-D, TeaRx and the CellDetect ® staining technology. Some risks such as delay in clinical trials pertaining to the Eye-D and TeaRx technology are evident and cannot be ruled out but the potential return may be quite significant. However, if the company generates a higher revenue growth as compared to our assumptions from existing products it should provide some upside to our calculated valuation. BioLight is still on a high cash burn but the company seems poised for long term growth when things turn positive after their products gain significant market share. We are initiating coverage of BioLight with a Buy rating and $14.00/share price target.

Developing nations is a major driving force

GBI Research forecasts that the glaucoma and DES market in India to grow at a CAGR of 9.9%, and in China at a CAGR of 5%. With populations of over one billion people in each of these countries and a high prevalence of both conditions, a strong market exists for products such as BioLight's. We expect that with technological innovations in treatment, as well as local governmental initiatives towards healthcare infrastructure in India and China, BioLight will be able to gain momentum in their sales and obtain meaningful market share in these countries over the mid-to-long term.

Supportive domestic government (Israel)

The local government comprising of Israel's finance, trade and labor ministry has sponsored incentives and made considerable effort to expand Israel's innovative capacity in biotechnology. Small biotech firms from Israel have shown improved research and innovation capacity with the involvement of scientists from the international academic community.

Investors

The key investors in BioLight, holding about 45% of BioLight's shares are Mr. Israel Makov, Chairman of Sun Pharmaceuticals and Given Imaging, and former CEO and President of Teva Pharmaceuticals, Mr. Dilip Shanghvi, founder and MD of Sun Pharmaceuticals, and Mr. Dan Oren, President and CEO of Dexcel Pharma.

Sun Pharmaceutical Industries Ltd., that manufactures and markets a wide range of pharmaceutical formulations for the U.S. generic market, is India's most valued drug company in terms of market capitalization and is also strong in the oncology segment. Mr.Shanghvi from Sun Pharma has a 17.5% stake in BioLight. Mr.Israel Makov is the second biggest investor in BioLight with 15.8% holdings. Dan Oren of Dexcel Pharma, the fourth-largest Israeli pharmaceutical manufacturer ranked by sales volume, has 11.7% holdings in the company.

BioLight also has three institutional investors who hold 20% of outstanding shares of BioLight.

RISKS

Although BioLight is making notable strides in developing targeted therapies, there are some meaningful associated risks with an investment in the company including;

Cash Burn Risk: Cash burn is a significant risk for the company and has been discussed in detail under Financial Conditions.

FX Risk: As BioLight has a global outreach for its products, the cash inflow as well as outflow are in USD in global territories and in NIS domestically. BioLight has dollar reserves which will help smooth some of the volatility in USD/NIS exchange rate.

Unforeseen delays in research and approvals: For the Eye-D® to gain significant market share, the clinical trials need to show favorable results such as: 1. the procedure must satisfy the physicians in that they are not inferior to the efficacy of topical drugs, 2. the procedure must be persistent in effect, and 3. the procedure needs to become a preferred option by patients over topical administration of the drug. A slow-moving/delay in clinical trials and a subsequent delay in obtaining regulatory approvals can hinder progress in a fast-paced research environment such as the biotech sector. Additionally, the specific regulatory approval process can be country or territory-specific, lending potential challenges in meeting the requirements of the various global regulatory agencies.

Even though topical medications in the glaucoma space have gained FDA approval, obtaining approval for the method of drug delivery may be challenging due to safety and efficacy issues. To be able to market the Eye-D® as a three or six-month sustained drug delivery device, the clinical trials need to be run for at least three or six months prolonging the development process. Any complications resulting from the delivery process may have negative implications on the marketability.

Reimbursement costs for implantable device: The cost comparison is exacerbated between latanoprost, a topical medication that can be self-administered, and the price to deliver the same using an implantable insert such as the Eye-D®. Not having a separate reimbursement code for such procedures could hamper market uptake.

Underlying assumptions for our model could be inexact: We assume a steady growth contribution from the BioLight products commencing in 2015. However, their product sales could vary significantly from our projections. In this case, our model could prove too optimistic or pessimistic resulting in realized sales that are very different from our estimates. Our assumptions are made using best-guesses based on market penetration of the product.

BioLight Israeli Life Sciences Investments Ltd.

	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E	2018 E	2019 E
Revenue	$0.24	$0.04	$0.1	$0.2	$0.3	$0.7	$1.5	$4.6	$8.6	$18.0
YOY Growth	-					*204.3%*	*115.1%*	*200.0%*	*85.7%*	*110.3%*
Cost of Goods Sold	$0.13	$0.03	$0.05	$0.12	$0.17	$0.37	$0.77	$2.31	$4.29	$9.02
Royalty Payments	$0.00	$0.00	$0.10	$0.10	$0.12	$0.30	$0.32	$0.37	$0.45	$0.62
Total COGS	$0.13	$0.03	$0.15	$0.22	$0.29	$0.67	$1.09	$2.7	$4.7	$9.6
Gross Income	$0.10	$0.01	$0.0	$0.0	$0.1	$0.0	$0.5	$1.9	$3.8	$8.4
Gross Margin	*42.8%*					*6.2%*	*29.3%*	*41.9%*	*44.8%*	*46.6%*
R&D	$4.64	$0.82	$0.75	$1.00	$0.75	$3.00	$3.27	$3.24	$3.19	$3.13
%R&D	*1972.4%*	*2007.0%*	*714.3%*	*434.8%*	*220.6%*	*419.1%*	*212.4%*	*70.1%*	*37.2%*	*17.3%*
SG&A	$3.10	$0.80	$0.90	$1.00	$0.70	$3.40	$5.00	$6.00	$8.00	$12.00
Impairment Loss	$0.8	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
%SG&A	*1319.1%*	*1949.7%*	*857.1%*	*434.8%*	*205.9%*	*475.0%*	*324.8%*	*129.9%*	*93.3%*	*66.5%*
Operating Income (EBITDA)	($8.4)	($1.6)	($1.7)	($2.0)	($1.4)	($6.4)	($7.8)	($7.3)	($7.3)	($6.7)
Pre-Tax Income (EBIT)	($9.4)	($1.6)	($1.7)	($2.0)	($1.4)	($6.4)	($7.8)	($7.3)	($7.3)	($6.7)
Finance Income	($0.1)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Finance Expenses	$0.6	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gain from sale of subsidiary	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Expenses	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Margin	-	-	-	-	-	-	-	-	-	-
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income	($10.20)	($1.7)	($1.7)	($2.0)	($1.4)	($6.4)	($7.8)	($7.3)	($7.3)	($6.7)
EPS	(0.02)	(0.003)	(0.003)	(0.003)	(0.002)	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)
Diluted Shares O/S	482	521	620	620	620	595	625	655	685	715

Source: Zacks Investment Research *Anita Dushyanth*

MANAGEMENT TEAM

BioLight

Israel Makov
Chairman
Mr. Makov is the former President & CEO of Teva Pharmaceutical Industries Ltd (2002-2007). Among Israel's most respected corporate leaders, he is widely credited with turning Teva into the world leader in generic pharmaceuticals. Prior to joining Teva, Mr. Makov led a number of companies in various industries, and founded Israel's first biotech company, Interpharm, which later went public in the U.S. Mr. Makov is Chairman of Given Imaging, Chairman of Sun Pharmaceutical Industries Limited., Chairman of Micromedic Technologies Ltd. and the Chairman of Eltav. Mr. Makov is a member of the Board of Directors of the Israel National Nanotechnology Initiative, an initiative he helped establish. He is also a member of the Executive Board and Management Committee of the Weizmann Institute of Science, and the Chairman of the Board of the Institute for Policy and Strategy at the Interdisciplinary Center of Herzliya. Mr. Makov has a B.Sc. in Agriculture and a M.Sc. in Economics from the Hebrew University in Jerusalem.

Suzana Nahum-Zilberberg
CEO
Mrs. Suzana Nahum-Zilberberg is the CEO of BioLight. Previously Mrs. Nahum-Zilberberg worked at Teva Pharmaceuticals Industries Ltd for 12 years in several positions, her last role being Vice President Asia and Pacific, leading the penetration of Teva into Japan and China. In her position Mrs. Nahum-Zilberberg led the JV agreement with Kowa Pharmaceutical in 2008 and the acquisition of Taisho Pharmaceutical in 2009, leading Teva to become the fifth largest generic company in Japan.
Mrs. Nahum-Zilberberg holds a BA in Accounting and Economics from Tel Aviv University, MBA in Finance and Marketing from Tel Aviv University and is certified CPA.

Itai Bar-Natan
CFO
Mr. Itai Bar-Natan is the CFO of BioLight. Previously Mr. Bar-Natan worked at Ernst & Young Israel and U.S for 10 years in several positions. His last role was a senior manager in the tech practice, leading diverse clients, including early stage through late stage, domestic, multinational and publically traded companies. Mr. Bar-Natan has vast experience in corporate finance, international corporate tax, fund raising to early stage clients , M&As, IPOs and secondary capital rising.
Mr. Bar-Natan holds a BA in Accounting (with honors) and Political Science from the Tel-Aviv University and is a CPA.

Efrat Makov
Board Member
Ms. Efrat Makov has extensive financial experience and background. Ms. Makov had served in various senior financial positions the latest was CFO of Aladdin Information Systems Ltd and CFO of Alvarion . Ms. Makov holds a BA in accounting and economics from Tel Aviv University.

Eli Shohet
Board Member
Mr. Eli Shohet serves as a strategic and business advisor at ADY Consulting Group. Prior to this role Mr. Shohet was a Co-CEO of Netafim. Previous to this, Mr. Shohet served in various senior positions at Teva Pharmaceuticals Industries Ltd over a 20 year period, including Senior Vice President of Business Development, Chief Integration Officer and VP Central and Eastern Europe. Mr. Shohet holds a BA in economics from Bar Ilan University.

Ron Weissberg
Board Member
Mr. Ron Weissberg is the President of CERAC Group, Director at Midroog, Director at The Israel Development Group, Director at BioLight and owner of R. Weissberg Management & Consulting.
Previously Mr. Weissberg had served as a Director & CEO of Portfolio Green, Chairman & CEO of Gadish Global, Chairman & CEO of ILD Insurance and Chairman of ICIC – Israel Credit Insurance Company. Mr. Weissberg holds a B. Sc in Industrial Engineering & Management from the Technion and an MBA in International Business & Finance from New York University.

Shmuel Perez
Board Member
Mr. Shmuel Peretz has served as the President of the European Division of Israel Aerospace Industries Ltd. from 2003 – 2005. Mr. Peretz served as a member of the board of Elscint Ltd. From 1991 – 1996 Mr. Peretz served as Vice President (Finance) of Israel's Aerospace Industries Ltd. Betwen 1980 – 2002 Mr. Peretz served as a member of the board of directors of numerous companies, including Elta Ltd., Magal Ltd., Medisel Technologies Inc. and Belgium Advanced Technologies. Mr. Peretz holds a B.A. in economics & political science from the Hebrew University in Jerusalem, as well as an M.B.A. from the New York Institute of Technology.

Rachel Adatto
Board Member
Dr. Rachel Adatto has a degree of Doctor of Medicine from the Hebrew University and Hadassah medical school and certified as an expert in women healthcare and midwives. Dr. Adatto served as senior physician at the Hadassah Mount Scopus Department of Obstetrics and Gynecology and as the Deputy Director of the hospital. In 1995 Dr. Adatto appointed as a Deputy Director General of the Shaare Zedek Medical Center in Jerusalem until 2007.

Among her public positions, Dr. Adatto found the National Council for Women's Health and appointed Council Chairwoman by the Minister of Health, was a Member of the Public Committee for Health Basket Allocation and was an advisor to the Minister of Health on the subject of women's health.

In 2009-2013 Dr. Adatto was a member of Israeli Knesset (Kadima party).
In addition to her medical degree Dr. Adatto has an MBA degree from the Hebrew University of Jerusalem's School of Business, awarded LL.B. degree from the Uno Academic College and is a qualified lawyer.

XLVision Sciences

Ronen Castro
***CEO IOPtima,* Developer of the IOPtiMate™**
Ronen Castro has vast experience in marketing & sales, business development and managing positions in medical device companies. In the last 18 years he has served in companies like Contec-Medical (Rigid Endoscopy products), Versamed (Software based Ventilation Machines), SLP (SleepMedicine and Respiratory products) and MetaCure (Implantable Gastric Stimulator for Diabesity). For the last 3 years prior to joining IOPtima, he was the CEO of Allium Medical Solutions (TASE:ALMD), a manufacturer of various MIS products. 2 year before, he served as the CEO of C-Boot, a manufacturer of advanced compression therapy products. He is also the founder of DCS Medical and EZ-Tube. Ronen Castro holds an MBA degree from Ben-Gurion University.

Keren Leshem
***CEO ViSci,* Developer of the Eye-D®**
Over a decade of experience in BD, licensing, Marketing & sales in Capital equipment, Medical Devices & Biotech. Previously Mrs. Leshem headed an Ophthalmic Medical device company, raised $2M and brought a strategic partnership for completing a working prototype & Human studies. Mrs. Leshem is a certified lecturer in one of Israel's leading universities teaching marketing and business English courses.

Eran Eilat, MD, Ph.D.
***Founder & CEO DiagnosTear,* Developer of the TeaRx**
A serial entrepreneur who has founded several biotechnology and medical device companies including, Otic Pharma which completed a successful phase II clinical trial, and then closed a significant financing round led by Orbimed, and AOPharma, which has developed a proprietary preservative free, multi-dose and user-friendly ophthalmic drug delivery device.
Dr. Eilat received an M.D. degree from the Sackler School of Medicine in Tel Aviv University, and a Ph.D. degree in Immunology from the Weizmann Institute of Science. He is the inventor of numerous patents in the medical and biotechnology fields.

Scientific Advisory Board (IOPtima)

Prof. Ehud Assia, MD
Inventor, CMO, Ophthalmic Surgeon, Israel

Prof. Alon Harris – M.S., Ph.D.
Ophthalmic Researcher, Indiana

Dr. Robert David, MD
Glaucoma specialist, California

Prof. Howard Barnebey, MD
Glaucoma specialist, Seattle

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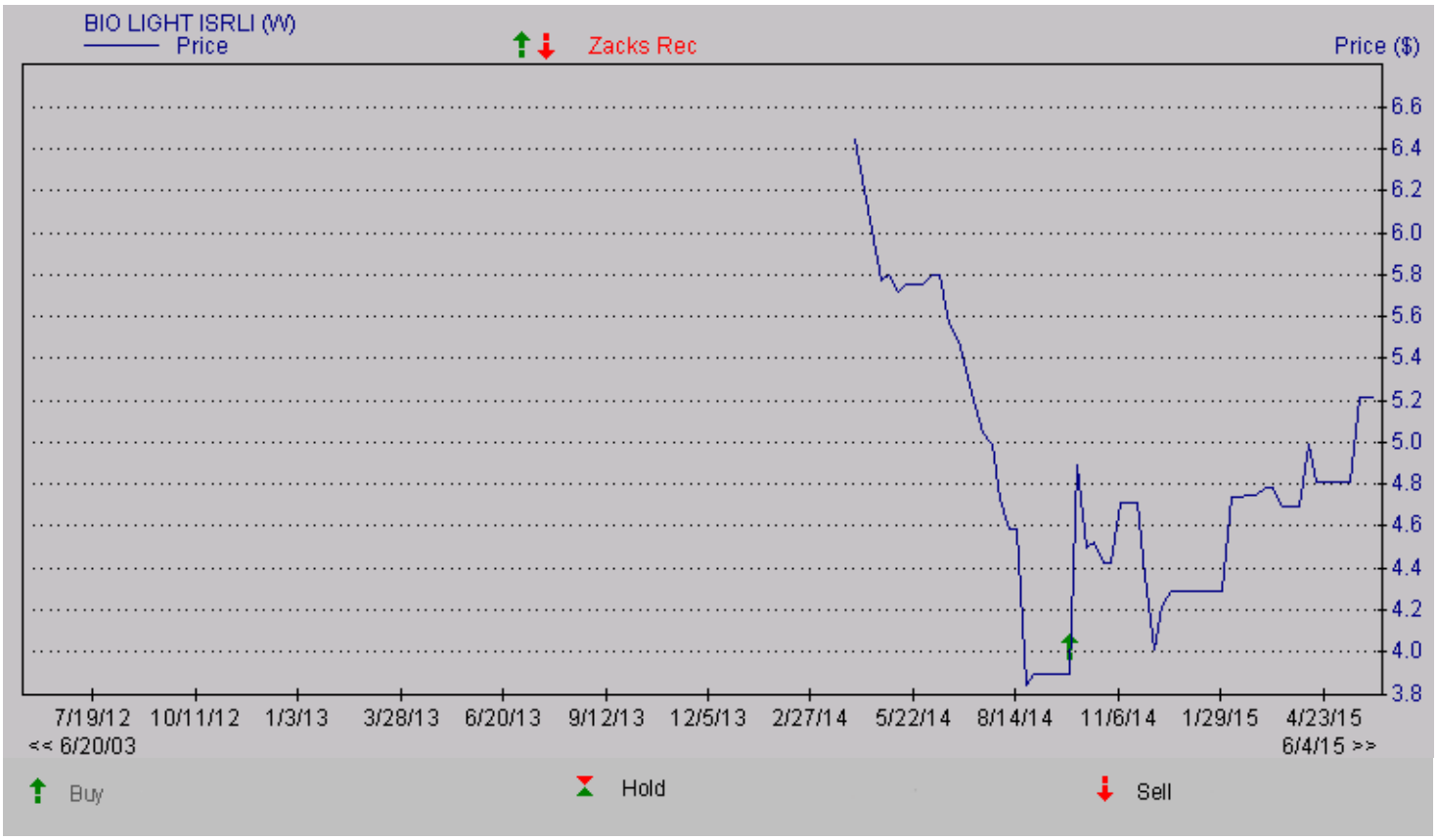

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