EDISON

BioLight Life Sciences

Quarterly update

IOPtiMate relative safety highlighted in publication

Pharma & biotech

A recent publication on a 111-patient trial on BioLight's IOPtiMate CO_2 laser surgical system suggests it provides intraocular pressure (IOP) reduction comparable to trabeculectomy, but potentially with a better safety profile. Sales in Europe and Asia are ongoing, and we expect clarity on a US regulatory strategy in H117. The firm had NIS31.8m in net cash at 30 September 2016 and we derive an rNPV valuation of NIS90.5-104.2m.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/14	0.9	(30.1)	(8.91)	0.0	N/A	N/A
12/15	1.4	(25.1)	(6.96)	0.0	N/A	N/A
12/16e	2.3	(23.9)	(5.98)	0.0	N/A	N/A
12/17e	6.6	(33.8)	(11.82)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

IOPtiMate reduces IOP by 43-47%, minimal VA loss

A mean IOP reduction of 43-47% vs baseline was measured across three years, and adverse events (including macroperforations, iris incarceration, the need for goniopuncture or needling) were well managed and without permanent visual acuity (VA) loss. Only 0.9% of patients had VA loss of more than two lines at three years, which is significantly less than what would be expected with trabeculectomy, historically the surgical procedure of choice for advanced chronic glaucoma. In a separate study (the TVT study), over 40% of patients undergoing trabeculectomy experienced VA loss at five years.

Q316 financials mostly in line with our projections

BioLight reported Q316 revenue, EBITDA loss and adjusted net loss per share of NIS0.92m, NIS5.1m and NIS1.50. These compare to our Q316 estimates of NIS0.35m, NIS5.6m and NIS1.92. IOPtiMate sales to customers in ex-US markets account for the bulk of BioLight revenue. The net loss figure removes NIS2.3m of non-controlling interest-associated loss belonging to the Micromedic subsidiary (BioLight owns 48% of Micromedic's outstanding shares and has consolidated its results). The Q316 operating cash burn (including the consolidation of Micromedic's financials) rate was NIS5.7m, and its 9M16 burn rate was NIS20.0m (we estimate NIS6-8m of this reflects Micromedic's operations).

Valuation: rNPV of NIS90.5-104.2m

On 30 September 2016, BioLight held NIS31.8m in net cash (NIS31.4m cash and equivalents and NIS0.4m in short-term deposits); most of these funds are held within BioLight's IOPtima subsidiary. After rolling forward our forecasts, we now have an rNPV of NIS90.5-104.2m (up from NIS90.5-97.6m, previously). We believe R&D spending and other operating costs will exceed IOPtiMate sales growth near term and we forecast the operating cash burn rate to increase to NIS31.7m in 2017 and NIS32.6m in 2018. We model that BioLight will need to raise NIS30.0m in both 2017 and 2018 to sustain its operations and R&D projects. For modelling purposes, we assign these financings to long-term debt.

22 December 2016

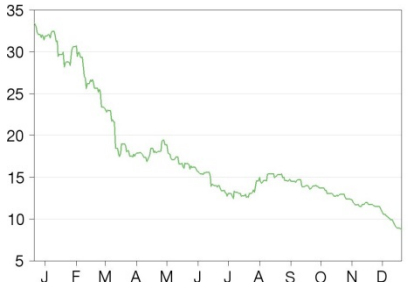
Price*	**NIS8.87**
Market cap	**NIS23m**

*Priced at 20 December 2016

NIS3.80/US$

Net cash (NISm) at 30 September 2016	31.8
Shares in issue	2.6m
Free float	45%
Code	BOLT
Primary exchange	TASE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(12.7)	(31.3)	(70.0)
Rel (local)	(15.6)	(30.5)	(68.5)

52-week high/low	NIS34.7	NIS10.1

Business description

Based in Israel, BioLight is an emerging ophthalmic company focused on the development and commercialisation of products and product candidates that address ocular conditions. Lead products IOPtiMate and VS-101 are directed towards the treatment of glaucoma.

Next events

FDA guidance on IOPtiMate regulatory strategy	H117
EyeD VS-101 Phase I/IIa data	H117

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Edison profile page

New published study on IOPtiMate multicentre trial

Geffen et al.[1] recently reported updated data from an 111-patient open-label study between 2007 and 2011 across nine sites spanning seven countries (Mexico, India, Russia, Italy, Spain, Switzerland and Israel) on BioLight's IOPtiMate device. IOPtiMate is carbon-dioxide (CO_2) laser-assisted sclerectomy (CLASS) system designed to reduce IOP for the treatment of glaucoma. Recruited patients had definitive glaucoma diagnoses and baseline IOP above 18mmHg despite taking maximal tolerated topical IOP-lowering (hypotensive) drug therapy and, given the stage of their disease, were all indicated for filtration surgery (trabeculectomy).

As discussed in our initiation report, BioLight believes the IOPtiMate CLASS system provides a safer and more precise alternative to trabeculectomies and glaucoma drainage implants (GDIs), with comparable IOP-lowering levels, a lower risk of complications, shorter recovery times and fewer post-op office visits. The IOPtiMate CLASS procedure involves cutting a section (flap) of sclera, temporarily lifting it and applying the CO2 laser beneath, to thin the scleral wall underneath. One of the risks with CLASS described in this study is that excessive thinning of the sclera can lead to macroperforations, which require additional corrective treatment (such as trabeculectomy).

In the study, complete success was defined as IOP measurements of 5-18mm Hg and an IOP reduction of at least 20% compared with baseline IOP, without the need for future hypotensive medications or repeat surgery. Qualified success referred to patients meeting the same parameters, but also included subjects who required hypotensive medications post-operatively.

Failure was defined as an IOP outside the above range, an IOP reduction below 20% compared to baseline IOP, severe loss of vision, intra-operative device-related macroperforations, or the need to undergo additional glaucoma procedures other than goniopuncture or bleb needling (two relatively minor in-office surgical procedures that can accompany glaucoma surgeries, and have low complication rates). Goniopuncture was performed in 18 (18.5%) patients and needling in 12 (12.4%) patients. In both cases, the procedures were performed in the first year of the study and there were no procedure-related complications.

Comparable IOP lowering efficacy to trabeculectomy

Data were collected on all 108 enrolled participants who received IOPtiMate CLASS treatment, and no technical device malfunctions occurred. The efficacy data are cited below and overall show an IOP reduction of 43-47% across the three years, which is comparable to the levels generally associated with trabeculectomy. Nearly 58% of patients reached complete success and did not require IOP-lowering medications after 24 months; the qualified success rate reached a peak of 91% at this period, although we highlight that both groups included patients requiring additional needling or goniopuncture procedures.

Exhibit 1: Efficacy data for IOPtiMate multinational study

Time Period	Mean IOP reduction (%)	*Complete success rate (%)	**Qualified success rate (%)
12 months	45.1	60.2	79.6
24 months	46.8	57.9	91.2
36 months	42.5	47.8	84.8

Source: Geffen N, Mimouni M, Sherwood M, et al. J Glaucoma. 2016 Dec; 25(12):946-951. Note: *IOP measurements between 5-18mm Hg and an IOP reduction of at least 20% compared with baseline, and without the need for medications or added surgery. **Same as complete success rate, but including patients requiring IOP-lowering medications.

[1] Geffen N, Mimouni M, Sherwood M, et al. J Glaucoma. 2016 Dec;25(12):946-951.

IOPtiMate-related adverse events manageable without lasting visual effects

There were five CLASS procedure-related macroperforations (4.6% of patients) that occurred as a result of excessive scleral tissue ablation. The study authors indicate that each case was successfully converted to trabeculectomy. They suggest that as CLASS has a learning curve, the rate of macroperforations could decrease as surgeons become more familiar with the treatment technique. There was also a relatively high rate of iris incarceration (nine cases, accounting for 8.3% of patients). In all cases, the iris incarcerations were successfully treated with YAG laser iridoplasty or surgical iris repositioning. Nonetheless, the reported rate of iris incarceration was typically higher than would be expected with GDIs, MIGS or filtration surgery.

IOPtiMate appears to carry less risk than filtration surgery

While this was an open-label study, some of the adverse-event levels can be compared to data from the the Tube vs Trabeculectomy study (TVT)[2], a five-year investigation that compared tube shunt surgery to trabeculectomy. The rates of hyphema and hypotony (both shorter-term post-surgical risks) for IOPtiMate were 4.6% and 2.8%, respectively, compared to 8% and 5%, respectively, for the trabeculectomy arm in the TVT study.

Best-corrected visual acuity (BCVA), likely the most significant long-term parameter affecting patients' visual function and quality of life, appears to show a more striking difference between trabeculectomy and IOPtiMate. The current IOPtiMate study showed that after three years, only 0.9% of patients experienced a significant BCVA loss of at least two Snellen chart lines. However, 43% of patients undergoing trabeculectomy in the TVT study experienced BCVA loss based on the same criteria. We note that differing time measurement periods (three years for the IOPtiMate study vs. five years for the TVT trial), may complicate direct comparisons between both studies.

While this IOPtiMate study shows that a reasonable number of treated patients had non-visually threatening adverse events (macroperforations, iris incarcerations, or events requiring goniopuncture or needling procedures, etc), they were largely well managed and did not appear to affect visual outcomes.

Limitations of current comparisons, possible directions for future studies

While this study suggests IOPtiMate may offer comparable IOP reduction to trabeculetomy and an overall safer profile, comparisons are limited by the absence of a control group, which may have affected subjects' randomization and treatment masking, and added subjectivity to the analysis. Thus, a direct comparison with trabeculectomy may not be fully reliable based on this study alone. The authors also suggest that a further limitation of this study is the loss of subjects to follow-up, which reached 58% at three years and may have led to selection bias. Finally, visual field deterioration (one of the hallmark parameters to measure glaucoma progression) was not evaluated during this study.

Hence, we estimate that further studies will be needed to persuade eye surgeons (particularly in developed markets) of the potential advantages of IOPtiMate vs competing glaucoma procedures, and strengthen the commercial case for the product. Further, as also stated in our initiation report, GDIs and minimally invasive glaucoma surgeries (MIGS) are increasingly replacing trabeculectomy in many clinical settings, and a more clinically pertinent head-to-head comparison could be done for the efficacy and safety of IOPtiMate to these procedures, rather than trabeculectomy.

[2] Gedde SJ, Herndon LW, Brandt JD et al. Am J Ophthalmol. 2012 May;153(5):804-814.e1.

Valuation

Our BioLight valuation continues to include the prospects for IOPtiMate, Eye-D VS-101 and TeaRx. We apply a risk-adjusted net present value (nNPV) model with a 12.5% cost of capital. For each of these projects, we provide a weighted rNPV based on BioLight's ownership in the associated parent company. For IOPtiMate, we continue to apply a lower probability of success for our US forecasts than our ex-US market forecasts, as the product has yet to receive US regulatory clearance, while it is already cleared for sale in Europe and China. Eye-D VS-101, an extended-dose implant delivering sustained release of latanoprost, remains the largest potential source of revenue for the company and our 20% probability of success estimate reflects its early clinical development stage.

Exhibit 2: BioLight's upcoming catalysts

Event	Timing
Guidance from FDA on regulatory pathway for IOPtiMate	H117
VS-101 Phase I/IIa data	H117
TeaRx 510(k) clearance and US launch	2017

Source: Company reports

We have maintained our operating revenue and timing forecasts for 2017 and beyond, and rolled forward our forecasts. Given these changes we now obtain an rNPV of NIS90.5-104.2m (up from NIS90.5-97.6m, previously).

Exhibit 3: BioLight rNPV assumptions

Product contributions (net of R&D costs)	Indication	rNPV (NISm)	rNPV/share (NIS)	Probability of success	Launch year	Peak sales (US$m)
IOPtiMate for ex-US markets (70% weighted)	Glaucoma	91.2	34.99	70.0%	2015	21.4 in 2023
IOPtiMate in US market (70% weighted)	Glaucoma	27.2	10.44	40.0%	2020	21.9 in 2025
VS-101 (97% weighted)	Glaucoma	81.0	31.06	20.0%	2020	69.8 in 2026
TeaRx (80% weighted)	DES diagnosis	29.7	11.40	50.0%	2017	19.8 in 2024
Corporate costs & expenses						
SG&A expenses		(59.1)	(22.66)			
Net capex, NWC & taxes		(79.9)	(30.66)			
Value of Micromedic shares (MCTC, TASE)*		6.4	2.44			
Total rNPV		96.4	37.00			
Net cash (debt) (Q316)		31.8	12.20			
Total equity value**		128.2	49.20			
FD shares outstanding (000) (Q316)		2,607				

Source: Edison Investment Research. Note: *5.29m shares held with 13 December 2016 price of NIS0.92 per share; **excludes the impacts from any dilution resulting from any future equity offerings

Financials: Q316 results mostly within expectations

BioLight reported Q316 financials in November 2016, with revenue, EBITDA loss and adjusted net loss per share of NIS0.92m, NIS5.1m and NIS1.50. These compare to our Q316 estimates of NIS0.35m, NIS5.6m and NIS1.92. The bulk of company revenue reflects IOPtiMate sales to customers in ex-US markets. The adjusted net loss calculation excludes the NIS0.03m expense item relating to the company's share of losses of an affiliate accounted for at equity. Including this figure, the reported IFRS net loss was NIS1.51 per share. Both these net loss figures remove NIS2.3m of loss reflecting the non-controlling interest attributed to the Micromedic subsidiary (BioLight owns 48% of the outstanding shares of Micromedic). Our financial forecasts do not include projections or considerations for Micromedic.

The Q316 operating cash burn (including the consolidation of Micromedic's financials) rate was NIS5.7m, and its 9M16 burn rate was NIS20.0m. On 30 September 2016, BioLight held NIS31.8m in net cash (NIS31.4m cash and equivalents and NIS0.4m in short-term deposits); most of these funds are held within BioLight's IOPtima subsidiary. We estimate NIS6-8m of BioLight's 9M16 burn rate reflects Micromedic's operations.

We continue to forecast IOPtiMate sales of NIS5.7m in 2017 and NIS11.7m in 2018 (with NIS0.9m and NIS5.7m in 2017 and 2018 TeaRx sales, respectively). SG&A costs are projected to rise from NIS8.2m in 2017 to NIS10.6m in 2018. We expect R&D costs over this period will be driven by Eye-D VS-101 and IOPtiMate US clinical studies, with R&D costs projected to rise to NIS27.6m in 2017 and NIS25.2m in 2018 (from NIS13.0m in 2015).

Hence, while we expect IOPtiMate revenue to increase in coming quarters, we believe R&D spending and other operating costs will exceed such sales growth near term and we forecast the operating cash burn rate to increase to NIS31.7m in 2017 and NIS32.6m in 2018. We model that BioLight will need to raise NIS30.0m in both 2017 and 2018 to sustain its operations and R&D projects. For modelling purposes, we assign these financings to long-term debt.

BioLight's reported financials consolidate the results from Micromedic, although BioLight has no direct liability or obligation to it. Micromedic has near-zero revenue (under NIS0.05m per year) and had a 2015 segment loss of NIS8.3m. Our model does not include forecasts for Micromedic.

Exhibit 4: Financial summary

NIS(000)	2013	2014	2015	2016e	2017e	2018e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	82	941	1,391	2,300	6,617	17,425
Cost of Sales	(23)	(538)	(734)	(934)	(2,978)	(7,841)
Sales, General & Administrative	(9,016)	(8,529)	(11,956)	(11,570)	(8,245)	(10,614)
Research & Development	(18,419)	(18,560)	(13,045)	(12,298)	(27,600)	(25,200)
EBITDA	(27,376)	(26,686)	(24,344)	(22,502)	(32,206)	(26,230)
Depreciation	(1,066)	(3,884)	(1,306)	(667)	(1,836)	(2,400)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(28,442)	(30,570)	(25,650)	(23,170)	(34,041)	(28,630)
Exceptionals	(1,220)	(5,886)	(2,475)	(5,133)	0	0
Other	0	0	0	0	0	0
Operating Profit	(29,662)	(36,456)	(28,125)	(28,303)	(34,041)	(28,630)
Net Interest	500	448	543	(753)	237	(347)
Profit Before Tax (norm)	(27,942)	(30,122)	(25,107)	(23,922)	(33,804)	(28,978)
Profit Before Tax (FRS 3)	(29,162)	(36,008)	(27,582)	(29,055)	(33,804)	(28,978)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(17,617)	(17,216)	(16,784)	(15,598)	(30,892)	(27,827)
Profit After Tax and minority interests (FRS 3)	(18,837)	(23,102)	(19,259)	(20,731)	(30,892)	(27,827)
Average Number of Shares Outstanding (m)	1.4	1.9	2.4	2.6	2.6	2.6
EPS - normalised (NIS)	(12.87)	(8.91)	(6.96)	(5.98)	(11.82)	(10.60)
EPS - normalised and fully diluted (NIS)	(12.87)	(8.91)	(6.96)	(5.98)	(11.82)	(10.60)
EPS - (IFRS) (NIS)	(13.76)	(11.96)	(7.98)	(7.95)	(11.82)	(10.60)
Dividend per share (NIS)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	13,323	8,002	9,832	8,004	10,600	16,490
Intangible Assets	12,307	7,106	6,869	6,691	6,691	6,691
Tangible Assets	1,016	896	2,963	1,313	3,909	9,799
Current Assets	21,009	32,432	53,439	28,978	25,651	18,038
Short-term investments	185	6,408	385	372	372	372
Cash	17,716	22,196	50,697	27,953	22,083	10,810
Other	3,108	3,828	2,357	652	3,196	6,855
Current Liabilities	(4,898)	(6,552)	(6,605)	(5,428)	(5,428)	(1,367)
Creditors	(4,898)	(6,552)	(6,605)	(5,428)	(5,428)	(1,367)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(7,325)	(8,144)	(9,605)	(10,110)	(40,110)	(70,110)
Long term borrowings	0	0	0	0	(30,000)	(60,000)
Other long term liabilities	(7,325)	(8,144)	(9,605)	(10,110)	(10,110)	(10,110)
Net Assets	22,109	25,738	47,061	21,443	(9,287)	(36,949)
CASH FLOW						
Operating Cash Flow	(26,725)	(27,435)	(24,580)	(22,539)	(31,676)	(32,635)
Net Interest	500	448	543	(753)	237	(347)
Tax	0	0	0	0	0	0
Capex	(201)	(402)	(182)	(512)	(4,432)	(8,290)
Acquisitions/disposals	(37)	0	(837)	(227)	0	0
Financing	11,152	38,374	47,320	2,554	0	0
Net Cash Flow	(15,311)	10,985	22,264	(21,477)	(35,870)	(41,272)
Opening net debt/(cash)	(215)	(17,901)	(28,604)	(51,082)	(28,325)	7,545
HP finance leases initiated	0	0	0	0	0	0
Other	32,997	(282)	214	(1,280)	0	0
Closing net debt/(cash)	(17,901)	(28,604)	(51,082)	(28,325)	7,545	48,818

Source: Company reports, Edison Investment Research. Note: The reported financial results consolidate Micromedic's financials, and forecast financial results (2016e and beyond) do not include Micromedic operations.

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