EDISON

BioLight Life Sciences

Clinical trial data

Promising Eye-D VS-101 Phase I/IIa data

Pharma & biotech

BioLight reported positive results from a 77-patient US Phase I/IIa study on Eye-D VS-101, being developed as an extended-dose platform for treating glaucoma. We have raised our estimate for the candidate's probability of commercial success to 30% (from 20%), which, with other adjustments, leads to an increase in our rNPV valuation to NIS121.6-135.7m.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/15	1.4	(25.1)	(6.96)	0.0	N/A	N/A
12/16	2.1	(26.3)	(5.55)	0.0	N/A	N/A
12/17e	4.9	(27.0)	(6.93)	0.0	N/A	N/A
12/18e	11.3	(33.7)	(8.63)	0.0	N/A	N/A

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

24% reduction in Diurnal IOP at 12 weeks

The Eye-D VS-101 is an insert that is placed in the lower lid conjunctiva in an in-office procedure that delivers a controlled amount of latanoprost. In the Phase I/IIa study, patients were randomised into four groups, with three receiving a VS-101 insert (at differing dose levels per group) and the control group receiving latanoprost 0.005% eye drops. BioLight has not yet specified the precise dosing quantities for the VS-101 treatment arms, but indicated that one of the doses showed a 24% reduction in diurnal (daytime average) intraocular pressure (IOP) from baseline (from 23.5mmHg to 17.9mmHg). The firm reported that the VS-101 insert was well-tolerated, and most adverse events were expected, and found to be mild and transient, although we await further details in a subsequent publication or conference presentation.

Next step could be a Phase IIb study

We believe there is a strong unmet need for continuous-dosage glaucoma medication delivery systems for up to 30% of glaucoma patients, given that many patients are elderly and may have difficulties applying topical eye drops properly each day. BioLight indicates that the next step for VS-101 development will likely be a larger Phase IIb study using as a base, the identified preferred dose found in the now-completed Phase I/IIa study.

Valuation: Risk-adjusted rNPV of NIS121.6-135.7m

After raising our EyeD VS-101 probability of success estimate from 20% to 30%, factoring in the completed June 2017 NIS11.5m rights offering at NIS11.20 per share (which increased shares outstanding by 39%), and adjusting other forex and market changes, we now obtain an rNPV of NIS121.6-135.7m (up from NIS92.9-103.4m, previously). We estimate that BioLight's H117 net cash position will be NIS27.2m (with NIS11.6m held at the parent company and the remainder at its subsidiaries), with it having sufficient funds on hand to maintain operations into Q417. Our base case model assumes that BioLight will raise NIS18m in H217 and NIS30m in 2018 to maintain its operations and development strategy. For modelling purposes, we assign these financings to long-term debt. We have not adjusted our model for the potential IOPtima sale to Chengdu.

6 August 2017

Price	**NIS16.40**
Market cap	**NIS60m**
	NIS3.58/US$
*Priced as at 02 August 2017	
Net cash (NISm) at H117e	27.2
Shares in issue	3.6m
Free float	43%
Code	BOLT
Primary exchange	TASE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	32.7	29.0	16.9
Rel (local)	33.1	26.5	14.7
52-week high/low	NIS16.6		NIS8.4

Business description

Based in Israel, BioLight Life Sciences 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

H117 results	August 2017
Decision on IOPtiMate US regulatory strategy	H217

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Eye-D VS-101 positive Phase I/IIa data

On 24 July 2017, BioLight reported positive results from the Phase I/IIa study on Eye-D VS-101, which is being developed as an extended-dose treatment for glaucoma by BioLight's ViSci subsidiary (of which it holds a 97% interest). The Eye-D VS-101 is a non-biodegradable insertable product that is placed in the lower lid conjunctiva in an in-office procedure. Over several months, it delivers a controlled amount of latanoprost, a widely used Prostaglandin F2α analogue (PGA) that lowers intraocular pressure (IOP) in patients with glaucoma.

In this first-in-human study on Eye-D VS-101, patients with open angle glaucoma (OAG) or ocular hypertension were randomised and divided into four groups, with three receiving VS-101 inserts (at differing dose levels per group) and the control group receiving latanoprost 0.005% eye drops once daily. BioLight has not yet specified the precise dosing quantities of each of the three treatment arms. The sustained release Eye-D VS-101 inserts were tested for 12 weeks and compared to once-daily latanoprost 0.005% eye drops for the same period.

The Phase I/IIa results reflect data from 77 patients, collected from 19 US clinical sites. The firm reported that a single placement of Eye-D VS-101 at one of the three tested doses provided a sustained reduction in diurnal IOP[1] of 24% at 12 weeks; in this arm baseline diurnal IOP was 23.5mmHg and 12-week diurnal IOP was 17.9mmHg. The firm has not yet specified whether there was a positive dose-response relationship among the three treatment arms, and what percentage changes occurred in each of those arms, but we expect further data will be released as part of a research article publication or at a conference.

Adverse effect profile appears favourable, but awaiting further details

BioLight reported that the VS-101 insert was well-tolerated, and most adverse events were found to be mild and transient. The company has not yet specified whether there were any patient discontinuations/drop-outs and which specific adverse events occurred, but with any foreign body implant or insert, the risk of dry eye or mechanical corneal irritation is to be considered. In addition, it would be helpful to know whether the VS-101 insert has any effect on central corneal thickness (CCT), given that prolonged topical PGA usage has been associated with a reduction in CCT (some studies find an inverse relationship between CCT and glaucoma risk or progression).

Strong market potential for continuous-dosage glaucoma product

As stated in our initiation report, there is a strong unmet need for continuous-dosage glaucoma medication delivery systems, given that many patients are elderly and may have difficulties applying topical eye drops properly each day. Okeke et al.[2] determined that 50% of glaucoma patients do not adhere to their regimen 75% of the time. Poor treatment compliance is associated with worsening glaucoma progression and to date, we are not aware of a viable approved continuous-dosage glaucoma drug delivery system. We continue to estimate a continuous glaucoma drug delivery system such as Eye-D VS-101 could target up to 30% of the glaucoma population, or up to 0.83 million people in the US, reflecting those patients poorly compliant with topical medication.

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1 As IOP can fluctuate throughout the day, a diurnal measure comprising the mean average of three measures throughout the day (8:00am, 10:00am, and 4:00pm) was used to measure IOP across all study arms at all tested intervals.

2 Okeke CO, Quigley HA, Jampel HD, et al. Ophthalmology. 2009;116:191–9

Next step for Eye-D VS-101 could be larger Phase IIb study

BioLight indicates the next step for VS-101 development will likely be a larger Phase IIb study using as a base, the identified preferred dose found in the now-completed Phase I/IIa study. It may also entertain partnership considerations. If the next study is successful, the firm plans a pivotal Phase III under the 505(b)(2) regulatory pathway. Under 505(b)(2), the applicant may rely on much of the existing data already established on latanoprost, and hence the pivotal study would likely be shorter and less costly than what would be required for a new drug application (NDA) or premarket approval (PMA). Our model continues to assume a 505(b)(2) pathway, with BioLight spending c $8m on VS-101 R&D across 2017 and 2018, before partnering the product prior to starting a Phase III study (funded by the partner) in late 2018.

Competition emerging in continuous-dose glaucoma market

While the early VS-101 Phase I/IIa data appears potentially promising, there are emerging competitive products under development for extended-dose glaucoma treatment. Many extended-dose PGA-drug eluting platforms are in development, and several are at more advanced stages than Eye-D VS-101 and may reach the market more quickly.

Exhibit 1: Selected extended-dose glaucoma treatment platforms under development

Product	Company	Stage or status	Description	Notes
Bimatoprost SR	Allergan plc	Phase III underway	Biodegradable, intracameral (injection into anterior chamber angle) implant providing gradual release of bimatoprost (a PGA)	In Phase I/II study (n=75), a single administration maintained IOP reduction in 92% of patients at 4 months, and 71% at 6 months, with favourable efficacy and safety
ENV515 (travoprost XR)	Envisia Therapeutics	Phase II underway	Biodegradable proprietary nanoparticle formulation of PGA travoprost, injected into anterior chamber, aiming for lower IOP for up to 6 months per dose	Interim 11-month analysis of first Phase II study cohort showed sustained IOP reduction of 25% vs baseline and favourable safety, dose escalation phase of trial is underway
Helios insert	ForSight Vision5	Phase II	Non-invasive ring that rests on ocular surface (under the eyelids) and slowly releases approved PGA (bimatoprost) over several months, to lower IOP	Non-invasive nature of device a potential differentiator vs most other extended-dose products; Phase III study planned in H217; 130-pt Phase II study showed mean IOP reduction of 4-6mmHg at 12 weeks, and sustained reduction at 6 months
iDose	Glaukos	Phase II	Implant that is injected and secured in the anterior chamber, and designed to provide a sustained release of a PGA (travoprost) to lower IOP	US Phase II study (n=150) recruitment completed May 2017, with data expected H217
L-PPDS	Mati Therapeutics	Phase II	Punctal plug (placed in nasolacrymal duct) that slowly elutes PGA drug latanoprost	120-pt Phase II study assessing effect on IOP at 12-wks (NCT02014142)
OTX-TP	Ocular Therapeutix	Phase III planned	Depot placed non-invasively into punctum and designed to slowly deliver PGA travoprost onto ocular surface for up to 90 days	First of two planned Phase III studies started in October 2016 (n=550), with IOP changes at weeks 2, 6, and 12 as primary endpoints; second study to start in H217

Source: Edison Investment Research, company reports

Allergan's Bimatoprost SR is in Phase III studies but requires a more invasive injection into the ocular globe (and not simply into conjunctiva, like VS-101); Envisia's ENV515 and Glaukos's iDose similarly use ocular injections. Some competing platforms use more recent approved PGA drugs like travoprost or bimatoprost.

A less invasive extended-dose treatment alternative is the Helios insert (ForSight Vision5, acquired by Allergan in August 2016 for $95m plus milestones), which is a ring that rests on the ocular surface and elutes bimatoprost. This insert is scheduled to enter Phase III trials in H217. Given positive Phase I/IIa data with prolonged IOP reduction and the non-invasive nature of EyeD VS-101 instillation, one could start to compare the Eye-D VS-101 programme's stage and status with that of the Helios programme at the time of its purchase by Allergan. The $95m price tag paid by Allergan is decidedly above BioLight's current market capitalisation, although we highlight that the Helios insert had considerably more human data (251 human patients treated across three clinical studies) at the time of the Allergan deal.

Products inserted into the punctum (also relatively non-invasive) are Mati's L-PPDs and Ocular Therapeutix's OTX-TP. Ultimately, the success of VS-101 will depend on its competitive profile in terms of IOP-lowering and ease of application, and patient comfort compared to alternatives.

Financials

BioLight's shareholder rights offering (described in our 19 June 2017 update note) was subscribed at a 96% level, which led to the sale of 1.028m new shares at NIS11.20 per share, and gross proceeds of NIS11.5m. The offering increased BioLight's shares outstanding by 39%. The completion of the rights offering helped fulfil the firm's imminent need to raise additional funds, as although BioLight finished Q117 with NIS20.2m in net cash (NIS19.8m cash and equivalents and NIS0.4m in short-term deposits), NIS12.5m was held at IOPtima and NIS3.1m was held at its other subsidiaries (including Micromedic). Hence, the parent company (BioLight) only had c NIS4.7m in net cash available at Q117.

Given our forecast Q217 operating cash burn rate of NIS4.3m and the NIS11.5m rights offering, we estimate BioLight, including all subsidiaries, had an end-H117 net cash position of NIS27.2m. However, we assume that no inter-company transfers took place since Q117 (and that the c NIS15.6m held by subsidiaries in Q117 would not be directly available to the parent company), and that the parent company (BioLight) would have NIS11.6m net cash available in H117. We assume this would be sufficient for BioLight to fund its operations into Q417.

This runway could potentially also be sufficient to allow for the closing or finalisation of the IOPtima sale to Chengdu, described in our 2 May 2017 research note. The currently proposed terms of this transaction (term sheet) value IOPtima in its current form (pre-closing) at above $30m (given that the first step of the proposed transaction involves a $7m investment into IOPtima for a 19% stake in the company). Hence, if the deal is finalised, there may be a positive upward response to BioLight's share price, given that its entire market capitalisation and enterprise value at present are lower than the implied valuation of BioLight's IOPtima stake (70%) under the terms applied to the current term sheet offer. Hence, we believe that the company would be justified in anticipating an uplift in its share price in the near future (upon a conclusion of the IOPtima sale, if it is successful), at which point another financing round may be envisioned.

Following the completion of the rights offering, we now model that BioLight will raise NIS18.0m in H217 (compared to our prior estimate of NIS30.0m for the entire 2017 fiscal year) in debt to sustain its operations and R&D projects. We continue to model that BioLight will raise NIS30.0m in 2018 and NIS25.0m in 2019. For modelling purposes, we assign these financings to long-term debt.

Given the uncertainty as to whether the Chengdu transaction will proceed, we have not adjusted our model or valuation for this potential transaction (our model continues to assume that IOPtima will operate as a separate, BioLight-controlled entity). We continue to assume that IOPtiMate ex-US sales will account for the majority of near-term BioLight revenue, and that R&D and other operating costs will exceed sales growth in the near term. We have not materially changed our G&A and R&D estimates for the remainder of 2017 and for 2018.

Valuation

As we do not include completion of the Chengdu transaction in our forecasts, our BioLight valuation continues to include the prospects for IOPtiMate, Eye-D VS-101 and TeaRx. We apply a risk-adjusted net present value (rNPV) model with a 12.5% cost of capital. For each of these projects, we provide a weighted rNPV based on BioLight's ownership of the associated subsidiary 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 remains the largest potential source of revenue for the company, and following the Phase I/IIa data, we have raised our probability of success estimate to 30% (from 20% previously). After rolling forward our forecasts and adjusting forex assumptions (and the public market value of held Micromedic shares), we now obtain an rNPV of NIS121.6-135.7m (up from NIS92.9-103.4m, previously).

Exhibit 2: BioLight Life Sciences 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	94.2	25.92	70.0%	2015	$21.4 in 2023
IOPtiMate in US Market (70% weighted)	Glaucoma	25.2	6.94	40.0%	2021	$22.6 in 2026
VS-101 (97% weighted)	Glaucoma	124.1	34.15	30.0%	2020	$69.8 in 2026
TeaRx (80% weighted)	DES diagnosis	26.5	7.30	50.0%	2017	$19.8 in 2025
Corporate costs & expenses						
SG&A expenses		(57.8)	(15.90)			
Net capex, NWC & taxes		(92.4)	(25.41)			
Value of Micromedic shares (MCTC, TASE)*		5.0	1.38			
Total rNPV		**125.0**	**34.39**			
Net cash (debt) (H117e)		27.2	7.49			
Total equity value**		**152.2**	**41.88**			
FD shares outstanding (000) (H117e)		3,634				

Source: Edison Investment Research. Note: *5.29m shares held with 1 August 2017 price of NIS0.946 per share. **Excludes the impact from any dilution resulting from any future equity offerings.

Exhibit 3: Financial summary

NIS000s	2014	2015	2016	2017e	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	941	1,391	2,111	4,877	11,255	23,260
Cost of Sales	(538)	(734)	(996)	(2,288)	(5,065)	(10,467)
Sales, General & Administrative	(8,529)	(11,956)	(10,360)	(9,328)	(9,573)	(12,193)
Research & Development	(18,560)	(13,045)	(10,982)	(17,794)	(27,800)	(21,800)
EBITDA	(26,686)	(24,344)	(20,227)	(24,533)	(31,182)	(21,200)
Depreciation	(3,884)	(1,306)	(3,190)	(1,616)	(2,400)	(2,400)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(30,570)	(25,650)	(23,417)	(26,149)	(33,582)	(23,600)
Exceptionals	(5,886)	(2,475)	(7,357)	241	0	0
Other	0	0	0	0	0	0
Operating Profit	(36,456)	(28,125)	(30,774)	(25,908)	(33,582)	(23,600)
Net Interest	448	543	(2,836)	(874)	(123)	(757)
Profit Before Tax (norm)	(30,122)	(25,107)	(26,253)	(27,023)	(33,706)	(24,357)
Profit Before Tax (FRS 3)	(36,008)	(27,582)	(33,610)	(26,782)	(33,706)	(24,357)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(17,216)	(16,784)	(14,467)	(23,392)	(31,352)	(23,830)
Profit After Tax and minority interests (FRS 3)	(23,102)	(19,259)	(21,824)	(23,151)	(31,352)	(23,830)
Average Number of Shares Outstanding (m)	1.9	2.4	2.6	3.4	3.6	3.6
EPS - normalised (NIS)	(8.91)	(6.96)	(5.55)	(6.93)	(8.63)	(6.56)
EPS - normalised and fully diluted (NIS)	(8.91)	(6.96)	(5.55)	(6.93)	(8.63)	(6.56)
EPS - (IFRS) (NIS)	(11.96)	(7.98)	(8.37)	(6.85)	(8.63)	(6.56)
Dividend per share (NIS)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	8,002	9,832	5,282	7,953	13,792	17,792
Intangible Assets	7,106	6,869	3,910	3,910	3,910	3,910
Tangible Assets	896	2,963	1,372	4,043	9,882	13,882
Current Assets	32,432	53,439	30,031	31,838	20,095	18,115
Short-term investments	6,408	385	417	381	381	0
Cash	22,196	50,697	25,057	26,542	12,064	5,059
Working Cap./other	3,828	2,357	4,557	4,915	7,650	13,056
Current Liabilities	(6,552)	(6,605)	(6,988)	(5,460)	(908)	(1,759)
Creditors	(6,552)	(6,605)	(6,988)	(5,460)	(908)	(1,759)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(8,144)	(9,605)	(11,915)	(29,617)	(59,617)	(84,617)
Long term borrowings	0	0	0	(18,000)	(48,000)	(73,000)
Other long term liabilities	(8,144)	(9,605)	(11,915)	(11,617)	(11,617)	(11,617)
Net Assets	25,738	47,061	16,410	4,714	(26,638)	(50,468)
CASH FLOW						
Operating Cash Flow	(27,435)	(24,580)	(24,106)	(24,857)	(36,115)	(24,847)
Net Interest	448	543	(2,836)	(874)	(123)	(757)
Tax	0	0	0	0	0	0
Capex	(402)	(182)	(370)	(4,386)	(8,239)	(6,400)
Acquisitions/disposals	0	(837)	(227)	0	0	0
Financing	38,374	47,320	2,554	11,510	0	0
Net Cash Flow	10,985	22,264	(24,985)	(18,606)	(44,478)	(32,004)
Opening net debt/(cash)	(17,901)	(28,604)	(51,082)	(25,474)	(8,923)	35,555
HP finance leases initiated	0	0	0	0	0	0
Other	(282)	214	(623)	2,055	0	0
Closing net debt/(cash)	(28,604)	(51,082)	(25,474)	(8,923)	35,555	67,560

Source: BioLight Life Sciences reports, Edison Investment Research. Note: The reported financial results consolidate Micromedic's financials, and forecast financial results (2017e and beyond) do not include Micromedic operations.

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