

BioLight Life Sciences

Potential sale of IOptima to a Chinese firm

BioLight's IOptima subsidiary (of which BioLight holds a 70% ownership stake) signed a non-binding term sheet on 19 April 2017 for it to be acquired by a Chinese company, Chengdu Kanghong Pharma. While there is uncertainty on whether the deal will proceed, the transaction could potentially provide IOptima shareholders with \$17m (NIS62m) within six months of completion. Our model, which does not yet include this proposed transaction, derives an rNPV valuation of NIS98.5-106.9m.

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	5.4	(24.8)	(9.35)	0.0	N/A	N/A
12/18e	11.5	(33.6)	(12.00)	0.0	N/A	N/A

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

Multi-step transaction could provide liquidity

The proposed transaction is arranged in several tranches, whereby, on signing, initially Chengdu would invest \$7m in IOptima for a 19% stake in the company, and then within six months gain exclusive Chinese distribution rights to the IOptiMate glaucoma laser treatment system. Six months after signing, Chengdu would acquire additional IOptima shares from the existing shareholders, raising its stake to 60%, for \$17.2m. This amount will be allocated to IOptima shareholders on a pro rata basis according to the preferences assigned to different classes of IOptima shares, and hence the potential allocation to BioLight has not yet been disclosed. In two further stages, scheduled for 2019 and 2021, Chengdu would acquire the remaining IOptima shares, with pricing dependent on its profitability.

BioLight in need of funding by mid-2017

BioLight finished 2016 with NIS25.5m in net cash (NIS25.1m cash and equivalents and NIS0.4m in short-term deposits), but most of this (NIS16.3m) is held at IOptima. With NIS1.6m held at its other subsidiaries, the parent company (BioLight) had c NIS7.1m in YE16 net cash. Even if the IOptima sale moves ahead, we estimate that, given the timing of transaction proceeds, BioLight may still require additional financing by mid-2017 to continue development of its remaining key programmes, namely Eye-D VS-101 and TeaRx.

Valuation: Risk-adjusted NPV of NIS98.5-106.9m

After pushing back our US IOptiMate and TeaRx revenue timing forecasts by approximately one year each, and rolling forward our forecasts (for all products, including Eye-D VS-101), we now obtain an rNPV of NIS98.5-106.9m (up from NIS90.5-104.2m, previously). Our model does not yet include the proposed IOptima sale transaction. Our base case model forecasts that BioLight will need to raise NIS30m in both 2017 and 2018 to maintain its operations and development strategy. For modelling purposes, we assign these financings to long-term debt.

Sale of subsidiary

Pharma & biotech

30 April 2017

Price **NIS12.39**

Market cap **NIS32m**

*Priced as at 25 April 2017

NIS3.67/US\$

Net cash (NISm) at 31 December 2016 25.5

Shares in issue 2.6m

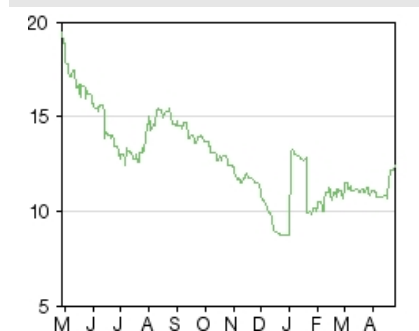
Free float 45%

Code BOLT

Primary exchange TASE

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 10.5 26.5 (31.5)

Rel (local) 9.6 24.6 (30.6)

52-week high/low NIS19.4 NIS8.7

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

Company decision on IOptiMate regulatory strategy 2017

Eye-D VS-101 Phase I/IIa data H217

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BioLight intends to sell IOPTima stake to a Chinese firm

Following the suspension of [a privatisation attempt](#) by an unnamed Chinese investor and with an imminent funding need (by Q217), BioLight has sought potential transactions to raise funds. On 19 April 2017, its IOPTima subsidiary (of which BioLight holds a 70% ownership stake) signed a non-binding term sheet, which calls for it to be sold to a Chinese company, Chengdu Kanghong Pharma. The proposed transaction is arranged in several tranches, whereby, on signing, initially Chengdu would invest \$7m in IOPTima for a 19% stake in the company, and within six months gain exclusive distribution rights to IOPTima's main product, the IOPTiMate¹ glaucoma laser treatment system, in China (currently the product's largest market). Six months after the initial \$7m investment, Chengdu would acquire additional shares in IOPTima from the existing shareholders for \$17.2m (about NIS62m), thereby raising its stake to 60% (this would value IOPTima at about \$42m at that point). This amount will be allocated to IOPTima shareholders on a pro rata basis and according to the preferences assigned to different classes of IOPTima shares. While BioLight owns 70% of IOPTima equity, the different IOPTima share classes and their assigned preferences have not been disclosed, and hence the potential allocation to BioLight (of this \$17.2m payment) has not yet been disclosed.

In two further stages, scheduled for 2019 and 2021, respectively, Chengdu would acquire the remaining shares in IOPTima (acquiring 20% in each stage) using a pricing formula dependent on IOPTima's profitability (and that is calculated separately for each stage), and that can reflect an IOPTima valuation of between \$40.5m to \$56.25m.

However, given the suspension of the prior BioLight privatisation attempt due to Chinese regulatory restrictions on foreign investments, there remains moderate uncertainty on whether the Chengdu IOPTima sale will proceed as planned.

BioLight finished 2016 with NIS25.5m in net cash (NIS25.1m cash and equivalents and NIS0.4m in short-term deposits), but most of this (NIS16.3m) is held at the IOPTima subsidiary. With NIS1.6m held at its other subsidiaries, the parent company (BioLight) has c NIS7.1m in net cash available. As BioLight does not intend to invoke a fund transfer from its subsidiaries, BioLight signalled, prior to the Chengdu announcement, that it would need to obtain additional funding in Q217 to fund its operations. If the IOPTima sale proceeds, BioLight would, within six months of closing, obtain some of the proceeds from the sale (although the exact amounts are currently unknown due to the differing share classes and preferences). Hence, it is currently unclear how much of the funding needed to advance BioLight's remaining ophthalmic projects, primarily EyeD VS-101 (to provide controlled drug release to glaucoma patients), and TeaRx (a multi-parameter dry eye syndrome [DES] diagnostic test), will be generated from this transaction step. We expect that if this sale moves ahead and once the six-month milestone is reached, BioLight will provide details on the IOPTima share class allocations and on its expected proceeds from the \$17.2m payment from Chengdu.

Nonetheless, given that Chengdu's initial \$7m investment would go into IOPTima, and not the existing investors (namely BioLight), we estimate BioLight may still require some additional financing by mid-2017, even if the acquisition proceeds (due to the timing scenarios involved for the planned payments to existing IOPTima shareholders including BioLight).

¹ IOPTiMate is a proprietary carbon-dioxide laser-assisted sclerectomy (CLASS) device for treating glaucoma.

IOPtima concentrating on Asian market

IOPtima (BioLight) had been focusing on IOPtiMate sales primarily to Asia and China, and then to parts of Europe (France, Germany, certain Eastern European countries), and Latin America. In 2016, BioLight reported NIS2.1m in sales revenue, substantially all of which was derived from IOPtiMate sales, versus our estimate of NIS2.3m. BioLight has not publicised specific geographic breakdowns of IOPtiMate sales, but we believe the majority of sales to date have been in Asia. However, even prior to the Chengdu announcement, BioLight had indicated that it was considering changing the product's distributor in China.

For the US market, our model continues to assume that the FDA will require a Class III premarket approval (PMA) pathway for commercial registration, which would expand the scale of clinical studies required (vs a Class II pathway) and increase associated costs. US pivotal PMA study sizes of around 500 patients or more are common for glaucoma surgical devices. We assume that a 500-patient PMA-enabling study will start in H118 (versus our prior forecast of H117), costing about \$8m, and could lead to US clearance and launch in early 2021 (from 2020, previously).

TeaRx service contract helps validate the platform

DiagnosTear, one of BioLight's subsidiaries (with an 82% ownership interest), signed a services agreement in February 2017 with an undisclosed pharmaceutical company, whereby DiagnosTear will provide analysis services using the TeaRx multi-parameter diagnostic assays as part of a clinical trial for DES. This reflects the first time that TeaRx will be employed as part of a clinical trial, and BioLight indicates this contract agreement should provide revenue in the hundreds of thousands of Israeli shekels range, and a positive gross margin, over the term of the services agreement (likely to be within 12 months).

As DES is a multifactorial, chronic condition with different potential causes and contributors,² which can possibly be identified through measuring different biomarkers, one of the key objectives is for the TeaRx multi-parameter assay to differentiate sub populations of responders and non-responders to the proposed DES drug treatment. Should the study show that TeaRx is effective at differentiating between responders and non-responders, the parties may extend their collaboration in a subsequent stage to enter a joint-development project of a potential companion diagnostics solution or test.

TeaRx US clinical programme pushed back into 2018

As reported in our initiation report, BioLight previously conducted two US clinical studies comparing TeaRx's composite DES diagnostic measure with a composite of four established legacy DES assessment tests. The studies showed a strong positive correlation between TeaRx and the four applied tools, but the company will need to complete another US study prior to obtaining FDA 510(k) regulatory clearance. BioLight management indicates that it has received agreement from the FDA on the proposed protocol for this study, but it plans to delay the start of this study into Q118, which pushes back the potential US launch for TeaRx as a diagnostic tool into H218. We had previously modelled, in accordance with management's prior guidance, that a US launch could occur in H217.

Our timeline forecasts for Eye-D VS-101, an in-office insertable product that provides the controlled release of latanoprost, are largely unchanged. BioLight announced on 26 April 2017 that the last

² DES has been associated with inflammatory factors affecting aqueous tear production, inflammatory factors affecting the regulation of meibomian gland function, obstruction of the meibomian and accessory tear glands, medication interactions, mechanical or radiation injury to the cornea or ocular adnexa, autoimmune diseases and other factors.

patient in the ongoing Phase I/IIa study of Eye-D VS-101 has completed his treatment, and it expects to provide results in H217. If Eye-D VS-101 results are positive, the company then plans to complete a larger scale Phase IIb trial and then a pivotal Phase III under the 505(b)(2) regulatory pathway. BioLight intends to partner VS-101 with a major ophthalmic biopharma firm prior to starting pivotal studies. 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.

Micromedic subsidiary advancing bladder cancer diagnostic

BioLight owns 5.29m shares of Micromedic (MCTC, TASE), or about 34% of current shares outstanding. Micromedic is an Israel-based firm developing proprietary diagnostic tests for cancer detection, using its histochemical staining platform (termed CellDetect), which is designed to facilitate the differentiation between cancer cells and normal cells. CellDetect is based on combining the effects of a proprietary plant extract and generic dyes. Micromedic's initial diagnostic product is being advanced for bladder cancer, and has received CE mark approval in Europe.

Bladder cancer affects mostly males, particularly those above age 55 (median age of diagnosis is 73). The National Cancer Institute (NCI) estimates that there are nearly 700,000 people living with the condition in the US, with over 79,000 new US cases per year and almost 17,000 deaths. Bladder cancer is conventionally diagnosed with cystoscopy (where a thin camera-mounted tube is inserted into the bladder under anaesthesia). According to the American Cancer Society (ACS), about 85% of bladder cancers are detected when the cancer is confined only to the bladder (ie before having spread to other tissues), with five-year survival rates of 96% (when it is in-situ, or only in the inner layer of bladder wall) or 70.1% (when it has invaded into deeper bladder cell layers). Bladder cancers that have spread beyond the bladder can have five-year survival rates as low as 15% (per ACS). Hence, early detection is critical. Further, as regression and recurrences can often occur, treated patients are generally monitored every three to six months for at least three years post-treatment (and once yearly thereafter). Cystoscopy is an invasive test, and less invasive urine sample analysis methods are not sensitive enough to reliably detect low-grade tumours.

CellDetect platform may provide non-invasive urine analysis for bladder cancer

Micromedic believes that its CellDetect platform could potentially provide a less invasive approach to bladder cancer diagnosis, using urine test samples and proprietary dye testing methods that can provide high enough cancer cell specificity and sensitivity, particularly for early stage tumours, in under 30 minutes. The firm reported a blinded study across nine centres in Israel (121 healthy subjects and 96 patients with bladder cancer), where the sensitivity was 84.4% and specificity was 82.7%. The results also indicated that the urine test's negative predictive value (NPV), defined as the probability of a false-negative result, was 98.5%.

While the product has CE mark approval in Europe, management believes the largest commercial opportunity will be in the US, with pricing that can be double that of average EU pricing (the current approved bladder cancer product is sold at an approximate price of \$20-30 per test).

Micromedic is also undertaking a 100-patient study in Israel on a CellDetect-based diagnostic product for prostate cancer, but does not expect commercialisation in this indication for at least several years.

Micromedic hired a new CEO, Guy Lerner, in H216, who has raised the firm's emphasis on commercialising the bladder-cancer based product, and is attempting a parallel commercialisation

process for the US market. In addition to seeking conventional product approval through 510(k) clearance process (which may require additional studies), the new management team is also seeking to sell the product directly to specific US CLIA (Clinical Laboratory Improvement Amendments) certified laboratories, which would be permitted to use the product on human test specimens without requiring additional medical device (eg 510(k) or PMA) approvals. While Micromedic sales to date have been sparse (NIS0.03m in 2016), the company expects meaningfully higher revenue and sales in 2017, given in part the initiative to target existing US CLIA laboratories.

Recent Micromedic equity raise provides funding into 2018

Micromedic also raised NIS3.5m (c \$1m) in a February 2017 equity offering of 4.4m shares, and 2.2m warrants (exercisable at NIS0.94 per warrant and expiring in August 2017). Given its year-end 2016 cash position of NIS1.0m, we estimate that the firm now has sufficient resources to fund operations into Q417 and potentially into 2018. The company indicated the offering had sufficient investor demand for potentially up to NIS5.6m, but opted to cap the offer size at NIS3.5m.

Prior to the NIS3.5m financing, BioLight held 48% of Micromedic's outstanding shares, and as it did not participate in this offering, it now owns 34% of outstanding shares. However, BioLight plans to continue to consolidate Micromedic's financials into its own operating results, as it has "effective control" of Micromedic (it is by far the single largest Micromedic shareholder, its chairman and chief financial officer hold similar roles at Micromedic and its chief executive officer is Micromedic's vice chairman). Micromedic now has 15.37m shares outstanding.

2016 results largely in line with forecasts

BioLight recently reported 2016 financial results, with revenue of NIS2.1m, an EBITDA loss of NIS20.2m and an adjusted net loss per share of NIS5.55. These compare to our 2016 estimates of NIS2.3m, NIS22.5m and NIS5.98, respectively. The bulk of company revenue (c 99%) reflects IOPTiMate sales to customers in ex-US markets. The adjusted net loss calculation excludes NIS7.0m in other/non-specified expenses and a NIS0.4m expense item relating to the company's share of losses of an affiliate accounted for at equity. Including these amounts, the reported IFRS net loss to equity holders was NIS8.37 per share. Both these net loss figures (IFRS reported and adjusted) also remove NIS11.8m of loss reflecting the non-controlling interest attributed to the Micromedic subsidiary (BioLight owned 48% of the outstanding shares of Micromedic at year-end 2016, but now owns 34%). The total reported 2016 net loss, including the Micromedic non-controlling interest, was NIS33.6m. Our model and financial forecasts do not include projections or considerations for Micromedic.

Financials

The 2016 operating cash burn rate was NIS24.1m (excluding NIS2.8m in net interest costs). At YE16, BioLight held NIS25.5m in net cash (NIS25.1m cash and equivalents and NIS0.4m in short-term deposits), but most of this (NIS16.3m) is held at the IOPTiMate subsidiary. With NIS1.6m held at its other subsidiaries, the parent company (BioLight) has c NIS7.1m in net cash available. As BioLight does not intend to invoke a fund transfer from its subsidiaries, BioLight signalled, prior to the Chengdu announcement, that it would need to obtain additional funding in Q217 to fund its operations and development projects. We continue to model that BioLight will need to raise NIS30.0m in both 2017 and 2018 to sustain its operations and R&D projects. We also assume a NIS25.0m raise 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 IOPTiMate

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 revenue, and that R&D and other operating costs will exceed sales growth in the near term. We have deferred some of our R&D expenditure forecasts, given our assumption that the TeaRx and US IOPTiMate studies will start approximately one year later than previously anticipated. We project R&D costs of NIS18.4m in 2017 and NIS27.8m in 2018, versus our prior forecasts of NIS27.6m, and NIS25.2m, respectively.

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 in 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 our 20% probability of success estimate reflects its early clinical development stage.

Exhibit 1: BioLight's upcoming catalysts

Event	Timing
Guidance from FDA on regulatory pathway for IOPTiMate	2017
VS-101 Phase I/IIa data	Mid-2017
TeaRx 510(k) clearance and US launch	H218

Source: BioLight Life Sciences reports

We have pushed back our US IOPTiMate and TeaRx revenue timing forecasts by approximately one year each, and have rolled forward our forecasts (for all products, including Eye-D VS-101). Given these changes we now obtain an rNPV of NIS98.5-106.9m (up from NIS90.5-104.2m, 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	36.13	70.0%	2015	\$21.4m in 2023
IOPTiMate in US Market (70% weighted)	Glaucoma	25.4	9.74	40.0%	2021	\$22.6m in 2026
Eye-D VS-101 (97% weighted)	Glaucoma	82.5	31.63	20.0%	2020	\$69.8m in 2026
TeaRx (82% weighted)	DES diagnosis	26.5	10.17	50.0%	2018	\$19.8m in 2025
Corporate costs & expenses						
SG&A expenses		(55.0)	(21.10)			
Net capex, NWC & taxes		(78.1)	(29.97)			
Value of Micromedic shares (MCTC, TASE)*		4.8	1.85			
Total rNPV		100.2	38.45			
Net cash (debt) (Q416)		25.5	9.77			
Total equity value**		125.7	48.22			
FD shares outstanding (000s) (Q416)		2,607				

Source: Edison Investment Research. Note: *5.29m shares held with 19 April 2017 price of NIS0.91 per share. **Excludes the impacts 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	5,449	11,532	23,833
Cost of Sales		(538)	(734)	(996)	(2,452)	(5,189)	(10,725)
Sales, General & Administrative		(8,529)	(11,956)	(10,360)	(8,060)	(9,486)	(12,162)
Research & Development		(18,560)	(13,045)	(10,982)	(18,400)	(27,800)	(21,800)
EBITDA		(26,686)	(24,344)	(20,227)	(23,463)	(30,943)	(20,854)
Depreciation		(3,884)	(1,306)	(3,190)	(1,622)	(2,400)	(2,400)
Amortization		0	0	0	0	0	0
Operating Profit (before exceptionals)		(30,570)	(25,650)	(23,417)	(25,085)	(33,343)	(23,254)
Exceptionals		(5,886)	(2,475)	(7,357)	0	0	0
Other		0	0	0	0	0	0
Operating Profit		(36,456)	(28,125)	(30,774)	(25,085)	(33,343)	(23,254)
Net Interest		448	543	(2,836)	288	(261)	(890)
Profit Before Tax (norm)		(30,122)	(25,107)	(26,253)	(24,797)	(33,605)	(24,143)
Profit Before Tax (FRS 3)		(36,008)	(27,582)	(33,610)	(24,797)	(33,605)	(24,143)
Tax		0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(17,216)	(16,784)	(14,467)	(24,379)	(31,280)	(23,674)
Profit After Tax and minority interests (FRS 3)		(23,102)	(19,259)	(21,824)	(24,379)	(31,280)	(23,674)
Average Number of Shares Outstanding (m)		1.9	2.4	2.6	2.6	2.6	2.6
EPS - normalised (NIS)		(8.91)	(6.96)	(5.55)	(9.35)	(12.00)	(9.08)
EPS - normalised and fully diluted (NIS)		(8.91)	(6.96)	(5.55)	(9.35)	(12.00)	(9.08)
EPS - (IFRS) (NIS)		(11.96)	(7.98)	(8.37)	(9.35)	(12.00)	(9.08)
Dividend per share (NIS)		0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed and non-current assets		8,002	9,832	5,282	8,092	13,982	17,982
Intangible Assets		7,106	6,869	3,910	3,910	3,910	3,910
Tangible Assets		896	2,963	1,372	4,182	10,072	14,072
Current Assets		32,432	53,439	30,031	32,842	19,614	17,812
Short-term investments		6,408	385	417	417	417	0
Cash		22,196	50,697	25,057	30,098	14,529	8,355
Other		3,828	2,357	4,557	2,327	4,668	9,457
Current Liabilities		(6,552)	(6,605)	(6,988)	(6,988)	(931)	(1,802)
Creditors		(6,552)	(6,605)	(6,988)	(6,988)	(931)	(1,802)
Short term borrowings		0	0	0	0	0	0
Long Term Liabilities		(8,144)	(9,605)	(11,915)	(41,915)	(71,915)	(96,915)
Long term borrowings		0	0	0	(30,000)	(60,000)	(85,000)
Other long term liabilities		(8,144)	(9,605)	(11,915)	(11,915)	(11,915)	(11,915)
Net Assets		25,738	47,061	16,410	(7,969)	(39,249)	(62,923)
CASH FLOW							
Operating Cash Flow		(27,435)	(24,580)	(24,106)	(20,815)	(37,017)	(23,884)
Net Interest		448	543	(2,836)	288	(261)	(890)
Tax		0	0	0	0	0	0
Capex		(402)	(182)	(370)	(4,432)	(8,290)	(6,400)
Acquisitions/disposals		0	(837)	(227)	0	0	0
Financing		38,374	47,320	2,554	0	0	0
Net Cash Flow		10,985	22,264	(24,985)	(24,959)	(45,569)	(31,174)
Opening net debt/(cash)		(17,901)	(28,604)	(51,082)	(25,474)	(515)	45,054
HP finance leases initiated		0	0	0	0	0	0
Other		(282)	214	(623)	0	0	(0)
Closing net debt/(cash)		(28,604)	(51,082)	(25,474)	(515)	45,054	76,228

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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