EDISON

Brighter

Earnings update

CE marks for Actiste device received

Healthcare equipment & services

Brighter recently announced that it has received CE marking for the Actiste device. In fact, it has received two CE marks as Actiste is regulated under both the EU Medical Devices Directive and the In Vitro Diagnostics Directive due to the multiple functions of the device. Initially, the company will focus on establishing service in the Gulf Cooperation Council (GCC), especially the United Arab Emirates (UAE), Sweden and South-East Asia (in particular Thailand and Indonesia).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	1.4	(22.8)	(0.40)	0.0	N/A	N/A
12/18	1.1	(48.8)	(0.74)	0.0	N/A	N/A
12/19e	0.5	(77.4)	(0.96)	0.0	N/A	N/A
12/20e	24.5	(91.4)	(1.11)	0.0	N/A	N/A

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

Successfully navigating a complex CE mark process

The CE marking for the Actiste device was more complicated than a conventional application as Actiste combines the functionality of multiple other devices: a blood glucose meter, a lancet and an insulin injection apparatus. Because of this it is regulated under both the Medical Devices Directive (MDD) and the In-Vitro Diagnostics directive (IVDD). To further complicate the issue, these regulations are relatively new and are in the process of being rolled out across Europe, increasing the burden on reviewers. These CE marks are a major milestone for the company.

Initial target market is the GCC

Based on International Diabetes Federation (IDF) calculations, the prevalence of adults (aged 20–79 years) with type 2 diabetes (T2D) in the countries of the GCC ranged from 9.9% to 17.6% in 2015. Also, there are a disproportionate number of disease-related complications in the region with an estimated 40–70% of worldwide disease-related foot amputations occurring in GCC countries. Beyond the GCC, Brighter plans to focus on South-East Asia (especially Thailand and Indonesia), as well as Sweden.

A different model for Actiste

Actiste is being commercialised via a different model than other diabetes technologies, where the company is offering the product paired with its Benefit Loop service that includes both delivery of consumables as well as cloud-based health data delivery. The basic plan includes data sharing with relatives and caregivers, while the extensive plan includes physician networks.

Valuation: SEK1,174m or SEK13.69 per basic share

Our valuation has increased to SEK1,174m from SEK1,099m, although it is slightly lower on a per share basis (SEK13.69 from SEK13.85). The increase is driven by lower net debt (SEK1.6m vs SEK21.5m) and rolling forward our NPVs.

5 September 2019

Price	**SEK13.12**
Market cap	**SEK1124m**
	US$0.10/SEK
Net debt (SEKm) at 30 June 2019 + subsequent raises	1.6
Shares in issue	85.7m
Free float	80.8%
Code	BRIG
Primary exchange	NASDAQ First North
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	15.1	30.9	53.1
Rel (local)	14.4	25.7	52.6
52-week high/low	SEK14.67	SEK7.86	

Business description

Brighter is a Swedish healthtech company focused on the development and commercialisation of self-monitoring and self-treatment health solutions for diabetes. Its lead product, Actiste, combines three critical components of daily diabetes management, a blood glucose meter, a lancet and an injection apparatus into one device with mobile connectivity to Brighter's cloud-based service called the Benefit Loop.

Next events

CE mark decision on Actiste	Upcoming

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Edison profile page

Navigating a complicated regulatory process

In Europe, diagnostic equipment is regulated as medical devices and in vitro diagnostics are regulated as a separate product class, but both are administered through the Conformité Européenne (CE) marking system. A CE mark is an indication that products of certain classes meet the health and safety requirements set forth for that class, and is applied to a wide range of products including those outside of healthcare. CE marks are grated by 'notified bodies' or independent bodies that are nominated for review of these products by member states. The CE marking process is substantially less burdensome than the approval process in the US. Although it is generally easier for a product to enter the market in Europe and the system affords more flexibility, devices and in vitro diagnostics are regulated by a larger number of agencies on both the EU and member state level. However, in 2017 the EU initiated a modernisation and harmonisation process through the passage of the new so-called Medical Device Directive (MDD) and In Vitro Diagnostic directive (IVDD). Member states have until 2020 to become compliant with the MDD and until 2022 for the IVDD. Because Actiste combines the functionality of a glucose meter, lancet and insulin injector, it is regulated under both the MDD and IVDD, which significantly increased the complexity of the review process. It is quite an achievement for Actiste to successfully obtain the necessary CE marks under this regulatory regime.

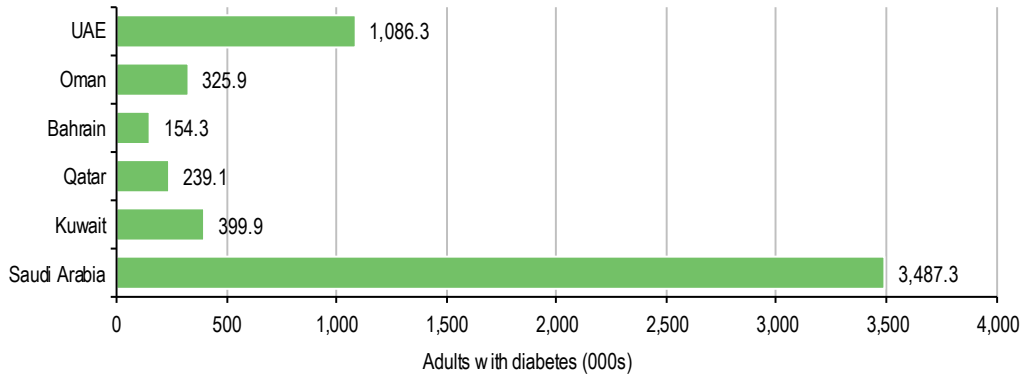
As a reminder, due to the combined functionality of the Actiste device, the company estimates that the number of steps for daily treatment and measurement is reduced by up to 67%. The Actiste device is delivered as part of a subscription-based service that includes different levels of data sharing, continuous replenishment of everyday supplies delivered directly to the home, and digital services designed to facilitate, improve and streamline the treatment.

Brighter's cloud-based platform, called the Benefit Loop, and associated companion applications for IOS and Android were previously CE-marked. Together, the Benefit Loop and its applications collect, manage and analyse data for the purpose of sharing critical treatment information with friends, relatives, caregivers and healthcare providers to improve self-management outcomes.

Top priority markets: GCC and South-East Asia

Following the CE marking, the company plans to initially launch the product in the countries of the Gulf Cooperation Council (GCC). The rapid economic development seen in the GCC region has fuelled growing rates of diabetes and diabetes-related complications. The region has some of the highest rates of the disease in the world, ranging from 9.9% to 17.6% of the population (Exhibit 1) and affecting millions of people. The disease is also typically more poorly controlled in this region than in other countries, and an estimated 40–70% of worldwide disease-related foot amputations occur in GCC countries. This positions Actiste as an attractive solution to increasing compliance and improving patient engagement with healthcare in these countries.

Exhibit 1: Adults with diabetes aged 20–79 in countries of the GCC



Source: IDF Diabetes Atlas, Seventh Edition

Additionally, the company is interested in targeting a selection of countries in South-East Asia (SEA), in particular Thailand and Indonesia. The epidemiology of the disease in this region is similar to the GCC countries in that a population with historically low rates of type 2 diabetes (T2D) is seeing increased rates of the disease as a result of economic development. According to the 2017 IDF Diabetes Atlas, an estimated 9.6% of the SEA population (on an age-adjusted basis) is living with the disease. This is similar to rates seen in Europe for instance. However, complicating this is that historically the disease was rare and under recognised resulting in a general lack of knowledge and almost half (45.8%) of these individuals in the region going undiagnosed. Approximately 55% of those with the disease in this region die before the age of 60.[1] According to one study conducted in SEA, 22% and 36% of patients with T1D and T2D, respectively, have never had HbA1c diagnostic tests.[2]

Valuation

Our valuation has increased to SEK1,174m from SEK1,099m, although it is slightly lower on a per share basis (SEK13.69 from SEK13.85). The increase is due to lower net debt (SEK1.6m vs SEK21.5m) following the Q219 financial results and subsequent share offerings (totalling SEK15.8m). Additionally, we have rolled forward our NPVs, which has increased our valuation.

Exhibit 2: Valuation of Brighter

Program	Market	Probability of success	Launch year	Upper tier launch pricing ($ per month)	Lower tier launch pricing ($ per month)	Peak revenue ($m)	Valuation (SEKm)
Actiste	Nordic region	30%	2019	131.3	71.6	5.5	21.8
	Gulf Cooperation Council countries	30%	2019	112.5	61.4	45.7	178.3
	South East Asia	30%	2019	93.8	51.1	54.7	226.7
	EU	25%	2019	133.9	73.0	243.1	680.0
	US	20%	2021	143.1	78.0	193.1	421.0
Unallocated costs							(152.5)
Total							1,175.2
Net debt (at 30 June 2019 including July capital raises) (SEKm)							(1.6)
Total firm value (SEKm)							1,173.6
Total shares (m)							85.7
Value per basic share (SEK)							13.69

Source: Edison Investment Research

[1] Ramachandran, A. (2012).

[2] Pathan, F., et al. (2018). Hypoglycaemia among Insulin-Treated Patients with Diabetes: Southeast Asia Cohort of IO HAT Study. *Journal of the ASEAN Federation of Endocrine Societies, 33*(1), 28-36

Financials

The company reported a loss of SEK23.7m for Q219. The increase over Q119 (SEK15.8m) is part due to a SEK4.4m write-off that the company recorded because some of its consumables in inventory expired on account of the CE mark delay. Other increased costs include higher external costs (SEK19.1m vs SEK16.6m in Q119), presumably due to CE marking costs and preparations for the commercial launch. We have increased our expected loss for 2019 to SEK77.4m from SEK63.5m to account for these adjustments. The company ended the quarter with SEK23.1m in cash and SEK40.5m in debt following a series of financings during the period. Subsequent to the end of the period, the company raised SEK15.8m in additional capital through direct offerings. We estimate that the company will require SEK20m in additional capital in 2019 in finance operations and SEK70 in capital (up from SEK60m previously) for 2020. We expect these requirements to be met through the company's financing agreement with Winance, worth up to SEK160m (for more details, please refer to our previous note).

Exhibit 3: Financial summary

SEK000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	1,377	1,052	462	24,532
Cost of Sales	0	0	(497)	(4,906)
Gross Profit	1,377	1,052	(35)	19,626
Sales, General and Administrative Expenses	(9,153)	(13,014)	(20,451)	(21,269)
EBITDA	(19,744)	(44,163)	(63,814)	(76,992)
Operating Profit (before amort. and except.)	(19,946)	(44,326)	(63,844)	(77,021)
Intangible Amortisation	0	0	0	0
Other	31,416	24,455	31,274	0
Exceptionals	0	0	0	0
Operating Profit	(19,946)	(44,326)	(63,844)	(77,021)
Net Interest	(2,897)	(4,476)	(13,576)	(14,390)
Other	(4,449)	(4,278)	(583)	0
Profit Before Tax (norm)	(22,843)	(48,802)	(77,420)	(91,412)
Profit Before Tax (FRS 3)	(27,292)	(53,080)	(78,002)	(91,412)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(22,843)	(48,802)	(77,420)	(91,412)
Profit After Tax (FRS 3)	(27,292)	(53,080)	(78,002)	(91,412)
Average Number of Shares Outstanding (m)	68.2	71.7	81.4	82.2
EPS - normalised (ore)	(40.00)	(74.00)	(95.87)	(111.24)
EPS - FRS 3 (SEK)	(0.40)	(0.74)	(0.96)	(1.11)
Dividend per share (ore)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	84,961	112,430	133,029	152,722
Intangible Assets	76,794	102,929	122,527	142,125
Tangible Assets	4,738	8,537	9,537	9,632
Other	3,429	965	965	965
Current Assets	26,393	58,186	64,240	22,169
Stocks	0	7,070	5,171	5,171
Debtors	15,931	34,308	32,727	4,033
Cash	10,017	9,031	20,182	6,805
Other	445	7,777	6,160	6,160
Current Liabilities	(23,965)	(63,698)	(53,496)	(53,496)
Creditors	(15,528)	(11,805)	(13,022)	(13,022)
Short term borrowings	(8,437)	(51,893)	(40,474)	(40,474)
Long Term Liabilities	0	0	(20,000)	(90,000)
Long term borrowings	0	0	(20,000)	(90,000)
Other long term liabilities	0	0	0	0
Net Assets	87,389	106,918	123,773	31,395
CASH FLOW				
Operating Cash Flow	(24,582)	(68,249)	(76,040)	(62,717)
Net Interest	0	0	0	0
Tax	(99)	0	0	0
Capex	(34,852)	(29,986)	(20,619)	(20,660)
Acquisitions/disposals	0	0	0	0
Financing	7,913	34,655	72,444	0
Conversion of convertible debt instruments	43,065	43,065	0	0
Dividends	0	0	(261)	0
Other	(195)	(14,406)	6,804	0
Net Cash Flow	(8,750)	(34,921)	(17,672)	(83,377)
Opening net debt/(cash)	(1,733)	(1,580)	42,862	40,292
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	8,597	(9,521)	20,243	0
Closing net debt/(cash)	(1,580)	42,862	40,292	123,669

Source: Brighter reports, Edison Investment Research.

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