SENSEONICS HOLDINGS INC (NYSE AMERICAN: SENS)
Price: $1.00
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Introduction

Senseonics Holdings Inc. is a relatively new provider of Continuous Glucose Monitors (CGMs) for Type 1 and 2 diabetes. Senseonics offers one product, its Eversense CGM (sold as Eversense XL in Europe) While Senseonics operates in the competitive Continuous Glucose Monitor market, it is the sole provider of a long-term, implantable monitor.

The company's stock is trading near its 52 week low due to its dismal Q3 earnings ($4.3mm actual vs 6.1mm consensus) and management's subsequent shift in guidance for 2019 earnings (from $25-30 million to $20-22million). However, this miss in net revenue is a short term consequence of temporary customer acquisition costs (through the Eversense Bridge Program) and a longer than expected commercialization in the US.

Continuous Glucose Monitors (Eversense)

Eversense updates a patient's phone every 5 minutes with their most current insulin levels.

1. The implantable sensor is inserted by a trained healthcare professional (currently approved for behind the arm in the US). It is a quick procedure, requiring a simple incision and the wound typically heals within a day or two.
2. The patient sticks a removable transmitter using an adhesive, directly over the sensor. This smart transmitter provides on-body vibration and high/low insulin alerts in addition to amplifying the signal and beaming data to the Eversense smartphone application.
3. Every 90 or 180 days, the patient goes to their doctor to get the previous sensor removed and a new one inserted.

Investment Thesis

1. The global CGM market is projected to reach USD $1.3 billion by 2025 growing at a 5-yr CAGR of 15.8%[1], driven by an increase in wearable technology, diabetes and obesity rates, and expansion to new markets (Asia-Pacific).[2]
    a. In the US, CGMs market penetration for Type 1 diabetes was estimated at 31% in 2017 compared to 6% in 2011[3].
        i. TAM = ~27 million people diagnosed with diabetes as of 2015[4].
    b. In Europe, penetration for type 1 diabetics ranges from 5%-30%.[5]
        i. TAM = 60 million people with diabetes.[6]
    c. Global Type 1 Diabetes has risen at consistently at 3% since 1990[7].
        i. TAM = 232 million people are diagnosed with diabetes, but over 463 million people have the disease as of 2019.[8]

2. Senseonics' patented technology, the world's only long-term implantable CGM, offers it a wide array of competitive advantages. It is also the most accurate technology. As the market for CGMs grows, its long-term duration will serve as a key differentiator and allow access to a niche segment.

3. By offering a long-term alternative, Eversense will be able to beat out competitors substantially on unit economics. Eversense has already been given 180 day approval in Europe and will likely get the approval from the FDA to be used in the US. As they extend the duration of their sensors, the costs structure of the business will rapidly change.
    a. Current consumer's price per for Eversense is estimated at $6-7 in the US
    b. As insurance coverage improves and duration of sensor shifts to 180 days, this will correspond to a price per day of Eversense at ~ $3. This is much more attractive than Dexcom's $7-10 cost per day, and much closer to Abbott's $2 cost per day (which has been achieved at the sacrifice of accuracy). The same sensor and procedure's cost will now be spread out over double the amount of time.
    c. Also, due to the high operating leverage of the industry, as the company reaches scale we estimate they will be able to meaningfully reduce the costs of producing Eversense and achieve a gross margin of ~40%.

[1] https://www.marketwatch.com/press-release/158-growth-for-continuous-glucose-monitoring-cgm-market-size-by-2025-global-revenue-to-reach-13259-million-2019-09-04
[2] https://www.alliedmarketresearch.com/global-continuous-glucose-monitoring-systems-market
[3] https://medcitynews.com/2019/06/quick-comparison-of-medtronic-abbott-dexcom-senseonics-cgms-from-ada-2019/
[4] https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html
[5] https://www.meddeviceonline.com/doc/european-diabetes-care-market-shaped-by-innovation-shifting-competitive-landscape-0001
[6] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics
[7] https://jme.bioscientifica.com/view/journals/jme/51/1/R1.xml
[8] https://www.diabetesatlas.org/upload/resources/2019/IDF_Atlas_9th_Edition_2019.pdf

Sector Overview

Continuous Glucose Monitors (CGMs) are quickly becoming the standard care in Type 1 diabetes[9]. CGMs has been proven to improve glycemic control in patient using insulin injections and insulin pumps (majority of Type 1 diabetes)[10]. There is also significant potential growth in the transition to type 2 diabetes care as well.[11] The FDA ranks Senseonics' as most accurate overall, ahead of Dexcom[12].

Business Overview

Senseonics Holdings, Inc. develops Continuous Glucose Monitors (CGMs) for type 1 and 2 diabetes. Founded in 2014 as ASN Technologies Inc., the company was subsequently restructured after the acquisition of Senseonics Inc. Senseonics Inc. was founded in 1996, and had been committed to researching various sensor technologies until 2010, when it shifted focus to commercializing the worlds longest-lasting implantable CGM (Eversense).

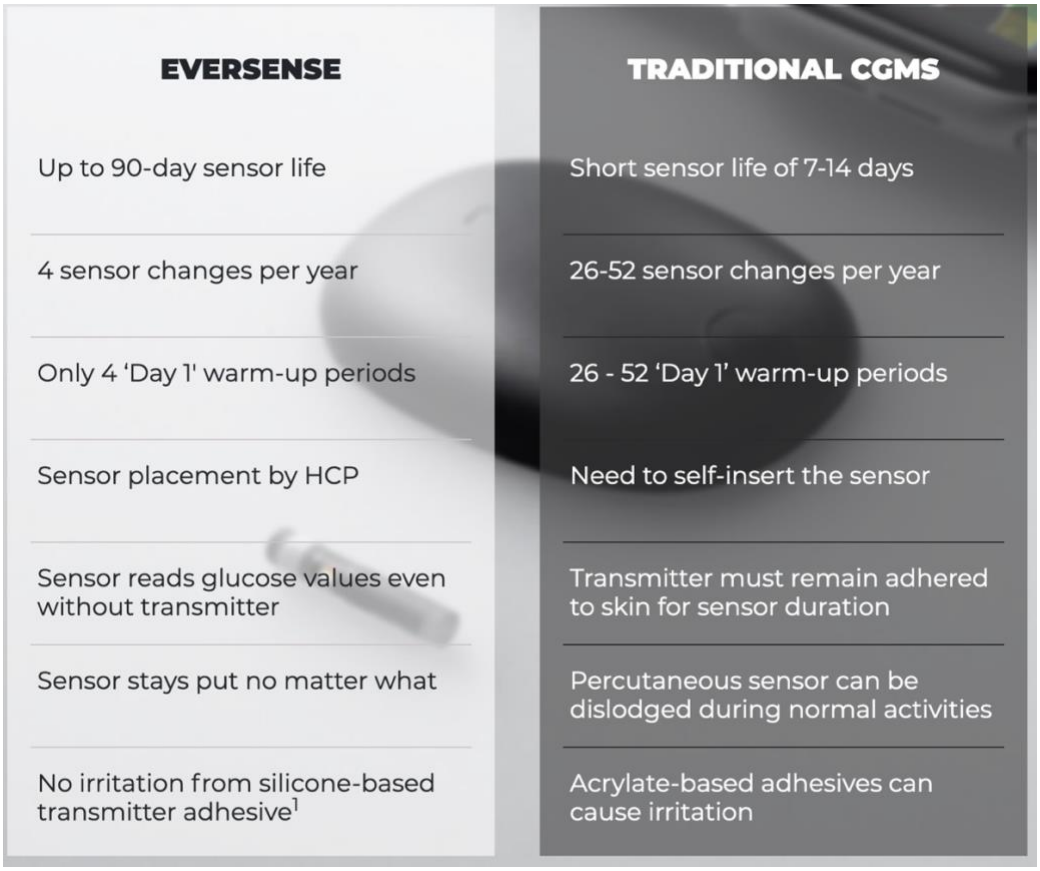
Senseonics sells two variations of the same product, Eversense and Eversense XL. Eversense has regulatory approval for sale in the US and Europe and is a 90 day sensor, while Eversense XL has regulatory approval in Europe and is a 180 day sensor. While there are several competing CGM manufacturers, the duration of these sensors are 6-14 days. Senseonics is the sole provider of a 90 and 180 day sensor.

Revenue is split between US (20%) and Europe (80%). Eversense was launched in Europe first (June 2016), and obtained FDA approval for the US recently (May 2018). I expect this split to lean more towards the US over the next few years, as Eversense establishes a foothold in this market.

Domestically, Senseonics partners with local distributors and also offers the product direct to customers. Internationally, the company has exclusive agreements with Roche Diabetes Care through January 2021 (primarily Europe though recently negotiated to include Asia, Africa, and the Middle-East)[13].

Quarterly revenues tend to reflect a certain level of seasonality, with European distributors typically stocking up on inventory in Q4. Similarly, as US Distributors inventory requirements fluctuate, short term sales of Eversense follow.

[9] https://medcitynews.com/2019/06/quick-comparison-of-medtronic-abbott-dexcom-senseonics-cgms-from-ada-2019/
[10] https://jamanetwork.com/journals/jama/fullarticle/2598770
[11] https://diatribe.org/biggest-news-diabetes-technology-drugs-and-nutrition-highlights-ada-2019
[12] https://medcitynews.com/2019/06/quick-comparison-of-medtronic-abbott-dexcom-senseonics-cgms-from-ada-2019/
[13] https://www.fiercebiotech.com/medtech/roche-senseonics-extend-diabetes-monitor-distribution-deal-to-bric-countries



Competitive Landscape

Currently, there exist four major players in this market. Dexcom, Abbot Laboratories, Senseonics, and Medtronic. Note: Senseonics is *significantly smaller* in market capitalization.

Company	Device Name	Market Cap	FDA Approval (Non-Adjunctive Use)	Sensor Duration	Overall Accuracy (FDA)[14]	Medicare Coverage[15]
Senseonics	Eversense	0.176B	Y	90 Days (US) / 180 Days (EU)	87%	Y
Dexcom	G6	18.571B	Y	10 Days	83%	Y
Abbott	Freestyle Libre	146.255B	Y	14 Days	81%	Y
Medtronics	Guardian 3	148.94B	N	7 Days	79%	Y (Soon)

[14] https://diatribe.org/biggest-news-diabetes-technology-drugs-and-nutrition-highlights-ada-2019
[15] https://www.ptcommunity.com/journal/article/full/2019/9/550/continuous-glucose-monitoring-review-available-systems

Medtronic and Abbott are both large diversified companies, with medical tech accounting for less than 50% of total revenue. Dexcom is another pure play company that only creates CGM monitors, so it is the most similar company in terms of business model. However, Dexcom is already operating on a much larger scale and is profitable.

Pricing War / Size Disadvantage

Senseonics, Dexcom, and Medtronic's products all cost around $5-10 per day. However, Abbott's FreeStyle system was brought to market at approximately ½ the price of its competitors.[16] While the FreeStyle is significantly less accurate, customer research indicates 75% of Dexcom users were willing to switch from the G6 to the FreeStyle, and this was primarily due to the lower price point. Furthermore, R&D budgets of competitors are significantly larger and their ability to commit to drawn out pricing wars is a significant threat.

> *Mitigating Factors:* Senseonics is likely to be approved for 180 days use in the US. While the fixed costs of producing a sensor are quite high, by doubling the duration of use of the sensor from 90 to 180 days, the company is able to meaningfully alter the unit economics (by half). A 180 day approval is extremely plausible because it already exists in Europe. Eversense also dominates a niche segment of the market for CGMs: it is not directly substitutable by another sensor because of its competitive duration.

Competition from Integrated CGM/Pump Systems

Medtronics, a key competitor, has both its Guardian 3 CGM and its Minimed 530G / 630G insulin pump systems. Thus, it is in the best position for vertical integration, especially given the ultimate goal of a seamless system where CGM's are linked to insulin pumps. A majority of diabetics still manually administer their medication, and places with the highest penetration of insulin pumps, such as the United States, only have 20-30% usage rates[17]. Integrated CGM/Pump systems seem to be the ultimate "end goal" in diabetes care. Currently, two companies (Medtronics and Tandem Diabetes Care) have FDA approval for CGM-integrated insulin pumps.[18]

> *Mitigating Factors:* In the next few years, with the CGM market itself so underpenetrated, it is unlikely for integrated systems to be the driving force in a consumer's decision making process. Looking further down the road, while it is definitely easier to integrate CGMs and insulin pumps within a company, that wouldn't stop Eversense from simply partnering with another insulin pump manufacturer. If the end goal really is in creating the "artificial pancreas", Eversense's superior accuracy and duration time actually set it up to be the 'least disruptive' and thus most desirable sensor.

[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4717510/

[17] https://www.endocrinologyadvisor.com/home/decision-support-in-medicine/endocrinology-metabolism/diabetes-and-the-use-of-insulin-pumps/

[18] http://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_SENS_2018.pdf

Expanding Duration/Capabilities from Competing Sensors

Given the size and R&D budgets of competitors, it is extremely plausible that they will seek to expand the duration of their devices in the future. Dexcom is already developing a 14-15 day sensor with Verily called the G7.[19] This new sensor is expected to be significantly smaller and fully disposable, making it significantly more convenient for customers (a key competitive advantage of the Eversense). Abbott has also recently gotten approval for their Libre 2, which will not require daily fingerstick calibrations and makes it significantly more convenient for consumers. As competitors expand the duration and capabilities of their sensors, Senseonic's superior technology and niche segmentation is under threat.

Mitigating Factors: While competitors are definitely making strides in expanding their duration, Eversense is also doing so on a different order of magnitude. Dexcom and Abbott focus on expanding from 14-20 days, and might even aim for 30. Eversense, however, is pipelining a 365 day sensor. These minor improvements to duration by competitors are not a serious threat.

Growth Strategy

Expanding International Presence

Senseonics has been renegotiating contracts with international distributor Roches Diabetes Care to expand the range of countries covered. Recently, they expanded the scope of their contract with Roche to include exclusive rights to key emerging markets (India, China, Russia, Brazil). While the company is focused on US and Europe sales in the near term, expanding its reach to Africa, Asia, and the Middle-East is crucial for long term growth as these markets are predicted to experience the highest growth rates in the CGM market (Asia with a forecasted CAGR of 20-30%)[20].

I expect Senseonics to continue partnering with Roche Diabetes Care. While management expects US sales to capture an increasing share of total revenue in the future, the growth of the business internationally will still be actively managed by maintaining relationships with Roche.

Eversense Bridge Program/ Increases in 3rd party health insurance coverage (government and private coverage

In an effort so speed up widespread adoption of the Eversense device, Sensenoics announced the launch of the Eversense Bridge Program in Q1 2019. This program offers the Eversense CGM to people whose insurance does not cover it at a subsidized price of $99 plus the cost of sensor insertion. The second sensor is also sold at this price, but subsequent sensors are sold at higher prices.[21] While this has temporarily reduced margins, we expect this to be a significant near term driver for Eversense user growth (Bridge program accounted for ~50% of users).

Key to the successful transition from the Bridge Program to full paying customers is the increase in health insurance coverage. As more health insurance providers start to cover

[19] https://diatribe.org/whats-coming-dexcom-2020-low-cost-slimmer-fully-disposable-cgm
[20] https://www.alliedmarketresearch.com/global-continuous-glucose-monitoring-systems-market
[21] https://www.mobihealthnews.com/content/senseonics-launches-program-low-cost-eversense-cgm-systems

Eversense, the company's margins and net revenue will improve. In Q3 2019, Eversense reported approximately 160 million lives now covered under health insurance (well above the anticipated 100 million lives by the end of 2019). The company is also now officially covered by Medicare[22], which is a widely accepted catalyst for future private health insurance coverage. As they continue to pursue more health coverage, I see this as a key driver for US revenue.

Certified Eversense Specialist Network (Prescription Rates and Procedure Ease)

After noting that there are more prescribers of Eversense than people capable of performing the insertion procedure, management has made this program one of its top priorities to driving product penetration in the US. In addition to increasing the number of prescribing endocrinologists, the company is training dermatologists, surgeons, and primary physicians to perform the insertion/removal of Eversense.

Currently 1000 of the 2100 endocrinologists in the US are prescribers of Eversense (doubled from Q2 to Q3 in 2019). This program will be essential in improving prescription rates, which are a key driver for revenue. The program also diversifies the range of people capable of performing the routine surgery, which is essential to sustain a long-term base of customers who will be requiring quarterly insertions/removals.

Competitive Advantages

1. Patented Technology (Moats)
    a. Niche Market: Senseonics' Eversense, the world's *only* long term CGM system, gives it patent-protected access to a niche market. While other systems must be replaced every 10 days, Eversense lasts up to 90 days in the US and is approved for up to 180 days in Europe.[23] the convenience of this technology makes it the most likely to be quickly adopted by consumers switching to CGMs for simpler options.
    b. FDA Approval: Dexcom G6, Abbott's Libre, and Senseonics' Eversense are the only three devices that have FDA approval for non-adjunctive use (meaning they can be used to recommend insulin dosing without the need for separate, fingerstick readings).[24] This is an essential approval to have to any potential new entrant, and can take over a year to be approved.
    c. Customer Experience: Eversense's patent protected sensor is the only one that is surgically inserted into the body and is thus much less troublesome and much more ergonomic.[25] It is administered by a healthcare professional rather than self administered. Diabetics are already visiting their doctor multiple times a year routinely, so it requires no additional trips. A procedure by a healthcare professional is also less risky than having to manually insert the device.

[22] https://www.marketwatch.com/press-release/medicare-establishes-national-payment-rate-for-eversense-cgm-system-2019-11-12
[23] https://www.mobihealthnews.com/content/north-america/senseonics-scores-coveted-non-adjunctive-labeling-claim-eversense-cgm
[24] 2019 https://medcitynews.com/2019/06/quick-comparison-of-medtronic-abbott-dexcom-senseonics-cgms-from-ada-2019/
[25] https://www.eversensediabetes.com/eversense-innovation

d. Accuracy: Eversense is FDA proven to be the most accurate overall sensor. Furthermore, Eversense was proven to be more accurate than Dexcom and Abbott's devices in an ADA study.[26]

2. Unit Economics
    a. Senseonics' unit economics for its Eversense dramatically improve as the duration of the device is extended. 180 day approval is very likely to happen, and this fundamentally halves the cost per day. Currently, estimates puts the cost per day for Eversense to be at around $6-7 in the US. Upon approval of 180 day duration, this cost per day drops to $3 per day, which is significantly more competitive than Dexcom's estimated $7-10 per day cost, and much closer to Abbott's $2 per day cost. Abbott has only been able to achieve this $2 per day cost by sacrificing the accuracy of their product.

Financial Health

As Senseonics is still at a very early stage, it is currently still not profitable. Net Revenue has, however, been growing at a CAGR of 692% from 2015-2018. My forecast of a 261% CAGR from 2015-2021 is higher than the current consensus of 255% due to my view that as the company continues to win insurance coverage in the US, the percentage of its user base on the costly Eversense Bridge Program will reduce, and the company will retain a higher percentage of gross revenue (which is not reported under GAAP, but is indicated by management on earnings calls). In 2019, Management indicates that approximately 50% of Eversense users had some sort of Bridge assistance. I forecast that to decline to 30% by 2020 (conservative) driven by higher then expected growth in insurance coverage (160 million lives vs. expected 100 million).

Furthermore, Gross Margin in 2018 was -44%, and is estimated to remain negative until 2020. However, my forecast for gross margin in 2020 is significantly better than consensus (15% vs. 10%), driven by the higher expectations for net revenue.

The company been raising capital through a mixture of debt/equity offerings since its IPO in 2016. In 2019, it has issued $82mm in convertible bonds (2025), an additional $25mm in equity, and a $45mm revolver (2024).

As of Q3 2019, Senseonics has $130mm of cash on hand, however cash burn still seems to be a concern (-$125mm operating cash flow LTM Q3 2019). The company has announced plans to cut 30% of planned headcount, and is making clear strides to reduce cash burn. Senseonics will definitely depend on capital raises in the near future.

[26] https://diabetes.diabetesjournals.org/content/67/Supplement_1/14-OR

Inside Ownership

~10.7% of SENS is owned by individual insiders. Management have all been increasing positions since the company's IPO in March 2016. Roche Holding Ag also holds a 13.95% stake in SENS. I'm confident that SENS is committed to the long term prospects of the CGM market. Furthermore, the partnership between Roche Diabetes Care also seems much stronger in light of the close relationship with its parent holding company.

Risks

Failure to achieve FDA approval for 180 day use in the US

Senseonics has launched its PROMISE 180-day sensor clinical study for FDA approval in the US. If the company does not obtain this approval in the near future, it will not be able to offer the same degree of convenience to its US customers, falling short on its key differentiator with competitors.

Mitigating Factors: It is highly anticipated to obtain 180 day approval given the fact that it already has CE approval for sale in Europe, and that the product has been successful so far. In the US there has only been one recall (844 sensors representing 1.4% of sensors sold from March-August 2019).

Catalysts

1. Complete Insurance Coverage in the US
    a. Eversense is currently at 160mm lives covered (above expected 100m lives covered by end 2019). Once they reach full coverage (~265million), they will no longer need to utilize the Bridge Program to gain customers and will retain a significantly higher share of gross revenue.
    b. The recent announcements of being Medicare and Blue Shield coverage, coupled with above average covered lives growth in 2019 imply that complete coverage is attainable in the coming years.
2. FDA approval for 180 day use
    a. A single sensor will last twice as long with costs staying the same, significantly altering the unit economics of the business (halving consumer price per day)
    b. The corresponding convenience of a 180 day vs 90 day sensor significantly improves the value proposition of Eversense compared to short duration CGM competitors (2 yearly sensor changes vs. 26-52 yearly sensor changes)

Valuation

The market values high-growth companies like Senseonics on earnings multiples. After looking at comparable companies, I have complied a list of implied valuations for FY 2022 assuming ~33,000 US patients in 2022. This is fairly conservative: if we only look at type 1 diabetics (1.25m in the US), if 60% use CGMs by 2022 that implies Senseonics has a market share of 7.6%. Within CGM users in 2022, ~10% of users picking Eversense for its long-duration is extremely plausible.

Company	Market Cap	EV/Sales (Consensus)			
		Current	2019E	2020E	2021E
Senseonics	0.201B	6.8x	7.7x	3.8x	2.1x
Dexcom	18.571B	15.9x	14.1x	11.7x	9.8x
Tandem	3.618B	11.4x	9.5x	7.8x	6.5x
Medtronics	148.94B	5.5x	5.4x	5.2x	4.9x
Abbott	146.255B	5.4x	5.3x	5x	4.6x

Given extremely negative short term prospects, I believe the market has assigned an extremely low multiple on Senseonics future earnings. By 2022, the business will be significantly more mature, and is projected to have nearly full insurance coverage in the US. Furthermore, with the growth of the CGM market, I believe Eversense will have had sufficient time to demonstrate its full value proposition as an effortless system requiring less frequent changes.

FY 2022 Implied Share Price

		EV/Sales Multiple				
	2022E Sales (M)	1.5x	2x	2.5x	3x	3.5x
-10%	123.99	0.79	1.10	1.42	1.73	2.05
-5%	130.84	0.84	**1.17**	**1.51**	**1.84**	2.17
0%	137.73	0.90	**1.24**	**1.59**	**1.94**	2.29
5%	144.62	0.95	**1.31**	**1.68**	**2.05**	2.41
10%	151.50	1.00	1.38	1.77	2.15	2.54

Base Case (Forecasted 2022 Revenue with a 2.5x multiple)

Implied Price: $1.59

Bull Case (5% greater revenue with 3x multiple)

Implied Price: $2.05

Bear Case (-10% revenue with 1.5x multiple)

Implied Price: $0.79

Conclusion

Senseonics' recent quarterly performance has panicked investors and resulted in significantly poorer market sentiment for the longer term growth prospects of the company. However, its strong competitive advantages, such as its fundamentally appealing value proposition as a hassle-free CGM and the unit economics of 180 day/potentially year long sensor set it apart from competitors.

As Eversense continues to expand its prescriber/patient outreach, insurance coverage, and international distribution chains, the company will move beyond this short term earnings volatility.

Looking forward, I am particularly interested in tracking:

1. Q4 Revenue (Net and Gross)
2. Insurance Coverage by end 2019 (already above 100m target)
3. Status of the PROMISE 180 FDA clinical trials (already started)
4. Capabilities/Duration of Dexcom, Abbott, and Medtronic's Sensors
5. Sales of CGMs by Roche Diabetes Care in newly negotiated markets (India/China)

SENSEONICS

	DEC '15	DEC '16	DEC '17	DEC '18	DEC '19 E	DEC '20 E	DEC '21 E	DEC '22 E
Sales (Net)	38	332	6373	18913	21,000	42,737	81,350	137,735
Cost of Goods Sold (COGS) incl. D&A	-	660	9985.266	27329	34,100	38,749	53,154	79,263
Gross Income	-	-328	-3612.266	-8416	-13,100	3,988	28,196	58,471
SG&A Expense	28731.826	42105	52700.734	79162	111,161	115,390	130,159	137,735
EBIT (Operating Income)	-28812	-42433	-56313	-87578	-124,261	-111,402	-101,963	-79,263
Nonoperating Income - Net	35	105	311	1680	1680	1680	1680	1680
Interest Expense	1100	1602	3099	8282	10,700	12,900	12,000	12,000
Unusual Expense - Net	-	-	-	-209	-	-	-	-
Consolidated Net Income	-29877	-43930	-59101	-93971	-133,281	-122,622	-112,283	-89,583
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%
Net Taxes	0	0	0	0	0	0	0	0
Net Income	-29877	-43930	-59101	-93971	-133,281	-122,622	-112,283	-89,583
Preferred Dividends	407	0	0	0	0	0	0	0
Net Income available to Common	-30284	-43930	-59101	-93971	-133,281	-122,622	-112,283	-89,583

	15-18 CAGR	15-21 CAGR	15-22 CAGR
Sales (Net)	692%	259%	222%

Gross Margin (%)	-99%	-57%	-44%	-62%	9%	35%	42%
SGA % of Sales	12682%	827%	419%	529%	270%	160%	100%

Gross Sales Forecast	**Dec '19E**	**Dec '20E**	**Dec '21E**	**Dec '22E**
US	9,200	19745.5	42378.78	77130.23
YoY Growth		*115%*	*115%*	*82%*
OUS	16,800	31,920	54,264	81,396
YoY Growth		*90%*	*70%*	*50%*
Total Gross Sales	26,000	51,666	96,643	158,526
YoY Growth		*50%*	*47%*	*39%*

US Sector	**Dec '19E**	**Dec '20E**	**Dec '21E**	**Dec '22E**
Covered Lives (Thousands)	160,000	200,000	250,000	265,000
Patients Base	4	8.585	18.42556	33.53488
YoY Growth		*115%*	*115%*	*82%*
Gross Sales/Patient (In Dollars)	2300	2300	2300	2300
Eversense Bridge Users	2	3.434	5.527667	6.706976
Eversense Bridge Users (% of Patients)	50%	40%	30%	20%