BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

Weekly News Bulletin– Issue No.2 February 9, 2018

In this issue…

Wearables are the second biggest revenue driver for Apple 3 years after they were introduced– FEB. 3, 2018

Last September, Apple pulled back the curtain on some of its healthcare upgrades More recently it has rolled out a pilot program for its health app supporting health record access. Apple had sales of $88.2 million with net income of $20 million for the last three months of 2017. That compared with $78.3 million for the same period in 2016.

Apple's smartwatch had its best quarter ever and gained significant marketshare, according to CEO Tim Cook citing IDC. Apple's wearables were also strong in China.

Some companies have worked to develop their technology with Apple smartwatches. Last fall, AliveCore secured FDA clearance for an EKG tool for Apple's smartwatch that's designed to flag atrial fibrillation.

Cedars Sinai rolled out an Apple smartwatch app that allows users to manage their medical records, connect with their care team and search for a doctor by name, condition or specialty.

Speaking of apps, app store revenue reached a new record and was twice that of Google Play, Cook said. Quarterly visitors also reached a high.

But Apple is ever searching for more custom- ers, particularly more efficient ways of getting them. It has rolled out a new program to do that called Apple at Work. Although not specifically geared for any one industry the goal, aside from the obvious, is to make the process for companies that want to buy Apple products across their business more efficient.

- **From Tim Cook, Apple CEO**

"We're extremely interested in this area. And, yes, it is a business opportunity. If you look at it, medical health activity is the largest or second-largest component of the economy, depending on which country in the world you're dealing with. And it hasn't been constructed in a way where the focus at the device level is making great products from a pure point of view. The focus has been on making products that can get reimbursed through the insurance companies, And so in some ways we bring a totally fresh view into this and say, 'Forget all of that. What will help people?"

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Medical device companies: These 15 performed the best in 2017

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Examples of some of "the best"

January 28, 2018

- The past year was a year of product launches for Chicago-based **Hill-Rom**. One of the most promising product launches involved the Centrella smart bed system, designed with a strong healthcare value proposition around increased patient safety, satisfaction and caregiver efficiency.
- **Merit Medical** (South Jordan, Utah) managed to beat Wall Street expectations on third-quarter earnings, even as the disposable medical device maker engages in an acquisition spree.
- Formed by the $2.7 billion merger of Italy's Sorin and Cyberonics in October 2015, **LivaNova** (London) continues to expand its offerings in neuromodulation – which remains one of the hottest areas of growth in the medical device industry.
- 3D printing is a new thing for many medical device companies. Align Technology (San Jose, Calif.) has been a pioneer. (**Invisalign**)
- The New Zealand–based company is a designer and maker of products and systems for use in respiratory care, acute care, and treating obstructive sleep apnea. Fisher & Paykel HEALTHCARE
- Competition in the robotic surgery space is increasing, but that hasn't stopped growth at **Intuitive Surgical**, which remains the space's big kid on the block.

Source: https://www.medicaldesignandoutsourcing.com/

Wearable Medical Devices Market 2018 by Device– Kuam News, Feb, 2018

The Wearable Medical Devices Market is Expected to Reach USD 14.41 Billion By 2022 from USD 6.22 Billion in 2017, at a CAGR of 18.3%.

The key factors driving the growth of this market include increasing penetration of smartphones and growing number of smartphone-based healthcare apps compatible with wearable devices and growing preference for wireless connectivity among healthcare providers. However, the high cost of wearable devices and data security issues may hinder the growth of the market to a certain extent during the forecast period.

Market Restraints

- High Cost of Wearable Devices and Lack of Reimbursement
- Data Security Issues

Challenges

- Limited Battery Life
- Complexity in the Design of Devices

Opportunities

- Growing Awareness and Preference for Home Healthcare

Challenges

- Limited Battery Life
- Complexity in the Design of Devices

Brexit and Medical Devices

In this issue...

- **Brexit: The Hard Reality of "No Deal" for the Medical Device Industry January 24, 2018 by Ronald Boumans and Annette van Raamsdonk**

- All manufacturers worldwide, whether in Europe or elsewhere, can be affected by another issue: CE certificates for EU regulations can only be issued by Notified Bodies based within the EU. This also means that all certificates issued by UK-based Notified Bodies will become void after 29 March 2019. After that date, manufacturer can no longer place devices that need a valid CE certificate on the European market using a British Notified Body.

- As the importer is defined as an entity placing a device from a third country on the EU market, UK-based companies can no longer be used by other third countries as importers for the EU. For distributors this may result in unexpected consequences. If the distribution network is not changed, EU-based distributors placing devices on the European market from a manufacturer or importer based in the UK will themselves be considered importers. Even without full application of the Medical Devices Regulation (MDR), this change will already have consequences because the Product Liability Directive 85/374/EEC places liability with the importer.

- What are the potential effects?

- UK self-isolation would be felt in all corners of the European Single Market. Distribution networks will be affected downstream from UK-based Economic Operators. This will be a problem for UK-based companies, but an opportunity for EU-based organizations. This will probably not have negative effects on the availability of devices for the European patient. Whether the same can be said for the smaller UK market is less certain.

- A bigger effect involves the early expiration of certificates. If nothing is done, a large number of manufacturers relying on UK-based Notified Bodies will suddenly be orphaned.

Europe Hit Deep with Regulatory Changes

The UK's vote to exit from the EU comes at a time when Europe is full of great change pertaining to the medical device industry, particularly with the introduction of the new EU Medical Device Regulation (MDR), the In Vitro Diagnostic (IVD) regulation and the update to ISO 14155.

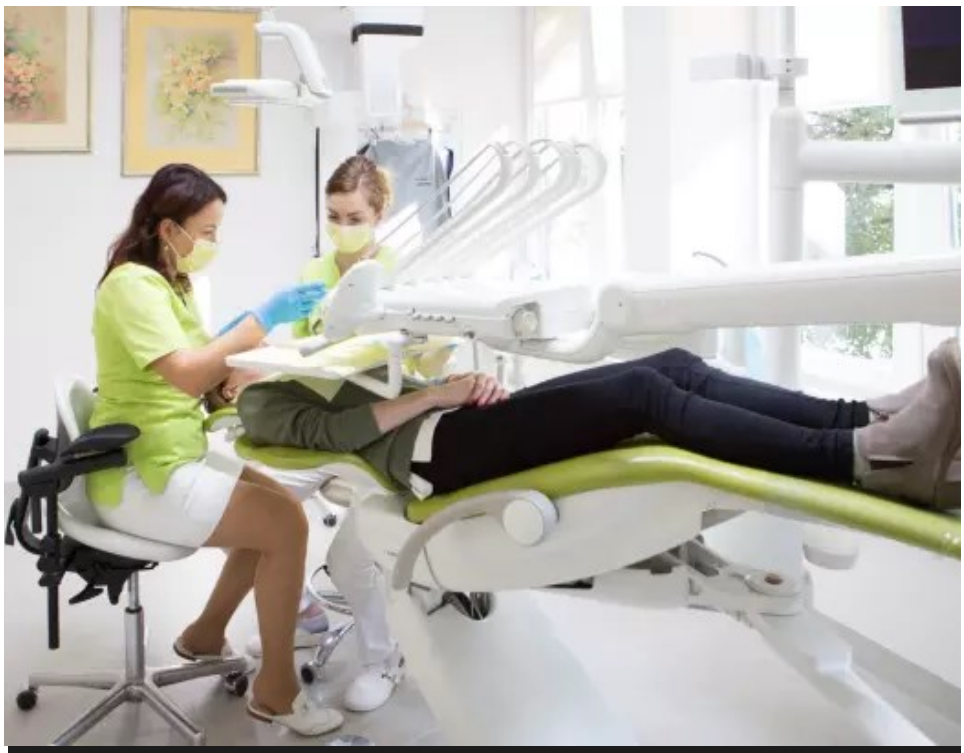
In total, these changes will require that approximately 300 standards – developed to support the soon-to-be-outdated EU Medical Device Directive (MDD) – be reviewed and assessed for relevance following the introduction of the new regulations. (The MHRA will continue to prepare for the MDR/IVD/ISO implementation and oversee the integral work that is carried out by the five notified bodies in the UK, who themselves assess the majority of devices currently placed on the EU market.)

Oct, 2017

MARKETS

EASTERN EUROPE

"The region has also attracted more patients from former Soviet republics, who do not always have easy access to professional medical services and equipment at home, say clinical suppliers. They are more likely to come to central Europe to undergo more complex surgeries than western visitors." "



Medical tourism on the rise in central and eastern Europe, Financial Times Oct. 2017

For many years Gdansk, the biggest city on Poland's Baltic coast, has attracted foreign tourists to its historic center, romantic riverbank and sandy beaches in nearby villages. More recently, tourists have found another reason to travel there: dental clinics. "When we started 10 years ago, we were almost the only business here which targeted international patients," says Anna Sarzynska, the owner of Anna Dental Clinic in the centre of Gdansk. "Today the market has spread, almost every clinic in the city offers its services to foreigners." Ms Sarzynska says that around 80 per cent of her clients come from abroad, mainly from Scandinavia, but also from the UK and Ireland. She has hired an extra person to organize stays for patients that include hotel bookings and sightseeing and she requires perfect English of everyone in her team.

Medical tourism is on the rise in central and eastern Europe — it has been growing 12-15 per cent annually, according to research published this year by PwC, the consultancy. In 2016, 488,000 foreign patients came to Poland for treatment, according to the Polish Association of Medical Tourism. Magdalena Rutkowska, the owner of Medical Travel Partner, a consultancy, has been working in medical tourism since 2010 and says that she has seen an increased interest in investing in the sector.

The growth of medical tourism in Poland has been mirrored in other central European countries. Hungary also has a reputation for specialising in dental services for foreigners, while Czech Republic has developed a market in cataract surgery. Poland is well known for its plastic surgeons as well as dentists. "This market has very high potential but it is not entirely developed," says Szymon Piatkowski, head of CEE healthcare advisory at PwC. "The region has specialized in simple treatments that do not need prior consultation. There is room for development for clinics that carry out more complex, sophisticated surgeries," he adds. Patients come to central Europe from the west and the east. Those from Germany, the UK and Nordic countries usually choose one-day, cosmetic treatments or stays in medical spas, attracted by competitive prices that can be two to three times lower than in their home countries.

This is “For Us” page...

- Wearables and remote care, will, undoubtedly, change the face of the healthcare industry. This means the technologies are increasingly focusing to reach out to the end user– the patient.

- Our main target has changed to the “patient” with the Strategy 2020. We know that it is unrealistic to think we can switch to new technologies in two years. But what we can do is prepare to follow this trend closely, understand it well and develop our value proposals continuously for each and every product. By doing this, we will be able to create the brand around them so that when the times is right, any new product we bring to the market as innovation will be readily accepted.

- We are still not there yet with market information that is gathered continuously. Every new news is old news in a matter of days. How do we catch up with this trend? Once we start, it gets easier to accumulate information. Gathering information we need to get rid of any bias and be really open to any piece of information. And then of course...analyze...analyze...analyze

Something to think about- What is emotional intelligence?

Within the last few years, emotional intelligence has become a popular terminology and is especially important for sales and marketing. Created by John D. Mayer of the University of New Hampshire and Peter Salovey, of Yale, emotional intelligence is defined as “the ability to accurately perceive your own and others’ emotions; to understand the signals that emotions send about relationships; and to manage your own and others’ emotions”.

Let us not forget our 2018 Vision and Mission Statements

Our Mission

Our compassion for healthy life is leading us to focus on innovative thinking and new technologies in order to provide medical devices that make living easier, more affordable and effective.

Our Vision

We believe in a world where everybody is taken care of, comfortable and happy, in sickness and in health.

Let us always remember to develop value proposals for our customers in line with our vision and misson so that it becomes part of who we are.

Contact Us

If you have any specific area that you need information on, please contact Corporate Marketing so we can focus on the specific areas to research to speed up your efforts.

Gülderen Somar,Director, Corporate Marketing

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