



Press release

Dignitana AB (publ)

Lund, Sweden, August 24, 2017

## Dignitana publish interim financial report for Q2, 2017

Interim Financial Report - Summary:

<b>Key Ratios</b>					
	<b>Q2 2017</b>	<b>Q2 2016</b>	<b>Q1-Q2 2017</b>	<b>Q1-Q2 2016</b>	<b>Full year 2016</b>
<b>Dignitana Group</b>					
Net revenues, TSEK	5 758	957	11 886	2 108	8 902
Total revenues TSEK	5 852	966	12 029	2 173	9 122
Net profit after financial items, TSEK	-10 813	-7 672	-18 922	-13 575	-32 269
Cash and bank balances, TSEK	10 121	51 541	10 121	51 541	32 864
Earnings per share before and after dilution, SEK	-0,53	-0,43	-0,93	-0,78	-1,72
<b>Dignitana AB</b>	<b>Q2 2017</b>	<b>Q2 2016</b>	<b>Q1-Q2 2017</b>	<b>Q1-Q2 2016</b>	<b>Full year 2016</b>
Net revenues, TSEK	4 636	801	9 948	1 919	7 767
Total revenues TSEK	4 729	809	10 091	1 983	7 986
Net profit after financial items, TSEK	-10 911	-7 702	-19 100	-13 629	-32 457
Cash and bank balances, TSEK	9 157	50 691	9 157	50 691	31 744

## Significant events during the period

- Q2 saw continued growth in Dignitana's roster of installed and contracted sites. This quarter a total of 20 new partner sites were signed with 11 of them installed in Q2, bringing the total number of installed and pending sites to 87 locations in 21 states.
- Dignitana has gained a strong foothold in the U.S. market with the highest incidence of cancer diagnosis now with 19 DigniCap sites in the New York metro area, 18 sites in California, and 15 sites in Florida.
- Continuing to establish partnerships with leaders in cancer care, in Q2 Dignitana contracted and/or installed DigniCap machines in 5 of the top 50 cancer centers in the U.S.

### About Dignitana AB (publ)

Dignitana is a Swedish public company, based in Lund, and manufacturer of the medical cooling device DigniCap®. Dignitana AB is listed on the Nasdaq First North Stockholm and has appointed Erik Penser Bank as Certified Adviser. For more information, visit [www.dignitana.com](http://www.dignitana.com)

### About the scalp cooling system DigniCap®

Dignitana's core product - DigniCap® - is a patented scalp-cooling system that offers cancer patients the ability to keep their hair during chemotherapy. DigniCap® provides continuous cooling with high efficacy, safety and acceptable patient comfort.



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- Dignitana partnered with an organization called CHILL, Cancer-related Hair Loss, International Leadership and Linkage, in an initiative to collect evidence-based patient information and provide clinical guidance for health practitioners and scalp cooling patients.
- Dignitana AB added two new employees to further strengthen the Swedish organization, a Production and Support Manager and a Quality Engineer.
- Dignitana Inc. continued to grow the U.S. team with the addition of two new employees, a Patient Support Specialist in New York and a Finance Manager in Dallas.
- Dignitana exhibited at the annual ASCO (American Society of Clinical Oncology) meeting that took place in Chicago, June 2-6, 2017.

## Significant events after the end of the period

- The 510(K) submitted to the FDA in Q1 was approved by the FDA on July 3, 2017. The clinical indications for DigniCap were expanded from breast cancer in women to cancer patients with solid tumors.
- Dignitana AB hired a Senior Software Engineer who started working in August.
- On July 20 Board Member Magnus Nilsson resigned from his position due to changes in his current professional responsibilities.
- On August 4 Dignitana signed a contract with Dignity Health, the fifth largest health system in the U.S. and the largest hospital provider in California. This agreement allows any of the 19 cancer centers in the Dignity Health network to sign up for the DigniCap system.
- The board has decided to issue 100,000 warrants to employees in Dignitana AB. The price for the warrants is set to 1,24 SEK and has been calculated according to the Black&Scholes formula. Each warrant carries the right to purchase one share during June 1 to 30, 2020 at the price of 17,60 SEK.

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## **Comments from Johan Ericsson, VD Dignitana AB (publ)**

With 18 months of experience in the U.S. market, Dignitana has established a solid operational foundation and a reputation for excellence in scalp cooling and top-tier support to both clinicians and patients. During Q2 we signed 5 of the top 50 cancer centers in the U.S., Moffitt Cancer Center (Florida), New York-Presbyterian University Hospital of Columbia and Cornell (New York), Mayo Clinic Phoenix (Arizona), Mayo Clinic Jacksonville (Florida) and NYU Langone Medical Center (New York). We have now partnered with medical facilities in 21 states across the U.S. including 11 of the top 50 cancer centers and 9 NCI (National Cancer Institute) designated cancer centers. This focus on excellence is critical to Dignitana as we move forward to lead the market in clinical expertise and product innovation.

The DigniCap implementation is well underway at Memorial Sloan Kettering in the New York metro area. The eight sites have treated more patients in each month sequentially since installation and we expect that trend to continue.

A new agreement with Piedmont Cancer Institute in Atlanta opens a new and significant market for the company in Georgia, helping us expand the foothold of Dignitana across the southern U.S.

The strategy of slow and steady growth within a medical organization was seen in Q2 as two large medical groups expanded DigniCap to more locations, with UHealth in Miami adding one site and UCHealth in Colorado providing DigniCap at two additional sites.

The pay-per-treatment business model in the U.S. is growing steadily. As we are educating our market in a completely new treatment, our focus has been on ensuring high quality treatment in advance of number of treatments. If we are not successful in high quality installations, we will miss the chance to establish our brand for this kind of treatment. Due to this, we have not fully reached our expectations in respect to number of treatments, but we have seen a steady increase each month. The model is attractive for both partner sites and patients as it enables very low startup costs for the sites and patients pay for only the treatments that they use.

Dignitana has partnered with CHILL, Cancer-related Hair Loss, International Leadership and Linkage, in an initiative designed to collect and track evidence-based patient information and provide clinical guidance for health practitioners and scalp cooling patients. Led by six globally-recognized experts in cancer care, data collected through the initiative will help

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establish industry-standard best practices and ensure maximum effectiveness of these treatments worldwide.

### **Insurance reimbursement**

Insurance coverage for scalp cooling is not yet standard in the U.S. where DigniCap® treatment cost is typically paid by the patient. With insurance reimbursement for scalp cooling this therapy would be available to a wider patient population. Reimbursement success varies depending on plan, coverage, and location. Across the U.S. DigniCap patients have submitted insurance claims and received reimbursement for treatment costs at varying levels since DigniCap received FDA clearance in 2015. With the July 2017 expansion of DigniCap clinical indications to include patients with solid tumors, claims for reimbursement and demand for coverage are increasing as more patients utilize this life changing treatment at infusion centers across America. The JAMA publication in February 2017 was an important first step toward providing third-party payers with the scientific data needed to provide reimbursement for DigniCap treatments. In conjunction with publication in other scholarly journals, Dignitana has published the scientific data needed to fulfil the first pre-condition for reimbursement, and is now working directly with patients to assist them in submitting the documentation for reimbursement.

### **FDA clearance**

As mentioned above, on July 3 the FDA cleared the Company's request to expand our product's indication from women with breast cancer to include patients with solid tumor cancers. This was a major milestone for the company and was the outcome of a significant regulatory effort by Dignitana. The expanded FDA clinical indication provides a second opportunity to lead the market, as Dignitana is now the only scalp cooling system to have clearance for solid tumors in the U.S. The ruling enables the company to offer this important therapy option to three times the number of patients we could treat under our initial clearance, increasing the potential scalp cooling market in the U.S. from 255,000 new breast cancer cases each year to more than 800,000 men and women diagnosed with solid tumors. Already we have received increased interest in this wider indication from our sites and prospective sites. Due to the logistics of many U.S. infusion centers, for some facilities it will take time to make accommodations in space and workflow to include scalp cooling as a treatment option for men and women, as well as for solid tumors beyond breast cancer.

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## Media awareness and marketing initiatives

Media interest in DigniCap is consistently high as we have pitched local and national consumer media with an emphasis on patient-focused stories and ongoing coverage in scientific journals and clinical publications. Q2 saw **284** media placements garnering more than **180 million** impressions through print, online and broadcast media channels. Highlights this quarter include [Marie Claire](#), [Health eNews](#), [Popular Mechanics](#), [WNYW](#), and [ASCO Post](#). Additional marketing initiatives include cooperative marketing with medical facilities and targeted advertising in key markets and online channels.

Dignitana exhibited at the annual ASCO meeting in Chicago in June, the world's largest clinical cancer meeting attracting more than 30,000 oncology professionals from around the world. With on-site demonstrations to increase understanding of scalp cooling, the interest in DigniCap was very high generating several key sales leads. In Q2 Dignitana also exhibited at three other large clinical conferences in the U.S.: Community Oncology Alliance in April, Oncology Nursing Society Congress in May, and Multi-National Association of Supportive Cancer Care in June. Each of these events provided a highly visible platform to directly connect with a targeted clinical audience and build awareness of DigniCap.

## Operations and development

Production and quality are essential to our operations, and during Q2 resources have been added to these functions in Sweden. We have hired a Production and Support Manager and a Quality Engineer to support our expansion.

To get a successful patient outcome, fitting of the cap and the patient experience are critical. During Q2 we have started two significant product development projects within these areas.

## Market update

Moving forward, international sales efforts are focused on those markets where we have established capable distribution partners such as our existing relationships in Europe, Mexico, and Australia.

As we look at expanding into the densely-populated Asian market, Dignitana is working with Konica Minolta and, in collaboration, plans to commence the PMDA approval process clearance in Japan to provide DigniCap in Japan.

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### Financial comments

- Group revenues in Q2, 2017 increased to 5,852 TSEK, compared to 966 TSEK for the same period last year. Dignitana Inc. shows increasing revenues as the monthly leasing fees continues to increase as more and more systems are installed, and pay per treatment revenues increases due to more installations, and also higher usage rates on already installed systems. Revenues in Dignitana AB decreases due to Sysmex not taking any orders in Q2.
- As of September 2015, Dignitana AB, the parent company of the Dignitana group, reports consolidated group financials, including the subsidiary Dignitana, Inc. in USA. Costs related to the subsidiary are now being paid by Dignitana, Inc. Other costs such as regulatory, quality, FDA and product development will continue to be paid by the parent company.
- Every month Dignitana, Inc. will invoice the customers a fixed rental fee for DigniCap® and a pay per treatment fee based on the number of completed treatments. Since Dignitana AB continue to own the systems, part of the revenue will be transferred to the parent company.
- A transfer pricing agreement has been established between Dignitana AB and Dignitana, Inc. to determine how the result will be shared between the companies. Other external expenses in Dignitana AB include costs related to the transfer price agreement between the companies.
- Fixed tangible assets in Dignitana AB continue to increase since systems leased to customers in the U.S. will be capitalized as assets and depreciated over five years.

The complete report will be found on our webpage <http://www.dignitana.se/eng>

### For more information:

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*This information is information that Dignitana AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, by the above contact, for publication at 8.00 am (CET), August 24, 2017.*

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