

# DIGNITANA

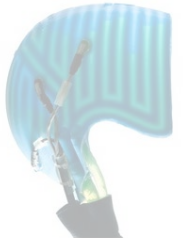
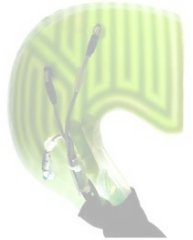
Management Presentation  
Erik Penser Bank  
18-19, Dec. 2017

DIGNICAP  
*Proven Innovation in scalp cooling*



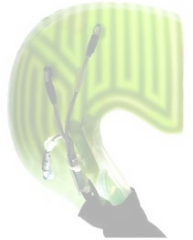
# Agenda

- The Company
- The Product
- The Market
- Investment Case



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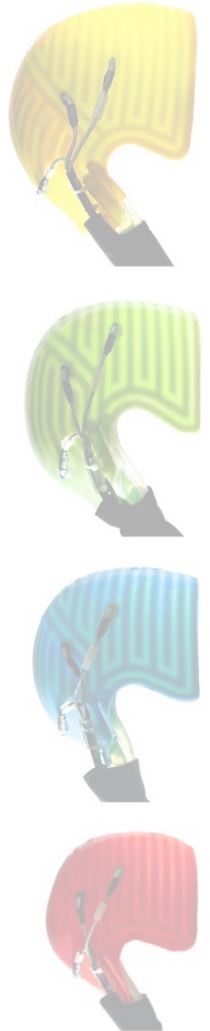
# Dignitana AB

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[www.dignitana.se](http://www.dignitana.se)  
[info@dignitana.se](mailto:info@dignitana.se)

# Dignitana, Inc.

*A wholly-owned subsidiary of Dignitana AB  
and North American Distributor*

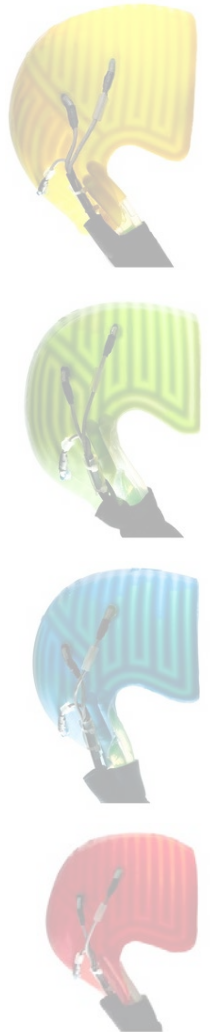
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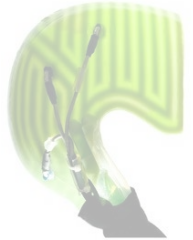
# The Company

- Dignitana AB, founded 2007, is a Swedish medical technology company listed on the Nasdaq First North stock exchange in Stockholm as DIGN.SE
- Dallas-based Dignitana, Inc. is a wholly owned subsidiary of Dignitana AB and is responsible for North American distribution and support for the DigniCap® Scalp Cooling System.
- The DigniCap® Scalp Cooling System is a patented scalp cooling system that reduces chemotherapy-induced hair loss and is used worldwide.
- In December 2015 DigniCap® became the first FDA cleared scalp cooling system with indication for treatment of women with breast cancer.
- ***In July 2017 DigniCap® received FDA clearance for expanded clinical indications and is now cleared for solid tumors in men and women***



# Leadership

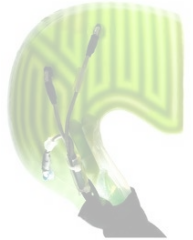
- Chairman of the Board is Semmy Rulf, former board member of Vitrolife, Jolife, ProstaLund, current board member Xvivo Perfusion.
- CEO of Dignitana, Inc. is William Cronin, former founder of Chemo Cold Caps, LLC, President of C3 Device Partners and board member of Dignitana AB.
- CEO of Dignitana AB is Johan Ericsson, formerly at Flex Design (formerly Flextronics), Sony Ericsson, Assa Abloy, CellaVision, and Axis Communications.



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# Agenda

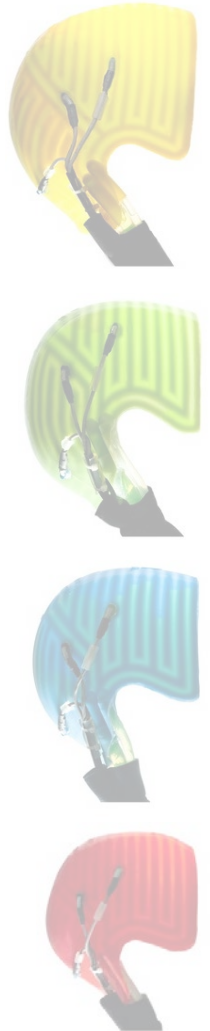
- The Company
- **The Product**
- The Market
- Investment Case



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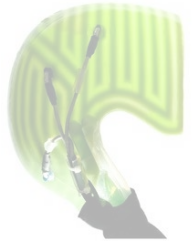
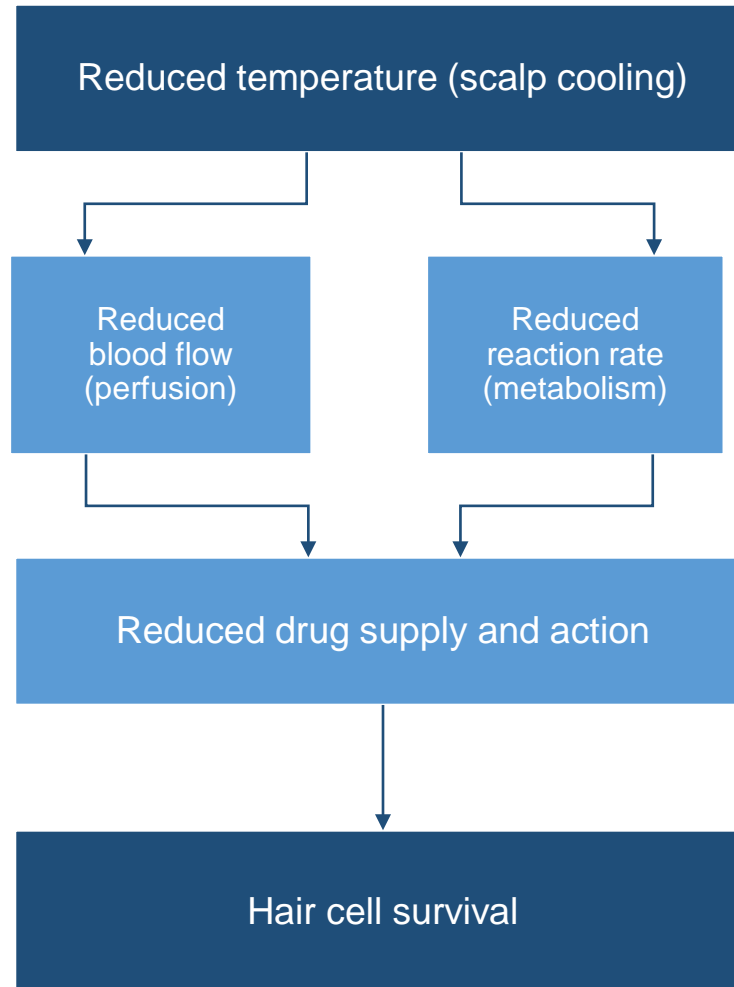
# The DigniCap® Scalp Cooling System



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# What is Scalp Cooling?



# The DigniCap® Scalp Cooling System

The DigniCap® Scalp Cooling System consists of three main parts:

- Cooling and control system (DigniC3) – independently controlled dual system can treat 2 patients simultaneously
- Form-fitting silicone cap (DigniCap®) connected through a coupling system and hoses to the cooling unit.
- Outer neoprene cap (DigniTherm) is placed over the silicone cap.



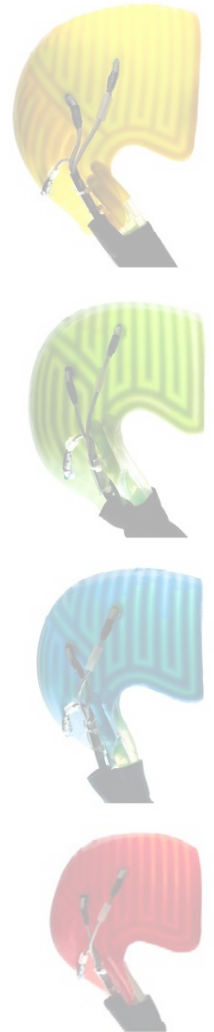
DigniC3 -  
cooling  
and  
control  
unit



DigniCap  
inner cap



DigniTherm  
Click Cap  
outer cap



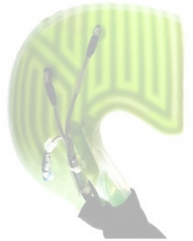
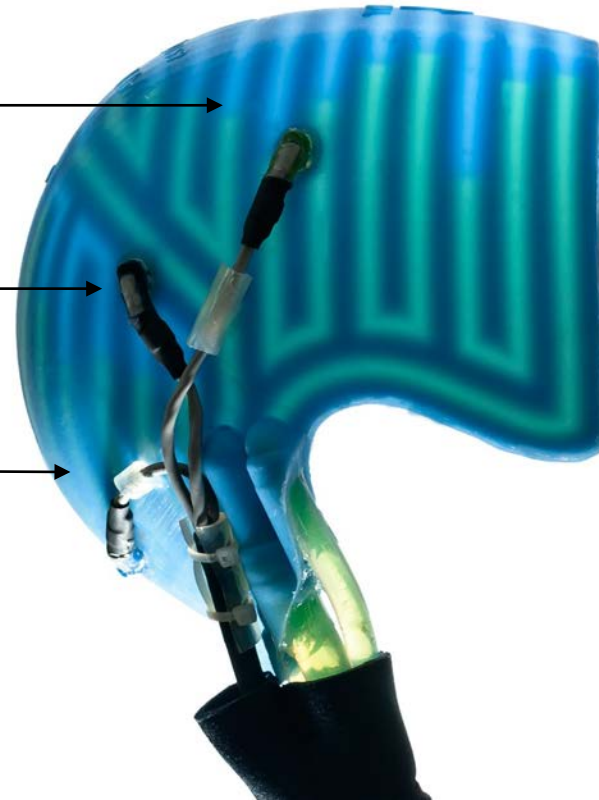
# The Intelligent Scalp Cooling System

Patented dual sensor-monitored cooling compartments (front and rear) for temperature management to ensure consistent, uniform cooling, plus a security sensor to ensure scalp temperature always remains above 32° F/0° C

Front sensor (green)  
measures the temperature  
on the front of the scalp.

Safety sensor (black)  
prevents sub-zero  
temperatures.

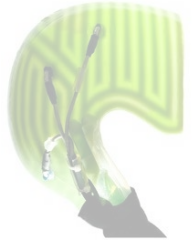
Rear sensor (blue)  
measures the temperature  
on the rear part of the scalp.



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# DigniTherm™ Click Cap

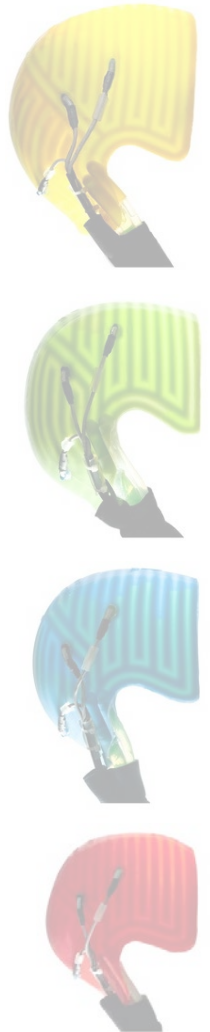
- Launched December 2017
- Engineered with the BOA® Closure System
- Ensures a close fit for optimal results during the scalp cooling process to minimize chemotherapy induced hair loss.
- Easy for patients to quickly achieve a precise fit that stays in place throughout treatment



# Indications For Use

The DigniCap® Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced hair loss in cancer patients ***with solid tumors***.

*-FDA July 3, 2017*



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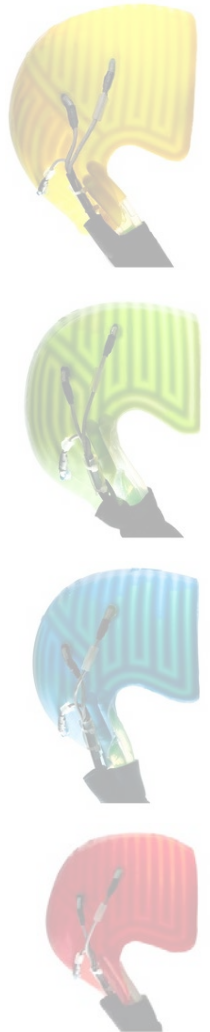
# Clinical Publications



The DigniCap® Scalp Cooling System is highly effective in reducing chemotherapy-induced alopecia.



*"The incidence of scalp metastases was low regardless of scalp cooling. This analysis suggests that scalp cooling does not increase the incidence of scalp metastases."*

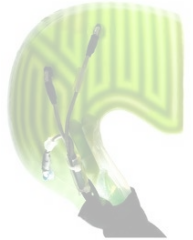


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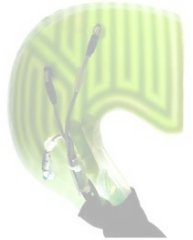
# Growth in Product, Service & Support

- Ongoing product development initiatives to support technical advancements
- Established Clinical Support Team led by experienced oncology RN provides training to facility's clinical staff to ensure smooth implementation and workflow
- Patient Support Center offers patients fast, easy and direct access to experts via website, email, phone, or mobile app
- Localized marketing and media support provide community awareness and customized messaging
- Versatile pricing models to meet the business needs of practices



# Service and Support

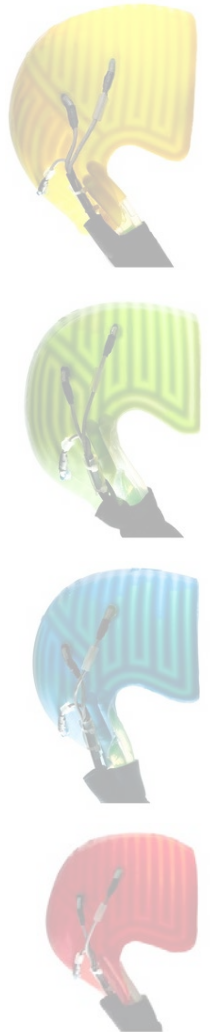
- US market demands an elevated level of service and support
- Dignitana partners with sites and provides a high level of attention and ongoing training
- DigniCap Patient Support Center offers patients fast, easy and direct access to experts via website, email, phone, or mobile app
- Established Clinical Support Team led by experienced oncology RN provides training to facility's clinical staff to ensure smooth implementation and workflow
- Localized marketing and media increase community awareness
- Clinical Support Line answered 24/7



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# Insurance Coverage for Scalp Cooling

- No universal coverage yet
- No unique CPT code for scalp cooling yet
  - Patients are successfully using CPT 97039 (Constant attendance, physical medicine, scalp cooling, unlisted modality)
- Many recent successes with individual reimbursement thru Aetna, BCBS and Horizon in varying amounts from \$50 to full treatment cost
- ***Aetna has stated scalp cooling is medically necessary on their website, but that doesn't guarantee coverage***
- DigniCap provides documentation to patients
- Updates posted at [dignicap.com/insurance](http://dignicap.com/insurance)





# Scalp Cooling (Hypothermia) to Prevent Hair Loss During Chemotherapy

[Print](#) | [Share](#)

Number: 0290

## Policy

Aetna considers scalp cooling (i.e., using ice-filled bags/bandages, cryogel packs, or specially designed devices (e.g., Chemo Cold Cap, DigniCap, ElastoGel, Paxman Scalp Cooling System and Penguin Cold Cap)) medically necessary as a means to prevent hair loss during chemotherapy.

## Background

Hair loss is a potentially distressing side effect of several cytotoxic drugs. Scalp cooling has been suggested to prevent hair loss.

A Medicare National Coverage Determination explains that keeping the scalp cool during chemotherapy has been noted to reduce the risk of hair loss. The cooling may be done by packing the scalp with ice-filled bags or bandages, or by specially-designed devices filled with cold-producing chemicals activated during chemotherapy. The NCD states that while ice-filled bags or bandages or other devices used for scalp hypothermia during chemotherapy may be covered as

## Policy History

[Last Review](#) > 04/28/2017

Effective: 10/13/1998

Next Review: 03/08/2018

[Review History](#) >

[Definitions](#) >

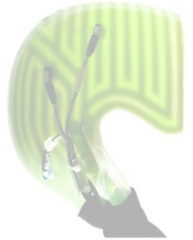
## Additional Information

[Clinical Policy Bulletin Notes](#) >



# Agenda

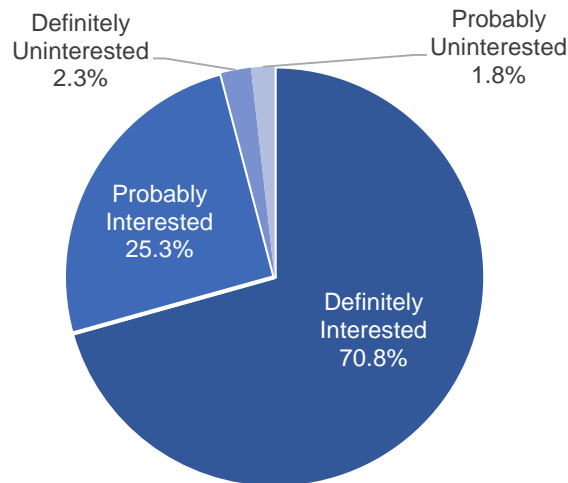
- The Company
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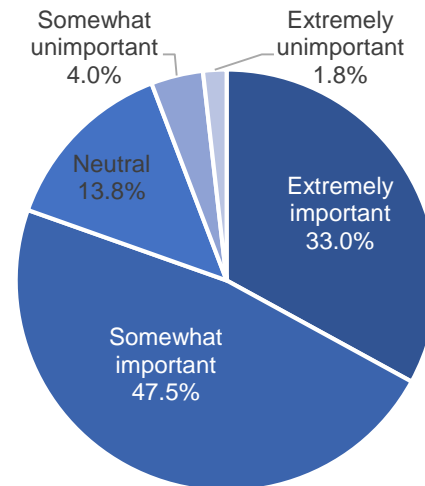
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# Who is interested in Scalp Cooling?

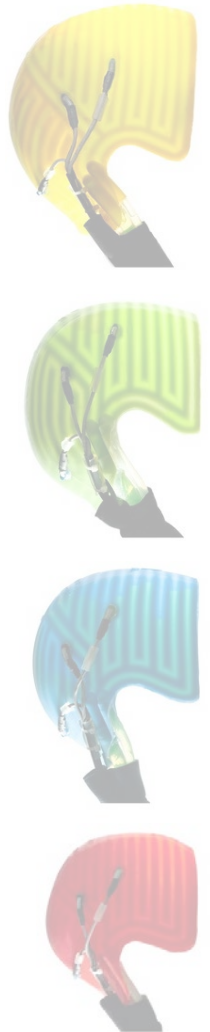
- Hair loss, experienced by most patients during chemotherapy, is consistently ranked as a **very distressing side effect**
- Reducing hair loss **contributes significantly** to the increased well-being and **quality of life for patients.**
- After a short introduction to scalp cooling, **96% of surveyed women** showed interest in scalp cooling and **81% said the availability of scalp cooling was an important factor in selecting a medical center**



Interest in Scalp Cooling



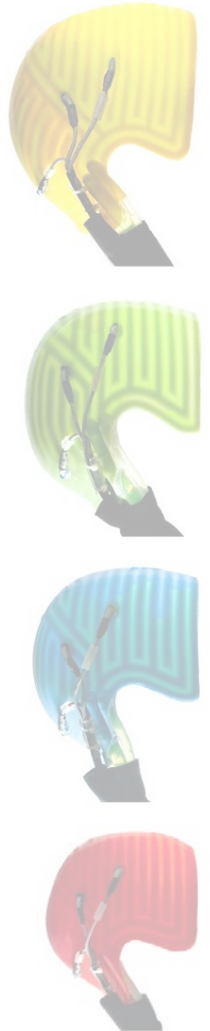
Importance of Scalp Cooling Availability





# The Market

- Over 800,000 total incidences of solid tumor cancers each year in the United States
- Included in that are 255,000 new incidences of breast cancer each year in the United States
- Of the 255,000 in the US, approximately 60% are on regimens that would be compatible with DigniCap
- Breast Cancer is the most common malignancy among women worldwide with 1.5 million new breast cancer patients are diagnosed worldwide each year.
- The US market for scalp cooling is worth approx. \$275 million/year for breast cancer and an additional \$435 million for other solid tumors.
- There are over 2,000 cancer treatment facilities in the U.S.



# Excellence in Cancer Care

Over **100 centers** in **22 states**  
**10 NCI-Designated Cancer Centers**

1. Alabama
2. Arizona
3. California
4. Colorado
5. Connecticut
6. District of Columbia
7. Florida
8. Georgia
9. Illinois
10. Kansas
11. Kentucky
12. Louisiana
13. Maryland
14. Michigan
15. New Jersey
16. New York
17. North Carolina
18. Ohio
19. South Carolina
20. South Dakota
21. Texas
22. Wisconsin

**UCSF Helen Diller Family  
Comprehensive Cancer Center**  
San Francisco, California

**University of California  
Los Angeles Jonsson  
Comprehensive Cancer Center**  
Los Angeles California

**City of Hope  
Comprehensive Cancer Center**  
Duarte, California

**University of Colorado  
Cancer Center**  
Aurora, Colorado

**Laura and Isaac Perlmutter  
Cancer Center at NYU Langone**  
New York, New York

**Memorial Sloan Kettering  
Cancer Center**  
New York, New York

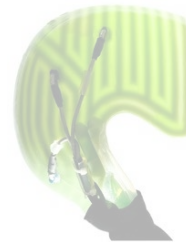
**The Tisch Cancer Center  
at Mount Sinai**  
New York, New York

**Herbert Irving Comprehensive Cancer  
Center at Columbia University**  
New York, New York

**The Comprehensive Cancer Center  
of Wake Forest University**  
Winston-Salem, North Carolina

**Moffitt Cancer Center**  
Tampa, Florida

NCI-Designated Cancer Centers are institutions dedicated to research in the development of more effective approaches to prevention, diagnosis, and treatment of cancer. There are 69 NCI-Designated Cancer Centers.



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# Business Model Worldwide

Dignitana AB

United States

Europe

Asia

Middle East

Mexico

South America

Australia

Dignitana, Inc.  
wholly-owned subsidiary  
with sales organization.

Sysmex Europe GmbH

Konica Minolta Medical & Graphic Inc

Tesla Medical Solutions

Celeritas Trading

Aurora BioScience

Stand alone systems

Stand alone systems

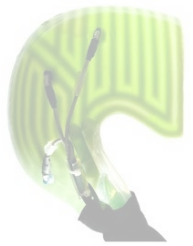
Stand alone systems

Stand alone systems

Stand alone systems

Stand alone systems

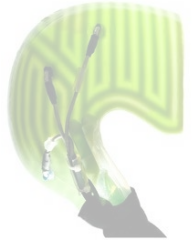
Lease & pay per treatment



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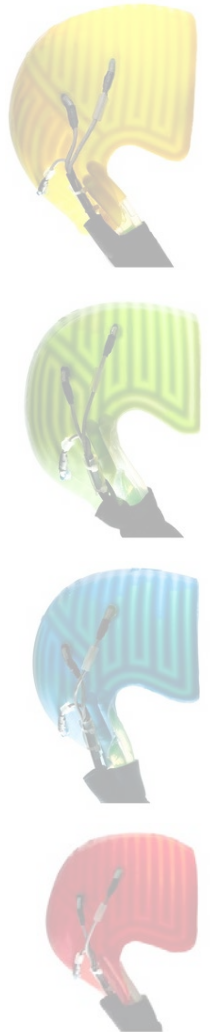
# United States Business Model

- US is the primary market for the Company and represents half of the total medical device market.
- US headquarters established in Dallas in December 2015
  - Highly skilled and knowledgeable sales and support staff
  - Standard contract for US facilities:  
two year lease at  
≈ \$1,000/month  
plus \$275-350/treatment.



# Scalp Cooling Demand Increasing

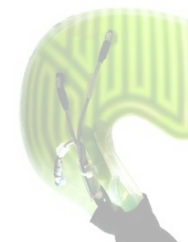
- Targeting Comprehensive Cancer Centers (100 to date)
- Reimbursement anticipated by 2018
- DigniCap pivotal trial published in JAMA February 2017
- FDA expanded clinical indications in July 2017 has generated wider clinician and patient interest



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# DIGN Performance 2017

Key Ratios							
	Q3 2017	Q2 2017	Q1 2017	Q2 2016	Q1 2016	Q1-Q2 2016	Full year 2016
<b>Dignitana Group</b>							
Net revenues, TSEK	4 550	5 758	6 127	957	1 134	2 108	8 902
Total revenues TSEK	4 565	5 852	6 177	966	1 199	2 173	9 122
Net profit after financial items, TSEK	-10 338	-10 813	-8 109	-7 672	-5 903	-13 575	-32 269
Cash and bank balances, TSEK	6 192	10 121	17 995	51 541	11 293	51 541	32 864
Earnings per share before and after dilution, SEK	-0,51	-0.53	-0.40	-0,43	-0.35	-0,78	-1,72
<b>Dignitana AB</b>	Q3 2017	Q2 2017	Q1 2017	Q2 2016	Q1 2016	Q1-Q2 2016	Full year 2016
Net revenues, TSEK	3 283	4 636	5 312	801	1 119	1 919	7 767
Total revenues TSEK	3 299	4 729	5 362	809	1 174	1 983	7 986
Net profit after financial items, TSEK	-10 257	-10 911	-8 189	-7 702	-5 927	-13 629	-32 457
Cash and bank balances, TSEK	3 766	9 157	17 762	50 691	10 895	50 691	31 744

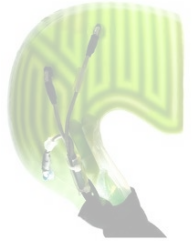


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# Investment Case

*Large market potential in the U.S.*

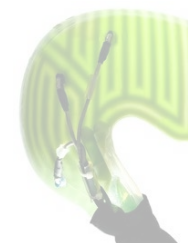
- Breakthrough in December 2015 with FDA clearance and again with expanded indications in July 2017
- First mover advantage
- Organization now well-established in the US
- Improved U.S. business model with pay-per-treatment + machine lease
- High margins
- US market is valued to approx. \$700 m yearly



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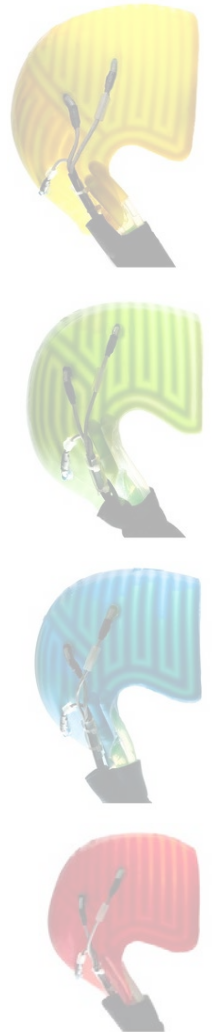
# Shareholders

Shareholders on 31 December 2016	Number of Shares	Percentage of capital and votes
Eurosund	3 750 122	18
Avanza Pension	2 112 906	10
C3 Device Partners LP	1 780 747	9
Hodges Capital	1 627 500	8
Nordnet Pension	641 756	3
Green Park & Golf Ventures	629 397	3
ML, Pierce, Fenner & Smith Inc.	371 064	2
Semmy Ruif	368 100	2
Citibank, CBNY- Charles Schwab, New York	254 233	1
Citibank, CBLDN-UBS, London	152 000	1
William Cronin	147 021	1
Others	8 599 535	43
<b>SUM</b>	<b>20 274 164</b>	<b>100</b>



# 2017 Dignitana Initiatives & Results

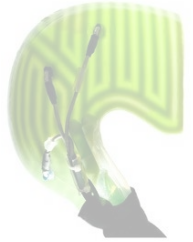
- Expand clinical indication with FDA to include all solid tumor cancers - **ACHIEVED**
- Increase unit effective utilization rates per site - **ACHIEVED**
- Enhance cap fit through partnership with Boa Technology - **ACHIEVED**
- Build on growing momentum and demand- **ACHIEVED**
- Continue pursuing and closing multi-site deals- **ACHIEVED**
- Utilize equipment financing option - **ACHIEVED**
- Reevaluate global distributor program - **ACHIEVED**



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# 2018 Initiatives/Usage of Funds

- Transfer of operational activities to US
- Accelerate equipment development efforts
- Hire additional regional sales reps
- Expand market awareness
- Insurance reimbursement

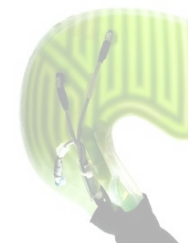
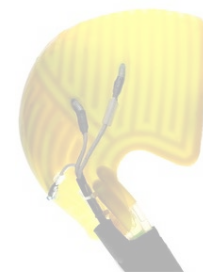
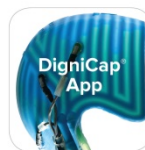


# DIGNICAP<sup>®</sup>

*The first name in scalp cooling*



[www.dignicap.com](http://www.dignicap.com)



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