



Financial Report Q1 - 2017

Results and financial position

Q1 Report - Summary:

Key Ratios			
Dignitana Group	Q1 2017	Q1 2016	Full year 2016
Net revenues, TSEK	6 127	1 134	8 902
Total revenues TSEK	6 177	1 199	9 122
Net profit after financial items, TSEK	-8 109	-5 903	-32 269
Cash and bank balances, TSEK	17 995	11 293	32 864
Earnings per share before and after dilution, SEK	-0,40	-0,35	-1,72
Dignitana AB	Q1 2017	Q1 2016	Full year 2016
Net revenues, TSEK	5 312	1 119	7 767
Total revenues TSEK	5 362	1 174	7 986
Net profit after financial items, TSEK	-8 189	-5 927	-32 457
Cash and bank balances, TSEK	17 762	10 895	31 744

Significant events during the period

- March record month. The most important contract during the period is with The University of Miami Health System (UHealth) for four sites. UHealth is the largest provider of cancer care in south Florida. As we demonstrate the efficacy and demand for the product, UHealth will add DigniCap® units to additional sites.
- Dignitana has continued to develop its U.S. subsidiary, Dignitana Inc. New resources were added during Q1 to properly support the growing roster of sites and patients. Two new clinical support personnel were hired for the New York City metropolitan area, a Florida-based salesperson was added to accelerate growth in the southeast, and an Operations Manager was added in the Dallas office.
- Dignitana AB hired a Supply Chain Manager starting March 1.
- Dignitana installed the 17 systems to Memorial Sloan Kettering Cancer Center in New York that were ordered in the end of 2016.
- Dignitana's pivotal study for FDA clearance was published in the February 14th issue of *Journal of American Medical Association (JAMA)* along with two positive editorials.



- The 510(K) for solid tumors has been submitted to the FDA and is currently under review.

Significant events after the end of the period

- As per April 15, Dignitana Inc. will be responsible for global sales.
- Additional sites have been contracted and announced through the typical process, including highly-ranked Mayo Clinic, Moffitt and NYU facilities.
- Dignitana AB hired a Production and Service Manager April 1.
- Dignitana Inc. hired an Accounting Manager April 24.
- Dignitana AB obtained credit from a Swedish bank to provide capital for increased DigniCap unit production

Scheduled financial reports

Interim Financial Report Q2 – 2017	24 August 2017
Interim Financial Report Q3 – 2017	23 November 2017
Year-End Report for 2017	22 February 2018

Information about operations

Dignitana operates in the field of medical technology. Dignitana has developed a patented medical cooling system, DigniCap®, which reduces chemotherapy-induced hair loss. DigniCap® provides continuous cooling with high efficacy, safety and acceptable patient comfort and contributes to the well-being of patients during very difficult period of their lives.

In the field of oncology, DigniCap® is being established as the market leader and de facto global standard for scalp cooling to prevent chemotherapy-induced hair loss.

Dignitana has offices in Lund, Sweden and Dallas, TX, U.S.A.

Comments from Johan Ericsson, CEO, Dignitana AB (publ)

Dignitana installed the 17 systems to Memorial Sloan Kettering Cancer Center (MSKCC) in the New York area that were ordered in the end of 2016. This is the most important contract so far for Dignitana. MSKCC is ranked number two among U.S. cancer centers. During the quarter, installations have started at multiple sites with good results.

Dignitana continue to grow on the U.S. market and during Q1, 2017 we signed 14 new contracts giving us a total of 69 sites across the United States. The most important contracts are with Memorial Sloan Kettering Cancer Center and University of Miami Health System.



New business model in the US

The new business model that we introduced in the U.S. market is now taking off. The model consists of a fixed monthly leasing fee for the system and a pay-per-treatment fee. This model is attractive for both our partner sites and patients as it enables very low to no startup costs for the sites and patients pay for only the treatments they use the DigniCap® system.

In the U.S., the DigniCap® treatment is currently paid for by the patient themselves. With healthcare reimbursement for the DigniCap® scalp cooling system, this therapy can be available to a wider patient population. Dignitana is working on getting the scientific data published and thereby increasing the scientific value and awareness of the DigniCap® Scalp Cooling System, which is a precondition for reimbursement.

New publications in highly ranked medical journals

Following the publication of the effectiveness, safety and tolerability of the DigniCap® scalp cooling system in the highly ranked medical journal *JAMA* on February 14, 2017, another scalp cooling paper was published in *Breast Cancer Research and Treatment* on March 8, 2017; “Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis.”. The authors conclude that the incidence of scalp metastases was low regardless of scalp cooling which suggests that scalp cooling does not increase the incidence of scalp metastases. The theoretical increased risk for scalp metastases following scalp cooling should no longer be a reason for restricting the use of scalp cooling for patients undergoing chemotherapy. Also, the Quality of Life data presented at San Antonio Breast Cancer Symposium in December 2016; “Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy induced alopecia”, is currently being revised into a full-length paper for publication.

Dignitana Inc. is working closely with the clinical sites where DigniCap® has recently been installed to ensure proper training. Clinical support resources have been added to meet the increasing demand from new sites and expanding usage.

Request for wider Indications for use

In the U.S., the DigniCap® was cleared by the FDA only for women with breast cancer since this was the study population in the pivotal study. Dignitana believes that there is no scientific or clinical basis to limit this technology to breast cancer patients when, in fact, it is currently approved and being used throughout the world safely and effectively for treating patients with all types of solid tumors undergoing chemotherapy. The 510(K) requesting a wider indications for use of the DigniCap® scalp cooling system has been submitted to the U.S. FDA and is currently under review.

Dignitana strongly believes that the combination of scientific publications, healthcare reimbursement, and expanded indications for use will greatly increase the usage of scalp cooling in the U.S. over time.



U.S. media interest in DigniCap® remained strong during Q1, 2017 in the U.S. With the results of the clinical trial featured in [The Journal of the American Medical Association](#) and the official announcement of the DigniCap® machine being offered at Memorial Sloan Kettering, media coverage reached a high this quarter with **485** media placements garnering more than **899 million** impressions through online and broadcast media channels. Highlights include [The New York Times](#), [Mashable](#), [CBS Evening News](#) and [The Washington Post](#).

Efficient supply chain

During the year, we have continued to develop the Swedish and the U.S. organization. In Sweden, Supply Chain and Operations resources have been added and in U.S. additional sales and support staff have been added to support and grow our rapidly expanding customer and patient sites.

We are working hard to supply to the increased number of systems required to fulfil orders. Significant effort has been directed to the supply chain as well as logistics and product improvements. Dignitana is continuously evaluating options to enhance and facilitate cap fitting to improve patient outcome. Two development projects have started to provide a better user experience.

Market update

In March Dignitana delivered 15 systems to our European distributor, Sysmex Europe GmbH.

With the focus on success in the U.S., fewer resources have been put into other markets such as the UK and the rest of the world where we do not have distributor agreements. To ensure that company resources are appropriately allocated in regard to sales and unit placement opportunities, Dignitana, Inc. will now handle all outside distributor relationships.

Financial comments

- Group revenues in Q1, 2017 increased to 6,177 TSEK, compared to 1,134 TSEK for the same period last year, and by more than 50 % compared to the previous quarter. The monthly leasing fees increases as more and more systems are installed, and pay per treatment revenues increases both due to more installations, but also higher usage rates on already installed systems.
- 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.

Staff

Company staff in Dignitana AB totaled 9 (8) people as of 31 March 2017. Dignitana Group totaled 20 (13) people as of 31 March 2017.

Future Prospects

Dignitana is in an intensive product launch phase in several markets, which may cause sales to differ from one quarter to the next. Future capitalization may become necessary to build the organization for successful penetration of selected markets.

The share

Shares in Dignitana AB (publ) were listed on Nasdaq First North Stockholm on 30 November 2011 after having been listed at Aktietorget since June 2009. Total shares in the company are 20,274,112 after the shares issue during May-June 2016 and there is one class of share. Every share carries an equal right to shares of company assets and profit, and the right to a single vote at the annual general meeting of shareholders. There are 387,000 warrants issued in the company. The warrants carry the right to purchase 222,000 shares in the period 1 to 30 June 2018 and 165,000 shares in the period 1 to 30 June 2019 and will, on full exercise, increase the company share capital by SEK 387,000. Erik Penser Bank act as Certified Adviser for the company.

Related party shareholdings

	Shareholding	Warrants
Johan Stormby via Eurosund AB	4 130 726	
William Cronin	1 939 229	30 000
Semmy Rülff	380 654	
Magnus Nilsson	32 904	
Erik von Schenck	10 769	
Johan Ericsson	6 384	

Review by auditors

This financial report has not been subject to review by the company auditors.



Policies for preparation of the interim financial report

Swedish Annual Accounts Act (1995:1554) and Swedish Accounting Standards Board General Recommendations BFNAR 2012:1 Annual reporting and consolidated financial statements (K3).

Submission of the interim financial report

Lund, 24 May 2017

Dignitana AB (publ) - Board of Directors

Semmy Rölf	Chairman
Johan Stormby	Director
Magnus Nilsson	Director
Erik von Schenck	Director
William Cronin	Director



Dignitana AB, publ

Corporate registration number:
556730-5346

Dignitana Group

Income statement, SEK	Q1 2017	Q1 2016	Full year 2016
Operating income			
Net revenues	6 126 929	1 133 719	8 901 796
Own work capitalized	14 975	41 397	159 510
Other income	<u>35 592</u>	<u>24 209</u>	<u>60 441</u>
Total income	6 177 496	1 199 325	9 121 747
Operating expenses			
Goods for resale	1 663 981	554 276	3 417 238
Other external expenses	6 329 862	3 110 731	19 579 950
Personnel expenses	4 676 537	2 909 869	16 564 044
Depreciation of tangible and intangible assets	1 403 217	365 942	3 950 200
Other operating expenses	<u>31 415</u>	<u>75 711</u>	<u>214 643</u>
Total operating expenses	14 105 012	7 016 529	43 726 075
Operating profit/loss	-7 927 516	-5 817 204	-34 604 328
Result from financial investments			
Interest income and similar items	-	388	2 340 561
Interest expenses and similar items	<u>-181 843</u>	<u>-86 121</u>	<u>-5 414</u>
Total income from financial investments	-181 843	-85 733	2 335 147
Net profit after financial items	-8 109 359	-5 902 937	-32 269 181
Results for the Period	-8 109 359	-5 902 937	-32 269 181
Total shares at the period-end before and after dilution *	20 274 112	16 774 164	20 274 112
Average number of shares before and after dilution *	20 274 112	16 774 164	18 804 511
Earnings per share before and after dilution *	-0,40	-0,35	-1,72

* No dilution during the period



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Dignitana Group

Statement of Financial Position, SEK

	2017-03-31	2016-03-31	2016-12-31
Fixed assets			
<u>Intangible assets</u>			
Capitalized expenses for development	13 592 154	14 031 840	13 862 201
<u>Tangible assets</u>			
Equipment, tools, and installations	11 841 657	3 280 817	9 692 357
Total Fixed Assets	25 433 811	17 312 657	23 554 558
Current Assets			
<u>Inventories and similar</u>			
Finished goods and goods for resale	3 724 882	7 831 669	2 480 593
Advance payments to suppliers	_____ -	<u>742 910</u>	_____ -
	3 724 882	8 574 579	2 480 593
<u>Current receivables</u>			
Accounts receivable	4 631 317	494 927	3 061 351
Current tax assets	290 094	246 738	227 931
Other current receivables	2 002 108	391 259	790 987
Prepaid expenses and accrued income	<u>1 528 104</u>	<u>450 600</u>	<u>855 329</u>
	8 451 623	1 583 524	4 935 598
<u>Cash and bank balances</u>	17 994 652	11 292 707	32 864 372
Total Current Assets	30 171 157	21 450 810	40 280 563
Total Assets	55 604 968	38 763 467	63 835 121



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Dignitana Group

Statement of Financial Position, SEK	2017-03-31	2016-03-31	2016-12-31
Equity and Liabilities			
Equity			
<u>Restricted equity</u>			
Share Capital (20,274,112 shares par value SEK 1, previous year 16,774,164)	20 274 112	16 774 164	20 274 112
Fond for development expenses	<u>2 614 829</u>	<u>-</u>	<u>2 180 475</u>
	22 888 941	16 774 164	22 454 587
<u>Non-restricted equity</u>			
Other paid-in capital	32 969 399	24 000 654	65 584 871
Results for the period	<u>-8 109 359</u>	<u>-5 902 937</u>	<u>-32 269 181</u>
	24 860 040	18 097 717	33 415 690
Total Equity	47 748 981	34 871 881	55 870 277
Current liabilities			
Accounts payable	4 709 155	2 266 206	3 529 331
Other current liabilities	407 244	252 238	412 252
Accrued expenses and deferred income	<u>2 739 588</u>	<u>1 373 142</u>	<u>4 023 261</u>
Total current liabilities	7 855 987	3 891 586	7 964 844
Total Equity and Liabilities	55 604 968	38 763 467	63 835 121



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Dignitana Group

Changes in equity, SEK	Q1 2017	Q1 2016	Full year 2016
Opening balance	55 870 277	40 786 300	40 786 300
New share issue	-	-	52 499 220
Issue expenses	-	-	-5 554 273
Subscribed warrants	-	-	358 050
Translation difference on consolidation	-11 937	-11 482	-50 161
Results for the period	<u>-8 109 359</u>	<u>-5 902 937</u>	<u>-32 269 181</u>
Closing balance	47 748 981	34 871 881	55 870 277



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Dignitana Group

Statement of cash flows, SEK	Q1 2017	Q1 2016	Full year 2016
Operating Activities			
Operating income before financial items	-7 927 516	-5 817 204	-34 604 328
Adjustments for items not affecting cash flows	1 388 242	324 545	4 083 125
Interest received	-	388	844
Interest paid	-33	-14	-5 414
Income tax paid	-	-	-
	<u>-6 539 307</u>	<u>-5 492 285</u>	<u>-30 525 773</u>
Changes in inventories	-3 905 487	89 578	-1 038 588
Changes in other current receivables	-3 697 835	900 554	-151 450
Changes in other current liabilities	<u>-108 857</u>	<u>-2 962 372</u>	<u>1 110 887</u>
Cash flows from operating activities	-14 251 486	-7 464 525	-30 604 924
Investing activities			
Acquisition of fixed assets	<u>-606 297</u>	<u>-273 348</u>	<u>-2 925 925</u>
Cash flows from investing activities	-606 297	-273 348	-2 925 925
Financing activities			
New share issue of share capital	-	-	3 499 948
New share issue premium reserves	-	-	48 999 272
Issuance costs	-	-	-5 554 272
Subscribed warrants	<u>-</u>	<u>-</u>	<u>358 050</u>
Cash flows from financial activities	0	0	47 302 998
Cash flows in the period	-14 857 783	-7 737 873	13 772 149
Cash and cash equivalents at start of the period	32 864 372	19 042 062	19 042 062
Translation difference on cash and cash equivalents	-11 937	-11 482	50 161
Cash and cash equivalents period-end	17 994 652	11 292 707	32 864 372



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Corporate registration number: 556730-5346

Parent Company

Income statement, SEK	Q1 2017	Q1 2016	Full year 2016
Operating income			
Net revenues	5 311 926	1 118 595	7 766 692
Own work capitalized	14 975	41 397	159 510
Other income	<u>34 813</u>	<u>13 790</u>	<u>60 138</u>
Total income	5 361 714	1 173 782	7 986 340
Operating expenses			
Goods for resale	1 663 981	518 240	3 265 760
Other external expenses	7 896 470	4 014 205	24 428 369
Personnel expenses	2 397 822	2 046 523	10 960 933
Depreciation of tangible and intangible assets	1 379 450	360 690	3 908 383
Other operating expenses	<u>31 415</u>	<u>75 711</u>	<u>214 643</u>
Total operating expenses	13 369 137	7 015 369	42 778 088
Operating profit/loss	-8 007 424	-5 841 587	-34 791 748
Result from financial investments			
Interest income and similar items	-	388	2 340 561
Interest expenses and similar items	<u>-181 843</u>	<u>-86 121</u>	<u>-5 414</u>
Total income from financial investments	-181 843	-85 733	2 340 561
Net profit after financial items	-8 189 267	-5 927 320	-32 456 601
Results for the period	-8 189 267	-5 927 320	-32 456 601



Dignitana AB, publ

Corporate registration number: 556730-5346

Parent Company

Statement of Financial Position, SEK	2017-03-31	2016-03-31	2016-12-31
Fixed assets			
<u>Intangible assets</u>			
Capitalized expenses for development	13 592 154	14 031 840	13 862 201
<u>Tangible assets</u>			
Equipment, tools, and installations	11 622 249	3 226 130	9 471 099
<u>Financial assets</u>			
Participations in group companies	420 010	420 010	420 010
Receivables from group companies	<u>-</u>	<u>-</u>	<u>-</u>
	420 010	420 010	420 010
Total Fixed Assets	25 634 413	17 677 980	23 753 310
Current Assets			
<u>Inventories and similar</u>			
Finished goods and goods for resale	3 724 882	7 831 669	2 480 593
Advance payments to suppliers	<u>-</u>	<u>742 910</u>	<u>-</u>
	3 724 882	8 574 579	2 480 593
<u>Current receivables</u>			
Accounts receivable	3 147 955	455 193	1 896 467
Current receivables from group companies	1 135 248	-	905 162
Current tax assets	290 094	246 738	227 931
Other current receivables	1 962 801	389 630	727 709
Prepaid expenses and accrued income	<u>630 906</u>	<u>440 185</u>	<u>321 420</u>
	7 167 003	1 531 746	4 078 689
<u>Cash and bank balances</u>	17 761 870	10 895 424	31 744 387
Total Current Assets	28 653 755	21 001 749	38 303 669
Total Assets	54 288 168	38 679 729	62 056 979



Dignitana AB, publ

Corporate registration number: 556730-5346

Parent Company

Statement of Financial Position, SEK

Equity and Liabilities	2017-03-31	2016-03-31	2016-12-31
Equity			
<u>Restricted equity:</u>			
Share Capital (20,274,112 shares par value SEK 1, previous year 16,774,164)	20 274 112	16 774 164	20 274 112
Fund for development expenses	<u>2 614 829</u>	-	<u>2 180 475</u>
	22 888 941	16 774 164	22 454 587
<u>Non-restricted equity:</u>			
Retained earnings	32 732 733	24 001 114	22 178 689
Share premium reserves	-	-	48 999 272
Issue expenses	-	-	-5 554 273
Results for the Period	<u>-8 189 267</u>	<u>-5 927 320</u>	<u>-32 456 601</u>
	24 543 467	18 073 794	33 167 087
Total Equity	47 432 408	34 847 958	55 621 674
Current liabilities			
Accounts payable	4 014 084	1 309 935	2 917 110
Current liabilities to group companies	-	922 809	-
Other current liabilities	407 244	252 238	412 252
Accrued expenses and deferred income	<u>2 434 433</u>	<u>1 346 789</u>	<u>3 105 943</u>
Total current liabilities	6 855 760	3 831 771	6 435 305
Total Equity and Liabilities	54 288 168	38 679 729	62 056 979



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