



Year End Report 2015

Results and financial position

Year-end Report - Summary:

Key Ratios				
Dignitana Group *	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Net revenues, TSEK	277	-	4 749	-
Total revenues TSEK	441	-	5 510	-
Net profit after financial items, TSEK	-5 272	-	-16 569	-
Cash and bank balances, TSEK	19 042	-	19 042	-
Earnings per share before and after dilution, SEK	-0,31	-	-1,08	-

<small>* No consolidated group report during 2014, read more on Financial comments, page 5.</small>

Dignitana AB	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Net revenues, TSEK	277	8 978	4 749	20 334
Total revenues TSEK	441	9 406	5 510	21 220
Net profit after financial items, TSEK	-5 263	-1 090	-16 570	-10 914
Cash and bank balances, TSEK	18 622	1 094	18 622	1 094

Significant events during the year

- On 8 December 2015, Dignitana received clearance from the American Food and Drug Administration (FDA) to begin selling the scalp cooling system, DigniCap®, in the USA.
- Dignitana participated in the yearly breast cancer meeting, San Antonio Breast Cancer Symposium (SABCS), which opened the day after the company received the FDA clearance. The news was greeted very positively during the symposium and the company received a large number of enquiries expressing interest. Dignitana caught the media's attention including CBS Morning News as well as a number of local TV stations.
- The United States Patent and Trademark Office has granted Dignitana a patent that adds protection to the company's scalp cooling technology. The new patent protects Dignitana's unique channel system design in the cooling cap.
- In May, the company took part in the annual ASCO cancer congress in Chicago where the results of the clinical study were presented. The company's poster was chosen from among 500 others to be presented in a poster discussion that was very well attended. In connection with the congress, NBC Nightly News broadcast a long feature about the DigniCap® system and how it



can improve the quality of life for patients. The results for the clinical study showed that the DigniCap® scalp cooling system reduced hair loss in 7 out of 10 breast cancer patients.

- Dignitana has started a subsidiary, Dignitana Inc, in the USA and appointed Bill Cronin to run the company. The company has set up its office in Dallas, Texas. Following the FDA clearance, a total of five persons were hired at Dignitana Inc.
- During the year, Dignitana carried out two share issues. In January, a share issue to existing shareholders raised 16.9 Million SEK for the company before issuance costs. In July, a share issue targeting a number of American investors brought in a further 28 Million SEK before issuance costs.

Significant events after the end of the year

- The company has signed contracts with six customers in the USA. The first installations of DigniCap® at customers' facilities are in progress.

Scheduled financial reports

Interim Financial Report Q1 – 2016	25 May 2016
Interim Financial Report Q2 – 2016	25 August 2016
Interim Financial Report Q3 – 2016	24 November 2016
Year-end report for 2016	23 February 2017

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 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, USA.



Comments from Jan Richardsson, CEO, Dignitana AB (publ)

For Dignitana, 2015 will go down in the company history as a milestone year in which we finally received the FDA clearance and the green light to sell in the USA. We have fought long and hard during the Pre Market Approval (PMA) process which was then transformed into a *de novo* 510 (k). After intensive and close cooperation with the FDA, the company was granted clearance the day before the most important breast cancer symposium (San Antonio Breast Cancer Symposium) in the USA started. Interest from the USA has been much better than our highest expectations both from the medical profession and patients. At present, the clearance covers all types of breast cancer. The company will look to expand the indication for use of our device to other varieties of solid tumors by means of a supplementary application to the FDA.

The company and its' marketing efforts were assisted by tremendous press and media coverage during 2015. NBC Nightly News did a lengthy and excellent feature story on Dignitana during the annual American Society of Clinical Oncology Conference (ASCO) in Chicago at the end of May. The story reported on a clinical trial participant that did not experience hair loss during her chemotherapy treatment. Since May the company has been featured on CBS Morning News, in the New York Times Science Edition and some additional fifty TV or newspaper articles. This coverage has created tremendous awareness of and demand for our device from both patients and treatment providers.

The company began setting up an American subsidiary, Dignitana, Inc. while the regulatory process was being completed. Bill Cronin, who has several years of experience in the US scalp cooling industry was appointed to build up the new organization. The head office is located in Dallas and there are five employees at present. The sales force covers all of the USA and all team members have previous experience in scalp cooling.

The three states where success is especially important for us are California, Texas and New York. As well as being the three most populated states, many top rated cancer treatment facilities are located there and will be integral to driving adoption rates for our product in the US.

To date, we have six contracts signed by sites in the USA. These customers represent a cross section of the US oncology market and range from small community centers to larger research facilities and are spread across the USA. The business model we adopted for the American market has been proven to work. In short, we lease out the system and are paid per treatment. The new payment model means that turnover should increase meaningfully and lead to better profitability in the long run.

We are working on obtaining healthcare reimbursement for DigniCap® in the USA. We will have to show that DigniCap® has a positive effect on the quality of life of patients and much of this information was collected during the clinical trial.

Deliveries to our European distributor, Sysmex Europe GmbH, have dropped significantly in 2015, after we delivered large volumes in 2014. Sysmex experienced important sales growth, but they built up large inventories which they are now obliged to reduce. Sysmex plays an important role in



our product development process as they have stringent requirements concerning product quality and performance.

Sales in China are awaiting the Chinese government's approval of patient remuneration rates. We need to undertake an approval process in each state which delays the overall process. Our distributor, Konica Minolta Medical & Graphic, is working patiently with Chinese hospitals and the appropriate authorities. Konica Minolta has selling rights in Japan as well and has now started the process to obtain regulatory approval there.

Annual turnover was significantly lower than in 2014, very much due to Sysmex not living up to the volume intake that we had originally agreed upon. I hope that Sysmex will start reordering during the course of 2016.

Financial comments

- As of September 2015 Dignitana AB reports consolidated group financials, including the subsidiary Dignitana, Inc. Costs related to the subsidiary starting September 1, are now being paid by Dignitana, Inc. FDA-related costs will continue to be capitalized in the Parent Company. The Company reports no comparative figures for the Group as it did not exist during 2014.
- Own work capitalized in the income statement amounts to 146 TSEK during Q4 and 609 TSEK during the whole year and refers to the time Dignitana staff has put into the FDA project. Along with the other costs of the clinical study and FDA project these costs are capitalized as intangible assets. The total amount of intangible assets amounted to SEK 13.7 million SEK. DigniCap® system including accessories used in the clinical study are capitalized as tangible assets and depreciated over five years. The value of these amounts to 1.6 million SEK.
- Dignitana AB costs in the USA to set up the subsidiary and prepare for the launch cannot be capitalized as assets. These costs are included in the external costs, amounting to about 1.9 million SEK for Q4 and accumulated to 5.5 million SEK for the whole year.
- Inventory in stock is higher than the corresponding period last year, as the company manufactured and built inventory ready to be delivered to the USA with short term notice.

Staff

Company staff in Dignitana AB totaled 7 (8) people as of 31 December 2015. Dignitana Group totaled 12 (-) people as of 31 December 2015.



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 the Nasdaq First North listing of the Stockholm Stock Exchange on 30 November 2011 after having been listed at Aktietorget since June 2009. Total shares in the company after new share issues in January and July 2015 are now 16,774,164 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 222,000 warrants issued in the company. The warrants carry the right to purchase an equal number of shares in the period 1 to 30 June 2018 and will, on full exercise, increase the company share capital by SEK 222,000. Erik Penser Bankaktiebolag is Certified Adviser for the company.

Related party shareholdings

	Shareholding	Warrants
Johan Stormby via Eurosund AB	3 835 676	-
William Cronin	1 800 572	30 000
Semmy Rülf	326 979	-
Jan Richardsson	40 547	100 000
Magnus Nilsson	30 554	-
Erik von Schenck	10 000	-
Erika Bågeman	7 988	10 000
Madelaine Roos	6 416	10 000
Tobias Fritz	5 836	10 000



Review by auditors

This year-end 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 year-end report

Lund, 24 February 2015

Digitana AB (publ) - Board of Directors

Semmy Rülf Chairman

Johan Stormby Director

Magnus Nilsson Director

Erik von Schenck Director

William Cronin Director



Digitana AB, publ

Corporate registration number:
556730-5346

Digitana Group

Income statement, SEK	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Operating income				
Net revenues	276 733	-	4 748 987	-
Own work capitalized	146 270	-	609 301	-
Other income	<u>17 751</u>	-	<u>152 031</u>	-
Total income	440 754	-	5 510 319	-
Operating expenses				
Goods for resale	256 764	-	2 820 735	-
Other external expenses	3 093 596	-	11 203 674	-
Personnel expenses	2 310 033	-	7 736 718	-
Depreciation of tangible and intangible assets	114 095	-	364 915	-
Other operating expenses	<u>12 401</u>	-	<u>179 681</u>	-
Total operating expenses	5 786 889	-	22 305 723	-
Operating profit/loss	-5 346 135	-	-16 795 404	-
Result from financial investments				
Interest income and similar items	-449	-	255 680	-
Interest expenses and similar items	<u>74 606</u>	-	<u>-29 108</u>	-
Total income from financial investments	74 157	-	226 572	-
Net profit after financial items	-5 271 978	-	-16 568 832	-
Results for the Period	-5 271 978	-	-16 568 832	-
Total shares at the period-end before and after dilution *	16 774 164	-	16 774 164	-
Average number of shares before and after dilution *	16 774 164	-	15 307 889	-
Earnings per share before and after dilution *	-0,31	-	-1,08	-

* No dilution during the period



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Dignitana Group

Statement of Financial Position, SEK

	2015-12-31	2014-12-31
Fixed assets		
<u>Intangible assets</u>		
Capitalized expenses for development	13 884 250	-
<u>Tangible assets</u>		
Equipment, tools, and installations	2 066 318	-
Total Fixed Assets	15 950 568	-
Current Assets		
<u>Inventories and similar</u>		
Finished goods and goods for resale	9 260 407	-
Advance payments to suppliers	<u>817 035</u>	<u>-</u>
	10 077 442	-
<u>Current receivables</u>		
Accounts receivable	325 291	-
Current tax assets	88 169	-
Other current receivables	1 634 700	-
Prepaid expenses and accrued income	<u>522 025</u>	<u>-</u>
	2 570 185	-
<u>Cash and bank balances</u>	19 042 062	-
Total Current Assets	31 689 689	-
Total Assets	47 640 257	-



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Digitana Group

Statement of Financial Position, SEK **2015-12-31** **2014-12-31**

Equity and Liabilities

Equity

Share Capital (16,774,164 shares par value SEK 1)	16 774 164	-
Other capital	40 570 624	-
Translation difference on consolidation	10 344	
Results for the period	<u>-16 568 832</u>	<u>-</u>
	24 012 136	-
Total Equity	40 786 300	-
 Current liabilities		
Accounts payable	5 221 138	-
Other current liabilities	234 742	-
Accrued expenses and deferred income	<u>1 398 077</u>	<u>-</u>
Total current liabilities	6 853 957	-
 Total Equity and Liabilities	47 640 257	-



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Digitana Group

Changes in equity, SEK	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Opening balance	46 078 363	-	14 578 346	-
New share issue	-40 000	-	42 385 552	-
Subscribed warrants	-	-	380 890	-
Translation difference on consolidation	19 915		10 344	
Results for the period	<u>-5 271 978</u>	<u>-</u>	<u>-16 568 832</u>	<u>-</u>
Closing balance	40 786 300	-	40 786 300	-



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Digitana Group

Statement of cash flows, SEK	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Operating Activities				
Operating income before financial items	-5 346 135	-	-16 795 404	-
Adjustments for items not affecting cash flows	311 785	-	99 574	-
Interest received	-449	-	255 680	-
Interest paid	74 606	-	-29 108	-
Income tax paid	—	—	—	—
Changes in inventories	-4 866 970	-	-7 399 552	-
Changes in other current receivables	-296 445	-	2 137 497	-
Changes in other current liabilities	<u>329 558</u>	—	<u>309 404</u>	—
Cash flows from operating activities	-9 794 050	-	-21 421 909	-
Investing activities				
Acquisition of fixed assets	<u>-877 923</u>	—	<u>-3 407 030</u>	—
Cash flows from investing activities	-877 923	-	-3 407 030	-
Financing activities				
New share issue of share capital	-	-	5 095 302	-
New share issue premium reserves	-	-	39 899 161	-
Subscribed warrants	-	-	380 890	-
Issuance costs	<u>-40 000</u>	—	<u>-2 608 911</u>	—
Cash flows from financial activities	-40 000	-	42 766 442	-
Cash flows in the period	-10 711 973	-	17 937 503	-
Cash and cash equivalents at start of the period	29 734 120	-	1 094 213	-
Translation difference on cash and cash equivalents	19 915		10 346	
Cash and cash equivalents period-end	19 042 062	-	19 042 062	-



Dignitana AB, publ

Corporate registration number:
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Parent Company

Income statement, SEK	Q4 2015	Q4 2014	Full year 2015	Full year 2014
Operating income				
Net revenues	276 733	8 977 776	4 748 987	20 334 390
Own work capitalized	146 270	297 423	609 301	297 423
Other income	<u>17 751</u>	<u>130 469</u>	<u>152 031</u>	<u>588 180</u>
Total income	440 754	9 405 667	5 510 319	21 219 992
Operating expenses				
Goods for resale	256 764	5 784 058	2 820 735	12 261 400
Other external expenses	3 258 984	2 237 782	11 379 367	9 802 113
Personnel expenses	2 140 672	2 238 561	7 568 634	9 470 107
Depreciation of tangible and intangible assets	108 844	89 738	357 984	265 470
Other operating expenses	<u>12 401</u>	<u>144 538</u>	<u>179 681</u>	<u>325 520</u>
Total operating expenses	5 777 664	10 494 677	22 306 401	32 124 610
Operating profit/loss	-5 336 910	-1 089 009	-16 796 082	-10 904 618
Result from financial investments				
Interest income and similar items	-449	481	255 680	2 601
Interest expenses and similar items	<u>74 606</u>	<u>-1 417</u>	<u>-29 108</u>	<u>-12 075</u>
Total income from financial investments	74 157	-936	226 572	-9 474
Net profit after financial items	-5 262 753	-1 089 946	-16 569 510	-10 914 092
Results for the period	-5 262 753	-1 089 946	-16 569 510	-10 914 092



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Corporate registration number: 556730-5346

Parent Company

Statement of Financial Position, SEK 2015-12-31 2014-12-31

Fixed assets

Intangible assets

Capitalized expenses for development	13 884 250	9 927 264
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Tangible assets

Equipment, tools, and installations	2 010 934	1 855 948
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Financial assets

Participations in group companies	420 010	-
Receivables from group companies	<u>417 620</u>	<u>—</u>
	837 630	0

Total Fixed Assets	16 732 814	11 783 213
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Current Assets

Inventories and similar

Finished goods and goods for resale	9 260 407	3 219 220
Advance payments to suppliers	<u>817 035</u>	<u>318 571</u>
	10 077 442	3 537 790

Current receivables

Accounts receivable	325 291	1 664 606
Current tax assets	88 169	56 389
Other current receivables	1 633 030	1 858 317
Prepaid expenses and accrued income	<u>522 025</u>	<u>1 128 370</u>
	2 568 514	4 707 682

<u>Cash and bank balances</u>	18 621 895	1 094 213
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Total Current Assets	31 267 852	9 339 686
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Total Assets	48 000 666	21 122 899
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Corporate registration number: 556730-5346

Parent Company

Statement of Financial Position, SEK **2015-12-31** **2014-12-31**

Equity and Liabilities

Equity

Restricted equity:

Share Capital (16,774,164 shares par value SEK 1, previous year 11,678,862)	16 774 164	11 678 862
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Non-restricted equity:

Non-restricted equity	3 280 374	13 813 576
Share premium reserves	39 899 161	-
Issue expenses	-2 608 911	-
Results for the Period	<u>-16 569 510</u>	<u>-10 914 092</u>
	24 001 114	2 899 484
Total Equity	40 775 278	14 578 346

Current liabilities

Accounts payable	4 467 051	5 112 049
Current liabilities to group companies	1 132 402	-
Other current liabilities	227 858	373 231
Accrued expenses and deferred income	<u>1 398 077</u>	<u>1 059 273</u>

Total current liabilities	7 225 388	6 544 553
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Total Equity and Liabilities	48 000 666	21 122 899
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