

## DanDrit Biotech USA, Inc.

#### Equity Research Report, 15 July 2015

# Late stage clinical cancer pipeline provides significant upside to current market value

Our Discounted Cash Flow valuation of DanDrit Biotech USA, Inc. suggests a very significant upside to the current share price. The Dendritic Cells cancer vaccine MelCancerVac (MCV) is the main pipeline asset, primarily being developed in the adjuvant setting of late stage non-resectable Colorectal Cancer.

We are estimating an enterprise valuation of 171 million dollars, compared to the current market cap of 38 million dollars. However in order to unlock the enterprise value upside, DanDrit needs to execute on its objectives during the coming months by getting its pivotal phase III 174 patients trial underway in Italy and begin enrolling patients. We are very confident this will happen during the current quarter. Secondly the myTomorrows Compassionate Use program needs to begin enrolling patients in Europe, also during this quarter. We are also confident in this taking place.

The company has adapted a virtual business model, with requires only a minimum of infrastructure and a handful of full-time employees as all clinical and manufacturing activities are outsourced to a CRO/CMO, i.e. contract research/manufacturing organization.

A positive outcome of the MCV phase III study, will move our pipeline valuation estimates up with approx. USD 230 million to USD 401 million, corresponding to USD 43 dollars per share. We would consider a statistical significant outcome with a P-value < 0.05 as positive. This would create value in the pipeline beyond the CRC stage IV Adjuvant setting, as the likelihood of attracting a partner to take on the Colorectal Cancer Stage III adjuvant trial as well as the Lung Cancer trial would have increased dramatically.

A mediocre or a negative outcome of the MCV phase III trial would decimate our pipeline valuation by approx. USD 145 million to USD 26 million, corresponding to 2.72 USD per share. We would consider a statistically insignificant p-value > 0.10 as mediocre/negative. This outcome would essentially close the door for good to the Colorectal Cancer stage IV market opportunity as well as to the Lung Cancer market opportunity. At the same time it would be extremely difficult to attract a partner or a buyer of the company on reasonable terms.

We believe DanDrit Biotech has a fairly good chance of succeeding in its phase III trial, as the company has wisely chosen to pursue stage IV NED (no evidence of disease) patients that have undergone complete resection surgery for both the primary tumor and liver metastases and are then pretreated with chemotherapy ahead of MCV vaccination. The expected median Progression Free Survival for this group of patients is around 2 years, which will give MCV enough time to stimulate a sufficient immune response to fight the tumor cells as they return.

Secondly DanDrit is pre-screening patients for the colorectal cancer associated antigen MAGE-A which is expressed in the MCV antigen cell line. Thereby patients who are likely not to respond to treatment will be excluded from participating in the trial.

#### **Company Overview**

Company	DanDrit Biotech USA, Inc.
Country	USA
Life Science Segment	Therapeutics
Technology platform	Dendritic Cell Vaccines
Medical focus	Oncology
Public Listing	OTC Bulletin Board
Ticker	DDRT
Number of Shares	9,533,290
Market capitalization	38.1 million USD
Actual share price	4.00 USD per share

#### Recommendation

Recommendation	Buy
Share Price Target (12M)	\$18 per share
Enterprise Value	171 million USD
Upside/Downside	+350%
Investment risk (12M)	Low
Daily turnover (6M)	4,238 USD

#### Stock Chart - OTC Bulletin Board



#### Pipeline - Net present value per share



### **Company Profile**

#### **About Dandrit Biotech**

Dandrit Biotech USA Inc. is a biopharmaceutical company focused on developing and commercializing cancer vaccines, based on the company's proprietary dendritic cell technology. The company was founded in Denmark in 2001, as a spin-off from the Danish Cancer Society following more than 10 years of research within dendritic cells carried out at the institution. In 2014 Dandrit Biotech USA Inc. was established in the United States following a Reverse Acquisition of 100% of the outstanding share capital in Dandrit Biotech A/S. The Company is currently listed on the American OTC Bulletin Board under the ticker DDRT.

Dendritic cells have proven to play a key role in the immune system in order to generate a strong and potent vaccine response against tumor cells. In April 2010 the first therapeutic cancer vaccine - Provenge - gained market approval in the United States for patients with metastatic prostate cancer. Provenge, developed by the American Biotech company Dendron Corporation, is considered to have marked the final breakthrough and proofof-concept for immunotherapy as a drug class. Provenge is a personalized autologous dendritic cell based vaccine, of which blood is extracted from the patient in order to generate the vaccine that is then re-injected into the patient via IV infusion. DanDrits leading pipeline candidate, MelCancerVac (MCV) is a personalized polytopic dendritic cell vaccine with intradermal administration, and is begin developed in colorectal cancer to prevent cancer reoccurrence following resection of the primary tumor and chemotherapy.

To date DanDrit Biotech has conducted three smaller non-randomized clinical phase II studies with MCV; two in metastatic colorectal cancer, and one in metastatic non-small cell lung cancer. The efficacy data has been encouraging in all three studies, which have led the company to prepare for a larger randomized multicenter phase IIB/III study in 174 patients with advanced colorectal cancer. The study will be initiated this year.

Furthermore Dandrit Biotech has established a European compassionate use program for MCV which on a per patient basis allows treatment with non-registered medicines for patients with life threatening diseases.

#### Virtual business model

DanDrit Biotech has adapted a smooth virtual business model that requires a minimum of infrastructure as all clinical and manufacturing activities are outsourced to Contract Research Organizations (CRO) and to Contract Manufacturing organizations (CMO). Currently as of June 2015 there were just 3 employees in Dandrit Biotech.

DanDrit Biotechs corporate headquarter is located in one of the largest bio science parks for innovation in Denmark; The Symbion Science Park in Copenhagen. The Company holds space used for work and storage of cells and biological material in freezers. In the United States Dandrit Biotech has office space in New York, USA. All offices are on a rental basis, with a three month period for notice of termination.

This makes the company highly efficient and flexible financially, as the G&A cost are reduces to a minimum, while the majority of expenditures can be allocated to creating value in the pipeline through clinical trial execution. Secondly the virtual organization is designed to make DanDrit an attractive and easy-to-implement acquisition target for larger biotech and pharmaceutical companies as the value of the company is highly concentrated in solid assets. In order words you get to buy the pipeline and the financial assets, while the fixed cost side associated with the takeover of the slim virtual organization is insignificant.

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Specifically the vaccine manufacturing process in Europe is outsourced to Cellin Technologies based in Estonia, and for the Middle East region the company has signed up with Riyadh Pharma for regarding both manufacturing and commercialization. The management of clinical trials is outsourced to the Italian cancer organization GISCAD. Finally for the compassionate use program for MCV DanDrit has struck a deal with the dutch foundation MyTomorrows.

#### Management and board of Directors

The organization at DanDrit Biotech currently consists of three employees:

#### •Chief Exective Officer Eric Patterson Leire (age 57)

The management team at DanDrit Biotech is lead by Chief Executive Officer Dr. Eric Patterson Leire. He has served as CEO at DanDrit Biotech A/S since 2011 and as a Director of the Board since 2009. Furthermore Mr. Leire has served for two years from September 2012 as Chief Executive Officer and director of DKTI A/S, a listed Danish investment company. Currently Mr. Leire also serves on the Board of Directors at Novicol Canada. Mr. Leire has a solid management background within vaccines and clinical development, which includes 15 years of experience at major global pharmaceutical companies such as Pharmacia, Pfizer and Schering Plough. Mr. Leire has been involved in the development and market launch of several important oncology drugs such as IntronA, Rituxan and Ontak. Furthermore Mr. Leire has been a partner at the venture fund Medwell Capital Corp and BioFund Venture Capital and served as CEO of the two US-based biotechnology companies APT Therapeutics and Paringenix. Mr. Leire is a Medical Doctor and also holds a MBA in Management.

#### •Chief Financial Officer Lone Degn (age 49)

In April 2015 Lone Degn was appointed to serve as Chief Financial Officer of the Company. Ms. Degn replaces Robert Wolfe as CFO. Mr. Wolfe resigned as CFO in late April 2015. Ms. Degn has previously for a period of 8 years served as financial controller at Saxo Bank until 2013. Thereafter Ms. Degn has served as an independent consultant for LD Consulting. Previously, she worked 7 years at KPMG in Denmark. Ms. Degn has a B.A. Degree in Business Administration from Copenhagen Business School.

#### ·Head of Manufacturing Berit Schultz

Berit Schultz joined DanDrit Biotech A/S in 2007 and did her thesis in Immunology at the company. In 2010 she became a full time employee responsible for the manufacturing of the dendritic cell vaccines. Berit Schultz holds a Master degree in Biochemistry.

#### **Board of Directors**

The Board of directors currently includes five members:

#### •Chairman of the Board N.E Nielsen (age 66)

N.E Nielsen is a lawyer and has served as chairman of board at DanDrit Biotech A/S since June 2013. Mr. Nielsen is a partner at Lett Law Firm in Denmark since April 2011. His practice areas are capital market conditions, securities law, boards of directors, managerial, finance and acquisitions. He currently serves as a board member or chairman at numerous Danish and international companies. Mr. Nielsen's vast international board experience is considered valuable to DanDrit Biotech.

#### •Director of the Board Jacob Rosenberg (age 50)

Jacob Rosenberg holds a medical doctor degree and a degree in medical science from the University of Copenhagen. Mr. Rosenberg is also a professor in surgery. Mr. Rosenberg has served as director of the board since May 2012. Furthermore he served as chairman of DanDrit Biotech A/S from 2003 to 2009. Mr. Rosenberg is one the leading experts in cancer and Dendritic cell technology and he has also overseen DanDrit Biotech's previous clinical trials in Denmark.



#### DanDrit Biotech Organization diagram



#### •Director of the Board Eric Patterson Leire (age 57)

Eric Patterson Leire has served on the board since 2009 and is also in charge of daily operations as the CEO of the company. As previously stated Mr. Leire has extensive experience in the pharmaceutical and biotechnology industry, which is considered valuable to the Board.

#### Director of the Board Aldo Michael Noes Petersen (age 53)

Mr. Petersen has served on the Board since 2013. Aldo Petersen holds B.A. degree in Economics from Copenhagen Business School, and has broad Business experience and knowledge of the capital markets. Mr. Petersen has since 2011 served as Chairman of LiqTech International Inc and is CEO at APE Invest A/S, a private Danish investment company. Mr. Petersen has also been involved as a major investor in Greentech Energy Systems A/S, a renewable energy company that builds wind farms in several European countries. Furthermore he has been a well known face in the Danish sports industry through engagements in the two largest professional football clubs in Denmark.

#### **Scientific Advisory Board**

The Scientific Advisory Board of DanDrit Biotech consists of people with profound knowledge and experience within immunology, Dendritic Cell biology and therapeutic applications. They have all contributed to the development of DanDrit Biotech since the inception in 2001.

#### •Professor Mogens H. Claesson

Mogens H. Claesson is a Medical Doctor (1966) in immunology from the University of Copenhagen. Today he is employed as a professor in Immunology at the Medical Faculty also at University of Copenhagen. Mogens H. Claesson's research is focused on experimental and clinical studies in tumor immunology and inflammatory diseases.

#### Professor Gerold Schuler

Gerold Schuler is a Director of the Department of Dermatology at the University Hospital in Erlangen, Germany and furthermore serves as a member of the Austrian Academy of Sciences. He has been a leader in studies of dendritic cell biology with an emphasis on the role of the cytokines GM-CSF, IL-4 and IL-13 in Dendritic cell differentiation.

#### Doctor Sjoerd H. van der Burg

Sjoerd H. van der burg serves as Associate Professor and Head of Laboratory of Clinical Oncology at the Leiden University Medical Centre, Netherlands. He is an expert in tumor immunity and cancer immunotherapy with an emphasis on cancer vaccines.

#### •Professor Jesper Zeuthen

Professor Zeuthen is the original founder of DanDrit Biotech and is considered one of the pioneers within dendritic cell Immunotherapy. He holds a Master Science degree in molecular biology and a Doctor Science degree in biology from the University of Copenhagen. In addition he has served as a Managing Director and Senior Partner at the Bankinvest Group, Copenhagen, Denmark.

#### Share capital

In November 2013 DanDrit Biotech USA, Inc. was established by merging into the empty-shell company Putnam Hills Corp, listed on the American OTC Bulletin Board. In agreement with a sole shareholder in Putnam Hills Corp, it was decided to cancel 4,400,000 shares of the outstanding stock capital consisting of in total 5,000,000 shares, as inducement to later on acquire at least 90% of the outstanding shares in DanDrit Biotech A/S.

It was also agreed that 1,440,000 new shares of DanDrit Biotech USA should be issued ahead of the acquisition of DanDrit Biotech A/S. These "cost free" common shares is allocated for consulting and legal services



valued at 5 dollars per share or 7,200,000 dollars in total.

In February 2014 DanDrit Biotech USA become the parent company following the acquisition of 100% of the issued capital stock in DanDrit Biotech A/S. The exchange ratio was 1.498842 new DanDrit Biotech USA, Inc shares per existing DanDrit Biotech A/S share, leading to a total of 6,000,000 new shares issued in the new US based parent company, including 185,053 shares of Common Stock reserved for issuance to DanDrit Biotech A/S shareholders who had not in time consented to the share exchange.

A total of 8,040,000 shares were outstanding in DanDrit Biotech USA following all transactions, whereof 7,440,000 were newly issued shares and 600,000 were original shares in the hands of previous shareholders at Putnam Hill Corp.

Later in February 2014 DanDrit Biotech USA filed a statement to register 2,400,000 new shares of common stock in an Initial Public Offering (IPO) of up to an aggregate of 12,000,000 dollars in gross proceed with a purchase price of 5.00 dollars per share. The IPO-filing was declared effective by the SEC in August 2014.

In November 2014 at closing of the initial offering period, an aggregate of 1,093,290 shares of Common Stock had been sold, raising total gross proceeds of 5,466,450 dollars. Less offering costs of 156,360 dollars, the net proceeds were 5,310,090 dollars.

Since then the company has outside the initial offering attracted further investment capital by selling a total of 400,000 shares raising gross proceeds of 2,000,000 dollars.

In summary DanDrit Biotech USA has raised 7,466,450 dollars through the issuing of 1,493,290 new shares. By the end of March 2015 the total number of shares outstanding in the company was 9,533,290 shares.

#### Shareholders

Following the IPO and attraction of additional investor capital outside the offering, the company now has a broad group of professional Danish investors whereof several have an ownership above 5%.

Orginally the two majority investors in DanDrit Biotech A/S was Media-Invest Danmark and Sune Olsen/Sune Olsen Holding ApS. They now hold 1,951,423 shares or 20.5% of the shares outstanding in the new American parent company, DanDrit Biotech USA.

Amongst the 5% holders is also the Danish investment fund DKTI A/S, which represents 189 investors also. DKTI A/S holds ownership of 5.8% of the stock capital.

Furthermore in March 2015 RS Group ApS flagged a ownership of 515,000 shares corresponding to a 5.68% of the shares outstanding. Also in March Karsten Ree Holding B ApS flagged an ownership of 500,000 shares, corresponding to 5.52% of the share capital in DanDrit Biotech USA.

In total, investors which each controls above 5% of the outstanding shares, has ownership of 5,516,947 shares, corresponding to 57.8% of all issued shares.

The executive management team and the board of directors hold 40,091 or 0.4 % of the share capital.

This leaves approximately 4,000,000 shares or 42% of the share capital in hands of other investors.

#### **Share Capital development**

Share Capital Transactions	Shares	New Total
Putnan Hills Corp.	5.000.000	5.000.000
Cancelled Putnan Hills Shares	-4.400.000	600.000
New Shares before Exchange	1.440.000	2.040.000
DanDrit Biotech A/S Exchange	6.000.000	8.040.000
Initial Public Offering	1.093.290	9.133.290
New investors outside IPO	400.000	9.533.290

#### **Current shareholders**

Shareholder	Shares	% Ownership
Eric Leire	8.615	0,09%
NE. Nielsen		
Jacob Rosenberg	31.476	0,33%
Aldo Petersen		
Lone Degn		
Directors/Officers Total	40.091	0,42%
Sune Olsen & Sune Olsen Holdin	1.157.500	12,12%
Paseco & Northern Biotech Fund	852.900	8,93%
Media-Invest Danmark A/S	793.923	8,31%
NLBDIT 2010 Services	600.000	6,28%
DKTI A/S	555.869	5,82%
Bele Invest & Roas Holding	541.755	5,67%
Ree Holding	515.000	5,39%
RG Group	500.000	5,23%
5% Shareholders Total	5.516.947	57,75%
Issued shares Total	9.553.310	100,00%



## **Pipeline & Technology**

#### **About Dendritic cells**

DanDrit Biotech was established as a spin-off from early academic work at the Danish Society of Cancer suggesting that certain cells (dendritic cells) in the immune system can be sensitized to tumors that carries foreign antigens not recognized by the immune system on its own. Dendritic cells are present as a natural part of the immune system and are primarily found in skin and epithelial membranes in for instance the nose, colon and lungs. Like macrophages-cells whose role is to engulf and then digest, cellular debris and pathogens, dendritic cells are involved in the processing of antigens and their presentation to the cells that directly carry out the immune response through antibody generation (B lymphocytes) or cell killing activity (T- lymphocytes). Like macrophages, dendritic cells are mobile and once stimulated by an antigen, activated macrophages and dendritic cells move from their host tissue to lymphatic tissues where they encounter and stimulate cells that mediate the immune response.

#### Mechanism of action for dendritic cells in cancer

Dendritic cells are among the first to meet foreign antigens in the human body and therefore holds promise as a potent anti-cancer treatment without the traditional toxicities characterized by chemotherapy and other broadly based cell targeted anticancer therapies.

Following the encounter and processing of the foreign antigens the dendritic Cells moves on to the lymph nodes/ lymphatic tissue, where the antigens are presented to other immune cells including T-lymphocytes, which possess cell killing capabilities. The T-lymphocytes then gets activated by the dendritic cells and makes them capable of killing tumor cells carrying the foreign antigens recognized by the dendritic cells. This whole process causes the tumor to stop growing and may even cause tumor regression, without killing normal healthy cells.

#### **Dandrit Tehnology**

DanDrit uses a dendritic cell technology similar to the Dendreon's FDA approved Provenge cancer vaccine. Provenge is an autologous (personal) cellular immunotherapy used intravenously in the form of infusion for the treatment of men with advanced prostate cancer. The drug was developed by the Dendreon Corporation. In April 2010, Provenge was approved by the US FDA (Food and Drug Administration) for treating men affected with advanced metastatic prostate cancer. The approval of Provenge marked the first commercial breakthrough of therapeutic cancer vaccines in the world.

DanDrit has the capability to manufacture dendritic cells in the laboratory (in vitro) from monocyte precursor blood cells taken from cancer patients eligible for DanDrit's vaccine. This is achieved by exposing monocytes the two cytokines IL-4 (interleukin 4) and GM-CSF (Granulocyte Macrophage Colony Stimulating Factor). The dendritic cells are then introduced to a panel of broken down cells that contains a selected range of foreign tumor antigens. This cancer cell lysate contains many "non-self" antigens of the cancer family. Although coded by the human genome, these antigens are not normally expressed in tissues other than cancer. Once sensitized in vitro, the immature dendritic cells are matured by exposure to the DanDrit proprietary cytokine cocktail. The now mature dendritic cells can be reinjected to the patient via a simple 0.2 ml intra-dermal injection and they will find their way to the lymphatic tissues. There, they will stimulate multiple Tcell killing lymphocytes which will become sensitized to the cancer-specific antigens present in the lysate, which it was blinded to before. Thereafter the tumor cell mechanism begins as the dendritic cells now containing recognizable tumor-antigens gets in contact with immune cell that have cell killing capabilities. To the right is a photo of a dendritic cell instructing a Tlymphocyte to kill tumor cells. The use of a patient's own dendritic cells (autologous therapy) as a vaccine vehicle eliminates the risk of unwanted



#### The DanDrit Biotech vaccine technology



# Dendritic cell instructing a T-lymphocyte to kill tumor cells



Dendritic cell = turquoise T-lymphocyte = gold

safety concerns associated with potential allergic reactions from an off-the-shelf/fits all vaccine.

Furthermore DanDrits proprietary vaccine technology contains other features that could allow for competitive advantages compared to Provenge and other personal cancer vaccine technologies:

- First of all the vaccine targets several cancer specific antigens (polytopic), versus just one targeted antigen one for Provenge. Potentially this allows for a broader immune response and consequently a larger anti-tumor response.

- Secondly the vaccine uses off-the-shelf cancer-specific antigens (allogenic tumor lysate), as opposed to patient specific antigens (autologous tumor lysate). Therefore DanDrit does not need a patient's tumor cells to manufacture the vaccine.

- Thirdly the vaccine can be manufactured and injected into the patient just eight days after the required small amount of blood cells (250 ml) has been collected from the patient through a process known as leukapheresis.

#### **Intellectual Properties**

MelCancerVac (MCV), DanDrit Biotech's lead cancer vaccine candicate, is based on proprietary technology and is protected by several issued patents. Furthermore the company holds four key patents within dendritic cells, which are protected by relevant international extensions:

 Pharmaceutical composition for inducing an immune response in a human or animal (filed 2002, expires in 2022)

The patent covers and describes the usage of an allogenic melanoma cell lysate MCV-pulsed autologous Dendritic Cells (DC) vaccine expressing at least one of six MAGE-A antigens overexpressed by the cell line being the source of the lysate. The patent covers the antigen composition used in the generation of MelCancerVac and the claims for producing MelCancerVac

• Protocol for generating dendritic cells (filed in 2006, expires in 2032)

This patent covers the generation of dendritic cells based on a blood sample of 200 ml. The patent differs from other DC generating patents by the utilization of reduced temperature and a single blood sample. DanDrit has developed a method that covers the generation of immature dendritic cells under reduced temperature settings which by further activation has been shown to give a high yield of homogeneous and fully matured DCs.

 Method for generating tolerogenic dendritic cells employing decreased temperature (filed in 2008)

DanDrit has expanded the method of development of mature dendritic cells to also include the generation of regulatory DCs. In addition to DCs used for cancer immunotherapy, DanDrit has developed an additional arm of DCs, namely regulatory/tolerogenic DCs to be used for treatment of various autoimmune diseases such as Type 1 diabetes and Multiple Sclerosis.

## • Micro RNAs as markers of the functional state of a dendritic cell (filed in 2008)

This patent covers and demonstrates that functionally different DCs carry unique microRNA signatures. By examining a handful of microRNA profiles one can analyze the function of DC vaccines

It is expected that DanDrit will continue to patent its innovations, for instance within Dendritic Cell production systems and Cell Quality control. Furthermore DanDrit will continue to pursue patents of non-core technologies, which will be made available for out-licensing, as this will



optimize the company's long term revenue stream and preserve working capital for its key pipeline activities for MelCancerVac. Non-core applications of dendritic cell technologies held by DanDrit includes applications within diabetes and infectious diseases.

In addition to the intellectual properties DanDrit Biotech has so far obtained these trademarks:

•MelCancerVac™ •MelVaxin™ •DanDrit™

#### **MelCancerVac**

DanDrit's primary clinical vaccine candidate MelCancerVac (MCV) is a cellular immunotherapy for treatment of cancer. MCV comprises of two elements;

•Autologous dendritic cells obtained by the activation of patient-specific blood cells (monocytes)

•Proprietary allogenic tumor lysate from a melanoma cell line expressing a range of cancer antigens, notably the MAGE-A family, which is found in many tumors, and importantly with no expression in normal cells.

In order for a patient to respond to treatment with MCV, a significant antigenmatch between the patient's own tumor and the proprietary allogenic tumor lysate is crucial. By analyzing each patient's tumors by RT-QPCR (Reverse Transcriptase Quantitative Polymerase Chain Reaction), it is possible to select patients that have the best chance of success with MCV. Typically if more than half of the 14 antigens in the MCV lysate is co-expressed with the antigen biopsy from the patient it is considered a good match and therefore a good candidate for MCV-treatment. However, other uncharacterized antigens may also be present that might promote a response.

#### Encouraging clinical data to date

So far three clinical trials with MCV have been conducted in two different cancer types; Non-small cell lung cancer (NSCLC) and colorectal cancer (CRC). Patients enrolled in these studies have all been in the terminal stage IV setting (metastatic disease) and the patients have failed to respond to previous treatment options such as surgery and chemotherapy. Several patients have responded very well to MCV-treatment and have experienced tumor stabilization or even tumor regression.

In the following is an overview of the clinical data from the trials:

• Colorectal cancer Phase I/II study at the Gentofte Hospital, Denmark – November 2004 to April 2006

The purpose of the study was to study the tolerability and effect of MCV given as intradermal injections to patients with metastasizing colorectal cancer, where there was no indication for surgery or chemotherapy. The first part was a phase I study to investigate whether treatment with MCV was toxic. No toxicity was observed and the study continued into phase II to study the effect and tolerability of MCV.

In total 20 patients with metastatic colorectal cancer not curable by resection and with no further conventional therapy options available were treated using an older vaccine version of the MCV loaded with lysate of allogeneic melanoma cells. At the completion of the trial 20% (4 out 20 patients) experienced stable disease. No toxicity was observed.

#### • Colorectal cancer Phase IIa at the National Cancer Centre, Singapore – June 2005 to June 2007

This single arm phase II clinical study was sponsored and funded by the Singapore National Cancer Centre (NCC) to investigate the efficacy of intradermal vaccination with MCV in patients with advanced colorectal cancer. The study used DanDrit's patented procedure for generating dendritic



	A-1	A- 2	A- 3	A-4	A- 5	A- 6	A-7	A- 8	6-V	A- 10	A- 11	A- 12	A- 13	A- 14	A- 15	A- 16	A- 17	A- 18	A- 19	A- 20	A- 21	A- 22	A- 23	A- 24	A- 25	A- 26	A- 27	A- 28
	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
MelCancerVac	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	C	0	0	0	0
Patient 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Patient 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

() No Charge () some expression () medium expression () high expression Low match in patient 1, but high match in patient 2.

*I.e. patient 2 is a good candidate for MCV-treatment.* 



cells. All included patients had tumors which 'antigenically' correlated with the vaccine, i.e. were MAGE-A positive. The purpose of the study was to investigate the objective efficacy and specific immunologic response of the MCV vaccination. The first patient was enrolled in June 2005, and by June 2007 a total of 20 patients had been treated and evaluated. The patients were diagnosed with advanced progressive colorectal cancer and then pretreated with chemotherapy and before starting MCV-treatment. The trial utilized an improved version MCV with an improved cell line that will also be used in future studies. All patients were considered to have no further indication for surgery or treatment with chemotherapy. Each patient received up to 10 intradermal vaccinations at biweekly intervals. The 20 patients received a total of 161 vaccinations. Treatment was well-tolerated with minimal adverse events. Quality of life measurement using global health score was high at baseline and did not change during the duration of the trial. At the completion of the trial 40% (7 stable disease and 1 partial tumor regression) were found to benefit from the vaccine. While patients with single metastatic sites in either lung or nodal regions tended to have more durable responses, Stable Disease was also attained in patients with bulky multiple metastases. The Median Progression Free Survival (PFS) was only 2.4 month, however 25% (5 patients) had a PFS > 6 months, and 2 of these patients were still progression free several years later. Furthermore significant immunological responses were observed in vivo as a delayed type hypersensitivity (DTH) reaction against the vaccine product. Results from the trial were presented orally at the AACR meeting in Singapore in November 2007. In September 2008 the Singapore government validated the clinical data by approving a named patient program for MCV that allows for treatment with MCV at cost at the National Cancer Center in Singapore.

A meta-analysis of clinical data in the same setting with other vaccine vaccines was performed to evaluate the strength of the MCV-results. In total 32 clinical trials with cancer vaccines in patients with advanced colorectal cancer reported a Clinical Benefit Rate in 11.2% of patients and an overall response rate (Complete Response and Partial Response) of 0.9%. The defined clinical benefit rate (Complete Response, Partial Response, Stable Disease) was observed in 17% (12 of 70) of colorectal cancer patients who received dendritic Cell vaccines. In this contect the 40% clinical benefit rate seen in the MCV-trial seems superior which might be due to its polytopic nature, its allogenic adjuvant-like components, the quality of the Dendritic Cell preparation/maturing, the intradermal route of vaccine injection securing optimal lymph drainage to regional lymph nodes, the presence of MAGE expression in both patients and vaccine and the increased frequency of delivery (10 injections).

## •Non-Small Cell Lung Cancer Phase IIa study at the Herlev Hospital, Denmark January 2006 to September 2009

DanDrit sponsored and funded this MCV clinical trial in Non-Small Cell Lung Cancer (NSCLC) conducted at Herlev Hospital, University of Copenhagen in Denmark. The NSCLC trial was designed as an open-label, phase II clinical study. Enrolled patients had disseminated, inoperable NSCLC after chemotherapy. The patients did not want further chemotherapy and no other systemic treatments could be offered to them. 28 patients with advanced or metastatic non-small cell lung cancer were treated in the study. All patients had disseminated and inoperable NSCLC following chemotherapy and no further treatment options available. 25% (7 patients) had prolonged stable disease following the vaccinations and of these 18% (5 patients) were found to respond to the vaccine immunologically. The median overall survival was 7.4 months. Two patients were still alive at the time of analysis. An exploratory analysis showed that patients with stable disease had significantly (P = 0.007) better survival (18.1 months median) compared to those with progressive disease (6.2 months median). Although the median time to tumor progression was short at 2.4 months, 5 patients (18%) experienced a prolonged PFS of more than 6 months, and two of them continued to be progression-free at time of analysis ( >27 months and >37 months respectively). Conclusively, to get a broader perspective on



theefficacy of the MCV-treatment in NSCLC, the investigators recommended that a randomized trial should be conducted.

#### Overall clinical safety

No MCV-vaccination to date has demonstrated life-threatening side effects. The only potential adverse events associated with the dendritic cell vaccine identified to date are injection site reactions, flu-like symptoms with fevers up to 39-40 degrees Celsius, chills, and headaches in some patients. The occurrence of these adverse events was primarily grade 1-2 and therefore did not require additional treatment or hospitalization.

#### Proposed phase III trial in advanced colorectal cancer

DanDrit Biotech has proposed a design for a randomized placebo-controlled phase III trial to confirm and validate the existing data from previous completed single armed phase II trials. The proposed study is anticipated to enroll 174 patients at 30 sites in Italy.

DanDrit will work with the GISCAD Foundation (the Italian Group for the Study of Gastrointestinal Carcinoma) in Italy and with IRCCS University Hospital San Martino, all of which are recognized as among the world's premier cancer research and treatment facilities. The GISCAD Group has conducted multiple clinical trials in colorectal cancer including most recently the TOSCA trial, a clinical trial evaluating FOLFOX-4 3 months vs. 6 Months and Bevacizumab as adjuvant therapy for patients with Stage II/III CRC. The network of Italian hospitals enrolled 3,800 patients in this trial.

DanDrit has sought scientific advice from the Italian Medicine Agency (AIFA) in connection with the Phase /III trials in Italy and will also request a pre-Phase II/III meeting with the FDA. GISCAD provides preparation and assistance for the Scientific Advice process in EMEA including the following activities.

The subjects included will be stage IV Colorectal Cancer patients, which before inclusion will have undergone resection of the primary tumor as well as metastases, followed by adjuvant chemotherapy. As a consequence, at enrollment all patients in both the active vaccine arm and the control arm will have no evidence of disease (NED).

All participants will be screened for MAGE-A expression and for Dendritic cell "fitness" using IL-12p70 as a marker. This will insure that only subjects that are likely to benefit from the therapy will be enrolled.

Although the number of potential stage IV patients is significant, only approximately 10-20%, will have complete resections of their primary tumors and metastatic disease with no detectable residual disease (i.e. NED). This coupled with a competitive oncology vaccine research environment will put pressure on accrual milestones.

Patients will be treated 10 times with 14-day intervals with intradermal vaccinations followed by 5 vaccinations with 2-months intervals. Patients in the control-arm will receive a reference treatment, (placebo as no treatment is approved as of today).

The co-primary endpoints will primarily consist of Relapse Free Survival (RFS) at 18 months between the control arm and the MCV arm and secondly Overall Survival. A tumor progression event is established if a patient develops new tumor lesions measured by CT scan - in that case any further vaccinations will be ceased. Based on an external study in a similar group of colorectal cancer patients comparing FOLFOX adjuvant therapy to no adjuvant therapy following resection of primary tumor end liver metastases, DanDrit has estimated a mean RFS for the control arm of 26 months. MCV is expected to generate a Mean RFS of 42 months, representing a RFS increase of 61.5% vs. the control arm (See graph to the right). In terms of statistical analysis, the study design allows for 80% power to detect a 50% reduction in PFS at 18 months. Quality of Life and CEA (Carcino-Embryonic

DanDrit Biotech USA, Inc.



#### MelCancerVac Phase III Overview

Purpose	To determine the safety and efficacy of The MCV- vaccine in colorectal cancer and to determine its ability to prevent recidivism in stage IV colorectal patients with no evidence of disease (after resection of metastase and chemotherapy)
Study Type	Interventional
Study design	
Endpoint (primary) Endpoint (secondary)	Efficacy : Progression Free Survival at 18 months and overall Survival Carcino-Embryonic Antigen (CEA); Quality of Life
Intervention Model	Parallel assignment 174 patients
Allocation	Randomized
Adaptive Design Treatment	Purpose: seamless Phase II/III clinical trial
neutinent	administration) followed by ten vaccines every two months
Location	Italy and USA
Expected Duration	Three years
Eligibility	Stage IV colorectal cancer patients After resection of metastase and no evidence of disease (CT scan and CEA back to normal) Vaccine therapy given after FOLFOX or FOLFIRI

#### Phase III MCV Trial Design

Advanced colorectal cancer patients after resection of liver metastasis and chemotherapy. No evidence of Disease



Antigen) which are biomarkers for colorectal cancer will be secondary endpoints. An interim analysis measuring RFS and CEA levels will be conducted as 18 months data becomes available for the first 90 patients. DanDrit will then decide whether to adjust the number of patients in the study, and whether to expand the trial with additional 150 patients in the United States to a total of 324 patients. An Independent data monitoring committee (IDMC) headed by chairman Professor Axel Grothey, Mayo Clinic and data safety monitoring board (DSMB) will assist in the interim assessment for efficacy and safety.

The study in regards to the interim analysis at 18 months is expected to be completed within 2 years. Patient accrual time is expected to be 2 years.

#### **Clinical phase III trial partnership with GISCAD**

In April 2015 DanDrit signed a final collaboration agreement with GISCAD Foundation for the execution of the phase III trial with MCV in 174 patients with Stage IV colorectal cancer and no evidence of disease (NED). GISCAD will assist DanDrit in the identification, enrollment, compliance monitoring and management of the 30 clinical sites in Italy. Professor Alberto Sobrero at San Martino Hospital of Genoa will be the Principal Investigator of the randomized multicenter study. The clinical study is expected to start in Q3 2015. Right now DanDrit is awaiting the final regulatory study approval which is expected in August 2015.

#### Other clinical plans with MCV going forward

DanDrits primary clinical strategy is focused on conducting the Italian phase III trial, however a parallel registration trial to obtain approval of MCV in China, might be initiated. China has recently put in place a drug approval system that includes a low-cost clinical approval pathway especially for Chinese biotechnology companies. A registration trial therefore would be conducted under China's State Food and Drug Administration regulations and with a Chinese oncology pharmaceutical partner, such as the TASLY Group or 3S Bio. Contacts with 3S Bio, TASLY Group and TTY Biopharm have already been initiated. The approval for local biotechnology players is advantageous, since costs for a pivotal clinical trial in China are estimated at one tenth of EU or U.S. costs. If DanDrit decides to pursue Chinese development of MCV, it will be through a Chinese partner, which will be in charge of clinical development, manufacturing and commercialization.

Also DanDrit are in discussions with the National Cancer Institute (NCI) in the United States to sponsor a phase I/II study for MCV in combination with a PD-1 immune checkpoint inhibitor. The study will be in bladder cancer stage II patients, i.e. with cancer cells localized to the bladder only. The likely format of the study will be 50 patients divided into two arms; MCV only and MCV+PD-1. It is still early in the process and further regulatory and technically issues in terms of manufacturing and production of the vaccine in the United States will have to solved, so the trial is not expected to start until second half 2016.

DanDrit is also evaluating the possibility of initiating studies in other solid tumor types such as esophageal cancers which have a high expression of the MAGE-A antigen. Surgical resection is currently the only potential cure with or without neo-adjuvant or adjuvant chemo-and/or radiotherapy, the five year survival rate is less than 20%. At first presentation, approximately 50-60% of patients with esophageal cancers is not eligible for surgery and have very poor outcome.

#### myTomorrows Compassionate Use Program agreement

In December 2013, DanDrit entered into an agreement with the Dutch company MyTomorrows (MT), regarding a compassionate use program – a so called Patient Name Use Program - for MCV. myTomorrows provides patients that are excluded from clinical trials access to non-registered drugs in development, with focus on disease areas with unmet needs. myTomorrows will be responsible for identifying cancer patients eligible for MCV-treatment, informs patients and facilitates requests for access to the





vaccine. myTomorrows will also be in charge of regulatory issues, recruitment, logistics, and drug safety. DanDrit's potential liabilities are limited to quality control of cGMP manufacturing of MCV. The program will cover certain European markets and it will allow Dandrit to sell one year of MCV-treatment (10 vaccines) to patients.

MCV is expected to be launched first in Denmark and Estonia, followed by Netherlands, France and Turkey. Later on the program will expanded to Sweden and Belgium. DanDrit will pay myTomorrows a royalty on a country to country basis for 20 years on MCV sales sold under the agreement. Either party may terminate the agreement with 180 days written notice. The cost per patient is expected to be 22,000 dollars, with a margin on sale in the 50% range for DanDrit. The vaccine will be produced in the manufacturing facility in Estonia, with a vaccine production capacity for treatment of up to 500 patients annually.

The first revenue from the program is expected in 2015. DanDrit also anticipates that this program may contribute to lowering the cost of manufacturing of the clinical lot through economy of scale. This program is also expected to generate valuable real life data for MCV.

#### Partnership with Ryiadh Pharma

In April 2015 DanDrit signed a partnership agreement for MCV with the pharmaceutical company Riyadh Pharma covering the Saudi Arabian market. The purpose of the deal is to promote the use of cancer vaccine technology, i.e. MCV, in the Middle East. Ryiadh Pharma will be responsible for the manufacturing of MCV in accordance with scientific standards and international quality standards. In essence this is a compassionate use program like the agreement with myTomorrows, which at first will focus on four hospitals in Saudi Arabia, and is later expected to be expanded to other part of Middle East, e.g. Dubai and Qatar. The sales price and margin contribution is expected to be similar to the myTomorrows program. The incidence of colorectal cancer is extremely high in Saudi Arabia and only second to breast cancer. Furthermore research report suggests that the incidence of colorectal cancer in Saudi Arabia could quadruple by year 2030.

#### Next generation of the off-the-shelf vaccine technology

In 2013 DanDrit has entered into negotiations with the Etablissement Français du Sang (EFS) regarding access to their GeniusVac Technology. The GeniusVac technology is an allogenic irradiated plasmacytoid dendritic cell line. This technology may allow DanDrit to develop a 100% off-the-shelf cancer vaccine, named MCV2. DanDrit and EFS are now working on a feasibility proof-of-concept test before establishing further collaboration. Potentially MCV2 could offer multiple advantages over MCV:

•The vaccine could be mass-produced in a unique manufacturing facility •Fully standardizable product and therefore guarantee of homogeneity of the clinical trials material

Cost efficient process

•All manufacturing process can then be out-sourced (DanDrit does not need to support its own GMP manufacturing facility)

•The MCV2 vaccine could be more likely to have higher potential efficacy than MCV. The allogenic DC's are further regarded as MHC-incompatible foreign invaders. Then, they induce an inflammatory reaction that further promotes the recruitment and activation of endogenous DC's at the vaccination site. This hypothesis has now been verified in rat and mouse cancer models in which tumor growth was significantly reduced by therapeutic vaccinations with tumor-loaded allogenic DCs.

#### Other preclinical pipeline assets

DanDrit is also evaluating the antigen-platform MelVaxin, which is basically similar to the lysate component of MCV. DanDrit proposes injecting MelVaxin into the skin to promote natural dendritic cell responses that will attack the tumor expressing antigens. It is necessary to inject MelVaxin with an



immuno-stimulator such as GM-CSF, BCG or novel adjuvants (such as 3M's TLR7 and TLR8 agonists). A preclinical program has been planned in minipigs. These animals have immune response profiles, particularly of skin injection, that are very close to human. However the MelVaxin program is currently on hold, and will only be reinitiated if resources become available.

DanDrit also has established methods to derive tolerogenic dendritic cells from peripheral blood monocytes, similar to the approach used to generate immunogenic dendritic cells in MCV. In MCV dendritic cells are derived in such a way that the resulting dendritic cells promote an immune reaction. However, dendritic cells may also be derived in such a way that they are tolerogenic, i.e. they promote immune tolerance. In this way the tolerogenic dendritic cells are used to turn off an undesirable immune reaction. Promoting immune tolerance can be used to treat autoimmune diseases such as early stage type I diabetes or to help prevent rejection of tissue transplantation. DanDrit has filed patents to cover the generation of tolerogenic dendritic cells.

Furthermore DanDrit has developed methods for fast track production of mature immunogenic dendritic cells. Currently it requires eight days of growth in culture, however the efficiency of producing MCV could be improved if the time required to generate dendritic cells could be significantly reduced. DanDrit has tested protocols for generating dendritic cells in either two days or five days. These new fast track methods are covered by DanDrit's existing dendritic cell technology patent. This fast-track production technology could be of commercial interest for other companies working in non-competitive areas of dendritic cell technology.

Lastly DanDrit has patented a method using microRNAs to characterize dendritic cells and establish a basis for quality control. To date there are few dendritic-cell specific antigens and those existing are covered by patents. DanDrit has patented its microRNA approach developed with Bioneer.

### **Financials**

#### Full year 2014 financial result

DanDrit reported a net deficit for the full year 2014 of 2.4 million dollars. There was no sales income in 2014 compared to 32,738 dollars in 2013. The sales in 2013 came from the compassionate use program in Singapore and this program was discontinued in 2014.

DanDrit's operating expenses totaled 2.4 million dollars in 2014, representing an increase of 0.6 million dollars or 37% compared to 1.8 million dollars in 2013.

The cost of goods climbed to 0.3 million dollars in 2014 from 0.1 million dollars in 2013 due to increased costs of technology transfer for the lysate antigen manufacturing.

Furthermore general and administrative expenses rose to 1.6 million dollars compared to 1.2 million dollars in 2013, representing an increase of 33%. The increase was related to costs associated with the audit and the costs associated with becoming publically traded in November of 2014. General and administrative expenses include office rental, website management, insurance, and salaries.

Also consulting expenses rose 21% in 2014 to 0.5 million dollars versus 0.4 million dollars in 2013. The increase relates to valuation of DanDrit Biotech A/S in preparation for the Share Exchange, the preparation of the IPO-filing in August 2014 and consultant services for the proposed phase III clinical trial.

At year end 2014 the cash preparedness was 5.0 million dollars, of which 2 million dollars was cash held in escrow. There was a positive cash flow of 3.0 million dollars in 2014, reflecting mainly a net income from financing activities



'000 Dollars	FY2014	FY2013	+/- Dev.	+/- %
Product sales	0,000	0,033	-0,033	-100%
Total revenue	0,000	0,033	-0,033	-100%
Cost of goods	-0,296	-0,109	-0,186	-171%
Sales & Distribution				
Research & Development				
General & Administrative	-1,645	-1,234	-0,411	-33%
Consulting	-0,470	-0,390	-0,079	-20%
Depreciation and Amortizatio	-0,019	-0,038	0,019	50%
Total operating expenses	-2,429	-1,772	-0,658	-37%
Operating Income	-2,429	-1,739	-0,690	-40%
Financial items	-0,119	-0,408	0,289	71%
Income before taxes	-2,548	-2,147	-0,401	-19%
Income taxes	0,178		0,178	
Net Income	-2,371	-2,147	-0,224	-10%

#### Full Year – Key Financial Figures

OUU Dollars	FY2014	FY2013	+/- Dev.	+/- %
Cash Flow - Operating	-2,034	-2,131	0,096	5%
Cash Flow - Investing	-1,646	-0,324	-1,321	-407%
Cash Flow - Financing	6,670	2,470	4,200	170%
Net Cash Flow	2,990	0,014	2,976	20645%
Cash in hand	3,009	0,019	2,990	15910%
Cash held in escrow	2,030	0,077	1,952	2520%
Total Cash preparedness	5,038	0,096	4,942	5134%
Equity	3,482	-1,684	5,166	307%
Non-current Liabilities	0,000	0,000		
Total Liabilities	1,758	2,135	-0,377	-18%
Total Assets	5,240	0,450	4,789	1063%
Shares outstanding (number)	9.533.290	6.000.000	3.533.290	59%
Employees (number)	3	3	0	0%
Earnings per share (EPS)	-0,25	-0,36	0,109	31%

of 6.7 million dollars.

The number of shares outstanding grew from 5,814,495 shares by year end 2013, to 9,553,290 shares by year end 2014. The total gross proceed raised from the IPO and the issuing of the new shares outside the IPO was 7.5 million dollars, reflection the issuing of 1,493,290 shares. The Company has used part of the proceeds to repay notes payable and related accrued interest totaling 1.4 million dollars.

#### First Quarter 2015 Financial result

DanDrit reported a net loss of 1.3 million dollars in Q1 2015 versus a net loss of 0.4 million dollars in Q1 2014.

During Q1 2015 there were no sales under the new myTorrows compassionate use program in Europe for the MCV vaccine.

The cost of production for MCV lysate antigen was 44,622 dollars in Q1 2015 compared to 17,739 dollars in Q1 2014.

In total DanDrit's operating expenses was 0.9 million dollars, reflecting an increase of 110% compared to operating expenses in Q1 2014 of 0.4 million dollars. The significant increase reflects primarily an increase in consultant services of 291,998 dollars in Q1 2105 compared to 61,145 dollars in Q1 2014. Also the company reported 151,813 dollars in Research and Development expenses related to preparations for the phase III trial with MCV. Specifically the cost was allocated towards formulating, improving, validating and creating alternative or modified processes related to and expanding the use of the MCV vaccine.

General and administrative expense also climbed slightly with 14% to 372,996 dollars versus 326,428 dollars in Q1 2014. This increase was mainly related to costs associated with the audit and salary expenses due to the resignation of the previous Chief Financial Officer Robert Wolfe.

In Q1 2105 DanDrit reported a loss on financials items of 387,861 dollars compared to a loss in Q1 2014 of 13,948 dollars. The increase reflects interests on related party loans and a loss on currency transactions reflecting the surge in danish kroner against the dollar.

By the end of March 2015 DanDrit had a cash preparedness of 3.4 million dollars. The net cash flow in Q1 2015 was 0.4 million dollars, despite a net deficit in the operating cash flow of 2.0 million dollars, as 2.0 million dollars previously held in escrow was released and thereby strengthened the cash position.

DanDrit had by end of March 2015 net operating loss carry-forwards of approximately \$2.4 million dollars for Danish tax purposes and net operating loss carry-forwards of approximately 0.2 million dollars for U.S. Federal Tax purposes.

#### Outlook 2015

DanDrit has recently changed its fiscal year from January-December to July-June. The Company will therefore during the transition period file its next annual report for a six months period, i.e. January 2015 to June 2015.

For the full calendar year 2015 DanDrit expects operating expenses to ramp up ahead of the start of the phase III trial, in relation to cost for clinical trial sites, manufacturing, consulting, contract research and development and compensation. However the management believe the current cash position of 3.4 million dollars by the end of March 2015 is sufficient to fund the company for the next 12 months

By July 2015 according to the company guaranteed additional funding investments from existing shareholders have been provided in the order 2



'000 Dollars	Q1 2015	Q1 2014	+/- Dev.	+/- %
Product sales				
Total revenue	0,000	0,000	0,000	
Cost of goods	-0,045	-0,018	-0,027	-152%
Sales & Distribution				
Research & Development	-0,152	0,000	-0,152	
General & Administrative	-0,373	-0,326	-0,047	-14%
Consulting	-0,292	-0,061	-0,231	-378%
Depreciation and Amortizatio	-0,004	-0,007	0,003	40%
Total operating expenses	-0,865	-0,412	-0,453	-110%
Operating Income	-0,865	-0,412	-0,453	-110%
Financial items	-0,388	-0,014	-0,374	-2681%
Income before taxes	-1,253	-0,426	-0,827	-194%
Income taxes	0,000	0,000	0,000	
Net Income	-1,253	-0,426	-0,827	-194%

#### First Quarter – Key Financial Figures

'000 Dollars	Q1 2015	Q1 2014	+/- Dev.	+/- %
Cash Flow - Operating	-2,044	-0,438	-1,606	-367%
Cash Flow - Investing	2,470	-0,393	2,862	729%
Cash Flow - Financing		0,866	-0,866	-100%
Net Cash Flow	0,426	0,036	0,390	1094%
Cash in hand	3,435	0,054	3,380	6206%
Cash held in escrow		0,424	-0,424	-100%
Total Cash preparedness	3,435	0,478	2,956	618%
Equity	2,671	-2,186	4,858	222%
Non-current Liabilities	0,000	0,000	0,000	
Total Liabilities	0,972	3,098	-2,126	-69%
Total Assets	3,643	0,911	2,732	300%
Shares outstanding (number)	9.533.290	7.854.947	1.678.343	21%
Employees (number)	3	3	0	0%
Earnings per share (EPS)	-0,13	-0,05	-0,077	-142%

#### Financial guidelines 2016-2018

Est. USD 17M over 3 years

USD M.	Year 1	Year 2	Year 3	Total
Clinical trial	2.95	2.30	2.65	7.90
Manufacturing	0.8	0.25	0.25	1.3
Admin / payroll	1.4	1.4	1.4	4.2
Reg / Account	0.5	0.4	0.4	1.3
IP costs	0.3	0.15	0.15	0.6
Misc.	0.3	0.3	0.3	0.9
Total				16.20

million dollars. This capital investment is expected during July-September 2015.

The company has also provided a schedule for the start of the myTomorrows compassionate use program. The program has been delayed slightly due to regulatory issues, but is on target to start taking in patients in July-September 2015.

Furthermore the company is planning to move the company from the current listing on the OTC Bulletin Board to the New York Stock Exchange. However in order to pursue this strategy a certain minimum trading liquidity on a daily basis in the stock is required, as well as a minimum number of shareholders in the company. Also a share price above 3 dollars per share is required. It is therefore uncertain when DanDrit will succeed in this matter.

#### **Competitive Cancer Vaccine landscape**

In recent years the interest and focus in cancer immunotherapy has increased sharply, following the commercial breakthrough defined by the FDA-approval of Dendreon's autologues dendritic cancer vaccine Provenge in metastatic prostate cancer in April 2010.

The immunotherapy efforts in the medical community can be divided three main segments:

•Off-the-shelf cancer vaccines (allogenic vaccines)

Personalized cancer vaccines (autologues vaccines)

•Classic medicine targeting immune-regulating antigens (checkpoint inhibitors, immune modulators etc.)

Numerous off-the-shelf cancer vaccines have shown promise in early clinical Phase I and II trials, but so far have had difficulties meeting primary endpoints in pivotal Phase III clinical trials. Recent high profile failures include Merck/Oncothyreon's MUC-1 peptide vaccine Stimuvax in lung cancer and GSK/Argos's MAGE-A3 vaccine in melanoma. Both vaccines failed in phase III despite very impressive phase II data.

The class of personalized vaccines is so far the only class of therapeutic vaccines that have succeeded in bringing a medicine to the market. Provenge has consistently shown an increase of 4-5 month in survival versus placebo corresponding to approximately 25% reduction in mortality. Following market approval in 2010 Provenge achieved sales around 300 million dollars annually, but Dendron never capitalized on the scientific breakthrough due a failed business model, which in the end crushed the company on massive high operating costs and a unsustainable high long term debt. In recent years the focus for the personalized vaccine segment has shifted towards blood cancers like leukemia and lymphoma, in which new companies like Kite Pharma and Juno Therapeutics have demonstrated very impressive clinical data in early Phase I/II trials. The valuation of these companies is now in the range 3-5 billion dollars, despite only early clinical data, a questionable safety profile and still several years to potential market approval.

The class of checkpoint inhibitors and immune modulators is so far from a commercial perspective the most successful. Bristol Myers Squibb's Yervoy has marked the scientific breakthrough approved in metastatic melanoma several years ago and is now topping 1 billion dollars in annual sales. While Yervoy targets the CTLA-4 protein which acts like a break on the immune system, other checkpoint inhibitors like PD-1 and PD-L1 is now gaining momentum in aggressive cancers like lung cancer. Recently Bristol Myers Squibbs Opdivo and Mercks Keytruda have been approved by the FDA. Research reports suggest that as the class of check inhibitors gain approval in other types of solid tumors, it will achieve annual sales above 30 billion dollars in the 2022-2024 timeframe. However from a scientific point of view checkpoint inhibitors should work synergistically, when combined with a regular cancer vaccine (either allogenic or autologus).



## Peer Valuation Cancer Immunotherapy

		-		F /
Company	Immune class	Marketcap	Equity	Pipeline
Juno Therapeutics	Personalized	4.910	1.000	3.910
Kite Pharma	Personalized	2.870	386	2.484
Celldex	Off-the-shelf	2.480	376	2.104
Bavarian Nordic	Off-the-shelf	1.339	188	1.151
Northwest Bioth.	Personalized	831	-71	902
Agenus	Off-the-shelf	784	46	738
Dendreon Corp	Personalized	495	-332	827
Oncothyreon	Off-the-shelf	388	106	282
Galena BioPharma	Off-the-shelf	275	59	216
Argos Therapeutics	Personalized	133	15	118
Prima Biomed	Personalized	60	23	37
ImmunoCellular Th.	Personalized	44	32	12
DanDrit Biotech	Personalized	38	3	35
Industry average		1.127	141	986
Adillian LIC Dellana				

Million US Dollars

#### Peer Valuation – Marketcap (million USD)



#### Peer Valuation – Equity (million USD)



#### Valuation comparison

DanDrits only direct competitors in the colorectal cancer space include Bavarian Nordics CV-301 and Immatics which are developing a peptide vaccine in the setting. However recently Bavarian Nordic has abandoned development of CV-301 in colorectal cancer and will instead pursue main development in the lung cancer indication and in combination with PD-1 a checkpoint inhibitor. Furthermore Immatics colorectal cancer trial is just in phase I, and therefore several years behind DanDrits MCV.

In the graphs to the right we have taken a look at the valuation of some of the most relevant public listed competitors in the cancer immunotherapy universe and compared it to the current market valuation of DanDrit. Both from a Market cap perspective and from a pipeline valuation perspective the valuation of DanDrit rank in the bottom.

## **Pipeline Discounted Cash Flow Valuation**

#### **Overall cancer market**

With 12,667,500 estimated number of new cancer cases in 2008, cancer remains the main cause of death in developed countries, accounting for approximately 33% of deaths. In the United States 1.64 million new cancer cases were registered in 2012 and with 0.58 million associated deaths. In Europe the number of new cancer cases for 2012 was estimated at 3.45 million with a 1.75 million deaths. The cancer market has a high growth potential for the coming years with an expected 11% annual growth rate for the years 2013-2020. This makes the cancer market the fastest growing pharmaceutical market with total forecasted sales of 153 billion dollars in 2020.

#### MCV pricing per patient

DanDrit intends to price a full course of MCV-treatment per patient at 35,000 dollars. We find this price reasonable and fully justified in comparison with a per-treatment price of chemotherapy in colorectal cancer at approximately 30,000 dollars and a cost per patient of Provenge in prostate cancer at 93,000 dollars. We are therefore comfortable using 35,000 dollars per treated patient in our valuation modeling.

#### Net profit Margin

The net profit margin for cancer drugs are often very high, as these drugs are premium priced, while manufacturing and marketing costs are more or less on par with the industry as a whole. We are expecting a net margin around 55% for MCV as DanDrit at this point has the full rights to the vaccine (no third party royalty obligations at all). A 55% net contribution margin is a bit below average for many cancer drugs, however we believe that a personalized vaccine format does require some extra manufacturing and distribution costs, compared to classic off-the-shelf-drugs.

#### MCV lifecycle following market approval

We are using a standard 10-year modeling for this parameter, meaning that in our model, MCV will be on the market for 10 years following market approval.

#### Weighted Average Cost of Capital (WACC) at 15%

The WACC is the minimum return that a company must earn on an existing asset base to satisfy its creditors, owners, and other providers of capital, or they will invest elsewhere. In general we are operating with a WACC of 15% for biotech companies which are still in the risky part of their development phase. DanDrit Biotech clearly falls within this category, as in order to create long term value in the pipeline for its shareholders the company is expected to increase its cash burn rate in the coming quarters as the phase III trial gets underway.



#### Peer Valuation – Pipeline (million USD)



#### Cancer Mortality – Deaths each year

Population	USA	EU	Combined
Population	325,200	508,200	833,400
Lung	0,125	0,205	0,330
Colon	0,050	0,085	0,135
Bladder	0,017	0,038	0,055

Million people

#### Cancer Incidence - New cases each year

Population	USA	EU	Combined
Population	325,200	508,200	833,400
Lung	0,190	0,315	0,505
Colon	0,150	0,250	0,400
Bladder	0,075	0,150	0,225

Million people

#### Cancer Prevalence – Living with cancer

Population	USA	EU	Combined
Population	325,200	508,200	833,400
Lung	0,500	1,000	1,500
Colon	1,100	2,200	3,300
Bladder	0,500	1,000	1,500

Million people

#### Definition of current pipeline assets

The only clinical active compound as of today in DanDrits pipeline is MCV. Besides the objective of taking MCV to the market in the Colorectal tumor resection stage IV adjuvant setting, the company is also aiming to expand the label further to include colorectal patients with stage IV non-resectable tumors as well as patients with stage III locoregional advanced recectable tumors. But in order to obtain the official label it would require another pivotal study, likely to be executed by a license partner. It is however likely that there will be some off label sales in the stage IV non-resectable setting, if MCV is approved in the stage IV resectable setting.

For the MCV Non-small cell lung cancer (NSCLC) indication, no clinical trials are planned at this time. DanDrit is likely to keep the lung cancer trial on hold until the company has been either acquired or have signed a license deal for MCV. However the Lung cancer indication does hold some value due to the early phase clinical study already completed some years ago.

For the bladder cancer indication, DanDrit is early in the planning process of the phase I/II study sponsored by NCI. This study is however not likely to begin until late 2016.

Also DanDrit has an early preclinical program for its Tolerogenic Dendritic Cell vaccine, which is targeting autoimmune diseases like diabetes and Multiple Sclerosis. The company intends to divest it to third party during the coming year.

Finally DanDrit has set up compassionate use programs in Europe with myTomorrows and in Middle East with Rylyadh Pharma.

To summarize, below are the projects that we are prepaid to attribute value to at this point in time:

- MCV Colorectal cancer Stage IV patients Adjuvant setting following resection of primary tumor and liver metastases
- MCV Colorectal cancer Off label sales into Colorectal cancer non-resectable stage IV setting following market approval in stage IV resectable adjuvant setting
- MCV Colorectal cancer Stage III patients Adjuvant setting
- MCV Non-small cell lung cancer Adjuvant setting
- MCV Bladder cancer Stage II patients local cancer
- Tolerogenic Dendritic Cell Vaccine Diabetes and MS
- MCV Compassionate Use Programs Europe and Middle East

#### Colorectal cancer market

Colorectal cancer is the fourth leading cause of mortality among all cancers. In 2007 approx. half a million patients were clinically diagnosed in the US, EU and Japan, and the colorectal cancer therapeutics market was worth USD 6.9 billion. The United States was leading the sales with a market size of USD 4.3 billion (63%), EU had sales of USD 2.2 billion (32%) while Japan was third with sales of USD 0.4 billion (5%). In 2013 total sales were 8.3 billion dollars and with an annual growth rate around 2% sales will climb to 9.4 billion by 2020.

The marketed Colorectal cancer drug landscape comprises a wide range of treatment options, including targeted therapies, such as Avastin and Zaltrap, and a range of immunotherapies and chemotherapies. However, the lack of awareness and screening programs in developed nations are barriers to improving patient survival rates and reducing treatment costs.



# Valuation: MCV Colorectal Cancer Stage IV adjuvant setting

#### Number of patients eligible for treatment

Approx. 20% of the colorectal cancer patients are diagnosed with metastatic disease and approx. 30% of these will undergo primary tumor and liver resection. This means that the potential target audience for MCV if market approved in the proposed Stage IV adjuvant setting, will be: 2,200,000 prevalence patients in the EU and US combined \* 20% \* 30% = 132,000 patients. However patients are also required to be MAGE-A positive and furthermore to have a healthy immune system likely to respond to a dendritic cell based vaccine. Our estimate is that approx. half of patients can fulfill this criteria bringing the number of eligible patients to 66,000. If we assume that MelCancerVac will have a penetration rate of 25% at its peak, this would indicate that 16,500 patients annually will be treated with MelcancerVac. A course of treatment is estimated to cost USD 35,000 which would allow for peak sales estimate of: USD 35,000 \* 16,500 patients = USD 577.5 million

#### Chance of market approval

We are estimating a 35% chance that MCV will make it to the market in this indication. This is a relatively aggressive estimate at this point, as MCV has only completed two smaller non-randomized phase IIa trials. However the clinical data have been encouraging and furthermore we believe that the target audience in the phase III study suits MCV very well, due to an projected median progression free survival of approx 2 years for the patients being enrolled. This will give MCV the necessary time to build up a potent immune response against the tumor cells. For comparison the FDA-approved dendritic cell vaccine Provenge, was tested in metastatic prostate cancer patients which had a median <u>overall survival</u> expectancy of just below two years.

#### Expected Approval / market launch

We expect a market launch of MCV in 2023. This is quite conservative, however delays in the 1-2 years range are quite normal in this industry. IN our model MCV will be out-phased from the market in 2033, i.e. 10 years after launch.

#### Annual sales growth rate

It is likely that the market uptake of MCV will be quite fast following approval, as MCV will be the only vaccine available within colorectal cancer. We are therefore estimating that DanDrit Biotech on average will be able to grow sales with 20% annually following market launch.

 Discounted Cash Flow value of MCV in Stage IV Colorectal Cancer adjuvant setting

With the above assumptions we have found that MCV in the stage IV colorectal adjuvant setting has a net present value of USD 85.9 million or 9.00 dollars per share.

#### Valuation: MCV Colorectal Cancer Off label Sales

Following the approval of MCV in the stage IV adjuvant colorectal cancer setting, we consider it reasonable to assume some off label sales in other settings of colorectal cancer. For instance doctors might try MCV in patients with stage IV cancer that have not undergone resection of liver metastases. The size of this market opportunity would be the 70% of stage IV patients that does not undergo tumor-resection. If we consider a modest 5% penetration rate additional 7,700 patient would be treated, generating an off label sales of: USD 35,000 \*7,700 patients = USD 269.5 million.

The likelihood of off label sales occurring will be tied to the approval of MCV in the Stage IV resectable adjuvant setting, and therefore we are suggesting a similar chance of market approval for off label sales, i.e. 40%. Market



colorectal calleer	i adicite ta	iget addientee
Prevalence US and EU		2.200.000
Mage-A positive	50%	1.100.000
+ Metastatic cancer (Stage IV)	20%	220.000
+ Undergo tumor resection	30%	66.000
Estimated penetration rate	25%	16.500

#### CRC - Stage IV Non-resection (off label)

Colorectal Cancer	Patient ta	rget audience
Prevalence US and EU		2.200.000
Mage-A positive	50%	1.100.000
+ Metastatic cancer (Stage IV)	20%	220.000
+ No tumor resection	70%	154.000
Estimated penetration rate	5%	7.700

#### CRC - Stage III advanced disease setting

Colorectal Cancer	Patient ta	rget audience
Prevalence US and EU		2.200.000
Mage-A positive	50%	1.100.000
+ Locoregional cancer (Stage III)	30%	330.000
+ Cancer spread lymph nodes	33%	108.900
Estimated penetration rate	25%	27.225

#### Lung Cancer - Stage II+III adjuvant setting

Lung Cancer	Patient	target audience
Prevalence US and EU		1.500.000
Mage-A positive	35%	525.000
+ Stage II or III cancer	50%	262.500
Estimated penetration rate	10%	26.250

#### Bladder Cancer - Stage II disease setting

Bladder Cancer	Patient ta	rget audience
Prevalence US and EU		1.500.000
Mage-A positive	40%	600.000
+ local invasive cancer (Stage II)	25%	150.000
Estimated penetration rate	10%	15.000

launch will also take place in 2023 and annual sales growth will be estimated to 20% as well.

• Discounted Cash Flow value of MCV Off label sales in the Colorectal cancer non-resectable setting With the above assumptions we have found that MCV in the Off label colorectal cancer setting represents a net present value of USD 40.1 million or USD 4.2 per share.

# Valuation: MCV Colorectal Cancer Stage III adjuvant setting

#### Number of patients eligible for treatment

Approx. 30 % of all colorectal cancers are stage III at first diagnosis. Stage III cancer is defined as a tumor burden that is still localized, however spread to lymph nodes has begun. We believe that DanDrit is likely to target the most advanced Stage III patients, which have tumor spread to a minimum of four lymph nodes nearby the primary tumor. This group of patients consists of approx. 1 out of 3 stage III patients, and has a 5-year survival rate of just 44% - So more adjuvant treatment options following resection of primary tumor are warranted. Using these estimates we find that advanced Stage III patients eligible for MCV treatment would be: 1,100,000 patients \* 30% \* 33% = 108,900 patients.

If we assume that 1 out of 4 doctors (penetration rate 25%) are willing to prescribe MCV to patients we end up with 27,225 patients treated each year and an annual peak sale of: USD 35,000 \* 27,225 = USD 953 million. Whether this is a likely scenario is difficult to answer. It is clearly more difficult to fully penetrate a stage III setting as the patients often have more treatment options available in case of tumor reoccurrence, in comparison to treating terminal metastatic stage IV patients. On the other hand, MCV is likely to perform better in earlier settings of cancer, as the immune system of the patients will assumedly be more functional and healthy.

We assume market launch of MCV in stage III colorectal cancer in 2025. Furthermore we are putting an "option-like" and very narrow 5% chance of market approval at this point, as DanDrit Biotech has no plan to executive a randomized pivotal phase III study anytime soon. However a positive outcome for the phase III study in the adjuvant resectable stage IV setting will increase the value of the CRC stage III setting program significantly.

 Discounted Cash Flow valuation of MCV – Colorectal cancer – Stage III resectable patients – Adjuvant setting
With the above assumptions we have found that MCV in the Stage
III adjuvant setting has a net present value of USD 15.3 million or
USD 1.60 per share.

#### Valuation: MCV Non-small Cell Lung cancer adjuvant setting

#### Number of patients eligible for treatment

Around 1.5 million people are alive with Lung cancer in the United States and Europe. About 85% to 90% of lung cancers are NSCLC. There are 3 main subtypes of NSCLC. The cells in these subtypes differ in size, shape, and chemical make-up when looked at under a microscope. But they are grouped together because the approach to treatment and prognosis (outlook) are very similar. Approximately 25% to 30% of cases are diagnosed as locally advanced disease (stage III) and 40% to 50% with a diagnosis of metastatic disease

Progress in the treatment of lung cancer, has been slow. One of the most significant advances has been the identification of benefit associated with the use of adjuvant chemotherapy in resected early stage disease. MCV has



been tested in terminal stage IV NSCLC patients in a small open-labeled phase II trial, but to gain market approval the correct approach is likely to pursue adjuvant therapy in earlier stage patients (II+III) following resection. We can only give rough estimates for the potential peak sale for MCV in NSCLC as it remains unclear which type of patients DanDrit is likely to pursue if another lung cancer trial was to be initiated by a partner. We believe that approx. half of all Lung cancer patients would be eligible for MCV treatment however competition in the lung cancer is very intense with competing checkpoint PD-1 inhibitors reaching the market in 2014 and 2015. A rather low penetration rate around 10% is therefore likely. Our best estimate of a peak sale is therefore: USD 35,000 \* 1,500,000 \* 50%(stage II/III) \* 35%(MAGE-A positive) \* 10% (penetration rate) = USD 919 million

As the Lung cancer indication is not being actively pursued by DanDrit Biotech right now we are allocating a conservative 5% chance of market approval in 2025. There is a tremendous upside in the Lung Cancer valuation if the phase III trial in the colorectal stage IV adjuvant setting has a positive outcome. This will reopen MCV in Lung cancer as a key pipeline asset.

 Discounted Cash Flow valuation of MCV – Non-small cell lung cancer – Adjuvant setting
With the above assumptions we have found that MCV in the adjuvant Lung Cancer setting holds a net present value of USD 14.8 million or USD 1.55 per share.

#### Valuation: MCV Bladder Cancer Stage II setting

#### Number of patients eligible for treatment

Bladder cancer is the 9th leading cause of cancer globally with 430,000 new cases and 165,000 deaths occurring in 2012. In USA and EU combined bladder cancer causes around 225,000 new cases and is responsible for 55,000 deaths each year. The long term survival rate is however quite good, with approx 75% alive five years after diagnosed. Therefore the prevalence of bladder cancer is high with about 1.5 million people living today in the USA and EU with bladder cancer.

Research has revealed a high incidence around 40% of MAGE-antigen expression in bladder cancers and furthermore MAGE expression has been observed more frequently as the tumor's pathological stages advanced. As a result, MAGE is increasingly suggested to be a useful target for active immunotherapy against bladder cancer. DanDrit is in the early planning process of clinical phase I/II study in combination with a PD-1 inhibitor. The study is likely to be sponsored by the NCI in the United States, and will recruit 50 patient randomized to either MCV alone or MCV+anti-PD1. The selected patients are likely to be stage II, i.e. patients with tumor still localized to the bladder but invasive, with spread beyond the basement membrane into the connective tissue. At initial presentation around 25% of all bladder cancers belong to the non-muscle invasive tumors. It is likely that DanDrit will not be able to start the study until late 2016 as some regulatory as well as practical issues still need to be solved.

If market approved in stage II Bladder Cancer we are expecting a low penetration rate around 10%, as other immunotherapeutic agents are available in this cancer, for instance Bacillus Calmette-Guerin (BCG) which stimulates immune responses that can destroy cancer cells within the bladder. However if MCV is approved in combination with an PD1-inhibitor penetration is likely to be higher driven by a higher cure rate.

Peak sale estimate in the bladder cancer indication: USD 35,000 \* 1,500,000

#### Valuation – Discounted Cash Flow

Indication	Phase	%	Launch	PeakSale	Partner	Net	Net Prese	ent Value	% of Total
		Chance				Margin	Milion	Per Share	Value
MCV - Colorectal Cancer Adjuvant stage IV	Phase III	35%	2023	578	Own	55%	86	9,00	50%
MCV - Colorectal Cancer stage IV non- resectable (off label)	Phase III	35%	2023	270	Own	55%	40	4,20	24%
MCV - Colorectal Cancer Advanced Stage III	Phase II (on hold)	5%	2025	953	Own	55%	15	1,60	9%
MCV - Lung Cancer Stage II & III	Phase II (on hold)	5%	2025	919	Own	55%	15	1,55	9%
MCV - Bladder cancer Stage II	Phase I/II (Planned)	10%	2025	525	Own	55%	17	1,77	10%
Tolerogenic Vaccine Autoimmune diseases	Pre- clinical	1%	2028	1.000	Own	55%	2	0,22	1%
Compassionate Use Programs	Launch Q3 2015	90%	2015	25	myTom orrows & Riyadh Pharma	50%	20	2,05	11%
Operating Expenses	Short term (3 year period)	100%	2015				-16	-1,65	-9%
Operating Expenses	Long term (6 year period)	60%	2018				-11	-1,19	-7%
Cash							3	0,31	2%
Debt							0	0,00	0%
Total							171	17,86	100%
WACC 15% Number of shares: 9.553.290							Million US	Dollars	

#### Pipeline - Net present value per share





\* \*25%\* 40% \* 10% = USD 525 million

We are allocating a 10% chance of market approval in 2025, as DanDrit is actively pursuing clinical development in this indication, and the high MAGE-expression increases the likelihood of success, however study start is still some quarters away.

• Discounted Cash Flow valuation of MCV – Bladder Cancer – Stage II – therapeutic setting With the above assumptions we have found that MCV in the therapeutic Bladder cancer setting holds a net present value of USD 17.0 million or USD 1.77 per share.

#### Valuation: Tolerogenic Vaccine autoimmune diseases

#### Number of patients eligible for treatment

DanDrit Biotech has a single early preclinical program for its Tolerogenic Dendritic Cells vaccine. By promoting immune tolerance instead of inhibiting immune tolerance, it can be used to treat autoimmune diseases by turning of an undesirable immune response. Targeted diseases are Diabetes, organ transplant and Multiple Sclerosis. DanDrit Biotech intends to out-license this asset as soon as possible, if possible.

We believe that the Tolerogenic vaccine program could reach the market in 2028 and eventually achieve a peak sale around USD 1.0 billion. However the likelihood of successful outcome is very poor, just around 1% at this early point in the development phase.

- Discounted Cash Flow valuation of Tolerogenic Dendritic Cell Vaccine – Diabetes and MS
- With the above assumptions we have found that the Tolerogenic Dendric cell vaccine program for autoimmune diseases represents a net present value of USD 2.1 million or USD 0.22 per share.

#### Valuation: Compassionate Use Programs

#### Number of patients eligible for treatment

DanDrit Biotech has compassionate use programs for MCV underway in both EU and Middle East. The compassionate use program handled by myTomorrows is expected to treat the first patient in Q3 2015, while sales in The Middle East handled by Riyadh Pharma is expected to treat the first patient in 2016.

DanDrit is expecting a sales price per patient around USD 22,000, both in Europe and in Middle East. Expected net contribution margin from sales is estimated to be around 50%.

Especially in the Middle East the market opportunity is significant, as due to the high frequency of colorectal cancers there is a large unmet medical.

It is important to stress that the compassionate use programs allows treatment of all cancers that are MAGE-A positive, which besides colon, lung and Bladder also include cancers of the head and neck, liver, melanoma and others.

In 2016 we expect compassionate use sales around USD 3 million. We are estimating a total peak sale of USD 25 million for the two compassionate use programs by year 2024, with annualized sales growth of 20%.

#### DanDrit Biotech valuation - If highly positive outcome of Phase III trial (considered positive if p-value < 0.05)

Indication	Phase	%	Launch	PeakSale	Partner	Net	Net Prese	ent Value	% of Total
		Chance				Margin	Milion	Per Share	Value
MCV - Colorectal Cancer Adjuvant stage IV	Phase III	70%	2023	578	Own	55%	172	17,99	42%
MCV - Colorectal Cancer stage IV non- resectable (off label)	Phase III	70%	2023	270	Own	55%	80	8,40	20%
MCV - Colorectal Cancer Advanced Stage III	Phase II (on hold)	30%	2025	953	Own	55%	92	9,62	22%
MCV - Lung Cancer Stage II & III	Phase II (on hold)	10%	2025	919	Own	55%	30	3,09	7%
MCV - Bladder cancer Stage II	Phase I/II (Planned)	25%	2025	525	Own	55%	42	4,42	10%
Tolerogenic Vaccine Autoimmune diseases	Pre- clinical	2%	2028	1.000	Own	55%	4	0,44	1%
Compassionate Use Programs	Launch Q3 2015	100%	2015	25	myTom orrows & Riyadh Pharma	50%	22	2,28	5%
Operating Expenses	Short term (3 year period)	100%	2015				-16	-1,65	-4%
Operating Expenses	Long term (6 year period)	100%	2018				-19	-1,98	-5%
Cash							3	0,31	1%
Cash							0	0,00	0%
Total							410	42,93	100%
WACC 15%		Number	of shares	: 9.553.29	0			Million US	Dollars





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- Discounted Cash Flow valuation of MCV Compassionate Use programs – MAGE-A positive cancers
- With the above assumptions we have found that the Compassionate use programs represent a net present value of USD 20.0 million or USD 2.05 per share.

#### Total estimated pipeline and company value

In total the MCV-programs represents a current value of USD 173 million for the company, while Tolerogenic Vaccine represents a value of USD 2 million. This adds up to a total pipeline value of USD 175 million. The compassionate use programs for MCV represents net present value of USD 20 million. On top of this DanDrit has a current cash position of USD 3 million. Therefore according to our DCF-model all assets have holds value of <u>USD 198 million</u>.

The operating expenses in year 2015-2018 we are estimating at USD 6 million annually. This represents a negative net current value of USD 16 million. Also we have added a 60% "risk" of long term operation expenses occurring in the timeframe 2019-2024. The net present value of this cash flow is USD -11 million. So the total negative current impact from operating expenses is <u>USD -27 million</u>.

When we subtract the assets from the liabilities, we reach a final Net Present Value of the company of USD 171 million or USD 17.86 dollars share.

#### Valuation impact following positive or negative phase III

## • Pipeline upside in case of positive outcome of the MCV phase III study

A highly positive outcome of the MCV phase III study, will move our pipeline valuation up with approx. USD 230 million to USD 401 million (USD 43 per share). We would consider a statistical significant outcome with a p-value below 0.05 as positive. This would create value in the pipeline beyond the CRC stage IV Adjuvant setting, as the likelihood of attracting a partner to take on the Colorectal Stage III adjuvant trial as well as the Lung Cancer trial would have increased dramatically.

• Pipeline downside in case of negative or mediocre outcome of the MCV phase III study

A mediocre or a negative outcome of the MCV phase IIB trial would decimate our pipeline valuation by approx. USD 145 million to USD 26 million (USD 2.72 per share). We would consider a statistically insignificant p-value above 0.10 as mediocre/negative. This outcome would essentially close the door for good to the Colorectal stage IV market opportunity as well as to the Lung Cancer market opportunity. At the same time it would be extremely difficult to attract a partner or a buyout of the company on reasonable terms.

#### DanDrit Biotech valuation - If negative or mediocre outcome of Phase III trial (p-value > 0.10 considered negative)

Operating Expenses Short term arm period (3 year period) 2015 (5 year period) 2015 (5 year period) 25% 2018 (5 year perio	11 -16 -5 3 0 <b>26</b>	1,14 -1,65 -0,49 0,31 0,00 <b>2,72</b>	42% -61% -18% 12% 0% <b>100%</b>
Operating Expenses Short term and the second	11 -16 -5 3	1,14 -1,65 -0,49 0,31 0,00	42% -61% -18% 12% 0%
Operating Expenses     Short term (3 year period)     100%     2015       Operating Expenses     Iong term (6 year period)     25%     2018       Cash     Expenses     Expenses     Expenses	11 -16 -5 3	1,14 -1,65 -0,49 0,31	42% -61% -18% 12%
Operating Expenses     Short term (3 year period)     100%     2015       Operating Expenses     Eng term (6 year period)     25%     2018	-16 -5	1,14 -1,65 -0,49	42% -61% -18%
Operating Expenses (3 year 100% 2015 period)	-16	1,14	42% -61%
Pildilid	11	1,14	42%
Compassionate Use Programs     Launch Q3 2015     50%     2015     25     & 60% Riyadh Nexron			
Tolerogenic Vaccine Autoimmune diseases 0% 2028 1.000 Own 55%	0	0,00	0%
MCV - Bladder Phase I/II 5% 2025 525 Own 55%	8	0,88	32%
MCV - Lung Cancer Phase II (on hold) 0% 2025 919 Own 55%	0	0,00	0%
MCV - Colorectal Cancer Advanced Stage III 2% 2025 953 Own 55%	6	0,64	24%
MCV - Colorectal Cancer Stage IV non- resectable (off label) 9 Phase III 5% 2023 270 Own 55%	6	0,60	22%
MCV - Colorectal Cancer Adjuvant Phase III 5% 2023 578 Own 55% stage IV	12	1,29	47%
Indication Phase % Launch PeakSale Partner Margin	Net Pres n Milion	ent Value Per Share	% or Total Value





## **SWOT Analysis**

#### **DanDrit Biotech Strengths**

- A flexible and cost efficient organization with few full time employees. This makes DanDrit a clean takeover candidate for a larger Biotech or Pharmaceutical company that seeks to enter the cancer vaccine market.
- Clinical late stage phase III company with a clear path forward in terms of creating value in the MCV-program.
- No IP or third party royalties for MelCancerVac. Basically this means that DanDrit Biotech and its shareholders get to keep the full revenue stream in case MCV gains market approval.
- Strong and loyal group of professional Danish investors is backing up the company.

#### **DanDrit Biotech Weaknesses**

- MCV is a personalized vaccine requiring multiple vaccinations over a 1-2 year period. This might cause fewer doctors to recommend the treatment and it might scare patients away from treatment.
- It might be considered a weakness of the company that it has basically been in a "stand still" mode for the last few years, and have generated no clinical data from the MCV-program since 2009.
- The non-small cell lung cancer indication is difficult to approach as the disease is more aggressive than colorectal cancer and therefore not very suitable for immunotherapy. Furthermore the data generate in non-small cell lung cancer seems somewhat less impressive than the data in CRC.
- DanDrit Biotech only has MCV in clinical development, and efforts to move an off-the-shelf vaccine into clinical trials is still a few years out. This basically makes MCV a-make-or-break for the company. If MCV fails so does the company.
- Low cash position and increasing cash burn in the coming years.

#### **DanDrit Biotech Opportunities**

- The field for cancer vaccines within colorectal cancer is wide open. To our knowledge DanDrit Biotech is the only participant currently in late stage clinical development.
- An approval in CRC Stage IV patients will likely generate significant off label sales from other CRC settings, including stage IV nonresectable and stage III resectable.
- A merger with another cancer vaccine company might prove to provide a lucrative exit opportunity for DanDrit and its shareholders ahead of phase III data in colorectal cancer.

#### **DanDrit Biotech Threats**

- Superior dendritic off-the-shelf vaccine technology could be a threat to DanDrits personalized vaccine approach.
- The space for immune therapies is changing very rapidly these years, and the traditional cancer vaccine approach could be replaced with other technologies that simulate vaccines, e.g. immune modulating drug.
- Slower than expected patient recruitment in the phase III trial could delay marketing approval for a few years worst case.



### Conclusion

Our Discounted Cash Flow valuation of DanDrit Biotech USA, Inc. suggests a very significant upside to the current share price. We have estimated an enterprise valuation of 171 million dollars, compared to the current market cap of 38 million dollars. However in order to unlock the enterprise value upside, DanDrit needs to execute on its objectives during the coming months by getting the pivotal phase III trial underway in Italy and begin enrolling patients. We are very confident this will happen during this current quarter (Q3 2015). Secondly the myTomorrows Compassionate Use program needs to begin enrolling patients in Europe, also during this quarter. We are also confident in this taking place.

In terms of the outcome of the phase III study in colorectal cancer we believe DanDrit Biotech has a fairly good chance of succeeding for several reasons:

- Dendritic Cell based vaccines has already proven its worth, provided by the favorable outcome in overall survival of three randomized trials with Provenge in metastatic prostate cancer patients which had a life expectancy of just below 2 years.
- MelCancerVac is a second generation dendritic Cell Vaccine compared to Provenge as multiple antigens are being targeted.
- The MelCancerVac schedule for treatment is very intense as each patient will receive more than 10 vaccinations in just one year. For comparison Provenge treatment is only given three times during a one month period. Potentially this difference in vaccination will allow for a very potent immune and sustained response in MCV treated patients.
- MelCancerVac has shown a clinical benefit ratio of impressive 40% in a small open labeled phase II study despite treating terminal metastatic colorectal patients with just an expected median survival of a few months. Furthermore a single patient (5%) even experienced tumor shrinkage, and two patients (10%) have survived for several years.
- For the phase III trial DanDrit has wisely chosen to pursue stage IV NED (no evidence of disease) patients that have undergone complete resection surgery for both the primary tumor and liver metastases and are then pretreated with chemotherapy ahead of MCV vaccination. The expected median Relapse Free Survival for this group of patients is around 2 years, which will give MCV enough time to stimulate a sufficient immune response to fight the tumor cells as they return.
- DanDrit is pre-screening for the colorectal cancer associated antigen MAGE-A which is expressed in the MCV antigen cell line. Thereby patients who are likely not to respond to treatment will be excluded from participating in the trial.
- The adaptive design of the study which allows for an interim data look at PFS and CEA-biomarker data as 90 patients has passed the 18 months mark, will give Dandrit Biotech the possibility to adjust its statistical modeling by enrolling more patients into the trial if necessary. Thereby the study will turn into a registration study, which will potentially increase interest from the pharmaceutical industry and secondly help speed up recruitment. Secondly if the early interim data look is a failure, DanDrit will be able to close the study down early, and preserve shareholders money and give patients the opportunity to explore other treatment alternatives.

