



Northwest  
Biotherapeutics  
house of Cards is  
ready to collapse

October 28, 2015

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## Summary

In 2016, Northwest Bio will have been developing the DCVax dendritic vaccine for exactly 20 years. This bio-failure-in-the-making exhibits all the obvious signs of a looming disaster: clinical trials stretching over decades, half a dozen trial amendments and extensions, lack of reliable results and publications, an utter deliberate mess in reporting on them, and most recently, a sudden shadowy halt to patient enrollment in the Phase 3 trial of the company's lead candidate. NWBO has used probably every trick in the book to prevent the inevitable end and announcing the results of its clinical trials, and for a good reason: as long as failure is not announced, the dream can live on and fresh money can be raised by NWBO which then feeds it to NWBO's CEO private companies. The lack of corporate governance has allowed NWBO's CEO, Chairperson and President Powers (former VP Global Finance at Enron) to unscrupulously use the company as her personal checking account to financially support her investment in NWBO and other private companies, mostly Cognate Bioservices, by transferring massive amounts of cash, shares and warrants to herself and companies she owns and controls. In addition, we believe NWBO has been involved in various undisclosed transactions with (i) Powers and her companies, (ii) at least one major shareholder and with (iii) its "independent director" Dr. Navid Malik.

Phase Five's team analyzing NWBO was comprised of Phd's and analysts with strong medical background, together with financial experts with extensive background in uncovering fraudulent companies. We have studied NWBO inside out, and below is a brief summary of our findings:

- **Clinical development fiascos and forthcoming clinical failure.** NWBO has been developing DCVax for 20 years now. According to NWBO, DCVax is a platform technology that uses activated dendritic cells (the master cells of the immune system), and is designed to reinvigorate and educate the immune system to attack cancer cells. We present in the second part of this report the data that shows why DCVax has very little chance of succeeding in its ongoing glioblastoma trial;
- **Ripping off minority shareholders.** Powers and her companies (the "Toucan Group") invested in NWBO approx. \$16 million of cash<sup>1</sup> since she first invested in NWBO in 2004 and her current holdings are estimated at \$150 million. Public shareholders have been less fortunate and have mostly been losing money on NWBO as dilution followed dilution. This poses a mathematical challenge - how did a \$16 million investment turned into \$150 million while the share price has mostly gone south? The answer is simple - through related party transactions. NWBO's filings show that a significant portion of the proceeds from shares issued to investors found its way to the Toucan Group, led by NWBO's contract manufacture "partner" and R&D outsourcer – Cognate Bioservices Inc. Over the years, an astonishing amount of \$310 million was transferred from NWBO to the Toucan Group in the form of cash, shares, warrants, options and all kinds of other benefits. **This totals to approx. 54% of the loss recorded by the company since**

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<sup>1</sup> Loans repaid by NWBO have been deducted from the calculation

**Powers invested in it in 2004.** In addition to this obscene wealth transfer, NWBO's financials disclose that the company managed to spend another \$115 million on R&D which was not paid to Powers' company<sup>2</sup>. Since 2011, when NWBO started its Phase III trial, it recorded a total of \$220 million of R&D costs. Based on our experience with comparable Phase III clinical trial, the cost of such trials is between \$30 and \$60 million. In light of these finding, we believe Cognate has significantly over-charged NWBO for R&D services, in addition to other baseless transfer of wealth from the company to the Toucan Group as we will discuss in this report;

- **Diverting cash and shares to CEO's private company.** According to evidence we gathered, Powers and her companies were cash-strapped for many years and had debts outstanding which prevented them from from paying due taxes, let alone to continue investing in NWBO. In order to prevent dilution to Powers' companies and provide funds to Cognate, the following scheme was used:
  - Instead of NWBO issuing shares to outside investors to raise funds and pay Cognate for R&D services, Cognate and NWBO (both under common control of Powers) entered into an agreement to convert invoices issued by Cognate to shares and warrants at a pre-agreed low price, causing massive dilution to shareholders. As of June 2015, we estimate the result of this one-sided agreement to be the issuance of approx. \$81 million worth of shares and warrants to Cognate for the settlement of \$47 million of outstanding invoices. Cognate on the other hand, borrowed money for its operations from third parties and settled the debt in shares of NWBO. This would leave the difference between the price the shares were bought and the price the shares were sold with Cognate instead of NWBO's shareholders, while not making it obvious to investors that Powers has sold shares;
  - Issuance of \$21 million worth of shares and warrants to Cognate as an "inducement" to enter into an agreement with NWBO;
  - Issuances of shares with no consideration to Powers' companies;
  - Issuances of shares to third parties to cover Cognate's debt with no consideration to NWBO; and
  - Issuances of options to Powers personally upon her appointment as CEO, which at the time equaled to approx. 10% of the issued and outstanding shares of the company.
- **Corporate governance failure.** This practice has not gone unnoticed. A Class action lawsuit has been filed which sheds some light on the company's corporate governance and board of directors' practices. According to the claim, board of directors' minutes provided by NWBO reveal that in many cases no discussion was held about the transactions' fairness to NWBO shareholders and no alternatives were even considered or discussed;
- **\$5 million worth of securities transferred to a company incorporated by an analyst covering the share, turned director.** Our research has uncovered that Dr. Navid Malik, NWBO's 2012 nominated independent director and member of its audit, compensation and nomination committee, released in 2010 a very bullish research report on NWBO. Shortly after, a company he had just incorporated in Delaware received approx. \$5 million worth of shares and warrants of NWBO from Powers' Toucan Fund II vehicle, shares

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<sup>2</sup> Calculated based on NWBO's disclosures of related party transactions

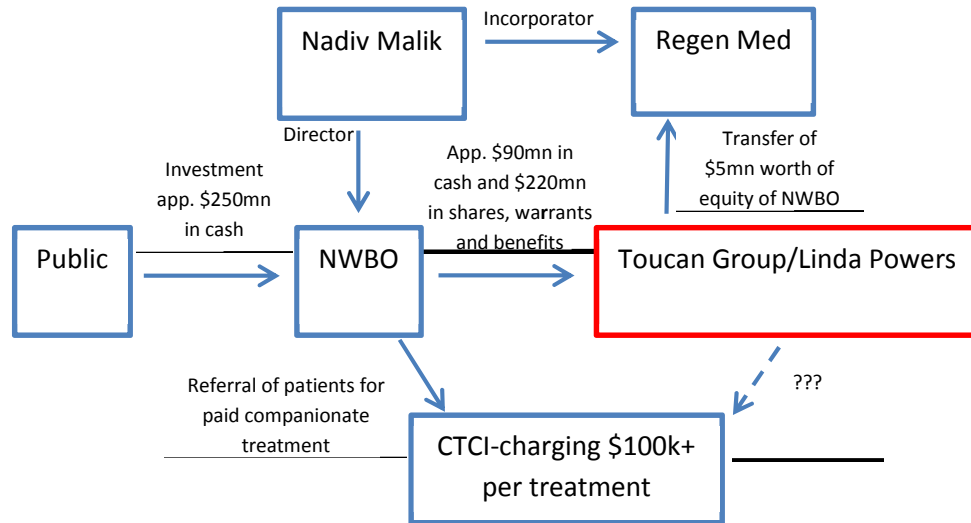
that were subsequently sold by the company. Malik's involvement with NWBO prior to his nomination as director has been concealed from investors and we question the legitimacy of this transaction and his independence as a director;

- **Transfer of patents to related parties without disclosure.** NWBO transferred the majority of its patents to an entity controlled by Powers in 2004 without any disclosure in its SEC filings. Powers transferred 6 of the patents back to NWBO in 2012 only again to transfer a couple of days later 19 patents and applications to a different major shareholder of the company without any disclosure in its SEC filings. Furthermore, NWBO still claims in its current filing to own some of the patents it transferred years ago;
- **Ghost writers promote the company and its treatment on financial and cancer related websites.** Previous publications have accused NWBO and its PR firms to have successfully used paid writers on financial platforms and forums to promote the shares of the company. NWBO cannot promote the use of DCVax as it has not been approved by the FDA. However, it is approved for "compassionate" (paid) treatments in a very limited number of countries. NWBO's problem is that with the lack of clinical data, oncologists do not usually recommend DCVax as an experimental treatment. We present additional evidence that suggest that ghost writers work their way not only on financial forums and Twitter to promote the company, but also on forums aimed at cancer patients, promoting the company's unapproved treatment. If NWBO is found to be behind these ghost writers, we believe it will have severe consequences, since it will not only arouse the interest of the FDA, but also the families of patients that paid for the treatment and did not survive.
- **We suspect Powers controls a clinic providing paid "compassionate" treatments of NWBO's unapproved DCVax.** We suspect that an Israeli medical center (the International Center for Cell Therapy & Cancer Immunotherapy, or CTCI) that has been selling NWBO's unapproved DCVax treatment to terminally ill patients for hundreds of thousands of dollars may be indirectly owned by Powers and her companies. In addition, NWBO refers GBM patients to get the unapproved paid treatment from CTCI in Israel, outside of the company's clinical trial, as the treatment is not approved in the US. To top that, CTCI was accused by the Israeli Health Ministry of running unapproved experiments in humans and has been unwilling to provide information on these treatments requested by the Ministry. NWBO's financial statements do not provide enough disclosure to verify that these payments by patients have actually been transferred to NWBO.
- **Use of NWBO cash for the benefit of NWBO's CEO private company.** We believe Powers used \$30 million of NWBO's cash for the actual benefit of Cognate – acquiring a huge production site in England - that according to our analysis of the evidence will most probably be used by Cognate rather than NWBO.

Powers has used various schemes to keep the DCVax story alive, including delaying the release of clinical results; results which we believe would kill the DCVax story and prevent Powers from transferring funds and shares to the Toucan Group. We believe that DCVax will be a failure with no statistical significance and doubt the FDA will accept the company Phase 3 end point of progression free survival. We have no doubt that the SEC will get involved and

look into the transaction between NWBO, and the Toucan Group, CTCL, Navid, Minhas and Mehiel. And when the truth will emerge, we doubt that any of the current management of NWBO will be involved in a public company in the future. We also believe that the FDA will take actions to cease NWBO's "compassionate" program.

The report is divided into two parts, the first part discusses the forensic findings and the second part discusses the clinical data, or better phrased, the lack of clinical data. The following chart provides a condensed overview of the major parties involved in the NWBO scheme (for a detailed chart see Appendix 4):



## Part 1

### Background

Northwest Biotherapeutics, Inc. (“NWBO”) was incorporated in 1998 and is engaged in developing and commercializing immunotherapy products to treat cancers. The company’s main technology platform is the DCVax (short for Dendritic Cells Vaccine) which uses activated dendritic cells to mobilize patients' own immune system to attack their cancer<sup>3</sup>.

In the early 2000s, due to financial difficulties, NWBO conducted two significant changes in its operational and financial structure. First, from 2002 through 2004, the company significantly reduced its headcount from 67 to 8 employees and also halted all of its activities except for its DCVax product. Then, in April 2004, the company signed a recapitalization agreement with Toucan Capital Fund II, L.P. (“Toucan Fund II”) following which Toucan Fund II and its related parties provided the company with loans and became its majority shareholder with more than 90% ownership as of the end of 2004<sup>4</sup>.

Established in 2001 by Linda F. Powers and her husband Robert F. Hemphill Jr, Toucan Fund II was a \$40 million venture fund focused on investments in life sciences and information technology companies. According to publications, Toucan Fund II raised \$4 million investment from the DBED (“Department of Business and Economic Development”)<sup>5</sup>, a Maryland state agency, \$4 million from West Virginia Enterprise Advancement Corporation<sup>6</sup>, \$28 million from Toucan Capital and additional \$4 million from third party investors. Toucan Fund II received a license from the Small Business Administration (SBA) to act as a Small Business Investment Company (SBIC) and started its investments in 2001. SBICs are for-profit privately owned and managed investment funds, licensed and regulated by the SBA, that use their own capital plus funds borrowed with an SBA guarantee to make equity and debt investments in qualifying small businesses. According to the program, Toucan Capital could borrow \$2 for each \$1 invested and leverage the \$40 million to a total of \$120 million.

Since its inception, Toucan Fund II invested in several healthcare companies including Cognate Bioservices Inc., Artecetel, Inc., Oncocidex, Inc., Vesta therapeutics, Inc. and Theradigm, Inc. In 2010, Toucan Fund II holding in NWBO was transferred to a new fund – Toucan Capital Fund III (“Toucan Fund III”) and in 2011 Toucan Fund II was dissolved.

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<sup>3</sup> [http://edgar.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm#item1](http://edgar.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm#item1)

<sup>4</sup> <http://www.sec.gov/Archives/edgar/data/1072379/000095013304004379/w68775sc13dza.htm>

<sup>5</sup> <http://msa.maryland.gov/megafile/msa/speccol/sc5300/sc5339/000113/001000/001166/unrestricted/20053271e.pdf>

<sup>6</sup> <http://wveda.org/documents/2013.pdf>



Powers and Hemphill hold control and are managing directors in several of the “Toucan family of companies” as they like to call them. Among them: Toucan Capital Corporation, Toucan Partners, LLC and Toucan Management, LLC. Both Hemphill and Powers are energy veterans – prior to co-founding Toucan Capital, Hemphill was Executive Vice President of the AES Corporation, where he worked since 1981, and Powers served as Senior Vice President for Global Finance of the notorious Enron from 1994-1997<sup>7</sup>. This important and interesting piece of information is missing in Powers’ current bio<sup>8</sup>.

Soon after Toucan Capital took a controlling stake in NWBO, Powers joined the board. In 2007 Powers became Chairperson of the board and in 2011 also President and CEO. Since Powers took control of the company it focused mainly on two products: DCVax-L for GBM brain cancer and DCVax-Direct for all types of inoperable solid tumors. During this time, NWBO did two reverse splits (15:1 in 2007 and 16:1 in 2012) and raised a total of approx. \$250 million in cash and recorded losses of more than \$570 million. Management team and the company’s clinical data have been highly controversial and no analyst is covering its shares. Yet, its share price has fluctuated significantly over the last few years as the result of extensive PR work.



According to NWBO’s latest filings, Powers and her companies own 29% of the issued and outstanding shares and 48% on a fully-diluted basis (including warrants and options)<sup>9</sup>. As NWBO is currently trading for \$388 million, the holdings of the shares, options and warrants are worth about \$150 million. While NWBO continuously diluted shareholders over the years, Powers was able to maintain a significant holding in the company mostly through related party transactions and by issuing shares and warrants to her companies with significant discount to market prices. In total, we estimate that Powers, through all her different companies, invested only \$16 million of cash in the company and converted about \$47 million

<sup>7</sup> <http://www.bloomberg.com/research/stocks/private/person.asp?personId=124881&privcapId=1342115>

<sup>8</sup> <http://www.nwbio.com/about-us/>

<sup>9</sup> Diluted holding is based on 2014 10-k/A

of invoices of Cognate into equity. Bearing in mind that the share price of NWBO has mostly gone south since she first invested in the company, this information is even more striking.

This was made possible since Powers has a tight grip over NWBO. She is currently serving as Chairperson, President, CEO and Principle Accounting Officer of NWBO (NWBO does not have a Chief Financial Officer since 2008). In addition, she is the sole director of its UK subsidiary and sole director of Cognate. As is evident from several lawsuits filed over the years, Powers and Toucan have the final word in all the companies they control and Powers is deeply involved with every detail.

## Financial difficulties of the Toucan Group

As a background to the story, one needs to understand the financing condition of the Toucan Group. The lack of funds is a motive that is recurring in all of the Toucan companies we encountered. This shortage probably did not allow Powers to continue and support NWBO and therefore Powers had to turn to more “creative” ways to maintain her share in NWBO and to generate liquidity to cash-starved Cognate.

After reading the lawsuits involving Powers and Toucan, we can conclude that the most common factor relating to all of these lawsuits, and also to NWBO, is a constant lack of financing. This is also evidenced by the fact that there are about 10 different lawsuits filed by the government due to non-payment of taxes due by Toucan Management between 2009 and 2012, the fund management company.

Following are the extracts from these lawsuits:

- **Manufacturers and Traders Trust Company (MTTC) Vs Toucan Management and Linda Powers<sup>10</sup>**

MTTC provide Toucan Management, LLC (the management company of Toucan Capital Fund II) two loans totaling \$1,000,000 in March and June of 2008. After failing to repay the debt on time, MTTC filed a complaint searching for the repayment of the principal, interest and legal fees amounting to \$1,156,420.

As a guarantor of the loans, Powers was asked by MTTC to repay the debt, but just like Toucan Management she:

***“refused, and continues to refuse, to pay Plaintiff all amounts that the Guarantor owes thereunder”***

One should wonder why a company managing \$120 million venture capital fund and its owner had trouble repaying a \$1 million loan...

- **JJ & W, Llc Vs Toucan Capital Fund II, LP<sup>11</sup>**

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<sup>10</sup> Manufacturers and Traders Trust Company Vs. Toucan Management, Docket No. 308127v

<sup>11</sup> JJ & W, Llc Vs Toucan Capital Fund II – Docket No. 1-09-CV-148658

Toucan Capital Fund II entered into a lease agreement with JJ & W for a building in California. According to the complaint, the building was in the use of Cognate. Starting April 2009 and through July 2009, when the complaint was filed, Toucan and Cognate failed to pay the rent for the building. The total amount owed to JJ & W was approx. \$360,000, inclusive of fines and legal fees.

- **State of Maryland Central Collection Unit Vs Cognate Therapeutics, Inc., Theradigm, Inc. and Toucan Capital Fund<sup>12</sup>**

Cognate and Theradigm entered into a lease agreement with the University of Maryland. In December 2010 the two companies abandoned the University facilities leaving behind a debt of \$146,517 after they failed to pay the rent for the period between May and December 2010.

The plaintiff's attorneys claimed that Toucan Fund should be liable for the debt of Cognate and Theradigm because:

***"The Defendants Theradigm and Cognate exist as corporate alter egos for Defendant Toucan".***

Furthermore, they claim that Toucan Capital Fund:

***"directs the selection of the various key employees; has the power to dismiss those employees; direct the conduct and scope of work", and also that:***

***"Toucan, as shareholder in Theradigm and Cognate corporations, failed to adequately capitalize the entities, has potentially siphoned corporate funds, create and retain adequate corporate records..."***

- **Socius CG II, Ltd. ("Socius") Vs Northwest Biotherapeutics, Inc<sup>13</sup>**

In 2011, Socius purchased three invoices amounting to \$1.65 million that were issued to NWBO by Cognate. Socius agreed to pay Cognate \$1.65 million in cash for these invoices, but only after court approval for the settlement of the debt by NWBO (which means, it is a riskless transaction for Socius). Socius sued NWBO for the settlement of the invoices and the court approved what seems to have been a pre-packed settlement in which NWBO issued 4.85 million shares to Socius, which represents a 30% discount on the market price<sup>14</sup>. Using this mechanism, allowed cash-strapped Cognate to tap into quick cash from Socius without NWBO filing a registration statement with the SEC and without Powers being identified with selling shares of NWBO (a recurring theme). Cognate got quick cash, Socius a 30% guaranteed profit and NWBO's shareholders got diluted...again.

- **University of Pittsburgh Vs Artecet, Toucan Capital Corporation, Toucan Capital Fund II and III and Toucan Partners<sup>15</sup>**

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<sup>12</sup> State of Maryland Central Collection Unit Vs Cognate Therapeutics, Inc., Docket No. 24C23001423

<sup>13</sup> Socius CG II LTD vs Northwest Biotherapeutics Inc, Docket No. BC455733

<sup>14</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420411012386/v213351\\_8-k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420411012386/v213351_8-k.htm)

<sup>15</sup> University of Pittsburgh V. Artecet, Docket No. 2:15-cv-01049-TFM

The University and Artecetel signed a license agreement to certain patent rights on August 2012. According to the agreement, the University granted Artecetel rights to make, use and/or sell this patent in return for license fee and other legal fees related to the patent rights.

Artecetel breached the agreement by failing to make payments in the amount of \$377,741 and therefore was sued by the University in August 2015.

Since Toucan Corp. Toucan Fund II and III and Toucan Partners were believed to be the sole, majority or controlling shareholders of Artecetel, the university asked the court to make them liable for Artecetel's debt. The plaintiffs claimed that:

***"Artecetel was one of a number of portfolio companies in which the Toucan Companies invested and over which the Toucan Companies held complete control. As such, there was a substantial intermingling of the affairs of Artecetel and the Toucan companies".***

They also note that:

***"all interaction, negotiation, and communications relating to the license between Artecetel and the University were actually handled by either Powers or J. Kelly Ganjei, a "resident entrepreneur" at Toucan Corp... In addition, the Toucan Companies also used the assets of Artecetel as if they were its own, and transferred much-needed assets of Artecetel for use by other companies in the Toucan portfolio".***

Further, they provide an example of such assets transfer:

***"For example, in 2011, at the direction of Powers, Artecetel lent Northwest Biotherapeutics, Inc – another company in the Toucan Companies' portfolio and of which Powers was the Chief Executive Officer - \$734,000 to be used as funding for ongoing clinical trials..."***

Eventually, they reach the same conclusion as the attorneys involved in other lawsuits against Toucan's portfolio companies:

***"Artecetel is a mere façade and/or alter ego of the Toucan Companies"***

And:

***"Artecetel is a sham corporation without capital or assets which was used as a device by the Toucan Companies to wrongfully avoid individual liability"***

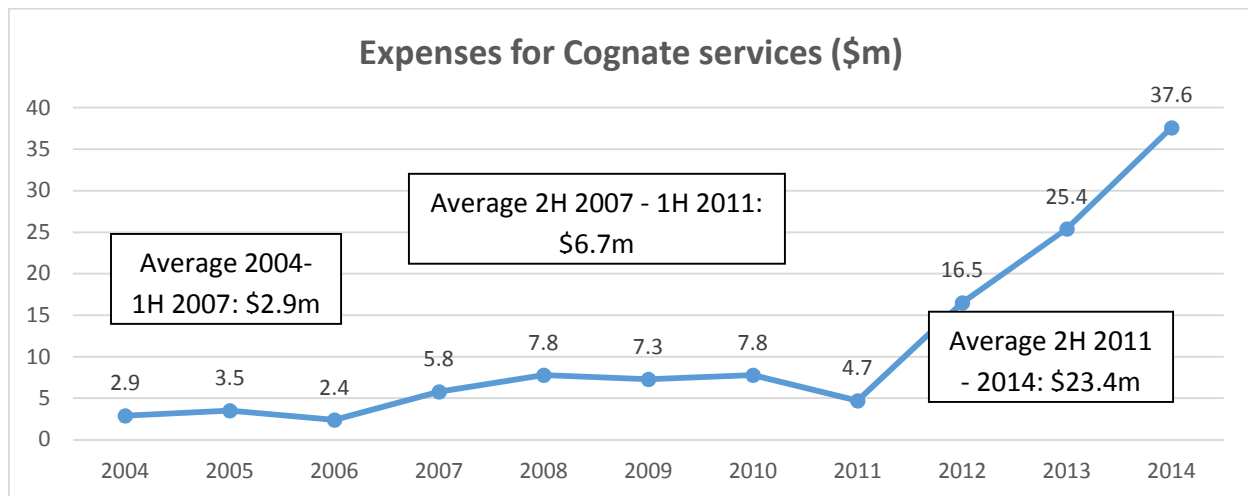
## Modus Operandi

Cognate BioServices (formerly – “Cognate Therapeutics”) was founded by Toucan Capital, Dr. Annemarie Moseley and Alan Smith in 2002<sup>16</sup>. In July 2004, Cognate was chosen by NWBO to manufacture NWBO’s product candidates. In its 2004 10-K NWBO mentioned that it:

***“...did not find any other contract research organization who could meet our needs in order to rapidly restart our clinical programs”.***

Cognate plays a major role in this scheme as its gives perceived legitimacy (at least on the surface of it) for the transfer of cash and shares from NWBO to Toucan Group. On May 17, 2007, Powers was appointed as chairperson of NWBO’s Board of Directors<sup>17</sup> and on the very same day a new manufacturing agreement between NWBO and Cognate was signed<sup>18</sup>. Such coincidence also occurred in the second quarter of 2011 – during that quarter Powers was appointed as the CEO and President of NWBO (on top of her Chairperson position)<sup>19</sup>, and towards the end of that quarter a new manufacturing agreement was signed with Cognate<sup>20</sup>. **This agreement is at the heart of the scheme to divert funds and shares from NWBO to the Toucan Group. Based on this agreement, a total of \$254 million of costs were recorded by NWBO in the form of cash, shares, warrants and other benefits.**

Since Powers was appointed as CEO in 2011, the billings of Cognate to NWBO have shot to the moon, and rising:



<sup>16</sup> [http://www.umbc.edu/blogs/umbcnews/2003/04/cell\\_therapy\\_firm\\_cognate\\_ther.html](http://www.umbc.edu/blogs/umbcnews/2003/04/cell_therapy_firm_cognate_ther.html);  
<http://www.sernova.com/press/?ID=104>

<sup>17</sup> <http://www.nwbo.com/about-us/>

<sup>18</sup> SC 14A, p.22: <http://www.sec.gov/Archives/edgar/data/1072379/000095013408009517/v40394dedef14a.htm>

<sup>19</sup> <http://www.nwbo.com/about-us/>

<sup>20</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420411047212/v231319\\_10q.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420411047212/v231319_10q.htm)

On top of the ever-growing billing for Cognate's services, Cognate (i.e. Powers) and NWBO agreed that some of the amounts owed to Cognate would be convertible into shares of NWBO (this agreement is subject to a class action lawsuit filed and we will discuss it separately). The first transaction of that kind occurred on November 23, 2011, shortly after Powers took over as President and CEO – debt owed by NWBO to Cognate in the amount of \$9.2 million was converted into 2.875 million shares of NWBO using a conversion price of \$3.20 per share (adjusted for the 2012 reverse split). At the time, the share price was \$5.92 and NWBO recorded \$7.8 million loss on conversion due to the difference between the carrying amount of the liability and the market value of the shares issued. That conversion was the starting point for further beneficial conversion to Cognate/Powers or as commonly known: shareholder dilution. The following table summarizes the Cognate invoice conversions made from 2011 through 2014:

Year	A/P converted	Fair value of equity issued	Loss on Conversion
2011	\$9,200,000	\$17,000,000	\$7,800,000
2012	\$7,500,000	\$10,600,000	\$3,100,000
2013	\$13,500,000	\$21,000,000	\$7,500,000
2014	\$16,800,000	\$32,800,000	\$16,000,000
<b>Total</b>	<b>\$47,000,000</b>	<b>\$81,400,000</b>	<b>\$34,400,000</b>

While equity-based payments makes sense in the case of a company that lacks cash to fund its operation, it is unclear why NWBO's shareholders had to surrender so much of the value of the company to Cognate and Powers.

In January 2014, NWBO and Cognate signed four new manufacturing agreements. These agreements reaffirmed the debt conversion mechanism that was agreed upon earlier and determined that NWBO will pay:

***"at least half of all invoices in unregistered, restricted common stock and warrants of our company at an initial price of \$4.00 per share... this arrangement will continue for 18 months from the execution of those agreements or until terminated by mutual agreement"***<sup>21</sup>.

This debt conversion agreement has proved to be catastrophic for NWBO's shareholders when the share price rose. As part of the four new agreements, NWBO also made equity-based initiation fee to Cognate in the form of restricted shares and warrants in a value of \$21.3 million. In the consolidate statement of cash flows for 2014 this amount is defined as: ***"Stock and warrants issued to Cognate BioServices as compensation under Cognate Agreements"***<sup>22</sup>.

<sup>21</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

<sup>22</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

Furthermore, over the years, NWBO provided Cognate with inducements that were not related either to its services or to the debt owed to it. For example, in 2012 NWBO paid \$2.2 million to an ***“outside party in order to settle a note payable that Cognate owed to an unrelated party”***<sup>23</sup>. NWBO also mentioned that it ***“does not expect reimbursement from Cognate”***. More recently, on June 30, 2014, Cognate purchased shares and warrants of NWBO for a cash purchase price which was lower by \$2.4 million than the value of these shares and warrants. The \$2.4 million were recorded as ***“inducement charge”***<sup>24</sup>.

The table below demonstrates the impact of NWBO’s relationship with Cognate, Fund II and III, Toucan Partners, Toucan Corporation and Powers since the inception of that relationship in mid-2004:

	Costs recorded in millions (\$)
Cognate - R&D and services	141.5
Cognate - 2014 agreement initiation fee	37.1
Cognate - A/P conversion benefit	34.4
Cognate - other benefits	4.6
Cognate - loss on warrants issued under 2014 agreement	40.8
Toucan Funds II & III - inducement expenses	26.4
Toucan Partners - inducement expenses	12.1
Powers - salary	2.5
Powers - equity compensation	9.3
Total Toucan Group	308.7
Other R&D expenses	135
All other expenses	125.9
<b>Total accumulated deficit</b>	<b>\$569.6</b>

Accumulated deficit for the period 2004-H1 2015 was calculated by subtracting the accumulated deficit as of December 31, 2003 from the accumulated deficit as of June 30, 2015.

This chart illustrates how Toucan is responsible for most of NWBO’s expenses since 2004 through 2014. Most troubling, even more than the absurd R&D expenses, is the outrageous amount of \$100 million of wealth transferred, the result of various kinds of benefits and inducements that were given to the Toucan Group on account of common stockholders and the source for most of Powers current estimated \$150 million holdings in NWBO.

<sup>23</sup> [http://edgar.sec.gov/Archives/edgar/data/1072379/000114420413020507/v3338517\\_10k.htm](http://edgar.sec.gov/Archives/edgar/data/1072379/000114420413020507/v3338517_10k.htm)

<sup>24</sup> 2014 10-k, p. F-18, note 9:

[http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

"We issued to Toucan Capital and Toucan Partners 4,287,851 and 2,572,710 shares of common stock, respectively. In connection with the issuance of these shares, we recognized a further reduction of earnings applicable to common stockholders of \$12.3 million in June 2007"

2007 10-k

"In connection with the modifications of the Series A and Series A-1 Preferred Stock warrants, we recognized reductions in earnings applicable to common stockholders in June 2007 of \$2.3 million and \$16.4 million, respectively."

2007 10-k

Conversion of accounts payable to common stock - Cognate BioServices	4,195	\$ 16,776
Inducement expenses associated with Conversion of accounts payable to common stock and warrants - Cognate BioServices	-	8,654

2014 10-k

"Loan Conversion inducement: Costs of \$5.6 million in connection with conversion of certain related party loans payable into equity. In September 2009, Toucan Partners agreed to convert ..."

2009 10-k

"On November 23, 2011, the Company and Cognate executed the conversion of \$9.2 million dollars of amounts owed by Northwest Biotherapeutics, Inc. to Cognate Bioservices, Inc. into 46 million shares of common stock, using the agreed upon conversion rate of \$0.20 per share. The Company recognized a loss on conversion of \$7.8 million ..."

2011 10-k

"On October 16, 2012, the Company entered into conversion agreements with Toucan Partners ... The difference between the fair value of the shares of common stock and warrants issued in excess of the carrying amount of the liabilities amounting to \$1.9 was recorded as conversion inducement expense in 2012."

2014 10-k	For the years ended December 31,	
	2014	2013
Other income (expense):		
Inducement expense	(18,905)	(10,599)

"During the year ended December 31, 2014, \$16.8 million of accounts payable owed to Cognate BioServices was settled for 4.2 million shares and 2.2 million warrants. The non-cash inducement charge was \$16.0 million related to these transactions."

2014 10-k



## Class action lawsuit – The truth starts to leak out

The transactions with Cognate were only part of the related party transactions. NWBO did many transactions with other Toucan companies and these transactions did not go unnoticed. In June 2015, two shareholders filed a class action and derivative complaint against NWBO, its directors and the Toucan entities. The court sealed per the request of NWBO some of the details of the complaint. In the complaint, the minority shareholders focus on some of the abovementioned transactions with Cognate and especially the conversion agreement between NWBO and Cognate.

We believe their lawyers will find our report interesting to say the least.

Pursuant to Section 220 of the Delaware General Corporation Law, the minority shareholders demanded to inspect documents, such as board of directors' minutes, relating to the agreements and interactions with Cognate and other related parties. Eventually, NWBO provided the Plaintiffs with limited records and after inspecting them the Plaintiffs stated in their claim that:

***“the Board did nothing to ensure that the term of the Conversion Price Agreement or Conversions were entirely fair to NWBO and its minority stockholders”<sup>25</sup>.***

Moreover, they provided the following quote from a board meeting which was held on July 30, 2013, in which the board discussed the conversion agreement with Cognate:

***“The conversion price would be \$4.00 per share... However, in order for such an agreement to be accepted by Cognate, there would need to be a downside protection through most favored notion provisions”<sup>26</sup>.***

The quote's purpose was to demonstrate that not only did the board members fail to consider the adverse effect of the agreement on NWBO's stockholders, but also they considered only the possible downside to Cognate. The minutes reflect that Powers served as Chairperson of the meeting, while she was also the beneficial owner and director of Cognate. The Plaintiff claimed that the documents produced by NWBO in response to the Plaintiff's demand, revealed that the board did not (1) form a special committee of independent directors to evaluate and approve the conversion price agreement, (2) retain any independent legal counsel, financial advisor, or other advisors or experts to advise; (3) obtain any fairness opinion; (4) engage in any meaningful negotiation with Cognate or Powers regarding the terms of the agreement; or (5) consider any alternative transaction to raise the funds to pay Cognate.

In response, NWBO's directors claimed that the willingness of Cognate to accept payment in the form of shares, has been a key element in NWBO's progress in developing its products. NWBO's directors make the argument that if the share price of NWBO would drop, the conversion would be less favorable than it appears now in retrospect. But, according to the conversion agreement, the conversion price would be

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<sup>25</sup> Lerner v. Northwest Biotheapeutics Inc., 8:15-cv-02532-GJH

<sup>26</sup> Lerner v. Northwest Biotheapeutics Inc., 8:15-cv-02532-GJH

the lower of \$4 and the lowest conversion price offered to any other creditor. **This makes the directors' argument quite absurd, as Powers, who also owns Cognate, could cause NWBO to engage an agreement with any other creditor (probably with another member of the Toucan family) on a lower conversion rate for their debt and voilà, Cognate does not take any risk or lose money as the conversion rate would reset downwards.**

The minority shareholders complaint alleges that NWBO's management produced no documents evidencing negotiation, review, and/or approval by the Board (or any committee thereof) discussing the debt repaid by NWBO on behalf of Cognate which triggered the \$2.2 million "Inducement Expense" in 2012. In addition, the identity of the "Outside Party" which received the shares and warrants was not disclosed in NWBO's filings. **The complaint lists additional incidents involving agreements in which Powers held a position on both sides of the negotiation table which were beneficial to her private companies, with no documentation of negotiations or approval by the board of directors.**

Since Cognate is a private company we don't have too many details on its operations. However, employees are always a good source of information to reveal the truth, and especially if that person is the company's #1 employee – the CEO. In a lawsuit filed in March 2012 by Alan Smith, Cognate's CEO between 2002 and 2009, Smith claimed that he submitted his resignation:

***"because he was frustrated and uncomfortable with Cognate's precarious financial condition"***<sup>27</sup>

Furthermore, he noted that Cognate's debts were piling up:

***"in large part because of expenditures it incurred that inured solely to the benefit of Toucan, Powers, Hemphill and/or Cognate's sister companies"***<sup>28</sup>

Although Smith was the CEO, he claimed that:

***"Cognate's operations, other than the most routine aspects, were controlled largely, if not exclusively, by Powers and Hemphill";*** and that they (Powers and Hemphill):

***"often exercised that power for the benefit of themselves, Toucan and other of Toucan's holdings"***<sup>29</sup>

The lawsuit provides for the following key statement:

***"The relationship between Cognate and most, if not all, of Toucan's other companies are not arm's length"***<sup>30</sup>

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<sup>27</sup> Smith vs Cognate Bioservices Inc, et al, Docket No. 03C12002363, p.4 section 12

<sup>28</sup> Smith vs Cognate Bioservices Inc, et al, Docket No. 03C12002363, p.4 section 12

<sup>29</sup> Smith vs Cognate Bioservices Inc, et al, Docket No. 03C12002363, p.5 section 14

<sup>30</sup> Smith vs Cognate Bioservices Inc, et al, Docket No. 03C12002363, p.3 section 5

## NWBO's Independent Director Malik dealings with NWBO and Powers

We present evidence of undisclosed transactions between Dr. Navid Malik, NWBO's "independent" director and member of its Audit, Compensation and Nomination committees, and NWBO and the Toucan Group. While Navid covered NWBO as an analyst, **Regen Med Acquisition Corp. ("Regen Med")**, a company he has just incorporated in Delaware, received \$5 million worth of shares and warrants of NWBO from Toucan Fund II, soon after he released an extremely bullish report on NWBO. This and additional findings we present, cast serious doubt on Navid's ability to serve as a director of the company and over the legitimacy of the transactions that occurred between the Toucan Group, NWBO and Navid and his undisclosed partner Alia Minhas.

On April 17, 2012, NWBO announced that Dr. Navid Malik has joined the Board of Directors of the company<sup>31</sup>. However, Malik was no stranger to NWBO before he joined the Board. Malik, as an employee of Matrix Corporate Capital<sup>32</sup>, published in 2010 an extremely bullish "research" report on NWBO **with a price target of not less than \$70.4**<sup>33</sup> (adjusted for 2012 reverse split), 378% higher than the price of NWBO at the time. After its release, NWBO used the "report" for PR spins for a long period of time and it was also used by many promoters to give credibility to NWBO's R&D, although Malik's "research" report included the following footnote:

***"This document must be treated as a marketing communication as it has not been prepared in accordance with legal requirements designed to promote the independence of investment research."***

We believe it is fair to assume that Matrix and/or Malik were compensated for this publication in light of this footnote. Maybe even much more than a reader would imagine.

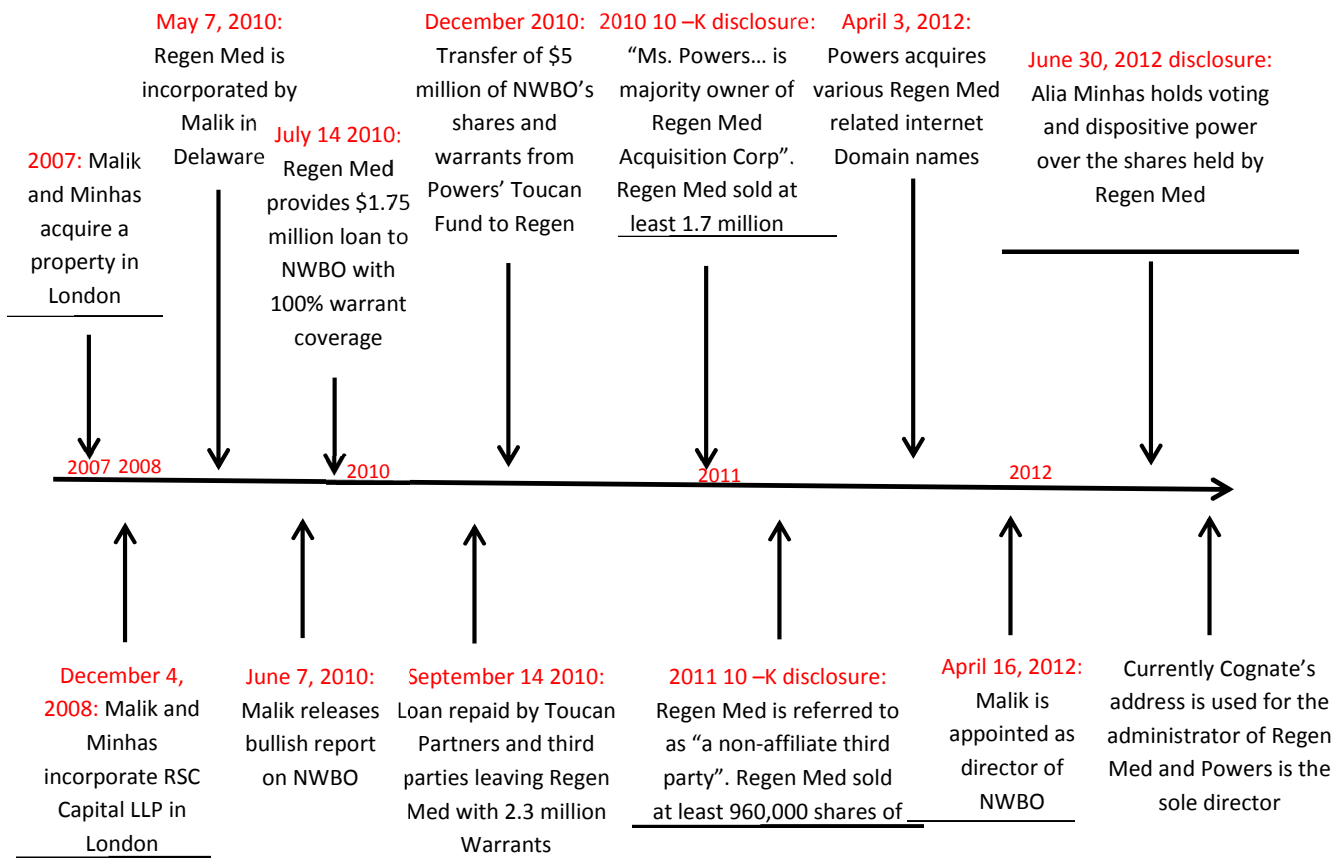
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<sup>31</sup> <http://www.nwbo.com/northwest-bio-welcomes-new-additions-to-the-board-of-directors>

<sup>32</sup> [https://register.fca.org.uk/ShPo\\_IndividualDetailsPage?id=003b000000LVXpYAAX](https://register.fca.org.uk/ShPo_IndividualDetailsPage?id=003b000000LVXpYAAX)

<sup>33</sup> [https://web.archive.org/web/\\*/http://www.biomedreports.com/research/doc\\_download/137-nwbo-dr-maliks-40-page-report.html](https://web.archive.org/web/*/http://www.biomedreports.com/research/doc_download/137-nwbo-dr-maliks-40-page-report.html) (Choose July 16 to download the report)

The following timeline illustrates the events surrounding Regen Med and David's transactions



Our research has uncovered that on May 7, 2010, one month before issuing his “report”, NWBO’s future director Malik, incorporated a Delaware company by the name Regen Med Acquisition Corp. Malik gave the following contact details when incorporating Regen Med:

Navid Malik  
c/o RSC Capital, L.P.  
Hawthorne House  
1 Cholmeley Park  
London N6 5ET

In addition, according to NWBO’s 2010 10-K, on July 14, 2010, only one month after Malik released his bullish piece, NWBO entered into an unsecured convertible loan with Regen Med, the same company he has just incorporated<sup>34</sup>. **According to NWBO’s disclosure, Regen Med provided a 60-day \$1.75 million bridge loan carrying 6% interest.** According to the same filing, **the Regen Med loan was repaid by a Toucan entity** (Toucan Partners) and other third parties. In later filings<sup>35</sup>, NWBO disclosed that Regen Med also received 2,333,333 (145,833 post reverse split) warrants as part of the bridge loan. **We believe Regen Med had actually taken no risk in providing this loan to NWBO and essentially was gifted warrants of NWBO.**

Furthermore, in NWBO’s 2010 10-K, NWBO stated that Powers is actually the majority owner of Regen Med:

***“...Ms. Powers is a managing member of Toucan Management, LLC, which is the manager of Toucan Capital, and is a managing member of Toucan Partners and is majority owner of Regen Med Acquisition Corp”.***

But, on the next page of the same 10-K **NWBO disclosed that on December 30, 2010, Toucan Fund II transferred 6,433,162 shares and 7,345,030 warrants to Regen Med, “a non-affiliated third party”.** This means that approx. \$5 million of shares and warrants were transferred to the company Navid has recently incorporated in Delaware, where it’s fairly difficult to get information about ownership.

Are you getting confused? How can Regen Med be incorporated by Navid, majority owned by Powers and be a non-affiliated third party?

In NWBO’s 2011 10-K Regen Med is not disclosed anymore as majority owned by Powers and referred to only as **“a non-affiliate third party”.**

Surprisingly, on June 30, 2012, **NWBO filed an S-1 identifying a certain Alia Minhas as the person who is holding the voting and dispositive power over the shares held by Regen Med.** NWBO continued providing this statement in later filings in 2012 until Regen Med dropped below the 5% holding threshold

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<sup>34</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420411023452/v218791\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420411023452/v218791_10k.htm)

<sup>35</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420412037417/v315727\\_s1.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420412037417/v315727_s1.htm)

which requires disclosure. **No relationship between Alia Minhas and Powers or Malik was disclosed by NWBO.**

**Our research has uncovered the following information regarding Alia Minhas and NWBO's director Malik which show without a doubt that Navid and Minhas are related:**

- **Minhas and Malik incorporated a UK partnership named RSC Capital LLP** on December 4, 2008, with the registered address: Hawthorne House, 1 Cholmeley Park, Highgate London N6 5NT<sup>36</sup>;
- According to the UK land register, **the property located at Hawthorne House, 1 Cholmeley Park, Highgate London N6 5NT was acquired in 2007 by Minhas and Malik**<sup>37</sup>;
- **Minhas and Malik were disclosed by Galena Bioparma Inc. as shareholders**<sup>38</sup>. Galena is currently under SEC investigation for using stock promoters to pump its share price while insiders sold shares<sup>39</sup>. Richard Pearson published in July 2014 an article in which he claimed that a PR firm linked to the Galena case was behind many of the bullish articles published on NWBO (we highly encourage readers to have a read)<sup>40</sup>. We will follow up later in our research on this point; and
- According to the UK Financial Service Authority (FSA), Minhas has been an investment adviser with Mulier Capital, a now dissolved London-based Biotech-focused boutique investment bank<sup>41</sup>.

NWBO's 2010 10-K filings disclose that Regen Med held as of March 31, 2011 only 4,689,330 shares of NWBO (after it received 6,433,162 shares from Toucan Fund II in 2010), meaning that **Regen Med sold at least 1,743,832 shares** (we say at least as it owned also warrants). In the 2011 10-K, NWBO disclosed that Regen Med owned only 3,727,462 shares as of April 9, 2012, meaning **it has sold at least another 961,868 shares**. Later filings do not provide any more details about Regen Med's holdings. Although after the transfer of shares in 2010, Regen Med owned approx. 8% of the then issued and outstanding shares, it never filed with the SEC any ownership form which it was obligated to do as it held more than 5% of the shares outstanding. **We do not believe this is a coincidence but rather an attempt to divert attention from Regen Med and its real beneficial owners.**

Powers did file an ownership form for 2010, but only in late 2014. In that form, when providing the details of the transaction in which the holdings of Toucan Fund II were distributed, Regen Med was referred to as **"persons not affiliated with Fund II or the reporting persons"**<sup>42</sup>, although in earlier filing NWBO disclosed that Regen Med was majority owned by Powers. We believe this to be untrue.

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<sup>36</sup> See appendix 1

<sup>37</sup> See appendix 2

<sup>38</sup> Prospectus, p.21: <http://investors.galenabiopharma.com/secfiling.cfm?filingid=1193125-13-336807&cik=1390478>

<sup>39</sup> <http://www.thestreet.com/story/12532765/1/galena-discloses-sec-investigation-focused-on-stock-touting-campaign.html>

<sup>40</sup> <http://seekingalpha.com/article/2301825-behind-the-promotion-of-northwest-bio>

<sup>41</sup> [https://register.fca.org.uk/ShPo\\_IndividualDetailsPage?id=003b000000KT3HgAAL](https://register.fca.org.uk/ShPo_IndividualDetailsPage?id=003b000000KT3HgAAL)

<sup>42</sup> [http://edgar.sec.gov/Archives/edgar/data/1072379/000114420414075185/xsIF345X03/v396408\\_4.xml](http://edgar.sec.gov/Archives/edgar/data/1072379/000114420414075185/xsIF345X03/v396408_4.xml)

While trying to get to the bottom of the relationship between Powers and Regen Med **we discovered that numerous internet domains owned by Regen Med were all acquired on April 3, 2012, all list Powers as the registrant and admin and all have a support@toucancapital.com email and Toucan's address as mailing address.** These domains are listed below:

- regenmedacquisitioncorp.com
- regenmedacquisition.net
- regenmedacquisition.org
- regenmedacquisitioncorp.com
- regenmedacquisitioncorp.net
- regenmedacquisitioncorp.org
- rmacfund.com
- rmacfund.net
- rmacfund.org
- rmacmgmt.com
- rmacmgmt.net
- rmacmgmt.org

In addition, **Powers is currently identified as the sole director of Regen Med, while the administrator of the company is located at the address of Cognate's corporate headquarters - 7513 Connelley Drive, suite 1, Hanover MD 21076.** In the lawsuit that was filed against Cognate by its prior CEO, Cognate's lawyers disclosed that Theraigm Inc., a Toucan Capital portfolio company, is owned by Regen Med.

**We believe Powers and Malik should come clean and disclose the real transactions that took place:**

- **What compensation was provided to Malik for publishing the 2010 report? Was it the transaction that netted Regen Med 2.3 million warrants? Who really provided the funds for Regen Med to loan to NWBO? Why where \$5 million of securities transferred from Powers to a company Navid incorporated?**
- **Why did NWBO disclose that Regen Med was majority owned by Powers and still claim it was an unrelated party? We urge Powers to reveal the ownership history of Regen Med.**
- **How come Minhas came to have voting and dispositive power over the shares held by Regen Med? Were Regen Med's shares really transferred to Minhas and Malik, or did they just serve as a proxy to hide Powers' sale of the shares held by Toucan Fund II without disclosing that she is actually selling?**

## How to draw attention of patients to an unapproved treatment that oncologists don't recommend?

According to *The Street* columnist Adam Feuerstein<sup>43</sup> the company is relies on (i) oncologists to recommend the treatment to patients or (ii) patients need to inquire about it <sup>44</sup>:

***“Northwest Bio cannot market DCVax in Germany. The company cannot advertise for patients or talk about the benefits and risks of DCVax because it remains an unapproved therapy. The only way DCVax gets used in Germany is if brain tumor patients ask their doctors about it, or if doctors recommend the experimental therapy to their patients.***

We believe the clinical data of the company has been of low quality and therefore oncologists have not rushed patients to enroll in the clinical trials of NWBO. This is evidenced by the very long time it took NWBO to enroll patients for their clinical trials, which we believe is due to the problematic scientific background of DCVax. So how do you get patients to ask about the treatment if oncologists are not impressed with DCVax?

As previously mentioned, Richard Pearson<sup>45</sup> provided in a Seeking Alpha article ample evidence linking NWBO to the PR firm MDM Worldwide and to stock promotion campaigns<sup>46</sup>. We believe this does not stop here. We believe that ghost writers have not only promoted the company on investor oriented platforms, but also on platforms aimed at GBM (Glioblastoma Multiforme-the most common type of brain tumor<sup>47</sup>) patients, in order to promote DCVax and its “superiority” to other alternatives and to persuade terminally ill patients to cuff up the north of \$100,000 needed for private-pay treatment.

Pearson also published the following copy of Redfish’s (which has been working for MDM) brochure which explains how to promote stocks by posting on message boards:

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<sup>43</sup> <http://www.thestreet.com/topic/45381/adam-feuersteins-biotech-blog.html>

<sup>44</sup> <http://www.thestreet.com/story/12525597/1/northwest-bios-german-smokescreen-obscures-DCVax-problems.html>

<sup>45</sup> <http://seekingalpha.com/author/richard-pearson>

<sup>46</sup> <http://moxreports.com/category/nwbo/>

<sup>47</sup> [https://en.wikipedia.org/wiki/Glioblastoma\\_multiforme](https://en.wikipedia.org/wiki/Glioblastoma_multiforme)



### Small Cap Content Social Media and Content Plans



#### Investor Board Participation.

In order to raise awareness by investors for a Small Cap firm, valid, credible content needs to be published, and investors need to be notified of the availability of this content.

**YAHOO! FINANCE**

**INVESTORSHUB** **Google**

One method of reaching investors for a specific company is via the firm's investor boards on the multiple financial publication sites.

These include but are not limited to:  
Yahoo Finance, Investors Hub, Google Groups

Although many of the postings on these sites are unprofessional and market manipulating in nature, the sites do attract the attention of investors and a percentage of postings are credible. It has been proven that credible and professional information will be noticed and engaged in by readers.

Critical to the successful and positive exposure to the Small Cap firm is engagement. Key in this engagement is to post links to credible articles and interviews about the company and subsequently actively participate in conversations about them. This gives the Small Cap firm a voice in the social media community, and a specific one focused to investors and stakeholders of the company, as well as new potential parties of interest.

*The primary intention of the investor board engagement is to participate in discussions and make available articles and interviews about the company.*

### The brochure marks some important takeaways:

1. Use the firm's investor board on multiple financial publication sites (yahoo finance, Investor Hub, Google Groups);
2. Credible and professional information will be noticed and engaged;
3. The key is to post links to credible articles and interviews and active participation in conversation about them.

### Presenting – "John1045" or "johnlane45":

"John" started his posting "career", as far as we know, on September 6, 2011, when he posted on NWBO's message board on the site InvestorsHub.com.

As of October 10, 2015, "John" posted as many as 1,144 posts on NWBO, which equates to almost one per day on average.



John1045 image used in various forums



**john1045**

[Send a Private Message](#)
[Follow This Member](#)
[Read Last 50 Messages](#)
[Ignore This Member](#)

Latest Posts	Boards Posted On	Boards Moderated	About	My Stocks (7)
	Board	Last Post		Posts
	Intellect Neurosciences, Inc. (ILNS)	10/14/2015 01:49:13 PM		355
	Petro Rio S.A. (HRTPY)	10/14/2015 05:43:35 AM		265
	NorthWest Biotherapeutics (NWBO)	10/10/2015 11:01:59 AM		1,144
	TapImmune Inc (TPIV)	06/09/2015 07:17:32 PM		42
	Ucore Rare Metals, Inc (UURAF)	05/01/2014 10:27:55 PM		13
	Celsion Corporation (CLSN)	01/30/2013 01:45:37 PM		1
	ImmunoCellular Therapeutics, Ltd. (IMUC)	01/19/2013 07:29:24 AM		10
	Stans Energy Corp. (HREEF)	01/01/2013 08:27:28 AM		4
	Cellceutix Corporation (CTIX)	01/01/2013 06:49:39 AM		1
	Acadia Pharmaceuticals Inc. (ACAD)	11/29/2012 11:04:49 AM		1
	Ocata Therapeutics Inc. (OCAT)	09/20/2012 08:47:47 AM		5
	BrainStorm Cell Therapeutics Inc. (BCLI)	07/23/2012 08:23:04 AM		1
	PharmaCyte Biotech Inc. (PMCB)	05/25/2012 12:22:55 PM		13
	Focus Graphite, Inc. (FCSMF)	03/21/2012 03:07:27 PM		2

On November 10, 2011, “John” also started to post on [www.cancercompass.com](http://www.cancercompass.com), a website created to help patients with cancer to get better information about their disease. “John” never posted anything that is not related to NWBO on Cancercompass<sup>48</sup>. “John” followed the Redfish recipe. Usually his posts were in the form of a link to a press release or providing “information” and “updates” on NWBO’s progress and even suggesting patients to contact NWBO. After reading all of “John’s” posts, it seems that he was not only promoting the company on investor oriented internet boards (which is an issue for the SEC), but also trying to build credibility for NWBO’s DCVax treatment on internet boards targeted at cancer patients (which is an issue for the FDA). “John’s” last post on Cancercompass was on May 19, 2014.

On August 26, 2014, “John” appeared on Twitter<sup>49</sup>, where he posted approx. 2,000 Tweets on NWBO in little more than one year using the same tactic Redfish suggests.

“John” also had a brief appearance on [www.inspire.com](http://www.inspire.com), a site created for people to discuss and share opinions on health issues,<sup>50</sup> where he posted only two PR announcements of NWBO, once in 2012 and once in 2014:

<sup>48</sup> <http://www.cancercompass.com/profile/johnlane45>

<sup>49</sup> <https://twitter.com/johnlane45>

<sup>50</sup> <https://www.inspire.com/john1045/discussions/>

### john1045's discussions

#### DCVax Approval in Germany



By john1045 · Posted March 20, 2014

In American Brain Tumor Association · 2 replies

(Reuters) - Germany has granted Northwest Biotherapeutics Inc special permission to sell its experimental brain cancer drug in the country, the company said, and its stock jumped as much as 36 percent ...

#### Northwest Bio Proceeding With a Phase I/II Clinical Trial of DCVax®-Direct



By john1045 · Posted September 20, 2012

In American Brain Tumor Association · 0 replies

Great news on progress in the fight against cancer! BETHESDA, Md., Sept. 20, 2012 /PRNewswire/ -- Northwest Biotherapeutics (OTC.BB: NWBO) (NW Bio), a biotechnology company developing DCVax® personalized ...

When the son of an Egyptian woman diagnosed with GBM asked for advice on DCVax<sup>51</sup>, John rushed to refer him NWBO for more information:

*“Good luck in my honest opinion I believe you are on the right track finding the best care for your mother, I would be doing the same thing as you. You are a good son!”*

When the son mentioned that his mother’s oncologist would not use non-FDA approved medications, a user named “SimonAl” came to the rescue to convince him otherwise. We present SimonAl, the German oncology student that never posted before or after on this site<sup>52</sup>. His only posts were numerous replies to the son’s posting (all grammatical errors are of the relevant poster):

*“Hello Nabil, I've read your message.*

*I am studying medicine in Germany and have finished my basic education. Now I'm studying for specialist oncology. Now that m exams for this term are over, and now that I've been granted two weeks of holidays, I'm reading about new treatments in cancer. DCVax-L is one of the treatment that got my attention, so I started reading about it.*

*DCVax-L is indeed in the testing phase, but it is phase III, meaning that this is the final phase before authorities can approve the treatment.*

*DCVax-L has delivered some outstanding results, as there are still two people alive (and doing daily activities, sports, ...) after they were treated on DCVax-L 10years ago for GBM!!! The overall survival and progression free survival was statistically significantly higher than standard of care treatment in the earlier testing phases with a p-value of 0.0003 (meaning that there*

<sup>51</sup> <http://www.cancercompass.com/message-board/message/all,72551,0.htm>

<sup>52</sup> <http://www.cancercompass.com/profile/SimonAl>

*would only be a 3/10000 chance that the higher overall survival and progressions free survival were due to coincidence).*

*The treatment is said not to be painful, doesn't have much side effects and should be rather "cheap" for a cancer treatment. As far as I know, Kings College does compassionate use as well, meaning if you pay for the treatment, they will treat you.*

*Please keep me informed, because I'm interested in your story."*

SimonAL even goes further and refers the son to a website to raise funds for the expensive treatment:

*"I understand that the treatment cost is high, but you might want to try this site to get funding for your mom:*

*<http://www.giveforward.com/cause/raise-money-for-medical-exp>"*

When the son was debating which treatment to pursue for his mother, SimonAL, as "a medical student specializing in oncology that is doing some research on new treatments in his free time", was comfortable making bold statement that DCVax was the best option for the mother:

*"DCVax-L is the best option for GBM treatment as being in its' phase 3 clinical trial. As a student in oncology that's my conclusion so far doing some research in my free time. ICT has too much HLA restrictions and can therefore only be useless in 40% of the cases vs DCVax-L which can always be used if the right path is followed after diagnosis. It is a pity that some oncologists stick to SOC. treatment and never take time for upcoming groundbreaking treatments like DCVax-L."*

Come in the lead actor "John" to support SimonAL and persuade the son:

*"SimonAL...I agree with you on DCVax-L and now they are in Phase I/II for DCVax-Direct at MD Anderson in Houston for all inoperable solid tumors in pancreas, colon, liver, melanoma where patients have no other treatment option available. We should start hearing results in next 60 days as this trial started back on June 13th. I also understand they will start this in UK as well and could be announced in coming weeks.*

*This groundbreaking science using the bodies immune system is showing some very striking results in prior trials.*

*The most important thing we can do is try to help provide information to patients and caregivers that there are other options available other than standard of care for that particular cancer that they can research and consult with their oncologist."*

SimonAL continues to persuade the son:

*"Here are the results of DCVax-L from earlier trials on GBM:*

**to date:**

**33% alive >4 yrs**

**27% alive >6 yrs**

**2 pts alive >10 yrs**

**That has never been achieved on GBM8**

**That's why I, as a future oncologist, believe this could become THE golden standard in GBM treatment. Next year we'll know for sure after the final phase 3 results."**

Commenting on the high costs, SimonAl urges the son not to consider the high costs of the treatment and reassuring that other oncologists share his view:

**"I don't think reimbursement will be an issue if you look at the results from earlier trials. It sound that you are somewhat disappointed that DCVax-L is my first choice for GBM if once approved. I've talked about it with colleague-oncologists and they were equally impressed about DCVax-L. I am not saying ICT is bad, but it's too limited because of HLA restrictions. Ps I don't like to talk about treatment costs. Rescueing a human life is worth more than all the money in the world. That's why I want to become oncologist in a few years: to save lives and to stand by patients and their family in their battle."**

Funnily enough, the son was wondering how come SimonAl, as a German oncology student, did not know of a competing technology by a German company named Immatic:

**"Simon, have alook at this one (IMA950), i actually wonder how you didn't notice it as its already a german manufacturer."**

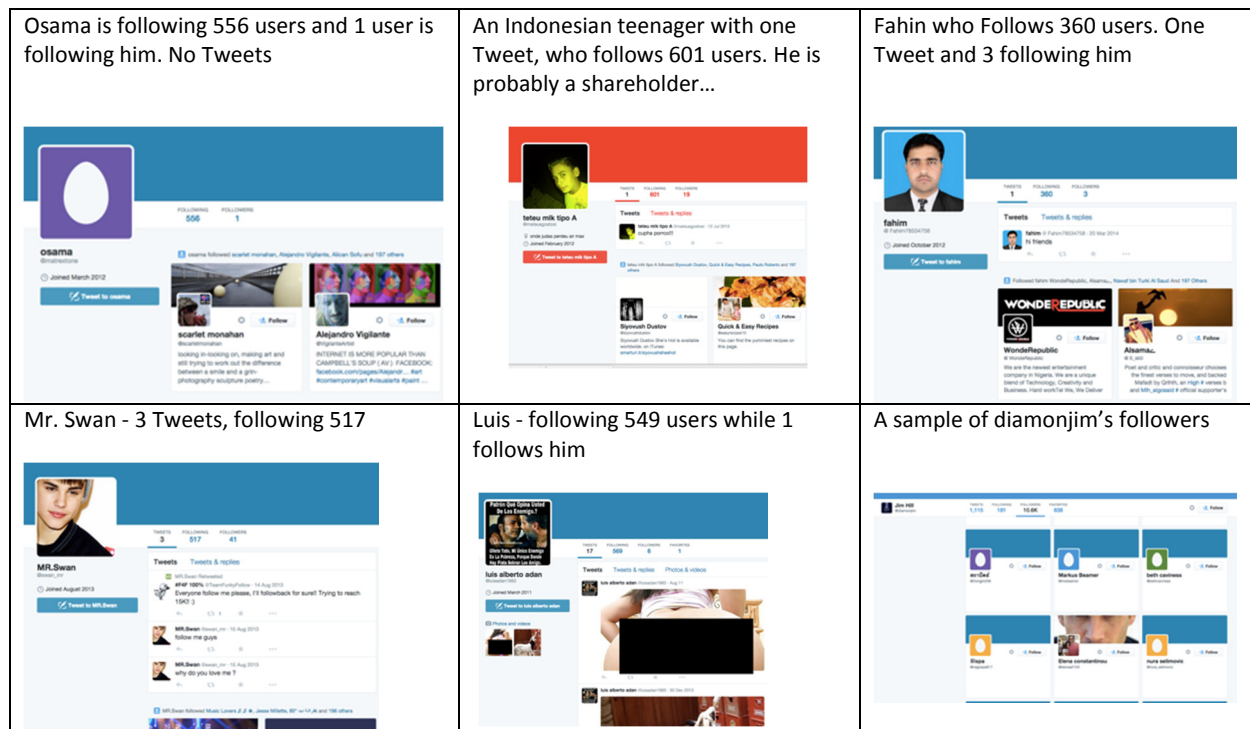
SimonAl goes on and on:

**"Yes, I am in med school. And now, I will be specializing for oncologist. I am convinced that chemotherapy is from the past and that immunotherapy will be the therapy for solid tumors and stem cells for non-solid tumors. IMO DCVax-L has showed incredible results and if you look at the p-values, I don't see any reason why they won't be duplicated in phase 3. If I would be already an oncologist, I would advice my GBM patiënt, if he/she complied with the inclusion criteria, to do the clinical trial. No pain, no toxicity. Thus in all cases a better way to have quality (no suffering after Rachid chemo/radiation dessin) with your beloved ones. And most probably; longer progression free survival and overall survival."**

As will be shown on page 34, the son did actually contact NWBO, which referred him to CTCI for private pay (more on CTCI later in this research).

We believe that if NWBO or its PR firm is responsible for posts by people pretending to be an authority and putting out statements such as that DCVax is the best option for treatment for these desperate people and push them to seek paid compassionate use with the unapproved DCVax at astronomical costs, the FDA will be very interested.

We also found what we consider fake Twitter users tweeting about NWBO. These users may be real people, but their motivation to post is questionable. For example Jim Hill AKA diamonjim<sup>53</sup>. Hill makes sure to Tweet occasionally something not related to NWBO, but mostly he just Tweets news and articles on NWBO (according to the Redfish recipe). We believe Jim is actually a real person<sup>54</sup>. **He has more than 10,000 followers, which we believe almost all have been paid for so that other users will find Hill's posts creditable.** Hill's fake followers are obvious when looking at their profiles. We gathered a handful of followers that are clearly (not) interested in NWBO:



In his LinkedIn and Twitter accounts, Hill provides links to a business of his. Using Wayback Machine<sup>55</sup> we learned that his business used to provide the following services:

***“Welcome to Passion Quest Inc. We are currently developing and expanding into a multi-faceted corporation which includes its original Coaching as well as design, writing, art and marketing.”***

<sup>53</sup> <https://twitter.com/diamonjim>

<sup>54</sup> <https://www.linkedin.com/in/diamondjim>

<sup>55</sup> <http://web.archive.org/web/20141218043641/http://passionquestinc.com/>



Hill tweeted some nonsense every couple of months since his first Tweet in March 2012. Nothing related to NWBO, shares or Biotech. Then, in November 2013, he started Tweeting about NWBO, and since then almost nothing but NWBO. This is not the only user with this behaviors pattern - there are more.

Moving on to InvestorsHub.com. Hill posted 616 posts on NWBO, and exclusively on NWBO. He is a moderator of the NWBO page on the site and, **according to other participants on the board, the only one that seems to actually get replies from NWBO's investor relations**<sup>56</sup>. **Hill started to post in November 2013, the same month he started to Tweet about NWBO. He posts almost daily.** We find the quote he has chosen for his profile hilarious: "Honesty is a very expensive gift. Never expect it from cheap people".

Diamondjim61 Honesty is a very expensive gift. Never expect it from cheap people.		
Latest Posts	Boards Posted On	Boards Moderated
Board	Last Post	Posts
NorthWest Biotherapeutics (NWBO)	10/13/2015 08:55:06 AM	616

Hill's first post was answering our "John"<sup>57</sup>:

***"John... thanks for all of your thoughtful insight regarding NWBO... where do you see that kind of detail on trades?"***

There are many funny posts of Hill:

- Hill learning to calculate share price<sup>58</sup>:

***"Its that simple?"***

***Market Cap/Shares=PPS?***

***That can't be the only thing. What determines Market Cap?"***

- Hill explains why he started investing in NWBO and "kills" his parents on the way<sup>59</sup>:

***"I don't quite remember what brought me to NWBO over a year ago. I am a diversified investor who follows a top broker out of San Diego. This is definitely not on his radar. Too risky of a play for him.***

<sup>56</sup> [http://investorshub.advfn.com/boards/read\\_msg.aspx?message\\_id=117617111](http://investorshub.advfn.com/boards/read_msg.aspx?message_id=117617111)

<sup>57</sup> [http://investorshub.advfn.com/boards/read\\_msg.aspx?message\\_id=93974788](http://investorshub.advfn.com/boards/read_msg.aspx?message_id=93974788)

<sup>58</sup> [http://investorshub.advfn.com/boards/read\\_msg.aspx?message\\_id=95746687](http://investorshub.advfn.com/boards/read_msg.aspx?message_id=95746687)

<sup>59</sup> [http://investorshub.advfn.com/boards/read\\_msg.aspx?message\\_id=97122456](http://investorshub.advfn.com/boards/read_msg.aspx?message_id=97122456)

*In the end, I believe fate brought me to invest in NWBO as both my parents died of cancer when I was young. Somehow, someday, Cancer is going pay me back for the loss and I believe this is it."*

- Hill explains why Powers does not want to do 1 on 1 with investors. Suddenly he is an expert in public company's events after he didn't know how market cap and share price are related<sup>60</sup>:

*"Hmm rumor has it that \$nwbo refuses to host 1x1 by Jeffries conference*

*This conference is the same time as ASCO so it make sense that Nwbo doesn't have time but what confuses me what is meant by to host and also the 1x1?*

*The "one on one" are special sessions set up between the company and interested investors - private... the company rents the space - invites the investor in for "special" meeting.. LOL.. really just a way to pump investors.. sometinmes good sometimes not so good..*

*I think the participating companies - like NWBO - have to pay for the pribviledge to "host" the one on one investor meetings and maybe, just maybe.. NWBO feels it dosen't have too... just a thought...."*

- Hill explains to an angry NWBO investor why insiders have not been buying shares after the price broke<sup>61</sup>:

*"I think there are restrictions on some of that.*

*I am certainly no expert, but if they buy shares are there not restrictions on how they can sell them... this prevents insider profiteering.*

*Besides if I already owned millions in the stock, wouldn't I want to diversify? Lol"*

We believe that the company is trying to work around this prohibition by posting information about DCVax on GBM forums. A quick search has found the following example regarding Germany: a new user that has posted a single post informing readers of the availability of the treatment in Germany (it is in German so we will spare you the translation)<sup>62</sup>. We believe the German Federal Institute for Risk Assessment will also be interested.

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<sup>60</sup> [http://investorshub.advn.com/boards/read\\_msg.aspx?message\\_id=98419843](http://investorshub.advn.com/boards/read_msg.aspx?message_id=98419843)

<sup>61</sup> [http://investorshub.advn.com/boards/read\\_msg.aspx?message\\_id=107020850](http://investorshub.advn.com/boards/read_msg.aspx?message_id=107020850)

<sup>62</sup> <https://forum.hirntumorhilfe.de/neuroonkologie/immuntherapie-9584.html>



## How to turn despair into \$\$\$?

GBM patients not enrolled to the company's clinical trials have been referred by NWBO to hospitals in Germany, the UK and probably mostly to an Israeli center to receive a paid "compassionate" treatment, a treatment for which NWBO is not allowed to charge money in the US and that has been described by the Israeli Ministry of Health as unapproved human trials. Desperate families are referred by NWBO to the controversial Professor Shimon Slavin and the CTCI center in Tel Aviv to receive NWBO's highly priced and unapproved treatment outside of the clinical trials conducted in the US and Europe. **We believe that evidence suggests that Powers might also control CTCI.**

The **International Center for Cell Therapy & Cancer Immunotherapy Ltd. ("CTCI")** is an Israel-based medical center which provides NWBO's DCVAX vaccine. According to its website<sup>63</sup>:

*"...provides groundbreaking treatments for patients with cancer or non-malignant diseases. Some of the treatments are provided in Israel, and others are provided in other locations, in accordance with local regulations. The cancer treatments include a broad range of personalized immune therapies, oncolytic virus therapies, and tailored drug regimens with reduced toxicity. The treatments for non-malignant diseases include regenerative therapies developed by CTCI for neurological diseases and other conditions correctible by bone marrow or adipose-tissue-derived stem cells."*

In July 2008, Cognate incorporated a subsidiary in Israel - Cognate Bioservices Israel Ltd. ("Cognate IL"). Cognate IL's registered address is 14 Weizman St. Tel Aviv, Israel, which is an office and hotel complex adjacent to Tel Aviv's medical center. According to Cognate IL's incorporation documents, its parent, Cognate Bioservices Inc. mailing address was stated with an Israeli accounting firm named Engel Bakshi & Co. Certified Public Accountants. The sole director at incorporation of Cognate IL was Linda Powers. In November 2008, Ilan Engel was added as director of Cognate IL and also identified as the manager of Cognate IL. It was reported in the local media when Cognate IL was set up that it would serve as a production and distribution facility for stem cells for local and European clients<sup>64</sup>.

Four months later, in November 2008, another company was incorporated by Mr. Engel: International Center for Cell Therapy & Cancer Immunotherapy Ltd. ("CTCI"). Its shareholder is a trust company named Orange Clover Trusties Ltd, which is registered at the offices of Engel-Bakshi. **The address of CTCI was disclosed as "c/o Cognate Israel at Weizman Street 14, Tel Aviv"**. This address was changed in February 2009 to the address of Engel-Bakshi CPA.

Our findings that suggest Powers might control CTCI include:

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<sup>63</sup> <http://ctcicenter.com/>

<sup>64</sup> <http://www.globes.co.il/en/article-1000347699>

- **The following domains were purchased in September 2008, two months before CTCI was incorporated, and are held on the name of Powers.** The address and contact details are those of Powers and Toucan Capital<sup>65</sup>:
  - ctcicenter.com
  - ctcicenter.net
  - ctcicenter.org
- **CTIC's initial address was the offices of Cognate IL.** Its current address is also the official address of Cognate IL<sup>66</sup>;
- Cognate IL and CTCI share the same directors and contact details;
- CTCI's privacy policy states<sup>67</sup>: ***"This policy applies only to the website, services and operations of CTCI, and the CTCI-related operations of other parties included in the content of CTCI's website, such as Northwest Biotherapeutics, Cognate BioServices and others"***;
- **A trustee holds the shares of CTCI to prevent exposing the real identity of the shareholder;**
- Professor Slavin, the person most associated with the center and who is believed to be the owner of the center by the public, provided a statement in the Israeli parliament that he does not own CTCI<sup>68</sup>:

***"there are things that will be revealed in court, but there are things that might not be revealed in court, for example that the clinic is owned by me, which is not true. I am an employee. That we charged 250..."***

In addition, in none of the legal proceedings against CTCI was he identified as an owner of CTCI; and;

- According to Professor Slavin's CV, he is, or was, a member of the scientific board of NWBO<sup>69</sup>.

There is no doubt that CTCI's medical and scientific director is the highly controversial Prof. Shimon Slavin<sup>70</sup>. We present some background information on Slavin:

- A prospective patient bothered to create a web page to warn patients from making advance payments to Slavin for consultation<sup>71</sup>.

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<sup>65</sup> [https://whoisology.com/archive\\_10/ctcicenter.com](https://whoisology.com/archive_10/ctcicenter.com)

<sup>66</sup> See appendix 3

<sup>67</sup> <http://ctcicenter.com/privacy-policy.htm>

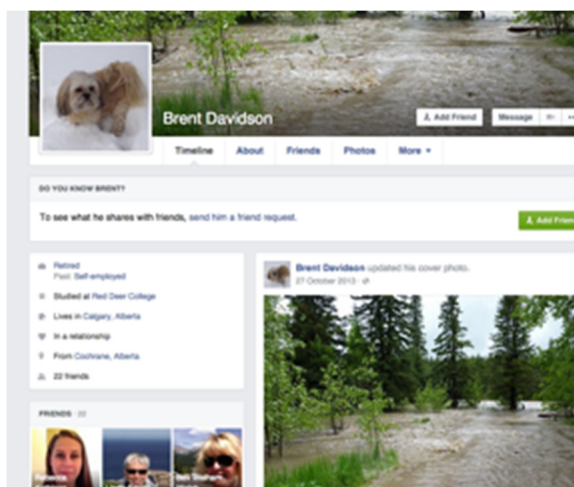
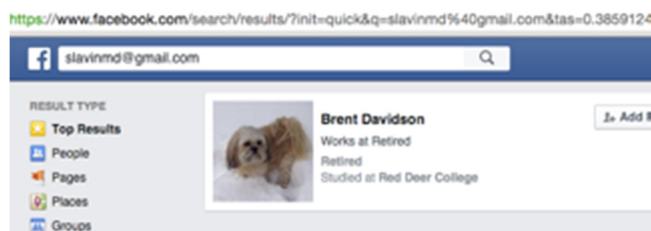
<sup>68</sup> Free translation from: [http://fs.knesset.gov.il/19/Committees/19\\_ptv\\_298850.doc](http://fs.knesset.gov.il/19/Committees/19_ptv_298850.doc)

<sup>69</sup> <http://www.repairstemcells.org/CV/SLAVINCV.aspx>

<sup>70</sup> <http://www.ctcicenter.com/prof-slavin-and-team.htm>

<sup>71</sup> <http://shimonslavin.synthasite.com/>

- Slavin uses the email address [slavinmd@gmail.com](mailto:slavinmd@gmail.com)<sup>72</sup>. Searching Facebook with Slavin's email leads to a user named Brent Davidson. This means that the person creating the Facebook account used the email address [Slavinmd@gmail.com](mailto:Slavinmd@gmail.com), i.e. Slavin or one of his staff.



Internet searches reveal various articles that claim that a Brent Davidson from Cochrane Alberta has been successfully treated by Slavin<sup>73</sup>:

***“Another multiple sclerosis (MS) patient from Canada is reporting improvements after adult stem cell treatment from Dr. Shimon Slavin in Israel. Brent Davidson, from Cochrane, Alberta, Canada, says the adult stem cells which improved his quality of life wasn’t cheap, but it was worth every penny.”***

We believe this suggests Brent Davidson is not a real person but someone created to lure Multiple Sclerosis patients to CTCL for treatment by Slavin.

<sup>72</sup> <http://www.omicsonline.org/2155-9864/2155-9864.S1http://www.omicsonline.org/2155-9864/2155-9864.S1.005-007.pdf.005-007.pdf>, <http://www.omicsgroup.org/journals/towards-possible-cure-of-cancer-by-immunotherapy-of-minimal-residual-disease-2165-7831-1000137.php?aid=50950>

<sup>73</sup> <http://www.omicsonline.org/2155-9864/2155-9864.S1http://www.omicsonline.org/2155-9864/2155-9864.S1.005-007.pdf.005-007.pdf>, <http://scienceblog.com/30059/canadian-multiple-sclerosis-patient-improves-after-stem-cell-treatment/#fGxcTXbQsPBoG0bm.97>

**In February 2014, in a rare action, the Israeli Ministry of Health ordered the center to stop providing treatments due to serious ethical and legal concerns.** The ministry accused Slavin and the center of conducting experiments in humans against the law. According to publications, the Ministry became aware of what was going on at CTCl after it was reported in the press that the family of a 9 year old boy was trying to raise \$250,000 for a “cancer vaccine” that could save the boy’s life. The Ministry of Health issued an order to CTCl to stop its treatments after **CTCl failed to cooperate with the Ministry and to provide details of the treatments provided (basic details such as whether there are any follow-ups on the patients’ progress after the treatment, reporting of the results of the treatment, complications, adverse events or successes etc.).**

According to Professor Gamzo, who was then the General Director of the Ministry of Health<sup>74</sup>:

***“I am concerned that He (Slavin) found a method to trade the desperation of patients. Most Israeli doctors do not recommend these treatments, as they have been forbidden abroad, except in clinical trials in hospitals. After all, not all patients are candidates to participate in a clinical trial. Slavin recruits anyone, without asking for any approval”***

Professor Gamzo continued:

***“Worst of all – he does what he does from the status of a former senior department manager. He uses this prestige to anesthetize and enthrall his patients, who were in a state of despair. This raises the concern of a cynical use of his prestige for providing treatment that I believe is unfounded and not effective. Also his prices seem inflated and exaggerated which raises the concern that patients are exploited. I am afraid there is no great science but rather a financial bonanza”***

Professor Avinoam Reches, the previous Chairman of The Ethics Committee of The Israel Medical Association commented on this matter:

***“The issue is well known to me from the time that the doctor (Prof. Slavin) worked at Hadassah (Hospital). My position is very clear: Each experiment must be approved by the Helsinki committee. The committee may approve the compassionate treatment of dying people, if there is no other treatment...”***

Moreover, Professor Reches added:

***“Above all, there is an explicit and unambiguous prohibition to charge a payment, directly or indirectly, for any treatment which is considered experimental. Any attempt to charge patients is a cynical exploitation of their despair and anxieties...”***

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<sup>74</sup> [http://www.israelhayom.com/site/newsletter\\_article.php?id=17835](http://www.israelhayom.com/site/newsletter_article.php?id=17835); and Free translation using Google translate from <http://www.israelhayom.co.il/article/186357>

CTCI and Slavin appealed to the Israeli high court against the order issued by the Health Ministry. The high court accepted the formalistic argument of the Center - that the Ministry does not have the authority to make CTCI stop providing the treatments, as this authority is not provided to the Ministry by law. Furthermore, the judges concluded that if the Ministry would like to stop Slavin, it should file a disciplinary complaint to revoke Slavin's license to practice medicine or to file charges against him<sup>75</sup>.

The Chairwoman of The Ethics Committee of The Israel Medical Association Dr. Tami Karni said on this matter:

***"We do not know the exact treatment Slavin provides because we have not been given the complete data about that.... Usually, it is common that if the treatment is benefiting the patient, the doctor must share his results with his colleagues so that other patients may benefit. The conduct of concealment is very problematic and raises doubts about the quality of care. I do not see any reason in the world why Slavin did not forward the complete data to the Ministry of Health (as requested by the Ministry)"***

In a cancer forum post, an Egyptian user posted an email that he received from an NWBO employee named Carol Powers (who we believe is Linda Powers' immediate family according to certain ownership filings with the SEC<sup>76</sup>) after he contacted NWBO regarding treatment for his mother. In the email reply, although she is aware to the fact that his mother does not meet the requirements to participate in the clinical trials, Carol Powers refers the user to CTCI for **"compassionate/private pay"** treatment at a cost of more than \$100,000. The following is the email reply that the user posted on July 2013 (underlining was made by us)<sup>77</sup>:

***"Dear Mohamed:***

***I apologize for the delay in getting this note out to you, but I am writing on behalf of Northwest Biotherapeutics in response to your inquiry about the DCVax cancer vaccine. Please know we are so sorry to learn of your mother's recent GBM diagnosis – we certainly understand how difficult this whole experience can be for the patient and the entire family and we know how few treatment options are available. Unfortunately, the clinical trial that Northwest is conducting in the US and UK is only for those patients who are newly diagnosed with GBM, who meet certain protocol requirements, and who had their surgery at the clinical trial site.***

***Again it is unfortunate, but there are currently no medical clinics in Egypt or Europe where access to DCVax can be provided as part of a special treatment option provided in concert with your mother's regular cancer treatment protocol. We do have a collaborative arrangement with a clinic in Israel and we are able to manufacture and administer DCVax on a very limited,***

<sup>75</sup> Translated from: <https://www.lawpubshop.co.il/?CategoryID=266&ArticleID=10547>

<sup>76</sup> <http://www.barchart.com/plmodules/?module=secFilings&filingid=7862942&type=CONVPDF&popup=1&override=1&symbol=NWBO>

<sup>77</sup> <http://www.cancercompass.com/message-board/message/all,72551,1.htm?mid=529478>

*compassionate/private pay basis there. Your mother would need to travel to Israel once while the vaccine is being made and then she would need to travel there occasionally for the administration of some or all of the 11 doses that are given over a 3 year period of time. She would not need to move there, however. (There is a very nice hotel attached to the clinic and so the stress of travel and finding accommodations in Israel can be minimized.) Depending on the Egyptian import requirements, your mother might be able to have some of the doses of DCVax administered by a physician in Egypt so she would need to return to Israel for a dose of the vaccine only occasionally....*

*I can be reached by phone (978.697.2526 US EDT) at any time.*

*Mohamed, I certainly hope that your mother will be able to find the right combination of treatments so that the cancer can be halted and she can regain strength with each day that passes. She will certainly be in our thoughts and prayers.*

*I look forward to connecting with you soon.*

*With warm regards,*

*Carol L. Powers, Patient Liaison*

*for Northwest Biotherapeutics*

*978.697.2526 cell US EDT"*

**We urge NWBO to reveal who owns CTCL and where do the revenues of the center go to.**

## NWBO Patents have been sold to Powers' company and to another major shareholder of NWBO without disclosure

The main asset of NWBO is its patents and NWBO goes into long disclosures about them. However, it seems that NWBO does not own the majority of its US patents. It has transferred them to Toucan Fund II and later to one of its largest shareholders, Dennis Mehiel. NWBO never disclosed these transactions.

In 2004, NWBO assigned 13 patents and applications to Toucan Fund II<sup>78</sup>. In March 2012 Toucan Fund II assigned 6 patents back to NWBO and a couple of days later NWBO assigned 19 patents and applications to Four M Purchaser LLC, which is owned by Dennis Mehiel (Mehiel will be discussed separately), a shareholder that invested \$3,000,000 in NWBO in 2010<sup>79</sup>. We have not found any disclosure in NWBO's SEC filings that NWBO transferred its patents to Powers' Toucan Fund II or to Mehiel.

The following is a screenshot from USPTO showing the assignment of 13 patents and applications from NWBO to Toucan Fund II in 2004:

Assignment Details		
14567-206: SECURITY AGREEMENT		
Date Recorded Apr 27, 2004	Reel/Frame 14567-206	Pages 34
<b>Assignor</b>		
NORTHWEST BIOTHERAPEUTICS, INC. Apr 26, 2004		
<b>Assignee</b>		
TOUCAN CAPITAL FUND II, L.P. 7600 WISCONSIN AVENUE SUITE 700 BETHESDA, MARYLAND UNITED STATES OF AMERICA 20814		
<b>Correspondent</b>		
COOLEY GODWARD LLP CARA L. HUPPRICH 11951 FREEDOM DRIVE RESTON, VA 20190		
<b>Properties (13 total)</b>		

The following is a screenshot from USPTO showing the assignment of only 6 patents and applications back from Toucan Fund II to NWBO:

<sup>78</sup> <http://assignment.uspto.gov/#/search?q=northwest%20biotherapeutics&sort=patAssignorEarliestExDate%20desc%2C%20id%20desc&synonyms=false>

<sup>79</sup> <http://www.secinfo.com/d12TC3.n7eh.htm>

27956-406	Mar 29, 2012	NORTHWEST BIOTHERAPEUTICS, INC.	8389278
RELEASE BY SECURED PARTY (SEE DOCUMENT FOR DETAILS).			
Assignee: NORTHWEST BIOTHERAPEUTICS, INC. Assignor: TOUCAN CAPITAL FUND II, L.P.			
Correspondent: GIBBONS P.C. ONE GATEWAY CENTER NEWARK, NJ 07102	First of 6 Assigned Properties Patent 8389278 (Mar 5, 2013) Generation of dendritic cells from monocytic dendritic precursor cells with GM-CSF in the absence of additional cytokines		

The following is a screenshot from USPTO showing the assignment of 19 patents and applications a couple of days later to Four M purchase LLC:

Reel/Frame 1	Execution Date 1	Owner (Assignee) 1	Patent 1
28069-752	Apr 2, 2012	FOUR M PURCHASERS, LLC	8409566
SECURITY AGREEMENT Assignee: FOUR M PURCHASERS, LLC Assignor: NORTHWEST BIOTHERAPEUTICS, INC.			
Correspondent: GIBBONS P.C. ONE GATEWAY CENTER NEWARK, NJ 07102	First of 19 Assigned Properties Patent 8409566 (Apr 2, 2013) THERAPEUTIC AND DIAGNOSTIC APPLICATIONS BASED ON THE ROLE OF THE CXCR-4 GENE IN TUMORIGENESIS		

As NWBO has never disclosed which of the company's patent would be material, we cannot rule out that the company does not own a significant part of its patents anymore. So even if DCVax is successful (which we doubt), it is not clear if NWBO will have the right to produce it without payment to Mehiel and whether he can sell licenses to the patents to other companies.

This goes even further. In its latest 10-K NWBO provided details of its latest patent, patent #8518636:

*"In September 2013, we announced that we had been issued U.S. patent #8,518,636, covering a next-generation process for manufacturing lower cost human dendritic cells of both a higher quality and higher reliability. This next generation system has already been cleared by the FDA for use in the manufacturing of dendritic cells for our clinical trials. These systems are now in*



*use producing the vaccines which have already been injected into the tumors of DCVax-Direct patients."*

According to the United States Patent and Trademark Office, this patent was already assigned in 2012 to Four M Purchase (Mehiel's company) and is not owned by NWBO anymore:

Patent Application Information Retrieval									
<a href="#">Order Certified Application As Filed</a> <a href="#">Order Certified File Wrapper</a> <a href="#">View Order List</a>									
_12/759,552		TANGENTIAL FLOW FILTRATION DEVICES AND METHODS FOR LEUKOCYTE ENRICHMENT						NWBI135084	
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<b>Assignments Data</b>									
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<b>Total Assignments: 1</b>									
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We call for Powers to reveal the details of the agreements that caused NWBO to hand over the rights to its patents to Toucan Fund II and Mehiel and the reasons for not disclosing the transactions.

## **\$40 million for a UK Facility that will be used by Cognate**

In 2014, NWBO announced that it purchased a facility in the UK in which it intends to manufacture its products for the European market<sup>80</sup>. When reviewing the purchase agreement, one will notice that the name of the entity acquiring the property is Aracaris Capital Limited (“ACL”)<sup>81</sup>. An Aracari is a medium sized Toucan.

In order to hold the property, a two-story structure was set up. ACL was incorporated on June 26, 2014, and according to its latest annual statement Powers is its sole director, a pattern we see in many of the Toucan companies. The sole shareholder of the structure holding the property is a company named Bedford Nominees (U.K.) LTD<sup>82</sup>. Bedford Nominees’ name was recently brought up by a Spanish prosecutor who alleges that the famous soccer player Lionel Messi used its services to avoid tax payments<sup>83</sup>.

The purchase transaction was completed in two phases: on August 19, 2014, 65,000 sq ft of existing building and 25 acres of land were purchased for \$20.8 million and on December 9, 2014 additional 12 acres of land and certain buildings were purchased for \$7.9 million (NWBO capitalized additional costs to get to the current book value of approx. \$40 million). According to NWBO, it plans that the existing building will be **“built out as part of the expansion of manufacturing capacity for its products in Europe”**<sup>84</sup>. There is no explanation as to why NWBO would need 25 acres of land. In its 8-k dated December 9, 2014<sup>85</sup>, NWBO provided details regarding the additional 12 acres that were purchased in the second phase. It can be understood from the filing that the land was purchased because it can be developed for DCVax manufacturing facility upon receiving of the necessary authorizations and site improvements.

**The current US facilities in which Cognate manufactures NWBO’s, in addition to other customers’, products are approximately 80,000 sq ft and, according to 2014 10-k, they are “sufficient to produce DCVax for at least several thousand patients per year”**<sup>86</sup>. Therefore, NWBO’s business logic underlying the purchase of 37 acres (1,600,000 sq ft!), an enormous amount of land, especially as Cognate seems to have sufficient capacity already, is not clear, putting it mildly.

The existing building is a 65,000 sq ft building which contains 10,170 sq ft of office space and a 54,830 sq ft warehouse. Authorities approved to change the classification of the building to class B2 (general

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<sup>80</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

<sup>81</sup> [https://www.sec.gov/Archives/edgar/data/1072379/000114420414069728/v393316\\_ex10-1.htm](https://www.sec.gov/Archives/edgar/data/1072379/000114420414069728/v393316_ex10-1.htm)

<sup>82</sup> Aracaris incorporation documents, directors and more can be found in:

<https://beta.companieshouse.gov.uk/company/09103328/filing-history>

<sup>83</sup> <http://greatripoffmap.globalwitness.org/#!/case/57744>

<sup>84</sup> 2014 10-k, P. F-16: [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

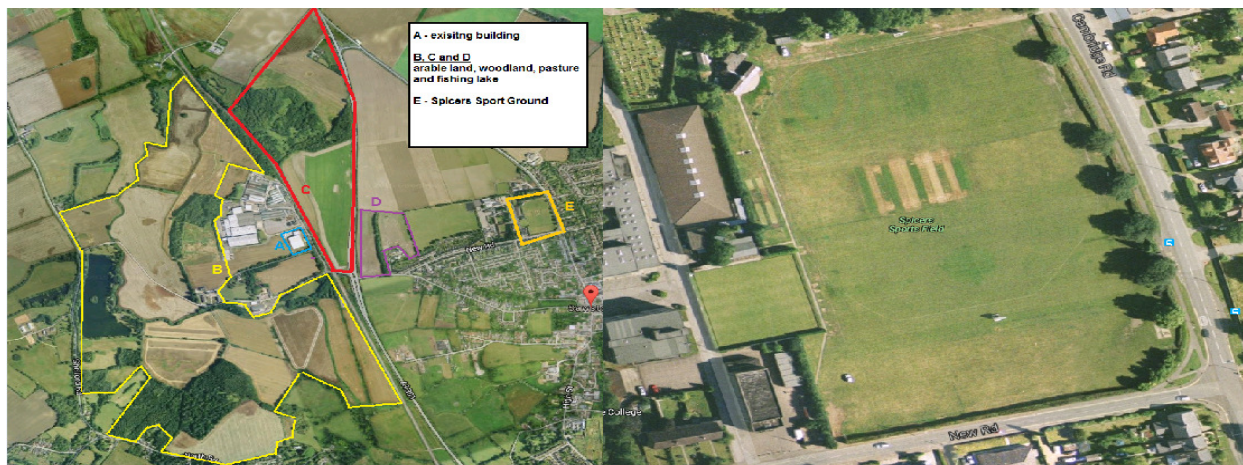
<sup>85</sup> [http://www.sec.gov/Archives/edgar/data/1072379/000114420414073984/v396605\\_8k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420414073984/v396605_8k.htm)

<sup>86</sup> 2014 10-k, P. 14: [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

industrial use)<sup>87</sup>. ACL filed a proposal to make an extension to the existing building from the current 65,000 sq ft to 90,955 sq ft. The following are pictures of the facility:



As mentioned, ACL also purchased 37 acres of land in the area surrounding the existing building – 25 acres at first and then another 12 acres. The purchase agreement does not provide the exact location of the 25 acres, but it does mention its general location. Our research found that the land is located in areas b, c and d, as presented in the left image below. **These areas contain arable land, woodland, pasture and fishing lake.** ACL also bought “Spicer’s Youth Centre” and “Spicer’s Sport Ground” which is the local cricket ground (right image).



So why did NWBO buy the existing building and the vast land surrounding it (including a cricket ground)?

<sup>87</sup> <http://plan.scambs.gov.uk/swiftlg/apas/run/WPHAPPDETAIL.DisplayUrl?theApnID=S/2091/14/FL&theTabNo=3&backURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%20%3Ca%20href=%27wphappsearchres.displayResultsURL?ResultID=913974%26StartIndex=21%26SortOrder=rgndat:desc%26DispResultsAs=wphappsresweek1%26BackURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%27%3Esearch%20Results%3C/a%3E>

This is what NWBO had to say in its 2014 10-k:

***“for several years, Cognate had undertaken to identify, inspect and evaluate potential manufacturing facilities and sites in Europe for the Company”<sup>88</sup>***

NWBO is not mentioned in any part of the purchase contract. Moreover, the guarantor of the contract is Cognate Bioservices Inc. As mentioned above, ACL filed a request to change the classification of the existing building. In its request, under “use” section, ACL states that:

***“CBS ultimately plans to build the largest Advanced Therapy Medicines (ATMP) manufacturing facility in Europe”<sup>89</sup>***

While “CBS” is not defined in the document, it is fair to assume that it means “Cognate BioServices”. A similar statement can be found in the extension plan that was submitted by ACL:

***“The site is to be operated by a contract manufacturer of cellular therapies and regenerative medicines”<sup>90</sup>***.

Clause 3.6.5 of the extension plan also states that the site will be fully operational and in full occupation no sooner than 5 years from the initial occupation. When fully operational, the site will be staffed by: 75 manufacturing staff, 10 warehouse staff, 30 scientists and 10 office staff.

Obviously, NWBO cannot occupy the facility with its current manpower and it is fair to assume that Cognate will be occupying the property de facto, and not NWBO that has outsourced all its production activities to Cognate. This might explain the future use of the existing building, but the use of the 1,600,000 sq ft of land is still a mystery.

**We find it hard to believe that the whole space is needed for the production of DCVax, and it is likely that Cognate will use the facility for its other customers. If a third party was manufacturing DCVax and not Powers'-owned Cognate, we doubt that NWBO would have purchased a facility for that manufacturer to use as its own, especially before it even successfully completed its clinical trials. Not suprisingly, NWBO does not own the US production facility.**

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<sup>88</sup> 2014 10-k, P. F-9: [http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

<sup>89</sup><http://plan.scams.gov.uk/swiftlg/apas/run/WPHAPPDETAIL.DisplayUrl?theApnID=S/2091/14/FL&theTabNo=3&backURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%20%3E%20%3Ca%20href=%27wphappsearchres.displayResultsURL?ResultID=913974%26StartIndex=21%26SortOrder=rgndat:desc%26DispResultsAs=wphappsresweek1%26BackURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%27%3Esearch%20Results%3C/a%3E>

<sup>90</sup><http://plan.scams.gov.uk/swiftlg/apas/run/WPHAPPDETAIL.DisplayUrl?theApnID=S/2091/14/FL&theTabNo=3&backURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%20%3E%20%3Ca%20href=%27wphappsearchres.displayResultsURL?ResultID=913974%26StartIndex=21%26SortOrder=rgndat:desc%26DispResultsAs=wphappsresweek1%26BackURL=%3Ca%20href=wphappcriteria.display%3Esearch%20Criteria%3C/a%3E%27%3Esearch%20Results%3C/a%3E>

**We believe this is another example of the use of funds of the publicly traded NWBO for the benefit of Powers' closely held, and according to recent lawsuits - cash strapped - Cognate.**

Our questions on this matter remain open:

- **Why is NWBO not a side to the contract? Why is Cognate the guarantor? We doubt it is a better guarantor than the NASDAQ listed NWBO that can easily raise cash for shares.**
- **Did ACL actually purchase the facility for the use of Cognate as Cognate itself did not have the funds to do so?** As can be noted in the different documents submitted by Aracaris, the facility will be used by "CBS" which is defined as a contract manufacturer of cellular therapies.
- When Cognate BioService Limited (UK) was set up in 2013, its filings clearly showed that Cognate Inc. is its owner. If that is the case for Cognate, **why would Powers use an opaque nominee structure to hide the actual ownership of the property when it comes to NWBO?**

**We believe that Cognate was supposed to buy the property for its expansion, but since it has been cash starved for many years, Powers decided to use the cash of NWBO to acquire the property.**

## Dennis Mehiel and Powers' "creative" financing

The abovementioned Mehiel that owns NWBO's patents is also a major shareholder of NWBO. According to Mehiel's filings, he acquired shares of NWBO in a number of transactions between 2009 and 2012. According to a 13G filing from February 2014, he owned 8% of the shares of the company. **In a 13G filing from February 2015, it is mentioned that he has provided a promissory note to Cognate which is convertible to 625,000 shares of NWBO.** Cognate disclosed in a Form 4 from July 2, 2015, that it transferred 650,000 shares to an unrelated party to settle a debt secured on its assets and that the lender has chosen to convert the debt to NWBO's shares held by Cognate. We believe that it is fair to assume that Mehiel is the "unrelated party" Cognate refers to. **In the same filing, Cognate disclosed that it has borrowed \$5 million from third parties to finance the NWBO development program. This debt was secured by shares of NWBO held by Cognate and was ultimately settled for 1,118,092 shares.**

These transactions, which unfortunately look like a habit of Powers, form a crooked shareholder-diluting cycle: NWBO pays for Cognate's services by issuing shares at significant discounts (as we have demonstrated), Cognate gains more control over NWBO and also uses NWBO shares to pay for its own debts. The question is – if investors want to own shares of NWBO (which is obvious since they are willing to receive them as payment), why doesn't NWBO issue shares directly to them for cash (at market price or with a more standard discount rate) and use this cash to pay Cognate? This will also dilute shareholders, but not as much as the current process and will leave NWBO with more cash at hand.



## Part 2

Much like our previous call on Vital Therapies' ELAD therapy, NWBO's DCVax works wonderfully *in theory*. Yet, much like VTL's ELAD, since NWBO's inception in 1996 there has actually **never been any solid indication** that DCVax has a chance of succeeding in an FDA-approved, adequately-controlled pivotal study. Actually, there has never been any solid scientific proof that any tumor-lysate-pulsed dendritic cell therapy is effective. The following chapters will demonstrate that the "efficacy data" of DCVax-L for Glioblastoma multiforme (GBM), which has been propping this stock on a cloud of hopes since its second Nasdaq IPO in 2012, is actually based on 2 hardly-relevant, largely cherry-picked, Phase 1 trials.

### Glioblastoma Multiforme

Glioblastoma multiforme is a fast-growing brain cancer that develops from star-shaped glial cells (astrocytes and oligodendrocytes) that support the health of the nerve cells within the brain. GBM has an incidence of two to three per 100,000 adults per year, and accounts for 52 percent of all primary brain tumors. Overall, GBM accounts for about 17 percent of all tumors of the brain (primary and metastatic). These tumors tend to occur in adults between the ages of 45 and 70.

The National Cancer Institute estimates that 22,850 adults (12,630 men and 10,280 women) were diagnosed with brain and other nervous system cancer in 2015.

### Prognostic Factors

GBM has a widely reported median survival of around 12-18 months after diagnosis<sup>91</sup>. **However, despite what NWBO likes to tell investors, long-term survival has been on the rise, particularly since the approval of temozolomide in 2005.**

In the current clinical setting, up to 28% of patients survive for 2 years<sup>92</sup>, and up to 16% of patients have been found to survive for more than 3 years<sup>93</sup>. The clinical and molecular factors that contribute to long-term survival are still unknown, but broad retrospective studies identified **young age and high Karnofsky score** to be strong predictors of survival of over 5 years for GBM patients, even for those patients whose cancer has recurred up to four times after surgery, radiation and chemotherapy<sup>94</sup>.

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<sup>91</sup> <http://cancerres.aacrjournals.org/content/68/14/5955.full>

<sup>92</sup> <http://cancerres.aacrjournals.org/content/68/14/5955.full>

<sup>93</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905088/>

<sup>94</sup> <http://brain.oxfordjournals.org/content/130/10/2596>

In the aforementioned review, the population of long-term survivors was found to have a median age of 51 years at diagnosis. Another study showed that the percentage of **patients younger than age 40 years who tend to survive more than five years is 34%**<sup>95</sup>. In comparison, shorter-term survivors showed a significantly higher age (median 60.9 years,  $P < 0.001$  – a statistically significant difference). The median follow-up time in the long-term survivor group was 7 years and the median survival time was 4.6 years (range 3.0–15.3 years). Median Karnofsky score at diagnosis for the entire population of long-term survivors was 80 (range 30–100).

Interestingly, the median age of all the newly diagnosed glioblastoma patients in NWBO's early-stage trials to-date was 45, and Karnofsky score – 90. According to the aforementioned statistics, at least 15% of these patients would have been expected to survive over 5 years with standard therapy, not 2-3%, as NWBO commonly advertises alongside their own "findings" in their presentations<sup>96</sup>.

NWBO also modified patient eligibility criteria between its Phase 2 and ongoing Phase 3 studies, and is currently recruiting patients who are younger and have a higher Karnofsky Score (see below) than before.

**Karnofsky score** is a performance status score which attempts to quantify cancer patients' general well-being and activities of daily life. The rating is as follows:

- 100 - Normal; no complaints; no evidence of disease.
- 90 - Able to carry on normal activity; minor signs or symptoms of disease.
- 80 - Normal activity with effort; some signs or symptoms of disease.
- 70 - Cares for self; unable to carry on normal activity or to do active work.
- 60 - Requires occasional assistance, but is able to care for most of their personal needs.
- 50 - Requires considerable assistance and frequent medical care.
- 40 - Disabled; requires special care and assistance.
- 30 - Severely disabled; hospital admission is indicated although death not imminent.
- 20 - Very sick; hospital admission necessary; active supportive treatment necessary.
- 10 - Moribund; fatal processes progressing rapidly.
- 0 - Dead

<sup>95</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037140>

<sup>96</sup> <http://nwbo.com/wp-content/uploads/2014/03/NWBT-corp-overview-Mar-20.pdf>

## Standard of care

Upon diagnosis, GBM patients who are eligible undergo surgical resection, followed by radiotherapy (20 - 90 Gy) and chemotherapy. Despite all the methods, recurrence of GBM is nearly universal, and several resections and radiotherapy rounds are not uncommon.

As of 2005, the addition of chemotherapy to radiation has become the first-line treatment for GBM<sup>97</sup>. Since the U.S. Food and Drug Administration's approval of temozolomide (TMZ, Temodal, Temodar), an alkylating cytotoxic agent, for the treatment of adult patients with newly diagnosed glioblastoma in 2005, the 2-year survival rate of glioblastoma patients has doubled to 27%.

Temozolomide is administered orally on a daily basis at a dose of 75 mg/m<sup>2</sup> throughout radiotherapy. Four weeks later, magnetic resonance imaging (MRI) is repeated, and TMZ is then given at a dose of 150-200 mg/m<sup>2</sup> daily for 5 days every 28 days for maintenance. MRIs are performed after every 2-3 cycles of TMZ treatment to ensure continuous stability or response of the tumor to treatment. In comparison to radiotherapy alone, in a large, randomized phase III<sup>98</sup> trial, TMZ treatment along with radiotherapy resulted in an improved median overall survival (OS) from 12.1 to 14.6 months and an increase in the 2-year survival rate from 10% to 27% and this finding has since been confirmed by additional reports<sup>99</sup>.

## Dendritic cell vaccines

Dendritic cells (DCs) are currently much in fashion in the clinical sphere. In theory, these cells are the ideal candidates for immunotherapy as they are the cells responsible for priming and directing the body's "killing machines" – the T Cells. An activated dendritic cell carries a "danger signal" – a digested piece of pathogen or disease tissue, called an antigen, and presents it to a cytotoxic T Cell, which gets activated and proceeds to locate and attack cells and organisms displaying this non-native warning signal.

Most DCs exist in an inert, inactive state in the body until they are faced with an immune threat. Mechanisms by which DCs get activated and ingest antigens for presentation are extremely complex and not yet fully understood. However, it is now generally accepted that DC activation must occur either in the presence of highly evolutionarily conserved microbial particles which act as agonists for the cells' Toll-like Receptors (TLRs), or in the presence of various proinflammatory messenger molecules called **cytokines**. Among these cytokines are: GM-CSF, IFN $\gamma$ , IL-4 (also found necessary for DC maturation), IL-1 $\alpha$ , IL-1 $\beta$  and many others.

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<sup>97</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905088/>

<sup>98</sup> <http://www.ncbi.nlm.nih.gov/pubmed/15758009>



The only dendritic cancer cell therapy to ever receive FDA approval is Dendreon's **Sipuleucel-T (Provenge)**. It bears some similarities to DCVax but generally is very different in that it uses already-differentiated DCs isolated from patients' blood and focuses only on one tumor antigen.

Provenge is marketed for the treatment of metastatic castration-resistant prostate cancer (mCRPC). It is an *in vitro* DC therapy in which a cytokine called Granulocyte-macrophage colony-stimulating factor (GM-CSF) is chemically fused to a single antigen present in 95% of prostate cancers – prostatic acid phosphatase (PAP). This GM-CSF-PAP fusion molecule is added to inactive, but already formed *in vivo*, DCs isolated from a patient and, in as-of-yet-unknown mechanism of action, the DCs take up the molecule via GM-CSF-specific channels, thereby also ingesting PAP. These GM-CSF-activated, PAP-specific DCs are then returned to the patient in order to elicit an immune response against PAP-bearing cells. In a 512-patient, placebo-controlled trial in 2007, Sipuleucel achieved a median overall survival (mOS) of 25.8 months comparing to 21.7 months for placebo-treated patients (P=0.032). In contrast with widely projected annual revenues of \$3-4 billion, Provenge raked in just \$321.5 million in 2012. Dendreon filed for bankruptcy in 2014.

## DCVax-L

Because a major limitation of DC therapy is that DC numbers in the blood are limited, isolating DC precursor cells, which are much more numerous, and then differentiating them into DCs *in vitro*, is theoretically a more economically viable option. The technology behind DCVax is based on the fact that various cytokines are able to induce DC monocytic precursor cells to differentiate into DCs. It is difficult to precisely describe NWBO's proprietary DCVax-L technology because the technology outlined in the company's main/latest patent has never been actually utilized by the company<sup>100</sup>. Furthermore, the technology described in the patent has been widely proven to be unable to produce potent dendritic cells<sup>101</sup>, despite the company describing the technology in 2013 as a way to produce "more potent dendritic cells"<sup>102</sup>.

In addition to the main patent, NWBO has filed several dozen patents<sup>103</sup>, some related closely to the DCVax preparation technology the company has been using. The vast majority of such patents seem to have never been granted, were withdrawn or have lapsed.

We believe the company does not currently hold a patent which protects the dendritic cell differentiation technology it is using, which is also likely because such technology is very widely used in similar studies all over the globe and was patented as early as 1994.

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<sup>100</sup> <https://www.google.com/patents/US8389278?dq=inassignee:%22Northwest+Biotherapeutics,+Inc.%22+grant&hl=en&sa=X&ved=0CCsQ6AEwAjgKahUKewiB0pSi6cjlAhXM1xQKHfVBXI>

<sup>101</sup> [http://www.jacionline.org/article/S0091-6749\(14\)00271-1/abstract](http://www.jacionline.org/article/S0091-6749(14)00271-1/abstract)

<sup>102</sup> <http://www.nwbio.com/nw-bio-receives-u-s-patent-on-broad-processes-for-producing-more-potent-dendritic-cells/>

<sup>103</sup> <https://patents.google.com/?assignee=northwest+biotherapeutics>

NWBO's non-functional patent is titled "Generation of Dendritic Cells from Monocytic Dendritic Precursor Cells with GM-CSF in the Absence of Additional Cytokines" and goes as follows:

1. Blood-derived CD14+ monocytes, especially those that express on their surface the receptor for GM-CSF, are isolated from the patient via leukapheresis
2. **GM-CSF alone and in the absence of other cytokines** is added to the precursor cells in order to differentiate them into DCs
3. TLR agonists are added in order to mature and prime the DCs in the presence of antigens of choice. The TLR agonists which NWBO uses are a combination of inactivated BCG and IFN- $\gamma$
4. Most importantly, instead of using specific antigens, like Dendreon, NWBO takes whole tumor tissue remaining from excision surgery, essentially blends (lyses) the tissue into small fragments, and these fragments are added to maturing DCs as a source of many various tumor antigens
5. The differentiated and tumor-lysate-primed cells are injected back into the patient
6. The precursor cells, mature DCs and DCs primed with antigens can each be cryopreserved at any time for future therapies

It isn't clear and has never been elaborated on what the current technology for preparing and incubating DCs is in the ongoing Phase 3 trial. However, the technology NWBO has used in their past clinical trials is similar to the one outlined in their patent: DC precursor cells were incubated with **GM-CSF and IL-4** cytokines to stimulate DC differentiation in Phase 1 and 2 studies of DCVax conducted at Cedars-Sinai and UCLA – a standard industry procedure for DC maturation. None of the DCVax studies published to date have used DCs incubated in the presence of a TLR agonist. Instead, TLR agonists (imiquimod or Poly LCIC) were used concurrently with the cells in a 2010 trial<sup>104</sup>.

We can be fairly certain that NWBO is not using additional TLR agonist treatment in the ongoing study: no TLR agonist is mentioned in their ongoing Phase 3 trial registered on ClinicalTrials.gov, which lists only "Drug: Dendritic cell immunotherapy" as the primary intervention, nor it is mentioned in any of the company's recent SEC filings or the letter of consent patients have to sign before enrolling in the trial<sup>105</sup>. If the company were using TLR agonist in addition to DCVax without disclosing this, it would likely constitute fraud.

<sup>104</sup> <http://www.ncbi.nlm.nih.gov/pubmed/21135147>

<sup>105</sup> [http://neurosurgery.ucla.edu/workfiles/Brain\\_Tumor\\_Program/11-000686-%20Main%20ICF%2007Nov2012.pdf](http://neurosurgery.ucla.edu/workfiles/Brain_Tumor_Program/11-000686-%20Main%20ICF%2007Nov2012.pdf)

## The history of DCVax-L development of GBM is as treacherous as it is long

NWBO likes to tell the story that DCVax-treated patients get cured forever and live long lives. For starters, the company's conduct since the first-ever DCVax-Brain trial results in 2002 tells a very different story. By now, DCVax trials for GBM have been amended, re-named and re-started four times, and the company is **still refusing to deliver Ph3 interim results which they have likely received 2014 as per their Data Safety Monitoring Board (DSMB) guidance**<sup>106</sup>.

With results as monumental as median progression-free survival (PFS) of 2 years, which would have been a quadruple of standard of care figures, surely hardly anything would need to be changed in the trial's protocol – least of all, changed four times<sup>107</sup>. There would also be no need to make a suicidal change to the trial's primary endpoint or to amend the eligibility criteria for patient enrollment, progressively aiming trials at younger and fitter patients, who have been clearly shown to be the longest living GMB sufferers (table 1).

Most certainly, with the miracles that NWBO likes to tell it performs, there would be absolutely no use for the oldest trick in the book of looking for efficacy where there is none by increasing the number of patients in the middle of a Phase 3 study<sup>108</sup>.

Finally, mind-blowing cancer cures don't have a tendency to get put on enrollment halts<sup>109</sup>.

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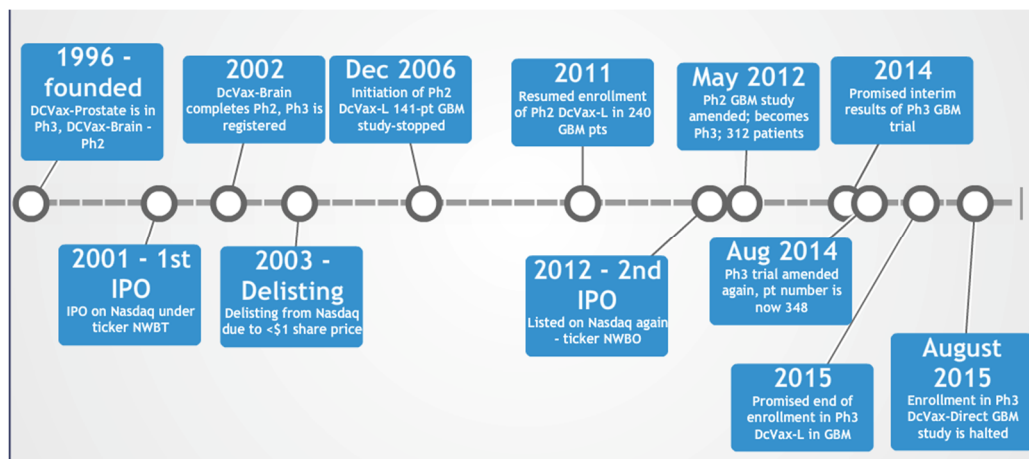
<sup>106</sup> <http://www.nwbio.com/nw-bio-receives-recommendation-to-continue-with-phase-iii-gbm-brain-cancer-trial/>

<sup>107</sup> <http://nwbio.com/wp-content/uploads/2014/03/NWBT-corp-overview-Mar-20.pdf>

<sup>108</sup> <http://www.nwbio.com/nw-bio-provides-update-about-phase-iii-DCVax-l-trial-for-gbm-and-information-arm-compassionate-use-case-patients/>

<sup>109</sup> <http://www.prnewswire.com/news-releases/nw-bio-confirms-phase-iii-trial-of-DCVax-l-for-gbm-brain-cancer-is-ongoing-300131912.html>

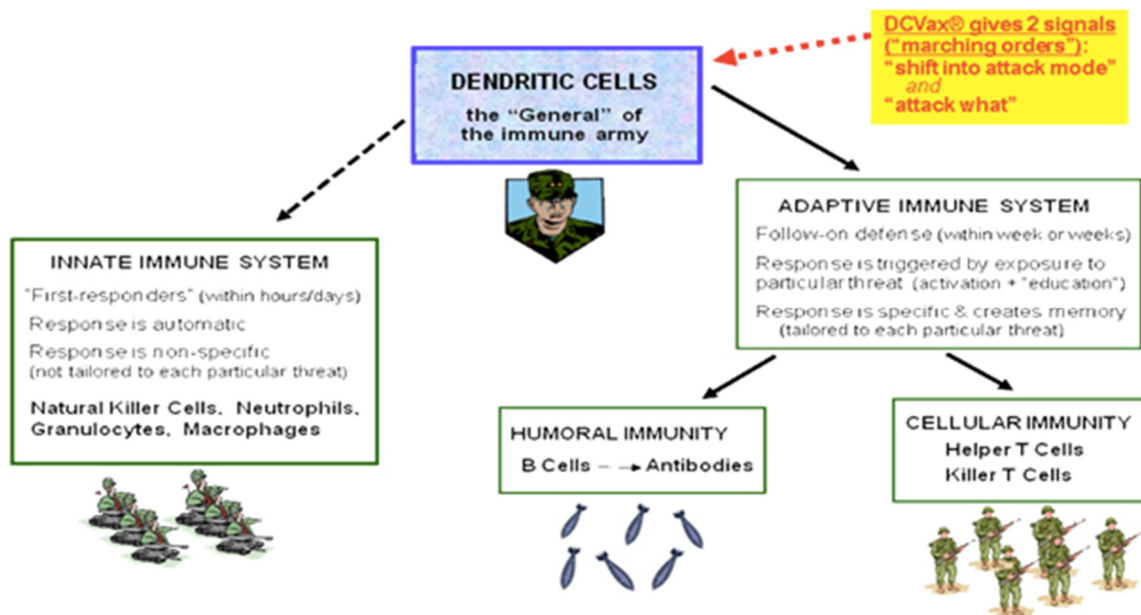
**Figure 2. The 20-year development of DCVax**



**Table 1. NWBO changed the primary endpoints for the DCVax Phase 3 trial; inclusion and exclusion criteria amendments have tended towards healthier, fitter patients with near-total tumor resection and healthier blood parameters between Phase 1 and Phase 3**

	<a href="#">Phase 1</a>	<a href="#">Phase 1/2</a> (links to same study <a href="#">1</a> & <a href="#">2</a> )	<a href="#">Phase 3</a>
<b>Indication</b>	Recurrent/newly diagnose GBM, Astrocytoma	Recurrent/newly diagnose GBM, Astrocytoma	Newly diagnosed, unilateral GBM (Grade IV)
<b>Primary endpoint</b>	Overall Survival	Overall Survival	Progression-Free Survival
<b>Surgical resection</b>	Complete & incomplete	Complete & incomplete	Total or near-total
<b>Karnofsky score</b>	≥ 60	≥ 60	≥ 70
<b>Age</b>	≥ 18	≥ 18	18 Years to 70 Years
<b>Hemoglobin</b>	>9.9 g/dl	>10 g/dL	>10 g/dL
<b>Total granulocyte count</b>	>1,000/ml	>1,500/ml	>1,500/ml
<b>Platelet count</b>	>60,000/ml	>100,000/ml	>100,000/ml
<b>Blood urea nitrogen (BUN)</b>	<30mg/dl	No greater than x1.5 times normal	No greater than x1.5 times normal
<b>Creatinine</b>	<30mg/dl	No greater than x1.5 times normal	No greater than x1.5 times normal
<b>Alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase</b>	<2x the upper limit of normal	<2x the upper limit of normal	<1.5x the upper limit of normal

Perhaps the most awful thing about NWBO is the way the company has reported DCVax results, and particularly the Houdini tricks the data from various trials have been pulling in NWBO reports and investor presentations. Fights have broken out in the comment section of Seeking Alpha articles between confused investors as to which reported data belonged to which published study (see Table 2 for clarification), and particularly how some 5 patients vanished in one investor presentation data set and some more appeared somewhere else<sup>110</sup>. The lack of mathematical sense is not due to NWBO having reinvented calculus as well as cancer, but rather because they have no faith in the mathematical prowess of their investors. Just look at how they try to explain DCVax<sup>111</sup>:



We don't blame the investors for being confused. Those who know NWBO, will know extremely well that there has never been a reference to a scientific study or a journal article in any of their presentations touting lifelong OS figures. But the company is clearly compensating for this with their publication section, which features no less than 200 scientific articles<sup>112</sup>. In what seems like an attempt to stun investors into bewilderment and admiration NWBO must have pasted in every publication produced by a "dendritic cell" Google search under the cheeky pretense of somehow being related to it. Either that, or the company's 8 employees performed a massive clinical trial and released a publication roughly every 3 weeks for the past

<sup>110</sup> <http://www.prnewswire.com/news-releases/nw-bio-confirms-phase-iii-trial-of-DCVax-I-for-gbm-brain-cancer-is-ongoing-300131912.html>

<sup>111</sup> [http://neurosurgery.ucla.edu/workfiles/Brain\\_Tumor\\_Program/11-000686-%20Main%20ICF%2007Nov2012.pdf](http://neurosurgery.ucla.edu/workfiles/Brain_Tumor_Program/11-000686-%20Main%20ICF%2007Nov2012.pdf)

<sup>112</sup> <http://www.nwbio.com/publications/>

10 years. Except of course, of these publications, exactly two pertain to DCVax and exactly three pertain to the company's founder/CSO Alton Boynton. That makes the publication section of NWBO's website roughly 2.5% relevant.

For the record, reputable companies (those than are not NWBO but which could be Immunocellular Therapeutics (IMUC) tend to advertise their own clinical articles written and performed by their own scientific staff<sup>113</sup>. This usually adds up to a slightly less audacious number than 200. Incidentally, out of the 13 publications IMUC lists on their website, it lists the very same publication as NWBO as their primary source – that is because the CEO of Immunocellular Therapeutics John Yu performed the Phase 1 study for NWBO, and, having seen the results, settled for a different DC approach.

Simply put, there have been only three completed clinical trials related to DCVax and which NWBO references with much entanglement: a Phase 1 study on 14 patients conducted by Yu, Wheeler *et al* at Cedars-Sinai, a Phase 1 study on 12 patients conducted by NWBO's favorite Linda Liau at UCLA which used tumor-associated peptides, and a Phase 1 28-patient study which became a Phase 1/2 and sometimes Phase 2 study conducted by Linda Liau using a TLR agonist (Table 2).

There are also several publications related to these studies, which seems to have been the source of the confusion. Interestingly, while referencing half of the internet in their publications section, NWBO forgot to add references to two of Linda Liau's main articles which tested a combination of a DC vaccination and a TLR agonist (likely not what NWBO is currently testing). However, NWBO never forgot to add the best of the findings from these irrelevant studies to their mind-boggling investor presentations.

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<sup>113</sup> <http://www.imuc.com/technology/publications>

**Table 2. Clinical studies run by NWBO to date**

Phase	Number of patients/ Indication	DC Protocol	Outcomes	Clinicaltrials.gov ref.	Related studies
I	<b>14</b> 9 recurrent GBM 3 recurrent AA <b>1 newly diagnosed GBM</b> 1 newly diagnosed anaplastic astrocytoma	PBMCs cultured in GM-CSF and IL-4, resulting DCs incubated with tumor lysate for 18h	OS = 133 weeks (30 months) for 8 recurrent GBM pts; <b>82 weeks (18 months)</b> for newly diagnosed GBM pt	None (Phase 1 trials are normally not registered)	<a href="#">Yu, Wheeler et al, 2004</a>
I	<b>12</b> 5 recurrent GBM (possibly 6) <b>7 newly diagnosed GBM (possibly 6)</b> <b>Note:</b> the journal article pertaining to this study features a contradicting error in the number of newly diagnosed GBM pts – see <a href="#">body</a> of article vs <a href="#">patient characteristic table</a>	PBMCs cultured in GM-CSF and IL-4, resulting DCs incubated with acid-eluted tumor-associated proteins enriched for MHC class I peptides	ORR = 8% mPFS = 15.5 months mOS = 23.4 months recurrent GBM: mOS = 11.7 months (not stat. sig. to hist. data) <b>pts w/ SD or no residual disease (NOT newly diagnosed GBM):</b> mPFS = 19.9, mOS= 35.8		<a href="#">Liau et al, 2005</a>
I	<b>28</b> 8 recurrent GBM <b>15 newly diagnosed GBM</b> 5 anaplastic astrocytoma  <b>Note:</b> different patient numbers for this study appear in different publications.	PBMCs cultured in GM-CSF and IL-4, resulting DCs incubated with tumor lysate overnight, If patients did not develop toxic side effects over 3 months, they received booster injections concurrently with Imiquimod cream or poly-ICLC (TLR agonists)	mPFS = 15.9 months mOS = 31.4 months <b>newly diagnosed GBM:</b> <b>mOS = 35.9 months</b> recurrent GBM: mOS = 17.9 months	<a href="#">NCT00068510</a>	<a href="#">Liau, Prins et al, 2011</a>  <a href="#">Liau, Prins et al, 2013</a>

**GBM:** Glioblastoma multiforme **mPFS:** median Progression-Free Survival (equivalent to Time-to-progression (TTP) **mOS:** median Over Survival  
**PBMCs:** peripheral blood mononuclear cell **GM-CSF:** Granulocyte-macrophage colony-stimulating factor **IL-4:** interleukin 4

Between 2006 and 2013 NWBO insisted the second Phase 1 study run by Liau and colleagues recruited only 17 patients. This could be because only 17 patients were recruited to the trial by that time, but this

number keeps getting tossed around to further the confusion. As of 2014, the total patient number from both of Liao's trials is, according to NWBO<sup>114</sup>, **39**:

"We and our collaborator, Dr. Linda Liao, conducted two prior Phase I/II clinical trials at UCLA with DCVax-L for GBM brain cancer. These trials consisted of 39 patients with newly diagnosed GBM and recurrent GBM, and a couple of other gliomas."

Where an extra patient from the two trials disappeared off to remains a mystery.

Now onto a typical NWBO investor presentation<sup>115</sup>:

## Lead Program: **DCVax-L** for Newly Diagnosed GBM

### Phase I/II Trials

- 20 newly diagnosed GBM; 14 recurrent GBM; 5 lower grade gliomas
- Standard of care (surgery & 6 weeks radiation & chemo) + DCVax-L
- Primary endpoint: safety; Secondary endpoint: progression free survival

	Standard of Care*	Matched Concurrent Controls**	DCVax-L
Progression (Tumor Recurrence)	6.9 mos	8.1 mos	2 years
Overall Survival	14.6 mos	17 mos	3 years
Long Tail of Survival	2 – 3% alive at 5 years		To date: 33% alive >4 yrs 27% alive >6 yrs 2 pts alive >10 yrs



\* N Engl J Med 352: 987-96, 2005

\*\* matched for age, gender, Karnofsky score, extent of surgical resection, and same std of care treatment, at same hospital, in same time period

Third-grade math would be sufficient to ensure bewilderment at these mathematical concoctions. No matter how many additions and subtractions we did, we failed to arrive at the number of 20 newly diagnosed GBM patients from the Phase 1 and 2 trials, even when you take into account the fatal error in the number of newly diagnosed and recurrent GBM patients in one of Linda Liao's articles (*see Table 2*).

<sup>114</sup> [https://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](https://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

<sup>115</sup> <http://nwbio.com/wp-content/uploads/2014/03/NWBT-corp-overview-Mar-20.pdf>



Another patient just went missing, and along with him, the identity of the data NWBO decided to cherry pick for their “nicely rounded up” PFS and OS values.

Even if we ignore the fact that the median age of newly diagnosed GBM patients the two Phase 1 studies NWBO references turned out to be a youthful long-term-GBM-surviving 45 and median Karnofsky score was a near-perfect 90 (patient characteristics of study number 1 and 2 are available<sup>116</sup>), the **PFS and OS numbers** NWBO brags about are **still not relevant**.

The simple reason for this is that NWBO nonchalantly pooled data from two studies which utilized different DC vaccines with different adjuvants. The first Phase 1 study by Liao didn't even use DCs incubated with tumor lysate, but rather specifically isolated tumor-associated proteins. The second study utilized a TLR adjuvant which is likely not what the company is currently testing. In other words, NWBO's prior clinical data is as relevant as their publications section.

## Other Dendritic Cell Studies for GBM have never confirmed NWBO's sensational findings

It may come as a surprise that DCVax-L development is just one in 22 of tumor-lysate DC studies to have taken place in the last decade. A large number of these studies have also targeted brain tumors, and particularly glioblastomas and astrocytomas.

**Despite the fact that the majority of the studies utilized DC precursors differentiated ex vivo with GM-CSF and IL-4, just like NWBO, and many utilized various maturation agents, none of the studies came close to achieving the same sensational OS and PFS values NWBO advertises.**

Table 3 shows several of such studies, along with the differentiation and priming method of DCs, followed by the studies' outcomes. A much more elaborate comparison of completed DC studies has been compiled by Linda Liao<sup>117</sup>.

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<sup>116</sup> <http://clincancerres.aacrjournals.org/content/11/15/5515/T1.expansion.htm>,  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3071163/table/T1/>

<sup>117</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810429/table/T1/>

**Table 3. Results from other dendritic vaccine studies with identical technology to DCVax don't come close to NWBO's OS/PFS findings**

Study	Tumor type	Nr of patients, Median age, KPS, etc	DC prep. Regimen & protocol	Outcomes
<a href="#">Fadul et al, 2011</a>	GBM	10 newly diagnosed GBM pts; median age 60 (48-78); median KPS 80 (70-90)	DCs differentiated from monocytic precursors using: AIM-V medium, GM-CSF, IL-4 + autologous tumor lysate along with TNF- $\alpha$ and PGE <sub>2</sub> . DCs administered via intranodal injection after radiation therapy and tomozolomide	mPFS = <b>9.5</b> months mOS = <b>28</b> months
<a href="#">Yamanaka et al, 2003</a>	GBM, anaplastic glioma	7 pts with newly diagnosed GBM, 3 pts with anaplastic glioma median age 46.5 (20-60) mKPS 54 (30-80)	PBMCs harvested and incubated with GM-CSF, IL-4 & 1% penicillin/streptomycin, then cultured overnight with tumor lysate in presence of KLH (an adjuvant). DCs administered into cervical node after surgical resection & beam radiation therapy (40 Gy to the tumour with 3-cm margins, 20 Gy boost to the whole brain)	1 PD, 1 SD (no PFS) mOS = <b>22</b> months
<a href="#">De Vleeschouwer et al, 2004</a>	Relapsing GBM	12 pts; median age 36 (11-78)	PBMC isolated from fresh blood samples & DC-differentiated in the presence of IL-4, GM-CSF for 7 days. Immature DC were loaded with tumour proteins along with TNF- $\alpha$ , IL-1 $\beta$ and PGE2	mPFS= <b>3</b> months; mOS= <b>10.5</b> months
<a href="#">De Vleeschouwer et al, 2008</a>	High-grade glioma; Relapsed GBM	56 pts with relapsed GBM, 51/56 had already received (several types of) chemotherapy	<i>As above</i>	mPFS= <b>3</b> months mOS = <b>9.6</b> months; <35 yrs was a predictor of better overall but not PFS, with a median OS of <b>15.4 months</b> for the younger patients versus <b>7.5 months</b> for the patients above 35 years (P = 0.012)

KPS: Karnofsky score

A question that should be asked most of all is, with all these DC-tumor-lysate studies, and so much hype, why is NWBO still single to boot in the development of DCVax, and why is DCVax the only DC-tumor-lysate technology in clinical development? The answer is because it doesn't work.

## Immunocellular therapeutics reported better survival numbers than NWBO before they failed

In what has now become the industry's rule of thumb, therapies sensationalized by small-scale, open label single Phase 1 studies don't live up to expectations in Phase 3. This is likely to be happening to NWBO soon and has already happened to NWBO's cousin technology ICT-107, developed by Immunocellular Therapeutics for GBM. Instead of using blended tumor to incubate DCs, IMUC chose 6 specific tumor antigens.

ICT-107 actually yielded better OS readings, and very similar PFS readings to those of DcVax in Phase 1 trials, but failed to significantly prolong overall survival in a follow-up 124-patient phase II trial with temozolamide vs temozolamide (Table 4).

**Table 4. Comparison of DcVax and ICT-107 Phase trial outcomes**

	<b>DcVax-L</b> (from Linda Liao's most recent Phase 1 study – see Table 2)	<b>ICT-107</b>	<b>ICT-107</b>
<b>Phase</b>	<b>1</b>	<a href="#"><u>1</u></a>	<a href="#"><u>2</u></a>
<b>Patients/indication</b>	15 newly diagnosed GBM	16 newly diagnosed GBM	124 newly diagnosed GBM
<b>OS</b>	35.9 months	38.4 months	18.3 months (vs. 16.7 for placebo)
<b>PFS</b>	24 months	17 months	11.2 months (vs 9 for placebo)
<b>2-year survival</b>	77%	80.2%	n/a

**NWBO's survival figures don't look so sensational now.**

## Ongoing DCVax GBM Phase 3

NWBO were meant to run a 348-patient global Phase 3 study<sup>118</sup>, which currently is not working out for them due to a halt on patient enrollment which was announced in August of 2015<sup>119</sup>.

This is the first time NWBO is running a placebo-controlled trial, which is a type of trial which kills technologies that do not work. It looks like DCVax already had a pre-death experience in August of 2014 when they suddenly announced an amendment to the number of patients and the number of statistical events, **particularly a lowering of the success threshold for their primary endpoint**<sup>120</sup>.

The trial would now recruit 348 total patients, up from a previous 312, and the number of "events" counted in the statistical analysis will increase from 110 to 248. The company also accounted that the threshold for satisfying the primary endpoint of the Phase III trial (which is PFS) will be lowered from requiring a 6-month difference to requiring only a 4-month difference between the PFS of the patients treated with DCVax-L and the PFS of patients in the control arm of the trial – in other words, the threshold for success is now inexplicably lower.

Those who are familiar with the industry will have seen many such tricks in the past, usually from companies who are making a last-minute desperate bid for efficacy. Usually, these bids end in tears.

## NWBO is committing DCVax homicide by using a PFS primary endpoint

This is perhaps the most frightening point of all for NWBO, especially in the extremely unlikely event that DCVax manages to show some sort of efficacy in Phase 3. In yet another amendment to their trial protocol, NWBO decided that their Phase 3 study will have a primary endpoint which is progression-free survival instead of overall survival, probably because it seems to them that DCVax has had a better effect on PFS than OS.

It is important to note that not only has PFS never been used as a primary endpoint for GBM before, but also that several companies have actually asked the FDA for this endpoint, and were not granted their wishes. Straight from a scientist's mouth, the reason for FDA disliking PFS is that<sup>121</sup>:

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<sup>118</sup> <https://clinicaltrials.gov/ct2/show/NCT00045968>

<sup>119</sup> <http://www.prnewswire.com/news-releases/nw-bio-confirms-phase-iii-trial-of-DCVax-l-for-gbm-brain-cancer-is-ongoing-300131912.html>

<sup>120</sup> <http://www.nwbio.com/nw-bio-provides-update-about-phase-iii-DCVax-l-trial-for-gbm-and-information-arm-compassionate-use-case-pati>

<sup>121</sup> <http://cancerres.aacrjournals.org/content/68/14/5955.full>

***“Survival represents the most objective standard for evaluating GBM therapy, in part because surgical tumor mass reduction does not necessarily correlate with prolonged survival.”***

In other words, because PFS does not mean anything.

Caught in another lie, NWBO was recently busted for claiming that they were in agreement with the FDA about amendment of their Phase 3 protocol,<sup>122</sup> which would have included the endpoint changes, when their recent SEC filings attested to just the opposite<sup>123</sup>:

***“The primary endpoint of our Phase III trial is progression free survival. Sometimes regulators have accepted this endpoint, and sometimes not. There can be no assurance that the regulatory authorities will find this to be an approvable endpoint for Glioblastoma multiforme cancer”***

If the trial does succeed with PFS as primary endpoint, there is a truly near-impossible chance that the FDA will accept a New Drug Application (NDA) from NWBO based on this, and the company will have to start all over again.

## The clinical halt

The hold on patient enrollment in the Phase 3 DCVax GBM trial was announced in August 2015, pending the submission of “additional regulatory information” by NWBO. As NWBO investors may know all too well, transparency is not a forte of NWBO’s CEO Linda Powers, and the crucial reason for the halt has not yet been disclosed. However, we fear that stern NWBO supporters may be in denial about the halt’s reasons.

While speculation is rife that the halt is due to “outstanding efficacy”, in actuality this event bears absolutely no resemblance to efficacy halts which are put in place when it becomes clear that depriving the control patient arm of the efficacious treatment would be unethical. This is particularly evident through the fact that, according to the company’s press release on the issue, the trial has been proceeding for at least two months with the recruited control- and active-arm patients (meaning, the placebo arm continued to receive placebo), while selection for new patients seems to be undergoing additional scrutiny. Certainly, placebo-arm patients haven’t been rushed to receive the phenomenal DCVax at least since August 2015<sup>124</sup>. Based on this, it could be speculated that certain patients who meet the trial’s selection criteria may have been found to be unsuitable, or perhaps at a safety risk, for receiving DcVax.

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<sup>122</sup> <http://www.nwbio.com/nw-bio-obtains-approvals-for-enhancements-of-phase-iii-trial-of-DCVax-I-for-gbm-brain-cancer/>

<sup>123</sup> [https://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266\\_10k.htm](https://www.sec.gov/Archives/edgar/data/1072379/000114420415016579/v403266_10k.htm)

<sup>124</sup> <http://www.nwbio.com/nw-bio-confirms-phase-iii-trial-of-DCVax-I-for-gbm-brain-cancer-is-ongoing/>

## **Appendixes**

Appendix 1



**FILE COPY**

**CERTIFICATE OF INCORPORATION  
OF A  
LIMITED LIABILITY PARTNERSHIP**

Partnership No. OC341862

The Registrar of Companies for England and Wales hereby certifies that

**RSC CAPITAL LLP**

is this day incorporated under the Limited Liability Partnerships Act 2000 as a limited liability partnership and that the partnership is limited.

Given at Companies House on **4th December 2008**.





Please complete in typescript,  
or in bold black capitals.

CHWP000

Please leave this box blank

OC341862

Full Name of Limited  
Liability Partnership

RSC Capital LLP

Situation of Registered  
Office

England and Wales

Insert "England and Wales", "Wales" or "Scotland"

Registered Office  
Address

Hawthorne House  
1 Cholmeley Park

Post town

Highgate

PO Box number  
only is not  
acceptable

County / Region

London

UK  
Postcode

N6 5ET

Will all Members from time to  
time be designated members?  
(List members overleaf)



YES



NO

If no, at least two of the  
listed members must be  
designated members

Number of continuation sheets  
attached to this application for  
incorporation

0

I certify that I am a: (Please tick appropriate box)



Solicitor engaged in the formation of this LLP



Member named overleaf of the LLP

And that the two or more persons named overleaf are associated for  
carrying on a lawful business with a view to profit.

Signed

*[Signature]*

Date

27/11/2008

You do not have to give any contact  
information in the box opposite but if you  
do, it will help Companies House to  
contact you if there is a query on the  
form. The contact information that you  
give will be visible to searchers of the  
public record.

Tel 07590 696 057

DX number

DX exchange

When you have completed and signed the form please send it to the  
Registrar of Companies at:

Companies House, Crown Way, Cardiff, CF14 3UZ DX 33050 Cardiff  
for partnerships registered in England and Wales or  
Companies House, 37 Castle Terrace, Edinburgh, EH1 2EB  
for partnerships registered in Scotland DX 235 Edinburgh  
or LP - 4 Edinburgh 2



A35 02/12/2008 274  
COMPANIES HOUSE



**List of Members on Incorporation**

Peers or others known by a title may use the title instead of or in addition to their name

Surname or Corporate name: **Minhas**

Forename(s): **Alia**

Member Reference Number \* (as advised by Companies House):

Date of Birth: Day 2, Month 8, Year 09

†† Usual Residential Address (or registered or principal office address in the case of a corporation or

†† Tick this box if the address shown is a service address for the beneficiary of a Confidentiality Order granted under the provisions of section 723B of the Companies Act 1985

Post town: **Hawthorne House**  
**1 Cholmeley Park**

County / Region: **Highgate**

Country: **London**

UK Postcode: **N6 5ET**

Country: **UK**

I consent to act as a member of the limited liability partnership named on page 1

(Please tick this box if consenting to act as a designated member) ☒

\* Voluntary information

Signed: **[Signature]** Date: **27/11/2008**

(Member to sign and date)

Peers or others known by a title may use the title instead of or in addition to their name

Surname or Corporate name: **Malik**

Forename(s): **Navid**

Member Reference Number \* (as advised by Companies House):

Date of Birth: Day 1, Month 7, Year 02

†† Usual Residential Address (or registered or principal office address in the case of a corporation or Scottish firm

†† Tick this box if the address shown is a service address for the beneficiary of a Confidentiality Order granted under the provisions of section 723B of the Companies Act 1985

Post town: **Hawthorne House**  
**1 Cholmeley Park**

County / Region: **Highgate**

Country: **London**

UK Postcode: **N6 5ET**

Country: **UK**

I consent to act as a member of the limited liability partnership named on page 1

(Please tick this box if consenting to act as a designated member) ☒

\* Voluntary information

Signed: **Navid Malik** Date: **27/11/2008**

(Member to sign and date)

NOTE: Unless there are at least two designated members, all members will be designated members.

## Appendix 2

Title Number : MX244829

This title is dealt with by Land Registry, Wales Office.

The following extract contains information taken from the register of the above title number. A full copy of the register accompanies this document and you should read that in order to be sure that these brief details are complete.

Neither this extract nor the full copy is an 'Official Copy' of the register. An official copy of the register is admissible in evidence in a court to the same extent as the original. A person is entitled to be indemnified by the registrar if he or she suffers loss by reason of a mistake in an official copy.

This extract shows information current on 7 SEP 2015 at 16:07:33 and so does not take account of any application made after that time even if pending in the Land Registry when this extract was issued.

### REGISTER EXTRACT

Title Number : MX244829

Address of Property : 1 Cholmeley Park, Highgate, London (N6 5ET)

Price Stated : £940,000

Registered Owner(s) : NAVID MALIK and ALIA JAWEED MINHAS of 1 Cholmeley Park, Highgate, London N6 5ET.

Lender(s) : Lloyds Bank PLC

Appendix 3

<input type="text" value="www.ctcicenter.com"/>	<input type="button" value="Lookup"/>
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## Contact Information

### Registrant Contact

Name: Linda Powers

Organization: CTCI

Mailing Address: 4800 Montgomery Lane, Bethesda Maryland 20814 us

Phone: +1.2404974060

Ext:

Fax:

Fax Ext:

Email: support@toucancapital.com

### Admin Contact

Name: Linda Powers

Organization: CTCI

Mailing Address: 4800 Montgomery Lane, Bethesda Maryland 20814 us

Phone: +1.2404974060

Ext:

Fax:

Fax Ext:

Email: support@toucancapital.com

### Tech Contact

Name: Linda Powers

Organization: CTCI

Mailing Address: 4800 Montgomery Lane, Bethesda Maryland 20814 us

Phone: +1.2404974060

Ext:

**Application for registration of a company**

טופס 1  
(תקנה 1)

אל : רשם החברות

**בקשה לרישום חברה**

לפי סעיף 8 לחוק החברות התשנ"ט 1999  
שם החברה המוצע :

**Company Name**

המרכז הבינלאומי לרפואה תאית ואימונותרפיה של הסרטן (CTCI)  
International Center for Cell Therapy & Cancer Immunotherapy (CTCI) LTD.

בעברית  
באנגלית

אני החתום מטה

**Shareholder: Orange Clover Trusted**

שם משפחה שם פרטי מספר זהות

תלתן כתום נאמניות בע"מ 512318189

שם תאגיד מספר

או

שמענו :

ישראל	רעננה	התעשייה	3	43654
מדינה	ישוב	רחוב	מס' בית	מס סלפון

אני מבקש לרשום חברה בשם לעיל או בשם אחר שיסכים לו רשם החברות,

**Registered address @ Cognate Bioservice Israel**

תל-אביב	ויצמן	14	קוגניט ביוסרוויס ישראל בע"מ
ישוב	רחוב	מס' בית	מיקוד אצל

ומצדד בזה

1. עותק תקנון חתום בידי בעלי המניות הראשונים שזהותם ואומתו בחתימת עו"ד כאמור בסעיף 23 (ב) לחוק.

לגבי יחיד

אני כשיר לייסד חברה ולהחזיק מניות בה, אינני מוגבל על פי דין, חוק ההוצאה לפועל התשכ"ז 1967. ופקודת פשיטת רגל (נוסח חדש) התש"ס 1980.

תאגיד

התאגיד נרשם כדון, ולא הוסלה עליו מגבלה בדיון.

2. הצהרת הדירקטורים הראשונים על נכונותם לכהן כדירקטורים.

**מסרות החברה : לעסוק בכל עיסוק חוקי**

**הון החברה :**

הון רשום 100,000 ש"ח המורכב מ- 10,000,000 מניות בנות 0.01 ש"ח כ"א לפי הסוג רגילות.

**אחריות בעלי המניות : מוגבלת במניות.**

תאריך: 2.11.2008

תלתן כתום נאמניות בע"מ  
512318189

דפוס גלילי / חוק  
מאמנו כ"ח

חתימה

אני עורך דין בקטי 3 כ"ח מאשר בזה כי אלו 15-א שזהותם ואומתו בחתימת עו"ד זהות מספר 0553311231 לאחר שהזהרתי כי עליו להצהיר את האמת וכי יהיה צפוי לעונשים הקבועים בחוק אם לא יעשה כן אישר נכונות הצהרתו לעיל, לדבות בדבר היותו מוסמך לחתום בשם התאגיד וחתימתו עליה בפני.

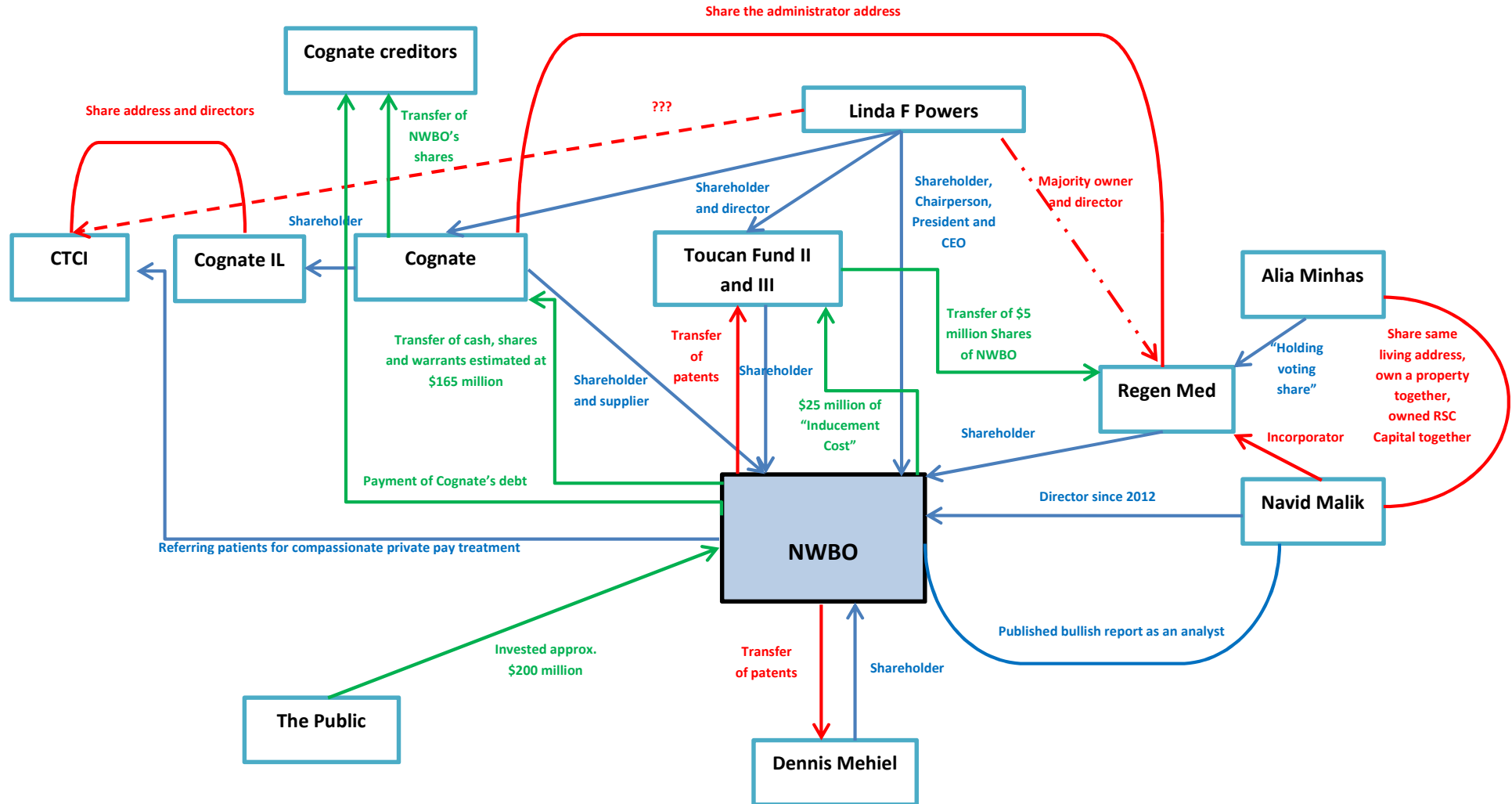
צפדי בקטי עו"ד, ר"ח  
95794

חתימת עורך הדיון  
שם : ד"ר צפדי בקטי  
מען : רמת השרון  
ת.ד. : 95794  
מס' רשיון : 15714

תאריך - 2.11.2008 @



Appendix 4



- Disclosed relationship
- Undisclosed relationship/transaction
- Transfer of wealth
- Partly disclosed relationship