

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2013-05-16** | Period of Report: **2013-05-16**  
SEC Accession No. [0001144204-13-029969](#)

([HTML Version](#) on [secdatabase.com](#))

FILER

**NORTHWEST BIOTHERAPEUTICS INC**

CIK: **1072379** | IRS No.: **943306718** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **001-35737** | Film No.: **13852079**  
SIC: **2834** Pharmaceutical preparations

Mailing Address

4800 MONTGOMERY LANE  
SUITE 800  
BETHESDA MD 20814

Business Address

4800 MONTGOMERY LANE  
SUITE 800  
BETHESDA MD 20814  
(240) 497-9024

---

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

---

FORM 8-K

---

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

---

Date Of Report (Date Of Earliest Event Reported): May 16, 2013

---

---

**NORTHWEST BIOTHERAPEUTICS, INC.**

---

(Exact Name of Registrant as Specified in Its Charter)

---

**Delaware**  
(State Or Other Jurisdiction Of  
Incorporation)

**0-33393**  
(Commission File Number)

**94-3306718**  
(I.R.S. Employer Identification No.)

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814  
(Address Of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code (240) 497-9024

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

**Item 8.01 Other Events.**

On May 16, 2013, Northwest Biotherapeutics, Inc. (the “Company”) issued a press release announcing that its Phase III clinical trial with DCVax-L for brain cancer has been initiated at King’s College Hospital in the UK. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K. The trial was initiated at King’s on May 10, 2013.

The information disclosed under this Item 8.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

**Item 9.01 Financial Statements and Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Northwest Biotherapeutics, Inc. dated May 16, 2013.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NORTHWEST BIOTHERAPEUTICS, INC

Dated: May 16, 2013

By: /s/ Linda Powers  
Name: Linda Powers  
Title: Chief Executive Officer and Chairman

# **NW Bio Initiates Phase III DCVax®-L Brain Cancer Trial In Europe: King's College Hospital In The UK Is First Site To Open**

## **Up To 30 European Sites To Join 46 Active Sites In The US**

BETHESDA, Md., May 16, 2013 /PRNewswire/ -- Northwest Biotherapeutics (NWBO) (NW Bio), a biotechnology company developing DCVax®-L personalized immune therapies for solid tumor cancers, today announced that its Phase III clinical trial with DCVax®-L for brain cancer has been initiated at King's College Hospital in the UK.

This is one of the first late-stage clinical trials in Europe with active immune therapies, and its opening is the culmination of years of planning, development and regulatory and institutional approvals. King's College Hospital, a major center for neuro-oncology, is leading the way for the many other European sites. Three other sites in the UK are also preparing to open, and nearly 20 sites in Germany are in various stages of preparation. In addition, medical centers in other European countries have requested to be added to the trial.

This Phase III trial is for newly diagnosed Glioblastoma multiforme (GBM), the most common and most lethal form of brain cancer. The trial is already well under way in the US, with 46 active sites at present, and is expected to enroll an aggregate total of 312 patients in the US and Europe. Notably, there are few competing brain cancer trials in Europe, although Europe has a population larger than the US.

DCVax-L mobilizes a cancer patient's whole immune system to attack the full set of biomarker targets on the tumor. Current standard of care for GBM brain cancer includes surgical removal of the tumor, followed by six weeks of daily radiation to the brain and daily chemotherapy, followed by monthly chemotherapy. With all of these treatments, GBM tumors typically recur within about 6.9 months, and the patients typically live for about 14.6 months. In prior Phase I/II clinical trials, in patients treated with DCVax-L the tumors typically did not recur for 2 years, and the patients typically lived for 3 years. A substantial percentage of patients lived even longer, and to date two patients have exceeded 10 years. In addition, DCVax-L is non-toxic and is anticipated to cost less than other recent cancer drugs.

Dr. Keyoumars Ashkan, Consultant Neurosurgeon [specialist] and Lead for Neuro-Oncology at King's College Hospital said: "We are pleased to be leading the way in bringing these novel immune therapies to patients in the UK. Brain cancers are some of the most lethal cancers, and there is a great need for new and better treatments."

“The positive data from the clinical trials in the US were very encouraging in delaying disease progression and extending survival times, without significant toxic side effects. We are hopeful that similar results will be seen in the large, randomized clinical trial which we have now launched in the UK.”

“This is an important landmark, as we begin patient recruitment in our pioneering Phase III trial of DCVax-L for brain cancer in Europe, the largest medical market in the world after the US,” commented Linda Powers, CEO of NW Bio. “This is one of the first late-stage clinical trials with active immune therapies in Europe, and is bringing patients a much needed new treatment option. We are excited to be launching this trial with King’s College Hospital, one of Europe’s premier opinion-leader institutions.”

### **About Northwest Biotherapeutics**

Northwest Biotherapeutics is a biotechnology company focused on developing immunotherapy products to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and on a cost-effective basis, in both the United States and Europe. The Company has a broad platform technology for DCVax dendritic cell-based vaccines. The Company’s lead program is a 312-patient Phase III trial in newly diagnosed Glioblastoma multiforme (GBM). GBM is the most aggressive and lethal form of brain cancer. The Company also previously received clearance from the FDA for a 612-patient Phase III trial in prostate cancer, and clearance from the FDA for Phase I/II trials in multiple other cancers. The Company also conducted a Phase I/II trial with DCVax for metastatic ovarian cancer together with the University of Pennsylvania.

### **About King’s College Hospital**

King’s College Hospital NHS Foundation Trust is one of the UK’s largest and busiest teaching hospitals, with more than 7,000 staff providing around 1,000,000 patient contacts a year. King’s has a unique profile, with a full range of local hospital services for people in the London boroughs of Lambeth and Southwark as well as specialist services to patients from further afield. The Trust is recognized internationally for its work in liver disease and transplantation, neurosciences, cardiac, haemato-oncology, stroke and major trauma. King’s also plays a key role in the training and education of medical, nursing and dental students with its academic partner, King’s College London. For more information, visit [www.kch.nhs.uk](http://www.kch.nhs.uk). You can also support the work of King’s College Hospital at [togetherwecan.org.uk/kings-college-hospital](http://togetherwecan.org.uk/kings-college-hospital).

## **Disclaimer**

Statements made in this news release that are not historical facts, including statements concerning future treatment of patients using DCVax and future clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “expect,” “believe,” “intend,” “plan,” “continue,” “may,” “will,” “anticipate,” and similar expressions are intended to identify forward-looking statements. Actual results may differ materially from those projected in any forward-looking statement. Specifically, there are a number of important factors that could cause actual results to differ materially from those anticipated, such as the Company’s ability to raise additional capital, risks related to the Company’s ability to enroll patients in its clinical trials and complete the trials on a timely basis, the uncertainty of the clinical trials process, uncertainties about the timely performance of third parties, and whether the Company’s products will demonstrate safety and efficacy. Additional information on these and other factors, including Risk Factors, which could affect the Company’s results, is included in its Securities and Exchange Commission (“SEC”) filings. Finally, there may be other factors not mentioned above or included in the Company’s SEC filings that may cause actual results to differ materially from those projected in any forward-looking statement. You should not place undue reliance on any forward-looking statements. The Company assumes no obligation to update any forward-looking statements as a result of new information, future events or developments, except as required by securities laws.

---