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(71) Applicant (for all designated States except US): **NAN-OTHERAPEUTICS, INC.** [US/US]; 13859 Progress Blvd., Suite 300, Alachua, FL 32615 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **TALTON, James, D.** [US/US]; 13859 Progress Blvd., Suite 300, Alachua, FL 32615 (US).

(74) Agent: **MCDONELL, Leslie, A.**; Finnegan, Henderson, Farabow, Garrett & Dunner LLP, 901 New York Avenue, Washington, DC 20001-4413 (US).

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(54) Title: PARTICULATE COMPOSITIONS FOR DELIVERY OF POORLY SOLUBLE DRUGS

(57) Abstract: Described herein are compositions comprising particles of poorly soluble drugs, in particular opioids, encapsulated by stabilizers, in particular polyethylene glycol (PEG). Further described are pharmaceutical compositions comprising such encapsulated compositions. Also described are methods of making such encapsulated particle compositions, and methods of making the corresponding pharmaceutical compositions. The encapsulated particle compositions described herein allow poorly soluble drugs to be administered with good bioavailability by routes that are non-invasive to patients, such as by oral administration.



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## INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER  
 INV. A61K9/50 A61K31/485 A61P25/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, BIOSIS, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/15699 A (SOUTHERN RES INST [US]) 8 March 2001 (2001-03-08)  claims 1,6-8 page 7, paragraphs 2,3 example 1	1-7, 10, 18, 19, 22-25, 27, 35, 44, 45
X	US 2005/048115 A1 (MANGENA MURTY [US] ET AL) 3 March 2005 (2005-03-03)  claim 1 paragraphs [0027] - [0029] examples 1-18	1-10, 18-20, 22-24, 27, 35, 36, 42-45



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

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\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040,  
 Fax: (+31-70) 340-3016

Authorized officer

Peris Antoli, Berta

## INTERNATIONAL SEARCH REPORT

International application No

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## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 7 157 102 B1 (NUWAYSER ELIE S [US]) 2 January 2007 (2007-01-02)</p> <p>claims 1,9,17,25 column 5, line 65 - column 6, line 17 column 9, lines 13-35 column 11, lines 54-56 examples II,IV,V</p>	<p>1-7,10, 18, 22-24, 27, 35-37, 44,45</p>
X	<p>EP 0 631 781 A (EURO CELTIQUE SA [LU]) 4 January 1995 (1995-01-04)</p> <p>claims 1-4 page 4, lines 38-41</p>	<p>1-8,10, 27,35, 37,42,43</p>
X	<p>WO 95/27482 A (ELAN CORP PLC [IE]; FREEMAN VIRGINIA [IE]; RAMTOOLA ZEBUNNISSA [IE]) 19 October 1995 (1995-10-19) claims 1,4-6,8-10,12</p>	<p>1-8,10, 27,35, 37,42,43</p>
X	<p>US 2007/020339 A1 (BEAR DAVID M [US]) 25 January 2007 (2007-01-25)</p> <p>claims 1-12 paragraphs [0011], [0031], [0034], [0035]</p>	<p>1,2,5-7, 27-31, 37,42,43</p>
X	<p>US 2004/110781 A1 (HARMON TROY M [US] ET AL) 10 June 2004 (2004-06-10)</p> <p>claims 1-15 paragraphs [0013], [0027], [0028]</p>	<p>1,2,5,6, 10-14, 27-37, 42,43</p>
Y	<p>EP 0 012 523 A (AMERICAN HOME PROD [US]) 25 June 1980 (1980-06-25) claims 1-4,12 page 6, paragraphs 1,2 page 7, lines 28-32 page 9, line 12 - page 10, line 17</p>	<p>1-53</p>
Y	<p>US 5 145 684 A (LIVERSIDGE GARY G [US] ET AL) 8 September 1992 (1992-09-08) claims 1-4,7,8,16-18 column 2, lines 31-43 column 4, line 64 - column 5, line 12</p>	<p>1-53</p>
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International application No  
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2007/008480 A (NANOTHERAPEUTICS INC [US]; TALTON JAMES D [US]) 18 January 2007 (2007-01-18) claims 1-5,8-10 page 1, paragraph 3 - page 2, paragraph 1 page 18, paragraph 3 - page 20, line 2 -----	1-53
Y	GB 1 456 618 A (BAYER AG) 24 November 1976 (1976-11-24) claims 1,8 page 1, lines 9-12,21-26,50-57 page 2, lines 19-25 -----	1-53
Y	EP 0 605 024 A (STERLING WINTHROP INC [US]) 6 July 1994 (1994-07-06) claims 1,2,4,5 page 2, line 54 - page 3, line 36 page 4, paragraph 1 page 5, paragraphs 4,6-8 -----	1-53
Y	US 6 270 806 B1 (LIVERSIDGE ELAINE [US] ET AL) 7 August 2001 (2001-08-07) claim 1 column 4, lines 52-68 -----	1-53
Y	EP 1 752 142 A (INST CIENTIFICO TECNOL NAVARRA [ES]) 14 February 2007 (2007-02-14) claims 1,2,9,15 paragraphs [0005] - [0009] paragraphs [0012] - [0017] -----	1-53
Y	KABANOV A V ET AL: "A NEW CLASS OF DRUG CARRIERS: MICELLES OF POLY(OXYETHYLENE)-POLY(OXYPROPYLENE) BLOCK COPOLYMERS AS MICROCONTAINERS FOR DRUG TARGETING FROM BLOOD IN BRAIN 1" JOURNAL OF CONTROLLED RELEASE, ELSEVIER, AMSTERDAM, NL, vol. 22, no. 2, 1 October 1992 (1992-10-01), pages 141-157, XP000291644 ISSN: 0168-3659 abstract -----	1-53

# INTERNATIONAL SEARCH REPORT

International application No.  
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## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claims 42-45 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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Information on patent family members

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