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(74) Agent: BEHROOZ, Alireza; Womble Carlyle Sandridge
& Rice, PLLC, P.O. Box 7037, Atlanta, Georgia 30357
(US).

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(71) Applicant (for all designated States except US): TALE-
CRIS BIOTHERAPEUTICS, INC. [US/US]; 4101 Re-
search Commons, 79 T.W. Alexander Drive, Research Tri-
angle Park, North Carolina 27709 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ARORA, Vikram
[US/US]; 101 Pember Place, Morrisville, North Carolina
27560 (US). PAMARTHI, Mohan [US/US]; 311 Capis-
trane Drive, Cary, North Carolina 27519 (US). SCUDERI,
Philip [US/US]; 7203 Crescent Ridge Drive, Chapel Hill,
North Carolina 27516 (US).

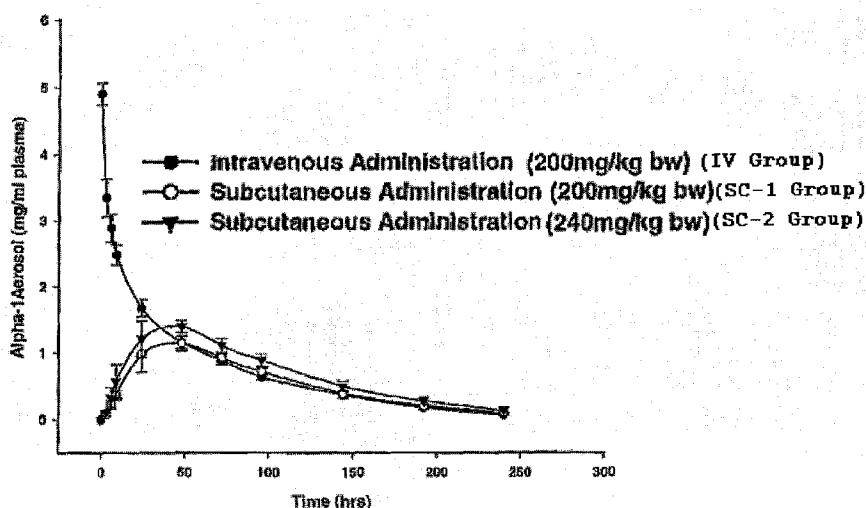
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[Continued on next page]

(54) Title: METHOD, COMPOSITION, AND ARTICLE OF MANUFACTURE FOR PROVIDING ALPHA-1 ANTITRYPSIN

FIG. 1



(57) Abstract: The present invention provides a method for providing alpha-1 antitrypsin (α 1-AT) to a subject, in particular a method for treating or preventing a disorder or disease associated with α 1-AT deficiency in the subject, wherein the method comprises providing, subcutaneously, a therapeutically or prophylactically effective amount of α 1-AT to the subject. Also provided is a composition and article of manufacture comprising α 1-AT, in particular a formulation suitable for subcutaneous administration of α 1-AT.



Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Published:

- *with international search report*

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18 June 2009

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/081911**A. CLASSIFICATION OF SUBJECT MATTER****A61K 38/57(2006.01)i, C07K 1/16(2006.01)i, C07K 14/81(2006.01)i**

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)

IPC 8: 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 practicable, search terms used)
eKIPASS(KIPO internal), Delphion, Pubmed (al-AT: alpha-1 antitrypsin, subcutaneous administration, hyaluronidase)**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X/Y	Piitulainen E, et al., Tailored pharmacokinetic dosing allows self-administration and reduces the cost of IV augmentation therapy with human alpha(1)-antitrypsin. Eur J Clin Pharmacol. 59(2):151-156 (Epub 1 May 2003) See abstract	3, 8/ 4, 9, 10
Y/A	WO 2005/047323A1 (ARRIVA-PROMETIC INC. et al) 26 May 2005 See example 1	4/ 3, 8-10
Y/A	Favre D. et al., Hyaluronidase enhances recombinant adeno-associated virus (rAAV)-mediated gene transfer in the rat skeletal muscle. Gene Therapy 7(16): 1417-1420 (Aug. 2000) See figures 2 & 3	9, 10/ 3, 4, 8
A	Brackertz D. et al., Proteinase inhibitors in rheumatoid arthritis. Ann Rheum Dis. 34(3): 225-230 (Jun 1975) See abstract and page 228	3, 4, 8-10
A	KR10-2004-0045528A (HWANG, WOO SUK) 02 Jun 2004 See page 2	3, 4, 8-10



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

"E" earlier application or patent but published on or after the international filing date

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search

22 APRIL 2009 (22.04.2009)

Date of mailing of the international search report

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CHO, Kyung Joo

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2008/081911**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.: 1, 2, 5-7
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1, 2, 5 to 7 pertain to methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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 all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/081911

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005-047323 A1	26.05.2005	AU 2004-288854 A1 CA 2545458 A1 EP 1685160 A1 US 2007-105768 A1	26.05.2005 26.05.2005 02.08.2006 10.05.2007
KR 10-2004-0045528 A	02.06.2004	None	