MAP Pharmaceuticals, Inc. Form 8-K December 19, 2008

UNITED STATES

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): December 19, 2008

MAP PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction

of Incorporation)

001-33719 (Commission 20-0507047 (IRS Employer

File Number)

Identification No.)

 2400 Bayshore Parkway, Suite 200, Mountain View, CA
 9

 (Address of Principal Executive Offices)
 (Zi

 Registrant s telephone number, including area code: (650) 386-3100

94043 (Zip Code)

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

" Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

1

Edgar Filing: MAP Pharmaceuticals, Inc. - Form 8-K

- " 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 1.01. Entry into a Material Definitive Agreement.

On December 19, 2008, MAP Pharmaceuticals, Inc. (the Company) entered into a License Agreement (the Agreement) with ASTRAZENECA AB, a Swedish corporation (AstraZeneca). Pursuant to the terms of the Agreement, the Company will license to AstraZeneca global rights to develop and commercialize MAP s proprietary nebulized formulation of budesonide, Unit Dose Budesonide (UDB), the next generation UDB therapy and combination nebulization therapies for the potential treatment of pediatric asthma. The Agreement is subject to review by the U. S. Government under the Hart-Scott-Rodino Act (the HSR Act) and will not become effective until the expiration or earlier termination of the waiting period (or any extension thereof). Either party may terminate the Agreement 150 days after the date of filing under the HSR Act, if the transaction is not effective by that date.

The Company and AstraZeneca will jointly clinically develop UDB in the United States with the Company executing the development plan. AstraZeneca will pay for up to a sixty-person sales force for the Company to jointly make sales calls to prescribers/doctors, or co-promote, UDB in the United States after product launch. AstraZeneca will fund this sales force for up to five years after the product launch. AstraZeneca will have rights to develop and commercialize UDB outside of the United States. AstraZeneca will reimburse the Company for the costs of future UDB development activities related to obtaining approval of UDB by the U.S. Food and Drug Administration, and will have the rights to develop follow-on products using different nebulizers or combinations of budesonide with other drugs.

Under the terms of the Agreement, AstraZeneca will pay the Company an upfront cash payment of \$40 million and an additional \$35 million upon the successful achievement of primary endpoint and safety results in the ongoing Phase 3 clinical study. In addition, the Company is eligible to receive up to \$240 million in other development and regulatory milestones. The Agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success.

The Company is also eligible to receive significant and escalating double-digit royalty payments on worldwide sales, as well as reimbursement for all royalties and certain milestone payments payable to Élan Pharma International Limited (Élan) pursuant to the license agreement with Élan (the Élan License Agreement). These payments will begin on the date of the first commercial sale of UDB or any other licensed product. In the event that any generic version of UDB or any other licensed product is sold by a third party, royalties would decrease according to specified formulas.

Pursuant to the terms of the Agreement, the Company and AstraZeneca agree, for a period until three years after the first commercial sale of a product in the United States, not to commercialize or assist any third party in commercializing any competing product. The Company also has the right to terminate the Agreement in relation to UDB if AstraZeneca commercializes another product for use in jet nebulizers.

The Company has agreed to indemnify AstraZeneca against any losses incurred in connection with, among other things, any intentional misconduct or gross negligence in performing any activity under the Agreement, the Company s negligent conduct of certain asthma studies and the administration of any licensed product in connection with such clinical studies, and for certain losses relating to the Company s agreements with Élan.

Following clearance under the HSR Act, the Agreement may be terminated by AstraZeneca (i) at will upon 90 days prior written notice and (ii) upon 60 days prior written notice if the primary endpoint or safety results in the Company s ongoing Phase 3 clinical study are not satisfactory. The Company may terminate (i) AstraZeneca s rights under the Agreement with respect to jet nebulizer products, if AstraZeneca commercializes a new competing product that has been approved for administration solely with a jet nebulizer or (ii) the Agreement if AstraZeneca seeks to invalidate certain intellectual property in-licensed or owned by the Company. Either party may terminate the Agreement in the event of an uncured material breach. AstraZeneca will be obligated to fund the remaining budget for the initial UDB development program if it terminates the Agreement at will or if it challenges certain patents or commercializes certain competing products that result in the termination of the Agreement by the Company.

In connection with the execution of the Agreement, the Company amended the Élan Agreements (the Élan Amendments), pursuant to which AstraZeneca will have certain rights to exercise and enforce certain of the Company s rights with Élan under the Élan Agreements prior to the expiration or termination of the Agreement. The Élan Amendments will automatically be rendered void in the event the Agreement does not become effective pursuant to the terms therein.

The foregoing summary is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to the Company s Current Report on Form 8-K/A. The Company intends to submit a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), requesting that it be permitted to redact certain portions of the Agreement. The omitted material will be included in the request for confidential treatment. The Élan Amendments, if they become effective, will also be filed as exhibits to the Company s Annual Report on Form 10-K.

Item 7.01. Regulation FD Disclosure.

The information in this Item, including Exhibit 99.1 attached hereto, is furnished pursuant to Item 7.01 of this Form 8-K. Consequently, it is not deemed filed for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references this Form 8-K.

In a press release issued on December 19, 2008, the Company announced that it had entered into the Agreement in a press release that is attached hereto as Exhibit 99.1.

The Company will host a conference call at 8:45 a.m. Eastern time / 5:45 a.m. Pacific time on Friday, December 19, to update stockholders on the Agreement and the collaboration with AstraZeneca for UDB announced today. Callers may join the call via telephone at 888-670-2248 (domestic) or 913-312-0980 (international). Access to the live webcast will be available via the Investor Relations section of the Company s Website at <u>www.mappharma.com</u>. A replay will also be available within 24 hours for at least seven days following the conference call.

Item 9.01. Financial Statements and Exhibits. (d) Exhibits

Exhibit No.Description99.1Press Release of MAP Pharmaceuticals, Inc., dated December 19, 2008

SIGNATURE

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.

Date: December 19, 2008

MAP PHARMACEUTICALS, INC.

By: /s/ Charlene A. Friedman

Name: Charlene A. Friedman

Title: Vice President, General Counsel and Secretary

INDEX TO EXHIBITS FILED WITH

THE CURRENT REPORT ON FORM 8-K DATED DECEMBER 19, 2008

Exhibit No.Description99.1Press Release of MAP Pharmaceuticals, Inc., dated December 19, 2008