

-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric: MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTINen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twIDAQAB MIC-Info: RSA-MD5,RSA, CnMEmbhrLf2YgWJcVM+wmcL4vd1G1ejqQS4HRM7fHx+hKETrLLPOiL4qM52N9tVM xqIfUEHijAbc7GbxnAy6zw== 0000921895-99-000737.txt : 19991025 0000921895-99-000737.hdr.sgml : 19991025 ACCESSION NUMBER: 0000921895-99-000737 CONFORMED SUBMISSION TYPE: 8-K PUBLIC DOCUMENT COUNT: 2 CONFORMED PERIOD OF REPORT: 19991018 ITEM INFORMATION: ITEM INFORMATION: FILED AS OF DATE: 19991022 FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 8-K SEC ACT: SEC FILE NUMBER: 001-12584 FILM NUMBER: 99732237 BUSINESS ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 BUSINESS PHONE: 3145799899 MAIL ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606
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FORM 8-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): October 22, 1999

SHEFFIELD PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware 1-12584 13-3808303

(State or other jurisdiction) (Commission) (I.R.S. Employer)

of incorporation)

File Number)

Identification

Number)

On October 18, 1999, Sheffield Pharmaceuticals, Inc. (the "Company") consummated a license and financing transaction with Elan International Services, Ltd. ("Elan") (an affiliate of Elan Corporation plc, an Irish pharmaceutical company) in accordance with the terms of the binding letter of intent dated September 30, 1999 (the "Letter of Intent"). A copy of the press release disclosing information relating to the consummation of the transaction and certain related matters is attached as an exhibit to this report, and is incorporated herein by reference.

Date: October 22, 1999

By:/s/ Loren Peterson

Loren Peterson
President and Chief Executive Officer

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EX-99.1

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PRESS RELEASE

[SHEFFIELD LOGO]

For further information contact:

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FOR IMMEDIATE RELEASE

SHEFFIELD PHARMACEUTICALS COMPLETES
LICENSING AGREEMENT WITH ELAN

--New joint venture will develop respiratory products utilizing Elan's proprietary NanoSystems technology--

St. Louis, MO - October 22, 1999 -- Sheffield Pharmaceuticals, Inc. (AMEX:SHM) today announced that it has completed its previously announced licensing agreement with Elan Corporation, plc for the development and commercialization of certain inhaled steroid products for the treatment of respiratory diseases. Under the terms of the agreement, a joint venture formed by the two companies has licensed certain pulmonary NanoCrystal(TM) dispersion technology from Elan Pharmaceutical Technologies, a division of Elan, for the development of these products. Sheffield agreed to provide the joint venture with access to certain of its pulmonary delivery systems. The venture partners will provide clinical development, regulatory, project development and business development guidance.

Under the terms of the transaction, Sheffield owns 80.1% of the new joint venture. Elan and Sheffield have committed an aggregate of \$5 million to the joint venture available on a draw-down basis to cover future operating and development costs. The joint venture has paid Elan a fee to license the NanoCrystal dispersion technology for use in the development of these steroid products. As part of the transaction, Elan has made an immediate \$17 million equity investment in Sheffield and committed up to an additional \$4 million in the form of three new classes of preferred stock convertible into common stock at premiums to Sheffield's current market price. Proceeds of \$5 million from the convertible preferred stock will be utilized by Sheffield for its own operating

purposes with the remainder used to support its share of the new joint venture. Elan will have the right to convert one of the new classes of Sheffield preferred stock into an additional ownership interest in Sheffield common stock or the joint venture. To satisfy the American Stock Exchange's requirements, Sheffield will seek shareholder approval for two of the new classes of preferred stock.

Thomas M. Fitzgerald, Chairman of Sheffield Pharmaceuticals stated, "We are pleased to conclude this important transaction with Elan Pharmaceutical Technologies and have the opportunity to aggressively develop several promising new products using our 'next generation' inhalation technologies. Having financial support and access to the NanoCrystal dispersion technology from Elan to complete this venture gives us the opportunity to develop products that otherwise could not be commercialized."

The joint venture will develop unique steroid products that utilize Elan's proprietary NanoCrystal(TM) dispersion technology. NanoCrystal(TM) dispersion technology enables delivery of poorly water-soluble medicines, such as steroids, by transforming these drug compounds into nanometer-sized particles that can be incorporated into traditional dosage forms, such as aerosol formulations.

The initial steroid products planned for development by the venture are:

- o A propellant-based steroid formulation for inhalation delivery in Sheffield's new generation metered dose inhaler, the Aerosol Drug Delivery System (ADDS).
- o A unit dose packaged steroid formulation for inhalation delivery in a standard commercial table-top nebulizer.
- o A steroid formulation for inhalation delivery in Sheffield's portable nebulizer, the Metered Solution Inhaler (MSI), subject to further agreement with Zambon Group, SpA which holds the exclusive license for all respiratory applications of the MSI.

Inhaled steroids are anti-inflammatory agents that address the underlying inflammation in the lungs of asthma and chronic obstruction pulmonary disease patients. The worldwide market for inhaled steroids is estimated at \$2 billion annually and growing at 20%.

Sheffield Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of later stage, lower risk pharmaceutical opportunities, particularly those utilizing unique pulmonary delivery technologies over a range of therapeutic areas. Sheffield has strategic alliances for pulmonary delivery development with Elan Corporation plc, Siemens AG and Zambon Group SpA. Investors can learn more about Sheffield Pharmaceuticals on its web site at www.sheffieldpharm.com.

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created hereby. Investors are cautioned that all forward-looking statements involve risks and uncertainty. Although the Company

believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any of the assumptions could be inaccurate, and therefore, there can be no assurance that the forward-looking statements included in this press release will prove to be accurate. Important factors that could cause actual results to differ materially from the forward-looking statements include the Company's need to obtain substantial additional capital (through financings or otherwise) to fund its operations and the progress of development and licensing/commercialization of the Company's technologies. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved.

-----END PRIVACY-ENHANCED MESSAGE-----