

EPIX MEDICAL INC
Form 8-K
February 17, 2004

[QuickLinks](#) -- Click here to rapidly navigate through this document

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): **February 17, 2004**

EPIX Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-21863
(Commission
File Number)

04-3030815
(IRS Employer
Identification No.)

71 Rogers Street Cambridge, Massachusetts 02142
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(617) 250-6000**

Item 5. Other Events.

On February 17, 2004, Epix Medical, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has determined that the New Drug Application (NDA) submitted for MS-325 (gadofosveset) has been accepted for filing by the Agency and has been designated for a standard review cycle. Acceptance for filing indicates that the FDA considers the NDA to be complete and ready for review. The target date for first FDA action in the standard review cycle is ten months from the December, 2003 date of submission. MS-325, a contrast agent designed specifically for vascular imaging with magnetic resonance angiography (MRA), is being co-developed by EPIX Medical, Inc. (Nasdaq:EPIX) and Schering AG, Germany (NYSE:SHR; FSE:SCH). A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 7. Financial Statements and Exhibits.

(c)

The following exhibits are furnished with this report:

