

INSMED INC  
Form 8-K  
September 28, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**Form 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**

**Date of Report (Date Of Earliest Event Reported): 09/27/2005**

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**INSMED INCORPORATED**

(Exact Name of Registrant as Specified in its Charter)

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**Virginia**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**0-30739**  
(Commission File Number)

**54-1972729**  
(I.R.S. Employer  
Identification No.)

**4851 Lake Brook Drive, Glen Allen, Virginia**  
(Address of Principal Executive Offices)

**23060**  
(Zip Code)

**(804) 565-3000**

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(Registrant's Telephone Number, Including Area Code)

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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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - 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 (17CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))
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**Item 8.01 Other Events**

On September 27, 2005, Insmed Incorporated issued a press release and announced the receipt of an Approvable Letter from United States Food and Drug Administration (FDA) for iPlex (rhIGF-I/rhIGFBP-3) (Mecasermin rinfibate), for the treatment of children with growth failure who suffer from Severe Primary IGF-1 deficiency (Primary IGFD). The Approvable Letter is an official notification that the FDA has completed the review of the iPlex New Drug Application (NDA) and has found the application to be sufficiently complete for full approval pending the submission of additional information.

**Item 9.01 Financial Statements and Exhibits**

A copy of the press release issued by Insmed Incorporated on September 27, 2005 is furnished as Exhibit 99.1. This information in the press release shall not be deemed filed for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act or the Exchange Act.

**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.

**Insmed Incorporated**

**Date: September 27, 2005**

**By: /s/ Geoffrey Allan, Ph.D.**

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**Geoffrey Allan, Ph.D.  
President, Chief Executive and  
Principal Executive**

**Exhibit Index**

**Exhibit No. Description**

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EX- 99.1 Press Release entitled **Insmmed Receives Approvable Letter for IPlex**